Standards of Accreditation in Health

Laboratory Kit v2.1/2020

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Thanks

In order to develop Standards of Accreditation in Health, SAS Laboratory Kit Study Group, people who contribute to standard development process, governmental, private and university laboratories in Turkey, specialist and occupational associations, health managers and employees, academics, patient rights employees, patients and patient relatives were asked for their opinions. Obtained feedback and suggestions via Opinion and Suggestion Platform which was established for this matter were evaluated during studies.

We would like to thank you to all institutions that provide laboratory services in SAS Laboratory Kit studies, public associations, other institutional and private stakeholders that set their heart on quality in health.

Department of Productivity, Quality and Accreditation in Health

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PROLOGUE

Prologue

Nowadays, rapid advances in medical technology and applications havebrought significant changes in physical and functional construction ofthe health services.

Emerging success rates of diagnosis and treatmentapplications, corresponding increases in number of patients and patient bedsturnover, people being more careful about health of themselves and theirfamilies can be listed as the cause of the physical and functional changes.

These changes affect structural, administrative and designative practices ofhospitals and emphasize the need to provide quality health care for patientswho need medical care as soon as possible.

So far, a few patient and organizational structure focused accreditationsystems have been established for the purpose of development of patientcare in the world at an optimal level of quality, creation of a safe patientcare environment, minimizing risks concerning patients and employees,a number of quality improvement and patient safety, and performance ofhealthcare institutions started to be evaluated within these systems.

In Republic of Turkey, foundation of accreditation have been laid in 2003 by studies initiated in the scope of Health Transformation Programme. An important phase of these studies which are conducted in accordance with the “Quality and accreditation for efficient and high quality” objective is development of standard kits which will be used for health institutions by our ministry. One of prepared sets in this context is “SAS Laboratory Kit” which enlightens “Turkey Accreditation in Health System”. This set which was developed for laboratories consists of two parts including standards, assessment criteria and guidelines.

In first part, you can find general information on historical development process relevant to Standards of Accreditation in Health.

Guidelines that include standard requirements which will help interpretation and implementation of standards and assessment criteria can be found in second part.

Standards of Accreditation in Health-Laboratory Kit was developed for medical

laboratories such as microbiology, biochemistry, pathology, immunology and genetics.

SAS Laboratory Kit which includes basic accreditation information is provided to all stakeholders for quality improvement in health services.

With the establishment of national accreditation structure in the axis of Standards of Accreditation in Health, three main elements of Transformation of Health Program has been completed. Developed quality of health structure specific for Republic of Turkey consists of two parts:

» Turkey Health Quality System

» Turkey Health Accreditation System

Turkey Health Quality System: The system is created by the Ministry of Health to raise the quality of health services in our country to the highest level within the scope of Health Transformation Program and to ensure patient and employee safety and patient and employee satisfaction. The system is mandatory for all public and private healthcare organizations in the 1st, 2nd and 3rd level in our country.

Turkey Health Accreditation System: It is a system based on SAS, which health care organizations will apply on a voluntary basis and become accredited according to their success. Accreditation of Health System is a program that will be applied to, for organizations that want to go beyond the current national quality state and put forth the difference in their quality level. It's organized as incentive for domestic and overseas health tourism because of including a document approved internationally.

In Turkey, this structure which is established in the field of health quality by Ministry of Health has significant importance for rising on a sturdy foundation in the framework of an awareness of a service that continuously improves and is sustainable.

First of all, The SAS Laboratory Set aims to determine the standards that define success targets in laboratory services. Standards of Accreditation in Health-Laboratory Kit was developed for medical laboratories such as microbiology, biochemistry, pathology, immunology and genetics.

The Standards are designed for self-governing laboratories serving all public, private and university status. Units that provide laboratory services in the hospital are not included in this set.

Department of Productivity, Quality and Accreditation in Health

Standards of Accreditation in Health - Laboratory Kit

Development of the Standards

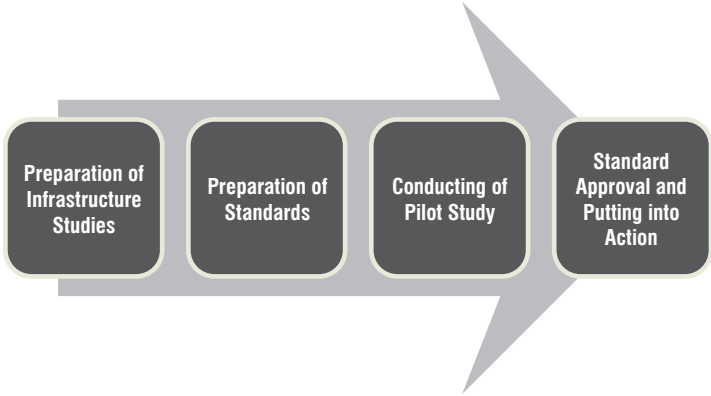
In Republic of Turkey, foundation of Ministry of Health (MOH) accreditation studies have been laid in 2003 and these studies gained significance among Health Transformation Programme (HTP) principles and MOH policies.

In the Health Transformation Program, emphasis is put on the planning and supervising roles of the Ministry of Health, that is on a Ministry structure and practice that determine the standards of service, set rules, and supervise the framework of practices and the level of implementation of these standards. The accreditation system is established Wwith the principle of "quality and accreditation for quality and effective health services" contained in the sixth component of the programme.

On the basis of the necessity of quality studies having international identity, first steps have been taken for establishment of the Health Accreditation System in Turkey in May, 2012. As a result of studies official co-operation have been initiated by negotiations with ISQua-the accreditor of accreditors on 20.03.2013. In the framework of negotiations and the agreement signed with ISQua, "ISQua International Principles for Healthcare Standards" have been analyzed in detail. On the basis of Decree Law No. 669, Standards of Accreditation in Health (SAS) are prepared by the Ministry of Health. Doing surveys and giving the certificate of accreditation for voluntary organizations is carried out by Institute of Turkey Quality and Accreditation in Health (TUSKA), which is established within the body of Turkish Health Institutes Presidency (TUSEB), on the basis of SAS.

Laboratory Kit of Standards of Accreditation in Health is prepared considering international and national quality studies, principles of World Health Organization and ISQua. (Appendix: Information Note) This kit has been created taking into account international developments, coverage of all service sections and compability for teleological interpretation. Also properties such as service and outcome-oriented approach, encouraging innovation in organizations, highlighting of applicability, being easy to use and inclusive were considered.

Standard development process is shown step by step on scheme below.



Objective and Scope Standards of Accreditation in Health Laboratory

Standards of Accreditation in Health is structured within the framework of principles of World Health Organization and ISQua such as patient safety, quality improvement, patient and service user focus, corporate planning and performance in accordance with basis of minimum risk, optimum quality, maximum security.

First of all, The SAS Laboratory Set aims to determine the standards that define success targets in laboratory services. Standards of Accreditation in Health-Laboratory Kit was developed for medical laboratories such as microbiology, biochemistry, pathology, immunology and genetics.

The Standards are designed for self-governing laboratories serving all public, private, university status and units that provide laboratory services in the hospital.

Goals of Standards of Accreditation in Health – Laboratory Kit

Standards of Accreditation in Health is prepared to accomplish quality goals shown below for ensuring quality of hospitals in the terms of needs and priorities of Turkey considering WHO Patient Safety goals, principles of ISQua, accreditation programs around the world across the globe.

Goals mentioned above must be achieved in order to accept that services provided by laboratories are in high quality.

These objectives can be addressed in two categories in general, goals contained in the first category defines the methods of service provision of institutions. In other words, it means organizational goals related to how good institutions provide services. (Efficiency, Efficacy, Productivity, and Healthy Work Life)

Goals contained in the second category directly concerns service users. (Patient Safety, Equity, Patient Orientedness, Convenience, Timeliness, Continuity).

Intention of categorization of targets presented here is only for clearance. For example, in an institution which cannot provide a healthy working environment it will be impossible to ensure a patient-focused approach. Besides goals not having priority relations between, achieving goals in accordance with each other is a significant point emphasized by the Standards of Accreditation in Health.

Definitions of SAS goals are shown below:

» **Efficacy:** Measure of achieving planned objectives

» **Efficiency:** Ability to perform tasks in a correct way

» **Productivity:** Relationship between provided service and the amount of resources used, use of minimum resources to achieve planned goals

- **Healthy Work Life:** Providing an ideal and safe working environment and infrastructure for health employees
- **Patient Safety:** Improvement activities and measures to be taken to keep all foreseeable hazards that can lead to harm service users at an acceptable risk level
- **Equity/Fairness:** Ensuring usage of all services depending of treatment and care needs equally without any discrimination
- **Patient Orientedness:** Ensuring participation of patient to diagnosis, treatment and care processes taking into account of his/her requests, needs and expectations for all services provided
- **Convenience:** Implementing more healing than harm of patient during decided medical treatment and processes
- **Timeliness:** Providing diagnosis, treatment and care services according to the needs of the patient in the most appropriate and in an acceptable period of time
- **Continuity/Sustainability:** Ensuring further medical services to go on chronologically and interdisciplinary and after discharge

Structure of SAS Laboratory Kit

Standards of Accreditation in Health – Laboratory Kit includes 7 aspects, 21 chapters, 38 standards and 147 assessment criteria.

SAS Laboratory Kit consists of standards, assessment criteria and related guidelines. In guidelines, goals, objectives and standard requirements can be found.Standards must be interpreted and implemented as a whole including assessment criteria and relevant guidelines.

Aspect Structure of SAS Laboratory Kit

Seven aspects of Standards of Accreditation in Health – Laboratory Kit are as following:

- Management and Organization
- Performance Measurement and Quality Improvement
- Healthy Work Life
- Patient Experience
- Health Services
- Support Services
- Emergency Management

General Objectives and Scope of Aspects

The aspects of SAS Laboratory Kit are determined on the basis of provided services in laboratories, management activities and people involved in service in a way that cover all sections of them.

» **Management and Organization**

In the aspect of management and organization, aim is to ensure a management structure which will maintain the continuity of functioning of hospital, along with creating an efficient corporate quality management structure consisting both executive management and employees.

To achieve this goal, hospital need to establish an organizational structure, determine basic policies and values, create a structure of quality management, maintain document management, install an adverse event system, implement risk management and training management, study for the development and improvement of health promotion, and establish a good corporate communication.

» **Performance Measurement and Quality Improvement**

Main aim of this aspect is to detect problems in time related to provision of services about especially administrative, financial and medical processes, correct them and conduction interventions for quality improvement. Achievement of this aim can be done by using determined corporate and SAS indicators.

» **Healthy Work Life**

In this aspect, for the provision of quality health service it's aimed to provide employees a healthy work environment and inspecting laboratories in employees' perspective.

For this purpose, hospitals need to create a structure for management of human resources, take precautions for factors threatening employee health and security and determine requirements to improve work life.

» **Patient Experience**

Patient experience aspect aims to examine services in perspective of patient for ensuring basic patient rights, patient safety and satisfaction.

To achieve this objective, hospital services provided need to be regulated in a way that protects the rights of patients and their caretakers, implements service accessibility in time, ensures comfort, safety and security of patient.

» **Healthcare Services**

Ensuring all provision of services in laboratory in the scope of SAS goals

is the aim of this aspect. For this purpose, laboratories need to implement studies related to laboratory services, prevention of infections, sterilization services chapters.

» **Support Services**

In support services aspect, it's aimed to establish required infrastructure for safety and continuity of medical service processes. For this purpose, laboratories need to form a plan about regulations for facility management, waste management, information management, materials and devices management and outsourcing.

» **Emergency Management**

This aspect aims laboratories to interfere in fastest and efficient way to prevent dangers and damage in situations such as natural disasters (earthquake, flood, etc.), emergencies(fire, explosion, etc.), baby or child abduction, sudden respiratory or cardiac arrest cases and violence to the employees.

Coding of Standards of Accreditation in Health

Coding system was developed in order to ensure the traceability of standards by providing them an identity.

Coding System

» Code of standard consists of four parts.

» First two parts consists of letters and last two parts consists of numbers.

» Alphabetical parts include two letters, and are abbreviations of related aspect and chapter.

» Numbers at last two parts (3rd and 4th parts) include two-digit numbers.

- Third part corresponds to standard number in chapter.
- Fourth part corresponds to assessment criterion number of standard.
- *In fourth part, "00" corresponds to standard itself, increasing digits like "01" and so on corresponds to order of assessment criteria.*

Codes related to aspects are as following:

ASPECT	CODE
Management and Organization	YO
Performance Measurement and Quality Improvement	PÖ
Healthy Work Life	SÇ
Patient Experience	HD
Health Services	SH
Support Services	DH
Emergency Management	AD

Codes related to each chapter are as following:

CODE	CHAPTER NAME
YO.OY	Organizational Structure
YO.PD	Core Policies and Ethical Values
YO.KY	Quality Management Structure
YO.DY	Document Management
YO.OB	Adverse Event System
YO.RY	Risk Management
YO.EY	Training Management
YO.Kİ	Institutional Communication
PÖ.Gİ	Monitoring of Indicators

CODE	CHAPTER NAME
SÇ.İK	Human Resources Management
SÇ.ÇG	Employee Health and Safety
HD.HD	Patient Experience
SH.LH	Laboratory Services
SH.EÖ	Prevention of Infections
SH.SY	Sterilization Management
DH.TY	Facility Management
DH.AY	Waste Management
DH.BY	Information Management
DH.MC	Material and Device Management
DH.DK	Outsourcing
AD.AD	Emergency Management

A coding example of a standard is given below:

STANDARD CODE	STANDARD	AC CODE	ASSESSMENT CRITERIA (AC)
YO.OY.01.00	An organisational structure to cover all laboratory activities must be established.	YO.OY.01.01	Organisational structure must be defined in a way that covers responsibilities related to governance and clinical governance.
		YO.OY.01.02	All vertical and horizontal relations in the organisational structure, from senior management to subunits, must be defined.
		YO.OY.01.03	Within the organisational structure, duties, powers and responsibilities of all units and staff must be defined.
		YO.OY.01.04	Responsibilities must be identified for units defined in organisational structure.
		YO.OY.01.05	An institutional plan should be established for the activities carried out in line with the organization's aims and objectives.
		YO.OY.01.06	Implementation of laboratory policies, procedures, processes and plans should be provided in all units within the organization structure.

STANDARDS and GUIDES

STANDARDS OF ACCREDITATION IN HEALTH - LABORATORY KIT							
ASPECT CODE	ASPECT	CHAPTER CODE	CHAPTER	STANDARD CODE	STANDARD	AC CODE	ASSESSMENT CRITERIA (AC)
YO	Management and Organization	YO.OY	Organizational Structure	YO.OY.01.00	An organizational structure to cover all laboratory activities must be established.	YO.OY.01.01	Organisational structure must be defined in a way that covers responsibilities related to governance and clinical governance.
						YO.OY.01.02	All vertical and horizontal relations in the organizational structure, from senior management to subunits, must be defined.
						YO.OY.01.03	Within the organizational structure, duties, powers and responsibilities of all units and staff must be defined.
						YO.OY.01.04	Responsibilities must be identified for units defined in organizational structure.
						YO.OY.01.05	An institutional plan should be established for the activities carried out in line with the organization's aims and objectives.
						YO.OY.01.06	Implementation of laboratory policies, procedures, processes and plans should be provided in all units within the organization structure.
				YO.OY.02.00	Laboratory must have all necessary authorization and permits for all of its activities.	YO.OY.02.01	Laboratory must have all necessary authorization and permits related to institutional services and staff working status for all its activities.
						YO.OY.02.02	The current and valid status of the necessary authorization and authorization documents for all services and personnel must be reviewed at least once a year and regularly when necessary.
		YO.PD	Core Policies and Ethical Values	YO.PD.01.00	Core policies and ethical values of laboratory must be defined.	YO.PD.01.01	Mission, vision and ethical values of laboratory must be defined in a clear and understandable manner.
						YO.PD.01.02	Laboratory must share its mission, vision and ethical values with the public.
						YO.PD.01.03	Corporate goals and objectives must be determined in accordance with mission, vision and values, the objectives of the medical and administrative departments should be compatible with the basic policies and values of the laboratories.
						YO.PD.01.04	Strategic planning for achievement of institutional goals and objectives in laboratory must be done by taking environmental and financial factors into account.
						YO.PD.01.05	An efficient budgeting(income/expense budget) must be in place in order to attain goals and objectives set.
						YO.PD.01.06	Laboratory must review and assess its institutional resources at regular intervals by taking into consideration plans prepared and budgets drafted with the aim of realising such plans.

STANDARDS OF ACCREDITATION IN HEALTH - LABORATORY KIT							
ASPECT CODE	ASPECT	CHAPTER CODE	CHAPTER	STANDARD CODE	STANDARD	AC CODE	ASSESSMENT CRITERIA (AC)
YO	Management and Organization	YO.KY	Quality Management Structure	YO.KY.01.00	Planning, implementation, coordination and continuity of quality improvement activities must be ensured.	YO.KY.01.01	A management structure must be established in order to ensure planning, implementation, coordination and continuity of quality improvement activities.
						YO.KY.01.02	The duties, powers and responsibilities of those involved in the management structure must be defined.
						YO.KY.01.03	The managerial structure should ensure the planning, execution and coordination of quality improvement activities.
						YO.KY.01.04	Responsible employees must be determined regarding at least the following topics: » Employee safety » Patient safety » Training » Facility management » Prevention of infections
		YO.DY	Document Management	YO.DY.01.00	Management of documents at laboratory must be ensured.	YO.DY.01.01	Policies, procedures, processes and plans related to all main functions covered by the SAS laboratory must be documented.
						YO.DY.01.02	Format of documents must be determined.
						YO.DY.01.03	Preparation, check, approval, up-to-datedness and storage of documents must be ensured.
						YO.DY.01.04	Rules to convey documents to relevant people must be set.
						YO.DY.01.05	Process related to monitoring of external documents to be followed by laboratory must be defined.
		YO.OB	Adverse Event Reporting System	YO.OB.01.00	Reporting of adverse events that may (near miss) or does (adverse) affect the safety of patients and staff negatively must be ensured, and necessary measures must be taken.	YO.OB.01.01	A system must be established in order to report adverse events that may or does affect the safety of patients and staff negatively.
						YO.OB.01.02	Case specific analysis must be conducted, and actions must be taken if necessary.
						YO.OB.01.03	Submissions on the system must be analyzed in ageneral, reported, and evaluated.

STANDARDS OF ACCREDITATION IN HEALTH - LABORATORY KIT							
ASPECT CODE	ASPECT	CHAPTER CODE	CHAPTER	STANDARD CODE	STANDARD	AC CODE	ASSESSMENT CRITERIA (AC)
YO	Management and Organization	YO.RY	Risk Management	YO.RY.01.00	Risks related to laboratory and laboratory related processes must be defined and managed.	YO.RY.01.01	There must be a regulation related to managing the risks that may occur in an Laboratory.
						YO.RY.01.02	A risk management plan must be prepared in order to manage risks related to laboratory and laboratory processes.
						YO.RY.01.03	Risk management plan must entail the following issues: • Patients • Relatives • Carers • Staff • Facility safety • Environmental safety • Administrative and financial processes. • Strategic risks • Comminucation processes with stakeholders
						YO.RY.01.04	Risks to be addressed within the scope of risk management must be determined, analysed and risk levels must be identified.
						YO.RY.01.05	Necessary measures must be adopted in line with the according to the risk level identified, and actions must be taken for improvement.
						YO.RY.01.06	Risks identified and effectiveness of improvement actions must be continuously monitored and reviewed periodically.
						YO.RY.01.07	Indicators for monitoring the effectiveness of risk management must be determined and monitored.
		YO.EY	Training Management	YO.EY.01.00	In accordance with quality improvement activities, training needs of staff must be determined, and it must be ensured that necessary training is conducted effectively.	YO.EY.01.01	Responsible in charge of the planning and coordination of training activities must be determined.
						YO.EY.01.02	Training needs must be identified on the basis of staff.
						YO.EY.01.03	Training plans must be prepared and implemented in line with training needs.
						YO.EY.01.04	Effectiveness of training plans and trainings carried out must be monitored and necessary improvement actions must be taken.

STANDARDS OF ACCREDITATION IN HEALTH - LABORATORY KIT							
ASPECT CODE	ASPECT	CHAPTER CODE	CHAPTER	STANDARD CODE	STANDARD	AC CODE	ASSESSMENT CRITERIA (AC)
YO	Management and Organization	YO.Kİ	Institutional Communication	YO.Kİ.01.00	Institutional communication activities must be carried out effectively.	YO.Kİ.01.01	Under the scope of institutional communication, target audience must be identified by taking laboratory structure, core policies and values into account and communication strategies for target audience must be determined.
						YO.Kİ.01.02	Target audience must be informed about laboratory activities and organization.
						YO.Kİ.01.03	Necessary actions must be taken to create a positive opinion among target audience.
PÖ	Performance Measurement and Quality Improvement	PÖ.Gİ	Monitoring of Indicators	PÖ.Gİ.01.00	Institutional indicators must be monitored and evaluated in order to continuously improve service provision processes regarding primarily administrative, financial and medical steps.	PÖ.Gİ.01.01	Indicators must be determined to include processes concerning service delivery, primarily administrative, financial and medical steps.
						PÖ.Gİ.01.02	Indicator cards must be created to cover issues related determination, collection, evaluation and monitoring of data to be used for indicators.
						PÖ.Gİ.01.03	Monitoring, evaluating and reporting of indicators must be carried out through information management systems.
						PÖ.Gİ.01.04	Necessary improvements must be made taking into consideration the analysis results for the indicators.
						PÖ.Gİ.01.05	The results of the SAS indicators must be submitted to the SAS Indicator Data System.

STANDARDS OF ACCREDITATION IN HEALTH - LABORATORY KIT							
ASPECT CODE	ASPECT	CHAPTER CODE	CHAPTER	STANDARD CODE	STANDARD	AC CODE	ASSESSMENT CRITERIA (AC)
SÇ	Healthy Work Life	SÇ.İK	Human Resources Management	SÇ.İK.01.00	A management structure that will fulfil the requirements concerning planning of human resources, improvement of work life and the personnel must be established.	SÇ.İK.01.01	The relation of the management structure with other management levels must be identified.
						SÇ.İK.01.02	Duties, authorities and responsibilities of those in the management structure and the qualifications they must have must be identified.
						SÇ.İK.01.03	Annual goals and work plans must be developed.
						SÇ.İK.01.04	Feedback processes aimed at determining satisfaction levels and comments and suggestions of the personnel regarding their work life must be identified.
				SÇ.İK.02.00	The requirements necessary to constantly improve recruitment and compliance processes of the personnel and their work life must be determined and fulfilled.	SÇ.İK.02.01	A personnel recruitment plan must be developed in line with human resources needs of laboratory.
						SÇ.İK.02.02	Personnel recruitment processes must be identified.
						SÇ.İK.02.03	Processes regarding ensuring the adaptation of the newly recruited personnel to laboratory must be identified.
						SÇ.İK.02.04	Duties, authorities, responsibilities of the personnel and the qualifications they should have and the performance criteria their job requires must be determined.
						SÇ.İK.02.05	Performance of the personnel must be measured, training needs must be determined to enhance the performance and necessary trainings must be provided.
						SÇ.İK.02.06	How and to what extent the current standards, protocols and evidence-based clinical guidelines accepted by laboratory are used by the personnel must be monitored and trainings aimed at ensuring the use of these standards and guidelines efficiently must be identified.
		SÇ.ÇG	Employee Health and Safety	SÇ.ÇG.01.00	Factors threatening the health and safety of employees should be identified and necessary Precautions should be taken to establish a healthy and safe working environment.	SÇ.ÇG.01.01	Responsible aimed at management of the factors that threaten employee health and safety must be determined.
						SÇ.ÇG.01.02	Risk analyses must be conducted on the factors that threaten employee health and safety and measures must be taken to eliminate or decrease the risks that threaten the safety.
						SÇ.ÇG.01.03	It must be ensured that employees use the personal protective equipment against the risks.
						SÇ.ÇG.01.04	Quality improvement activities that aim to ensure the continuity of employee safety must be planned.
						SÇ.ÇG.01.05	Physical and social opportunities that are necessary to improve the work environments and the work life must be provided and personal needs of the employee regarding work life must be met.

STANDARDS OF ACCREDITATION IN HEALTH - LABORATORY KIT							
ASPECT CODE	ASPECT	CHAPTER CODE	CHAPTER	STANDARD CODE	STANDARD	AC CODE	ASSESSMENT CRITERIA (AC)
HD	Patient Experience	HD.HD	Patient Experience	HD.HD.01.00	The services provided at laboratory must be organized in such a way as to protect the safety of patients and their carers.	HD.HD.01.01	Risk analyses must be conducted on the factors that threaten patient safety and measures must be taken to eliminate or decrease the risks that threaten safety.
						HD.HD.01.02	Quality improvement activities must be planned to ensure the continuity of patient safety.
				HD.HD.02.00	The services provided in laboratory must be organized in such a way as to protect patient and carer rights.	HD.HD.02.01	Laboratory must declare information on quality of services provided, service access conditions and patient rights.
						HD.HD.02.02	Patient or carers must be informed about the services related to laboratory services and patient responsibilities in processes in which patients are included.
						HD.HD.02.03	Activities must be planned in all service processes for the patient to be respected and to receive meticulous service.
						HD.HD.02.04	Patients must be able to examine the medical documents about themselves and receive a copy if requested.
						HD.HD.02.05	Arrangements must be made for the spiritual and cultural needs of the patient.
						HD.HD.02.06	Patient's consent must be obtained if the patient is to take part in a research or experiment, or if the information, data or materials about the patient are to be used in any way.
						HD.HD.02.07	Ethical dilemmas such as not treating the patient, withdrawal of the treatment or discontinuing the treatment must be addressed and settled in time.
						HD.HD.02.08	Patient must be informed that he/she has right to decline medical process/intervention which will be used.
						HD.HD.02.09	Processes for informing the patient or carer if unintended events that negatively affect the patient safety occur must be identified.

STANDARDS OF ACCREDITATION IN HEALTH - LABORATORY KIT							
ASPECT CODE	ASPECT	CHAPTER CODE	CHAPTER	STANDARD CODE	STANDARD	AC CODE	ASSESSMENT CRITERIA (AC)
HD	Patient Experience	HD.HD	Patient Experience	HD.HD.03.00	A system must be established to receive feedback (comments, suggestions and complaints etc.) from patients and their carers about the services that are provided.	HD.HD.03.01	The system's scope, methods and tools must be defined including receiving, investigating and resolving of all feedbacks.
						HD.HD.03.02	Patients and carers must be informed about how they can provide feedback.
						HD.HD.03.03	Feedback must be assessed.
						HD.HD.03.04	Necessary improvement activities must be planned for the results that come out of the feedback.
				HD.HD.04.00	Necessary precautions must be taken in order to provide patient able to reach services in time.	HD.HD.04.01	Patients must be provided with reception, orientation and consultation services that will facilitate the application process at laboratory and through which they can access all the information they need in the application process at laboratory.
						HD.HD.04.02	All the areas where the service is provided at laboratory must be organized so as to ensure patient comfort.
						HD.HD.04.03	Facilitating measures concerning access to services and waiting periods must be taken based on age, disease and disability.
						HD.HD.04.04	Service delivery processes must be organized in such a way as to ensure the laboratory test conductions of the patient in a timely manner.

STANDARDS OF ACCREDITATION IN HEALTH - LABORATORY KIT							
ASPECT CODE	ASPECT	CHAPTER CODE	CHAPTER	STANDARD CODE	STANDARD	AC CODE	ASSESSMENT CRITERIA (AC)
SH	Health Services	SH.LH	Laboratory Services	SH.LH.01.00	Laboratory physical environment must be established in a way that ensures test and employee safety.	SH.LH.01.01	In laboratory, designated areas for acceptance of samples, preparation prior to analysis, reporting of results after analysis must be arranged in a way that ensures safety of samples and tests.
						SH.LH.01.02	In all areas of laboratory, a healthy work environment must be ensured.
				SH.LH.02.00	A test guide must be prepared for informing of healthcare workers responsible with out of laboratory processes.	SH.LH.02.01	A guide including general information on tests being performed in laboratory, rules about extraction, transfer, acceptance of samples, test methods, reporting of results and interpretation must be prepared.
						SH.LH.02.02	Guide must be accessible by health care professionals.
						SH.LH.02.03	Related healthcare staff must be informed about the use of guide.
				SH.LH.03.00	Check of pre-analysis laboratory processes must be implemented.	SH.LH.03.01	Rules and procedures between test request and analysis must be defined.
						SH.LH.03.02	Rules regarding test requests must be determined and information and guidance provision for related physicians must be ensured.
						SH.LH.03.03	Training must be provided for related healthcare staff about extraction, transfer, acceptance of samples and pre-analysis preparation.

STANDARDS OF ACCREDITATION IN HEALTH - LABORATORY KIT							
ASPECT CODE	ASPECT	CHAPTER CODE	CHAPTER	STANDARD CODE	STANDARD	AC CODE	ASSESSMENT CRITERIA (AC)
SH	Health Services	SH.LH	Laboratory Services	SH.LH.04.00	Check of analytic processes related to laboratory tests must be ensured.	SH.LH.04.01	Rules and procedures between analysis and verification of result must be defined.
						SH.LH.04.02	Rules must be determined for the safe and effective use of devices in laboratory.
						SH.LH.04.03	Quality control studies related to reliability of test results must be implemented.
				SH.LH.05.00	Check of post-analysis processes related to laboratory tests must be ensured.	SH.LH.05.01	Information which is required to be in result reports must be determined.
						SH.LH.05.02	Reporting of test results timely and accurate must be ensured.
						SH.LH.05.03	Rules for interpretation of test results and clinical suggestions in reports must be determined.
						SH.LH.05.04	Process of safe and effective reporting panic/critical values must be defined.
						SH.LH.05.05	Rules related to preservation and archiving of leftover biological samples, uncompleted analysis samples and reports must be determined.
				SH.LH.06.00	Traceability of the processes related to laboratory tests must be ensured.	SH.LH.06.01	Records must be kept in regards to ensure traceability of samples and tests in all processes.
				SH.LH.07.00	Use of Bedside Test Devices (BSTD) must be regulated.		

STANDARDS OF ACCREDITATION IN HEALTH - LABORATORY KIT							
ASPECT CODE	ASPECT	CHAPTER CODE	CHAPTER	STANDARD CODE	STANDARD	AC CODE	ASSESSMENT CRITERIA (AC)
SH	Health Services	SH.EÖ	Prevention of Infections	SH.EÖ.01.00	Necessary measures must be taken for the prevention of infections.	SH.EÖ.01.01	Responsible must be determined for infection prevention and responsibilities must be defined.
						SH.EÖ.01.02	A programme must be created for the prevention of infections.
						SH.EÖ.01.03	Efficiency of the practices aimed at ensuring prevention of infections must be monitored.
		SH.SY	Sterilization Management	SH.SY.01.00	Processes concerning sterilization services must be identified and taken under control.	SH.SY.01.01	Physical areas and conditions in sterilization unit must be planned according to the process steps.
						SH.SY.01.02	The processes regarding sterilization, storage, transfer and use of the materials must be taken under control.
						SH.SY.01.03	Traceability of the evidence regarding time, device, method, implementer and control parameters must be ensured in each stage of the sterilization.

STANDARDS OF ACCREDITATION IN HEALTH - LABORATORY KIT							
ASPECT CODE	ASPECT	CHAPTER CODE	CHAPTER	STANDARD CODE	STANDARD	AC CODE	ASSESSMENT CRITERIA (AC)
DH	Support Services	DH.TY	Facility Management	DH.TY.01.00	All the areas at laboratory must be clean for the safety and satisfaction of patient, carer and personnel.	DH.TY.01.01	Risk levels must be determined in all the areas of laboratory to ensure the control of cleaning and infections.
						DH.TY.01.02	Cleaning rules for risk levels must be identified and a laboratory cleaning plan must be developed and implemented.
				DH.TY.02.00	Processes regarding catering must be identified.	DH.TY.02.01	Safe supply and storage of the food must be ensured.
						DH.TY.02.02	Processes regarding preparation of the food under the set conditions must be identified.
						DH.TY.02.03	Food must be served according to the set rules.
				DH.TY.03.00	The physical areas used by patients/carers must be safe and ergonomic.		
				DH.TY.04.00	Precautions should be taken in laboratory to ensure safety of life and property of patient/carer and the personnel.		
				DH.TY.05.00	A quality facility management structure and process must be established to ensure the quality and safety of laboratory services.	DH.TY.05.01	Responsible for planning and coordinating activities related to facility management must be determined.
						DH.TY.05.02	Risks originating from the facility must be detected and necessary measures must be taken.
						DH.TY.05.03	Continuity and safety of core facility resources must be ensured.
						DH.TY.05.04	Issues related to physical conditions and operations must be periodically.
						DH.TY.05.05	There must be arrangements facilitating access to departments inside laboratory.
						DH.TY.05.06	Measures must be taken to facilitate access to services by patients/staffs who are disabled, old or in need of help due to illness.
						DH.TY.05.07	Physical arrangements must be made to ensure the comfort of service users.

STANDARDS OF ACCREDITATION IN HEALTH - LABORATORY KIT							
ASPECT CODE	ASPECT	CHAPTER CODE	CHAPTER	STANDARD CODE	STANDARD	AC CODE	ASSESSMENT CRITERIA (AC)
DH	Support Services	DH.AY	Waste Management	DH.AY.01.00	Safe and effective management of waste produced at laboratory must be ensured to protect human and environmental health.	DH.AY.01.01	A Waste Management Plan must be prepared.
						DH.AY.01.02	Waste must be sorted at the source.
						DH.AY.01.03	Necessary steps must be taken to ensure that waste is transported, temporarily stored and disposed in appropriate conditions.
						DH.AY.01.04	Personnel involved in waste management must be trained.
		DH.BY	Information Management	DH.BY.01.00	A safe and effective information management system must be present at laboratories. .	DH.BY.01.01	Those in charge of carrying out and coordinating activities related to information management must be identified.
						DH.BY.01.02	The necessary technical and supporting infrastructure must be established for the efficiency of information management.
						DH.BY.01.03	Measures must be taken for the security of medical records that are physically stored.
						DH.BY.01.04	Necessary measures must be taken to ensure information security and confidentiality.
						DH.BY.01.05	It must be ensured that the information is timely and continual.
						DH.BY.01.06	Personnel must be trained for effective ensure of information management.

STANDARDS OF ACCREDITATION IN HEALTH - LABORATORY KIT							
ASPECT CODE	ASPECT	CHAPTER CODE	CHAPTER	STANDARD CODE	STANDARD	AC CODE	ASSESSMENT CRITERIA (AC)
DH	Support Services	DH.MC	Material and Device Management	DH.MC.01.00	Efficient, effective and safe use of materials and devices must be ensured.	DH.MC.01.01	Those in charge of management of materials and devices must be determined.
						DH.MC.01.02	Materials and devices must be determined and supplied in accordance with the needs of the institution.
						DH.MC.01.03	Materials must be conserved in proper conditions.
						DH.MC.01.04	Necessary physical conditions must be met to ensure that the devices work in proper working conditions.
						DH.MC.01.05	Personnel must be trained in material and device management.
						DH.MC.01.06	Necessary maintenance, calibration, adjustments and tests of the devices needed must be conducted.
						DH.MC.01.07	Rules must be set to ensure safe and effective use of materials and devices, the necessary protective material and information concerning the devices must be available.
						DH.MC.01.08	Management of hazardous substances must be regulated.
		DH.DK	Outsourcing	DH.DK.01.00	The services provided through outsourcing must be in line with the core policies and values of laboratory and Standards of Accreditation in Health.	DH.DK.01.01	The services to be outsourced must be determined in line with the core policies and values of laboratory.
						DH.DK.01.02	Scope and process of the outsourced services must be defined.
						DH.DK.01.03	It must be ensured that outsourced services will comply with Health Accreditation Standards.

STANDARDS OF ACCREDITATION IN HEALTH - LABORATORY KIT							
ASPECT CODE	ASPECT	CHAPTER CODE	CHAPTER	STANDARD CODE	STANDARD	AC CODE	ASSESSMENT CRITERIA (AC)
AD	Emergency Management	AD.AD	Emergency Management	AD.AD.01.00	Measures must be taken against cases like natural disasters or events that necessitate extraordinary response, intervention, first aid or evacuation.	AD.AD.01.01	Risk analyses must be conducted on events that require extraordinary response and intervention, first aid or evacuation and necessary measures must be taken.
						AD.AD.01.02	Planning must be done for preventive measures determined and possible emergencies.
						AD.AD.01.03	Trainings must be provided on emergency management and drills must be conducted.
				AD.AD.02.00	Timely intervention must be ensured in cases where the health professional is exposed to a risk of violence, or an act of violence is directed towards him/her.	AD.AD.02.01	An emergency alert system defined with Code White must be in place for intervention in cases where there is a risk or and actual act of violence towards health professionals.
						AD.AD.02.02	Those in charge of the management of the emergency alert system must be determined.
						AD.AD.02.03	Intervention team/teams must be determined.
						AD.AD.02.04	Code White trainings must be provided and drills must be conducted.
				AD.AD.03.00	There must be an arrangement in place to ensure timely response to fire.	AD.AD.03.01	There must be a fire detection system.
						AD.AD.03.02	Emergency alert system defined with Code Red must be established to respond in time in the case of fire.
						AD.AD.03.03	Those in charge of management of the emergency alert system must be determined.
						AD.AD.03.04	The equipment to be used while responding to fire, rules regarding safe use of this equipment, signs and instructions to be taken into account in the case of fire must be identified.
						AD.AD.03.05	Trainings must be provided on Code Red and drills must be conducted.

Management and Organization

Organizational Structure

Standard 1

Standard Code	Standard	AC Code	Assessment Criteria (AC)
YO.OY.01.00	An organisational structure to cover all laboratory activities must be established.	YO.OY.01.01	Organisational structure must be defined in a way that covers responsibilities related to governance, financial stewardship.
		YO.OY.01.02	All vertical and horizontal relations in the organisational structure, from senior management to subunits, must be defined.
		YO.OY.01.03	Within the organisational structure, duties, powers and responsibilities of all units and staff must be defined.
		YO.OY.01.04	Responsibilities must be identified for units defined in organisational structure.
		YO.OY.01.05	An institutional plan should be established for the activities carried out in line with the organization's aims and objectives.

Goal

To identify duties, authorities, responsibilities, liabilities, communication and approval mechanisms, to ensure sustainability in laboratory functioning, to ensure performance and inspection of the workflow of laboratory in a defined organizational structure.

Objectives

- » Efficacy
- » Efficiency
- » Productivity
- » Continuity

Standard Requirements

Establishment of Organisational Structure

Organizational structure of laboratory must be designed in a way that it will lead to the goals and targets defined on the basis of main policy and values.While designing organizational structure in this context, one of or several structure types such as Functional, Sectional or Matrix must be considered by evaluating main elements such as size of laboratory, service type, target group, other related institutions and their positions, internal and external necessities.

The organizational chart should be defined in one or more documents, illustrating the horizontal and vertical relationships among units from the top to the bottom one.

In the organizational chart, at least following issues must be addressed:

- » Speciality and division of services
- » Responsibilities and relations
- » Rules forauthority delegation
- » Coordination and integration points
- » Duties and positions of the employees

Governance

Responsibilities related to governance must be defined including the basic factors listed below:

- » Transparency
- » Accountability
- » Participation
- » Responsiveness
- » Rule of law
- » Efficiency
- » Equality
- » Strategic vision

Responsibilities related to clinical governance must be defined including the basic factors listed below:

» Clinical efficiency
» Clinical assessment
» Risk management
» Patient and public participation
» Staff and human resources management
» Education and training
» Use of information

Responsibilities related to financial stewardship must be defined including at least the basic factors listed below:

» Defining budget by institution and unit basis
» Ensuring efficient, economical and efficient use of the budget
» Control and monitoring of expenditures and income / outcome balance

For successful implementation of governance, clinical governance and financal stewardship. An efficient leadership, team work and communication must be ensured in political and clinical processes.

Defining Duties, Powers and Responsibilities of Units and Staff

Duties of units and staff included in the organizational scheme must be defined, and their powers and responsibilities must be clarified. Terms of reference must include relations between units as well and must be prepared in such a way that avoids uncertainty and confusion. Authorities and responsibilities assigned to units and individuals must be consistent.

Determining Unit Supervisors

Supervisors must be determined for the positions from the senior management to subunits.

Establishment of the Institutional Plans

An institutional plan should be established for the activities carried out in line with the organization's aims and objectives. The plan should be compatible with and linked to other institutional plans such as human resources, risk, financial plans.

Standard 2

Standard Code	Standard	AC Code	Assessment Criteria (AC)
Y0.0Y02.00	Laboratory must have all necessary authorisation and permits for all of its activities.	Y0.0Y02.01	Laboratory must have all necessary authorization and permits related to institutional services and staff working status for all its activities.
		Y0.0Y02.02	The current and valid status of the necessary authorization and authorization documents for all services and personnel must be reviewed at least once a year and regularly when necessary.

Goal

To ensure effective control and monitoring of healthcare services and support services provided at laboratory by making sure that these services are delivered only by people and institutions authorized under the national legislation.

Objectives

» Effectiveness » Efficiency » Productivity

Standard Requirements

All required authorization and permits described by the national legislationmust be determined for all service activities performed by laboratory. Within this scope;

» Laboratory must obtain the required activity permits, licenses, etc. at laboratory level and/or service area level.

» All activities consisting of traditional, complementary, alternative medicine practices and all other services provided apart from healthcare services (administrative, technical, etc.) must be performed by people authorised (diploma, certificate, specialty certificates, etc.) in the framework of all national health policies, legislation and other legal regulations. This authorization requirement applies to all staff including permanent, temporary, voluntary and casual employees.

Authorisation documents issued to the work area of the employees must be verified.

Core Policies and Ethical Values

Standard 1

Standard Code	Standard	AC Code	Assessment Criteria (AC)
YO.PD.01.00	Core policies and ethical values of laboratory must be defined.	YO.PD.01.01	Mission, vision and ethical values of laboratory must be defined in a clear and understandable manner.
		YO.PD.01.02	Laboratory must share its mission, vision and ethical values with the public.
		YO.PD.01.03	Corporate goals and objectives must be determined in accordance with mission, vision and values, the objectives of the medical and administrative departments should be compatible with the basic policies and values of the laboratory.
		YO.PD.01.04	Strategic planning for achievement of institutional goals and objectives in laboratory must be done by taking environmental and financial factors into account.
		YO.PD.01.05	An efficient budgeting (income/expense budget) must be in place in order to attain goals and objectives set.
		YO.PD.01.06	Laboratory must review and assess its institutional resources at regular intervals by taking into consideration plans prepared and budgets drafted with the aim of realising such plans.

Goal

To define principles to guide executives and staff in relation to institution's activities and strategic decisions by determining core policies and ethical values of laboratory.

Objectives

» Efficiency » Effectiveness » Productivity

Standard Requirements

Determining Mission, Vision and Ethical Values

» Mission and vision of institution must be determined based on information obtained with analysis of internal and external environmental conditions, and conditions that laboratory intends to attain.

» Laboratory must determine ethical values which include principles and rules that will lead all its activities. Issues such as ethical principles and rules of conduct, principles which highlight the focus onpatient and staff, can be addressed within the scope of laboratory ethical values.

» Laboratory must pay attention to ensure that itscore policies and ethical values are compatible with minimum ethical values of its staff and service receivers.

» Related to the services offered in the laboratory, in case of ethical dilemmas such as not being taken in to process, retreating or not continuing by the responsible person from the laboratory, how the process should be managed must be defined in advance and in this direction, it should be resolved in a short time and find solution. Managing the process should be defined if there are patients to decide whether they would like to get the treatment from somewhere else or who do not wish to continue the procedure without laboratory permission.

» The strategic plan should be periodically reviewed and should be revised as needed.

Sharing Core policies and ethical values with the Public

» Mission, vision and ethical values of laboratorymust be shared by the institution with the public periodically by using various communication tools (website, boards, promotion activities, etc.).

Determining Goals and Objectives

» Laboratorymust determine its goals and objectives on the basis of core policies and ethical values.

» The objectives of the medical and administrative departments should be in line with the objectives of the institution.

» Determined goals and objectives must be taken as basis for planning and implementing laboratory activities.

Strategic Planning

» Determined goals and objectives must be taken as basis for planning laboratory activities.

» During planning, internal factors (human resources, financial status, size, diversity of services, structural conditions, etc.), external factors (legal environment, corporate relations, public health structure, suppliers, competitors, etc.), features and feedbacks of service users, employees and society must be taken into account.

Quality Management Structure

Standard Code	Standard	AC Code	Assessment Criteria (AC)
YO.KY.01.00	Planning, implementation, coordination and continuity of quality improvement activities must be ensured.	YO.KY.01.01	A management structure must be established in order to ensure planning, implementation, coordination and continuity of quality improvement activities.
		YO.KY.01.02	The duties, powers and responsibilities of those involved in the management structure must be defined.
		YO.KY.01.03	The managerial structure should ensure the planning, execution and coordination of quality improvement activities.
		YO.KY.01.04	Responsible employees must be determined regarding at least the following topics: » Employee safety » Patient safety » Training » Facility management » Prevention of infections

Goal

To establish a quality management structure by defining the roles and responsibilities of all the staff from senior management to unitemployees at laboratory in quality improvement activities; to ensure that quality is continuously improved through the planning, implementation and coordination of qualityimprovement activities within this structure.

Objectives

- » Efficacy
- » Efficiency
- » Productivity
- » Continuity

Standard Requirements

Management Structure Related to Quality

» A management structure must be established within the laboratory to ensure planning,implementation, coordination and continuity of quality improvement activities.

» The duties, authorities and responsibilities of people involved in the management structure, and the vertical and horizontal relations of this structure must be defined.

» Quality supervisors to work in coordination with this management structure must be determined on the basis ofunits and/or processes;

The Planning, Execution and Coordination of Quality Improvement Activities

» Within the framework of Standards of Accreditation in Health, at least the following activities must be carried out to ensure planning, implementation and coordination of quality improvement activities:

- Ensuring planning and implementation of measurement, assessment, improvement and monitoring activities
  - √ Defining and implementing processes related to self-assessment (at least twice a year to cover all processes and sections)
  - √ Defining and implementing the scope and processes concerning patient/employee and stakeholders satisfaction surveys
  - √ Defining and implementing processes with the aim of obtaining patient/staff's and stakeholders opinions and suggestions
  - √ Monitoring performance related to quality improvement activities through indicators; planning and monitoring of activities aiming at the use of results obtained from such study for the purpose of improvement
  - √ Monitoring the results of the external evaluations carried out within the laboratory, defining and implementing processes so that the results can be used for the benefit of the institution

- Defining documentation processes related to quality activities, setting a documentation system, and ensuring its implementation within the rules required by the system

Determining Responsible Staff Regarding Quality Studies

» Within the scope of SASLaboratory Kit, responsible staff must be determined in relation to at least following issues: (Responsibilities can be merged in line with laboratory size and conditions.)

- Employee Safety (In the scope of the relevant legislation, in hospitals with Work Health and Safety Committee, responsibilities regarding employee health and safety are carried out by this committee.)
- Patient Safety
- Training
- Facility Management
- Control and Prevention of Infections

» Processes must be defined in order to ensure the cooperation and coordination of responsibleemployees with each other.

Document Management

Standard Code	Standard	AC Code	Assessment Criteria (AC)
YO.DY.01.00	Management of documents at laboratory must be ensured.	YO.DY.01.01	Policies, procedures, processes and plans related to all main functions covered by the SAS laboratory must be documented.
		YO.DY.01.02	Format of documents must be determined.
		YO.DY.01.03	Preparation, check, approval, up-to-datedness and storage of documents must be ensured.
		YO.DY.01.04	Rules to convey documents to relevant people must be set.
		YO.DY.01.05	Process related to monitoring of external documents to be followed by laboratory must be defined.

Goal

To manage quality activities efficiently by planning and putting into writing practice-related procedures and by conducting practices in line with written rules.

Objectives

» Efficiency » Effectiveness

Standard Requirements

Establishment of Document Management System

» Processes related to management of documents and rules related to operation of these processes must be defined:

» Definition must entail at least following processes:

- Determining the documents to be prepared
- Determining the format of the document
- Documents':
  - √ Preparation
  - √ Check and approval
  - √ Conveying to relevant people
  - √ Storage
  - √ Revision
  - √ Archiving and disposal

» External document tracking

Determining documents to be prepared

» Documents to be prepared must be determined taking into consideration Standards of Accreditation in Health, laboratory size, areas of service provision and processes.

» Policies, procedures, processes and plans related to all main functions of the laboratorymust be documented.

» Types of documents which can be prepared in line with SASLaboratory Kitare as follows:

- Procedure
- Instruction
- Guideline
- Form
- Plan
- Consent

- List
- Support documents:
  - √ Policy
  - √ Protocol
  - √ Objectives
  - √ Duty-Authority-Responsibility
  - √ Clinical Guidelines
  - √ Work flow
  - √ Chemıcal And Reactıve Substance (kit) Disposal Record
  - √ Meeting Minutes

Determining the Format of the Document

» All documents must include at least the following information:
  - √ Document name
  - √ Document code
  - √ Publication date
  - √ Revision date
  - √ Revision number
  - √ Page number/number of pages
  - Prepared By – Checked By – Approved By details

» In original copy of documents, position, title and original sign(s) of individual(s) must be indicated in the section: Prepared by – Checked by – Approved by

Preparing Documents

» Documents must be prepared must be determined taking into consideration Standards of Accreditation in Health, Laborotary size, areas of service provision and processes.

» Document must be prepared by relevant unit/committee/team members.

» Documents must be easy to understand, include concise information and must be clear.

Check and Approval of Documents

» Documents must be checked by the quality management unit and must be approved by the senior management.

Conveying Documents to Relevant People

» It must be ensured that the up-to-date versions of the documents are shared with relevant staff effectively.

» Necessary training must be provided for relevant staff on the documents prepared.

» Unless required, display of documents on boards must be avoided. Attention must be paid in order to ensure that documents displayed do not cause visual pollution.

Storage of Documents

» All original documents with wet signs must be storedin line with a systematic archiving plan and necessary measures must be taken tokeep contents of documents readable.

» Documents in the form of records related to actions taken in line with SASLaboratory Kit (corrective/preventive activity forms, minutes of meeting, etc.) must also be kept.

Revision of Documents

» Whenever there is a change in any of the processes of the laboratory, revision must be made immediately.

» During revision, all rules to be followed in the initial preparation of the document must be observed. Following the management approval, the revised document must be published, it must be conveyed to relevant people, and the revised document must be explained to relevant people within the scope of a training.

» Revision date and revision number must be indicated on the document revised. In the first publication of the document, revision number must be (0) and revision date must be kept blank. Old versions of documents must be archived in order to track revisions.

» A list of all documents used in the laboratorymust be kept and the listmust enable the tracking of revisions as well. Document list must include following information:

- Document Name
- Document Code
- Publication Date
- Revision Dates
- Revision Number

External Document Tracking

Tracking and up-to-datedness of external documents must be ensured through a method determined by the laboratory. Laboratorymust identify supervisors in charge of the tracking of external documents.

Archiving and Disposal of Documents

Rules for archiving and destruction of documents should be specified.

Adverse Event Reporting System

Standard Code	Standard	AC Code	Assessment Criteria (AC)
YO.OB.01.00	Reporting of adverse events that may (near miss) or does (adverse) affect the safety of patients and staff negatively must be ensured,and necessary measures must be taken.	YO.OB.01.01	A system must be established in order to report adverse events that may or does affect the safety of patients and staff negatively.
		YO.OB.01.02	Case specific analysis must be conducted, and actions must be taken if necessary.
		YO.OB.01.03	Submissions on the system must be analyzed in a general, reported, and evaluated.

Goal

To ensure that adverse events related to patient and staff safety with a potential to occur (near misses) or occur in the laboratoryare reported; to monitor them and to take necessary measures against events as a result of reports

Objectives

» Patient Safety

» Healthy Work Life

Standard Requirements

Adverse Event Reporting System

» A reporting system must be established in order to analyze events to take necessary measures and to prevent the repetition of errors by ensuring the reporting of events that may or does harm employees and patients at laboratory or have been noticed before the occurrence of harm.

» Under the scope of the adverse event reporting system, notification, analysis, reporting processes and steps regarding functioning of each process must be defined and supervisors in charge of these processes must be identified.

» Adverse Event Reporting System must consist of two modules:

- Patient Safety Module
- Staff Safety Module

» For the purpose of increasing efficiency and use of the system, cultivating a reporting culture at laboratory, learning lessons from events, developing learning process and devising solutions and encouraging the implementation of solutions; the system must be:

- Designed in a way that makes the staff feel safe, provide information such as name and location when needed,
- Based on voluntary reporting
- Accessible
- Easy to use
- Simple and easy to understand

» Patient safety module must be based on privacy. This module must be designed to collect at least the following information:

- Subject of the event
- Narration of the event
- Comments and suggestions related to event

Analysis and Improvements

» Notifications to the Adverse Event Reporting System must be analyzed on a case-by-case basis, improvement activities must be planned and implemented after analysis.

» General analysis of notifications to the system must be repeated regularly, reported and evaluated. According to evaluation as a result of general analysis, necessity of unit- or process-based improvement activities must be determined.

» All staff members must be informed about the importance of notification for patient and staff safety, how to do it and improvement activities carried out as a result of notifications.

Risk Management

Standard Code	Standard	AC Code	Assessment Criteria (AC)
YO.RY.01.00	Risks related to laboratory and laboratory related processes must be managed.	YO.RY.01.01	There must be a regulation related to managing the risks that may occur in Laborotary.
		YO.RY.01.02	Risk management plan must entail patients, relatives, carers, visitors, staff, facility safety and environmental safety and administrative and financial processes.
		YO.RY.01.03	Risk management plan must entail following issues: » Patients » Relatives » Carers » Staff » Facility safety » Environmental safety » Administrative and financial processes » Strategic risks » Comminucation processes with stakeholders
		YO.RY.01.04	Risks to be addressed within the scope of risk management must be determined, analyzed and risk levels must be identified.
		YO.RY.01.05	Necessary measures must be adopted in line with the according to the risk level identified, and actions must be taken for improvement.

		YO.RY.01.06	Risks identified and effectiveness of improvement actions must be continuously monitored reviewed periodically.
		YO.RY.01.07	Indicators for monitoring the effectiveness of risk management must be determined and monitored.

Goal

To prevent or minimize risks related tothe laboratory and services provided within the scope of patient, patient's relatives, staff, facility safety and environmental safety and administrative/financial processes.

Objectives

- » Patient Safety
- » Healthy Working Life
- » Efficacy
- » Efficiency

Standard Requirements

Scope of the Risk Management

Risk management must cover patient, employee, facility and environmental safety including administrative and financial processes.

Risk management must include all physical, chemical, biological, ergonomic, psychosocial factor and service based risks that may be faced in laboratuary.

Policies, processes and methods regarding risk management must be defined in relevant documents.

In risk management procedure, at least the following terms must be defined:

- » Goals and objectives
- » Scope
- » Risk management method
- » Obtaining opinions of the relevant employees
- » Reporting of the defined risks
- » Analysis of the defined risks, risk level detection and keeping records
- » Management of processes regarding required improvement actions

Risk Management Plan

» Risk management plan aims reviewing and observation of the risks.

The plan must cover at least the following topics:

» Process, action or factor in which the risk is evaluated

» Detected risks relevant to processes, actions or factors mentioned at the previous article

» Designated risk levels

» Precautions against the risks

» Responsible staff

» Designated time period for precautions

All defined risks must be registered in scope of the risk management plan. Risk record is a live document which needs to be updated regularly.

Identification and Analysis of Risks

» Taking into consideration the risk management scope, risks must be identified on the basis of unit, person and/or process.

» Risks must be analyzed in line with the method determined by the institution.

» Risk analysis method must be simple and easy to understand and implement.

» Risk levels must be rated in at least three categories (Low, medium, high) considering the possibility to occur and potential effects.

Improvement Actions

» According to identified risk levels, measures must be adopted on the basis of unit, person and/or process, and improvement actions must be taken.

Monitoring the Effectiveness of Risk Management

» Risks identified within the framework of risk management and effectiveness of improvement actions must be continuously monitored and reviewed periodically.

» Indicators for monitoring the effectiveness of risk management must be determined and monitored.

» Sustainability of measures taken must be ensured to achieve effectiveness in risk management effectiveness.

» Risk analysis must be updated periodically (at least once a year) or when necessary.

Training Management

Standard Code	Standard	AC Code	Assessment Criteria (AC)
YO.EY.01.00	In accordance with quality improvement activities, training needs of staff must be determined, and it must be ensured that necessary training is conducted effectively.	YO.EY.01.01	Responsible in charge of the planning and coordination of training activities must be determined.
		YO.EY.01.02	Training needs must be identified on the basis of staff.
		YO.EY.01.03	Training plans must be prepared and implemented in line with training needs.
		YO.EY.01.04	Effectiveness of training plans and trainings carried out must be monitored and necessary improvement actions must be taken.

Goal

To deliver necessary trainings to patient/carer and staff efficiently and effectively in line with quality improvement activities of laboratory.

Objectives

- Efficacy
- Continuity
- Productivity
- Efficiency
- Convenience

Standard Requirements

Training Management

» Responsible staff must be determined in order to manage the decision, planning, coordination, communication and evaluation procedures so as to implement effectively and efficiently the necessary trainings which must be provided for quality improvement at laboratory.

» Responsible staffmust determine the processes related to trainings and rules concerning the operation of procedures. Within this scope, the minimum processes which must be handled are as follows:

- Identifying training needs
- Preparing training plans
- Implementing the training activities planned
- Monitoring the effectiveness of training plan and trainings conducted and improving them

» Training responsibles must collaborate with other units and responsibles which operate under the scope of quality management.

Identifying Training Needs

» In line with the objectives of quality improvement, it must be identified who needs training on which subjects, at what level and scope. While identifying subjects and scope for training needs, the following must be assessed:

- The results of performance evaluation within the scope of quality improvement within the laboratory (self-evaluation, data derived from the indicators, etc.)
- Efficiency evaluation results of previous trainings,
- Feedback, requests and observations related to training activities.

» Training subjects must be categorised at least by hierarchical level, occupational group, specific to department and general. It must be identified which training will be delivered to which occupational group and throughuse of which content. Training subjects must cover at least the following general headings:

- Quality management trainings
- Patients' rights training for staff
- Patient and staff safety training for staff
- Risk management training for staff

- Trainings for patients
- Staff compliance trainings
- Device trainings
- Speciality trainings
- Trainings on new scientific advances
- Trainings for social purposes
- Self-development trainings

Planning and Implementation of Trainings

» Training plans must be developed to regulate processes of preparing content for trainings, determining methods and implementation and evaluation procedures in a systematic manner.

» Training plans must be developed as short-, medium- and long-term plans considering the nature of training need, priority of objectives to be achieved through training, time needed to achieve objectives, institutional policy of laboratory and targets and objectives of change process.

» Training plans must include at least the following:

- Training goals and objectives
- When, to whom and by whom the training will be delivered
- Training method
- Training stages if any (basic training, advanced training, theoretical and practical training, etc.)
- Training location
- Duration of training
- General headings concerning the content of training
- Materials needed for training
- Methods to evaluate training

» Trainings must be implemented in line with plans.

» Guidelines for general and department orientation training must be prepared and it must be ensured that orientation training is delivered right after a new recruitment is made.

» During the training period, in cases such as arise of a need for a trainingun-foreseen in the plan, a change training content or training method, training plan must be revised in a way that it can be traced back. It must be ensured

that staff have access to training materials and resources considered to be appropriate for sharing by training responsible staff.

Evaluation of Training

» Compliance with training plan prepared must be monitored, and measures must be taken to enhance compliance with the plan.

» Efficacy and effectiveness of training programs implemented must be evaluated on the basis of goals and objectives set.

» Evaluation must also cover trainer's performance.

» Some of the methods that can be used to evaluate the effectiveness and efficiency of training programs implemented are listed below:

- Pre-and post-test
- Self-assessments
- Observations
- Interviews with participants
- Evaluations with unit supervisors
- Questionnaires
- Measurement methods to measure training-induced change in behaviour (such as accepted scales)

Institutional Communication

Standard Code	Standard	AC Code	Assessment Criteria (AC)
YO.Kİ.01.00	Institutional communication activities must be carried out effectively.	YO.Kİ.01.01	Under the scope of institutional communication, target audience must be identified by taking laboratory structure, core policies and values into account and communication strategies for target audience must be determined.
		YO.Kİ.01.02	Target audience must be informed about laboratory activities and organization.
		YO.Kİ.01.03	Necessary actions must be taken to create a positive opinion among target audience.

Goal

To create public opinion based on positive attitude, behavior towards and trust in the laboratory and its activities, to ensure that policies and activities of laboratory are adopted by establishing permanent good relations with its target audience and to improve the effectiveness and quality of services throughthe feedbacks of target audience.

Objectives

- » Patient-Orientedness
- » Efficiency
- » Equity
- » Continuity

Standard Requirements

Identifying Target Audience and Communication Strategy

» Target audience means internal and external communication stakeholders of the hospital. (Institution employees, patient/patient relatives, suppliers, other governmental institutions, private institutions etc.)

» Under the scope of institutional communication, target audience must be identified by taking institution type, size, patient profile, regional features, people and institutions communicated and main policies and values, and communication strategies for target audience must be defined.

» Target audience must be identified by taking internal and external communication stakeholders into account.

» Within the framework of communication strategy, communication rules must be established for target audience within the laboratory. Within this scope at least the following issues must be addressed:

- Information and decision flow among units and elements of laboratory
- Information and decision flow in evaluation and inspection functions
- Communication during training and information activities
- Communication during activities aiming at enhancing motivation and taking ownership of institutional identity

» Communication rules regarding target audience outside the laboratory must be determined. These rules must consist of following rules at least:

- Informing external stakeholders such as patient/patient relatives, suppliers, other governmental institutions on services provided
- Communication between laboratory staff and patient/relatives or other employees who use the laboratory service
- Informing service buyers during diagnosis and treatment processes

Informing Target Audience

» Information activities specific to target audience identified must be conducted

» Activities must be done regarding on-line representation and promotion of the institution. Institutional website must be managed effectively, and it must be developed in a way to provide current, easy-to-use and adequate information. Target audience must be informed about at least the following issues:

- Core policies and values
- Organizational structure
- Service areas
- Activities carried out under the scope of social responsibility
- Human resources
- Public relations activities
- How to make an appointment
- Communication and travel
- Access to service within laboratory

» Since the staff at the laboratoryare important representatives for institutional communication they must be trained about the subject.

Creating Positive Public Opinion

In order to create positive public opinion in the target audience, first of all, information activities towards society about services provided and activities carried out must be conducted in line with needs and expectations of target audience.

While these activities can be conducted through information tools, it must be ensured that staff communicates effectively with patients and carers during service provision and senior management represents laboratory effectively outside and establishes good relations.

Monitoring Institutional Communication and Perception

Questionnaires about performance of institutional communication activities and in order to measure perception of current identity and image of Laboratory in the target audience must be conducted regularly, the results must be evaluated, and necessary actions must be taken to improve institutional communication strategies.

Performance Measurement and Quality Improvement

Monitoring of Indicators

Standard Code	Standard	AC Code	Assessment Criteria (AC)
PÖ.Gİ.01.00	Institutional indicators must be monitored and evaluated in order to continuously improve service provision processes regarding primarily administrative, financial and medical steps.	PÖ.Gİ.01.01	Indicators must be determined to include processes concerning service delivery, primarily administrative, financial and medical steps.
		PÖ.Gİ.01.02	Indicator cards must be created to cover issues related determination, collection, evaluation and monitoring of data to be used for indicators.
		PÖ.Gİ.01.03	Monitoring, evaluating and reporting of indicators must be carried out through information management systems.
		PÖ.Gİ.01.04	Necessary improvements must be made taking into consideration the analysis results for the indicators.
		PÖ.Gİ.01.05	The results of the SAS indicators must be submitted to the SAS Indicator Data System.

Goal

To detect and correct potential problems related to service delivery, primarily administrative, financial and medical processes, and ensure that interventions are carried out to improve quality.

Objectives

Objectives vary according to the features of indicators.

Standard Requirements

Identifying Indicators

» Institutional indicators must be monitored and evaluated in laboratory concerning processes related to service deliveryin order to improve quality continuously, primarily administrative, financial and medical steps.

» In order to continually improve the processes for service delivery, the SAS indicators which has to be monitored according to the type of institution service should be determined.

Indicator Cards

Indicator cards must be prepared for indicators identified. Indicator cards should include at least the following information:

» A short description of the indicator
» Reason for monitoring
» Linked process
» Calculation method/formula
» Target value
» Data source
» Data collection period
» Data analysis period
» Supervisors for collecting, monitoring, evaluating and analyzing data related to indicator
» People to share the results with
» Points of attention concerning indicator

Information Management System Infrastructure for Indicator Management

Necessary information management system infrastructure must be established in the purpose of indicators' data collection, monitoring and evaluation of results; and must be used effectively.

Collection and Analysis of Data and Improvements

It must be ensured that relevant staff members be involved in the data collection and analysis processes. Based on analysis concerning indicators, required corrective and preventive actions must be planned and implemented.

SAS Indicator Data System

Results of determined indicators at SAS Indicators List must be submitted to the SAS Indicator Data System.

Healthy Work Life

Human Resources Management

Standard 1

Standard Code	Standard	AC Code	Assessment Criteria (AC)
SÇ.İK.01.00	A management structure that will fulfill the requirements concerning planning of human resources, improvement of work life and the personnel must be established.	SÇ.İK.01.01	The relation of the management structure with other management levels must be identified.
		SÇ.İK.01.02	Duties, authorities and responsibilities of those in the management structure and the qualifications they must have must be identified.
		SÇ.İK.01.03	Annual goals and work plans must be developed.
		SÇ.İK.01.04	Feedback processes aimed at determining satisfaction levels and comments and suggestions of the personnel regarding their work life must be identified.

Goal

To define a management structure that will perform activities suchas assignment, coordination and assessment regarding necessary processes for the establishment of a healthy working life.

Standard Requirements

Management Structure and Its Relation with Senior Management

» A management structure that will perform all activity planning and coordination such as employment, orientation, improvement of and support to the personnel, providing the personnel with physical and social opportunities, minimizing safety risks that threaten employees and increasing motivation must be established at laboratory.

» Management relations such as where the new management structure will be in the hierarchy of laboratory management or to whom it will be responsible, which powers it will have, who will be in this structure and who will be responsible to this structure must be defined.

Duties, Authorities and Responsibilities

» Terms of reference must be prepared for people to be involved in management structure, and their responsibilities and authorities must be identified.

» Which qualifications employees involved in the structure must have must be defined in order to carry out all necessary duties and responsibilities.

Targets and Planning

» Newly formed management structure must define annual targets in order to ensure a healthy work life. Key factors such as which activities will be carried out, which measures will be taken and how much budget will be needed in order to reach the targets must be planned.

Comments and Suggestions from the Staff

» A feedback system shall be formed regarding obtaining all kind of feedbacks (opinions, suggestions, complaints etc.) of laboratory staff and clinic doctors who use laboratory services.

» Staff needs and expectations shall be determined.By taking these into account, in which scope and via which tools feedbacks will be obtained must be determined for ensuring their participation to decision mechanisms.

» Activities towards identifying the needs and expectations of the staff must meet at least the following requirements:

- Regularly conducted satisfaction questionnaires
- Personal and face-to-face interviews with the staff
- Obtaining opinions and suggestions of staff

Standard 2

Standard Code	Standard	AC Code	Assessment Criteria (AC)
SÇ.İK.02.00	The requirements necessary to constantly improve recruitment and compliance processes of the personnel and their work life must be determined and fulfilled.	SÇ.İK.02.01	A personnel recruitment plan must be developed in line with human resources needs of laboratory.
		SÇ.İK.02.02	Personnel recruitment processes must be identified.
		SÇ.İK.02.03	Processes regarding ensuring the adaptation of the newly recruited personnel to laboratory must be identified.
		SÇ.İK.02.04	Duties, authorities, responsibilities of the personnel and the qualifications they should have and the performance criteria their job requires must be determined.
		SÇ.İK.02.05	Performance of the personnel must be measured, training needs must be determined to enhance the performance and necessary trainings must be provided.
		SÇ.İK.02.06	How and to what extent the current standards, protocols and evidence-based clinical guidelines accepted by laboratory are used by the personnel must be monitored and trainings aimed at ensuring the use of these standards and guidelines efficiently must be identified.

Goal

To ensure that needs regarding continuous improving of work life and the processes of recruitment and adaptation of staff are identified and met.

Standard Requirements

Recruitment of Staff

» Laboratory must define in which service area and staff with whichqualifications is needed, must determine the feasibilityof recruitment and must plan main processes suchas recruitment and training in advance.

» In recruitment plan, the number and the quality of staff needed (training, knowledge, skills, etc.) must be included considering different disciplines and professional groups that will be able to meet needs concerning services to be provided.

» Need for staff must be regularly reviewed by preparing terms of references on the basis of departments and processes, and human resources must be planned by taking legal regulations into account. Measures must be taken regarding how recruitment will be made and which qualifications new staff must have and how many people will be recruited.

» Which documents and information is needed in the process of application and recruitment and steps regarding evaluation and approval process must be defined.

» Laboratory must inform new recruits about from which laboratory facilities they can benefit from, opportunities provided and employee rights.

Recruitment Processes

» Recruitment processes in laboratory must be described, and how staff planned to be recruited for previously defined tasks in the departments in need must be defined. Principles and processes regarding recruitment processes must be announced.

Adaptation of Staff

» Laboratory must define the processes that will enable new staff, recruited for the position opened in line with the needs, to adapt to the new working environment quickly and accurately. All kind of information such as main and professional rules, basic workprinciples, elements that may threaten personnel health and safety, hierarchical order and all facilities that may be used by the personnel must be provided to the personnel during recruitment and later regularly.

» Adaptation of staff to job and work environment must be assessed, and if needed, activities towards adaptation must be repeated.

Duties, Powers, Responsibilities and Performance Criteria

» Duties, powers and responsibilities of staff that is working or planned to be recruited must be identified in line with service processes in a way that they will encompass previously defined duties and responsibilities.

» Performance criteria defined as the performance of the duties by staff successfully must be identified, and staff should be informed about the criteria.

» Performance of staff must be measured on the basis of performance criteria set by laboratory. Measurements must be made at determined intervals and at least once a year by the laboratory. And that the measurement of staff be documented.

» In order to increase the employee performance, it must be determined which trainings will be provided and what their scope will be in line with the qualifications and needs of staff and required planning in relation to training must be done. Objectives of the trainings that will be provided within this scope must be defined in advance and it must be assessed after trainings whether the objectives set have been attained.

» Only trained and authorized staff shall use specific and medical devices and in the training plans, the need for training on such issues must be taken into account.

» How and to what extent current national/international standards, protocols, evidence based clinic guidelines and national clinical guides (if exists) accepted by laboratory are used must be monitored and trainings must be planned in order to ensure effective utilization of the standard and guidelines.

Employee Health and Safety

Standard Code	Standard	AC Code	Assessment Criteria (AC)
SÇ.ÇG.01.00	Factors threatening the health and safety of employees should be identified and necessary precautions should be taken to establish a healthy and safe working environment	SÇ.ÇG.01.01	Responsible aimed at management of the factors that threaten employee health and safety must be determined.
		SÇ.ÇG.01.02	Risk analyses must be conducted on the factors that threaten employee health and safety and measures must be taken to eliminate or decrease the risks that threaten the safety.
		SÇ.ÇG.01.03	It must be ensured that employees use the personal protective equipment against the risks.
		SÇ.ÇG.01.04	Quality improvement activities that aim to ensure the continuity of employee safety must be planned.
		SÇ.ÇG.01.05	Physical and social opportunities that are necessary to improve the work environments and the work life must be provided and personal needs of the employee regarding work life must be met.

Goal

To establish healthy work life environment in laboratory by removing or minimizing the elements that threaten the safety of staff.

Standard Requirements

Responsible of Personnel Health and Safety

» A responsible must be determined for detecting and taking measures against threats that exists or may exist against the laboratory personnel. In line with size of the laboratory and risks posed by safety threats, responsibilities for ensuring implementation and coordination of work in an efficient, continuous and systematical manner.

Risk Analyses

» First of all, assessment must be performed by identifying the risk factors that threaten the safety in terms of employee safety within laboratory and again by identifying their risk levels. After identifying risk factors, necessary action must be undertaken in order to remove or minimize the detected threats according to their priorities

» In order to secure personnel health and safety atlaboratory, at least the following issues must be addressed:

- Developing management policies in relation to health and safety of personnel
- Preventing infections
- Planning and implementation of health screenings
- Food safety
- Lighting
- Falls prevention
- Managing facility-borne risks
- Reducing needle stick injuries.
- Ergonomic factors
- Preventing violence against healthcare staff and responding to violence as soon as possible
- Preventing mobbing among staff
- Managing wastes threatening the safety of personnel
- Immunization
- Reducing unnecessary workload
- Stress management

» At laboratory, action must be taken in order to ensure that medical, psychological and other counseling and support services are always available for the staff.

» It must be ensured that near misses and adverse events which threaten employee safety are reported in order to treat staff with occupational disease and injuries.

Personal Protective Equipment

» Which personal safety equipment will be used in which departments must be defined and measures must be taken in order to ensure the use of these equipment.

» It is required that sufficient number of personal safety equipment having protective qualities is made available in designated working areas and trainings are organized for the employees about the operation of such equipment.

Quality Improvement

» In order to secure personnel health and safety, laboratories must plan and implement quality improvement activities in order to remove or avoid the elements that pose risks.

Improving Working Environment

» Improvement plans on issues such as physical environments of the personnel, materials and devices they use, chemical, physical and biological materials and working methods must be planned by taking personnel expectations into account.

» Achieving harmony between duties and employees' physical and mental capacities

» In order to reach an adequate level of health and safety; activities and trainings in order to encourage employees' professional improvement or motivation, to achieve communication of employees between units and departments and to ensure collaboration and dialogue effectively must be planned and implemented

» Necessary physical and functional arrangements must be made at laboratory for disabled or chronic health problems staff.

» It must be ensured that facilities offered to staff are easily accessible, practical and employee-oriented.

Patient Experience

Patient Experience

Standard 1

Standard Code	Standard	AC Code	Assessment Criteria (AC)
HD.HD.01.00	The services provided at Laboratory must be organized in such a way as to protect the safety of patients and their carers.	HD.HD.01.01	Risk analyses must be conducted on the factors that threaten patient safety and measures must be taken to eliminate or decrease the risks that threaten safety.
		HD.HD.01.02	Quality improvement activities must be planned to ensure the continuity of patient safety.

Goal

To ensure the safety of patients and carers in services provided by laboratory, and to organize provided services and processes in line with safety of patients and the carers by determining in advance the elements that could threaten their safety.

Objectives

» Patient Safety

Standard Requirements

Quality Improvement

» The risks for patient safety must be analyzed and evaluated; levels of risk must be determined and necessary improvement actions must be taken on the basis of the results of the analysis. Effectiveness of activities must be monitored.

» In this context, Laboratory must address following issues related to patient safety, which is mentioned in various sections of Standards of Accreditation in Health:

- Prevention Of Infection
- Falls Prevention
- Safe Injection Practices
- Medication Safety
- Nutrition
- Equipment Safety
- Identity Verification
- Information Safety
- Facility Safety
- Medical Device Safety
- Adverse Event Reporting System
- Waste Management

Standard 2

Standard Code	Standard	AC Code	Assessment Criteria (AC)
HD.HD.02.00	The services provided in laboratory must be organized in such a way as to protect patient and carer rights.	HD.HD.02.01	Laboratory must declare information on quality of services provided, service access conditions and patient rights.
		HD.HD.02.02	Patient or carers must be informed about the services related to laboratory services and patient responsibilities in processes in which patients are included.
		HD.HD.02.03	Activities must be planned in all service processes for the patient to be respected and to receive meticulous service.
		HD.HD.02.04	Patients must be able to examine the medical documents about themselves and receive a copy if requested.

		HD.HD.02.05	Arrangements must be made for the spiritual and cultural needs of the patient.
		HD.HD.02.06	Patient's consent must be obtained if the patient is to take part in a research or experiment, or if the information, data or materials about the patient are to be used in any way.
		HD.HD.02.07	Ethical dilemmas such as not treating the patient, withdrawal of the treatment or discontinuing the treatment must be addressed and settled in time.
		HD.HD.02.08	Patient must be informed that he/she has right to decline medical process/ intervention which will be used.
		HD.HD.02.09	Processes for informing the patient or carer if unintended events that negatively affect the patient safety occur must be identified.

Goal

To ensure that the rights of patients and carers are under guarantee in the delivery of services provided by the laboratory and that services and processes are arranged with this target in mind.

Objectives

- Patient-Orientedness
- Convenience
- Continuity
- Equity
- Timeliness

Standard Requirements

Information about Services and Patient Rights

- Laboratory must declare information on quality of services provided, service access conditions and patient rights.

- Patient right must cover the following topics:
  - √ Privacy
  - √ Dignity and respect
  - √ Information privacy
  - √ Patient safety and security
  - √ Patient Consent
  - √ Declining the treatment

» Patients and/or carers should be informed about relevant laboratory services (sample extraction, result reporting, etc.) which can be provided, responsibilities of the patient and other additional services.

» In case adverse events that affect patient's safety negatively occur, processes in relation to informing the patient or his/her carer must be defined.

Resolving Ethical Dilemmas

Ethical dilemmas like not treating, withdrawing the treatment or discontinuing the treatment must be addresses in time and resolved.

When there are ethical dilemmas, a solution must be found through decisions made jointly by the patient and doctor in such a way as to ensure patient safety and within the shortest time possible.

In the case of patients who do not accept the procedure despite the opinion of the physician, the procedures to be performed should be determined.

Choices and Preferences of Patients and Patient's Consent

During the health care process, consideration must be given to the choices and preferences of the patient.

Patient must be informed verbally by using a simple and understandable language before any planned medical intervention

The patient should be informed about the tests and interventional procedures to be carried out in line with the scope of service of the laboratory, for examinations that are performed outside of routine examination studies and that are of special importance (HIV, genetic test, etc.) and high-risk (biopsy, test under anesthesia, etc.) for the patient, the patient should be informed in detail and written consent should be obtained.

Access to Medical Documents

It must be ensured that patients have access to and take a copy of applied procedures, analyses or all the documents entailing private information about

themselves during and after service provision. Rules for obtaining patients' test results by who excluding the patient himself/herself, in which conditions and how shall be set in line with information safety principles. A policy needs to be determined for sharing of above-mentioned patient records with nonpatients.

Spiritual/Cultural Needs

Laboratory must ensure that patients receive service in accordance with their cultural and spiritual values. The staff should be informed about the related applications and their awareness should be increased.

In accordance with the cultural needs, necessary arrangements must be done in order to ensure privacy for women and men.

Standard 3

Standard Code	Standard	AC Code	Assessment Criteria (AC)
HD.HD.03.00	A system must be established to receive feedback (comments, suggestions and complaints etc.) from patients and their carers about the services that are provided.	HD.HD.03.01	The system's scope, methods and tools must be defined including receiving, investigating and resolving of all feedbacks.
		HD.HD.03.02	Patients and carers must be informed about how they can provide feedback.
		HD.HD.03.03	Feedback must be assessed.
		HD.HD.03.04	Necessary improvement activities must be planned for the results that come out of the feedback.

Goal

To make sure that necessary improvements are done by obtaining feedback from service users in a systematical manner.

Objectives

» Patient-focused

Standard Requirements

Feedback System

A feedback system must be established to receive all kinds of feedback (comments, suggestion, complaints etc.) from those who are provided with service at laboratory. Within this system; methods such as satisfaction surveys conducted regularly to receive comments and suggestions from patients and carers, one-on-one interviews or face-to-face meetings held when necessary, assessment of expectations and satisfaction levels before and after the service must be used.

Information on Feedback System

» Patients and their caretakers should be informed about how they can give feedback about services which they are offered, problems they face during service processes or issues related to laboratory and laboratory staff.

Assessment of Feedback

» Feedback received from patients and carers must be analyzed in a systematic manner, and the findings must be evaluated.

» The findings obtained through data analyses must be shared with the upper management and relevant units and benefit must be derived from feedback in an efficient manner.

Quality Improvement

As a result of the findings obtained from the feedback, what kind of improvements are necessary must be determined and how these improvements will be done must be planned according to the order of importance and these plans must be put into practice.

Standard 4

Standard Code	Standard	AC Code	Assessment Criteria (AC)
HD.HD.03.00	Necessary precautions must be taken in order to provide patient able to reach services in time.	HD.HD.03.01	Patients must be provided with reception, orientation and consultation services that will facilitate the application process at laboratory and through which they can access all the information they need in the application process at laboratory.
		HD.HD.03.02	All the areas where the service is provided at laboratory must be organized so as to ensure patient comfort.
		HD.HD.03.03	Facilitating measures concerning access to services and waiting periods must be taken based on age, disease and disability.
		HD.HD.03.04	Service delivery processes must be organized in such a way as to ensure the laboratory test conductions of the patient in a timely manner.

Goal

To put forward the measures that must be taken by the institution and to ensure the access to service to make sure that patients access the services provided by laboratory in a timely, efficient, effective and sufficient manner.

Objectives

- Patient-Orientedness
- Convenience
- Continuity
- Equity
- Timeliness

Standard Requirements

Reception, Orientation, Consultation

» In line with the information declared by laboratory about the services it provides, laboratory must provide patients that wish to receive service with detailed information they might need to help them make decisions.

» How the information concerning reception, consultation and orientation such as all the important locations within laboratory necessary for the application procedures that must be conducted by the patient and the carer, information and documents they might need and waiting rooms etc. will be provided for the patient must be planned and put into practice in advance.

Patient Comfort

» Arrangements must be done to meet the basic human needs such as keeping service areas clean, making sure there are waiting rooms where the patient can sit and have rest when needed, arranging shared areas like stairs, elevators, toilets and parking areas by taking into account needs of the patients and making sure there is no factor that threatens patient safety.

Facilitating Arrangements

» Arrangements must be in place for shared areas like stairs, elevators, toilets, parking areas and to ensure ramps and wheelchair services so that elderly, disabled people and people in need of help due to disease can access the services easily.

» Action must be taken to give priority to elderly, disabled people and people in need of help, due to disease that receive service from laboratory.

Laboratory Service Processes

» Procedures and steps of procedures must be examined in detail to detect system-related problems that might pose a risk for patient safety that prolonging access to laboratory services and measures must be taken to hold the procedure time in an optimal value and to increase efficiency.

» Laboratory must assess its service processes within this framework and document its work and plans aimed at increasing efficiency, productivity and safety.

Health Services

Laboratory Services

Standard 1

Standard Code	Standard	AC Code	Assessment Criteria (AC)
SH.LH.01.00	Laboratory physical environment must be established in a way that ensures test and employee safety.	SH.LH.01.01	In laboratory, designated areas for acceptance of samples, preparation prior to analysis, reporting of results after analysis must be arranged in a way that ensures safety of samples and tests.
		SH.LH.01.02	In all areas of laboratory, a healthy work environment must be ensured.

Goal

In Laboratory; to ensure that physical conditions are configured in a way that maintains convenient delivery of patient samples in appropriate conditions, storing, analyzing, test result reporting and to create a healthy working environment for personnel.

Objectives

» Patient Safety

» Healthy Work Life

Standard Requirements

» In Laboratory; sample extraction, preparation prior to analysis, storing, analysis and post-analysis, archiving, required fields for processes such as re-

porting the results, these areas must be conditions size, planning for the safe and effective use of space, ambient temperature, ambient humidity, ventilation conditions, noise control, arrangements for inputs and outputs, arrangements for emergencies, etc.). Necessary checks must be done and monitored in order to ensure determined conditions regarding these areas.

» Procurement and convenient usage of supplies and equipment needed for test safety in laboratory must be ensured.

Standard 2

Standard Code	Standard	AC Code	Assessment Criteria (AC)
SH.LH.02.00	A test guide must be prepared for informing of healthcare workers responsible with out of laboratory processes.	SH.LH.02.01	A guide including general information on tests being performed in laboratory, rules about extraction, transfer, acceptance of samples, test methods, reporting of results and interpretation must be prepared.
		SH.LH.02.02	Guide must be accessible by health care professionals.
		SH.LH.02.03	Related healthcare staff must be informed about the use of guide.

Goal

In order to ensure test safety in external laboratory processes, providing information to test relevant employees in a correct and efficient manner and to provide access to required documents.

Objectives

» Patient Safety
» Efficacy
» Efficiency
» Productivity

Standard Requirements

An informative guide for process between test request and use of result for patient's benefit must be prepared and be available to relevant employees.

Preparation of Laboratory Test Guide

» A test guide in accordance with scientific data, which reflects its unique conditions, consisting of all performed tests must be prepared.

» Laboratory test guide must contain at least up to date information about following topics:

- General information on laboratory tests conducted
- Sample and test compatibility
- Tests that require prior preparation and relevant rules
- Sample extraction rules
- Rules regarding laboratory sample transfer and acceptance
- Test methods
- Possible interference and cross reactions
- General information on consultation processes if available
- Information on reporting and interpretation of results
- Other specific test explanations

» Laboratory test guide must contain general working principles of laboratory and information on critical processes out of laboratory; also in guide, special explanations for tests must be addressed if needed.

Laboratory Test Guide Accessibility and Informing

» Up to date version of test guide must be accessible at all points between test request and use of test result for patient's benefit.

» Relevant employees must be informed about how to access and use test guide.

Standard 3

Standard Code	Standard	AC Code	Assessment Criteria (AC)
SH.LH.03.00	Check of pre-analysis laboratory processes must be implemented.	SH.LH.03.01	Rules and procedures between test request and analysis must be defined.
		SH.LH.03.02	Rules regarding test requests must be determined and information and guidance provision for related physicians must be ensured.
		SH.LH.03.03	Training must be provided for related healthcare staff about extraction, transfer, acceptance of samples and pre-analysis preparation.

Goal

To ensure laboratory test accuracy and reliability by taking processes between test request and analysis under control.

Objectives

- Patient Safety
- Efficiency
- Convenience
- Efficacy
- Productivity

Standard Requirements

Test Order

- Information and guidance support must be provided by laboratory in regards to ensure clinicians to make correct test request, by using tools such as providing information on indications in test guide, verbal briefings, training etc.
- Physician responsible with clinical trial of patient must fill required information completely during test request. If needed, patient's specific information which may affect clinical interpretation must be provided.
- Relevant clinicians must provide necessary support to laboratory specialists about determination of tests to be performed.

» Patients should be informed before and during the test about foods (type of food, fasting, satiety, etc.) and drugs that will affect patient safety and test results. Risks are determined for patient safety and measures should be taken.

Sample Extraction

» At diagnosis and planning treatment of patients, rules regarding taking samples for tests excluding urgent ones must be determined considering requirements such as disease stage, circadian rhythm and effects of hunger etc.

» Risks for patient safety related to equipment and devices during sample extraction should be determined and precautions should be taken.

» Sufficient information regarding self-sampling must be provided when task is needed to be performed by patient.

» Sample date must be correctly recorded.

» Request, taking sample, sample acceptance or rejection must be recorded on information management system (IMS) as separate stages and must be viewable by authorized users.

» Training must be provided for employees involved in sampling process.

» In pre-analysis phase, steps that require identity check (sample extraction, labelling, sample acceptance, etc.) and how this check will be done must be determined.

Sample Transfer

» Informing must be done about issues such as transfer containers to be used during sample transfer to laboratory, transfer method (manual methods, pneumatic system etc.), appropriate sample position and transfer temperature.

» Maximum acceptable sample transfer durations must be determined.

» Sample transfer must be carried out by responsible personnel and training must be provided for assigned employees about performing transfer task in determined duration and by using correct methods.

» Physician responsible with patient's clinical trial and other health employee must follow rules regarding sampling and transfer.

Sample Acceptance and Analysis Preparation

» For purpose of tests to give reliable results, regulations must be done regarding convenience evaluation of samples delivered to laboratory and sample acceptance/rejection.

» In records regarding sample acceptance/rejection, date, time, unit which the samples are sent from, by whom it was accepted/rejected, reason of rejection(if the sample is rejected) must be included.

- For incompatible samples, before rejection, employees must try to solve the problem. Especially for samples which are hard to re-extract, the sample must be inspected in sub-optimal conditions excluding the situations that consists an absolute rejection criterion.
- Laboratory samples must not be processed before acceptance.
- Acceptance or rejection of samples must be done through information management system.
- Training must be provided for relevant employees about how acceptance and rejection procedures are carried out.
- Analysis must be carried out regarding rejected samples, considering reasons for rejection and unit information where rejected sample is taken. Required corrective and preventative actions must be implemented.
- Rules regarding pre-analysis sample procedures on test basis must be determined and related training must be provided for relevant staff.

Standard 4

Standard Code	Standard	AC Code	Assessment Criteria (AC)
SH.LH.04.00	Check of analytic processes related to laboratory tests must be ensured.	SH.LH.04.01	Rules and procedures between analysis and verification of result must be defined.
		SH.LH.04.02	Rules must be determined for the safe and effective use of devices in laboratory.
		SH.LH.04.03	Quality control studies related to reliability of test results must be implemented.

Goal

To ensure continuity of quality improvement activities regarding laboratory analytical processes and patient safety.

Objectives

- Patient Safety
- Efficacy
- Efficiency
- Productivity
- Continuity

Standard Requirements

Laboratory analytical process covers the following topics:

» Performing tests

» Device Management

» Method Validation/Verification

» Quality Control Activities

Performing Tests

» Informative and comprehensive documents must be created in a waythat consist all stages of performing test process for purpose of ensuring standardization of performing test process and taking performing process under control.

» These documents must include at least the following sub-processes:

- Definition of cleaning, maintenance, repair and calibration processes related to devices to be used in test process
- Preparation and control of kits/materials to be used
- Test calibrations, internal and external quality assessment activities
- Methods regarding test performance process
- Possible interferences (eg: hemolysis, lipemia, bilirubinemia, drugs) and cross reactions
- Result approval
- Internal and external consultation processes if available

Quality Control Activities

Quality control activities are implemented actions for purpose of ensuring reliability of test procedure, testing and keeping under control that tests give results in convenience with expected aim.

Internal Quality Control Activities

» Sample features used in internal quality control activity must be similar to or same with routine patient samples. Samples must be processed in same procedure by using same methods.

» Internal quality control test levels and testing period must be determined in accordance with test type by taking test directions and national or international guidelines as basis.

» In the event of a change in test process or after device failure/maintenance/

calibration, internal quality control activities must be carried out.

- Which values are going to be accepted must be determined regarding internal quality control results. Corrective/preventive actions must be taken for inconvenient results.
- If there are inconvenient results in internal quality control activity, patient samples must not be processed.
- Internal quality control results must be recorded electronically or in hard copy. In order to ensure traceability of activity in these records, date/time information, test results, results obtained from corrective/preventative actions for inconvenient test results must be included.
- Regularly, regarding pathological sample inspection processes, various random samples must be tested by the expert in the scope of issues such as section quality, tissue trace, section width, scalpel marks and stain quality. Test results must be recorded.
- Training must be provided for employees on internal quality control process.

External Quality Assessment Activities

Which tests are to be included in which external quality program must be determined and external quality assessment must be conducted in compliance with working conditions that after-subscription program requires.

External quality assessment activities must be carried out considering terms below:

- External quality assessment test sample must be processed in same routine patient sample procedure by using same methods.
- Remaining sample from external quality assessment must be stored in appropriate conditions until test conclusion.
- Assessment results sent by external quality assessment program must be evaluated by a laboratory specialist.
- If assessment results are inconvenient, related root cause analysis and necessary improvement actions must be carried out.
- External quality assessment results, who it was evaluated by, root of problems (if exists) and related corrective/preventative actions taken must be recorded.
- In pathology laboratories, retrospective and prospective evaluations must be done in line with determined periods and methods in order to assess external quality/diagnosis validity.

Method Validation/Verification

- Method validation/verification must be carried out in order to determine conditions that ensure expected performance during routine use of tests performed in laboratory, to check if tests give results in compliance with

expected aim and to keep it under control. (See Clinical Laboratories Method Validation / Verification Guide)

» Implementing a full validation is not necessary when standard and validated methods (such as CE and FDA approved ones) are used. In this case, verification activity must be carried out for laboratory proficiency.

Measurement Uncertainty

» Measurement uncertainty regarding quantitative tests must be determined for result evaluations, deciding in accordance with measurement results, measurement result comparison, determination of compliance in accordance with limit values, and detecting laboratory performance that performs the test.

» In cases that measurement uncertainty is incompatible with aim of analysis result, expected uncertainty level must be achieved by carrying out either method change or required method improvements.

» Tests' measurement uncertainty data must be accessible when needed.

Standard 5

Standard Code	Standard	AC Code	Assessment Criteria (AC)
SH.LH.05.00	Check of post-analysis processes related to laboratory tests must be ensured.	SH.LH.05.01	Information which is required to be in result reports must be determined.
		SH.LH.05.02	Reporting of test results timely and accurate must be ensured.
		SH.LH.05.03	Rules for interpretation of test results and clinical suggestions in reports must be determined.
		SH.LH.05.04	Process of safe and effective reporting panic/critical values must be defined.
		SH.LH.05.05	Rules related to preservation and archiving of leftover biological samples, uncompleted analysis samples and reports must be determined.

Goal

To take necessary measures in test processes that take place after results' approval for ensuring use of results for patient's benefit and patient safety.

Objectives

- Patient Safety
- Convenience
- Continuity
- Efficacy
- Timeliness
- Patient-Orientedness

Standard Requirements

Out of laboratory processes that take place after results' approval consist of during and after post-analytical processes. These processes cover reporting of patient's test results and use of results for patient's benefit.

Patient Test Result Reports

- Minimum information to be included in test result reports must be determined by laboratory taking test based requirements and national/international standards.
- At least following time parameters must be included in reports:
  - Hospital/laboratory name
  - Name of the laboratory in which test is conducted
  - Patient name, surname
  - Clinician's name and surname who ordered the test
  - Order date and hour
  - Sample name
  - Test name
  - Date and time of sampling
  - Date and time of acceptance to laboratory
  - Result value unit
  - Reference range/value
  - Date and time of result's approval
- Clinicians' opinions and suggestions on design of the result reports must be considered. Report format must be designed dynamically with ability

that limitations of samples and interpretation of laboratory specialist can be integrated as needed.

» Rules regarding revised results reports should be identified and recorded.

Reporting Durations

» Minimum requirements for test completion time and reporting are as following:

- Test completion time must be determined separately for emergency and other tests considering hospital conditions, needs and scientific requirements.
- When determining completion time; considering tasks such as maintenance and cleaning of device, quality control activities, determination of optimal time must be taken as basis on not the minimum. For emergency tests, considering patient's clinical condition, minimum test completion time must be taken as basis.
- Health care employees must be informed about determined durations.
- Patients must be informed about the time of obtaining results.
- How to carry out informative activities must be determined when a change occurs. (Equipment failures, automation issues, etc.)

Interpretation of Test Results and Clinical Advices

In framework of determined rules by laboratory and in cases when needed, Information and guidance support for clinicians must be provided regarding interpretation of results. Here are a few practices that can be addressed within the scope of information and guidance support concerning interpretation of results:

- Reference ranges, decision limit
- Notification of test results with panic/critical values on time
- Including information about processing method in test guide
- Providing clinician access to measurement uncertainty information when needed
- Adding laboratory specialist interpretations and recommendations
- Additional test practices
  - √ Performing a pre-defined test (by clinician or laboratory specialist) added to system when a test results in a determined range (reflex tests)
  - √ Recommended patient-specific tests which are advised by laboratory specialist related to evaluation considering patient's clinical condition and test results. (reflection tests)
  - √ Showing traceability of laboratory processes about sample and test at final report (minimum time parameters)

- √ Discussing test results, diagnosis/treatment processes of specific cases at regular meetings (with participation of clinical and laboratory staff)

» Issues to be considered on interpretation of results are as following:

- Authority of adding explanatory text/comment must belong only torelevant laboratory specialist.
- Laboratory specialists must be careful about knowledge that is used in this field for being evidence-based, adequate and up to date.
- Becoming complicated of final reports using unnecessary information must be avoided.

» During reporting of antibiotic sensitivity test results, limited reporting principles must be followed in the scope of national and international standards.

» Identification and sensitivity test results of microorganisms which are important in clinical manner must be submitted to national surveillance systems.

Panic/Critical Value Notification

» Panic values for tests and rules for panic value notification process must be determined. At this step, following terms must be determined:

- Which tests are included for panic value application
- Which values are to be accepted as panic values on related tests
- What notification rules are going to be in case of presence of a panic value
- Whether related test will be repeated or not for test results with panic values and whether resampling will be requested or not
- How to set up test-based processes related to panic value results that repeat for the same patient

» Comments of clinical specialists must be obtained when determining panic values and it must be considered that panic value list can differ accordingto clinical specialty.

» Determined panic values must be defined on information management system.

» In the event of a panic value presence, a warning system must be established on information management systems to enable laboratory employees notice the panic value.

» Panic values for manually performed and manually entered test results must be defined on IMS.

» Warning system must be established in a way that can be noticed by laboratory employee before test result's approval.

» When panic value is noticed, notification of patient's physician or nurse must be done as emergency in accordance with determined rules.

» Records related to panic value notifications must be kept. These records must include at least the following information:

- Patient's name and surname
- Protocol number
- Unit
- Test name
- Panic value result
- Date and time of test result
- Person who performs panic value notification
- Person who is informed of panic value
- Date and time of notification

Archiving

» According to laboratory types and test profiles, how and for how long remaining biological samples from test samples are to be stored must be determined considering test repetitions regarding patient safety and legal processes.

» According to laboratory types and test profiles, rules regarding storage and archiving of completed analysis samples and reports must be determined.

» A practical and traceable method must be used for archiving.

Standard 6

Standard Code	Standard	AC Code	Assessment Criteria (AC)
SH.LH.06.00	Traceability of the processes related to laboratory tests must be ensured.	SH.LH.06.01	Records must be kept in regards to ensure traceability of samples and tests in all processes.

Goal

To ensure test processes' traceability for obtaining data related to analysis and improvement of laboratory processes.

Objectives

- Efficacy
- Efficiency
- Timeliness
- Continuity
- Patient Safety

Standard Requirements

- Traceability of taken sample and test must be ensured in laboratory records at all stages between pre-analytical and post-analytical processes.
- In laboratory information management system, at least the following entries about testing process must be included:
  - Patient's name and surname
  - Patient's age
  - Patient's gender
  - Protocol number
  - Order date and hour
  - Name, surname and unit of clinician who ordered the test
  - Sample type
  - If necessary, body part which sample was extracted from
  - Sampling date and time
  - Date and time of sample acceptance to laboratory and by whom it was accepted
  - Test which was used for test and method
  - If available, test repetitions and results
  - Date and time of result's approval
  - Name and surname of employee and laboratory specialist relevant to approval
- In case of conducting special tests, on which mediums and how the relevant information will be kept and stored must be determined.
- Pre-analysis, analysis and post-analysis processes of laboratory tests must be monitoring on IMS. Integration of tests that are executed via service procurement method as part of laboratory tests and the institution's information management system must be provided

Standard 7

Standard Code	Standard	AC Code	Assessment Criteria (AC)
SH.LH.07.00	Use of Bedside Test Devices (BSTD) must be regulated.		

Goal

To provide the control and safety of tests conducted with bedside test device.

Objectives

- Efficacy
- Efficiency
- Timeliness
- Continuity
- Patient Safety

Standard Requirements

- Responsible in the departments in which BSTD is used must be identified.
- Inventory of BSTD must be hold.
- Maintenance and cleaning of BSTD must be performed.
- Quality control tests for BSTD must be practiced and recorded.
- In case discordance is detected in the results of quality control, corrective and preventive actions must be started.
  - In case the device is out of use, alternative device or method to be used must be defined.
- Personnel that will use BSTD must be trained. The training must include the following topics at least:
  - Points to take into consideration in the preanalytic, analytic and postanalytic stages of the test
  - Evaluation of calibration and quality control results
  - Cleaning and maintenance of device
- All studied test results must be recorded in the patient file.

Prevention of Infections

Standard Code	Standard	AC Code	Assessment Criteria (AC)
SH.EÖ.01.00	Necessary measures must be taken for the prevention of infections.	SH.EÖ.01.01	Responsible must be determined for infection prevention and responsibilities must be defined.
		SH.EÖ.01.02	A programme must be created for the prevention of infections.
		SH.EÖ.01.03	Efficiency of the practices aimed at ensuring prevention of infections must be monitored.

Goal

To identify and prevent risks of health services related infections threatening the employees and patients

Objectives

» Patient Safety

» Healthy Work Life

Standard Requirements

Determination of Responsible Staff for Infection Prevention

Responsible must be determined for infection prevention, responsibilities and task fields must be defined. The minimum responsibility areas for infection control and prevention are as stated below:

- To determine an infection programme in accordance with the features and conditions of laboratory within the scope of scientific principles
- To ensure the coordination of infection control activities at laboratory
- To monitor the efficiency of activities specified and implemented in the programme for infection prevention, to make decisions on the necessary improvement activities, and to make suggestions to the administration

Creation of a Programme for Infection Control and Preventing

Scope of work for infection preventionand the programme to be established must be comprise according to following subjects at least:

- Evaluation of healthcare processes in terms of infection risk
- Hand hygiene
- Isolation measures
- Cleaning, disinfection, sterilization, asepsis, antisepsis
- Occupational infections of employees
- Prevention of infections in plant-based studies
- Making plans for extraordinary situations (epidemics, rare infections,etc.)
- Prevention of infections in support services such as laundry, catering, waste management and air conditioning systems

Evaluation of Health Care Processes in Terms of Infection Risk

Healthcare provision must be evaluated in terms of the patient and employee safety in all areas and processes. Measuresmust be taken and maintained against the risks determined. (For detailed risk assessment information, see. Risk Management Section under Management and Organization Aspect)

Hand Hygiene

Quality improvement activities relevant to hand hygiene must cover the following subjects at least:

- Determination of Hand Hygiene Rules
- Evaluation of Hand Hygiene Compliance
- Activities for Hand Hygiene Compliance

Setting Hand Hygiene Rules

Rules regarding hand hygiene in service provision areas must be set and the implementation must be ensured in accordance with these rules.

Assessment of Hand Hygiene Compliance

Hand hygiene compliance refers to the application of hand hygiene at the right time, using the appropriate method, in a correct way and for the right duration. Hand hygiene compliance means not only washing and rubbing the hand, but also practicing it in the **correct** way.

Hand hygiene compliance must be measured by such methods as monitoring of hand hygiene materials,surveys (for the awareness, level of knowledge and compliance of health care professionals) as well as the informed prospective observations. In accordance with the data obtained as a result of the evaluations, necessary improvement must be planned.

Actions for Improving Hand Hygiene Compliance

Following actions must be taken to improve hand hygiene compliance:

- Forming a hand hygiene policy
- Determining responsible staff for hand hygiene
- Supporting skincare of healthcare professionals
- Trainings
- Reminders and warning messages
- Facilitating cleaning material access

Some points are stated below in detail.

Supporting skincare of healthcare professional

Appropriate material must be provided to healthcare professionals with skin irritations and allergy history.

Trainings

All employees must be trained on hand hygiene. Contents and periods of the trainings must be determined by laboratory according to the occupational groups and needs detected through measuring results. Trainings must cover at least:

- Importance of hand hygiene
- Hand hygiene methods and indications
- Points to take into consideration
- Wearing gloves

Facilitating material access

Materials for hand hygiene must be available in all areas of health care. Laboratory must prepare plans for access to materials such as liquid soap, single-use towel in the hand washing areas/ lavatories.

Within the framework of recommendations in WHO guidelines, alcohol-based hand antisepticmust be available atpatient point ofcare. Patient point of care is the place where threeelementscome together:

- Patient
- Healthcare professional
- Care or treatment procedure including contact with the patient or his/her surroundings (within the patient's area)

This term precisely covers the setting of care and, thus, the need of hand hygiene in this setting. Alcohol-based antisepticmust be easily accessible in patient point of care.

All areas where patients are provided care and treatment must be regarded within this scope. The aim here is to organize the bedside products in such a way that the patient can reach them without leaving his/her area.

Isolation Measures

Laboratory must determine the conditions in which isolation measures must be implemented; the implementing rules and the required physical conditions (separate room, adequate distance between beds, adequate numbers of personnel etc). Healthcare professionals must be provided with training, sufficient personal protective equipment must be supplied and this equipment must be used in compliance with isolation measures.

Cleaning, Disinfection, Sterilization, Asepsis, Antisepsis

All areas used during service delivery and all equipment contacting with human tissues can be the cause of infection. Therefore, various procedures are applied in order to bringrelevant areas and instruments under control in terms of microorganisms:

- Cleaning
- Disinfection
- Sterilization
- Asepsis
- Antisepsis

Rules of cleaning, disinfection, sterilization and antisepsis processes must be determined.

- Following issues must be determined within these periods:
- Duration of application
- Range of application
- Method of application and material to be used
- Process for monitoring efficiency of implementation

Cleaning

Policies for laboratory cleaningmust be determined, plans must be formed, specific areas for infection must be determined andsupervisingstaffmust be identified. It must also be determined who will use which cleaning materials in

which area, and who would check how the materials would be applied and the effectiveness of the application must be determined.

Disinfection

- Disinfected surface, material, equipment and waste types must be determined.
- Disinfection type, disinfectant to be used and rules on how to use it (duration, quantity, controls or measures for ensuring efficient concentration, points to take into consideration in terms of patient and employee safety etc.)must be determined in accordance with the material used during disinfection procedures.
- In the areas where high-level disinfectant is used, ventilation must be configured in such a way that ensures employee safety.
- Technicians must be trained, and the status of application of disinfection must be monitored by the supervising staff under the rules of infection prevention programme.

Sterilization

- Materials and equipmentused in the laboratory and disinfection needs must be determined.
- Rules and operations for sterilization processes must be determined. Supervisorsof infection prevention must observe implementation within the frame work of rules determined. (See. Healthcare Services Aspect- Sterilization Section for detailed information.)

Asepsis and Antisepsis

Practice rules must be determined within the framework of asepsis and antisepsis principles and the relevant healthcare professional must be trained on this matter.

Occupational Infections of Employees

Healthcare professionals are responsible fortaking measures in order to protect both themselves and patients against infectious agents. These measures are presented in three groups:

1. **Measures to be taken before contact:** Immunization against infections which can be immunized, doing the routine medical screening
2. **Measures to be taken to prevent contact:** Protective measures to be taken against the risks which might be encountered during healthcare delivery (standard measures, isolation measures)
3. **Measures to be taken after contact:** Procedures of immunization, prophylaxis, follow-up and treatment which must be conducted in case of contact with any infectious agent

- Laboratory must define all the processes on the measures mentioned above.
- Actions must be taken to improve the levels of knowledge and awareness on infection protection of employees atlaboratory.

- Appropriate working environment and conditions must be provided for the employees to take necessary measures against infections. Necessary equipment must be procured.
- Medical screenings,which must be performedwithin the framework of risk analysis based upon the section at regular intervals, must be determined. A programme must be created for these.
- The procedures must be determined for the cases with positive scan results.
- Efficiency of applications within the framework of the programme must be monitored.
- Actions to be taken in case of contact with any infectious agentmust be determined. Authorities must be designated in order to ensure that these actions are carried out and controlled.

Infection Control in Support Services such as Laundry, Kitchen, Waste Management and Ventilation Systems

- Cleaning process of textile materials used in healthcare delivery must be monitored for infection control. It must be ensured that necessary measures are taken and maintained.
- Employees taking charge in the processes of supplying, storing, preparing and distributing foods given to the healthcare providers and service usersmust be monitored. Necessary measures must be taken and maintained.
- Processes of safe removal and disposal of infected wastes produced in healthcare delivery must be monitored. Necessary measures must be taken and maintained.
- Ventilation and air filter systems must be monitored for infection control. Necessary measures must be taken and maintained.

Monitoring and Evaluation

- Actions for infections prevention at laboratory must be monitored on the basis of process and outcome. Necessary actions must be taken for continuous improvement. In monitoring and evaluations; routine observations and controls, (Monitoring of blood-borne diseases etc.) process-based indicators determined for implementations must be used.
- Outcomes obtained from monitoring and evaluation must be analyzed. The compliance with targets that are set must be evaluated. Practicesmust be improved if necessary.
- Outcomes obtained must be shared with themanagement and relevant employees.
- Information and training must be provided for infection control and prevention of employees.

Sterilization Management

Standard Code	Standard	AC Code	Assessment Criteria (AC)
SH.SY.01.00	Processes concerning sterilization services must be identified and taken under control.	SH.SY.01.01	The processes regarding sterilization, storage, transfer and use of the materials must be taken under control.
		SH.SY.01.02	The processes regarding sterilization, storage, transfer and use of the materials must be taken under control.
		SH.SY.01.03	Traceability of the evidence regarding time, device, method, implementer and control parameters must be ensured in each stage of the sterilization.

Goal

To take laboratory sterilization processesunder control in an efficient and reliable manner.

Objectives

- Healthy Work Life
- Efficiency
- Efficacy
- Continuity

Standard Requirements

Process Control in Sterilization Service

» In all of the sterilization service related processes,quality ofthe used material, sterilization method, working and control rules regarding the equipment used and area of use must be determined and the relevant personnel must be provided with training on the issue. Corrective and preventive action must be taken to address irregularities identified in the processes.

Quality Control for Sterilization Process

» Physical-mechanical controls must be conducted according to the method of sterilization method that is used and records must be kept. Physical-mechanical controls contain records of program cycle including parameters like pressure, gas concentration, temperature, humidity, time and also records of maintenance and calibration of the device.

» Efficiency of sterilization must be assessed through chemical control methods.

» Whether sterilization has taken place or not must be assessed through biological control methods.

- Laboratory must determine minimum frequency of use of indicator for each sterilization method by taking into account issues like material load, patient profile, working frequency of the device and especially scientific requirements and laboratory must increase frequency of use when necessary.
- If the biological indicator is positive after the procedure, a retrospective follow-up of the material and patient must be conducted. All of the sterile material distributed until the use of biological indicator that tested negative must be reviewed.

Traceability of Sterilization Processes

» Traceability of the evidence regarding time, device, method, implementer and control parameters must be ensured in each stage of the sterilization.

» The following information concerning the records on the materials must be available at minimum:

- Records on maintenance, repair and calibration of sterilization device
- Cycle records of the device
- Tests conducted on the device (Vacuum leakage, Bowie Dick test etc.)
- Result of biological indicator
- Information on who applied the procedure in which stage
- Records on quality control work that is undertaken in each stage

Support Services

Facility Management

Standard 1

Standard Code	Standard	AC Code	Assessment Criteria (AC)
DH.TY.01.00	All the areas at laboratory must be clean for the safety and satisfaction of patient, carer and personnel.	DH.TY.01.01	Risk levels must be determined in all the areas of laboratory to ensure the control of cleaning and infections.
		DH.TY.01.02	Cleaning rules for risk levels must be identified and a laboratory cleaning plan must be developed and implemented.

Goal

To ensure safety and satisfaction of patient, carer and personnel by ensuring continuity and efficiency of cleaning in all the areas of laboratory.

Objectives

- Patient-Orientedness
- Healthy Work Life
- Continuity
- Patient Safety
- Efficiency

Standard Requirements

Determination of Risk Levels and Cleaning Rules with regard to These Levels

» Risk assessment for cleaning and infection control must be made in all the areas of laboratory.

» Cleaning rules, material to be used and physical conditions necessary to increase efficiency of cleaning must be determined in line with the risk levels that have been determined.

Development and Implementation of Laboratory Cleaning Plan

» Cleaning plan and related documents must be created so as to encompass all the areas of laboratory and the necessary work must be undertaken.

» The following issues must be handled at minimum in the documents:

- Risk level that is determined based on the unit or area
- Cleaning material to be used in the area in question
- Rules about cleaning and safe use of material and equipment
- Frequency of cleaning
- Cleaning rules
- Rules about how cleaning will be done after accidents that may cause potential mess
- How and by whom the control of cleaning will be conducted

Standard 2

Standard Code	Standard	AC Code	Assessment Criteria (AC)
DH.TY.02.00	Processes regarding catering must be identified.	DH.TY.02.01	Safe supply and storage of the food must be ensured.
		DH.TY.02.02	Processes regarding preparation of the food under the set conditions must be identified.
		DH.TY.02.03	Food must be served according to the set rules.

Goal

Provision of catering services by taking employees' wishes, needs, expectations and values into consideration

Objectives

» Healthy Work Life

» Efficiency

Standard Requirements

Supply and Storage of Food

» Rules to pay attention to with regard to supply according to types of food (qualifications that must be sought in line with types of food, quality control criteria, minimum documents and requirements necessary for admission of the supplier, transportation of food and its delivery) must be determined.

» Storage conditions (temperature, preservation time, packaging conditions if any, rules regarding arrangement of the food on the shelves and in the cabinets etc.) must be identified in line with types of food.

» When storing food, expiry dates must be followed-up in an efficient manner.

» The products in the storehouse must be arranged so as not to come into contact with the ground or wall and food products must be arranged separately.

Catering Preparation Processes

» Meals must be prepared in a hygienic way:

- The areas where the food is prepared must be different from other areas. (Food storage areas, areas where the dirtydishesare cleaned.)
- All the personnel must use protective equipment such as mask, bonnet, gloves and footwear)
- Material and equipment used while preparing food must be clean.
- Rules about sanitation of the food (like washing fruit and vegetables) must be determined and followed.
- Necessary conditions must be provided to ensure personal hygiene of personnel in charge of food in an efficient manner.

» Replicate samples must be taken from food to make the necessary analyses in the case of food poisoning. Cultural and moral values of the patient must be taken into account within the scope of catering services.

Catering Serving

» Food must be served in line with the types of the food and by taking into account warmth and presentation of the meal and hygiene rules.

» There must be a cover or lid on the food.

» Dinner trolleys and other equipment and material used in transportation and distribution of food must be cleaned and disinfected.

» The personnel distributing the food must use equipment like bonnet, gloves and mask.

Standard 3

Standard Code	Standard
DH.TY.03.00	The physical areas used by patients/carers must be safe and ergonomic.

Goal

To boost the morale and motivation of patients/carers by making sure that they are in a safe and comfortable laboratory environment.

Objectives

» Patient-Orientedness

» Patient Safety

Standard Requirements

Convenience of Physical Areas

» Convenient ventilation and lightning conditions must be met in a way that ensures safety and comfort of the patient in admission and sampling areas of the laboratory.

» Areas for personal hygiene needs of patients and carers must be determined. Sufficient hygiene materials must be provided for this purpose in these areas.

Standard 4

Standard Code	Standard
DH.TY.04.00	Precautions should be taken in laboratory to ensure safety of life and property of patient/carer and the personnel.

Goal

To ensure safety of life and property of patient/carer and laboratory personnel in an effective and efficient manner

Objectives

- Patient Safety
- Efficiency
- Healthy Work Life

Standard Requirements

Planning of Safety/Security Services

- There must be a plan in place to protect laboratory and people within from all kinds of threats, dangers and harm such as sabotage, theft, looting and physical violence and to maintain surveillance, supervision and control services in an uninterrupted manner.
- There must be arrangements to ensure safety in the laboratory.(surveillance camera, alarm system, security officer, etc.)

Ensuring Security of Patient/Carer and Employees

- Risk analyses must be made on safety of life and property and necessary measures must be taken.
- Risk analyses must encompass all the areas and units of laboratory. There must be designated areas where patients and employees can safely keep their personal belongings.

» Reporting process about events that threaten life and property security must be identified.

» Necessary improvement actions must be undertaken as a result of the analyses made.

Standard 5

Standard Code	Standard	AC Code	Assessment Criteria (AC)
DH.TY.05.00	A quality facility management structure and process must be established to ensure the quality and safety of laboratory services.	DH.TY.05.01	Responsible for planning and coordinating activities related to facility management must be determined.
		DH.TY.05.02	Risks originating from the facility must be detected and necessary measures must be taken.
		DH.TY.05.03	Continuity and safety of core facility resources must be ensured.
		DH.TY.05.04	Issues related to physical conditions and operations must be periodically.
		DH.TY.05.05	There must be arrangements facilitating access to departments inside laboratory.
		DH.TY.05.06	Measures must be taken to facilitate access to services by patients/staffs who are disabled, old or in need of help due to illness.
		DH.TY.05.07	Physical arrangements must be made to ensure the comfort of service users.

Goal

To establish the necessary infrastructure for permanent, safe and easily accessible service delivery for the patients and the personnel.

Objectives

- Efficiency
- Patient-Orientedness
- Continuity
- Patient Safety
- Timeliness
- Healthy Work Life

Standard Requirements

Management and Documentation

- Responsible must be determined in order to ensure planning and coordination of facility management-related activities. The duties and responsibilities of the personnel involved in facility management must be defined.
- Core and critical processes regarding facility management must be defined, and methods and rules thereof must be determined. The documents to be generated for this purpose must include at least the following:
  - Duties and responsibilities of the facility management responsible and supervisors
  - Processes related to the identification of the current status of the health facility
  - Improvement processes
  - Core facility resources
  - Access to facility services
  - Facility safety

Determination of Current Status and Improvements

- Current physical status and functional service efficiency of the health facility must be evaluated at regular intervals or when necessary.
- Risk analyses must be performed for facility safety.

» Necessary improvement activities must be carried out with regards to the current status and results of the risk analysis.

Core Facility Resources and Safety

» Continuity of core facility resources (Electricity, water natural gas, heating, cooling medical gas etc.) must be ensured for the uninterrupted delivery of health services.

» Timely maintenance and checks of core facility resources must be ensured for the uninterrupted delivery of health services.

» For all detected defects in systems, quality improvement studies should be carried out.

» Backup systems must be set in the case of possible critical failures. The risky areas covered by these systems must be determined by the facility management responsible.

Access to Facility Services

» Necessary arrangements for easy access to the laboratory departments must be provided to ensure patient and caretaker satisfaction. Necessary physical and functional arrangements must be realized taking groups of disabled patients and patients in need of special care into consideration. These arrangements must include at least the following:

- Guiding sings and services
- Waiting areas used by patients and carers
- Comfort and safety of laboratory service provision areas
- Facility wide arrangements for the disabled, the elderly or patients in need of help due to their conditions
- Environmental arrangements (car lots, landscape, etc.)

Waste Management

Standard Code	Standard	AC Code	Assessment Criteria (AC)
DH.AY.01.00	Safe and effective management of waste produced at laboratory must be ensured to protect human and environmental health	DH.AY.01.01	A Waste Management Plan must be prepared.
		DH.AY.01.02	Waste must be sorted at the source.
		DH.AY.01.03	Necessary steps must be taken to ensure that waste is transported, temporarily stored and disposed in appropriate conditions.
		DH.AY.01.04	Personnel involved in waste management must be trained.

Goal

To prevent waste from harming human health and the environment starting from the composition of the waste at laboratory until its delivery to the competent authority for the disposal.

Objectives

- Healthy Work Life
- Convenience
- Timeliness

Standard Requirements

Preparation of Waste Management Plan

» A Waste Management Plan must be prepared at laboratory. The Waste Management Plan must include at least the following:

- Source, amount and types of waste
- Measures related to the minimization of waste at the source
- Equipment and tools to be used in waste management
- Collection frequency and rules
- Temporary storage systems
- Cleaning and disinfection of relevant equipment
- Measures to be taken in the case of an accident
- Training of the personnel assigned to collect and transport waste
- Determining the institution to which the waste will be delivered
- Delivery of waste
- Monitoring of waste processes

» Waste management supervisor must be identified.

Waste Sorting at Source

» Waste must be defined at least in the following categories/types:

- Domestic Waste
- General domestic waste
- Packaging waste
- Medical Waste
  - √ Infectious waste
  - √ Pathogenic waste
  - √ Sharpy waste
- Hazardous Waste
- Radioactive Waste

» Waste generated must be sorted in accordance with their type.

» Waste must be put in separate bags/boxes having the required properties in accordance with their types.

» The amount of medical and hazardous waste must be measured and monitored on the basis of Laboratory. Processes related to waste should be examined in terms of requirements for reducing waste quantities.

» Arrangements must be made for recyclable waste.

Waste Transportation, Temporary Storage and Disposal Operations

» Waste must be collected by personnel trained to perform such tasks.

» The clothes worn by the personnel assigned with the collection and transportation of waste must possess the necessary properties.

» The collection and transport of waste should be carried out as far as possible from areas where human traffic is concentrated.

» Waste must be collected at the temporary storage area.

» There must be containers or temporary waste storerooms in sizes suitable to the size of Laboratory and having the suitable properties.

» Waste must be stored temporarily in such a way as not to exceed the maximum waiting period determined within the scope of the national legislation.

» The stored waste must be submitted to the competent authority for the final disposal.

» Waste store rooms must be cleaned and disinfected.

Waste Management Trainings

» Personnel working on waste management must be trained. Trainings must include at least the following:

- Types of waste and sorting of waste in accordance with their types
- Collection, transportation and temporary storage of waste
- Health risks, injuries and diseases which might be caused by waste
- Measures to be taken in the case of an accident or injury

Information Management

Standard Code	Standard	AC Code	Assessment Criteria (AC)
DH.BY.01.00	A safe and effective information management system must be present at laboratory.	DH.BY.01.01	Those in charge of carrying out and coordinating activities related to information management must be identified.
		DH.BY.01.02	The necessary technical and supporting infrastructure must be established for the efficiency of information management.
		DH.BY.01.03	Measures must be taken for the security of medical records that are physically stored.
		DH.BY.01.04	Necessary measures must be taken to ensure information security and confidentiality.
		DH.BY.01.05	It must be ensured that the information is timely and continual.
		DH.BY.01.06	Personnel must be trained for effective ensure of information management.

Goal

To ensure that medical and personal information obtained in the laboratory processes are recorded and stored properly and safely, and to ensure the communication of the needed information to the right person at the right time.

Objectives

- Efficiency
- Patient Safety
- Timeliness
- Continuity

Standard Requirements

Management and Documentation

- Information management supervisors must be identified, and their roles and responsibilities must be defined. The supervisors must identify the current situation in information management, detect the possible risks in the processes and initiate the necessary corrective and preventive activities.
- Information to be used in the information management process and the methods and rules pertaining to those must be determined with the needs and critical processes oflaboratory in mind. Documents to be prepared must comprise at least the following topics:
  - Physical and technological measures
  - Information security
  - Information confidentiality
  - Information continuity
  - Access to external information sources
  - Authorization
  - Remote access

Technical Support Infrastructure

Risks related to hardware and software problems must be detected, against which measures must be taken for the uninterrupted operation of information management systems.

Information Security and Confidentiality

» The confidentiality and security of personal or medical, written or electronic information obtained about personnel or patients is essential. Access to these records must be limited by way of authorization, and access by external sources must be under control.

» What information can be accessed by the users and when and how they can access it within the scope of the authorization must be defined; measures must be taken against unauthorized access.

» Computers connected to information management atlaboratory must be monitored to track unauthorized access.

» Data must be backed up on a regular basis in order to prevent data loss in cases of failure or unauthorized access; regular maintenance and tests must be performed on the servers to prevent failures, and the operation systems or software used in the server must be up-to-date.

» A system must be set to track the changes or deletion in the data when there is unauthorized or erroneous interference with the data from internal or external sources.

» Physically stored medical records must be stored in such conditions as to prevent any harm to the records, within the rules of the relevant legislation. The necessary physical and functional measures must be taken, and security of written information must be ensured for these types of records.

Timeliness and Continuity of Information

» Cases where information management systems have been disabled to make sure healthcare services are delivered on time and to ensure continuity, or where there are slowdowns or failures in the systems must be tracked, improvement must be made and it must be ensured that the information is timely.

» Retrospective follow-up of all the information collected must be performed in information management systems; thus, the continuity of information must be ensured.

Material and Device Management

Standard Code	Standard	AC Code	Assessment Criteria (AC)
DH.MC.01.00	Efficient, effective and safe use of materials and devices must be ensured.	DH.MC.01.01	Those in charge of management of materials and devices must be determined.
		DH.MC.01.02	Materials and devices must be determined and supplied in accordance with the needs of the institution.
		DH.MC.01.03	Materials must be conserved in proper conditions.
		DH.MC.01.04	Necessary physical conditions must be met to ensure that the devices work in proper working conditions.
		DH.MC.01.05	Personnel must be trained in material and device management.
		DH.MC.01.06	Necessary maintenance, calibration, adjustments and performance tests of the devices needed must be conducted.
		DH.MC.01.07	Rules must be set to ensure safe and effective use of materials and devices, the necessary protective material and information concerning the devices must be available.
		DH.MC.01.08	Management of hazardous substances must be regulated.

Goal

To ensure that materials and devices to be used are supplied in a timely manner and are used safely, with a view to consider the needs of the patients and the personnel.

Objectives

- Efficiency
- Convenience
- Healthy Work Life
- Productivity
- Timeliness

Standard Requirements

Management and Documentation

- In order to provide an effective management of materials and devices, all those in charge of planning, coordination and carrying out of all the processes must be determined. Tasks assigned to these people and their responsibilities must be identified.
- Methods and rules regarding the procurement, storage, tracking and use of materials and devices must be clearly identified. Documents regarding material and device management must be generated taking the needs of the laboratory and the critical processes into consideration. Documents to be generated must comprise at least the following issues:
  - Tasks and responsibilities of staff working on material and device management
  - Detection of material and device needs
  - Monitoring the life span of materials and devices
  - Establishment of a plan for the replacement and updating of materials and devices as necessary
  - Procurement of materials and devices
  - Storage of materials
  - Material orders
  - Transfer and preparation of materials
  - Safe use of materials and devices
  - Indicators for management of materials and devices

- Methods of intervention for dangerous situations which might occur during use of materials and devices
- Materials and devices possessing special properties, requiring special storage conditions or require specific technique or expertise to use
- Maintenance, adjustment and calibration of devices

Procurement of Materials and Devices

» Necessary measures must be taken for the timely procurement of the right materials and devices in order to ensure efficient delivery of healthcare services at laboratory.

» Rules and methods regarding the procurement requests for materials and devices must be determined. Within the framework of this action, laboratory must determine who can request materials and devices, the method for the request, and by whom and how the requests would be assessed.

» Materials routinely used or compulsory to keep must be identified, their critical stock levels must be determined and tracked.

» Procurement requests and consumption analyses must be taken into consideration while carrying out assessments to determine the types and quantity of materials and devices to be procured.

Storage and Transfer of Materials

» Unauthorized access to identified material storerooms and all the unit storages where medical consumption materials are preserved for over 24 hours must be restricted in line with patient safety and security.

» Materials must be preserved in suitable perseveration conditions in the storage areas in accordance with their properties. For this purpose, the necessary measures must be taken, and these measures must be monitored.

» Storage layout plans must be developed to ensure easy access to materials by the personnel and to prevent time loss in emergencies; the plans must be kept up-to-date.

» Measures must be taken against breaking and spilling during transfer, and the necessary equipment for safe transfer must be provided. The transfer personnel must be trained in the safe transfer of materials, and regarding special-property or hazardous materials.

Device Safety

» Protective equipment for the devices, information on safe usage information and guides must be available at usage areas; the relevant personnel must be trained in safe use of the devices.

- Physical arrangements in the areas where the devices are present must be realized in accordance with the working conditions of the devices.
- Calibrations, adjustments, tests and/or maintenance must be realized as frequently as stated in the technical documents of the manufacturers, in such a way as to meet the needs of thelaboratory and in line with the usage intensity and within a plan, for the purposes of safe operation, obtaining correct results, keeping the harm which might occur at a minimum.
- It must be ensured that devices requiring special technique/equipment/ expertise are used by trained and authorized people.

Management of hazardous substances

Documents regarding the management of hazardous substances should be available. In the documents, at least following information must be present:

- Safe transport, store and use of hazardous substances
- Things to do in case of spilling hazardous substances and being exposed to substances

Inventory of used hazardous substances should be made. The inventory should include at least the following information:

Hazardous substance's;

- Name, brand, active ingredient, type (powder, crystal etc.), method of use and expiration date
- Storage conditions
- Substances that interact with
- Things to do in case of contact
- Places of which it is used or stored
- Methods of transport
- Methods of disposal
- Signs that show the class of hazardous substance

The inventory must be in the store and usage area. Sign that shows name of the chemical substance and class of the hazardous substance must be enunciatively labeled. Users must be given training regarding the signs that show the class of hazardous substance.

Outsourcing

Standard Code	Standard	AC Code	Assessment Criteria (AC)
DH.DK.01.00	The services provided through outsourcing must be in line with the core policies and values of laboratory and Standards of Accreditation in Health.	DH.DK.01.01	The services to be outsourced must be determined in line with the core policies and values of laboratory.
		DH.DK.01.02	Scope and process of the outsourced services must be defined.
		DH.DK.01.03	It must be ensured that outsourced services will comply with Health Accreditation Standards.

Goal

To ensure that the services provided through outsourcing are in line with the core policies and values of laboratory and that they are provided in line with the targets determined in the Standards of Accreditation in Health.

Objectives

- Patient-orientedness
- Continuity
- Productivity
- Safety
- Efficiency
- Efficacy

Standard Requirements

Determining the Services to be providedvia Outsourcing

» Based on core policies and values, the reasons for the need to outsource and the targets aimed at the service to be provided must be determined.

» Laboratory must conduct a need analysis and make assessments on the services to be provided through outsourcing, and must determine its strategy.

Defining the Scope and Process of Outsourcing

» The services which the external service provider will provide for laboratory must be clearly defined and the completion process must be determined.

» Business processes must be clearly and precisely defined.

Compliance with the Standards of Services Provided through Outsourcing

» In accordance with the defined scope and business processes, methods for constant check of the services provided through outsourcing and checking criteria along with performance indicators must be identified.

Emergency Management

Emergency Management

Standard 1

Standard Code	Standard	AC Code	Assessment Criteria (AC)
AD.AD.01.00	Measures must be taken against cases like natural disasters or events that necessitate extraordinary response, intervention, first aid or evacuation.	AD.AD.01.01	Risk analyses must be conducted on events that require extraordinary response and intervention, first aid or evacuation and necessary measures must be taken.
		AD.AD.01.02	Planning must be done for preventive measures determined and possible emergencies.
		AD.AD.01.03	Trainings must be provided on emergency management and drills must be conducted.

Goal

To define the requirements to prevent people or physical elements from being harmedor to minimize that harm in emergencies such as natural disasters like earthquakes and floods, or in emergencies which would require medical intervention such as fires or explosions at laboratories.

Standard Requirements

Risk Analyses

Laboratory must determine the specific situations for the preventive measures needed to be taken for incidents requiring extraordinary response and intervention,

analyze which emergency situations may bring about what kind of dangers at the institution and must put forth what the necessary preventive measures must be.

Planning

» Laboratory must plan for the implementation of the preventive measures determined for the emergencies. The planning for the preventive measures must include at least the following:

- Deciding which preventive tasks must be performed
- Planning the necessary preventive investments and activities
- Budgeting investments and activities

» Constant reviewing through drills and observations done to see whether the measures and implementations developed serve their purpose

» What to do in case an incident requiring extraordinary response takes place, despite necessary preventive measures taken against possible emergencies which might take place at laboratories, must be pre-planned as well.

- An emergency management team must be formed atlaboratory and its responsibilities must be defined.
- Infrastructure which would make the management of emergencies easier (emergency alert system, communication system, etc.) must be planned.

Trainings and Drills

The most important point about emergency management is the fact that one must be prepared to emergencies that could be occurred. Training should be carried out at the determined frequency to create awareness in personnel, to cover all relevant processes and to minimize the risks at the time of the incident.

Standard 2

Standard Code	Standard	AC Code	Assessment Criteria (AC)
AD.AD.02.00	Timely intervention must be ensured in cases where the health professional is exposed to a risk of violence, or an act of violence is directed towards him/her.	AD.AD.02.01	An emergency alert system defined with Code White must be in place for intervention in cases where there is a risk or and actual act of violence towards health professionals.
		AD.AD.02.02	Those in charge of the management of the emergency alert system must be determined.
		AD.AD.02.03	Intervention team/teams must be determined.
		AD.AD.02.04	Code White trainings must be provided and drills must be conducted.

Goal

To define the requirements for the fastest and most effective intervention to take place in cases of respiratory or cardiac arrest atlaboratory.

Standard Requirements

Emergency Alert System (Code Blue)

» An emergency alert system must be put in place in order to respond in the shortest time possible to the patients, carers and all personnel who need emergency medical intervention.

» The emergency alert system must be structured in such a way as to cover the whole of laboratory and to enable reaching the sceneof incident in the shortest time possible at any time of day (3 minutes at the latest), taking into consideration the size of the institution and whether the institution comprises multiple buildings. The call system to be set up for the emergency alert system must be designed in such a way as to inform the personnel in a timely manner, ensure efficient and fast communication through short and clear messages, and prevent panic.

Supervisors

» Code Blue supervisors must be identified so as to ensure effective operation

in line with laboratory structure and type.

» The responsibilities of the Code Blue supervisors must include at least the following: trainings for the personnel, identifying the Code Blue intervention teams, organizing drills, tracking records, initiating corrective-preventive activities when necessary.

Intervention Teams

» There must be at least one physician and one other health professional trained in CPR (Cardio-Pulmonary Resuscitation) present in the Code Blue intervention team. The intervention team is responsible for going to the scene of the incident for which a Code Blue call has been alerted and for performing the intervention.

» There must be arrangement in place for during the center's working hours active functioning of the Code Blue alert system.

Medicines and Equipment

» The medicines and equipment that would be needed must be determined beforehand and an emergency response kit must be prepared. The emergency response kit must have at least the following: laryngoscope set and additional batteries (according to patient profile; for example, for children and adults appropriately), balloon-valve-mask system, masks in different sizes, oxygen pipe and masks, intubation tube (according to patient profile; for example, in child and adults appropriately), auxiliary airway tools (laryngeal mask, airway or kombi tube, etc), injectors, personal protection equipment.

Record-keeping

» Records must be kept about the intervention performed followingCode Blue call. The following information must be present at least in the records kept:

- When the call was made
- Information about the person who needed intervention
- Which interventions were performed
- Where the interventions were performed
- When and in how much time the team arrived at the scene of intervention
- Result of the intervention
- Who was present in the intervention team

» Analyses must be performed on the records kept and the results acquired from this practice must be periodically monitored.

Trainings and Drills

» Trainings to be provided for all the staff from managers to department staff, from cleaning personnel to security officers, regarding the importance of Code Blue and how it would be implemented must be planned.

» Drills regarding Code Blue must be conducted at least once a year. Records must be kept about the drill, the results of which must be assessed, and the necessary corrective measures must be taken.

Standard 3

Standard Code	Standard	AC Code	Assessment Criteria (AC)
AD.AD.03.00	There must be an arrangement in place to ensure timely response to fire.	AD.AD.03.01	There must be a fire detection system.
		AD.AD.03.02	Emergency alert system defined with Code Red must be established to respond in time in the case of fire.
		AD.AD.03.03	Those in charge of management of the emergency alert system must be determined.
		AD.AD.03.04	The equipment to be used while responding to fire, rules regarding safe use of this equipment, signs and instructions to be taken into account in the case of fire must be identified.
		AD.AD.03.05	Trainings must be provided on Code Red and drills must be conducted.

Goal

To ensure intervention in the shortest time possible in the case of a risk/attempt of violence, or when an actual act of violence is directed towards health professionals working at laboratory.

Standard Requirements

Emergency Alert System (Code White)

» An emergency alert system must be established for cases of risk/act of violence towards health professionals.

» The emergency alert system must be structured in such a way as to cover the whole of laboratory and to enable intervention at any time of day, taking into

consideration the size of the institution and whether the institution comprises multiple buildings. The call system to be set up for the emergency alert system must be designed in such a way as to inform the personnel in a timely manner, ensure efficient and fast communication through short and clear messages, and prevent panic.

Supervisors

» Code White supervisors must be identified by laboratory so as to ensure effective operation in line with laboratory structure and type.

» The responsibilities of the Code White supervisors must at least include the following: trainings for the personnel, organizing the drills, tracking records, initiating corrective-preventive activities when necessary.

Intervention Teams

» How the relevant staff, led by security officers, will intervene, and unit and institution- based measures will be implemented when there is a Code White alert must be determined. Security officers atlaboratory are responsible to intervene in the incident taking place in their area of responsibility as determined in Code White system.

» There must be arrangement in place for during the center's working hours active functioning of the Code White alert system.

Record-keeping

» Records must be kept about the intervention performed after the Code White call. The following information must be present at least in the records kept:

- When the call was made
- Information about the person who needed intervention and the person who committed the act of violence
- Reason for the act of violence
- How and where the intervention was performed
- When and in how much time the team arrived at the scene of intervention
- Result of the intervention
- Who were present in the intervention team
- Information about notification of legal authorities about the incident

» Analyses must be performed on the records kept and the results acquired from this practice must be periodically monitored.

Trainings and Drills

» Trainings to be provided for all the staff from managers to department staff, from cleaning personnel to security officers, regarding the importance of Code White and how it would be implemented must be planned.

» Drills regarding Code White must be conducted at least once a year. Records must be kept about the drill, the results of which must be assessed, and the necessary corrective measures must be taken.

DEFINITIONS and ABBREVIATIONS

Adverse Event: Events that may or does affect the safety of patient, relatives, employees or the other people negatively in health facilities.

Adverse events related to patient safety may occur in the terms of drug safety, transfusion safety, facility safety, falls and information security.

Adverse events related to employee safety may occur in the terms of stab wounds, facility safety, occupational infections, contact with blood and body fluids.

Analytic Period: Test processes between sample analysis and approval of the results

Antisepsis: Killing of microorganisms in or on living tissue or inhibition of reproduction of these microorganisms is called antisepsis.

Asepsis: The measures taken to avoid the migration of germ to clean surface, medium or material is called asepsis.

Basic Policy: Determining the health facility's mission and vision with corporate goals and objectives.

Calibration: A number of processes correlating between the values which a measuring device or measuring system show and known values of measured ones under certain circumstances.

Chemical Waste: Gas, solid or liquid waste of chemicals used in medical fields such as treatment or diagnosis and which may be harmful to the health of humans and the environment with various effects.

Code of Document: Providing traceability of the document, the document management system directory refers to the identification system established in accordance with the rules set by institutions and organizations.

Consent Document: Applied for medical Treatment, process will be transferred to the patient by health care providers with information and documents are created to get the consent of the patient.

Container: Temporary storage unit with 0,8 m3 volume at least, wheel,cap, caps lock, made of stainless metal, plastic or material and so on.

Contamination: Being infected with foreign matter. Transition of bacteria and virus from contaminated surface to another.

Contraindication: Situation that prevents a treatment administration or discovery of patient status/complication that prevents treatment or intervention

Corporate Communications: In the process of production and management; institution that make up the information flow between departments and elements, motivation, integration, education, decision making and control functions such as implemented in the framework of certain rules in order to ensure, and the process carried out taking into consideration the reputation of the institution while interacting with the external communication.

Date of Publish: The documents was refered to date of publish.

Decontamination: As well as, as a word includes all applications forremoval of micro-organisms or organic soils (cleaning, disinfection,sterilization), it is used in the meaning of removal of organic substancesand pathogens from a surface or material by pre-cleaning process comprising physical and / or chemical methods and making the surface ormaterial useable without using any personal protective before sterilizationor disinfection in practice.

Document: Environments containing the information.

External Document: Document not prepared by the institution itself, but benefited from the realization of the activities.

External Quality Assessment Programme: Programmes in which laboratory analytic performances are assessed in determined periods

External Quality Assessment Test Sample: In the scope of external quality assessment programmes, unknown test sample which is prepared by quality assessment center and is sent to participant laboratories in regular intervals

Facility Management: For health facility in order to achieve its purpose, it is coordination of all activities related to planning, application and management of necessary working environment physical and functional arrangements which provides the best way to meet the growing health care needs.

Fire Detection Systems: Indoorsystems that protect life and property against fire via early warnings

Form: Document prepared for filling write the desired data or information.

Goal: Refers to the general results that the organisation wants to reach in the long term.

Guide: The document was created for informational purposes and guidingactivities.

Hand Hygiene: It is a general term referring to any action of handcleansing.

Handover: In order to ensure the patient safety and continuity of care, itis a transfer of patient's special information from a caregiver to anotheror from a system featured in an organized team to another with a moderninteraction process transferred in an interactive way.

Hazardous Waste: Genotoxic, pharmaceutical and chemical wastesarising from units and wastes containing heavy metals and pressuredcontainers.

High-Level Disinfection: Some of the chemicals may kill all sporesby long term (3-12 hours) treatment. In similar concentrations but ina shorter treatment period (e.g. 20 minutes with glutaraldehyde) thesame disinfectant kills all microorganisms except bacterial spores. Thisprocess is called high-level disinfection.

Household Waste: Non-contaminated wastes, which is mainly originatedfrom kitchen, garden, and administrative units

IMS: Information Management System. Trained users and devices connected to the computer through a network of institutions, every effort is made to perform with electronic software to maintain the record.

Indication: It is a term, which refers that situations, in which should bedone an application, a treatment or a process.

Indicator: When a topic becomes digitized and measured, this is a toolthat contributes to making improvement activities.

Infectious Waste: All kinds of body fluids and human tissues, organs and other pathological material; blankets, sheets, bandages, adhesive tape, tampons, swab and other wastes; bacteria and virus retaining air filters which known as infectious agents carriers or likely to carry them.

Information Security: It means to protect the information from damagesand to prevent obtaining the information by unwanted users in anyenvironment using the appropriate technology in the right way for theright purpose.

Institution: Laborаties which provides service actively in Republic of Turkey

Institutional Structure (Design): Institutional structure includes authoritiesand responsibilities in institution and forming communication channels. Organizational structure of the health institution is formed after these studies.This structure is shown in the organization scheme. In the organization schemes, positions in the institution, units, departments and authority, responsibility and communication relations between them are shown.

Instruction: A single document containing the steps of the activity.

Intended Population: Employees of the company, people who getthe service and all the people that interact with the organization andinstitutions (media, insurance agencies, suppliers, government agencies, non-governmental organizations, universities, local government units, community leaders, experts, etc.)

Internal Quality Control: Control of measurement performance against know samples

Isolation Precautions: Activities carried out and measures to prevent transmission of apathogen microorganism from person to person, from person to envoirment or vice versa.

List: Similar items listed consecutively document.

Low Level Disinfection: In this process, in a short time (less than 10 minutes) most of the vegetative bacteria, some fungi and some viruses dies.

Matrix Structure: Matrix structure is the use of both functional and sectional structure at the same time in the health institution. For example, services provided in operation room require coordination of people and units that have different functions and from different departments.

Measurement Uncertainity: A parameter which defines value distribution which can be equal to measure, that defines reference range

Medical Gas: Gas that is produced and packed to be used in anestheticprocesses or diagnosis and treatment interventions.

Medical Waste: Infectious, pathologic and penetrating wastes whichresults from units.

Method Validation: A collection of studies for determining laboratory test method's desired performance conditions, checking that tests give results in comply with desired quality goals and keeping tests under control

Mission: It is the pure and general object, which determines the reason of health facility's being, its philosophy with provided products and services that lays down their unique differences and separate them from other health institutions.

Objective: States short term processes for reaching the goals. Objectives are more open and has measurable features comparing to goals.

Organization Scheme: It is a graphic that shows institutional structureas a whole and it also shows various relations between service units in acomprehensive order.

Outsourcing: It's the method of providing some services which take part in the hospital but not offered from an institution or organization out of the facility.

Panic/Critical Value: Result values that are in a high risk range for patient's condition that his/her doctor must be informed of as soon as possible and following diagnostic/ theuropathic/protective intervention is required without delay

Pathological Waste: Materials that are used for pathological examination and disposed of during surgical operations including tissue, organ, body parts, human fetus etc.

Performance: A term that defines output of an action qualitatively or quantitatively. In the terms of performance assessment in an institution, it means that how much employees contribute to organizational objectives.

Personal Hygiene Area: In accordance with the hygiene rules, these arethe areas like toilets, baths or sinks, which provides body cleaning andmeets hygiene needs.

Personal Protective Equipment: Equipment used by employee such as clothing, tool or materials against the risks and threats in working environment. Various personal protective equpiment may be needed to be procured in line with unit specialities.

Plan: the intended purpose ensure achievemant of steps, what, when,why and document that shows how to do it.

Post-analytic Period: Post-analysis processes after approval of the results

Post-postanalytic Period: Interpretation of the results for patients' benefit and determination of additional test requirements, and also in the term of making the right decision for diagnosis, treatment and follow-up of patients, provision of information and guidance support by laboratory

Pre-analytic Period: Covers all steps consisting of taking sample, transfer, sample acceptance to laboratory, storage and analysis preparation after patient test order until analysis period

Pre-preanalytic Period: Period for patient test order

Primary Facility Resources: It expresses the need of minimum formationof the infrastructure of technologies which will be used in the provision ofhealth care (water, electricity, air conditioning and medical gas systems,etc.).

Privacy: Represents the living area of the patient that has to be clarified for the patients care,treatment (test results, information about the diseaseand treatment) or for any other reason but hiding them from all otherindividuals in the society.

Procedure: Document describing how the execution of the activities ofa process.

Quantitative Tests: Tests that measures analysis component amount in a matter. In these tests, analyses are conducted quantitatively.

Reference Range: Lowest and highest value that a test can give as result by taking community profile as reference

Revision Date: The document was last updated refers to the date.

Revision Number: The document is updated refers to the number oftimes.

Risk analysis: It refers to identification of risks using methods allowing acomprehensive understanding of the risks, assessment of the severity ofthe damage in case of risks that may arise. In this context, risk analysis includes following processes; Identification of dangers which patients may be exposed to Determination of the frequency and level of exposure to hazards Assessment of which patient or patient groups are affected.

Risk: It refers to the probability of occurrence and the severity of an eventthat can damage human health as a result of exposure to a hazard.

Root Cause Analysis: Root causes are real reasons of problems. Root cause analysis is a study for determining these real reasons. In other words, it is a process practice for permanent solutions instead of temproary ones.

Sample: Biological material extracted that is convenient for ordered laboratory examination and which can provide information about source organ or tissue

Self-Assessment: An assessment in institution based on Standards of Accreditation in Health which is carried out by Quality Management Director

Sharp Waste: Wastes such as injection, injection syringe and all other subcutaneous venture injections, cylinders, cartridges and cans enclosingall the gases used in procedure, lancets, scalpel, knife, serum kit needles, surgical suture needles, biopsy needles, intracath, broken glass, bulbs, solid-lamellae, broken glass tubes and petri dishes and these waste maycause stinging, punching, scrape and injuries.

Staff/Employee/Personnel: "Staff, employee and personnel" terms in this standard set means all permanent, temporary, volunteer, daily or independent people involved in service provision.

Sterilization: Killing all microorganisms found on anybody or substance by physical or chemical methods including spores.

Supporting Document: Procedure, Direction, Guide, Form, Plan, List, Consent Document, and External Document or this document is supportive documents.

Temporary Storage: The process of keeping waste wait in units builtin the unit or containers for a temporary period not to exceed 48 hours before the transportation

Test: All applications in order to determine an analyte, cause or properties in a sample

Transportation: The process of transporting waste by convenient transportation vehicles from temporary storage units to disposal area.

Ultimate Disposal: Destruction or disarmament through incinerating orstoring the waste in plants where all measures provided in applicable legislation are taken without any damage to the environment and human health.

Value: Defined rules and principle series which directs their members to certain acts for securing the survival of institution.

Verification: Test system is a performance verification process that is applied once before using in the laboratory.

Vision: Expression of health facility's hope to reach the status under current conditions and its main philosophy for the future with sentences that features excellence and being ambitious

Waste Management Plan: Determining the general principles fornot harming the environment and human health when the process ofcomposing waste till disposal of them.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RELEVANT LEGISLATION of STANDARDS

Relevant Legislation of Standards			
Chapter Name	**Standard Code**	**Standard**	**Related Legislation**
Organizational Structure	YO.OY.01.00	An organizational structure to cover all laboratory activities must be established.	• Presidential Decree No. 1, Official Gazette Number 30474, 10/7/2018 • Operating Regulation of Inpatient Treatment Institutions, Official Gazette Issue:17927, 13.1.1983 • Health Services Fundamental Law, Official Gazette, Issue:3359, 15.05.1987 • Regulation on Medical Laboratories, T.R. Official Gazette Issue 28790, Date 09 .10.2013. • Tissue Typing Laboratories Directive, Number 47498, Date 28.11.2011. • 663 Sayılı Kanun Hükmünde Kararname, Resmi Gazete, Sayı:28103, 02.11.2011
	YO.OY.02.00	Laboratory must have all necessary authorization and permits for all of its activities.	
Core Policies and Ethical Values	YO.PD.01.00	Core policies and ethical values of laboratory must be defined.	• Regulation on Medical Laboratories, T.R. Official Gazette Issue 28790, Date 09 .10.2013. • Tissue Typing Laboratories Directive, Number 47498, Date 28.11.2011.
Quality Management Structure	YO.KY.01.00	Planning, implementation, coordination and continuity of quality improvement activities must be ensured.	• Regulation on Improvement and Evaluation of Quality in Health, Official Gazette, Issue: 29399, 27.06.2015.
Document Management	YO.DY.01.00	Management of documents at laboratory must be ensured.	• Directive on Medical Record and Archive Services of Inpatient Treatment Institutions, Official Gazette: Issue:10588 06.11.2001
Adverse Event Reporting System	YO.OB.01.00	Reporting of adverse events that may (near miss) or does (adverse) affect the safety of patients and staff negatively must be ensured, and necessary measures must be taken.	• Act No.6331 on Occupational Health and Safety, Official Gazette, Sayı : 28339, 30.6.2012 • Regulation on Improvement and Evaluation of Quality in Health, Official Gazette, Issue: 29399, 27.06.2015.

Relevant Legislation of Standards			
Chapter Name	**Standard Code**	**Standard**	**Related Legislation**
Risk Management	YO.RY.01.00	Risks related to laboratory and laboratory related processes must be defined and managed	• Regulation on Medical Laboratories, T.R. Official Gazette Issue 28790, Date 09 .10.2013. • Occupational Health and Safety Risk Assessment Regulation, Official Gazette Number: 28512, 29.12.2012 • Regulation on the Prevention of Exposure Risks to Biological Factors Official Gazette Number: 28678 ,15.06.2013 • Regulation on the Protection of Employees from Hazards of Explosive Environments Official Gazette Number 28633, 30/04/2013 • Regulation on Health and Safety Measures in Working with Chemical Substances Official Gazette, Number: 28733 12.08.2013 • Regulation on Protection of Employees from Noise-Related Risks Official Gazette, Number: 28721, 28.07.2013
Training Management	YO.EY.01.00	In accordance with quality improvement activities, training needs of staff must be determined, and it must be ensured that necessary training is conducted effectively.	• Regulation on Improvement and Evaluation of Quality in Health, Official Gazette, Issue: 29399, 27.06.2015. • Regulation concerning the Procedures and Principles of Occupational Health and Safety Trainings of Employees, Official Gazette, Issue: 28648, 15.05.2013. • Ministry of Health In-service Training Regulation Official Gazette Number:15296, 11.12.2009
Institutional Communication	YO.Kİ.01.00	Institutional communication activities must be carried out effectively.	
Performance Measurement and Quality Improvement	PÖ.Gİ.01.00	Institutional indicators must be monitored and evaluated in order to continuously improve service provision processes regarding primarily administrative, financial and medical steps.	• Regulation on Improvement and Evaluation of Quality in Health, Official Gazette, Issue: 29399, 27.06.2015.

Relevant Legislation of Standards			
Chapter Name	**Standard Code**	**Standard**	**Related Legislation**
Human Resources Management	SÇ.İK.01.00	A management structure that will fulfil the requirements concerning planning of human resources, improvement of work life and the personnel must be established.	• Regulation on Ministry of Health Appointment and Change of Location, Official Gazette, Issue: 28599, 26.03.2013 • Regulation concerning the Appointment Procedures and Principles of Healthcare Personnel to be appointed by open lot to the State Institutions and Organizations, Official Gazette, Issue: 29412, 10.07.2015 • Regulation on Appointment and Change of Location of Contracted Healthcare Personnel subject to the law no 4924 of Ministry of Health and Affiliated Corporations, Official Gazette, Issue: 29264, 11.02.2015
	SÇ.İK.02.00	The requirements necessary to constantly improve recruitment and compliance processes of the personnel and their work life must be determined and fulfilled.	• Tissue Typing Laboratories Directive, Number 47498, Date 28.11.2011. • 663 Sayılı Kanun Hükmünde Kararname, Resmi Gazete, Sayı:28103, 02.11.2011
Employee Health and Safety	SÇ.ÇG.01.00	Factors threatening the health and safety of employees should be identified and necessary Precautions should be taken to establish a healthy and safe working environment.	• Regulation concerning the Procedures and Principles of Occupational Health and Safety Trainings of Employees, Official Gazette, Issue: 28648, 15.05.2013. • Regulation concerning the Duty, Authorization, Responsibility and Educations of Occupational Safety Specialist, Official Gazette, Issue:28512, 29.12.2012. • Regulatiion on Occupational Health and Safety Services, Official Gazette, Issue:28545, 29.12.2012. • Occupational Health and Safety Law, Law No:6331, Date of Acceptence 20.06.2012. • Regulation on Occupational Health and Safety Committees, Official Gazette, Issue: 28532, 18.01.2013. • Notification concerning the Making Amendment on the Notification of Workplace Hazard Classess related to the Occupational Health and Safety, Official Gazette, Issue: 28602, 29.03.2013. • Regulation on the Use of Personal Protective Equipment at Workplaces, Official Gazette Number: 28695, 02.07.2013 • Circular on Formaldehyde and Xylene Measurement Standards Number:2599872, 28.02.2014

Relevant Legislation of Standards			
Chapter Name	**Standard Code**	**Standard**	**Related Legislation**
Patient Experience	HD.HD.01.00	The services provided in laboratory must be organized in such a way as to protect patient and carer rights.	• Regulation on Patient Rights, Official Gazette, Issue: 23420, 01.08.1998
	HD.HD.02.00	A system must be established to receive feedback (comments, suggestions and complaints etc.) from patients and their carers about the services that are provided.	
	HD.HD.03.00	Necessary precautions must be taken in order to provide patient able to reach services in time.	
Laboratory Services	SH.LH.01.00	Laboratory physical environment must be established in a way that ensures test and employee safety.	• Regulation on Medical Laboratories, T.R. Official Gazette Issue 28790, Date 09 .10.2013. • Tissue Typing Laboratories Directive, Number 47498, Date 28.11.2011.
	SH.LH.02.00	A test guide must be prepared for informing of healthcare workers responsible with out of laboratory processes.	• Regulation on Medical Laboratories, T.R. Official Gazette Issue 28790, Date 09 .10.2013.
	SH.LH.03.00	Check of pre-analysis laboratory processes must be implemented.	• Regulation on Medical Laboratories, T.R. Official Gazette Issue 28790, Date 09 .10.2013.
	SH.LH.04.00	Check of analysis laboratory processes must be implemented.	• Regulation on Medical Laboratories, T.R. Official Gazette Issue 28790, Date 09 .10.2013. • Tissue Typing Laboratories Directive, Number 47498, Date 28.11.2011.
	SH.LH.05.00	Check of post-analytic processes related to laboratory tests must be ensured.	• Regulation on Medical Laboratories, T.R. Official Gazette Issue 28790, Date 09 .10.2013
	SH.LH.06.00	Traceability of the processes related to laboratory tests must be ensured.	• Regulation on Medical Laboratories, T.R. Official Gazette Issue 28790, Date 09 .10.2013
	SH.LH.07.00	Use of Bedside Test Devices (BSTD) should be regulated.	• Regulation on Medical Laboratories, T.R. Official Gazette Issue 28790, Date 09 .10.2013

Relevant Legislation of Standards			
Chapter Name	**Standard Code**	**Standard**	**Related Legislation**
Prevention of Infections	SH.SY.01.00	Processes concerning sterilization services must be identified and taken under control.	• Operating Regulation of Inpatient Treatment Institutions, Official Gazette Issue:17927, 13.1.1983
Facility Management	DH.TY.01.00	All the areas at laboratory must be clean for the safety and satisfaction of patient, carer and personnel.	• T.R. Ministry of Health, General Directorate of Treatment Services, "Regulation on Infection Control of Inpatient Treatment Institutions", Official Gazette Issue: 25903, 11.08.2005.
	DH.TY.02.00	Processes regarding catering must be identified.	• Regulation of Food Hygiene, T. R. Official Gazette, Issue 281457, 17 December 2011.
	DH.TY.03.00	The physical areas used by patients/carers must be safe and ergonomic.	• Regulation on Patient Rights, Official Gazette, Issue: 23420, 01.08.1998 • Tissue Typing Laboratories Directive, Number 47498, Date 28.11.2011.
	DH.TY.04.00	Precautions should be taken in laboratory to ensure safety of life and property of patient/carer and the personnel.	• Regulation on Patient Rights, Official Gazette, Issue: 23420, 01.08.1998 • Legal Aid and White Code Practice Circular, Sayı:6367, 16.03.2016. • Regulation on the Implementation of the Law on Private Security Services, Official Gazette Number: 25606, 07.10.2004
	DH.TY.05.00	A quality facility management structure and process must be established to ensure the quality and safety of laboratory services.	• Republic of Turkey Ministry of Health, Department of Construction and Maintenance, "Comminque concerning the minimum technical standards to be complied in the current or new healthcare facilities", 30.10.2012. • Regulation on Elevator Operation, Maintenance and Periodic Control, Official Gazette Number 29396, 24.06.2015 • Regulation on Health and Safety Measures to be Taken in Workplace Buildings and Additions, T.R. Official Gazette Number 28710, 17.07.2013

Relevant Legislation of Standards			
Chapter Name	**Standard Code**	**Standard**	**Related Legislation**
Waste Management	DH.AY.01.00	Safe and effective management of waste produced at laboratory must be ensured to protect human and environmental health.	• Regulation on Medical Waste Control, T.R. Official Gazette, Issue 25883, 22/07/2005. • Regulation on Medical Waste Control, T.R. Official Gazette, Issue 25755, 14/03/2005. • Regulation concerning the General Principles of Waste Management, T.R. Official Gazette, Issue 26927, 05/07/2008 • Regulation on Regularly Waste Storage, T.R. Official Gazette, Issue 27533, 26/03/2010 • Waste Management Regulation, T.R. Official Gazette Number 29314, 02/04/2015
Information Management	DH.BY.01.00	A safe and effective information management system must be present at laboratories.	• Law on Protection of Personal Data, T.R. Official Gazette, Issue 29677, 07.04.2016 • Regulation on the Processing of Personal Health Data and Providing Privacy -20 Oct. 2016 Number: 29863 • Regulation on Patient Rights, Official Gazette, Issue: 23420, 01.08.1998
Material and Device Management	DH.MC.01.00	Efficient, effective and safe use of materials and devices must be ensured.	• Regulation on Medical Devices, T.R. Official Gazette, Issue 27957, 07/06/2011 • Circular on TKHK Stock Management and Movable Goods Applications Number:01586109, 01.07.2013 • Regulation on Principles and Procedures of Market Surveillance and Inspection by the Ministry of Health Official Gazette Number: 26563, 25.06.2007 • Movable Property Regulation Number: 26407, 18.01.2007 • Ministry of Environment, Dangerous Chemicals Regulation Official Gazette Number: 24379, 20/04/2001
Outsourcing	DH.DK.01.00	The services provided through outsourcing must be in line with the core policies and values of laboratory and Standards of Accreditation in Health.	• Regulation on Making Amendment in the Service Procurement Tender Application Regulation, • T.R. Official Gazette, Issue 29428, 28/07/2015

Relevant Legislation of Standards			
Chapter Name	**Standard Code**	**Standard**	**Related Legislation**
Emergency Management	AD.AD.01.00	Measures must be taken against cases like natural disasters or events that necessitate extraordinary emergency response, intervention, first aid or evacuation.	• Regulation on Disaster and Emergency Response Services,T.R. Official Gazette, Issue 28855, 18/12/2013 • Regulation concerning the Fire Protection of Buildings, T.R. Official Gazette, Sayı 26735, 19/12/2007 • Hospital Disaster and Emergency Plans (HAP) Implementing Regulation Official Gazette Number: 29301, 20/03/2015
	AD.AD.01.00	Timely intervention must be ensured in cases where the health professional is exposed to a risk of violence, or an act of violence is directed towards him/her.	• Regulation concerning the Procedures and Principles of Legal Support to be made to the Ministry of Health Personnel due to the crime made against them, Official Gazette Issue : 28277, 28.04.2012 • Circular on Employee Safety, Issue: 2012/23, 14.05.2012
	AD.AD.01.00	There must be an arrangement in place to ensure timely response to fire.	• Regulation on Disaster and Emergency Response Services, T.R. Official Gazette, Issue 28855, 18/12/2013 • Regulation concerning the Fire Protection of Buildings, T.R. Official Gazette, Issue 26735, 19/12/2007 • Ministry of Health Fire Prevention and Extinguishing Directive, Sayı:2652, 20/08/2008


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ANNEX

ANNEX.1

SAS Indicators List

SAS Indicators Table 1 – Management and Organisation Aspect

Manegement and Organisation		
Indicator Code	Indicator	Mandatory (M) / Optional (O)
Y.1.M	Target achievement rate	M
Y.2.M	Corrective/Preventive Action Completion Rate	M
Y.3.M	Document Revision Count	M
Y.4.M	Use of Adverse Event Reporting System	M
Y.5.M	Training Participation Rate of Staff	M
Y.6.M	Completion Rate of Planned Trainings	M

SAS Indicators Table 2

Healthy Working Life		
Indicator Code	Indicator	Mandatory (M) / Optional (O)
Ç.1.M	Staff Satisfaction Rate	M
Ç.2.M	Staff Exposure to Cutting/Puncturing Tool Injury Rate	M
Ç.3.M	Staff Exposure to Blood and Body Fluids	M
Ç.4.M	Completion of Staff Health Screenings	M
Ç.5.M	Exposure to High Risk Chemicals	M
Ç.6.M	Z Contact with Biosafety Level 3 microorganisms	M

SAS Indicators Table 3

Healthcare Services		
Indicator Code	Indicator	Mandatory (M) / Optional (O)
Clinical Laboratories		
S.1.M	Wrong Order Ratio for Clinical Laboratory Tests	M
S.2.M	Declined Sample Ratio for Clinical Laboratory Tests	
	• Incorrect Labelled Sample Ratio • Incorrect Sample Container Usage Ratio • Insufficient Sample Ratio • Sample with Hemolysis Ratio • Coagulated Sample Ratio • Ratio of Samples that Exceeds Maximum Transfer Duration	M
S.3.M	Incorrectly Identified Sample Ratio for Clinical Laboratory Tests • Rate of incorrectly identified samples recognized before work on sample • Rate of incorrectly identified samples recognized after work on sample	M
S.4.M	Missing Sample Rate	M
S.5.M	Repeated Sample Extraction Rate	M
S.6.O	Ratio of Undelivered Samples to Laboratory	O
S.7.O	Ratio of First Culture Sample Extraction before Giving Antibiotics to Inpatients	O
S.8.M	Blood Cultures Contamination Ratio	M
S.9.O	Ratio of Blood Culture Sample Extraction in compliance with Approved Protocols	O
S.10.M	Urine Cultures Contamination Ratio	M
S.11.M	Incompatibility Count/Rate of External Quality Control Tests	M
S.12.M	Incompatibility Count/Rate of Internal Quality Control Tests	
S.13.O	Rate of non-compliances among Cytological and Pathological diagnoses	O
S.14.O	Rate of non-compliance between surgical pathology and frozen section results	O

S.15.M	Ratio of Compliance between Direct Gram Stain and Final Identification	M
S.16.O	Ratio of Evaluation and Reporting in an Hour after Breeding Signal in Blood Cultures	O
S.17.M	Panic Value Reporting Ratio	M
S.18.M	Untimely Reported Result Ratio	M
S.19.M	Total Test Duration (for emergency and routine tests) • Average Duration between Order and Reporting • Average Duration between Sample Extraction and Reporting • Average Duration between Laboratory Acceptance and Reporting - Number of days when the automation is defective (M) - Number of days when the device is defective (O) - Rate of delays associated with the analytical process in the untimely results (M)	M
S.20.M	Incorrect Reporting Rate for Clinical Laboratory Tests	M
S.21.O	Clinician Satisfaction Rate for Clinical Laboratory Test	O
Infection Control		
S.22.M	Hand Hygiene Compliance Rate	M

SAS Indicators Table 4

Support Services		
Indicator Code	Indicator	Mandatory (M) / Optional (O)
D.1.M	Number of Breakdown Days in Basic Facility Resources	M
D.2.M	Response Time for Facilitybased Problems	M
D.3.M	Waste turnover rate (Determining how frequently the Z waste is collected from the temporary storing areas by relevant agency in charge)	M
D.4.M	Waste-related Hazardous Accident Count	M
D.5.O	Avarage Time Past Until Technical Unit has responded to Information Management System (IMS) failures	O
D.6.M	Duration of IMS down-time	M
D.7.M	Time Past Until Responding to Device Breakdown	M
D.8.M	Device Failure Frequency	M
D.9.M	Number of Breakdown Days for Devices	M
D.10.M	Information Management System Revision Requests • Rate of response • Length of time for responding	M

SAS Indicators Table 5

Emergency Management		
Indicator Code	Indicator	Mandatory (M) / Optional (O)
A.1.M	Rate of Completely Filled in Code White Event Form	M