Supplemental Table 1. Own concept of a medical laboratory relating to risk management and corresponding to the ISO15189:2012 and ISO22367:2020 requirements

A model of approach to risk management in a medical laboratory	**ISO31000:2018 – Risk management. Guidelines**	**Process identification from an organization (e.g., medical laboratory) according to ISO 9001:2015**	**ISO15189:2012 – Medical laboratories. Requirements for quality and competence**	**ISO22367:2020 – Medical laboratories. Application of risk management to medical laboratories**
Column A	Column B	Column C	Column D	Column E
Risk management analysis	**Principles, framework, process**	**Process approach**	**Management and technique requirements**	**Annex informative**
1. Risk management process planning	**1. Principles**	**1. Management processes**		
	Risk management improves performance and supports achievement of objectives.	Establishment of laboratory quality policy and objectives	**Management requirements**	
Leadership and commitment			Quality policy (section 4.1.2.3)	Not stated
Quality policy			Quality objectives (section 4.1.2.4)	Not stated
External and internal framework assessment for the medical laboratory	**2. Framework**	Internal and external communication process: laboratory policy, procedures, working instructions and other documents apply	**Management requirements**	
	It is the number of components that provide:		Communication (section 4.1.2.6)	Not stated
			Personnel's proposals (section 4.14.4)	Not stated
Description of the process or service for which the risk management analysis is performed	- fundamental elements: policy, objectives, leadership and commitment		Documents control (section 4.3)	Annex A, section A2
			User's feedback evaluation (section 4.14.3)	Not stated
			Resolution of complains (section 4.8)	Annex A, section A6
	- organizational arrangements: plans, organization chart, responsibilities, resources, processes, activities		**Technique requirements**	
Establishing an implementation strategy of the risk management framework: *			Release of results (section 5.9)	Not stated
			Laboratory information management (section 5.10)	Not stated
- defining a schedule		Monitoring and measuring process	**Management requirements**	
- informative and instructional sessions/meetings			Continual improvement (section 4.12)	Annex A, section A9
			Resolution of complaints (section 4.8)	Annex A, section A6
- periodic evaluation of the risk management framework efficiency			Management review (section 4.15)	Not stated
			Technique requirements	
- risk management plan revision if any significant changes occur			Personnel (section 5.1)	

Supplemental Table 1. Own concept of a medical laboratory relating to risk management and corresponding to the ISO15189:2012 and ISO22367:2020 requirements (Continued)

A model of approach to risk management	ISO31000:2018 – Risk management. Guidelines	Process identification from an organization	ISO15189:2012 – Medical laboratories. Requirements for quality and competence	ISO22367:2020
Column A	Column B	Column C	Column D	Column E
Risk management analysis	**Principles, framework, process**	**Process approach**	**Management and technique requirements**	**Annex informative**
1. Risk management process planning (continued)	**3. Risk management process**	**2. Processes of product or service achievement**		
Defining risk criteria: - scale of plausibility - scale of severity of effects - the way in which the risk is determined - the level to which the risk is acceptable or tolerable	Communication and consultation: It helps the relevant stakeholders to understand the risk, the basis on which decisions and reasons are made for certain necessary actions. Application and criteria domain, context of laboratory.	Process of supplies Service management process	**Management requirements** External services and supplies (section 4.6) **Technique requirements** Laboratory equipment, reagents and consumable (section 5.3) Pre-examination processes (section 5.4) Examination processes (section 5.5)	 Annex A, section A3 Annex A, section A12 Not stated Not stated
2. Risk identification Methods chosen for risk identification: brainstorming, Ishikawa diagram, FMEA, FRACAS.	Criteria definition: - risk size and type - criteria definition for risk evaluation Risk assessment: - risk identification	Service control process	**Management requirements** Identification and control nonconformities (section 4.9) Corrective actions (section 4.10) Preventive actions (section 4.11)	 Annex A, section A5 Annex A, section A7 Annex A, section A8
3 Risk analysis and evaluation Methods chosen for risk analysis: FTA, “5 Why?”, Pareto diagram.	- risk analysis - risk evaluation Risk treatment		**Technique requirements** Ensuring quality of examination results (section 5.6)	 Annex A, section A14
4. Risk treatment: - Risk response plan - Contingency plan	Monitoring and analysis Registration and reporting	**3. Support processes** Audit process Maintenance service process	**Management requirements** Evaluation and audits (section 4.14) **Technique requirements** Laboratory equipment, reagents and consumable (section 5.3)	Annex A, section A10 Annex A, section A12
5. Risk monitoring and control Using the QIs and RKIs in continuous quality improvement process		IT/LIS service process Service planning process (electricity, water supply, disposal of biological waste, human resources)	**Technique requirements** Laboratory information management (section 5.10) **Technique requirements** Accommodation and environmental conditions (section 5.2)	 Not stated Annex A, section A11

Note 1: The table must be read based on the color scheme highlighting the same requests in the standards used in a medical laboratory.
Note 2: * The strategy of the risk management is established by each medical laboratory.
Note 3: FMEA – Failure Modes and Effects Analysis, FTA – Fault Tree Analysis, FRACAS – Failure Reporting, Analysis and Corrective Action System, IT - Information Technology, LIS - Laboratory Information System, KRIs – Key Risk Indicators, QIs – Quality Indicators

Supplemental Table 2. Performance indicators and their targets for the selected objective: Patient identification

Product/service completion processes								
Analyzed Process	**List of specific objectives, calculation formula of KPIs/QIs and performance specifications established on our laboratory**			**Performance indicator analysis for a 1-year period**				
Pre-analytic process	**Selected specific objectives**	**Performance/Quality indicator (KPI/QI)**	**Target**	**2019**	**2020**	**2021**	**Target deviation**	**Results interpretation**
LIS registration of the test, Patient identification	SO2: Identification of errors associated with the registration of patient's identification data or requested tests	Number of complaints received from physicians/year	To aim for zero	0	0		-	Possible near-miss identification
		Number of patients who did not receive the solicited test results from the laboratory/year† (Pre-OutpTN)	To aim for zero	0.05%	0.137%		-0.137%	Lack of attention when introducing of information in the laboratory's database
		Number of samples not received in the laboratory/year† (Pre-NotRec)	Not to exceed 2% of the total number of requests received by the laboratory	0.32%	0.54%		-1.45%	Lack of adherence to the laboratory's procedures and policies

Note 1: This table is not comprehensive but is intended to provide examples of quality indicators in a medical laboratory.
Note 2: † - KPI/QI selected in a medical laboratory and found in the list of QIs IFCC-WG-LEPS
Note 3: IFCC-WG-LEPS - International Federation of Clinical Chemistry and Laboratory Medicine Working Group on Laboratory Errors and Patient Safety, LIS - Laboratory Information System, KPI - Key Performance Indicator, SO - Specific Objective, QI - Quality Indicator

Supplemental Table 3. Performance indicators and their targets for the selected objective: Blood sample collection

Product/service completion processes								
Analyzed Process	**List of specific objectives, calculation formula of KPIs/QIs and performance specifications established on our laboratory**			**Performance indicator analysis for a 1-year period**				
Pre-analytic process	**Selected specific objectives**	**Performance/Quality indicator (KPI/QI)**	**Target**	**2019**	**2020**	**2021**	**Target deviation**	**Results interpretation**
Blood sample collection	SO5: Increasing the quality of medical services by decreasing the number of nonconforming samples by 30% in 2021 compared to 2020	Total number of nonconformities/month	Not to exceed 2% of the total number of requests received by the laboratory	2.36%	3.42%		+1.42%	Insufficient knowledge and understanding of collection venous blood procedure and/or other laboratory's procedures
	SO6: Identification of possible interferences on biochemical tests (icterus, hemolysis, lipemia)	Number of samples with any degree of hemolysis/month	Not to exceed 2% of the total number of requests received by the laboratory	0.77%	1.11%		-0.89%	Lack of attention, experience and competence of the collection personnel
		Number of lipemic samples/month	Not to exceed 2% of the total number of requests received by the laboratory	1.24%	2.38%		+0.38%	Lack of patient information regarding the necessity of respecting the pre-analytical collection conditions
	SO7: Avoid rejection of samples to be tested	Number of free hemoglobin samples over 0.5 g/L per month† (Pre-Hem)	Not to exceed 1% of the total number of requests received by the laboratory	0	0		-	Insufficient knowledge and understanding of venous blood procedures

Note 1: This table is not comprehensive but is intended to provide examples of quality indicators in a medical laboratory.
Note 2: † - KPI/QI selected in a medical laboratory and found in the list of QIs IFCC-WG-LEPS
Note 3: IFCC-WG-LEPS - International Federation of Clinical Chemistry and Laboratory Medicine Working Group on Laboratory Errors and Patient Safety, KPI - Key Performance Indicator, SO - Specific Objective, QI - Quality Indicator

Supplemental Table 4. Performance indicators and their targets for the selected objective: Sample transport and processing

Product/service completion processes								
Analyzed Process	**List of specific objectives, calculation formula of KPIs/QIs and performance specifications established on our laboratory**			**Performance indicator analysis for a 1-year period**				
Pre-analytic process	**Selected specific objectives**	**Performance/Quality indicator (KPI/QI)**	**Target**	**2019**	**2020**	**2021**	**Target deviation**	**Results interpretation**
Sample transport and processing	SO8: Identification of errors associated with improper storage and transport of patient's samples	Number of tests with clinically impossible results/year	To aim for zero	1	2		+2	Lack of adherence to the laboratory's collection procedures
								Lack of adherence to the transport procedures
		Number of tests with pathological results without known clinical context/within-run	4	48	76		+72	Lack of attention when collecting and introducing information in the database
	SO9: Identification of errors associated with improper storage and transport of reagents	Number of subsequent samples with pathological results without known clinical context/within-run	4	0	0		-	Lack of adherence of personnel to the transport procedures
								Lack of attention, experience and competence of the collection personnel

Note 1: This table is not comprehensive but is intended to provide examples of quality indicators in a medical laboratory.
Note 2: KPI - Key Performance Indicator, SO - Specific Objective, QI - Quality Indicator

Supplemental Table 5. Performance indicators and their targets for the selected objective: Human resources

Support processes								
Analyzed Process	**List of specific objectives, calculation formula of KPIs/QIs and performance specifications established on our laboratory**			**Performance indicator analysis for a 1-year period**				
Pre-analytic process	**Selected specific objectives**	**Performance/Quality indicator (KPI/QI)**	**Target**	**2019**	**2020**	**2021**	**Target deviation**	**Results interpretation**
Human resources	SO1: Improving patient safety through training programs conducted in the first half of 2021 for personnel in charge of recording patient's data and information in the laboratory information system	Number of complaints received from physicians/year	To aim for zero	0	0		-	Possible near-miss identification
								The existence of 3 possible ways of patient data checking introduced in the LIS
								Delta check technique efficiency in identifying unexpected changes in results associated with patient misidentification
	SO3: Increasing the specialization degree of nurses at collection points through in-house training programs	Number of specialization courses/year† (Supp-Train)	3/an	1/an	1/an		-2/an	-lack of medical culture
	SO4: Updating the functions chart according to the requirements of the laboratory	Occupancy rate (%)	100%	100%	70%		-30%	-child growth leave
								-the salary does not meet the future staff expectations
	SO10: Increasing the satisfaction of the client's requirements and expectations by 30% in 2021.	Number of complaints received from physicians/year	To aim for zero	0	0		-	-possible near-miss identification

Note 1: This table is not comprehensive but is intended to provide examples of quality indicators in a medical laboratory.

Note 2: † - KPI/QI selected in a medical laboratory and found in the list of QIs IFCC-WG-LEPS
Note 3: IFCC-WG-LEPS - International Federation of Clinical Chemistry and Laboratory Medicine Working Group on Laboratory Errors and Patient Safety, KPI - Key Performance Indicator, SO - Specific Objective, QI - Quality Indicator

Supplemental Table 6. Failure Mode and Effect Analysis: Patient identification

Pre-analytical process													
Activities or functions of the process or requests	Identified risks	Risks effects	Risks causes (specific errors)	Inherent risk				Control measures		The results of the risk mitigation measures			
								Preventive measures	Detection measures	Residual risk			
				S	O	D	RPN			S*	O*	D*	RPN*
1	*2*	*3*	*4*	*5*	*6*	*7*	*8*	*9*	*10*	*11*	*12*	*13*	*14*
A3: patient identification	R3.1: error in patient identification with the information registered previously in LIS	• the result belongs to a different patient • image and credibility damage • incorrect diagnostic and inadequate therapeutic conduct • legal implications	• lack of attention of the person who registered the patient in LIS • language barriers • lack of training	5	1	5	25	• training program for the personnel to understand the importance of patient identification check before the start of collection procedure of biological samples	• Delta check – useful technique to capture unexpected changes of results • intern audits	5	1	4	20
	R3.2: assigning a wrong date of birth		• personnel with lack of experience										
	R3.3: incorrect patient name associated with the identification number		• lack of attention of the person who registered the patient in LIS • lack of training										
	R3.4: incorrect identification given by a family member, friend, nurse		• language barriers • personnel with lack of experience					• standardization of the entire process • personnel training	• none				

Note 1: The risks causes are written in the table corresponding to each identified risk. The risks effects are written in a single column because the level of risk are established according to the higher RPN.

Note 2: A – Activity, D – Detectability, LIS - Laboratory Information System, O – Occurrence, R – risk, RPN – Risk Priority Number, S – Severity

*** Parameters assessed after the implementation of control measures.**

Supplemental Table 7. Failure Mode and Effect Analysis: Blood sample collection

Pre-analytical process													
Activities or functions of the process or requests	Identified risks	Risks effects	Risks causes (specific errors)	Inherent risk				Control measures		The results of the risk mitigation measures			
								Preventive measures	Detection measures	Residual risk			
				S	O	D	RPN			S*	O*	D*	RPN*
1	*2*	*3*	*4*	*5*	*6*	*7*	*8*	*9*	*10*	*11*	*12*	*13*	*14*
A5: blood sample collection	R5.1: the type of vacutainer for the required test is inappropriate	• specimen rejection • recollection in an appropriate vacutainer for the required test • prolonged time around • lack of result • complaints • additional material and time cost • incorrect results due to concentration difference for a series of parameters • pain and more severe complications than those ones determined by the venous access	• lack of attention and knowledge of personnel • the lack of personnel experience • lack of attention, lack adhesion to the collection procedure	3	1	4	12	• periodically programs of personnel training • informative paper and electronic materials about blood collection • insurance policy	• intern audits • KPIs/QIs usage • SPC	3	1	3	9
	R5.2: arterial punction		• lack of attention and knowledge of collection personnel					• training courses and competences licenses	• Delta check – useful technique for unexpected change of results noticing • the color of the blood and blood pulsating flow	3	1	4	12

Supplemental Table 7. Failure Mode and Effect Analysis: Blood sample collection (continued)

Pre-analytical process													
Activities or functions of the process or requests	Identified risks	Risks effects	Risks causes (specific errors)	Inherent risk				Control measures		The results of the risk mitigation measures			
								Preventive measures	Detection measures	Residual risk			
				S	O	D	RPN			S*	O*	D*	RPN*
1	*2*	*3*	*4*	*5*	*6*	*7*	*8*	*9*	*10*	*11*	*12*	*13*	*14*
A5: blood sample collection	R5.3: approaching locations that should be avoided	• phlebitis, thrombosis, necrosis of tissues due to vein approaches at the scalp level for the new born or at the ankle level • lymphedema, pain and infections, complication that might occur as a venipuncture result at the upper limb on the same side with the mastectomy • nerves, tendons or arteries damage, if the veins are approached on the half of the sideway forearm, just above the thumb, or in the palm under the hand wrist • thrombophlebitis at the patients with coagulopathies or tissue necrosis at the diabetic patients	• lack of a set of specific measures for the children blood collection	4	1	3	12	• periodical reviews of collection procedure with the inclusion of pediatric specific measures	• intern audits • KPIs/QIs usage • SPC	4	1	3	12
			• lack of medical behaviour specific to oncological patients					• periodical reviews of collection procedure with the inclusion of oncologic specific measures					
			• lack of vein punction standardization					• training courses and competences licenses					
			• lack of measures for specific situations					• training courses and competences licenses					

Supplemental Table 7. Failure Mode and Effect Analysis: Blood sample collection (continued)

Pre-analytical process													
Activities or functions of the process or requests	Identified risks	Risks effects	Risks causes (specific errors)	Inherent risk				Control measures		The results of the risk mitigation measures			
								Preventive measures	Detection measures	Residual risk			
				S	O	D	RPN			S*	O*	D*	RPN*
1	*2*	*3*	*4*	*5*	*6*	*7*	*8*	*9*	*10*	*11*	*12*	*13*	*14*
A5: blood sample collection	R5.4: difficulties in vein palpation and needle insertion or the blood specimen cannot be obtained (“blind venopunction”)	• multiple venopunctions • nerves damages, arterial punction • specimen hemolysis • local complications: hematoma, pain	• lack of medical behaviour specific to oncological, elderly and obese patients	3	2	2	12	• preheating the venopunction location can help in locating the veins	• none	3	1	2	6
			• lack of specific set of measures when the blood does not flow inside the tube at the first needle insertion					• the doctor is informed by the involved nurse • incident recording					
	R5.5: selection of inappropriate punction needle dimension		• lack of procedure adherence					• training courses and competences licenses	• intern audits • KPIs/QIs usage • SPC				
			• lack of attention and knowledge of collection personnel					• same nurse will not do more than 2 venopunction attempts at the same patient, in the same moment					

Supplemental Table 7. Failure Mode and Effect Analysis: Blood sample collection (continued)

Pre-analytical process													
Activities or functions of the process or requests	Identified risks	Risks effects	Risks causes (specific errors)	Inherent risk				Control measures		The results of the risk mitigation measures			
								Preventive measures	Detection measures	Residual risk			
				S	O	D	RPN			S*	O*	D*	RPN*
1	*2*	*3*	*4*	*5*	*6*	*7*	*8*	*9*	*10*	*11*	*12*	*13*	*14*
A5: blood sample collection	R5.6: lack of a guide for establishing the number and type of tubes according to the test requests and the selection of the punction location based on the blood volume needed for collection (difficult collections for children, elderly, obese patients, oncologic patients or with cognitive disorders)	• insufficient blood collected • specimen nonconformity • lack of results • delay in diagnosis establishing and treatment initiation • anemia iatrogenic • complaints, anxiety	• lack of specific set of measures for children's blood collection	3	2	2	12	• collecting a higher volume of blood to obtain an appropriate serum volume for children's testing, who have a total blood volume lower and big hematocrit • a guideline to establish the relationship between maximum blood volume collected from the under 45 kilos patients and the percentage of the total blood volume can be collected, and respectively venopunctions frequency	• intern audits	3	2	2	12

Supplemental Table 7. Failure Mode and Effect Analysis: Blood sample collection (continued)

Pre-analytical process													
Activities or functions of the process or requests	Identified risks	Risks effects	Risks causes (specific errors)	Inherent risk				Control measures		The results of the risk mitigation measures			
								Preventive measures	Detection measures	Residual risk			
				S	O	D	RPN			S*	O*	D*	RPN*
1	*2*	*3*	*4*	*5*	*6*	*7*	*8*	*9*	*10*	*11*	*12*	*13*	*14*
A5: blood sample collection	R5.7: not respecting the collection recommended order to avoid carryover with the used additives	• erroneous results due to carryover with additives contained by the tubes collected previously • HBV and/or HIV infection	• lack of adherence to the collection procedure	3	2	2	12	• periodic training programs	• intern audits	3	1	2	6
	R5.8: accidental needle harming		• lack of adherence to the collection procedure					• applying first aid procedure	• none	4	1	2	8

Note 1: The risks causes are written in the table corresponding to each identified risk. The risks effects are written in a single column because the level of risk are established according to the higher RPN.

Note 2: A – Activity, D – Detectability, FMEA – Failure Modes and Effects Analysis, HBV – Hepatitis B Virus, HIV – Human Immunodeficiency Virus, O – Occurrence, R – risk, RPN – Risk Priority Number, S – Severity, SPC – Statistical Process Control, KPI – Key Performance Indicator, QI – Quality Indicator

*** Parameters assessed after the implementation of control measures.**