

Guide on how-to

# Pathology laboratory good practices manual guidelines.

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Annex 1



# Introduction

City Cancer Challenge (C/Can) and its network of partners support cities as they work to strengthen the quality of cancer care infrastructure.

By the end of 2019, seven C/Can cities had identified priority projects to develop and harmonise the quality of core cancer diagnostic and treatment services, including in pathology, radiology, nuclear medicine, surgery, radiotherapy, medical oncology, and palliative and supportive care.

In all cities, the local technical and executive committees have prioritised action to improve harmonisation and the quality of pathology diagnosis and proposed policy solutions to address common and persistent challenges, including the absence of written standard operating procedures and variability of pathology laboratory practices in the city.

Throughout the first cycle of technical assistance projects in the C/Can cities (2018-2019), the need was identified the need to develop guidance on the core elements that should be considered by the pathology technical groups into local policy solutions to advance the city projects and ensure that new cities joining C/Can benefit from what others have considered, developed and learned.

This document is expected to provide a starting point for local pathology and cytopathology professionals to assemble and work together and standardise best practices in public and private laboratories in their respective cities, regardless of their size or location. The primary aim is to increase the quality of services provided to the local community and work under conditions of better quality control and quality assurance of laboratory daily activities.

The recommendations outlined in this document were developed by Dr Beatriz Hornburg, a pathologist and external expert nominated by the American Society for Clinical Pathology (ASCP) to assist the pathology city project team in Asunción, Paraguay, in consultation with the C/Can team. The content of the document was generated as a result of various technical meetings between Dr Hornburg, the C/Can pathology project team in Asunción, Paraguay and the C/Can Technical Assistance team. The document has been reviewed by three external independent senior pathologists, Dr Dan Scungio, Dr Jeannette Guarner and Dr Darryl Elzie, nominated by ASCP and their comments and suggestions have been extremely helpful in making the document as practical and comprehensive as possible.

## INTERPRETING THIS DOCUMENT

The recommendations outlined in this publication are expected to be interpreted, analysed, and tailored taking into account the local context and the need to build a multisectoral and multidisciplinary consultative process within the city.

The guidelines introduced in this document are intended to be used by the local project teams as a resource to develop the first draft of their city pathology laboratory good practices manual. It must be discussed and adapted according to local needs and other related local laws and regulations.

The manual presents parameters and operational requirements, including diagnostic procedures, laboratory test procedures, sample handling, traceability, facilities, and physical structure that ensure a safer work environment, control of activities and improved patient care.

These parameters may be subject to local regulations and need to be adjusted accordingly. However, it is highly recommended that the items described are preserved and the required modifications added to the existing criteria, since they are core elements in any internal laboratory quality system.

The resulting local city pathology laboratory good practices manual should be accompanied by a corresponding regulatory framework to facilitate interpretation of both documents to all people involved in laboratory inspections (local health authorities) and laboratory staff.

# Structure and suggested contents

The pathology laboratory, for the purposes of this manual of good laboratory practices, encompasses the following areas: histopathology, cytopathology (gynaecological cytology and non-gynaecological cytology, including fine needle aspiration cytology and associated sample acquisition), immunohistochemistry, immunofluorescence, and molecular pathology.

The criteria herein are essential in providing the basis to build best laboratory practices habits, hence improving performance, creating a safe working environment and reliable and timely results for patients' adequate treatment.

# 1. Scope

## 1.1. COVERAGE

The manual applies to pathology laboratories, public and private, located within other healthcare establishments, such as hospitals, and/or isolated units. The items described below are criteria that will help management to meet the quality requirements that guarantee user procedures and processes performed within the specifications proposed by current health legislation.

## 1.2. RESEARCH ACTIVITIES

Pathology laboratories that conduct research activities must submit their projects for review and approval of the respective research ethics committees or local equivalent organs.

## 1.3. DOCUMENTATION

Each criterium described here should generate one or more documents, including manuals, policies, standard operating procedures (SOP), datasheet, or specific forms, which will produce a body of knowledge. Everything that is recorded, either physically or electronically, can be proved, compiled, and analysed; hence lessons learned will serve as grounds for new policies, routines, producing better outcomes.

## 2. General requirements

### 2.1. OPERATIONS

Pathology laboratories must operate in accordance with the requirements established by law and be licensed by the local health authority.

The laboratory must clearly display the opening hours for the public, whether on the premises or virtually (website/social media pages) [1] [2].

There must be a straightforward menu of tests offered by the laboratory, and insurance plans, if applicable, should be displayed physically (paper) or virtually (website/social media pages).

The laboratory director must be a legally qualified physician, preferably a pathologist, or according to local specific regulation. If there is no regulation regarding the laboratory director, the person who occupies this post should be an anatomic pathologist or cytopathologist, actively involved with the laboratory's activities. The active involvement of the laboratory director with the processes developed as well as with personnel engagement will ensure a successful quality system implementation [3] [4].

### 2.2. OUTSOURCED ACTIVITIES

The pathology laboratory may outsource support activities/processes when not performed directly by the laboratory to a third party under a legal contract, or according to local regulations [1] [5].



## 3. Organization

The pathology laboratory should have records of all procedures performed, in addition to all stages of laboratory tests, from collection and reception of specimens to delivery of reports and results.

These records must be an integral part of the quality manual and/or SOPs, validated by the laboratory director, who will also be responsible for approving their periodic review and necessary changes.

The laboratory director must ensure compliance with the recommendations contained in these documents, as well as that the institutions with which it establishes outsourcing contracts are in compliance with local regulations and with the documents provided by the laboratory when specific procedures or processes are carried out [3] [4].

## 4. Facilities

### 4.1. PHYSICAL AREA

Pathology laboratory activities take place in different areas, which must be sufficiently large enough for safe and efficient operational flow. Therefore, the dimensions, construction, and location must be in accordance with the activity developed in it and specific legislation in force (if existent) [1] [6].

People with disabilities or reduced mobility, including workers, must have guaranteed access to the laboratory, as defined by specific legislation.

Floor and wall covering materials must be suitable for the purpose, non-flammable, waterproof, washable, capable of disinfection, and chemical resistant.

The pathology laboratory must ensure that the installations, internal and external, are well-maintained, safe, comfortable, and clean. Preventive and corrective maintenance actions on the building installations must be carried on either by the laboratory or the institution where the laboratory is inserted or outsourced to a third party.

### 4.2. LIGHTING

The laboratory must be equipped with lighting compatible with the development of activities and comfort of the staff, in accordance with occupational parameters and local occupational legislation [6] [7].

### 4.3. VENTILATION

The laboratory must have a ventilation system compatible with the development of activities and in accordance with local occupational standards. The control standards for environmental air safety in the grossing room must be in accordance with the local occupational standards, as well as the air conditioning system. There must be a chemical fumes safety hood for handling chemicals, especially when highly volatile.

Air quality must follow local legislation parameters. If there are no local work environmental safety laws specifying parameters for air and air renovation volumes or standards for formalin and xylene air concentration levels, consider the references from the American Occupational Safety & Health Administration (OSHA), as described below:

Chemical	TWA*	STEL**
Formaldehyde	0,75 ppm***	2,0 ppm
Xylene	100 ppm	200 ppm

\*TWA – 8h time-weighted average exposure limit - 40 hours per week = 5 working days.

\*\*STEL – Short term average exposure limit - 15 minutes, maximum 4 times a day.

\*\*\*Ppm – parts per million.

#### 4.4. INSTALLATION

Workbenches must be suitable for laboratory procedures and have smooth, impermeable, non-corrosive surfaces that can be easily disinfected.

Organisation of the laboratory sectors, workbenches, and other supporting rooms and areas should be appropriately maintained, avoiding clutter, thus minimising the risk of accidents or loss of specimens, blocks, slides, and patient and staff belongings. One effective method suggested is the Japanese 5S Method [8]:

- › Seiri / Sort: separating essential from nonessential items.
- › Seiton / Straighten: organising essential materials and keeping them in specific locations.
- › Seiso / Shine: clean the work area.
- › Seiketsu / Standardise: establishing a system to maintain and make 5S a habit.
- › Shitsuke / Sustain: establishing a safe and sanitary work environment.

All rooms, cabinets, storage spaces, equipment (including cable voltage), electrical devices, and plugs should be labelled according to their function, content, voltage, and application.

# 5. Processes and procedures

Workflows help to identify the laboratory's sectors and their respective processes, allowing classification of documentation (SOPs, datasheets for temperature and other records) according to each area or sector displayed, including the supporting areas. Figure 1 describes an example of a basic pathology laboratory workflow, according to specimens processing and reports release, as well as the supporting areas, which are part of the institution but do not deal directly with specimens' preparedness and analysis.

Each pathology laboratory is encouraged to design a workflow flowchart according to the activities performed and types of specimens received. Observation of the actual workflow, display, and positioning of benches, equipment, and staff movement during working hours is important. This observation may reveal difficulties in operating equipment, poor productivity, and the need for other adjustments to facilitate an effective workflow.

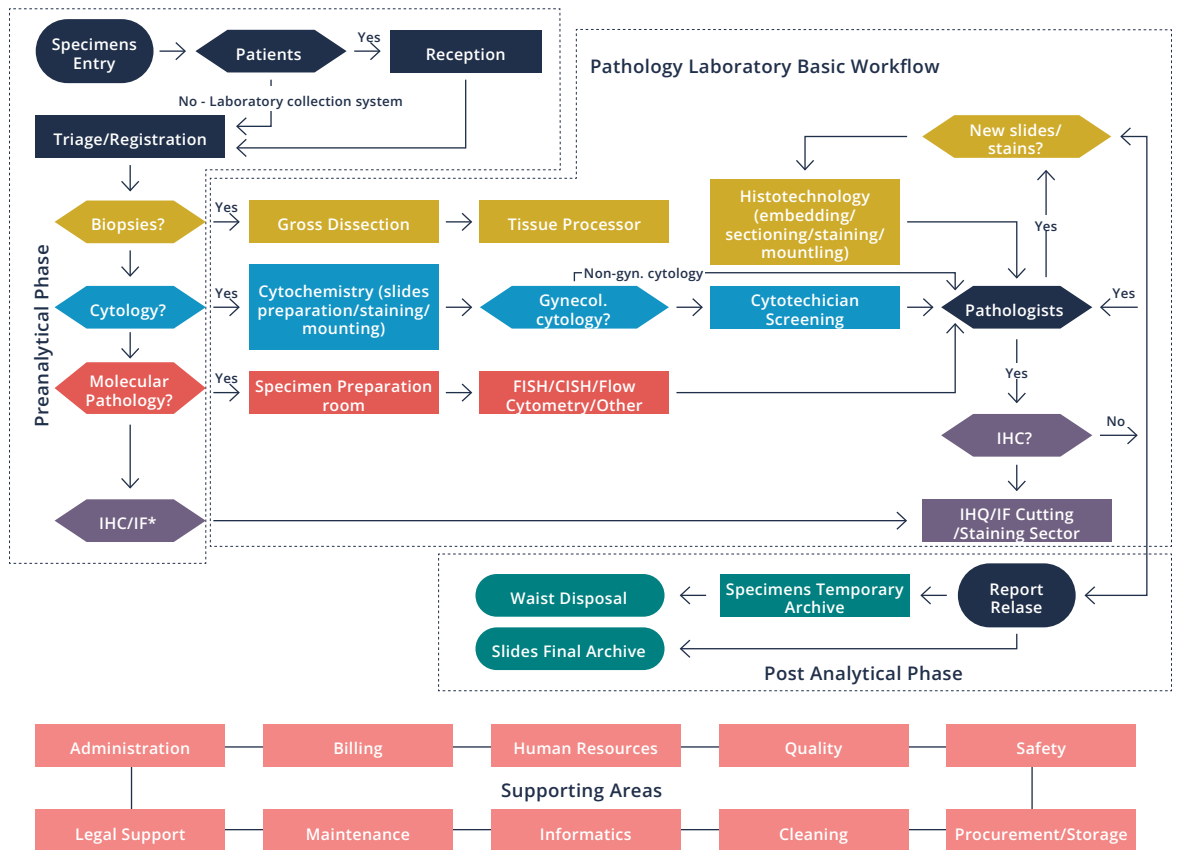


Figure 1. Pathology laboratory workflow (pre-analytical, analytical, and post-analytical phases).  
\*IHC - Immunohistochemistry; IF - Immunofluorescence.

## 5.1. PROCESS

Each laboratory operates according to three main phases of workflow based on the entry of specimens, processing, analysis, and report release, which are:

- › Pre-analytical phase (light blue background in the above flowchart): includes actions and factors that involve specimen acquisition, packaging, transport, and processing prior to analysis.
- › Analytical phase (light green in the flowchart): includes actions and factors related to the sample analysis process.
- › Post-analytical phase (light grey in the flowchart): refers to the phase of interpretation of results according to pathologists' experience in formulating the diagnosis (or differential diagnoses) to guide the patient treatment.

## 5.2. PRE-ANALYTICAL PHASE PROCEDURES

### 5.2.1. RECEPTION AND TRIAGE OF SPECIMENS

The first important step to ensure that specimens arrive to the laboratory in good condition, are identified, fixed, packaged, and with relevant information regarding the medical request is to provide a specimen collection manual to external collection sites like hospitals, clinics and independent medical offices. This manual will contain basic instructions regarding the minimum adequate size and anatomical site, patient identification on the medical request and specimen container, types of fixative according to each test guidelines, as well as instructions on packaging and transport. Criteria for specimen rejection must be clear, such as broken slides, containers without a sample, designations of containers and unmatched description of the medical request, among others.

Specimens must be identified upon reception in relation to the respective medical request, checking the correct completion of the items.

- › The identification on the specimen container must coincide with that on the medical request.
- › The medical request must be complete.
- › Patient identification must be readable.
- › It must include the name of the patient's mother to avoid exchanges in the case of homonyms.
- › It must include the name of the person responsible for collecting the specimen, as well as means for contacting them (phone, e-mail, office address, other).
- › When the specimens are already in slides, their integrity must be verified.
- › Packaging and fixation must be adequate.

Important: patients must be given a personal identification number (according to local regulations), the institution of origin (hospital, clinic, other), type of specimen (biopsy, cytology, etc.), clinical data, and type(s) of the test(s) requested. In order to ensure patients' individuality in the laboratory information system and avoid the exchange of specimens with homonyms, two or more identification parameters are needed and must be recorded in the laboratory information system and attached to the laboratory's operating (or specimen tracking) number. Examples: name of the mother, social security number, or other, according to local legislation.

### 5.2.2. PACKAGING AND CHECKING LABELS

- › Specimens must be properly packaged and labelled to avoid losses or technically make its analysis unfeasible.
- › Specimens that are not correctly packed or identified should be rejected before entering the laboratory, and the physician who signed the medical request should be contacted and given the proper explanation for the cause of rejection.

### 5.2.3. FIXATION

- › For an accurate result of the requested tests, it is necessary to collect, pack, and preserve the tissues properly with fixatives. It is a prerequisite to fixate the smears, biopsies, or surgical specimens, aiming at cellular and tissue structure preservation, with minimum distortion and avoiding tissue artifacts.
- › The solutions used for this purpose are called "fixatives," and their choice depends on the material to be examined, what is intended to be studied, and the staining technique to be used.
- › Verification of the correct conditioning and fixation of the specimen, as well as the correct and adequate filling of the medical request, is the responsibility of the physician or other professional who collected the specimen from the patient.
- › Fixation time is of fundamental importance for accurate test results. If not adequate, false-negative or false-positive results may occur. Therefore, the medical request forms should have the date and time of the collection of the specimen adequately filled by the attending physician, or equivalent person responsible, allowing the fixation span time to be known and adequately evaluated by the pathology laboratory [9].

#### 5.2.4. REGISTRATION

- › The specimen must be registered in a physical document or electronically (laboratory information system), with an internal single identification, operating or tracking number determined by the laboratory policies and information system requirements (if there are none, these should be established). All the information available from the patient must be connected with his or her laboratory identification number.
- › This single identification number should be traceable during all processes and stages of sample preparation, analysing, and archiving, so that it can be retrieved at any given moment if needed.
- › The patient specimen identification number, operating or tracking number, is created according to the laboratory's own criteria. Some laboratories use an alpha-numeric number such the example bellow:
  - P2012345 – P stands for anatomical pathology specimen, 20 stands for the current year the specimen is received, and 12345 is the sequence number that the specimen entered in the laboratory information system. The same criteria are used for cytology specimen (ex: C2012345) and so on.
  - Some laboratories use the sequence number since they opened, no matter the type of specimen.
  - The most important aspect is that the laboratory makes clear to the staff what are the criteria used for numbering specimens, how each specimen is unique and can be easily tracked and retrieved by the laboratory information system.

### 5.3. ANALYTICAL PHASE PROCEDURES

After triage, the specimens will be directed to the grossing room for macroscopic inspection, description, measurements, and sectioning of relevant diagnostic areas for histological processing and slide analysis.

- › Specimen checking: in the grossing room, another specimen integrity verification list should be carried out regarding identification, correlation with contents on the container's label and the respective medical request data. As stated above in the registration item, it is crucial to assure the traceability of the samples in the laboratory system during all stages of the process.
- › Grossing protocols: there should be specific protocols available with instructions on grossing specimens regarding category (radical surgery products, biopsies, simple surgical specimens, etc.). These protocols may be international references or locally developed. The bench and instruments must be carefully cleaned before starting to gross another specimen and after finishing grossing procedures. This avoids contamination of samples with fragments of the prior specimen.
- › Storage: specimens' remnants must be temporarily stored, so that if new samples are needed, or there is a problem with the report, another analysis may be performed. According to the laboratory storage capacity and local requirements, specimen remnants should be stored for at least 14 days. The laboratory director should determine a specific policy for specimen storage conditions and time.
- › Tissue processor operation instructions must be available for technicians and responsible staff, so as to avoid mishandling and accidents with samples. Equipment maintenance and reagent changes must be periodically scheduled. Temperature of the paraffin recipients must be kept between a range of 60°C to 65°C maximum and verified and recorded in a specific data sheet every day.
- › Embedding: to avoid burning specimens, the temperature of the paraffin bath and hot plate must be checked and recorded on a specific data sheet for each station every day before starting the process of embedding. Procedure for checking the correlation of the cassette number with the number of fragments in the embedding must be done for each specimen. Embedding must be carried out case by case, avoiding the exchange of samples or fragments when more than one cassette from different cases are open on the hot platform. Protocols on specific types of specimens embedding instructions should be available. For instance, skin fragments should be embedded with the epidermis to the same side, thus avoiding dislodging during sectioning. Instruments must be carefully cleaned between sample embedding to prevent block contamination. As a rule, specimens of different kinds must be intercalated when embedding so as to avoid contamination with specimens of the same kind; for instance: embed a stomach biopsy, then skin



biopsy, then another stomach biopsy, but preferably intercalate as many different specimens as possible to make it easier to track any contaminants.

- › Sectioning: it must be executed on a case by case basis, avoiding loss or exchange of samples. Microtome, blade, tweezers, flotation bath must be cleaned before starting another sample sectioning. Flotation bath hot water temperature must be at 40° to 50°C and verified and recorded in a specific data sheet for each cutting station.
- › Containers for used sharp objects must be available at all times during working hours.
- › Slide staining: the staining procedures may be manual or automated. Clear protocols should be available regarding the type of stain for routine microscopic analysis or specific analysis procedures, like fungi, acid-fast staining, etc. As a suggestion, one single slide containing a simple surgical sample, like an appendix or gallbladder, which can be easily inserted again, if necessary, should be run separately before starting the staining batch. Therefore, if adjustments to the staining procedure are needed, they can be made before the whole batch starts, ensuring good quality staining. Mounting can be done manually or automatically. Instructions for instruments and equipment operation should be available.
- › Slide labelling: each case should be labelled separately, avoiding printing a sequence of labels with different numbers to speed up the process, because there is a high risk of mislabelling specimens. If there is no label printer, then provide a permanent insoluble ink pen to write the number of the case on the slide. Avoid pencils, since the graphite on the side may vanish with handling and over time.
- › Immunohistochemistry can be manually or automatically executed. Procedures should be carried out in a separate room or area with sample identifications checking procedures. Protocols for antigen retrieval, antibody preservation, dilution (when applicable), and application. Instructions for instrument and equipment operation should be readily available.
- › Microscopic analysis: slides must be carefully transported to the microscopy room for pathologists' analyses. Protocols for microscopic description standards should be available. Cancer cases should have at least two pathologists signing out, whenever possible, and be classified according to UICC's TNM classification.
- › Cytology specimens' analysis [10]: for gynaecological cytology specimens, cancer screening may be performed by certified cytotechnicians or pathologists, depending on local conditions and norms. The Bethesda System for reporting gynaecological cytology and thyroid fine-needle aspiration (FNA) cytology if a local system does not exist. Accordance index [number of cases with the same classification (benign, atypical, malignant) between cytotechnician and pathologists' diagnostic opinions] should be periodically verified, preferably once a month.

- › Criteria for pathologist revision of cytology cases
  - At least 10% of all cases negative for neoplasia should be reviewed by an experienced pathologist.
  - Cases which cytotechnicians have some kind of doubt.
  - All cases suspicious for intraepithelial or invasive neoplasia.
  - All cases positive for neoplasia.
  - All unsatisfactory cases.

#### 5.4. POST ANALYTICAL PHASE PROCEDURES

After slide microscopic diagnostic analyses, a pathologist's report has been issued, samples will be stored and copies of the respective documents generated through sample processing and analysis.

All reports, regardless of their nature, must be legible, without scratches and deletions, written in the official local language, dated, verified, and signed by legally qualified pathologists. The reports' will be signed by the pathologist responsible for their release or by the laboratory director.

**Important:** reports and results must be released on a timely basis, allowing patients to receive treatment within an appropriate amount of time. The time interval between the specimen's entry into the laboratory information system and the release of results is the turnaround time (TAT). For small simple biopsies, a TAT of three days is recommended. For bone marrow, liver and kidney biopsies, which needed extra specific stains, and decalcification for bone marrow, a TAT of 5 days is acceptable. The recommended TAT is two to five days for small biopsies and 10 calendar days, including weekend days, for larger specimens.

- › Requirements for the pathology report
  - Identification, full address, and telephone number of the pathology laboratory where the specimen was analysed.
  - Identification of the laboratory director for the report release and his/her respective professional council registration number (or according to local professional and occupational legislation).
  - Identification of the professional responsible for releasing the test report or result and his or her respective professional council registration number (or according to local professional and occupational legislation).

- Name of the patient and his or her identification number in the laboratory information system, age, date of birth, social security number (or local equivalent) and name of the mother. Patient identification should always be as complete as possible.
- Date of specimen collection (when registered in the medical request, but the laboratory should seek this date, since it may affect the results of the test), date of entry in the laboratory, and date of report's release.
- Test specification, the anatomical site where the specimens were collected, according to the medical request (or information obtained by other means when the medical request lack this information). Name and contact information of the ordering physician.
- Sections for grossing description, microscopic description, and diagnostic impression, when applicable, not necessarily in this exact order. The laboratory may want to put the diagnostic impression before the other sections, regarding its importance for clinicians assisting the patients.

**Observation:** microscopic description may be optional, according to local customs, orientations, or legislation. Nonetheless, it is recommended that some types of specimens, such as non-tumoral liver biopsy, non-tumoral kidney biopsy, non-tumoral skin biopsy, and bone marrow biopsy, which are considered complex biopsies, should have detailed microscopic aspects described on the pathology report.

- Diagnostic impression or conclusion should be highlighted in the pathology report.

**Important:** in cancer cases, consider using synoptic report (or cancer templates, according to international references such as those provided by the International Collaboration on Cancer Reporting), UICC's TNM pathologic staging is mandatory, as well as the display of prognostic markers, and correlation with relevant previous tests of the same patient. It is highly recommended that pathologists integrate into the same report multiple tests of the same patient when observed that they are related to the same disease or anatomical site, especially when these tests entered the pathology laboratory information system at the same time, or within a few days.

- Observations pertinent to the sample interpretation and diagnostic impression should be highlighted in the pathology report, when applicable; along with the methodology used, when applicable. The patient's history of previous tests in the laboratory, particularly in cancer cases, is highly recommended; as are bibliographic references, when applicable.

› Rectification of reports:

Rectifications of any data contained in the pathology report already issued must be included in the patient's records, and any rectification or correction must be clearly explained in the same pathology report. Efforts to retrieve and properly discard false reports must be made, whenever possible. If there is a new request for a test report or result review recorded in the laboratory information system, the correlation and reference between the two tests (previous test number and the test review number) must be included with the respective pathology report.

› Report delivery :

The procedure for delivering reports must be described. Each report must be provided under a protocol or identification document, signed by both the person who handed it over and the person who received the results. Of course, whenever multiple reports are delivered to the same institution, they can be listed in a single protocol. If electronically delivered, it must be exclusively from the laboratory's website, under secure identification login and password. If delivered by fax, the time and date must be recorded and only delivered to an authorised person. If the report is expected to be delivered by mail and/or to the patient's representative, it must be under the patient's previous direct authorisation (or according to local medical council recommendations or legislation).

## 6. Filing and storing samples and reports <sup>[1]</sup> <sup>[6]</sup> <sup>[8]</sup>

### 6.1. STORAGE STRUCTURE

The pathology laboratory must have, on site, an area suitable for archiving reports, slides, and paraffin blocks that meets current local sanitary legislation for storage. The archiving method may vary as long as the slides can be quickly retrieved, according to the pathology laboratory filing system, rules, or policies. The items described below should be carefully observed:

- › Remnants of surgical pathology parts or specimens, and other biological samples, should be stored for a minimum period of 14 days – 45 days are advisable – after the respective pathology report's release date. Thus, if there are any problems with the test or its report, such as a medical request for a test report review or correction, the remnants are still available for more inspection and sectioning.
- › The paraffin blocks must be stored in an appropriate place, under room temperature control, and kept below 35° Celsius to avoid melting and mixing melted blocks and samples. The minimal recommended time for keeping paraffin blocks is 10 years (20 years is prudent) or according to local legislation.
- › Slides must be archived for at least 10 years (20 years is advisable for slides that are positive for neoplasia, regardless if suspicious for neoplasia, in situ or invasive neoplasia). In general, cervical cytology slides of cases with negative results should be kept for two years and a minimum of 20 (twenty) years those of cervical intraepithelial neoplasia (CIN) and invasive neoplasms, as well as those of histopathology (this, regardless of the diagnosis).
- › Paper reports must be stored appropriately. If reports are digitally stored, regular internal and external backups must be assured.
- › Temporary files and storage must maintain the quality, safety, and traceability of the samples.
- › In all cases (unsatisfactory, negative, and positive), the codification adopted to identify samples and patients' reports must always be safely kept, according to the technical standards determined and described in the SOPs.

Observation: in general, samples of liquids (urine, cavity liquids, and others) must be stored in a refrigerator or fixed until the laboratory releases the report. The materials can be discarded in one week after the respective reports are released. Local sanitary authority or medical council legislation must be observed.

## 7. Human resources

### 7.1. DEFINITION

Set of people who perform functions in the laboratory and are qualified according to regulatory councils and other supporting agencies. Laboratory working staff.

### 7.2. ROLES AND RESPONSIBILITIES

Laboratory director [3] [4]: a physician, legally qualified, anatomic pathologist, or cytopathologist, who assumes professional, scientific, organisational, administrative, and educational responsibilities for the services provided, including timely, reliable, and clinically relevant test results and compliance with applicable regulations and requirements.

Laboratory director's duties:

- › Exercise the responsibility and authority to implement and maintain quality standards and programs.
- › Respectfully provide and timely attention to the laboratory's users (patients, family members, doctors, colleagues, etc.), either in person or by telephone.
- › Elaborate ethical conduct manual, along with staff representatives, and ensure its observance.
- › Be actively involved in all administration, orientation, and teaching activities.
- › Promote and participate in research activities whenever possible, closely supervising these activities if the laboratory has a research and assistance vocation.
- › Establish the laboratory's organisation chart and supervise overall activities.
- › Define minimum requirements (qualifications) for the performance of each laboratory function.
- › Define the training program, either by mentoring a first-time employee or through continued education, for the performance of each task.
- › Promote the continuous training of employees.
- › Check the performance of staff in carrying out tasks.
- › Verify, implement, and validate new technologies, and ensure the training of the relevant staff, accordingly.

- › Ensure that operating procedures are regularly verified and provide changes to protocols already executed.
- › Define the proficiency test program and ensure corrective actions are implemented.
- › Ensure the implementation of measures related to employees' health, safety, and environmental protection.
- › Approve the laboratory's manuals, SOPs, and other relevant documents, ensuring their effective applicability, as well as the frequency of their updating.
- › Ensure that resources are continuously available, properly used and optimised.

**Pathologist/cytopathologist:** a qualified physician with a diploma of completion of medical school, residency of specific training in pathology and/or title of pathologist emitted by the local board of pathology, or according to local professional legislation.

**Pathology resident:** a qualified physician with a diploma of completion of medical school that is being trained to be a pathologist under the guidance, supervision, and responsibility of the laboratory director and other pathologists/cytopathologists registered effectively under contract with the laboratory board of directors/partners.

**Grossing technician:** trained professional, with high-level technical education and training, evidenced by proper documentation (according to local legislation) in practicing grossing techniques under the supervision of the laboratory director and other pathologists.

**Cytotechnician:** trained professional, with high-level technical education and training, proof of completion of the cytology technician course (cytotechnician) at an institution recognised by local authorities.

**Histology/histotechnology/histochemistry technician:** professional adequately trained, evidenced by proper documentation, able to perform duties related to embedding, sectioning, staining, mounting, and release of slides as well as other duties related to the histology/histotechnology area, as defined by the laboratory director, observing local professional and occupational legislation and cytology/cytochemistry Administrative Assistants.

## 8. Worker's health and occupational safety<sup>[1]</sup> <sup>[6]</sup>

### 8.1. EVALUATION PARAMETERS

In pathology laboratory services, the main parameters that evaluate the exposure of workers to various occupational risks are exposure to chemical substances, biological materials, and pathogens, physical risks arising from exposure to noise and heat, inappropriate furniture, posture and incorrect work risks, mechanical and accident risks due to inadequate physical arrangement and exposure to sharp objects.

### 8.2. IMPLEMENTATION OF PROTECTIVE MEASURES

Implementation of the following measures are recommended for employee health and safety

- › Training: workers must receive initial, continuous, and documented training related to their duties and according to the risk factors present in their work and environment, which must be thoroughly detailed in the SOPs for each service or professional activity.
- › Occupational health medical control programme (OHMCP): to promote and preserve the occupational health of workers, an OHMCP (or equivalent, should be drawn up based local health and safety legislation The OHMCP should include medical exams before employees take up their post, regular examinations, when returning to work after absence due to medical reasons, any time there is a job change, even in the same institution, and when dismissed from the position (or according to local health and safety legislation). The program should have prevention, screening, and early diagnosis of work-related health problems, including subclinical ones, in addition to the verification of the existence of cases of occupational diseases or irreversible damage to the workforce's health. This guideline means that there should be regularly monitoring professionals' health and occupational safety through medical examinations.

### 8.3. IMMUNISATION

Immunisation is a relevant measure to prevent disease in laboratories. The laboratory director must ensure that workers, regardless of their role and official ties to the pathology laboratory, are adequately vaccinated, with documented evidence, according to local legislation and criteria.



#### 8.4. ACCIDENTS, INCIDENTS, AND DAMAGE TO WORKERS' HEALTH

In cases of accidents, incidents, and any kind of damage to workers' health, even if the employee does not need to be away from work, the employer must carry out the emergency procedures, according to the level of damage occurred, and other proper notifications to local specific authority and family member (observing local occupational health and safety legislation).

#### 8.5. EMERGENCY MEDICAL CARE

Laboratories must have a written policy and flow description of medical assistance for emergencies in case of exposure to biological material, pathogens, chemicals, or when any other accidents occur, as well as procedures for accompanying and monitoring exposed workers.

**Important:** There must be written SOPs or management plans regarding the response to exposure to tuberculosis, Creutzfeldt-Jacob disease, hepatitis, immunodeficiency, respiratory viruses, or other local hazardous agents (observing local occupational health and safety legislation, and medical recommendations measures for exposure to hazardous agents).

## 9. Equipment and supplies<sup>[6][1]</sup>

Facilities and equipment must be maintained in good working order.

Calibration should be done on critical equipment (thermometers and automatic pipettes). Drying ovens, microtomes, water baths, microscopes, tissue processors, and refrigerators for blocks and dye storage must have corrective and preventive maintenance records.

Equipment used to perform immunohistochemical enzymatic reactions must be subject to daily temperature controls (maximum and minimum according to the manufacturer's technical information), properly recorded in paper or digital data sheets of forms.

Products and reagents must be available in adequate quantities and appropriately stored when not in use. Reagents and solutions with their valid date expired must be segregated appropriately and discarded.

***\*\* Reagents, antibodies, dyes, and other inputs used in carrying out tests must be within their expiration dates. When diluted or aliquoted, they must maintain the expiration date indicated on the batch of origin and according to the manufacturer's instructions; however, when colouring solutions with salts (in-house), these can be validated in the laboratory according to records performed that attest to the efficiency of prepared solutions, such as the use of controls with known characteristics.***

### 9.1. SUPPLIES

The pathology laboratory must have the equipment and supplies necessary to carry out all phases of testing, allowing the execution of pre-analytical, analytical, and post-analytical phases and/or technical procedures, including equipment and supplies to the supporting areas. It is essential to obtain supplies from reliable providers. Vendors should be evaluated according to the following criteria:

- › Timely delivery, as agreed by contract.
- › Goods must be delivered preserved and well packed, according to specific written conditions, and within valid date.
- › Merchandise must be of good quality and evaluated according to specific market and usage criteria.
- › Questions and other issues must be answered by the laboratory in a timely manner.
- › Politeness when dealing with laboratory representatives for negotiations.
- › Other criteria defined by the laboratory director and purchase and inventory staff.

## 10. Biosafety<sup>[6]</sup>

Biosafety is the condition achieved by a set of actions aimed at preventing, controlling, reducing, or eliminating the risk factors inherent to work-related activities, and that could compromise human, animal, plant health, the environment, and the quality of the work performed. Good laboratory practices require special infrastructure and work procedures within the laboratory health service, taking into account the workflow within the physical space and risk mapping. Local regulations regarding health services biosafety procedures must be observed and respective SOPs must be readily available to all laboratory staff.

Collective protection equipment (CPE) must be prioritised over Individual protection equipment (IPE).

### 10.1. BIOSAFETY INSTRUCTIONS

The pathology laboratory must keep written and updated biosafety instructions available to all staff, with records of regular and periodic training, including the following:

- › Rules and conduct for biological, chemical, physical, occupational, and environmental safety;
- › Instructions for handling IPE and CPE;
- › Procedures in case of accidents, including instructions in handling the spill kit in case of hazardous liquid spilling. The spill kit should be available in all technical areas with risk of hazardous chemicals spilling;
- › Handling and transportation of material and biological specimens.
- › Records of equipment delivery and receipt of instructions for use;
- › Fire drills must be periodically performed and recorded.

If there is no local official clinical laboratories biosafety standards body of knowledge or regulation, the laboratory should use the WHO laboratory biosafety manual [12].

## 11. Quality assurance <sup>[2]</sup> <sup>[6]</sup> <sup>[12]</sup>

The concept of quality in healthcare services varies, according to the entity issuing the concept by type of healthcare. The concept is continuously updated and challenged by professionals and specialists researching how to improve quality of health care delivered to the community.

The US Institute of Medicine (US-IOM) and the WHO have unique definitions of healthcare quality. The US-IOM (2013) defines healthcare quality as “the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.” The WHO (2006) defines healthcare quality as the process of making strategic choices in health systems. These definitions may apply to every aspect of healthcare but will vary according to the perspectives and mission of the respective organisation or discipline.

According to Maxwell L. Smith and Stephen Raab, quality in the pathology laboratory context is explained as follows:

- › Quality assurance (QA) is a global system of control activities that promote higher-level functioning of specific processes within the anatomic pathology laboratory;
- › Control activities include (1) quality control (QC) in individual areas of the anatomic pathology laboratory, (2) a global quality improvement (QI) plan for the organisation, and (3) regulatory compliance activities according to local legislation;
- › The main goal of QA, QC, and QI is to prevent medical error;
- › Traditional measures of quality in anatomic pathology include the following: diagnostic accuracy, patient/physician satisfaction, and specimen turnaround-time.

Assessments of quality performance can be made in a diversified manner, depending on the methodology adopted by each service. It is necessary to use knowledge recognised by the scientific community, capable of being reproduced in similar situations, through process validation, following significant criteria, and observing the variables of the methodology used.

Compliance is the most important term used in quality control and assurance. Laboratories are expected to provide good quality services that comply with a set of rules and standards set by local/state-province/country legislation, including timely results delivered to patients, adoption of safety measures to prevent accidents, etc.

**Important:** whenever an error is detected in any of the operating phases (pre-analytical, analytical, and post-analytical), a nonconformity must be recorded, followed by a root cause analysis, corrective actions, preventive actions, and monitoring of outcomes.

The improvement cycle is a popular tool and can be used to solve problems, correct errors, and discover gaps in a given process. When an error is identified, proceed with the root cause analysis

and try to find the source of the problem. This can be done by reviewing the process and trying to find which step was compromised. According to what is discovered as non-conformity root cause, specific correction and preventive measures must be established, including previous training or new training, if necessary. A modified version of the cycle is displayed in Figure 2.

### 11.1. QUALITY MANUAL (QM) AND STANDARD OPERATING PROCEDURES (SOP)

Pathology laboratories must have a QM, which will contain the menu of activities (types of tests performed by the service), the quality policies (mission, vision, and value), and how the laboratory works and must be approved, dated, and signed by the pathology laboratory director. Specific plans or procedures can thus be addressed, with their performing details described in their respective documents, but must be referred to in the QM. Each laboratory should develop its own QM with the minimal requirements described in these guidelines,

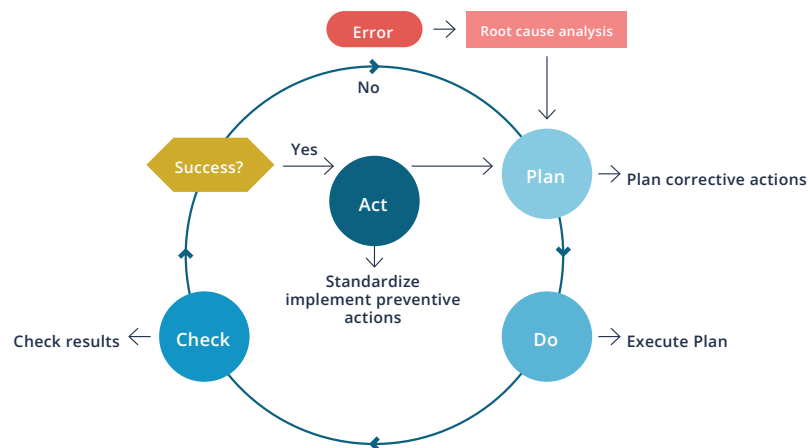


Figure 2. Adapted improvement cycle.

Annex I displays an example of a QM that can be used as a template to be adapted to local needs. The example provided in Annex I was written according to a hypothetical laboratory – Laboratory X – located in a fictional city – City Z – and aims to provide an idea of how to design these types of documents in terms of structure, content and order of items.

Document control is an essential part of a quality system. The basic hierarchy of documents is as follow:

- › 1st Level = quality and corporate governance manual – bylaws.
- › 2nd Level = quality Management Plan (QMP), second-level plans and manuals.
- › 3rd Level = SOPs: technical and administrative operation and management.
- › 4th Level = Records, controls, flowcharts, organisation charts, datasheets, and others.

Documents must be identified according to their specific role in the quality system. The laboratory can create its own coding method to determine the nature of the documents and to which sector, hierarchy, and function they belong. This identification must be clear and easy to find to all laboratory personnel, assuring that the proper instructions are used to perform a given task or function.

Example of document identification:

Sector - Type of Document (Manual/Plan/SOP)			Document Code		
Document Title- (Initials)			Version: 1.0	Pages: no	
Version	Entered into force in	Next Review in	Creator	Reviewer	Approver
1.0	dd/mm/yyyy	dd/mm/yyyy + 2y	Mr. X	Ms. Y	Laboratory Director
1.1	dd/mm/yyyy	dd/mm/yyyy + 2y	M. X	Mr. Z	Laboratory Director

The Laboratory Director must ensure that documents are read and understood by the staff. The laboratory must have a defined documentation process to verify staff have read/reviewed and understood all documents related to performing their function. Depending on the nature and sector of the document, all laboratory staff or only the people of a given sector must be aware of its content. For instance, all staff must know the laboratory code of ethics. Each sector of the laboratory should create its own, specific SOPs.

All documents can be indexed in a simple matrix, on paper or electronically, making it easy to find whenever a given document is needed for consulting, updating or modifying, removing, etc. What is recorded can be proved. Example of a document matrix (Word, Excel, other):

N°	Sector/ Code	Title	Version	Status	Creation date	Local	Last updating	Expiration date
1	Qua - MAQ	Quality Manual	1.0	In force	Dd/mm/yy	C:Arq/Past	Dd/mm/yy	Dd/mm/yy
2	Qua - SEG	Fire Drills	1.0	In force	Dd/mm/yy	Archive 1	Dd/mm/yy	Dd/mm/yy
(...)								

All reference documents, including SOPs, must be approved, dated, and signed by the laboratory director, which includes, at least, the following topics, when applicable:

- › Instructions for patient registration in the laboratory information system, with instructions on how to attend to patients, preparation for a determined test, patient information, and necessary clinical data.
- › Instructions for institutions that the laboratory serves on how to collect, identify, pack, preserve, and transport specimens (specimen collection manual). Acceptance and rejection criteria must be clearly displayed, stating that the specimens need to be handled with care and responsibility.
- › Preparation and processing of specimens for diagnostic interpretation.
- › Equipment: operation, preventive and corrective maintenance, cleaning.
- › Preparation, conservation, and storage of reagents and dyes.

- › Archives: how specimens and documents should be preserved, and for how long.
- › Procedures for internal and external, and or interlaboratory quality control programs.
- › Quality assurance procedures.
- › Technical health, safety, and environmental regulations in force should be addressed when applicable.
- › Human resources management and continued training programme.
- › Health services waste management plan, according to local legislation.
- › Informed consent form, where applicable, included in SOPs.
- › Hospitals, clinics, and medical services in which anatomopathological, cytopathological, and similar specimens are obtained must have the patient's free and informed consent form regarding the sending of their specimens to the respective pathology laboratories and or diagnostic and therapeutic support services, therefore guaranteeing the specimens' traceability from the source to the laboratory.
- › SOPs must be duly updated, identified, in sufficient quantities, according to the activities performed, and easily accessible to professionals who need them.

### 11.2. EXTERNAL EVALUATION

The pathology laboratory is encouraged to participate in external quality assessment programs, proficiency tests, or exchanges with other pathology laboratories when there is no specific proficiency testing, provided that such possibilities are duly described in SOPs or plan for proficiency testing or external quality evaluation programmes.

### 11.3. CONTINUING EDUCATION

The pathology laboratory is responsible for promoting the regular participation of professionals in continuing education programs provided by the laboratory, within the premises, or outside. The type, place of training, all activities carried out must be duly documented. To ensure training is effective, there should be some kind of verification, being it a written or verbal test after the training, or other method chosen by the institution and in line with local laws and regulations. The number of hours per year of continuing education that different staff working in the laboratory require varies according to local law or regulations.

#### 11.4. INTERNAL QUALITY CONTROL SYSTEM

The health service must have a record of the internal quality control system, appropriate to the routine and still perform it carefully, as follows:

- › Exchange of information between legally qualified professionals and the laboratory. For example, seeking clinical information when not available in the medical request or communication of critical results of a given patient to his or her doctor.
- › Control of routine cases: monitoring case workload in all aspects of the laboratory area, such as turnaround time (TAT), the number of delayed cases, the number of report rectifications, and cases that need critical diagnosis communication. The laboratory director should guide the establishment of indicators according to the type of laboratory and its workload capacity.
- › Measurement of devices/equipment functional indicators, such as how many times a given device needed maintenance, which will provide information if it is handled according to manufacturer instruction.
- › Verifying the sensitivity/specificity of the reagents and dyes used.
- › Periodic review of operational procedures.
- › Internal quality for cytology (core requirements):
  - 10% of benign gynaecologic cytologies must be reviewed by a pathologist
  - All malignant cytologies must be reviewed by a pathologist
  - A cytotechnologist cannot read more than 80 slides in an eight-hour shift
  - There needs to be a correlation of cytology to pathology in the same patients
  - All non-gynaecologic cytologies have to be reviewed by a pathologist
- › Internal quality for pathology (core requirements):
  - Correlation of frozen section to permanent section
  - Correlation of pathology with clinical presentation and response to treatments using tumour boards and other clinical conferences
  - Correlation of pathology with other laboratory results (microbiology, flow cytometry, molecular)
  - Consensus conferences between pathologists
  - Correlation of local pathology diagnosis with consultation diagnosis rendered by an expert in the field.



### 11.5. QUALITY INDICATORS [2] [13]

There are many definitions of indicators, depending on the context studied. The US Institute of Medicine defines quality of care as “the degree to which health care services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.” A quality indicator may be defined as an objective measure that evaluates a given aspect of a process against a criterium or sets of criteria, serving as a tool to monitor its evolution, efficiency, and outcome.

Indicators are tools translated in a unit of measure to evaluate a given activity performance, which can be by rate or coefficient, index, absolute number, fact, etc. an indicator must be valid (degree of compliance to identify situations needing quality improvement), sensitive (degree of ability to identify all cases with quality problems), specific (able to identify only cases with quality problems), simple (when easy to collect, calculate and analyse, the greater the probability of use), objective (clarity in the objective of the indicator increases the reliability of what is sought), and low cost (avoids unfeasibility and abandonment of the indicator). There are many ways to collect information and build an indicator, being one of them the following structure:

- › Indicator name – or the item that needs to be monitored (e.g. TAT)
- › Formula - manner of expression, basis for calculation (depends on type).  
Ex: TAT: 
$$\text{TAT} = \frac{\text{n}^\circ \text{ of reports released in a period of time}}{\text{total n of specimens entry in the same period of time}}$$
- › Type - rate, coefficient, index, percentage, absolute number, etc.
- › Information origin - where the information comes from, or the source of data collected to build the indicator. Ex: Workload of the histology sector defined by the number of blocks sectioned per day or the number of slides released per day.
- › Method – the study of the variation can be prospective, retrospective, transversal.
- › Sample – ex: number of cases
- › Responsible – person responsible for elaborating on the indicator.
- › Frequency - number of measurements/period
- › Objective/goal - reason, value, term, etc. Ex: monitor the number of hours cases are in standby for microscopic analysis; therefore, actions can be taken to minimise the standby time; thus, tests will be signing out faster.
- › Reference values - literature, benchmarking, internal parameters.

The laboratory director, along with each sector’s staff, will define which indicators apply best to improve their practice, processes, and activities.

Examples of indicators for monitoring quality in the settings of a pathology laboratory are suggested below:

**1. Global Indicators - used to monitor global efficiency of the laboratory services:**

- a. TAT, the timespan between the entry of specimens in the laboratory and the release of their respective reports;
- b. Patient/client satisfaction – the index of satisfied patients/clients with the services provided by the laboratory. It can be obtained through surveys, online questioner or paper forms at the reception desk;

**2. Preanalytical phase:**

- a. Cases rejected due to mislabelling of the container;
- b. Specimen loss during transportation to the laboratory;

**3. Analytical phase:**

- a. Grossing:
  - › Mislabelling of cassettes;
  - › Specimen/tissue contamination within the cassette (as introduced by contact with tools, equipment, or other specimens);
- b. Processing:
  - › Errors in processing (misplacing of fluids in tissue processor)
  - › Incomplete decalcification of bone specimens;
- c. Embedding:
  - › Tissue specimens incorrectly paired with cassettes;
- d. Sectioning:
  - › Incorrect case sections in slides;
  - › Microtomy deficiencies (wrong thickness, wrinkles, etc.);
  - › Tissue depleted because of shaving too much material;
  - › The entire tissue not present in the slide;
- e. Staining and Coverslipping:
  - › Slide contamination;
  - › Inadequate quality of staining;
  - › Inadequate quality of IHC/IF staining and controls;
- f. Case assembly:
  - › Slide mislabeling;
  - › Slide missing for a particular case;

**4. Post analytical phase:**

- a. Pathologist signs out:
  - › Dictation/description case mismatch (total or in part);
  - › Interpretation errors;
- b. Intraoperative procedure:

- › Mislabelled or missing slide or cassette;
  - › Specimen labelling errors, including separate or subsequently submitted portions;
- c. Reports delivery:
- › Wrong place delivery;
  - › Wrong report delivered;

#### 5. Specimens, reports and document retention and storage:

- › Retention and storage can be followed as recommended [2] [7] [8] or according to local guidelines and regulations or guidelines, if available.
- › Specimen parts and other biological samples remnants after grossing must be stored for a minimum period of two weeks after the respective definitive diagnostic reports or results were released.
- › Paraffin blocks must be stored for at least 10 years (preferably 20 years), in an appropriate place, free of insects, and in a controlled temperature room to preserve their physical integrity and easy retrieval when needed.
- › Histological and cytological slides negative for malignancy must be archived and stored for a minimum period of five years.
- › Histological and cytological slides positive for malignancy must be archived for a minimum period of 10 years.
- › Paper reports must be stored in an appropriate manner for at least five years if there is no electronic/digital backup. Electronic/digital reports must be filed for 20 years in appropriate media, and backup restore tests must be executed periodically in order to verify the integrity of the filed reports.
- › Technical documents, like SOPs, work instructions, datasheets, etc., must be filed and kept for at least two years, in chronological order.
- › Urgent results, in the scope of perioperative frozen sections or routine tests, can be transmitted verbally, doctor to doctor. This verbal transmission of information must be duly documented, citing the date, hour, and content or the diagnostic report.
- › Temporary files must maintain the quality, safety, and traceability of the samples and other documents.

#### 11.6. IN-HOUSE METHODOLOGIES [1] [14]

When the pathology laboratory uses in-house methods for testing, they must be included in the pathology report. In-house methodologies must be documented and validated by the laboratory staff and approved by the laboratory director.

## 12. Health services and waste management

Waste management should be done according to local legislation. However, if there is no local specific legislation, references [12] [15] can be used as guides for such purposes.

## 13. Transportation of human biological material <sup>[5]</sup> <sup>[6]</sup>

Human biological material referred to in this section may be composed of liquids, tissue, organs, body parts, and entire bodies (in case of autopsy). Some materials require specific transportation media and procedures. The containers are designated as follows:

1. Primary container – where the material is placed directly, with or without fixative;
2. Secondary container – where the primary container is placed to facilitate its transportation. It may contain more than one primary container;
3. Tertiary container – where one or more secondary containers are placed, like a larger box in a vehicle's trunk.

### 13.1. THE TRANSPORTATION OPERATION

Transportation operations must be recorded and standardised through written instructions available to all personnel involved in the transport process and be reviewed annually and/or whenever there is a change in procedures.

### 13.2. SPECIMENS TRANSPORT OUTSOURCING

The transport of human biological material can be carried out on an outsource basis utilising a written instrument that proves the outsourcing firm is complying with the specifications of the human biological material to be transported. This company must have a legal and licensed service provider, adequate infrastructure, as well as knowledgeable and trained personnel who work under the technical supervision of a professional proven to satisfactorily perform the services requested by the laboratory, meeting technical and legal requirements.

### 13.3. THE TRANSPORTATION VEHICLE

The transportation vehicle must have adequate hygiene and cleaning conditions and an appropriate mechanism that ensures the maintenance of good temperature and humidity conditions and the integrity of the tertiary packaging container and the biological material transported.

Safety containers for transportation and storage of human material must be transported in the rear or in a special compartment of motor vehicles. A spill kit should be available in vehicles.

#### 13.4. TRAINING

The personnel directly involved in each stage of the transportation process must have specific training provided by the laboratory or verified official third party. The training objectives must encompass the function performed, the nature of the material transported, and whenever there is a change in procedures. The effectiveness of this training must be periodically evaluated and documented.

#### 13.5. PACKAGING

The human biological material to be transported must be adequately packed in such a way as to preserve its integrity and stability, as well as the safety of the personnel involved during the transport process. The packaging stage of the biological material must be validated, considering the type of biological material and the purpose of transport, with the approval of the technical supervisor responsible for packaging. The packaging system must be used according to the specificities of the biological material transported.

#### 13.6. LABELLING

Labelling must be in accordance with the type, risk classification, and conservation requirements of the human biological material transported and contain the following:

- › Identification of the sender and recipient, in addition to full addresses and contact telephone numbers.
- › Proper identification of biological material/specimens.
- › Label and marking referring to the type of biological material transported, when applicable.
- › Warning phrases, when applicable.
- › Indication of the mode and direction of opening, when applicable.
- › Marking of approved packaging, when applicable and.
- › Telephone contacts, available twenty-four (24) hours, in case of accidents and incidents.

## 14. Collection station <sup>[1]</sup> <sup>[5]</sup>

### 14.1. CONCEPT

Collection stations are classified as branches of the main pathology laboratory, which activities include collecting and or receiving biological samples to send to their respective diagnostic centres. If tests are performed in these facilities, they must be submitted to the practices and regulations described above. Collection stations are always linked to another establishment, which is its maintainer and holder. These units can be detached from the main laboratory or located within other health establishments or not, such as hospitals, emergency services, commercial buildings, malls and other, providing that all safety measures are respected.

The main functions of a collection station are: care and orientation of patients for the necessary procedures for specimens' collection, identification and receipt of specimens, as well as adequate storage of all tissues and biological fluids for later transport, reports' release and delivery.

The collection station must have a qualified technician, responsible and registered under the respective class council.

### 14.2. PHYSICAL STRUCTURE

The collection station facility should comply with the following recommended requirements:

- › Reception / waiting area for patients and companions, with a minimum size of 1.2 m<sup>2</sup> per person.
- › The reception / waiting room and toilets that can be shared with another adjacent unit, if necessary.
- › Toilets for patients.
- › Specimens storage room with adequate equipment to keep specimens' integrity and traceability.
- › Procedures Room: Minimum size of 7.5 m<sup>2</sup>, for fine needle aspiration of superficial organs, and/or gynaecological cytology collection, and/or by incisional biopsies. When performing gynaecological procedures there must be a separate toilet.
- › Specimens triage area, with a minimum size of 3.0 m<sup>2</sup> with sink and running water.
- › Support areas [small kitchen (optional), cleaning material deposit, waste disposal site].
- › Equipment: must have a refrigerator for liquid storage.

- › Installation: sink, eyewash, computer desk.

Observation: the size of the rooms may be altered according to local laws or local decisions when adapting this manual. However, it is a good idea to provide plenty of space for the rooms to enable laboratory staff to work comfortably, as well as to accommodate a future increase of capacity.

#### 14.3. TECHNICAL RESPONSIBILITY

The Technical Responsible of the Collection Station must validate the Standard Operating Procedure - SOP of the establishment operation, guaranteeing its effective applicability and the frequency of its update.



# Glossary

**AREA:** it may be a separate compartment, a closet, or a designated space in a room. There is no presupposed dimension for this area. An open environment, without walls on one or more faces.

**BIOLOGICAL MATERIAL, SPECIMEN, OR SAMPLE:** fluids, secretions, tissues, any product of surgical procedure, small or large, and other human organs. It covers the following types: surgical pieces or anatomical pieces or surgery products of any nature, biopsy products, fine or thick needle aspiration products, liquids, smear slides, samples of secretions or spontaneous eliminations.

**CLEANING MATERIAL DEPOSIT (CMD):** room for the storage of appliances, utensils, and cleaning material, equipped with a washing tank.

**CYTOPATHOLOGY LABORATORY:** its main activity is the exercise of cytopathology including diagnostic cytology, cytochemistry, immunocytochemistry, and molecular biology.

**EQUIPMENT / MATERIAL DEPOSIT:** an area for the storage of pieces of furniture, appliances, equipment, and accessories for eventual use.

**ENVIRONMENT:** physically determined, specific, and adequate space for the development of certain activity or activities, characterised by different dimensions and facilities. An environment can consist of a room or an area.

**GROSS DISSECTION:** external analysis of surgical specimens or biopsies. It implies the preparation, description, and sectioning when applicable, of the samples to be sent for histological processing.

**HISTOCHEMISTRY:** a set of procedures for sample preparation on slides by staining using routine or special techniques, for the purpose of microscopic analysis or microscopy. The area of histochemistry may be inserted in the area of histotechnology.

**HISTOLOGIC PROCESSING, HISTOTECHNOLOGY:** a set of procedures and techniques used to dehydrate, clear, and paraffin sample fragments to be placed on slides, stained, and identified for further microscopic analysis. Histological processing is the responsibility of technicians in the histotechnology and histochemistry sector of the pathology laboratory.

**INFORMED CONSENT:** a document that describes the procedure to which a patient or his/ her sample will be submitted and must be signed by the patient. This document is restricted to those situations in which there are procedures, such as performing thin or thick needle aspiration and biopsies at the collection point.

**LABORATORY EQUIPMENT:** generic designation for a device used by the Laboratory as an integral part of sample preparation, processing, and interpretation.

**LABEL:** corresponds to the printed or lithographed identification and to the words/ numbers painted or engraved with fire, pressure, or self-adhesive, applied directly on containers, packages, wrappers, cassettes, slides cartridges, and any other packaging protector, and cannot be removed or altered during transportation and storage.

**LABELLING:** procedure for labelling, marking, and labelling packages intended for the transport of human biological material.

**LEGALLY QUALIFIED PROFESSIONAL:** A professional with a higher education level or a technician with the competencies assigned by law.

**MICROSCOPY:** this is the analysis under the microscope of samples previously prepared on slides, resulting in a diagnostic interpretation that will be described in a report.

**PATHOLOGY LABORATORY:** its main activity is the exercise of pathology or anatomic pathology, and it can exercise integrated activity of histochemistry (routine and special stains), immunohistochemistry and immunocytochemistry, molecular biology, cytopathology, clinical cytology, oncotic cytology, and transporting collected human biological material.

**QUALITY ASSURANCE SYSTEM:** organisational structure, responsibilities, procedures, processes, and resources for improving quality management and processes.

**REPORT:** It is the document generated by the laboratory containing information about the laboratory, the patient, and the data resulting from their exams and the legally qualified professional.

**ROOM:** room surrounded by walls along its perimeter and a door, with or without a window.

**STANDARD OPERATING PROCEDURE (SOP):** It is the written procedure that defines how to perform any laboratory activity to its full extent.

**SUPPORTING ENVIRONMENT:** room or area that supports environments intended for the purpose of a unit.

**TECHNICAL ACTIVITY MANUAL:** It is the collection of standard operating procedures.

**IN HOUSE METHODOLOGY:** reagents or analytical systems produced and validated by the laboratory itself, exclusively for its use, in research or in diagnostic support.

**TECHNICAL SUPERVISOR:** professional trained and assigned to perform the activities of implantation, execution, and monitoring of biological material transport processes.

**TRACEABILITY:** the ability to recover the history, the raw data related to the exams, and their quality controls, the location of biological samples, and their records.

**TRANSPORTER:** natural or legal person who transports human biological material from a sender to a specific consignee, including commercial, public, or private transporters and their cargo.

**VALIDATION:** a set of actions used to prove that operational procedures, processes, activities, or systems produce the expected result, with exercises conducted according to previously defined and approved protocols, with a description of tests and acceptance criteria.

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# Annex I

Note 1: This illustrates an example for structuring a Laboratory Quality Manual and SOP.

Note 2: Laboratory X is used as an example and it does not exist. The SOP mentioned in the text below are indications. The reader should interpret this a model to serve as a resource to develop a specific Laboratory Quality Manual and SOP.

Note 3: City Z does not correspond to any C/Can city. It is completely arbitrary to illustrate an example.

Note 4: Paragraphs or text written in blue correspond to explanations of the various sections of the document Text, tables, and figures written in black are examples of how to fill the items required based on the hypothetical Laboratory X.

## HEADER

Logo	Quality Management	Qua - QM - 1	
	Quality Manual	Version: 1.0	Page: 1 of n

Version	Entered into force in	Next Review in	Creator	Reviewer	Approver
1.0	dd/mm/yyyy	dd/mm/yyyy + 2y	Mr. X	Ms. Y	Laboratory Director
1.1	dd/mm/yyyy	dd/mm/yyyy + 2y	M. X	Mr. Z	Laboratory Director

## INTRODUCTION

A concise explanation about the subject to which the document is related.

Quality in a pathology laboratory is essential to guarantee patients' safety by providing timely diagnostic reports leading to adequate treatment. Engaging personnel in a Culture of Quality that permeates all aspects of the laboratory activities will result in more efficient processes, promote a safer working environment and satisfaction of laboratory professionals.

## OBJECTIVE

Description of what this document aims to achieve or is related to.

This manual aims to define guidelines to meet the Laboratory X management system requirements, establishing organisational, administrative, and technical responsibilities for the execution of services. It applies to the entire organisation and aims to be a tool for the continuous improvement of the quality management system implementation processes.

### INSTITUTIONAL PROFILE

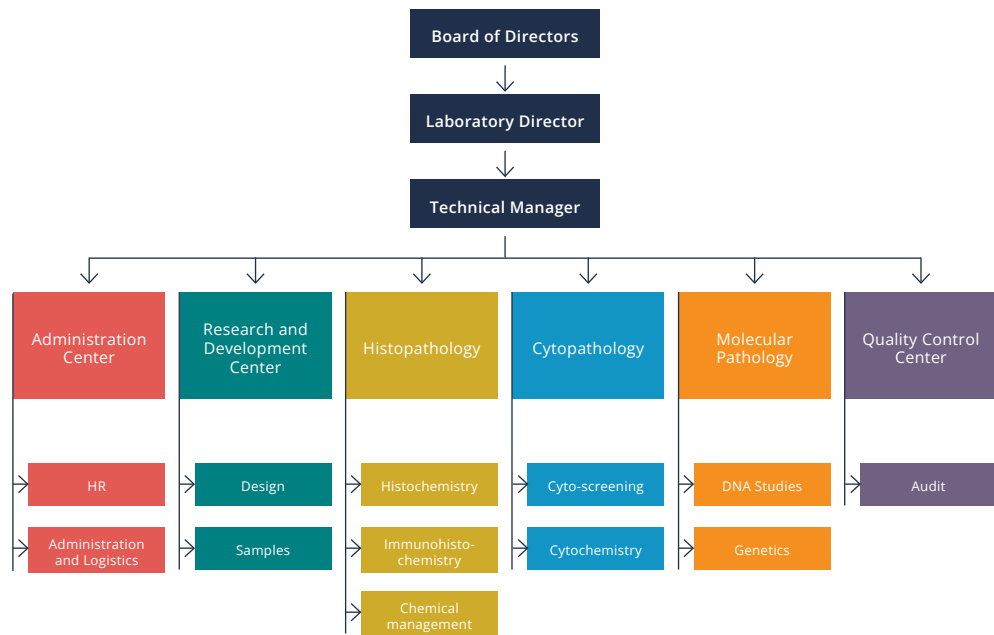
Brief description of the laboratory profile, types of tests or menu of activities, etc.

Laboratory X provides diagnostic tests in anatomic pathology, cytopathology, and molecular pathology, located in the city of Z. It is a private institution, with approximately 40% of its exams from the public health system and the other 60% from health insurance companies or private individuals. It started its activities in 1996 and is currently the reference service for the medical community in the region. Currently performs an average of 10,000 tests/month, of which approximately 60% are cervical cytology tests.

### ORGANISATION CHART

The organisation chart displays the laboratory's sectors in a logical hierarchy.

The general organisation chart establishes the hierarchy and the link between the board and the various sectors.



### APPLICATION

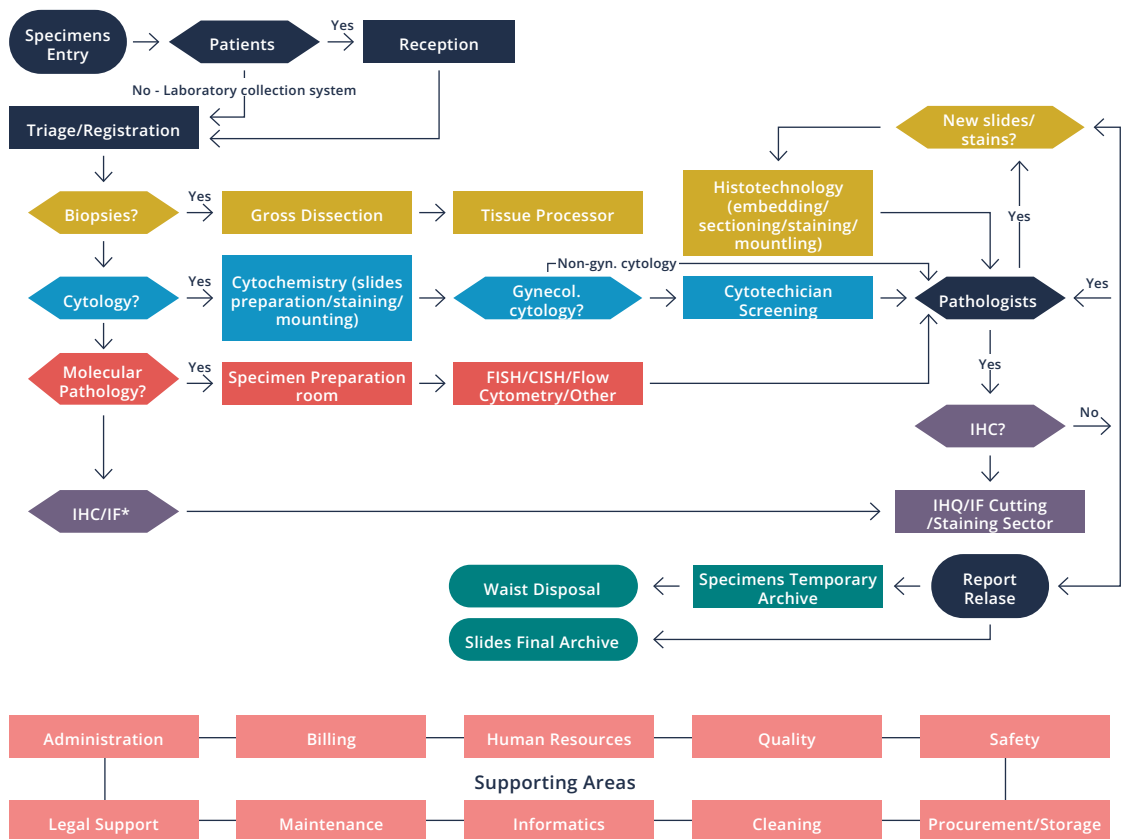
Describe which areas, or processes, the document applies to.

The institution's quality management system includes all processes involved in pathology diagnostics and supporting processes.

### PROCESS FLOWCHART

The process flowchart or map translates the logical order of the internal procedures of the organisation, and clarifies the interrelationship among sectors, pointing out limits and responsibilities, reaching each of the main procedures necessary for internal processes. It is the skeleton of the organisation.

Just as the idea of value to patients and physicians varies with time, processes evolve, undergoing refinements and adaptations over time, but attention must be paid to maintain effectiveness. If this evolution is recognized in time by a well-informed and skilled manager, he/she will be able to enter the circuit and redesign the processes to guarantee their effectiveness and efficiency.



### MISSION | STATEMENT OF THE ORGANISATION'S MISSION.

Laboratory X is a healthcare institution that provides diagnostic services, using modern scientific and technological methods, based on adherence to the principles of quality, respect, and timeliness to guarantee reliable results to patients and physicians, as well as the personal and professional fulfilment of employees. senior professionals

## VISION

### STATEMENT OF THE ORGANISATION'S VISION.

Laboratory X's vision is to be a national reference laboratory within 10 years, operating under the highest quality standards.

## VALUES

### STATEMENT OF THE ORGANISATION'S VALUES.

- › Respect for diversity and pluralism of ideas.
- › Commitment to quality.
- › Commitment to the defence of human rights.
- › Inseparability between work, teaching, and research.
- › Commitment to the scientific and technological development of medical assistance and pathology.
- › Commitment to preserving the environment.
- › Ethics and transparency.

## QUALITY POLICY

Statement of the organisation regarding its objectives, patient care, and employee satisfaction. Specific policies, like patient information security, code of ethics, etc., can be addressed in separate documents.

Laboratory X's quality policy is a set of objectives and doctrinal principles that aim at meeting the total satisfaction of its patients and physicians, offering services that meet and sometimes exceed their expectations. The main objective is to meet their needs regarding the quality of our services, prompt service, and punctual delivery, as well as promoting work in a partnership environment and valuing the person, encouraging training and the collaborative work, understanding that employees are the primary drivers of the quality of services, while maintaining an environment that motivates and encourages initiative. Similarly, we seek to prevent internal failures, so as to increase security and reduce the cost of non-conformities and obtain the highest quality services. We will always act based on professional ethics, while aiming to meet the highest standards and seeking improvement and modernizing equipment, processes, and controls.

### **LABORATORY DIRECTOR REPLACEMENT**

Describe the policy that will be adopted in the event of replacing the laboratory director or other relevant senior professionals considered essential to the continuity of the laboratory services.

In the event of replacing the laboratory director or a board member, it is the duty of the new director to ensure that the procedures being executed are in accordance with the institution's quality policy.

### **IF THE LABORATORY CEASES OPERATION**

Describe the policy in the event of the termination of the laboratory's activities.

Regardless of the reason, if the laboratory terminates its activities, the board and or laboratory director must guarantee the availability of all records, slides, blocks, and tissues that are under the custody of the organisation, when requested.

### **DOCUMENTATION STRUCTURE**

Description of the hierarchy of internal documents, how documents are structured, origin, and applicability. Maps and flowcharts can be used to demonstrate such order and structure.

The Quality management system documentation is constituted as follows:

- › Quality manual.
- › Quality management plan.
- › Standard operating procedure.
- › Records, spreadsheets, protocols, and daily functional documents, like contracts, orders, memoranda, etc.
- › External records and documents.



› **QUALITY MANUAL (QM)**

The strategic document of the quality management system outlines the quality policy and its scope. It defines the laboratory's attributions, responsibilities, and organisational structure.

› **QUALITY MANAGEMENT PLAN (QMP)**

Specific quality management document by area or sector of the laboratory (e.g. histopathology, cytopathology, molecular pathology), describing functional activities and general management.

› **STANDARD OPERATING PROCEDURE (SOP)**

SOPs describe in detail each process of the laboratory and are related to the area or sector's QMP. Institutional procedures must be reviewed every two (2) years or whenever necessary due to changes in processes.

› **RECORDS**

Documents of any nature, relevant for demonstrating quality and meeting the requirements established by the quality programs. They are usually presented in a spreadsheet, which will serve as a collection of data for performance indicators.

› **EXTERNAL DOCUMENTS**

Documents of external origin, such as standards, manuals, legislation that are identified and updated, with distribution controlled.

The process of preparing, reviewing, and approving documents and data for the quality management system is described in SOP-QUA-006– elaboration, review, and approval of document and data. This is an example of a document code and title. In this case, instead of describing the details on how documents for the quality management system are created, prepared, and reviewed, citing the respective SOP and directing the reader to the right document, making the process of finding a given document related to the subject easier.

The method for registering and controlling documents is in the procedure SOP-QUA-009 - library – registration and control (if available). Those procedures that are no longer performed as routine in the laboratory may be inactivated, as described in the SOP-MOD-001 - SOP Model "SOP inactivation" item (if available). (If more explanation is needed regarding a specific item, it can be placed in annexes to the main QM).

## MINIMUM DOCUMENT RETENTION TIME

Documents should be available in the system (physically or electronically), including inactivated ones. The laboratory can decide document retention time based on experience of past requisitions or on local norms.

Retention time is the minimum period in line with an acceptable practice.

Pathology reports are kept in an electronic system and are immediately available indefinitely.

Medical requests are kept in electronic files and physically, unless required by the health insurance companies to support respective invoices issued by the laboratory.

Records will be kept, electronically and physically, until the minimum retention period has been reached. The same rule is applied to procedural protocols, equipment control records, sample files, tissues, blocks, slides, photographic records, museum specimens, pathology catalogues, correspondence, telephone report records, equipment maintenance history, quality control and assurance records, accreditation documents, and inspection records, as well as financial records, orders, invoices and other administrative reports.

The main reasons for keeping documents or materials for long periods:

- › Diagnostic complementation or advanced clinical management.
- › Clinical audit.
- › Teaching and research, including epidemiological studies.
- › Data analysis for management or other purposes.
- › Evidence of litigation.
- › Historical purposes.
- › Good laboratory and clinical practices.
- › Reference service.

## MANAGEMENT RESPONSIBILITY

The laboratory management is committed to the quality management system development and implementation and to improve its effectiveness continuously. The focus of the organisation is to offer customers high-quality services that guarantee their recognition by the market. The institution has appointed the quality manager to be the director's representative in matters related to the quality management system, responsible for ensuring that processes required for the effectiveness of the quality management system are established, implemented, and maintained.

## INSTITUTIONAL OBJECTIVES

The institution's strategic objectives provide clear direction at all levels to ensure that resources are effectively managed, enabling individuals to prioritize and make decisions to support corporate strategies. The objectives are established at the highest management level through a strategic planning document. These objectives are disseminated in the various the sectors, ranging from strategic objectives at the corporate level to performance objectives for individual workers.

## CUSTOMER SERVICE/PATIENT CARE

How the laboratory will serve clients (doctors and patients), providing the best services possible to guarantee clients' satisfaction and safety.

The focus on the customer is continuously reinforced at all levels of the institution, and the TAT (Turnaround Time) indicator is the primary indicator in meeting customer requirements.

The goal monitored by this indicator is that 90% of the pathology reports be made available to clients (doctors and patients) in two business days. To achieve this, several tools were established in the laboratory information system to effectively control the release of reports and their availability. Contact with the patient is carried out indirectly through the relevant physician. The institution understands that to satisfy the patient it is necessary to guarantee the quality of services. Among the actions generated to serve them are making reports available via the website as well as physicians' case studies of patients and their statistics.

## SAMPLE TRACEABILITY

The institution has established and maintains documented procedures on the unambiguous identification of samples by appropriate means. Barcode labels are used from the time of entry in the laboratory premises throughout all stages of sample preparations and analysis to archives and storage.

## INTERNAL COMMUNICATION

Internal communication and people engagement are continuously done at all levels of the institution. The institution ensures that communication occurs with employees regarding the quality policy, work requirements, performance indicators and real results of performance and achievements.

The communication channels currently used are messages via the laboratory informatics system (LIS), sectorial dashboards, as well as quality and sectorial meetings. Telephone extensions in all sectors, and most of the workstations, are included in the communication infrastructure.

## RESOURCE MANAGEMENT

Laboratory X determines the availability of resources according to the volume of tests, new technologies, customer and employee needs, and market scenario aiming at the implementation and maintenance of the quality management programs. Thus, the institution provides the necessary resources for people, infrastructure, work environment, training, technology, suppliers, and financial resources so that all laboratory activities can run smoothly and adequately, guaranteeing reliable results.

### › HUMAN RESOURCES

All employees are trained and qualified to perform their tasks. When starting at the laboratory, employees go through an institutional integration programme and then joins the mentoring programme (if available), enabling them to perform the function for which they were hired. These programs are described in SOP – RH - 001 - personnel hiring and dismissal (if available). All documents belonging to employees are in their personnel folder stored in the HR department. The evaluation of employee performance is carried out through the individual dashboards, where the goals previously negotiated with the managers are displayed.

### › TRAINING

SOP-QUA-030 - Continued education clarifies the teaching and learning mechanisms applied in the laboratory. The entire mechanism for surveying training needs, planning, and organising training as described in this operating procedure.

› **EXTERNAL TRAINING**

In order to control the entire pre-analytical process, the institution promotes external training with those responsible for collecting samples, improving the quality of labelling, completeness of medical requests, time of specimen fixation, thus guaranteeing the specimens are well preserved and well-identified to provide reliable results.

Whenever necessary and/or upon request, courses are given to physicians, residents, and other health professionals, updating them on pre-analytical procedures and scientific subjects.

› **INFRASTRUCTURE AND WORKING ENVIRONMENT**

Management strives to provide, manage, and maintain the infrastructure and working environment necessary to ensure that services meet customer requirements.

The administration is also concerned with promoting the improvement and organisation of the working environment in the laboratory, as well as promoting the physical well-being of staff and guiding of investments that make it possible to increase productivity, safety, and well-being.

Infrastructure includes rooms, workspace, and utilities, equipment (hardware and software) and support services (including IT and communications).

Work environment includes heat, light, humidity, and airflow, and the location of the workplace.

Internal audits are carried out monthly to ascertain each sectors' working conditions, cleanliness, safety, and organisation.

› **EQUIPMENT**

To ensure that products and services meet the requirements and to avoid accidents, delays, and other costs due to equipment failure, the institution has a preventive equipment maintenance plan, with each equipment having an identification record and a performance dossier on the LIS, where all preventive maintenance applied to equipment is recorded, as well as any malfunctions.

Equipment that requires external maintenance will be scheduled once a year with a team of specialized technicians for this purpose. SOP-SEG-005 - equipment - cleaning, maintenance, and controls (if available) so as to clarify the entire mechanism for maintaining and recording equipment maintenance data.

› **EQUIPMENT CALIBRATION**

The laboratory has a formal calibration program for all measurement equipment that must be calibrated. The procedures SOP-QUA-026 - pipet calibration and SOP-QUA-010 – Ohmmeter calibration (if available) to clarify the calibration intervals and methods. The institution strives to ensure that the measurement equipment is calibrated according to the plan, identified with the calibration status and that all calibration records are retained.

If a measuring device is out of calibration (that is, outside the acceptable range), the institution must assess whether previous measurements may have caused damage to the products and if it did not meet the requirements. Whenever necessary, the institution takes the appropriate measures by recommending staff to write an Improvement Opportunity Report where the causes of lack of calibration must be assessed, and a corrective action plan must be established to avoid recurrence.

› **CONTRACTS**

Brief description of how the laboratory evaluates customers and the commercial relationship with them. Most of these clients are hospitals, clinics, and other laboratories to which professional support is provided.

The laboratory classifies its customers through the RFV (recency, frequency, value) classification, and each customer, according to these criteria, is in a class of customers designated as A, B, C, D, and E. Currently, there are 1149 clients distributed between classes A, B, C, and D, with approximately 10% of these being in classes A and B.

› **MANAGEMENT**

Each customer company has a folder in the administration area containing all documentation relevant to the specific agreement signed. This documentation includes the duly signed contract, the current tariffs, and the correspondence exchanged between parties. All contracts are controlled documents and must be registered as a document in the library and registered in the contract management database.

Once registered in the contract management database, they are monitored based on the expiration date; therefore, every contract of agreement can be reviewed on average thirty (30) days before expiration. If there is any inconsistency in the contract, the partner must be contacted and an event report recorded.

It is important to note that any new or renewed contract must, before being approved, pass the assessment of the legal sector.

## QUALITY PLANNING

Description of how the laboratory plans its quality system development and continuous improvement.

Quality planning at Laboratory X is carried out based on criteria established by laboratory quality accreditation programmes that establish standards through checklists divided into sections that cover all areas of the institution, prioritizing technical issues, but also focus on the interaction between the processes and the management of the institution as a whole.

Quality planning in the institution is continuous, based on the opportunities for improvement resulting from reports of internal occurrences and events recorded in its database.

Laboratory X plans and develops the necessary processes for production and service provision, ensuring that all customer requirements and quality management system requirements are met.

## QUALITY ASSURANCE

As part of the continuous quality improvement program, the quality and appropriateness of the laboratory's services are objectively monitored and systematically assessed to provide opportunities for improvement in patient care and to solve problems identified during processes runs.

The quality assurance program includes technical and procedural components, professional performance for specimen interpretation for the diagnostic conclusion and quality assessment of the final report. Quality assurance is a result-oriented process by which the performance of the laboratory is evaluated. Quality assurance actions focus primarily on the effective use of resources and quality of the final product (in the pathology laboratory, the final product delivered is the pathology report), and are closely related to market aspects. The quality assurance program is a set of integrated actions that includes elements of standardization, control, evaluation, and development of the preanalytical, analytical, and post-analytical phases, mainly related to the samples, the accuracy of the diagnosis, the adequate time of processing, and clear communication of the result, in addition to efficiency in the production of information and compliance with governmental and accreditation agencies. Each of these elements is systematically and periodically evaluated so that any sources of errors are identified and reduced.

## SUPPLIER SELECTION AND EVALUATION

The laboratory selects suppliers based on their ability to provide products and services according to service needs. The extent to which we selected, evaluated, and reassessed depends on the impact that their products and services have on the laboratory's products and services. The procedure SOP -ADM - 006 - evaluation and qualification of suppliers, supporting laboratories, as well as reference professionals (if available) establishes the criteria for evaluating and selecting suppliers. Any non-compliance with these criteria will generate an improvement opportunity report for negotiation with the supplier. The report and negotiation will define whether the supplier remains on the approved supplier list.

## CONTROL OF SAMPLES AND PRODUCTS

The requirements for the identification, tracking, and acceptance of samples are defined, and the tracking system allows an identification at each point of the processing. Correct identification is a fundamental element for the test. One cannot admit a test that is not unambiguously identified. The identification must privilege not only the patient but also the specimen. Inadequately identified samples should not be accepted for analysis. The availability of relevant clinical data is essential; however, its absence in the request does not prevent the data from being obtained later by direct contact with the attending physician. The criteria for collection and rejection of samples are described in SOP – EXP - 004 – specimen collection and delivery of reports (if available).

## PROCESS CONTROL

All the organisational processes are defined in the macro flow of processes. The macro flow demonstrates all the main and support processes, with each specific sector having its cockpit for controlling the implemented processes. Dashboards are available to all employees easily accessible through LIS, allowing each employee autonomy over the control of these processes. The procedures described are as follows: SOP-CTR-03 - flow control dashboards (if available).

## CLAIMS

The improvement opportunities database dashboard is the tool used to record customer requests and/or complaints. The procedure clarifying how customer requests are registered in this database is SOP-ADM-018 - reception: telephone service and client requests (if available). Depending on the type of customer request made, such as statistical reports, an improvement opportunity report is recorded to evaluate the request by the quality management department.

## CORRECTIVE ACTION

Corrective action is usually verified after an event/error or through an audit (8S, biosafety, internal, external, or through the monitoring of preventive action). Corrective action is implemented to eliminate the cause of a nonconformity, defect, or other undesirable situation, to prevent its repetition and must be monitored to verify its efficiency. When corrective actions are ineffective, conditions should be re-evaluated, and another corrective action taken for noncompliance. The procedure that describes the corrective action registration process is SOP-QUA-005 - corrective and preventive actions (if available).



## PREVENTIVE ACTION

Preventive action is usually verified on a day-to-day basis, after the occurrence of an error, or due to the change of methodology.

Preventive action is implemented to eliminate the cause of a possible nonconformity, defect, or other undesirable situation.

Preventive actions are generated from analysing problems related to error reports (Improvement Opportunity Forms); the main objective is to prevent the problem from recurring.

## INTERNAL AUDITS

Quality auditing is defined by ISO 19.011-1:2018 as a systematic and independent examination to determine if the quality activities and their results are in accordance with the planned provisions, whether these have been effectively implemented and whether they are adequate to achieve the objectives.

The quality audit is a key management tool to achieve the established objectives and provides objective evidence regarding the need to reduce, eliminate, and prevent nonconformities. The results of these audits are used to improve the organisation's performance.

Based on the requirements of the quality programmes, the laboratory chose to conduct internal sample audits weekly to ensure continuous quality improvement and meet the required criteria in a timely manner. The procedure that describes the internal audit process at the institution is SOP-QUA-020 - internal quality audit – instructions (if available).

## STATISTICAL CONTROLS

Description of how the main internal statistics are obtained, evaluated, and monitored. Indicators are particular to every laboratory; however, some of these indicators, like TAT, control delayed cases, the number of errors detected in each period, and others will help the laboratory improve the processes and make conscious decisions if one or more indicators are out of the expected pattern.

Quality indicators are monitored through a set of reports according to the functional objectives of each sector or activity in the laboratory. The methods of evaluating the data obtained aim to identify the causes of problems, actions aimed at improving quality, individual responsibilities in the execution of activities, and methods for evaluating the effectiveness of the corrective actions implemented. Quality indicators are based on the elements that contribute to the pathology report. These indicators include elements from the pre-analytical, analytical, and post-analytical phases, from sample reception, preparation, analysis, diagnosis, and communication of results.

Quality reports are grouped in their respective periods, and consolidation is carried out, followed by an assessment, problem-solving activities, and impact monitoring. The reports are presented and discussed in meetings with the board, staff, tumour boards and suppliers board.

Below are examples of indicators of the hypothetical laboratory X:

› **PRE-ANALYTICAL INDICATORS:**

- Unsatisfactory samples
- Training sample handling - external institution collection stations
- Local collection
- Control of preanalytical variables
- Preanalytical guidance

› **PROCESS INDICATORS:**

- Service requests
- Discrepancies
- Events
- False negatives - False positives - Gases
- Lighting
- Number of 5S inspections - Waste production
- Productivity
- Profitability
- Rework
- External review
- Noise
- TAT
- Processing time - continued training

› **POST-ANALYTICAL INDICATORS:**

- Index of complaints
- Customer opinion survey - epidemiological results
- Errors delivering results
- Diagnostic interpretation errors

› **HUMAN RESOURCES INDICATORS:**

- Accidents at work
- Employees' workload per shift
- Age distribution
- Distribution by sector
- Distribution by sex
- Smokers
- University graduate
- Salary mass

**MANAGEMENT CRITICAL ANALYSIS**

Management critical analysis is carried out based on the performance evaluation of the macro indicators linked to the strategy of the organisation (strategy planning document). For each improvement opportunity report evaluated, the indicators are inserted, with their respective problems linked. It is possible to assess the interface between event/indicator/problem and strategic planning document. The macro indicator report allows adding relevant data to the analysis and visualizing the graphic indicators in question. The model used by the institution allows a critical reflection of the processes based on the results obtained and also considerably increases the institution's credibility regarding the integration of its management system.

**COMPLIANCE WITH LEGISLATION**

Laboratory X is committed to complying with local legislation, at the city, state, and federal levels and the requirements are evident in the procedures for each specific area.

**QUALITY MANUAL OBJECTIVES**

Description of any object related to the manual, plan or SOP that is not or cannot be displayed in this document, and directs the reader to the place where it can be found.

**COPY CONTROL**

The following sentence can be placed in all documents before listing the people that should know, understand, sign (either on paper or electronically), and state that they will comply with the procedures described: "We, the undersigned, declare that we have read, understood, and are committed to faithfully following this standard operating procedure." The name of the employee, sector where he/she works, and signature should be captured in the document.



<https://citycancerchallenge.org/>

