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	Compiled by	Examined by	Approved by	Replaced	New version
Name				Code:	Code:
Date					
Signature					
Laboratory area:		No of copies:	Reason for change:		

Standard Operating Procedures (SOPs) are Quality Management (QM) documents which have to meet international standards and norms such as DIN EN ISO 15189, DIN EN ISO/IEC 17025, ISO 9000, CLSI (Clinical and Laboratory Standards Institute, formerly NCCLS) GP2-A5.

Each SOP contains a header and a footer with the following information:

Header:

- Name, location and/or logo of the laboratory;
- name of highest-ranked responsible person;
- descriptive title of the SOP
- no. of SOP (digits) may be associated with a code, indicating the SOP domain (e.g. methods/procedures = MP; health/safety = HS, equipment/maintenance = EM, administration = AD);
- no. of version (two digits, separated by a dot);
- date of release;
- page number, out of total number of pages.

Footer

- Compilation: date, name, signature
- Examination: date, name, signature
- Approvement for release: date, name, signature
- Code of the replaced SOP (if any) with date of replacement and signature of the responsible for decision
- Code of the new version (if any) with date of implementation and signature of the responsible for decision
- number of authorized copies per laboratory area
- reason for change of SOP.

All SOPs contain a table of contents based on a common format. However, most topics of content may be adapted, due to the different domain/area of SOPs.

1. Scope

Here is defined the specific scope of each SOP.

The generic SOPs in this document cover relevant technical procedures for microscopy, culture and drug susceptibility testing (DST) of *Mycobacterium tuberculosis* based on internationally accepted methods and mainly focused on the use of solid media. The use of commercially available manual or automated liquid methods for purposes of culture and/or DST and the use of line-probe assays for the detection of multi-drug resistant TB are not covered in the present document.

2. Definitions and abbreviations

List of all abbreviations and definitions used in each SOP

change control
Procedure for the monitoring of changes that have an influence on the product quality and/or quality assurance measures.

sample
Generic term to designate a part of a system; used in this document as the equivalent of "specimen".

CLSI:	Clinical and Laboratory Standards Institute
DIN:	Deutsches Institut für Normung
EN:	European Norm
EQA:	External Quality Assessment
IEC:	International Electrotechnical Commission
ISO:	International Organization for Standardization
QC:	Quality Control (previously referred as Internal Quality Assurance)
QM:	Quality Management
SOP:	Standard Operating Procedure
TB:	tuberculosis
WHO:	World Health Organization

3. Personnel pre-qualifications

3.1 Medical fitness

In accordance with national laws and practices, arrangements should be made for appropriate health surveillance of TB laboratory workers:

- before enrolment in the TB laboratory;
- at regular intervals thereafter, annually or bi-annually;
- after any biohazard incident;
- at the onset of TB symptoms.

Ideally, individual medical records shall be kept for up to 10 years following the end of occupational exposure.

Laboratory workers should be educated about the symptoms of TB and provided with ready access to free medical care if symptoms arise.

Confidential HIV counselling and testing should be offered to laboratory workers. Options for reassignment of HIV-positive or immuno-suppressed individuals away from the high-risk areas of the TB laboratory should be considered.

All cases of disease or death identified in accordance with national laws and/or practice as resulting from occupational exposure to biological agents shall be notified to the competent authority.

3.2 Education and training

List education and training topics which have to be given to successfully and safely carry out an activity.

The training shall be:

- given before a staff member takes up his/her post;
- strictly supervised;
- adapted to take account of new or changed conditions;
- repeated periodically, preferably every year.

4. Procedure

Process documents describe a set of interrelated or interacting activities that transform inputs into outputs; for a TB laboratory this means to transform an examination order into a result report. Procedure documents give step-by-step instructions for what needs to be done by the individual to successfully carry out an activity.

4.1 Principle

Short introduction to the basic principle(s) and/or reaction mechanisms underlying the particular procedure.

4.2 Samples

If there is no related (applicable) SOP available, please provide the following Information,

- type of samples/specimens that should be processed or analysed;
- labelling of the sample for proper identification throughout the procedure;
- the minimal amount needed;
- the method of collection;
- timing of the collection;
- additives for preservation of the analyte within the specimen during storage and/ or transportation;
- conditions for storage and transportation;
- the allowable time between collection and processing.

4.3 Equipment and materials

A list of equipment and materials must be carefully prepared and must include:

- the amount;
- quality (also the necessary specifications if required).

Instructions for calibration and maintenance should be included in the procedure only when these activities are performed each time the procedure is done. Instructions for equipment calibration, calibration verification, and maintenance that are performed other than when the equipment is used to perform an examination procedure should be written as separate SOPs.

4.4 Reagents and solutions

Instructions for stock and working solutions of reagents and solutions that are prepared at times other than when the actual procedure is performed should be written in separate SOPs.

The following information needs to be defined for all reagents

- quality and/or grade;
- detailed description of the safe preparation of solutions;
- proper labelling with name(s) of chemical(s), concentration, date of preparation, date of expiry and, when applicable, name of the person who prepared it;
- information about stability;
- storage conditions (e.g. temperature, light protection, humidity);
- storage location for flammable and alkaline/acidic reagents;
- quality control of reagents and media;
- regular check of stock for expiry dates and loss of quality.

4.5 Detailed instructions

A comprehensive description of the steps of the procedure, together with practical hints for the procedure.

4.6 Reading, interpretation, recording and reporting

Reading may provide qualitative, semi-quantitative or quantitative information. This information forms the basis for a laboratory report which requires interpretation within the clinical context. If applicable, specify:

- coding scheme used for interpretation;
- how to follow up for indeterminate results;
- how to resolve contradictory results;
- recording and files/forms used within the laboratory for documentation;
- report forms for results;
- dissemination of results to persons involved (clinician, epidemiologist, other laboratories);
- reporting method.

4.7 Quality control

Instructions for quality control (QC), including negative and positive controls, and – if necessary – for the workflow should be described in the SOP only when QC is performed each time within the procedure. Instructions for QC performed other than during the procedure should be the subject of a separate SOP.

QC procedures need to include the following :

- frequency with which controls should be done;
- number and levels of controls to use;
- type of quality control materials/strains to use;
- instructions for preparation and handling of control materials;
- corrective actions, if expected control criteria are missed;
- instructions for documentation of QC data/materials.

Measures for External Quality Assessment (EQA) must be described separately.

4.8 Waste management and other safety precautions

It is very important to establish and follow adequate waste management procedures: TB laboratory activities generate contaminated materials that represent a biohazard for laboratory personnel, as well as for the community and the environment. Specific recommendations must be described whenever necessary.

Good laboratory practice must be observed in the performance of each activity.

Specific SOPs must be compiled to cover the different aspects of safety measures (e.g. fire, electrical and chemical hazard, biosafety).

5. Related documents

Related documents include applicable national and/or international standards/norms and literature used in the preparation of the SOP. Specific forms used must be attached.

6. Rationale for change of SOP version

Laboratories need a process for timely should to include:

- establishing the need for revision;
- revising the SOP and any related documents that also need to be changed;
- reviewing the revised SOP;
- approving the revisions and recording the approval;
- archiving the new version of the SOP in the master file;
- providing working copies of the newly approved SOP to all appropriate personnel;
- instructing staff to familiarize themselves with any changes from the previous version – they should sign to confirm that they have done this;
- collect and discard all copies of the former version of the SOP.

Change control should be described in the original SOP.