

Accreditation of Medical Laboratories for PCR Testing

**Guideline for the Accreditation of Medical Laboratories Performing
Molecular Tests for Covid-19**

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On behalf of



On behalf of the Federal Government of Germany, the Physikalisch-Technische Bundesanstalt promotes the improvement of the framework conditions for economic, social and environmentally friendly action and thus supports the development of quality infrastructure.

Scope

This guideline provides specific criteria for the accreditation of PCR testing for Covid-19 in relation to EN ISO 15189:2012 (hereinafter: standard) as well as the *Good Microbiological Practice and Procedure* requirements described in the World Health Organization (WHO) Guideline titled *Laboratory biosafety guidance related to coronavirus disease 2019 (Covid-19)* and the WHO Guideline titled *Laboratory testing for coronavirus disease (Covid-19) in suspected human cases*. It is directed towards accreditation bodies (ABs) that assess molecular tests for Covid-19 in the medical field and towards medical laboratories responsible for Covid-19 molecular testing and seeking accreditation. The quality management system of a given laboratory shall contain acceptable solutions for all critical points. At the same time, the document aims to provide information for assessors involved in the accreditation process of these laboratories.

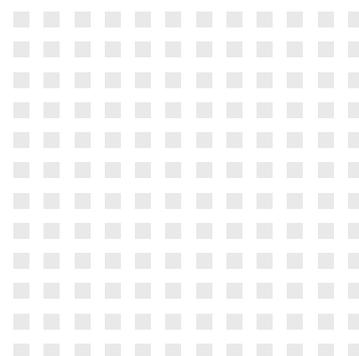
Applicant and accredited laboratories shall also comply with the national accreditation body's procedures for accreditation and with any national legislation in place.

The following definitions apply in understanding how to implement this guideline document:

- *shall* indicates a requirement
- *should* indicates a recommendation
- *may* is used to indicate that something is permitted
- *can* is used to indicate that something is possible – for example, that an organization or individual is able to do something.

In the ISO/IEC Directives, Part 2, Seventh edition, 2016, 3.3.3, a **requirement** is defined as an *expression in the content of a document conveying objectively verifiable criteria to be fulfilled and from which no deviation is permitted if compliance with the document is to be claimed*.

In the ISO/IEC Directives, Part 2, Seventh edition, 2016, 3.3.4, a **recommendation** is defined as an *expression in the content of a document conveying a suggested possible choice or course of action deemed to be particularly suitable without necessarily mentioning or excluding others*.



1. Management Requirements (§ 4)

§ 4.1 Organization and management responsibility

All regulatory requirements regarding the establishment and operation of laboratories performing molecular tests on human samples shall be applied. The head of the laboratory and/or the technical staff members responsible shall hold all necessary titles and/or certificates in accordance with relevant legal requirements. Impartiality and confidentiality shall be assured at all times.

Responsibilities, competences, and interactions among personnel are regulated. Effective communication between the laboratory and healthcare providers should be supported, especially communication with the physicians.

Each laboratory staff member shall be qualified for the task for which he/she is authorized. The responsible staff member shall guarantee that all requirements of the federal public health authorities are fulfilled.

A quality manager with distinct responsibilities and appropriate education shall be designated.

§ 4.2 Quality management system

A quality management system shall be implemented and structured in accordance with the requirements of EN ISO 15189:2012. Each member of the laboratory management shall know the relevant regulations and oversee their implementation. In particular, the requirements of the regulations (laws or directives) referred to shall be enforced.

The quality management system shall involve processes regarding the laboratory's:

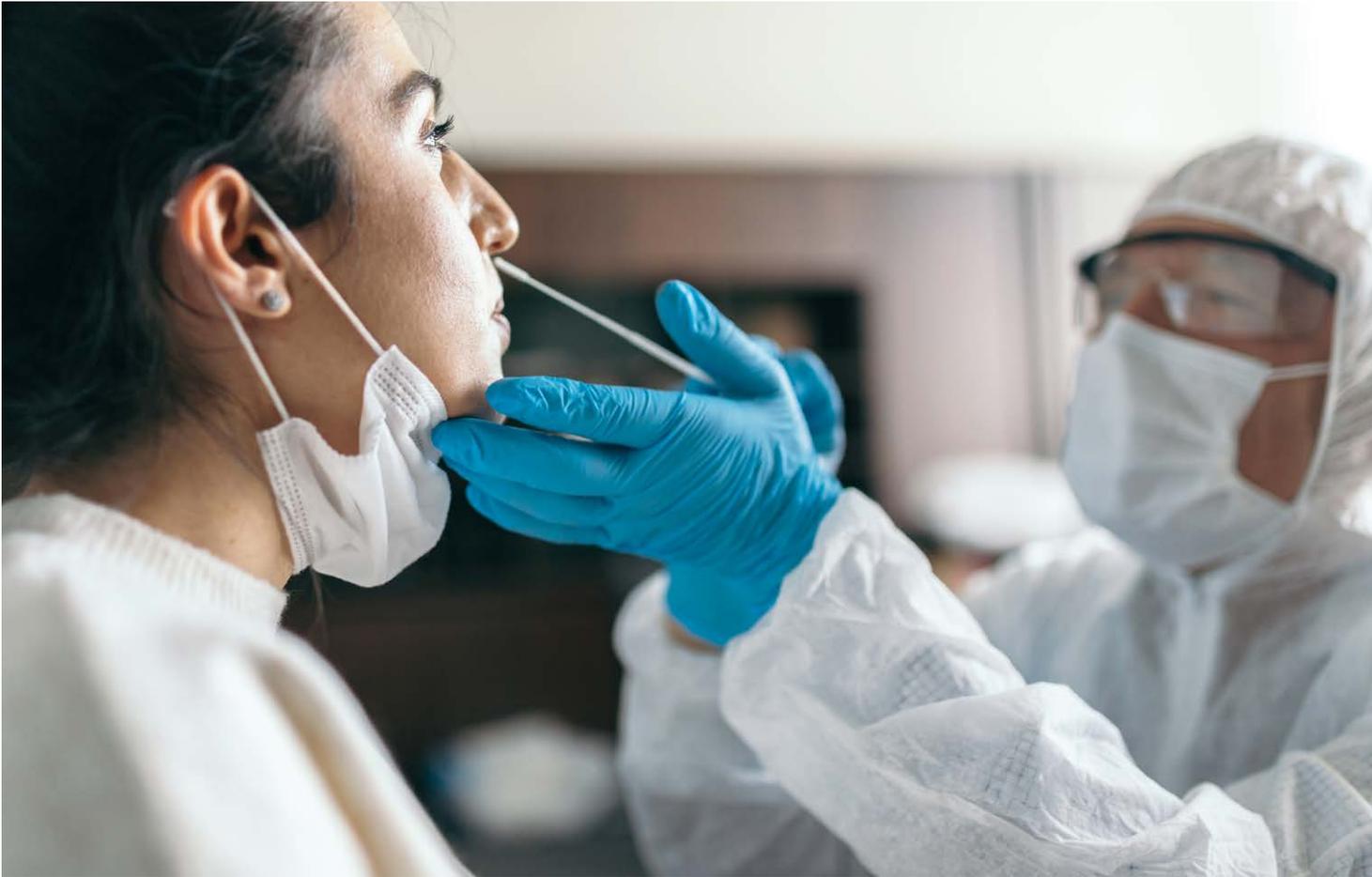
- a) legal and policy framework
- b) institutional and management framework
- c) human resources
- d) laboratory quality management
- e) evaluation and monitoring
- f) maintenance of equipment
- g) laboratory structure and design

§ 4.3 Document control

No additional interpretation of this clause of the standard is required.

§ 4.4 Service agreements

Medical laboratories should select and recommend the most appropriate assay based on the desired clinical application (screening, diagnosis, monitoring). The main purposes of these tests are to support the diagnosis of patients with Covid-19-like symptoms, to screen crucial target groups like healthcare workers for infections, and to test whether an individual who has recovered from Covid-19 is still infectious. In general, CE-marked diagnostics (In Vitro Diagnostics Medical Devices – IVDs) shall be used for the analysis of the health-relevant parameters of patients. For scientific studies, diagnostics (IVDs) without the CE marking may also be applied. Laboratory-specific methods shall be developed in accordance with the requirements of the given IVD if appropriate in terms of use of the system. Methods developed in-house and used or distributed on a commercial basis shall comply with the given IVD.



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§ 4.5 Examination by referral laboratories

Accredited laboratories should be preferred, if possible. The quality of the services performed shall be checked and rated regularly.

§ 4.6 External services and supplies

In general, certified suppliers (e.g., in accordance with ISO 9001, ISO 13485) or accredited subcontractors (e.g., in accordance with EN ISO/IEC 17025, EN ISO/IEC 17043) should be preferred for services and supplies. The quality of the services performed shall be checked and rated regularly.

§ 4.7 Advisory services

It is essential that molecular test results for SARS-CoV-2 be interpreted in the context of clinical observations, including the number of days since the onset of symptoms and the patient's epidemiological background. In addition, selecting patients based on a careful clinical or epidemiological examination will enrich the pre-test probability and thereby increase the post-test probability of positive results.

§ 4.8 Resolution of complaints

No additional interpretation of this clause of the standard is required.

§ 4.9 Identification and control of nonconformities

§ 4.10 Corrective action

False results shall be recalled in writing, commented on, and corrected immediately. It should be noted that procedures to guarantee the correct treatment of nonconforming testing are a very important part of the quality management system. Nonconforming testing and activities occur in many different areas and can be identified in many ways, including clinician complaints, quality control indications, instrument calibrations, checking of consumable materials, staff comments, reporting and certificate checking, laboratory management reviews, and internal and external audits.

§ 4.11 Preventive action

Standard precautions should be used to maintain a barrier between the specimen and the personnel during all handling procedures, as this will ensure the safety of healthcare workers, laboratory staff, and patients. All procedures shall always be performed based on risk assessment and only by trained staff members as per the relevant standard operating procedures (SOPs).

All technical procedures should be performed in such a way that the formation of aerosols and droplets is minimized (e.g., centrifugation, vortexing, sonication, pipetting of respiratory samples).

Biohazard containers shall be available for appropriate disposal of contaminated materials and should be located in the immediate vicinity of the working area. As a precaution, double-layered leak-proof bags should be used for collection of waste from high-risk areas.

Because polymerase chain reactions (PCRs), as with all other amplification reactions, are prone to contamination, in order to avoid or detect any potential contamination, appropriate controls and conditions shall be applied and implemented, including:

- contamination controls
- sufficient space allowing clear separation of the different steps
- environmental aspects
- appropriate equipment
- controlled workflow
- risk assessment

As soon as a contamination becomes evident, no further results shall be reported until the source of the contamination has been properly identified and eliminated.

§ 4.12 Continual improvement

The laboratory should take steps to reduce risks related to personal safety and diagnostic quality and to improve and expedite workflow.

§ 4.13 Control of records

The laboratory should keep records, including the following as a minimum:

- external services and suppliers' selection and approved list
- staff qualifications, training, and competence evaluations
- test requests
- instructions for informing patients and users
- sampling instructions (if done in the laboratory)
- contracts/arrangements for sampling (if done by third parties)
- transportation instructions and records of monitoring the transportation conditions (if samples are delivered to the laboratory)
- specimen handling/processing/storage instructions and files

- nucleic acid extraction protocols and files
- PCR amplification protocol(s) and files (including validation data, IQC and EQC files)
- waste handling instructions and monitoring
- laboratory monitoring
- equipment maintenance records (including calibration records)
- biorisk assessment
- biosafety measures/requirements
- examination results and reports

§ 4.14 Evaluation and audits

The laboratory should plan and conduct internal audits that specially emphasize the nucleic acid-based diagnostic procedures and practical aspects of laboratory work including quality and contamination control efforts. The audit should be conducted by technically competent auditors.

The laboratory, as required by the standard, shall conduct a risk assessment for all stages of the analysis (starting from sample collection, if taken on the laboratory's premises, up to sample reception and actual performance of the molecular test) to ensure that it is suitable for a safe and reliable performance of the prescribed tests that is within the given time limits and that it implements the appropriate control measures in order to counter potential risks. This risk assessment should also include a component comprising biosafety, laboratory biosecurity and ethical considerations; this component should focus on staff safety and exposure prevention. Risk assessments and mitigation measures are dependent on the following factors:

- the procedures performed
- identification of the hazards involved in the process and/or procedures
- the competency level of the staff members who perform the procedures
- the laboratory equipment and facility
- the biosafety measures taken
- the resources available

Each process step has its own assessed grade of risk. Specific hazards will be identified for each process step, such as aerosol exposure during sample processing, contact with eyes via splashing during sample processing, infectious material spills, and leaking sample receptors. Particular consideration should be given to risks related to human factors. The likelihood of errors and incidents is higher when staff training is insufficient and staff members are under pressure to produce rapid results.

For each risk identified, appropriate risk control measures should be selected and implemented to mitigate the residual risks to an acceptable level. Risks shall also be reviewed, monitored, and mitigated prior to and during implementation, and regularly during the life cycle of operation.

§ 4.15 Management review

The management review shall emphasize nucleic acid-based diagnostic testing procedures, internal and external quality control schemes, and educational aspects of the personnel.



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2. Technical Requirements (§ 5)

§ 5.1 Personnel

The requirements of the personnel who carry out the analysis and evaluate and sign the outcomes shall meet the requirements of the standard.

The medical laboratory's management should define the minimum levels of qualification and experience necessary for staff members within the laboratory while also ensuring that the persons responsible (head and deputy of the medical laboratory) possess the required professional title(s) enabling them to be officially in charge of the analyses.

The range and type of authorities and duties of laboratory staff members will vary in accordance with the size and scope of the laboratory. However, each laboratory should guarantee:

- the appointment of a competent deputy to the person in charge of nucleic acid-based techniques according to any legal requirements, if applicable
- that laboratory technicians possess at least a nationally recognized technical laboratory degree and are experienced in nucleic acid-based techniques.

Training, its effectiveness and work experience shall be documented for all staff members, including medical laboratory management. Training of personnel shall specifically include:

- a) procedures for
 - accurate patient and sample identification
 - proper collection techniques for the sample types likely to be encountered (e.g., upper respiratory specimens), where applicable
 - sample storage and handling requirements
 - reporting and documentation of adverse events and other nonconformities
 - prevention or containment of the effects of adverse events (e.g., first aid training)
 - emergency situations
 - use of computers and other relevant information technology

- b) safety and infection control procedures for protection of the personnel and patients
- c) patient privacy expectations and confidentiality of patient information (statutory and regulatory requirements may apply)
- d) assigned work processes and procedures

The laboratory should regularly validate and monitor the adequacy of qualification of the staff members involved, including the training required and their experience in molecular virology tests. For the diagnostic use and knowledge of biosafety, instructions shall be given, and retraining shall occur when necessary.

§ 5.2 Accommodation and environmental conditions

Access to the laboratory area is strongly restricted and visits by external parties shall be documented including the date, time, name, address and signature of the visitor. In order to minimize the risk of contamination, laboratories are obliged to demonstrate appropriate measures such as:

- 1) Separation of working areas for each individual step of a nucleic acid-based test procedure.

The following four distinct working areas/rooms are strongly recommended:

- a) mastermix preparation (*clean room*, shall be separate from other workflows with positive pressure if possible)
- b) sample handling processing
- c) nucleic acid extraction
- d) PCR amplification and analysis of amplicons (shall be separate from other workflows with negative pressure if possible)

If amplification and analysis are not combined and automated, additional specific safety requirements shall be fulfilled and documented to avoid contamination and prove correct handling.

- 2) Biosafety cabinets (at least BSL-2) should always be used; these should be routinely validated/certified and well-maintained in accordance with the procedures in place for proper use.
- 3) Unidirectional workflow and changing of protective clothing are mandatory. Each particular working area needs its own specifically labelled equipment, preferably in different colors (e.g., pipettes, centrifuges, adequate protective clothing, vials, heating blocs).
- 4) Refrigerators and freezers should not be shared between the reagent and sample preparation room/areas to prevent samples and nucleic acid isolates from being stored in the same place as reagents. Pre and post amplification reagents and nucleic acids (e.g., sample and PCR products) shall be stored in separate refrigerators or freezers located in separate locations, ideally in the respective rooms/areas.
- 5) Safety procedures shall be carefully defined and documented including precautions to prevent accidental contamination, regulations for protective clothing (e.g., laboratory coats, gloves and safety glasses/face mask), and prohibition of eating, drinking, or smoking in the laboratory.
- 6) To minimize the risk of contamination, the environment where samples are collected shall be cleaned and disinfected regularly. All surfaces in the laboratory should be easy to clean and decontaminate. No equipment should be maintained or repaired without having been decontaminated, and this process should be documented and validated. Appropriate disinfectants with proven activity against enveloped viruses should be used (e.g., hypochlorite [bleach], alcohol, hydrogen peroxide, quaternary ammonium compounds, and phenolic compounds).
- 7) Contaminated waste should be safely and efficiently treated within the laboratory and stored in the laboratory until it has been disposed of properly. Where decontamination is not possible in the laboratory area, or onsite, contaminated waste shall be packaged in a leakproof fashion for transfer to another facility.

§ 5.3 Laboratory equipment, reagents, and consumables

As part of a quality management system, laboratories are required to operate a program for the maintenance and calibration of their equipment. Specifically, for laboratories performing molecular tests, equipment may be categorized as:

- a) general service equipment not directly used for measurements (e.g., centrifuges, refrigerators, freezers)
- b) small pieces of measuring equipment directly related to the test result (e.g., pipettes)
- c) instruments for measurement and detection systems (e.g., for extraction, amplification, separation)
- d) computers and computer networks

General service equipment will typically be controlled and maintained by means of regular visual inspection, safety checks, and cleaning. Calibrations/performance checks and cleaning are required for equipment settings involved in the maintenance of the quality of the test or the analytical result (e.g., the temperature of a refrigerator).

Regular calibration, cleaning, and servicing of small measuring equipment shall be performed and documented. The handling of this type of equipment shall be documented if manufacturers' manuals and documentation are insufficient. To avoid contamination by means of pipettes, tips with an aerosol barrier (filter tips) are recommended.

Periodic performance checks as well as assignment of pre-determined limits of acceptability are required. The frequency of performance checks shall be determined based on previous experience with and the type and previous performance of the equipment. All service and maintenance work shall be documented. The use of the equipment shall be documented, including action taken in case of system failure.

§ 5.4 Pre-examination processes

The selection and collection of sample material are important elements of molecular methods. Laboratories that perform sampling on their premises shall ensure documentation of all procedures for this process and appropriate training of personnel for the proper collection, storing, packaging, and transportation of the samples.

The collected swabs should be transported to the laboratory in a viral transportation medium under cold conditions or at room temperature as per the relevant recommendations. Containers should be leakproof and have adequate strength, integrity, and volume to contain the specimen. Use of plastic containers that are free of any biological material on the outside of the packaging is highly recommended. In addition, containers should be correctly labelled, marked and recorded to facilitate identification.

Transportation within national borders shall take place in accordance with the national regulations associated with the transportation of infectious samples. When sending samples on a flight for international transportation, UN3373 biological substance, category B regulations should be followed.

A specimen received by the laboratory shall be accompanied by sufficient information to identify what it is, when and where it was taken or prepared, and which tests and/or procedures (if any) are to be performed.

The items should be unpacked in the BSC class II A1 or A2 or higher level. Staff members unpacking and receiving specimens shall be adequately trained on the hazards involved, how to handle broken or leaking containers, and how to handle spills and use disinfectants to manage any contamination.

The traceability of all activities from receipt, preparation, proper analysis, reporting of results, and storage to disposal of the sample shall be guaranteed.

§ 5.5 Examination processes

In general, tests can be categorized into four groups:

1. IVD labelled assays/tests
2. IVD labelled assays/tests modified by the laboratory as an unmet patient need was identified
3. Assays/tests developed by the laboratory (LDT)
4. Commercially available research use only (RUO) tests

In principle, a laboratory introducing a new method shall demonstrate and document the performance characteristics of the new method. If new commercialized test methods are introduced, the performance characteristics of each method shall be verified in the laboratory. If the new commercialized test method replaces a previously used method, the performance of the tests shall always be compared. The selection and performance of test methods shall be fully documented. An official approval of the new test methods prior to use in routine work shall be performed.

All technical procedures and methods shall be validated before being applied to routine diagnostics. The head of the laboratory is responsible for adequate validation and shall provide all means necessary to fulfill the task.

Verification

If a CE-IVD test or a method approved otherwise (i.e., by the scientific community) is used, the laboratory is required to provide objective evidence that the performance characteristics of the given test fulfill the requirements specified. During the evaluation, the selected assay should be assessed by verifying whether the assay meets the manufacturer's claim and the laboratory's setup.

The analytical performance verification of molecular tests for Covid-19 should include the following elements:

- **Limit of detection (LoD):** The LoD can be determined by limiting dilution studies using sufficiently characterized samples and should be provided. The LoD is determined as the lowest concentration for which $\geq 95\%$ of the replicates are positive. The laboratory should prepare five samples in the range of the LoD claimed and measure 8–12 replicates over five days,

and then employ Probit Regression Analysis to establish the concentration at which 95 % of samples return a positive result.

- **Precision:** Assessments should be made of both repeatability (i.e., testing the same sample under the same conditions) and reproducibility (i.e., testing the same sample under variable conditions such as different reagent kits, days, different analysts, and different instruments). For qualitative test results, the precision parameters can be expressed as the percentage of agreement.
- **Accuracy (trueness):** The accuracy of a test method expresses the closeness of agreement between the value found and the value accepted either as a conventional true value or an accepted reference value. The closeness of agreement observed is the result of the systematic error (bias, expressed as trueness) and the random error (expressed by the precision of measurement). To estimate the accuracy, at least 10 negative and 10 positive known samples should be analyzed. Contrived patient samples could be used by spiking an individual negative matrix with commercial viral materials. If this is not possible, pooled samples should be used. From the ratio [correct positive + correct negative]/[total number of samples], the accuracy of the method is calculated in percent. A concordance of >95 % is acceptable.

Validation

For in-house methods, methods for research use only, or modified validated methods, the validation of test methods, in accordance with the FDA guidelines, should include the following criteria as a minimum:

- Accuracy
- Limit of detection (analytical sensitivity)
- Cross-reactivity/microbial interference (analytical specificity)
- Reportable range
- Robustness
- Interferences
- Clinical evaluation (clinical sensitivity and clinical specificity)

Validation studies are conducted by different means:

- By the manufacturers (for IVD tests).
- By the scientific community (for standard materials and standard methods) – these studies are officially published.
- By the laboratory itself (for methods developed in-house or for already-validated methods that have been significantly modified in-house for specific purposes).

Records of all performed verifications/validations shall be safely stored for future reference.

§ 5.6 Ensuring quality of examination results

Internal quality control

Internal quality control requires the analysis of positive and negative samples in order to demonstrate the adequate performance of the separation procedures and proliferation of the genetic material of the virus.

When using the CE-IVD test, the laboratory shall apply the requirements proposed by the manufacturer of the test.

In accordance with the FDA guidelines, when using an internal method or research-only method, it is recommended that the laboratory use a combination of the following control materials/samples to ensure that the method is effective:

- **Internal process control (IPC):** Included in each clinical sample and controls for specimen quality; demonstrates that nucleic acid has been generated by the extraction process. Examples include endogenous RNA control such as RNase P (RP) control and exogenous RNA such as MS2 bacteriophages.
- **Extraction control (EC):** Serves as a negative extraction control for monitoring any cross-contamination that occurs during the extraction process; can validate extraction reagents and successful RNA extraction when used in combination with certain IPCs. Examples include a previously characterized negative patient sample.

- **External positive control or positive template control (PTC):** Contains SARS-CoV-2 genomic regions targeted by the test. The positive control is used to monitor for failures of rRT-PCR reagents and reaction conditions.
- **No template (negative) control (NTC):** used to monitor non-specific amplification, cross-contamination during experimental setup, and nucleic acid contamination of reagents. Examples include nuclease-free, molecular grade water and buffers.

External quality control

External quality control requires the participation of the laboratory in proficiency testing (PT) schemes. However, because such schemes have only recently been made available, and until the results have been received, the laboratory is required:

- a) to explore the possibility of participating in an organized ring trial.
- b) to send representative samples (altogether 10 to 20 samples, including both positive and negative ones) to a reference laboratory for result validation.
- c) to include in its planning the participation in appropriate external quality control schemes in accordance with the relevant AB's policy.

§ 5.7 Post-examination processes

Review of results

The laboratory shall have procedures to ensure that authorized personnel review the results of examinations before such results are released and evaluate them in accordance with an internal quality control procedure and, as appropriate, available clinical information and essential background information provided with the diagnostic request (if applicable).

Careful interpretation of weakly positive results is needed, as some assays have shown to produce false signals at high Ct values. If test results are invalid or questionable, the patient should be resampled and retested. If no additional samples from the patient are available, RNA should

be re-extracted from the original samples and retested by highly experienced staff. Results can be confirmed by an alternative molecular test or via virus sequencing if the viral load is sufficiently high. Laboratories are urged to seek reference laboratory confirmation of any unexpected results.

Disposal of clinical samples

As a general laboratory protocol, all personal protective equipment used and laboratory waste generated during the sample processing should be decontaminated before being discarded. Similarly, all laboratory waste generated during the processing of Covid-19 samples should be decontaminated before final disposal to a biomedical waste management facility.

§ 5.8 Reporting of results

§ 5.9 Release of results

Results shall be reported in accordance with the requirements and recommendations of ISO 15189:2012 and any reporting guidelines, if appropriate for the tests performed.

To properly identify the medical laboratory patient and the test procedures, and to properly present the results, the report shall consist of the following as a minimum:

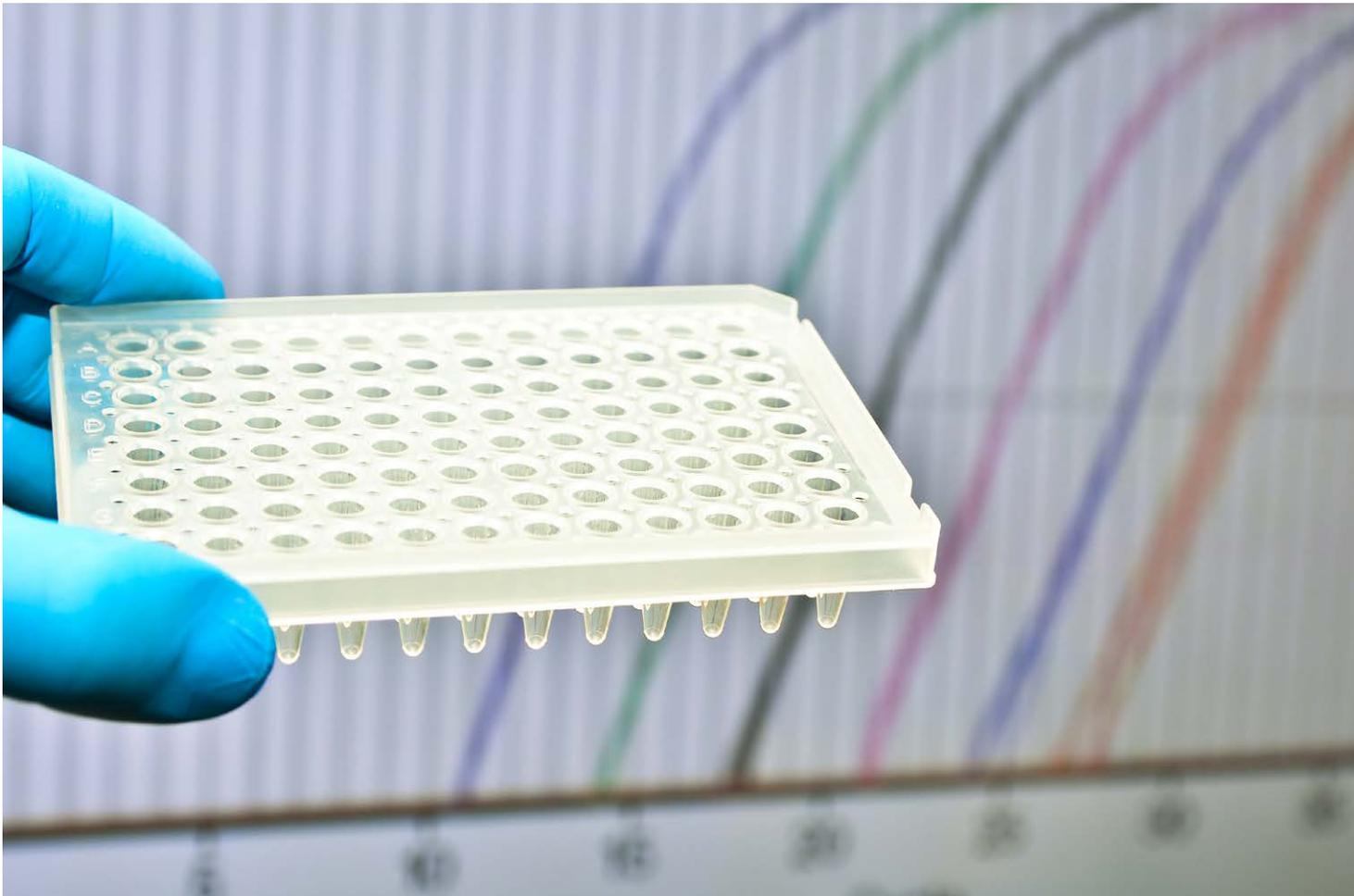
- a) identification of the laboratory performing the tests
- b) patient identifiers and/or identification number
- c) unique sample identification
- d) name and address and/or identification of the submitting medical department or individual authorized medical doctor
- e) date of receipt
- f) date of report, type of report
- g) type of specimen, including date and time of sampling
- h) test principle/technique
- i) presentation of test result(s)
- j) where necessary, limitations of test methods should be mentioned in the interpretation
- k) approval by authorized individual(s)

Confidentiality shall be guaranteed at all times including the certainty that only authorized persons will receive the test results and information regardless of the method of transmission (e.g., mail, phone, fax, e-mail by computer). The policy for the retention or release of information shall comply with current laws and directives.

Laboratories should follow national reporting requirements. In general, all test results, positive or negative, should be immediately reported to the national authorities. Regular interaction between public health experts, clinicians, and local laboratory experts to discuss strategies, potential problems, and solutions should be considered an essential part of an adequate Covid-19 response. A rapid turnaround time of test results can have a positive impact on the outbreak.

§ 5.10 Laboratory information management

The laboratory shall have access to the data and information needed to provide a service that meets the needs and requirements of the user. The laboratory shall have a documented procedure to ensure that the confidentiality of patient information is maintained at all times. The laboratory should also define the requirements of LIS functionality related to managing increased test demand during the Covid-19 crisis, including tools for requesting tests, standardized request sets integrated into a computerized provider request entry module, notifications of shipping requirements, automated triaging based on digital metadata forms, and the establishment of databases with contact details of other laboratories and primary care physicians to enable automated reporting.



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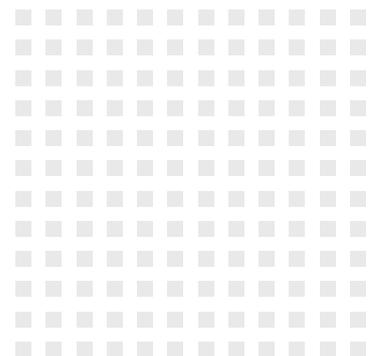
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Abbreviations

AB	Accreditation body
BSC	Biological safety cabinet
EQC	External quality control
FDA	Food and drug administration
IQC	Internal quality control
IVD	In vitro diagnostics
LDT	Laboratory developed test
LoD	Limit of detection
PCR	Polymerase chain reaction
PT	Proficiency testing
RUO	Research use only
SOP	Standard operating procedure





Imprint

Published by

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