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Healthcare organization management — Guidance for healthcare organizations' response to the surging diagnostic demands in a pandemic

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

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Foreword

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This document was prepared by Technical Committee ISO/TC 304, Healthcare organization management.

Any feedback or questions on this document should be directed to the user’s national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Diagnostic testing plays a critical role in triaging patients, making informed treatment decisions, enabling contact tracing, and carrying out epidemiological studies for policy making. During the mid to later phases of the COVID-19 pandemic, the demand for diagnostic testing became higher with the reopening of economies and businesses when large scale testing of the asymptomatic population was required [1]..

The surging demand for diagnostic testing in a pandemic poses challenges in human resources capacity, and in supply chain management not only within diagnostic laboratories but also within entire healthcare organizations. Healthcare organizations have limited numbers of laboratory personnel and skilled workers for providing diagnostic testing which can lead to staff burn-out related to the delivery of diagnostic services (e.g., specimen collection and diagnostic testing). The overworking of staff can also impact the accuracy of testing and the turn-around time (TAT) of the test result.

Lengthy TAT in turn leads to overcrowding in units for persons-under evaluation for highly infectious disease as well as significant delays in patient care for the patients who need emergency care whether for infectious pandemic symptoms but also for patients under investigation for non-pandemic related symptoms (e.g., acute stroke care, emergency operation).[2,3] Moreover, increased TAT for the pandemic infectious agent, can also impact the performance and TAT of other routine laboratory functions including the tests of critically ill patients.[4] Accurate test results with rapid TAT are crucial for successful intervention and care within a pandemic response.[5] All of these factors can contribute to global disruption in the provision of healthcare services and patient flow within a healthcare organization leading to patient overload in the emergency department and intensive care unit, and subsequently prolong the length of hospital stay [3].

The solution to the above challenges normally should be to increase laboratory capacity. However, increasing the laboratory capacity abruptly is not feasible within a short time leading to a more challenging situation. Healthcare organizations need to find alternative solutions to address the surging diagnostic demand by optimizing available resources and overcoming the limitations set by laboratory capacity.

This document aims to strengthen global capabilities for surging diagnostic demand for upcoming pandemics based on the experience of different countries including the lessons learned, and suggest innovative approaches to meet the demands of pandemic testing. A standardized framework for healthcare organizations to follow during a pandemic can facilitate a consistent strategy globally, leading to better coordination and more effective response. Moreover, having an international standard for diagnostic surge would improve the public trust and confidence in healthcare organizations' response to the pandemic.

Healthcare organization management — Guidance for healthcare organizations' response to the surging diagnostic demands in a pandemic

1 Scope

This document provides guidance and considerations for healthcare organizations to deliver diagnostic tests timely and accurately in a pandemic by leveraging innovative approaches to overcome the limitations of laboratory capacity as follows:

— mitigating threats encountered in providing diagnostic services during a pandemic;

— consideration for quality assurance of diagnostic service provision in a pandemic context; and

— possible response measures to the surge in diagnostic demand.

This document does not apply to the details for providing pandemic response medical tests such as the specimen collection protocols in the specimen collection units or screening stations (e.g., Walk-through or Drive-through), experiment procedures, and quality management systems of medical laboratories. Also, this document omits the pandemic responses related to the medical treatment of infected patients in the care units (e.g., emergency unit, in-patient unit) and transferring of confirmed patients in the healthcare organization during a pandemic.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 15190, *Medical laboratories — Requirements for safety*

ISO 15189, *Medical laboratories — Requirements for quality and competence*

ISO 20658, *Requirements for the collection and transport of samples for medical laboratory examinations*

ISO 7101, *Healthcare organization management — Management systems for quality in healthcare organizations — Requirements*

ISO/TS 22583:2019, *Guidance for supervisors and operators of point-of-care testing (POCT) devices*

ISO/PAS 45005:2020, *Occupational health and safety management — General guidelines for safe working during the COVID-19 pandemic*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
accuracy
closeness of agreement between a measured quantity value and a true quantity value of the measurand

Note 1 to entry: The concept "measurement accuracy" is not a quantity and is not given a numerical quantity value. A measurement is said to be more accurate when it offers a smaller measurement error.

Note 2 to entry: The term "measurement accuracy" should not be used for measurement trueness and the term "measurement precision" should not be used for measurement accuracy, which, however, is related to both these concepts.

Note 3 to entry: Measurement accuracy is sometimes understood as closeness of agreement between measured quantity values that are being attributed to a measurand.

[SOURCE: ISO/IEC Guide 99:2007, definition 2.13]

3.2
adverse event
any untoward medical occurrence, inappropriate patient management decision, unintended disease or injury, or untoward clinical signs in subjects, users, or other persons, with any connection to study related activities, whether or not related to the IVD medical device under investigation

Note 1 to entry: Adverse events can be caused by, for instance, insufficient or inadequate instructions for use, deployment, installation, operation, or any malfunction of the IVD medical device under investigation.

Note 2 to entry: This definition includes the malfunction or deterioration of a device which has not yet caused death or serious injury, but which could lead to death or serious injury.

Note 3 to entry: This definition is not intended to be used in determining whether an event is reportable to a regulatory authority.

Note 4 to entry: For users or other persons, this definition is restricted to events related to investigational (IVD) medical devices.

Note 5 to entry: False negative or false positive results are not considered an adverse event unless in an interventional study, inappropriate patient management decisions are made based on those false results.

Note 6 to entry: [SOURCE: ISO 20916:2019, 3.2]

3.3
emergency use in vitro diagnostic medical devices
emergency use-IVD medical device
in vitro diagnostic medical device(s) (3.6) which urgently permitted to introduce/use (in) the market under minimum requirements or fast audit program in disaster situations, such as *pandemic* (3.9) infectious diseases

3.4
external quality assessment
EQA
international, national or local program designed to provide regular, external, independent quality assessment of a medical laboratory's analytical performance, and assist in detecting bias of reported results compared to other laboratories.

Note 1 to entry: Also known as Proficiency Testing (PT).

Note 2 to entry: EQA is the term used in this document.

[SOURCE: ISO/TS 20914:2019, 3.10]

3.5
false-negative result
negative result by the tested method that is actually confirmed as a positive result

[SOURCE: ISO 16140-1:2016, 2.23]

3.6
in vitro diagnostic medical device
IVD medical device
medical device, whether used alone or in combination, intended by the manufacturer for the in vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes

Note 1 to entry: IVD medical devices include reagents, calibrators, control materials, specimen receptacles, software, and related instruments or apparatus or other articles and are used, for example, for the following test purposes: diagnosis, aid to diagnosis, screening, monitoring, predisposition, prognosis, prediction, determination of physiological state.

Note 2 to entry: In some jurisdictions, certain IVD medical devices can be covered by other regulations.

[SOURCE: ISO 18113-1:2022,3.1.33]

3.7
internal quality control
IQC
set of procedures and specified materials used by laboratory staff for the repetitive monitoring of analytical performance of measuring systems

[SOURCE: ISO/TS 20914:2019, 3.13]

3.8
medical laboratory
laboratory
entity for the examination of materials derived from the human body for the purpose of providing information for the diagnosis, monitoring, management, prevention and treatment of disease, or assessment of health

Note 1 to entry: The laboratory can also provide advice covering all aspects of examinations including appropriate selection, the interpretation of results and advice on further examinations.

Note 2 to entry: Laboratory activities include pre-examination, examination and post-examination processes.

Note 3 to entry: Materials for examination include but are not limited to, microbiological, immunological, biochemical, immunohaematological, haematological, biophysical, cytological, tissue and cells, and genetic material.

[SOURCE: ISO 15189:2022, 3.20]

3.9
pandemic
worldwide spread of a disease

[SOURCE: ISO/PAS 45005:2020, 3.5]

3.10
point-of-care testing
POCT
examination performed near or at the site of a patient

[SOURCE: ISO 15189:2022, 3.22]

3.11
referral laboratory
external laboratory to which a sample or data is submitted for examination

Note 1 to entry: A referral laboratory is one to which laboratory management chooses to submit a sample or sub-sample for examination, data for analysis or interpretation, or when routine examinations cannot be carried out.

Note 2 to entry: This differs from a laboratory to which submission of samples is required by regulation, or a so called reference laboratory, e.g. public health, forensic, tumour registry, or a central (parent) facility to which submission of samples is required by structure.

[SOURCE: ISO 15189:2022, 3.27]

3.12
risk management
systematic application of management policies, procedures and practices to the tasks of analysing, evaluating, controlling and monitoring risk

[SOURCE: ISO/IEC Guide 63:2019, 3.15]

3.13
specimen
discrete portion of a body fluid or tissue or other sample associated with the human body taken for examination, study or analysis of one or more quantities or characteristics to determine the character of the whole

Note 1 to entry: The International Medical Device Regulators Forum (IMDRF) uses the term specimen in its harmonized guidance documents to mean a sample of biological origin intended for examination by a medical laboratory.

[SOURCE: ISO 15198:2022, 3.25, modified — the preferred term 'primary sample' has been deleted.]

3.14
stakeholder
person or organization that can affect, be affected by, or perceive themselves to be affected by a decision or activity

Note 1 to entry: A decision maker can be a stakeholder.

[SOURCE: ISO 22367:2020, 3.39]

3.15
turn-around time
TAT
Time interval between the specimens received in the laboratory to the time of reports dispatched with verification

[SOURCE: The electronic Journal of the International Federation of Clinical Chemistry and Laboratory Medicine 2019 Mar; 30(1): 14–24]

3.16
validation
verification, where the specified requirements are adequate for an intended use

EXAMPLE A measurement procedure for creatinine concentration in human serum can also be validated for the measurement of creatinine concentration in human urine.

Note 1 to entry: ISO 9000:2005, definition 3.8.5, defines validation as confirmation, through the provision of objective evidence that the requirements for a specific intended use or application have been fulfilled.

[SOURCE: ISO/IEC Guide 99:2007, definition 2.45]

3.17
verification
provision of objective evidence that a given item fulfils specified requirements

EXAMPLE 1 Confirmation that a given reference material as claimed is homogeneous for the quantity value and measurement procedure concerned, down to a measurement portion having a mass of 10 mg.

EXAMPLE 2 Confirmation that performance properties or legal requirements of a measuring system are achieved.

EXAMPLE 3 Confirmation that a target measurement uncertainty can be met.

Note 1 to entry: The item can be, e.g., a process, measurement procedure, material, compound or measuring system.

Note 2 to entry: The specified requirements can be, e.g., that a manufacturer's claims or specifications are met.

Note 3 to entry: In legal metrology, verification pertains to the examination and marking and/or issuing of a verification certificate for a measuring instrument.

Note 4 to entry: Verification should not be confused with calibration or validation.

Note 5 to entry: In chemistry, verification of identity of entity involved, or of activity, requires a description of the structure or properties of that entity or activity.

Note 6 to entry: ISO 9000:2005, definition 3.8.4, defines verification as confirmation, through the provision of objective evidence that specified requirements have been fulfilled.

[SOURCE: ISO/IEC Guide 99:2007, definition 2.44]

4 Mitigating threats encountered in providing diagnostic services

4.1 Threats encountered

4.1.1 Identification of threats

Healthcare organization shall aware of possible threats that can be encountered in the process of providing diagnostic services during a pandemic.

The threats may include the following, but are not limited to:

— shortage of IVD medical devices including equipment, consumables and reagents;

— shortage of personal protective equipment (PPE);

— limited availability of skilled laboratory professionals;

— deterioration of the accuracy and quality of test results due to overworking of healthcare workers;

— prolonged turn-around time (TAT) of both pandemic and non-pandemic related medical tests; and

— diagnostic service providers become infected by the pandemic disease leading to increase in HR shortage.

4.1.2 Establishment of a threat mitigation plan

Healthcare organization shall develop a plan to mitigate the possible threats.

The plan should include the following, but is not limited to:

— implementing measures to ensure the health and safety of workers and patients;

— developing strategies for stockpiling and emergency procurement of resources such as PPE, and IVD medical devices, including equipment, consumables, and reagents;

— providing training and education for workers to prepare for the pandemics;

— implementing quality assurance measures;

— maintaining safety requirements of the medical laboratory and developing Standard Operating Procedures (SOPs) for managing the increased volume of hazardous and non-hazardous healthcare waste; and

— developing communication strategies with external organizations.

Note 1 See ISO 15189:2022 7.8 for continuity and emergency preparedness planning within the medical laboratory.

Note 2 See ISO 7101:2023 6.1.3 for risk management process and 8.2.2 for contingency planning for facilities and services.

4.2 Supply chain disruption of resources for diagnostic testing

4.2.1 Supply chain integrity

In any possible event in a supply of necessary resources, the healthcare organization shall establish a plan to maintain the continuity of the diagnostic services. The healthcare organization shall identify the stakeholders who need to cooperate outside the organization (e.g., IVD manufacturers or suppliers) and review its supply chain's integrity to provide uninterrupted pandemic response tests.

Note 1 Surging diagnostic demands may exacerbate not only staffing shortages but also a shortage of relevant medical devices and PPE supplies.

Note 2 Strong collaboration between healthcare organization and the manufacturers of various products is needed proactively before the onset of a declared pandemic as well as during a pandemic crisis to maintain the supply chain integrity.

4.2.2 Supply chain expansion

Healthcare organization shall identify additional relevant suppliers of IVD medical devices and PPE to meet the surging demand of the diagnostic testing.

Note During the diagnostic surge, usual suppliers of healthcare organization may not be able to provide enough supply of IVD medical devices and PPE. In this situation, healthcare organization is recommended to purchase from additional relevant suppliers.

4.2.3 Test reliability

The healthcare organization shall ensure that the measures do not harm the reliability of the diagnostic services.

4.3 Shortage of laboratory personnel

4.3.1 General

Healthcare organization shall consider addressing the possible shortage of laboratory personnel to provide diagnostic tests for a pandemic in advance of pandemic onset.

Healthcare organization may consider cross-training staff to work in multiple departments aiming to relieve the shortage of laboratory personnel in the pandemic.

Healthcare organization shall ensure cross-trained personnel are adequately qualified and have enough biosafety knowledge.

4.3.2 Continuity of test service provision

The measures to maintain the continuity of diagnostic service for the pandemic disease should not hinder the diagnostic services of other endemic diseases.

Note During the surge of diagnostic demand in a pandemic, all laboratory personnel are allocated to do the pandemic diagnostic testing. It might cause the deterioration of routine laboratory procedures for other non-pandemic related testing.

4.3.3 Quality assurance

Healthcare organization shall ensure the increase in workload of laboratory personnel does not lead to a decline in the quality of laboratory tests.

These plans may include, but are not limited to:

— referring tests unrelated to the pandemics to referral laboratories (See 6.1.1); and

— reallocating the tasks within the healthcare organization (See 6.1.2).

Note During a pandemic, healthcare organizations experience surging demand for the pandemic response medical tests, which lead to burn-out of staff related to diagnostic service delivery (e.g., specimen collection, medical tests). The overworking of staff can affect not only the accuracy of testing but also the TAT of the test result, and employees' mental and physical well-being.

4.4 Health and safety of healthcare workers

4.4.1 Safety against infection

Healthcare workers are exposed to the same or higher risks of infection transmission as the general public in pandemics. From a human resources perspective, the increasing workload of relevant workers due to increasing diagnostic demands, and the transmission of pandemic disease to workers of healthcare organizations should be considered significant threats.

4.4.1.1 Within organization

Healthcare organization shall ensure health and safety and protection of healthcare workers related to the diagnostic service delivery in accordance with the relevant standards, and applicable regulatory requirements.

Note 1 See ISO/PAS 45005:2020 for protect workers' health from workplace-related events in pandemics.

Note 2 See ISO 20658 for the safety of the collection, transport, receipt, and handling of samples.

Note 3 See ISO 15190 for the safety of medical laboratories (e.g., biosafety, waste disposal, PPE).

Note 4 See ISO/TS 22583:2019, clause 9 for the safety of the point-of-care testing (POCT) procedure.

4.4.1.2 Outside organization

Healthcare organization shall establish organizational principles to prevent the healthcare workers from acquiring an infection from the community (community-acquired infection).

The organizational principles should include the following but not limited to:

— personnel health monitoring routine for the healthcare workers to detect symptoms early on and establish mechanisms for reporting, and early warning;

— emergency response plans;

— vaccination plans; and

— Education in infectious disease testing and best safety practices shall be conducted.

4.4.2 Mental health

Measures to address psychosocial risks among healthcare workers shall be implemented by the healthcare organization.

5 Quality assurance

5.1 Responsibility

Healthcare organization should conform to the quality and competence requirements for the appropriate service format (medical laboratory and/or POCT) to ensure accurate diagnosis when providing pandemic response medical tests, even if the pandemic crisis becomes critically strained.

Note Healthcare organizations generally provide IVD tests at a medical laboratory (e.g., molecular diagnostic test) or a practice point near the patient (e.g., POCT) according to the complexity of the tests.

The medical laboratory to provide pandemic response testing services should adjust the capacity while maintaining the quality of the practice even under pressure of pandemic waves.

Note Healthcare organization may consider outsourcing the laboratory services that are not related to the pandemic from external service providers (6.1.1).

5.1.1 Qualification

Healthcare organization shall comply with the relevant qualification requirements for the relevant diagnostic services provided during a pandemic.

— Healthcare organization can refer to ISO 15189 for the qualification requirements.

— Quality standards, such as WHO's Laboratory Quality Standards,[6] etc., those reflect the requirements of ISO 15189 may also be utilized.

— If the country is eligible for relevant requirements or nationally recognized quality programs for clinical laboratories, it may also be utilized.

Where applicable, healthcare organization shall satisfy the additional requirements set by pandemic response authority to provide the pandemic response medical tests. For example, the country’s pandemic response authority may impose requirements, such as verifying the accuracy of the tests, before providing the pandemic response medical tests.

5.1.2 Risk Management

The medical laboratory shall apply a series of risk management measures to solve the problem or prevent the reoccurrence of the same problem according to the feedback.

Note See ISO 22367[7] for the application of risk management to medical laboratories.

5.2 Collaborative response with the stakeholders

5.2.1 Establishing collaborative network

Healthcare organization should participate in a collaborative network (the network) organized by national response agencies and relevant professional institutions. However, if a government-initiated collaborative network does not exist, healthcare organizations may participate in a network initiated by formal association(s) representing medical laboratories or related expert groups. Furthermore, if it is still not possible, healthcare organizations may establish a collaborative network between nearby healthcare organizations.

Note 1 In the early stages of a pandemic, healthcare organizations often suffer due to a lack of knowledge about the pandemic, such as the mode of transmission, virulence, and severity of disease particularly including the mortality rate, etc. From the perspective of the pandemic response medical tests, collaborative response with peer experts and relevant stakeholders is an effective way to ensure the quality and continuity of the services, although there is still likely to be some uncertainty during a pandemic.

Note 2 Collaboration and communication are crucial parts of public health emergency response.

5.2.2 Collaboration with pandemic response authorities

Healthcare organization shall establish effective communication with the pandemic response authority to receive up-to-date information in addressing the rapidly changing pandemic context.

5.2.3 Information exchange

Healthcare organization should actively share any information that can affect the testing procedure, characteristics of pandemic disease and testing quality with relevant stakeholders.

The information to be shared should include any unique feature, or requirements to implement an emergency use-IVD medical device.

5.3 Advisory committee

5.3.1 Structure

An advisory committee made up of experts who specialize in areas such as medical laboratory, supply chain, and relevant clinical fields, shall be established within the healthcare organization or the network (See 5.2.1) to ensure the quality of pandemic response medical tests.

In case where establishing an advisory committee for the purpose of diagnostic surge management is not possible, any existing committee within the healthcare organization or the network may take the role of the advisory committee.

5.3.2 Role

5.3.2.1 General

The advisory committee should perform the activities listed in sections 5.3.2.2 to 5.3.2.8, among others, to ensure the quality of the tests.

The advisory committee should provide relevant information and advice to the healthcare organization's top management.

5.3.2.2 Guideline

The advisory committee should provide guidelines to ensure the health and safety of healthcare workers in situations where the characteristics of diseases in the early stages of the pandemic are uncertain.

5.3.2.3 Training

The advisory committee should provide the necessary education to relevant healthcare workers to ensure safety against infection and the quality of the tests.

5.3.2.4 Prioritization of diagnostic tests

The advisory committee should advise to prioritize diagnostic testing strategy to achieve optimal outcomes based on factors such as the availability of resources, TAT, diagnostic demand, and diagnostic performance.

5.3.2.5 Reviewing performance of emergency use-IVD medical devices

The advisory committee should evaluate the performance of IVD medical devices approved by accelerated regulatory pathway in real-world settings.

Note Some example methods for the evaluation include utilizing a qualified medical laboratory within the network or an independent laboratory to conduct experimental procedures for all available emergency use-IVD medical devices in the market. This is particularly useful for identifying product-specific experimental tips or weaknesses.

5.3.2.6 Sharing of information and experience

The advisory committee should share experiences related to the provision of pandemic response testing services to relevant stakeholders.

Communication platforms (e.g., conference, newsletter, website, helpdesk) can share ongoing technical experiences and information accumulated in pandemic response testing services to ensure an accurate diagnosis. The advisory committee should evaluate the reliability of any information related to the pandemic response medical tests before officially posting the data.

All experience and information that can help with the implementation of the testing procedures, gathered during the performance review of emergency use-IVD medical devices (See 5.3.2.4), shall be provided to medical laboratories.

5.3.2.7 Advice on ensuring test reliability

The advisory committee should provide recommended measures to ensure the reliability of diagnostic tests for pandemic response.

Providing necessary guidance to facilitate the process of providing pandemic response medical tests on a large scale in a timely and accurate manner.

5.3.2.8 Scientific case review of abnormal test results

The advisory committee should participate in scientific case reviews for certain test results from IVD medical devices in the case where there have been suspected a medical device adverse event.

Note 1 The results may vary depending on the time after exposure to the infectious agent, the condition of the sample, and the applied technology. In context of a pandemic, the quality of emergency use-IVD medical devices may progress continuously over time, and the accuracy of test results may also vary. However, for the general public who do not fully understand this, it can hamper the reliability of the pandemic response medical tests provided by healthcare organizations.

Note 2 The transparency of the review process is also important.

The advisory committee should investigate and provide rational solution for suspicious results, such as ambiguous or inconsistent results from the pandemic response medical tests.

5.3.2.9 Surveillance of emerging variants

The advisory committee should investigate and verify the possible new variants from the healthcare organization and inform the pandemic response authority.

5.3.3 Keeping up-to-date

Healthcare organization should be aware of any information provided by IVD manufacturers or related institutions such as pandemic response national authorities, relevant academic societies, etc.

Any information identified from scientific case reviews (5.3.2.7) should be fed back to the relevant IVD medical device manufacturer or the relevant medical laboratories so this information can be utilized to improve the product or the examinations in the future.

5.4 Emergency use-IVD medical devices

5.4.1 General

Healthcare organization may use emergency use-IVD medical devices approved through the accelerated regulatory pathways in the early phase of a pandemic when there are no available commercial IVD medical devices with formal regulatory approval.

5.4.2 Risk Awareness

Healthcare organization shall be conscious of the quality concern of the emergency use-IVD medical devices approved via an accelerated regulatory pathway during a pandemic to keep up with the increased demand.

Healthcare organization shall actively investigate, and report adverse events related to the emergency use-IVD medical devices. See ISO 15189:2022 6.4.6 and 6.6.6 for adverse event reporting of equipment, reagents, and consumables.

5.4.3 Organization's response

Healthcare organization shall establish response measures to overcome the risks related to emergency use-IVD medical devices.

Note See ISO/TS 5798:2022[8] and CLSI EP43-Ed1[9] for further detail on implementing medical tests using IVD medical devices, which have been approved via an accelerated regulatory pathway.

— Healthcare organization should secure well-trained and highly experienced experts to mitigate and overcome the risks that come with emergency use-IVD medical devices.

— Healthcare organization should enable those experts to share their experiences and knowledge of using emergency use-IVD medical devices with other laboratories, IVD manufacturers, and pandemic response authorities[10].

— Healthcare organization should include the advisory committee in establishing response measures to overcome the problems related to implementing emergency use-IVD medical devices.

5.4.3.1 Role of advisory committee

Medical laboratories should discuss any unexpected issues related to the examination procedure or testing results with the advisory committee. The advisory committee should share the information gained from this process with medical laboratories and relevant IVD manufacturers.

5.4.3.2 Quality assessment measures

Healthcare organization should establish a series of quality monitoring measures (e.g., internal quality control (IQC) and external quality assessment (EQA) programs) for the pandemic response medical tests.

Note If there is no EQA program available, an inter-laboratory comparison with designated reference laboratories can be used as an alternative.

Healthcare organization should collaborate with the manufacturers to improve the quality of relevant IVD medical devices which have been approved via the accelerated regulatory pathway to ensure an accurate diagnosis.

5.4.3.3 Clinical performance evaluation

Healthcare organization can contribute to the quality improvement of IVD medical devices by participating in the clinical performance evaluation of IVD medical devices, reporting medical device adverse events to the manufacturers, etc.

5.4.3.4 Monitoring the emergence of new variants of pathogen

Healthcare organization should monitor any possible emergence of new variants of pathogens.

5.4.3.5 Information sharing

Healthcare organization shall provide information related to the quality of the emergency use-IVD medical devices and any significant findings from their testing the relevant IVD manufacturers. Useful feedback can

help to reduce the risks and improve the quality and competence of both medical laboratories and relevant IVD medical devices. Useful feedback includes, but is not limited to:

— issues observed during validation or verification processes of emergency use-IVD medical devices;

— issues observed during IQC processes;

— issues observed during EQA or inter-laboratory comparison processes;

— issues discovered in the processes of diagnostic service delivery, such as specimen collection, transfer, and examination;

— issues drawn in the scientific case review process (5.3.2.7); and

— information on suspected emergence of variant pathogens and issues observed in the detection of variants by emergency use-IVD medical devices.

The information generated in the medical laboratory may be utilized for public purposes, such as epidemiological investigations and monitoring of the emergence of variant pathogens and may need to comply with the national laws and relevant regulations.

6 Response to the surge in diagnostic demand

6.1 Strategy to maximizing workforce

6.1.1 Outsourcing test items

Healthcare organization should consider outsourcing test items if needed. This approach makes it possible to secure more workers who can perform the pandemic response medical tests.

Note 1 See ISO 15189:2022 6.8 for externally provided products and services when healthcare organization considers outsourcing the test items.

Note 2 See ISO 7101:2023 8.8 for supplies and services from external providers.

6.1.2 Reallocation of tasks

Healthcare organization should consider procuring a list of staff who have experience conducting medical tests for infectious diseases and cross-trained staff (4.3.1), especially molecular diagnostic tests, even if they are currently engaged in other tasks. They can be a crucial reserve for medical laboratory staffing when the demands for medical staff outweigh the current number of available staffs.

6.2 Strategy to maximize capacity to conduct diagnostic tests

6.2.1 Point-of-care testing (POCT)

Healthcare organization may consider introducing POCT. Before implementing a POCT, the healthcare organization shall review the trade-off between the risk of false-positive or false-negative results and the convenience of the test.

6.2.2 Pooled sample molecular testing

Healthcare organization should consider implementing pooled sample molecular testing in the medical laboratory. Before introducing pooled sample testing, the medical laboratory shall confirm the clinical performance (e.g., clinical sensitivity, clinical specificity) of the pooled sample tests to be introduced.

When the pooled sample method is utilized, the organization shall include the information in test report.

6.2.3 Introduction of automated system

Healthcare organization should consider implementing an automated system for pandemic response medical tests, as a full automation system for molecular tests can decrease the manual processing time required. As a result, this can increase the number of tests checked/reviewed while maintaining high accuracy.

6.2.4 Utilization of non-medical laboratories

Healthcare organization should not request the pandemic response testing to non-medical laboratories. However, when in the extreme surging demand, the pandemic response testing can be requested to non-medical laboratories which are being oversighted by qualified medical laboratory or laboratory experts. In such cases, the referring healthcare organization shall be responsible for the quality of pandemic response diagnostic tests requested to non-medical laboratories.

Note During a pandemic, some non-healthcare institutions such as pharma companies and academic laboratories have collaborated to provide pandemic response testing services and to scale up pandemic response medical testing capacity rapidly[11,12].

Bibliography

[1] Cabrera, C., et al., 2022. Systematic Approach to Address Early Pandemic's Diagnostic Unmet Needs. Front. Microbiol.,, **13**. Available From: https://doi.org/10.3389/fmicb.2022.910156

[2] US Food and Drug Administration. (US FDA), 2021. South Korea's Response to COVID-19. Available From: https://www.fda.gov/media/149334/download

[3] Park, J. and E. Chung, 2021. Learning from past pandemic governance: Early response and Public-Private Partnerships in testing of COVID-19 in South Korea. World development, **137**: p. 105198-105198. Available From: https://doi.org/10.1016/j.worlddev.2020.105198

[4] Chuang, H.N., et al., 2022. Laboratory Surge Response to the COVID-19 Pandemic: An Incident Command System Approach. J Multidiscip Healthc, **15**: p. 1083-1088. Available From: https://doi.org/10.2147/jmdh.S358096

[5] World Health Organization (WHO). 2022. Strategic preparedness, readiness and response plan to end the global COVID-19 emergency in 2022. Available From: https://apps.who.int/iris/bitstream/handle/10665/352861/WHO-WHE-SPP-2022.1-eng.pdf?sequence=1

[6] World Health Organization (WHO). 2011. Laboratory Quality Standards and their Implementation. Available From: https://apps.who.int/iris/bitstream/handle/10665/206927/9789290223979_eng.pdf?sequence=1&isAllowed=y

[7] ISO 22367:2020, *Medical laboratories — Application of risk management to medical laboratories*

[8] ISO/TS 5798:2022, *In vitro diagnostic test systems — Requirements and recommendations for detection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) by nucleic acid amplification methods*

[9] CLSI EP43-Ed1:2021, *Implementing a Laboratory Test Under Emergency Use Conditions, 1st Edition*

[10] Shin, H.-S., et al., 2021. National Academy of Medicine of Korea (NAMOK) key statements on COVID-19. Journal of Korean Medical Science, **36**(41). Available From: https://doi.org/10.3346/jkms.2021.36.e287

[11] Aisyah, D.N., et al., 2021. Laboratory Readiness and Response for SARS-Cov-2 in Indonesia. Frontiers in public health, **9**. Available From: https://doi.org/10.3389/fpubh.2021.705031

[12] Conor Hale. 2020. GSK, AstraZeneca to launch COVID-19 testing lab at University of Cambridge. Accessed on: 2024 10 Oct. Available From: https://www.fiercebiotech.com/medtech/gsk-astrazeneca-to-launch-covid-19-testing-lab-at-cambridge-university