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Healthcare organization management — Pandemic response — Requirements for surging diagnostic demand

Management des organisations de soins de santé — Réponse en cas de pandémie — Exigences liées à la demande croissante en matière de diagnostic

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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.

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Introduction

During the COVID-19 pandemic, the demand for diagnostic testing increased 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 resource capacity and supply chain management, not only within diagnostic laboratories but also entire healthcare organizations. The increased workload on existing limited numbers of laboratory personnel and skilled professionals to perform diagnostic testing can lead to overworking and burn-out of staff, which can impact the accuracy of testing and the turn-around time (TAT) of test results.

Lengthy TAT, in turn, leads to overcrowding in units for persons under evaluation for highly infectious diseases. Similarly, this generates significant delays in emergency care for patients with infectious pandemic symptoms and patients under investigation for non-pandemic-related symptoms (e.g. acute stroke care and 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 testing 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 prolonging the length of hospital stays[3].

The solution to the above challenges should be to increase laboratory capacity. However, increasing the laboratory capacity abruptly is not feasible within a short time frame, which can lead 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 the capabilities for responding to surging diagnostic demand in upcoming pandemics. This document is based on the experiences of different countries in previous pandemics, particularly, COVID-19, including lessons learnt. It suggests innovative approaches to meet the surging demand for medical testing services that can occur in any future pandemic. A standardized framework for healthcare organizations to follow during a pandemic can facilitate a more effective pandemic response and can enhance public trust in healthcare organizations' response to the pandemic.

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Healthcare organization management — Pandemic response — Requirements for surging diagnostic demand

1 Scope

This document outlines requirements 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:

— mitigation of threats encountered in providing diagnostic services during a pandemic;

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

— possible response measures to the surge in diagnostic demand.

This document does not cover the specific procedures involved in 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), experimental procedures and the quality management systems of medical laboratories. Furthermore, this document does not address the pandemic responses related to the medical treatment of infected patients in care units (e.g. emergency unit and in-patient unit) and the transferring of confirmed patients within 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 15189:2022, *Medical laboratories — Requirements for quality and competence*

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.

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