



BSI Standards Publication

Health informatics — Guidelines for exchanging data generated by portable polymerase chain reaction (PCR) devices for point-of-care testing (POCT) between screening centre and clinical laboratory

National foreword

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A list of organizations represented on this committee can be obtained on request to its committee manager.

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Health informatics — Guidelines for exchanging data generated by portable polymerase chain reaction (PCR) devices for point-of-care testing (POCT) between screening centre and clinical laboratory

Informatique de santé — Lignes directrices pour l'échange de données générées par des dispositifs portables de réaction de polymérisation en chaîne (PCR) pour les examens de biologie médicale délocalisée (EBMD) entre le centre de dépistage et le laboratoire clinique

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Foreword

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This document was prepared by Technical Committee ISO/TC 215, *Health informatics*.

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Introduction

The COVID-19 pandemic has highlighted the need to establish robust social infrastructures capable of conducting high-volume diagnostic tests and swiftly identifying confirmed cases at an early stage. However, traditional clinical diagnostic testing typically involves prolonged result turnaround times, especially in clinical laboratories handling hundreds of specimens daily.

Facing this challenge, innovative vendors have developed portable point-of-care testing (POCT) devices capable of conducting real-time PCR testing specifically for diagnosing infectious diseases. These advancements facilitate swift and accurate detection of infectious pathogens.

The problem with this method is there are no technical documents that explain how to operate portable real-time PCR devices in the POCT environment and transmit their results into information systems. This is because traditional laboratory-based specifications do not cover specific use cases, such as PCR devices outside of clinical laboratories.

The objectives of this document are to identify specialized use cases for real-time PCR testing systems utilizing portable POCT devices in the POCT environment and to define datasets pertaining to result information. By using the guidelines in this document, the portable real-time PCR systems can achieve not only the interoperability with laboratory information systems, but also an easy integration across them without making additional efforts.

