Technical Specification

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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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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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

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

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.

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1 Scope

This document identifies specialized use cases related to the information exchange between clinical laboratories and portable polymerase chain reaction (PCR) devices designed for real-time testing to diagnose infectious diseases.

This document introduces the portable PCR devices for point-of-care testing (POCT). Characteristic and differentiated use cases of these devices are listed separately from those that occur with portable POCT devices in existing clinical laboratory.

This document is applicable, but not limited, to the following use cases of portable PCR devices for POCT:

a) general test;

b) reconciliation of patient information;

c) cancel and rerun test;

d) on-site quality control (QC) process.

This document also provides guidelines on how to represent and exchange results from portable PCR testing devices in a POCT environment applicable to the use cases described above.

This document is not intended to provide guidelines relating to traditional diagnostic testing results within a clinical laboratory and does not cover cybersecurity aspect.

2 Normative references

There are no normative references in this document.

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
COVID-19
infectious disease caused by the new coronavirus SARS-CoV-2 discovered in 2019

[SOURCE: ISO/PAS 45005:2020, 3.6]

3.2
point-of-care testing
POCT
testing performed near or at the site of a patient, with the result leading to possible change in the care of the patient

Note 1 to entry: Adapted from ISO 15189:2022, 3.22.

3.3
polymerase chain reaction
PCR
enzymatic procedure which allows in vitro amplification of DNA

[SOURCE: ISO 22174:2024, 3.1.17]

3.4
real-time PCR
method which combines *PCR* (3.3) and fluorescent probe detection of amplified product in the same reaction vessel

[SOURCE: ISO 17822:2020, 3.40]

3.5
quality control
QC
system of maintaining standards in manufactured products by testing a sample of the output against the specification

4 Use cases

4.1 General

Clause 4 describes the specialized use cases and interactions related to data flow between the portable PCR devices used in the screening centre and laboratory information systems.

4.2 General test

4.2.1 Scenario

This subclause delineates a scenario and its sequence for transmitting test results from portable PCR devices to the laboratory information system under the general testing case.

— A patient has COVID-19 symptoms and visits a nearby screening centre. A healthcare professional at the screening centre collects specimens of the patient and conducts a real-time PCR test utilizing a portable device on-site. The test result is positive. The real-time PCR system transmits results to the laboratory information system. Subsequently, the patient promptly returns home and self-quarantines for two weeks.

4.2.2 Sequence

Figure 1 shows the sequence of general test, which includes the following steps:

1) Request test: request a real-time PCR test to the screening centre from internal/external professionals and systems.

2) Confirm test: transmit/enter test information to a portable real-time PCR system and wait to perform the test.

3) Analysing: perform the test to analyse the specimen in accordance with the requested test information.

4) Send results: send the test result to a laboratory information system.

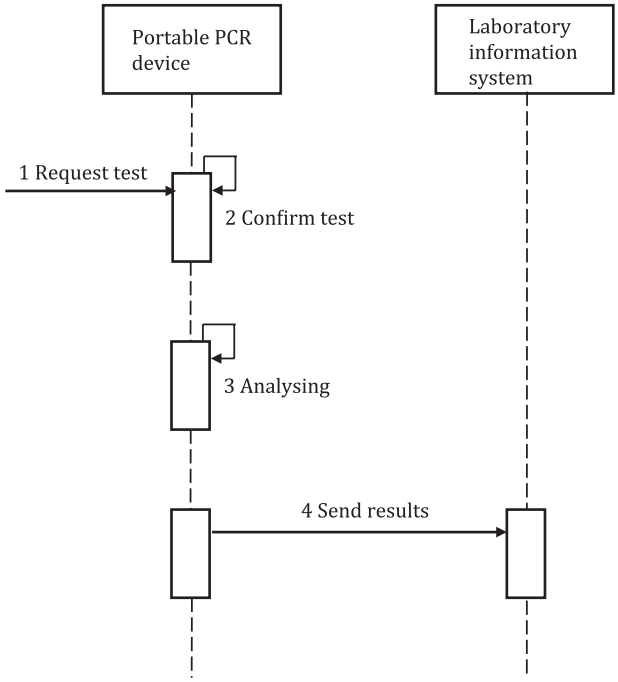

Figure 1 — Sequence diagram of general test

4.3 Reconciliation of patient information

4.3.1 Scenario

In the context of rapid screening test utilizing portable real-time PCR devices, various exceptional situations can occur in contrast to typical laboratory procedures. A representative use case can be reconciliation procedure due to insufficient patient information.

— At the screening centre, to quickly perform numerous real-time PCR tests, the person in charge of tests inputs an official identifier into each patient information without other demographic details. Once the tests are completed, the screening centre sends the test results to the laboratory information system without including patient demographics. In the laboratory information system, a data validator requests the patient's demographics from a hospital by using their official identifier and enters them into each patient information.

— An unconscious patient is transported to a nearby hospital by ambulance. During transit, a paramedic takes the patient's specimen. Upon the patient's arrival at the hospital, an immediate real-time PCR is conducted to swiftly screen for infectious diseases. During this procedure, the hospital assigns a temporary identifier to the patient. The test outcome shows a negative result. The real-time PCR system sends results to the laboratory information system. When the patient regains consciousness, their identity is confirmed, and the temporary patient information in the test results is rectified and updated to reflect the accurate details.

4.3.2 Sequence

Figure 2 shows the sequence of reconciliation of patient information, which includes the following steps:

1) Request test with insufficient patient information. Patient information can be empty or only identifiers have been entered.

2) Issue a temporary patient identifier: before confirming the test, temporary identifiers such as a waiting number should be issued to the patient if patient information is empty.

3) Confirm test: transmit/enter test information to a portable real-time PCR system and wait to perform the test.

4) Analysing: perform the test to analyse the specimen in accordance with the requested test information.

5) Aggregate and fill missing patient information on the PCR system side:

   a) Send missing patient info: the PCR system should input patient demographics and official identifiers such as the social security number or medical record number (MRN) into patient information. Patient information holders, such as patients themselves, hospitals or organizations can provide relevant information.

   b) Fill missing patient info: the PCR system fills in the patient information provided by patient information holders.

   c) Send results: send the test result including patient information to a laboratory information system.

6) Aggregate and fill missing patient information on the laboratory information system (LIS) side:

   a) Send results: send the test results either without patient information or with only temporary patient identifier to a laboratory information system.

   b) Send missing patient info: patient information holders, such as patients themselves or hospitals, organizations can provide relevant information.

   c) Fill missing patient info: the LIS fills in the patient information provided by patient information holders, and both patient information and test results should be merged and stored in the LIS.

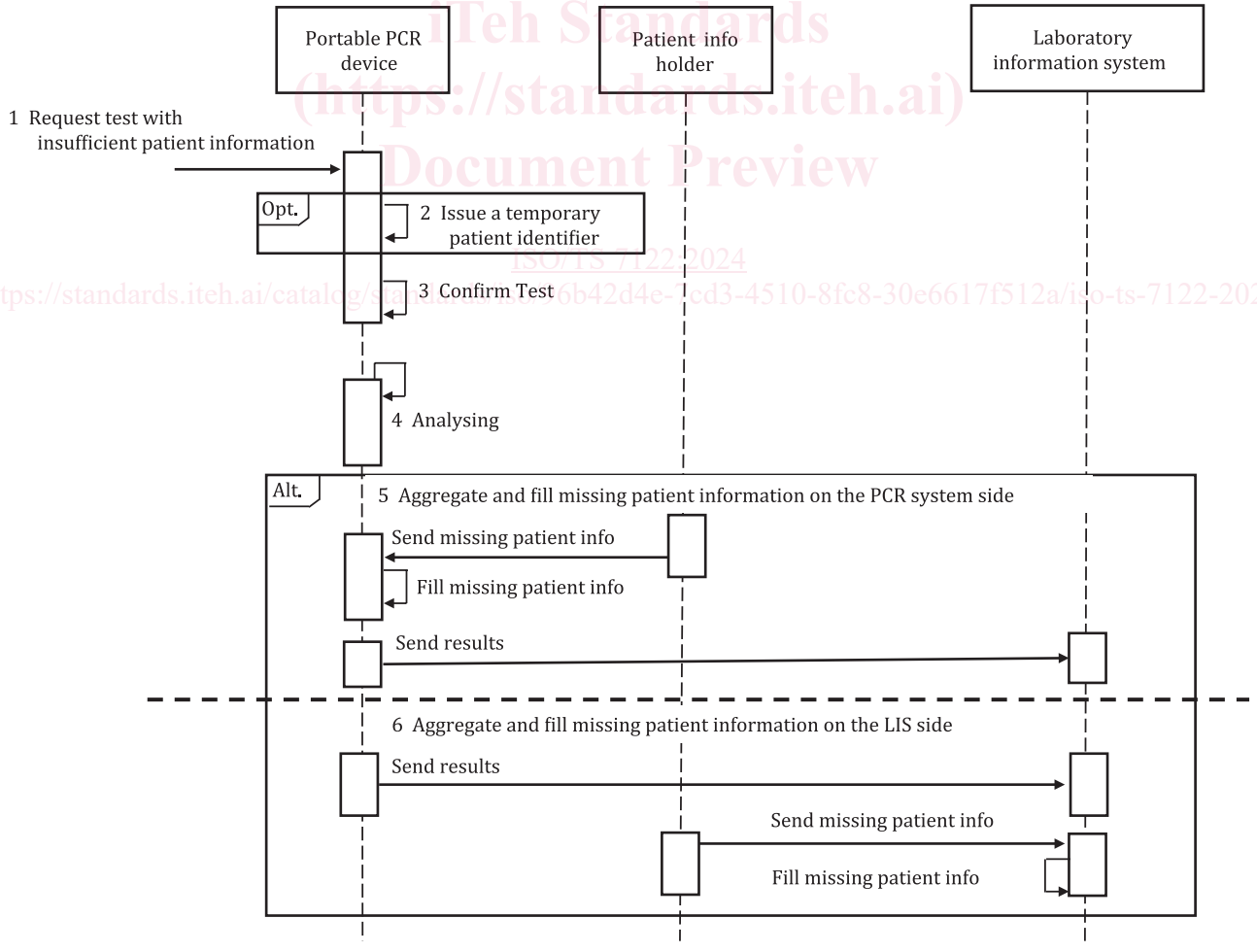

Figure 2 — Sequence diagram of reconciliation of patient information