Technical Specification

ISO/TS 7122

First edition
2024-12

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

Reference number
ISO/TS 7122:2024(en)

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Published in Switzerland

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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.

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

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.

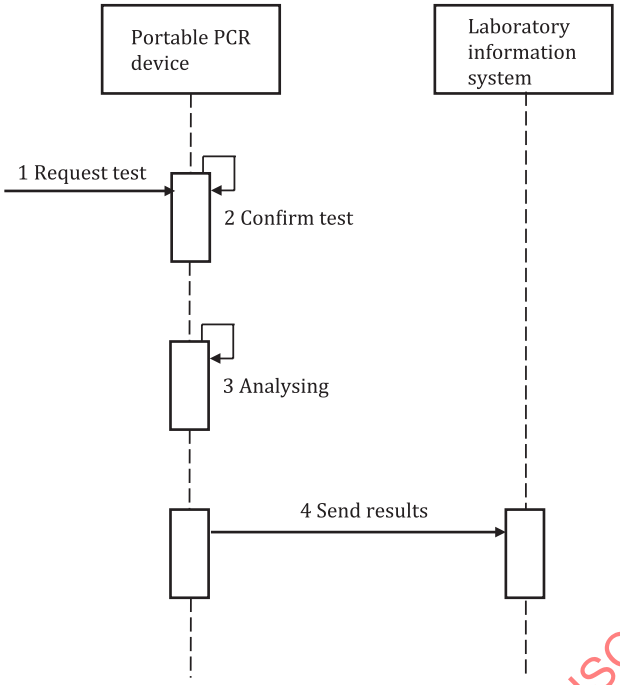

Figure 1 — Sequence diagram of general test

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.

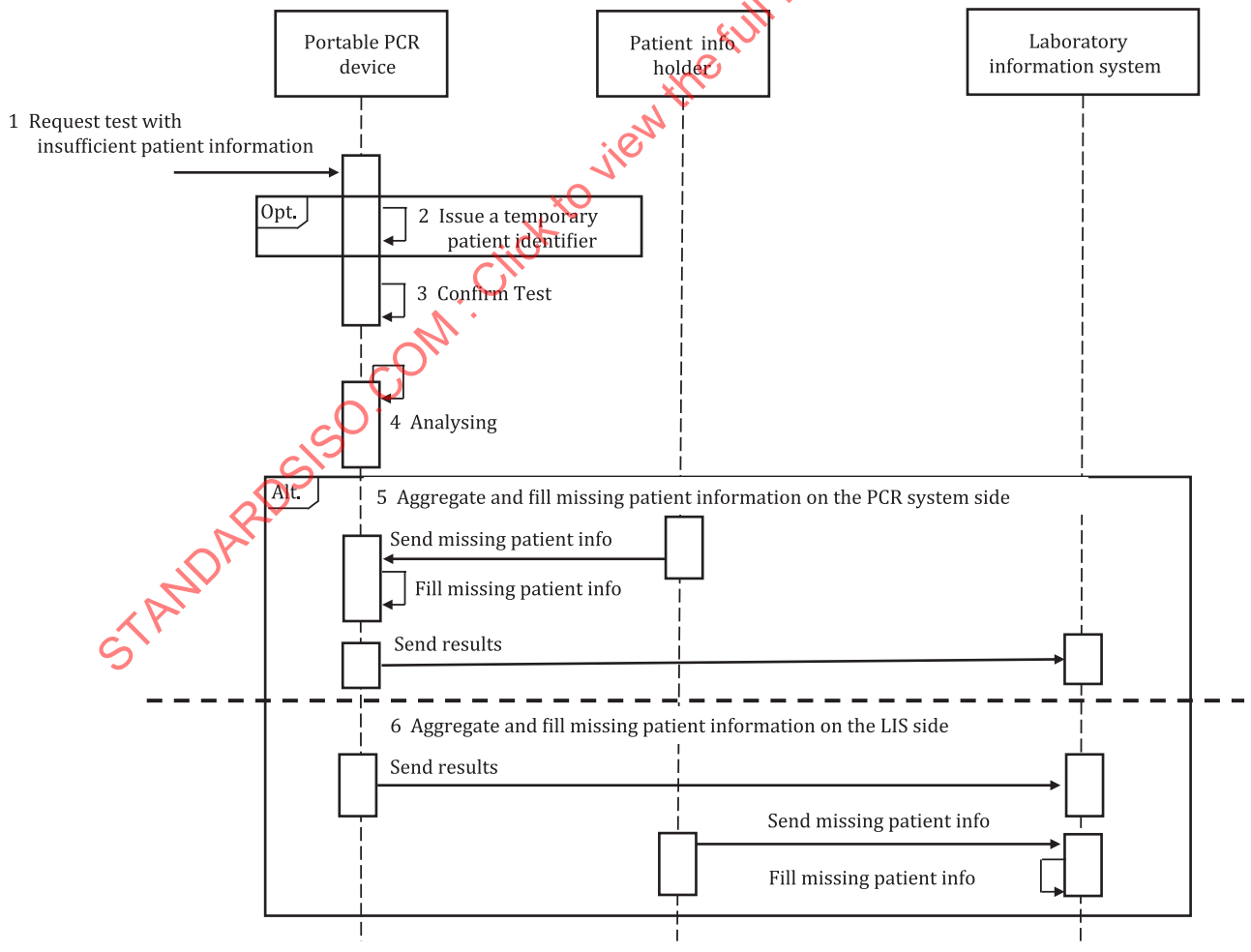

Figure 2 — Sequence diagram of reconciliation of patient information

4.4 Cancel and rerun

4.4.1 Scenario

Cancellations and restarts can occur due to various environmental factors when conducting tests with portable PCR testing device at the screening centres, for example in the following scenarios.

— A real-time PCR test is cancelled because the specimen stored at the screening centre has expired and the centre failed to maintain specimen temperature.

— A specimen collection container stored at a screening centre is damaged and its identification tag becomes contaminated. It is impossible to identify specimens, so the succeeding real-time PCR tests are cancelled.

— A real-time PCR test is completed normally at a screening centre, but the same test is rerun to improve reliability.

4.4.2 Sequence

Figure 3 shows the sequence of cancel and rerun, 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.

   a) Option: cancel before analysing: cancel the process before the test.

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

   a) Option: cancel before analysing: cancel the process during the test.

   b) Option: rerun the test after cancel or complete the test.

4) Send results: send the test result to a laboratory information system. The information should include “cancel” or “rerun” information if the test was cancelled or rerun.

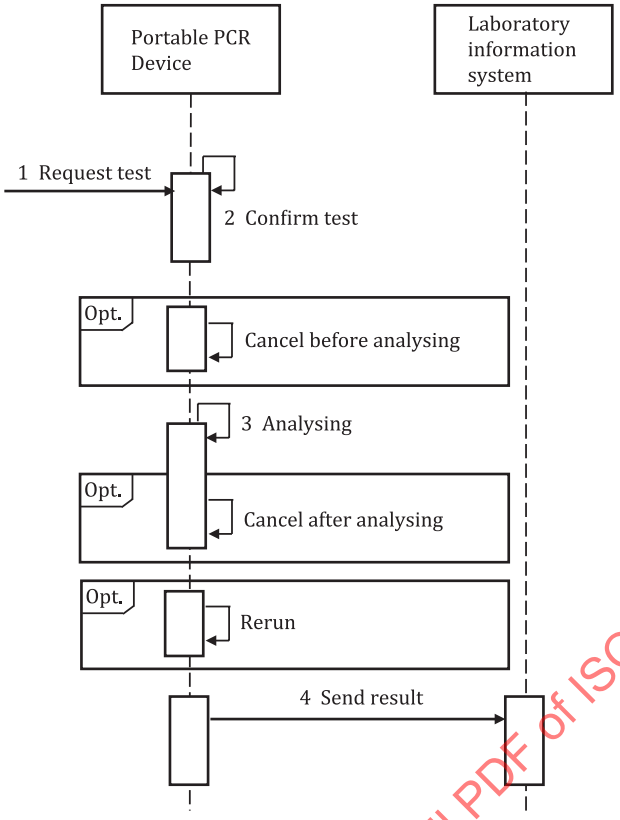

Figure 3 — Sequence diagram of cancel and rerun

4.5 On-site quality control (QC)

4.5.1 Scenario

Screening centres for infectious diseases, often located outside healthcare facilities, require frequent quality control (QC) process due to unstable temperatures, locations or electricity. In such unstable environments, unpredictable QC can be required. This subclause presents use cases for on-site QC under these conditions.

— A real-time PCR test is stopped because the power supply of the screening centre is unstable. After fixing the power issue, QC is performed to inspect the device and rerun the test.

— The screening centre does a QC every day before starting their work because the environment is unstable. QC is performed to check the work process before opening the screening centre.

— In accordance with the work process defined by the screening centre, QC is performed to prevent malfunction of a portable real-time PCR system after testing a certain number of specimens.

4.5.2 Sequence

Figure 4 shows the sequence of on-site QC, which includes the following steps:

1) Request QC: request and clearly indicate that this is a QC test, not a general test. The QC can be requested due to the electric power, unstable environment such as temperature of screening centre or characteristic of PCR process outside of healthcare facilities.

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

3) Perform QC: analyse the QC specimen according to the requested QC test information.

4) Send QC Result: send the QC result to a laboratory information system.

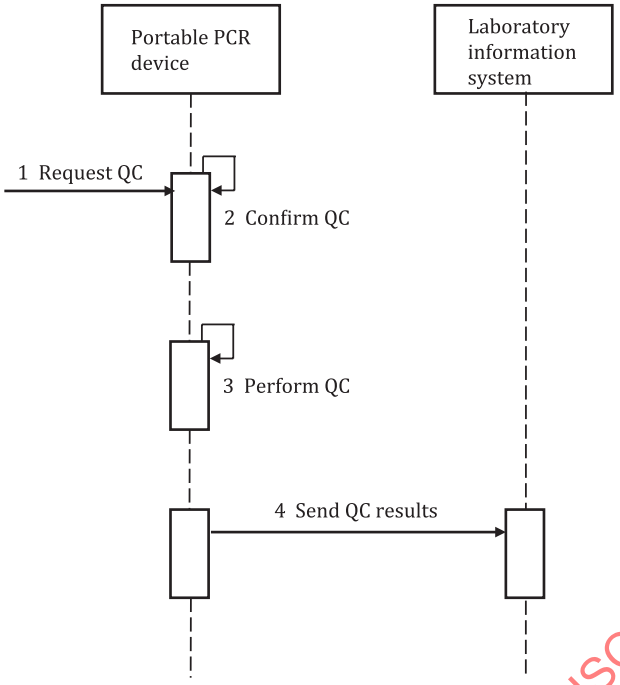

Figure 4 — Sequence diagram of on-site quality control (QC)

5 Dataset

5.1 Data concept

The core data generated from a portable POCT device can be structured as shown in Figure 5. Concepts not included in the data concept provided in this clause can adopt a general data model such as HL7 V2 or HL7 FHIR.

The portable PCR devices should transmit information to the laboratory information system using the data implementation methods defined in HL7 V2 or HL7 FHIR. Data implementation methods from other standards can also be used. Compliance with the data model provided in this clause allows for the use of HL7 V2, FHIR, or other standard methodologies.

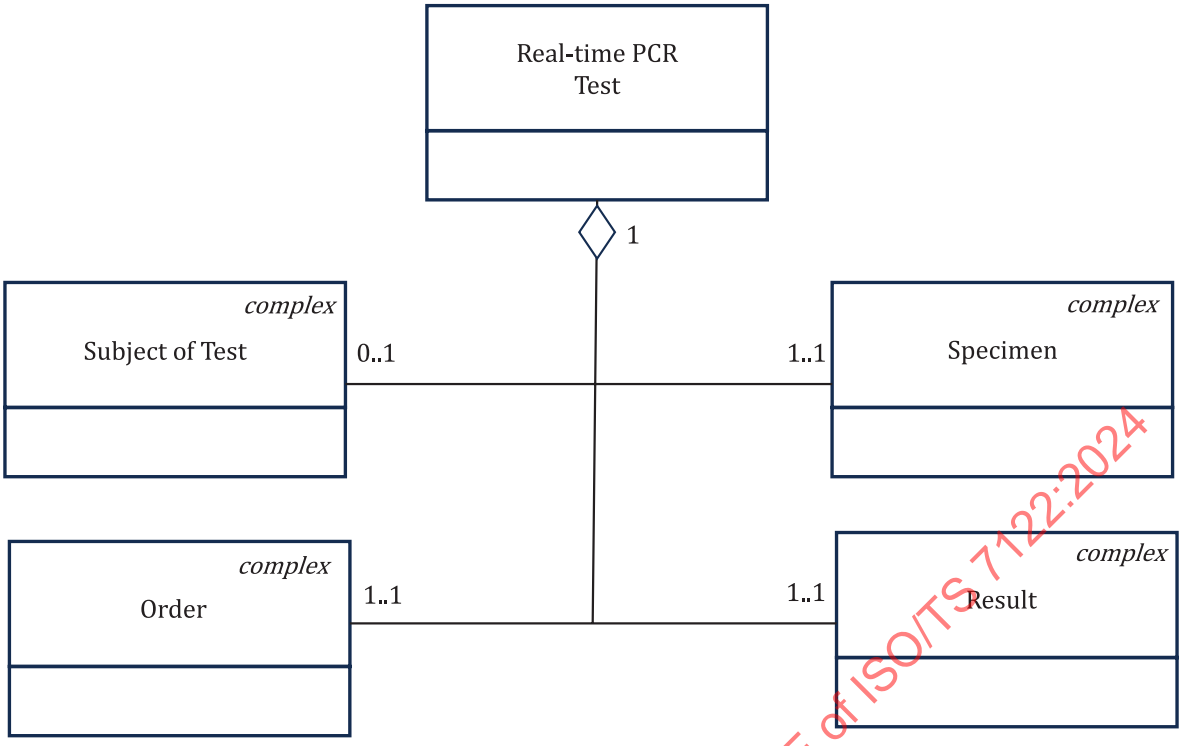

Figure 5 — Concept diagram of core data

5.2 Subject of Test

The Subject of Test is an object to represent the subject who is tested through real-time PCR devices. It can be optional since it may refer to a control solution for QC or an animal undergoing test.

The expression of "Subject of Test" is recommended to follow the data specification of "subject of care" as described in ISO/TS 22220. Considering the characteristics of a PCR testing environment utilizing portable devices, however, the following specification should be provided. It is possible to update subject of test data in hospital information systems, including LIS, using the data specified in ISO/TS 22220. This is not within the scope of this document.

The attributes which make up the Subject of Test object, the data types and the description of characteristics for each attribute are shown in Table 1.

Table 1 — Data fields of 'Subject of Test' object

No.	Attribute	Cardinality	Element	Description
1	ID	1..1	Data type	Identifier
			Description	An identifier for this subject of test.
			Classification	Required
2	IDType	1..1	Data type	Enumeration
			Description	The type of Identifier for subject of test.
			Classification	Required
			Enumeration values	usual | official | temp | secondary | old
3	Name	0..1	Data type	HumanName
			Description	A name associated with the subject of test, consisting of first name, middle name and last name.
			Classification	Optional
4	Telecom	0..1	Data type	String
			Description	A contact detail for the subject, such as a telephone number or an email address.
			Classification	Optional
5	Address	0..*	Data type	String
			Description	An address for the individual.
			Classification	Optional
6	Birthdate	0..1	Data type	DateTime
			Description	The date of birth of the individual.
			Classification	Optional
7	Gender	0..1	Data type	Code
			Description	The gender that the patient is considered to have for administration and record keeping purposes.
			Classification	Optional
			Terminology	Various codes can be adopted to represent gender, and the preferred code system is the HL7 Administrative Gender code defined in "http://hl7.org/fhir/administrative-gender".

5.3 Order

The Order is an object to represent the order that caused a real-time PCR test.

The attributes which make up the Order object, the data types and description of characteristics for each attribute are shown in Table 2.

Table 2 — Data fields of 'Order' object

No.	Attribute	Cardinality	Element	Description
1	Purpose	1..1	Data vype	Enumeration
			Description	It specifies the purpose of the portable real-time PCR system operation, such as general testing, quality control and/or calibration.
			Classification	Required
			Enumeration values	General | QC – True positive | QC – True negative | Calibration | Verifying calibration | ElectronicQC | DailyQC
2	Status	1..1	Data type	Enumeration
			Description	It specifies the status of the order, such as completed, cancelled and/or on-hold.
			Classification	Required
			Enumeration values	completed | cancelled | rerun | on-hold
3	ReasonOfStatus	1..1	Data type	Enumeration
			Description	It specifies the reason for the current status of the order. The reason is comprised of cancel reason, rerun reason and QC reason and so forth.
			Classification	Required
			Enumeration values	Routine | Device validation | System changed | Process validation | Calibration | Device Malfunction | Unstable Power | Specimen Damaged | Safety Issue | Cancellation | Result validation | Unknown
4	Source	0..1	Data type	String
			Description	The identifiers of the system that request the order.
			Classification	Optional
5	Destination	0..1	Data type	String
			Description	The identifiers of the system that receive the order.
			Classification	Optional

5.4 Specimen

The Specimen is an object to represent samples analysed in a real-time PCR device.

The attributes which make up the Specimen object, the data types and description of characteristics for each attribute are shown in Table 3.

Table 3 — Data fields of 'Specimen' object

No.	Attribute	Cardinality	Element	Description
1	SpecimenID	1..1	Data type	Identifier
			Description	It identifies specimens and should be unique between the source and destination systems.
			Classification	Required
2	Type	1..1	Data type	Code
			Description	It represents the type of specimen which can be blood, saliva, etc. The types of specimens used for quality control, not targeting living subject, can be control solutions and so forth.
			Classification	Required
			Terminology	Various codes can be adopted to represent type of specimen, and the preferred code system are the HL7 Specimen Type code defined in https://terminology.hl7.org/5.1.0/CodeSystem-v2-0487.html and LOINC[12].
3	Role	0..1	Data type	Code
			Description	It indicates the role of the specimen, such as testing, control specimen and calibrator.
			Classification	Optional
			Terminology	Various codes can be adopted to represent role of specimen, and the preferred code system is the HL7 Specimen Role code defined in "https://hl7.org/fhir/codesystem-specimen-role.html"
4	CollectedTime	0..1	Data type	DateTime
			Description	It specifies the timestamp of specimen collection or sampling.
			Classification	Optional

5.5 Result

The Result is an object to represent the results analysed by a real-time PCR device.

The attributes which make up the Result object, the data types and description of characteristics for each attribute are shown in Table 4.

Table 4 — Data fields of 'Result' object

No.	Attribute	Cardinality	Element	Description
1	TestID	1..1	Data Type	Identifier
			Description	It identifies tests and should be unique between the source and destination systems.
			Classification	Required
2	TestType	1..1	Data Type	Code
			Description	It represents the type of test.
			Classification	Required
			Terminology	Various codes can be adopted to represent type of test, and the preferred code system is the LOINC.
3	Status	0..1	Data Type	Enumeration
			Description	It indicates the rerun status for the result, such as original or rerun.
			Classification	Optional
			Enumeration Values	Original | Rerun | Cancelled | QC | Unknown
4	AnalyseTime	0..1	Data Type	DateTime
			Description	It specifies the timestamp of when the specimen is analysed by the real-time PCR devices.
			Classification	Optional
5	TestValue	0..1	Data Type	Numeric
			Description	It specifies the numerical results from analysis by real-time PCR devices.
			Classification	Conditional[a]
6	Units	0..1	Data Type	Code
			Description	It specifies the unit of measurement when the test results are numeric.
			Classification	Conditional[a]
			Terminology	Various codes can be adopted to represent units of measurement, and the preferred and representative code system is the UCUM[13].
7	Interpretation	0..1	Data Type	Code
			Description	It specifies the status when the test results are qualitative such as positive or negative, rather than numerical.
			Classification	Conditional[b]
			Terminology	Interpretation code can be adopted various codes to represent interpretation of measurement, and the preferred code system is the HL7 Observation Interpretation code defined in "https://terminology.hl7.org/5.1.0/CodeSystem-v3-ObservationInterpretation.html".

[a] Required if results are presented in numeric format, otherwise optional.

[b] Required if qualitative results are presented (e.g. positive or negative), otherwise optional.

6 Data guidelines for use cases

6.1 General test use case

6.1.1 General

The guidelines in 6.1 are provided only for attributes that should be specifically considered for the “General test” use case.

6.1.2 Subject of Test

a) ID: in the case of a general test, the ID of the subject of test should be the official ID used by healthcare organization or an official identification.

b) IDType: in the case of a general test, the IDType should be set to “official” or “usual”.

c) Name: this attribute should be filled in if provided.

d) Telecom: this attribute should be filled in if provided.

e) Address: this attribute should be filled in if provided.

f) Birthdate: this attribute should be filled in if provided.

g) Gender: this attribute should be filled in if provided.

6.1.3 Order

a) Purpose: in case of a general real-time PCR, this attribute should be set to “General”.

b) Status: in case of a general real-time PCR, this attribute should be set to “completed”.

c) ReasonOfStatus: in case of a general real-time PCR, this attribute should be set to “Routine”.

d) Source: if a real-time PCR test is requested and taken within a screening centre, these elements should be the same as the Destination attribute value.

e) Destination: if a real-time PCR test is requested and taken within a screening centre, these elements should be the same as the Source attribute value.

6.1.4 Specimen

Role: in case of a general real-time PCR, this attribute should be set to “p” if HL7 Specimen Role code is adopted.

6.1.5 Result

a) Status: in case of a general real-time PCR, this attribute should be set to “Original”.

b) TestValue: this attribute is required if the results are presented in numeric format.

c) Units: this attribute is required if TestValue attribute exists.

d) Interpretation: this attribute is required if the results are presented in qualitative results such as positive or negative.