

QIAstat-Dx[®] LIS Interface Specification

QIAstat-Dx Respiratory Panel Plus



IVD

REF

691224

R1

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Purpose and Scope

Purpose

The purpose of this document is to specify the exchange information of the QIAstat-Dx Respiratory Panel Plus with an external computer system.

This external system, which plays the role of the Automation Manager, is typically a Laboratory Information System (LIS) or a laboratory Data Manager computer system. In this document, the external system will be generically referenced as LIS.

The protocol used for the information exchange is the international Health Level Seven (HL7), 2.5. This document describes the content that is specific for this panel and is exchanged within messages.

Scope

This document describes the exchange information for any version of the QIAstat-Dx Respiratory Panel Plus ADF and any version of the Application Software starting from 1.4 with an external LIS.

Definitions and acronyms

Table 1. Definitions and acronyms

Word or acronym	Definition
ADF	Assay Definition File
HL7	International (Health Level Seven)
LIS	Laboratory Information System
LOINC	Logical Observation Identifiers Names and Codes
OBX	Observation/Result Segment. It is the smallest indivisible unit of a report message to the HIS/LIS.
SNOMED	Systematized Nomenclature of Medicine

Coding Systems

The information exchanged uses 3 different coding systems: STAT-DX, LOINC and SNOMED.

STAT-DX coding system

STAT-DX is a QIAGEN proprietary coding system. All information exchanged by the QIAstat-Dx system uses this coding system except for the result code.

The name of the assay is coded as **RPP** in the HL7 field OBR 4.1 Universal Service Identifier.

Example

```
OBR|1|||RPP|||20220513123347|20220513134437|||||||||||||F
```

The sample type is coded as indicated in the following table:

Table 2. Sample type

Specimen-type text 4.2	Specimen-type identifier 4.1
UTM	410

Example

```
SPM|1|414480707||410^UTM^STAT-DX|||||P
```

Analyte names and short names in HL7 are the alternate test name and the alternate test identifier, respectively.

Alternate test name OBX 3.5	Alternate test identifier OBX 3.4
Influenza A	Flu A
Influenza B	Flu B
Influenza A H1N1 pdm09	Flu A H1N1 pdm09
Human Coronavirus 229E	Cor 229E
Human Coronavirus OC43	Cor OC43
Human Coronavirus NL63	Cor NL63
Human Coronavirus HKU1	Cor HKU1
Parainfluenza virus 1	PIV1
Parainfluenza virus 2	PIV2
Parainfluenza virus 3	PIV3
Parainfluenza virus 4	PIV4
Influenza A H1	Flu A H1
Influenza A H3	Flu A H3
Human Rhinovirus/Enterovirus	RV/EV
Adenovirus	ADV

Alternate test name OBX 3.5	Alternate test identifier OBX 3.4
Respiratory Syncytial Virus	RSV
Human Metapneumovirus	hMPV
<i>Mycoplasma pneumoniae</i>	MP
<i>Bordetella pertussis</i>	BP
<i>Chlamydomphila pneumoniae</i>	CP
SARS-CoV-2	SARS-CoV-2

Example

OBX | 1 | CE | 76078-5^Influenza virus A RNA^LN^Flu A^Influenza A^STAT-DX | Flu
A | 260385009^NEGATIVE^SCT | | | | F | | | | administrator^Administrator | | 001298 | 20220513134437

LOINC coding systems

Analyte names and short names can also be transmitted using LOINC.

Test name OBX 3.2	Test identifier code OBX 3.1	Source
Influenza virus A RNA	76078-5	https://loinc.org/76078-5
Influenza virus B RNA	76080-1	https://loinc.org/76080-1
Influenza virus A H1 2009 pandemic RNA	77028-9	https://loinc.org/77028-9
Human coronavirus 229E RNA	88610-1	https://loinc.org/88610-1
Human coronavirus OC43 RNA	88626-7	https://loinc.org/88626-7
Human coronavirus NL63 RNA	88618-4	https://loinc.org/88618-4
Human coronavirus HKU1 RNA	88604-4	https://loinc.org/88604-4
Parainfluenza virus 1 RNA	76084-3	https://loinc.org/76084-3
Parainfluenza virus 2 RNA	76085-0	https://loinc.org/76085-0
Parainfluenza virus 3 RNA	76086-8	https://loinc.org/76086-8
Parainfluenza virus 4 RNA	76087-6	https://loinc.org/76087-6
Influenza virus A H1 RNA	77026-3	https://loinc.org/77026-3
Influenza virus A H3 RNA	77027-1	https://loinc.org/77027-1
Rhinovirus+enterovirus RNA	88721-6	https://loinc.org/88721-6
Adenovirus DNA	76070-2	https://loinc.org/76070-2
Respiratory syncytial virus RNA	76089-2	https://loinc.org/76089-2
Human metapneumovirus RNA	77024-8	https://loinc.org/77024-8
<i>Mycoplasma pneumoniae</i> DNA	88720-8	https://loinc.org/88720-8
<i>Bordetella pertussis</i> DNA	43913-3	https://loinc.org/43913-3
<i>Chlamydomphila pneumoniae</i> DNA	88718-2	https://loinc.org/88718-2
SARS-CoV-2	94500-6	https://loinc.org/94500-6

Example

OBX | 1 | CE | 76078-5^Influenza virus A RNA^LN^Flu A^Influenza A^STAT-DX | Flu
A | 260385009^NEGATIVE^SCT | | | | F | | | | administrator^Administrator | | 001298 | 20220513134437

SNOMED coding system

For laboratory-based reporting, SNOMED is recommended for OBX-5 when results are coded and CE data types are used. The following table is a list of SNOMED codes for qualitative results.

Observation value OBX 5	Qualitative or quantitative result OBX 5.1	Value shown on the instrument
10828004	POSITIVE (qualifier value)	Positive
260385009	NEGATIVE (qualifier value)	Negative
373068000	UNDETERMINED (qualifier value)	Invalid
42425007	EQUIVOCAL (qualifier value)	Equivocal

FluA rule

There is a rule that needs to be taken into consideration for this panel, where some analytes can be reported as equivocal while Influenza A will not be reported at all. This depends on the internal control (IC) and the Influenza A results. This is described in the following table:

IC	FluA	H1	H3	H1N1
Failed	UNDETERMINED	UNDETERMINED	UNDETERMINED	UNDETERMINED
Failed	UNDETERMINED	UNDETERMINED	UNDETERMINED	EQUIVOCAL
Failed	UNDETERMINED	UNDETERMINED	EQUIVOCAL	UNDETERMINED
Failed	UNDETERMINED	UNDETERMINED	EQUIVOCAL	EQUIVOCAL
Failed	UNDETERMINED	EQUIVOCAL	UNDETERMINED	UNDETERMINED
Failed	UNDETERMINED	EQUIVOCAL	UNDETERMINED	EQUIVOCAL
Failed	UNDETERMINED	EQUIVOCAL	EQUIVOCAL	UNDETERMINED
Failed	UNDETERMINED	EQUIVOCAL	EQUIVOCAL	EQUIVOCAL
Failed	POSITIVE	UNDETERMINED	UNDETERMINED	UNDETERMINED
Failed	Positive, but not reported	UNDETERMINED	UNDETERMINED	POSITIVE
Failed	Positive, but not reported	UNDETERMINED	POSITIVE	UNDETERMINED
Failed	Positive, but not reported	UNDETERMINED	POSITIVE	POSITIVE
Failed	Positive, but not reported	POSITIVE	UNDETERMINED	UNDETERMINED
Failed	Positive, but not reported	POSITIVE	UNDETERMINED	POSITIVE
Failed	Positive, but not reported	POSITIVE	POSITIVE	UNDETERMINED
Failed	Positive, but not reported	POSITIVE	POSITIVE	POSITIVE
Passed	NEGATIVE	NEGATIVE	NEGATIVE	NEGATIVE
Passed	NEGATIVE	NEGATIVE	NEGATIVE	EQUIVOCAL
Passed	NEGATIVE	NEGATIVE	EQUIVOCAL	NEGATIVE
Passed	NEGATIVE	NEGATIVE	EQUIVOCAL	EQUIVOCAL
Passed	NEGATIVE	EQUIVOCAL	NEGATIVE	NEGATIVE
Passed	NEGATIVE	EQUIVOCAL	NEGATIVE	EQUIVOCAL
Passed	NEGATIVE	EQUIVOCAL	EQUIVOCAL	NEGATIVE
Passed	NEGATIVE	EQUIVOCAL	EQUIVOCAL	EQUIVOCAL

IC	FluA	H1	H3	H1N1
Passed	POSITIVE	NEGATIVE	NEGATIVE	NEGATIVE
Passed	Positive, but not reported	NEGATIVE	NEGATIVE	POSITIVE
Passed	Positive, but not reported	NEGATIVE	POSITIVE	NEGATIVE
Passed	Positive, but not reported	NEGATIVE	POSITIVE	POSITIVE
Passed	Positive, but not reported	POSITIVE	NEGATIVE	NEGATIVE
Passed	Positive, but not reported	POSITIVE	NEGATIVE	POSITIVE
Passed	Positive, but not reported	POSITIVE	POSITIVE	NEGATIVE
Passed	Positive, but not reported	POSITIVE	POSITIVE	POSITIVE

Example negative value

OBX|1|CE|76078-5^Influenza virus A RNA^LN^Flu A^Influenza A^STAT-DX|Flu A|260385009^NEGATIVE^SCT| || || |F| || | |administrator^Administrator| |001298|20220513134437
 OBX|2|NM|^Flu A.Ct^Influenza A Ct^STAT-DX|Flu A|NA| || || |F| || | |administrator^Administrator| |001298|20220513134437
 OBX|3|NM|^Flu A.EndPoint^Influenza A End Point^STAT-DX|Flu A|NA| || || |F| || | |administrator^Administrator| |001298|20220513134437

Example positive value

OBX|4|CE|76080-1^Influenza virus B RNA^LN^Flu B^Influenza B^STAT-DX|Flu B|10828004^POSITIVE^SCT| || || |F| || | |administrator^Administrator| |001298|20220513134437
 OBX|5|NM|^Flu B.Ct^Influenza B Ct^STAT-DX|Flu B|34.15| || || |F| || | |administrator^Administrator| |001298|20220513134437
 OBX|6|NM|^Flu B.EndPoint^Influenza B End Point^STAT-DX|Flu B|13884.77| || || |F| || | |administrator^Administrator| |001298|20220513134437

Example equivocal value

OBX|7|CE|77028-9^Influenza virus A H1 2009 pandemic RNA^LN^Flu A H1N1 pdm09^Influenza A H1N1 pdm09^STAT-DX|Flu A H1N1 pdm09|42425007^EQUIVOCAL^SCT| || || |F| || | |administrator^Administrator| |001298|20220513134437
 OBX|8|NM|^Flu A H1N1 pdm09.Ct^Influenza A H1N1 pdm09 Ct^STAT-DX|Flu A H1N1 pdm09|34.15| || || |F| || | |administrator^Administrator| |001298|20220513134437
 OBX|9|NM|^Flu A H1N1 pdm09.EndPoint^Influenza A H1N1 pdm09 End Point^STAT-DX|Flu A H1N1 pdm09|13884.77| || || |F| || | |administrator^Administrator| |001298|20220513134437

Example invalid value

OBX|10|CE|88610-1^Human coronavirus 229E RNA^LN^Cor 229E^Coronavirus 229E^STAT-DX|Cor 229E|260385009^UNDETERMINED^SCT| || || |F| || | |administrator^Administrator| |001298|20220513134437
 OBX|11|NM|^Cor 229E.Ct^Coronavirus 229E Ct^STAT-DX|Cor 229E|NA| || || |F| || | |administrator^Administrator| |001298|20220513134437
 OBX|12|NM|^Cor 229E.EndPoint^Coronavirus 229E End Point^STAT-DX|Cor 229E|NA| || || |F| || | |administrator^Administrator| |001298|20220513134437
 OBX|13|CE|88626-7^Human coronavirus OC43 RNA^LN^Cor OC43^Coronavirus OC43^STAT-DX|Cor OC43|260385009^NEGATIVE^SCT| || || |F| || | |administrator^Administrator| |001298|20220513134437

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