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LIS Interface Specification

QIAstat-Dx[®] GI Panel 2 Mini B&V



IVD

REF

691424

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Purpose and Scope

Purpose

The purpose of this document is to specify the exchange information of QIAstat-Dx GI Panel 2 Mini B&V (Cat. no. 691424) 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 information for the QIAstat-Dx GI Panel 2 Mini B&V Assay Definition File (ADF) version 1.2 or above, as well as the application software on an external computer system version 1.4 or later.

Definitions and Acronyms

Table 1. Definitions and acronyms

Word or acronym	Definition
ADF	Assay Definition File
CE	Coded Element
HL7	International (Health Level Seven)
LIS	Laboratory Information System
LOINC	Logical Observation Identifiers Names and Codes
OBR	Observation Request
ORC	Name of alternate coding system
SNOMED	Systematized Nomenclature of Medicine
STAT-DX	Proprietary coding system from QIAGEN

Coding Systems

The information exchanged uses three 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 default “LIS Assay Name” corresponds to the name defined in the ADF, in this case “GI2 Mini B&V”. However, the LIS Assay Name cannot contain any of the following characters: \&~|^ . Therefore, we recommend that the user edits the LIS Assay Name to “GI2 Mini BV”. The name of the assay would then be coded as “GI2 Mini BV” in the HL7 field OBR 4.1 Universal Service Identifier.

Example

OBR|1|||GI2 Mini BV|||20240327161331|20240327172955| |||||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
Para-Pak® C&S	980
FecalSwab™	999

Examples

SPM|1|541032949||980^Para-Pak C&S^STAT-DX|||||P

SPM|1|541032950||999^FecalSwab^STAT-DX|||||P

In HL7, analyte names and short names are the alternate test names and the alternate test identifiers, respectively. In the “OBX 3.6 Name of Alternate Coding System” section, these should be indicated as STAT-DX.

Table 3. Alternate test names and identifiers for OBX 3.4 and 3.5

Alternate test name OBX 3.5	Alternate test identifier OBX 3.4
Campylobacter	CAM
Salmonella	SAL
Shiga-like toxin E. coli (STEC)	STEC
Shigella	SHIGE
Norovirus	NOR

Example

OBX|1|CE|97312-3 ^ Campylobacter coli+jejuni+upsaliensis DNA ^ LN ^ CAM ^ Campylobacter ^ STAT-DX|CAM|260385009 ^ NEGATIVE ^ SCT|||||F||||labuser ^ labuser||001743|20240327172955

For the case of the FecalSwab sample type, the analyte Shiga-like toxin *E. coli* (STEC) is not part of the intended use of the product so it is never reported.

The internal control (IC) is also reported as an analyte.

Table 4. Analyte test name and identifier

Alternate test name OBX 3.5	Alternate test identifier OBX 3.4
IC	IC

LOINC coding system

Analytes names are also sent using the LOINC coding system. In the “OBX 3.3 Name Of Alternate Coding System” section this analyte name should be indicated as LN.

Table 5. LOINC coding system for analytes

Test name OBX 3.2	Test identifier code OBX 3.1	Source
Campylobacter coli+jejuni+upsaliensis DNA	97312-3	https://loinc.org/97312-3/
Salmonella sp DNA	97313-1	https://loinc.org/97313-1/
Escherichia coli Stx1+Stx2 toxin stx1+stx2 genes	80679-4	https://loinc.org/80679-4/
Shigella species+EIEC invasion plasmid antigen H (ipaH) gene	70242-3	https://loinc.org/70242-3/
Norovirus genogroup I+II RNA	92692-3	https://loinc.org/92692-3/

Example

OBX|1|CE|97312-3 ^ Campylobacter coli+jejuni+upsaliensis DNA ^ LN ^ CAM ^ Campylobacter ^ STAT-DX|CAM|260385009 ^ NEGATIVE ^ SCT|||||F|||||labuser ^ labuser||001743|20240327172955

For the case of the FecalSwab sample type, the analyte Shiga-like toxin *E. coli* (STEC) is not part of the intended use of the product so it is never reported.

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:

Table 6. SNOMED codes for qualitative results

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

There are some examples of these cases at the end of the document.

Example negative value

OBX|1|CE|97312-3 ^ Campylobacter coli+jejuni+upsaliensis DNA ^ LN ^ CAM ^ Campylobacter ^ STAT-DX|CAM|260385009 ^ NEGATIVE ^ SCT|||||F|||||administrator ^ Administrator||001025|20240410114348OBX|2|NM|^ ^ ^ CAM.Ct ^ Campylobacter Ct ^ STAT-DX|CAM|NA|||||F|||||administrator ^ Administrator||001025|20240410114348OBX|3|NM|^ ^ ^ CAM.EndPoint ^ Campylobacter End Point ^ STAT-DX|CAM|NA|||||F|||||administrator ^ Administrator||001025|20240410114348

Example positive value

OBX|7|CE|80679-4 ^ Escherichia coli Stx1+Stx2 toxin stx1+stx2 genes ^ LN ^ STEC ^ Shiga-like toxin E. coli (STEC) ^ STAT-DX|STEC|10828004 ^ POSITIVE ^ SCT|||||F|||||labuser ^ labuser||001484|20240410114348OBX|8|NM|^ ^ ^ STEC.Ct ^ Shiga-like toxin E. coli (STEC) Ct ^ STAT-DX|STEC|32.32|||||F|||||labuser ^ labuser||001484|20240410114348OBX|9|NM|^ ^ ^ STEC.EndPoint ^ Shiga-like toxin E. coli (STEC) End Point ^ STAT-DX|STEC|276389.92|||||F|||||labuser ^ labuser||001484|20240410114348

Example invalid value

OBX|4|CE|97313-1 ^ Salmonella sp DNA ^ LN ^ SAL ^ Salmonella ^ STAT-DX|SAL|373068000 ^ UNDETERMINED ^ SCT|||||F|||||labuser ^ labuser||001484|20240410114348OBX|5|NM|^ ^ ^ SAL.Ct ^ Salmonella Ct ^ STAT-DX|SAL|NA|||||F|||||labuser ^ labuser||001484|20240410114348OBX|6|NM|^ ^ ^ SAL.EndPoint ^ Salmonella End Point ^ STAT-DX|SAL|NA|||||F|||||labuser ^ labuser||001484|20240410114348

Examples

The following is an example of a negative result:

MSH|^~\&|DiagCORE000001012||MYLIS||20240410141609||OUL ^ R22 ^ OUL_R22|M202404101416090003|P|2.5|||||UNICODE UTF-8PID|1||mix5SPM|1|540635622||980 ^ Para-Pak C&S ^ STAT-DX|||||P
OBR|1|||GI2 Mini BV||20240410102746|20240410114348|||||||||FORC|SC
OBX|1|CE|97312-3 ^ Campylobacter coli+jejuni+upsaliensis
DNA ^ LN ^ CAM ^ Campylobacter ^ STAT-

DX|CAM|260385009 ^ NEGATIVE ^ SCT|||||F|||||administrator ^ Administrator||001025|2024
0410114348

OBX|2|NM|^ ^ ^ CAM.Ct ^ Campylobacter Ct ^ STAT-

DX|CAM|NA|||||F|||||administrator ^ Administrator||001025|20240410114348

OBX|3|NM|^ ^ ^ CAM.EndPoint ^ Campylobacter End Point ^ STAT-

DX|CAM|NA|||||F|||||administrator ^ Administrator||001025|20240410114348

OBX|4|CE|97313-1 ^ Salmonella sp DNA ^ LN ^ SAL ^ Salmonella ^ STAT-

DX|SAL|260385009 ^ NEGATIVE ^ SCT|||||F|||||administrator ^ Administrator||001025|20240
410114348

OBX|5|NM|^ ^ ^ SAL.Ct ^ Salmonella Ct ^ STAT-

DX|SAL|NA|||||F|||||administrator ^ Administrator||001025|20240410114348

OBX|6|NM|^ ^ ^ SAL.EndPoint ^ Salmonella End Point ^ STAT-

DX|SAL|NA|||||F|||||administrator ^ Administrator||001025|20240410114348

OBX|7|CE|80679-4 ^ Escherichia coli Stx1+Stx2 toxin stx1+stx2 genes ^ LN ^ STEC ^ Shiga-like toxin
E. coli (STEC) ^ STAT-

DX|STEC|260385009 ^ NEGATIVE ^ SCT|||||F|||||administrator ^ Administrator||001025|2024
0410114348

OBX|8|NM|^ ^ ^ STEC.Ct ^ Shiga-like toxin E. coli (STEC) Ct ^ STAT-

DX|STEC|NA|||||F|||||administrator ^ Administrator||001025|20240410114348

OBX|9|NM|^ ^ ^ STEC.EndPoint ^ Shiga-like toxin E. coli (STEC) End Point ^ STAT-

DX|STEC|NA|||||F|||||administrator ^ Administrator||001025|20240410114348

OBX|10|CE|70242-3 ^ Shigella species+EIEC invasion plasmid antigen H (ipaH)
gene ^ LN ^ SHIGE ^ Shigella ^ STAT-

DX|SHIGE|260385009 ^ NEGATIVE ^ SCT|||||F|||||administrator ^ Administrator||001025|202
40410114348

OBX|11|NM|^ ^ ^ SHIGE.Ct ^ Shigella Ct ^ STAT-

DX|SHIGE|NA|||||F|||||administrator ^ Administrator||001025|20240410114348

OBX|12|NM|^ ^ ^ SHIGE.EndPoint ^ Shigella End Point ^ STAT-

DX|SHIGE|NA|||||F|||||administrator ^ Administrator||001025|20240410114348

OBX|13|CE|92692-3 ^ Norovirus genogroup I+II RNA ^ LN ^ NOR ^ Norovirus ^ STAT-

DX|NOR|260385009 ^ NEGATIVE ^ SCT|||||F|||||
administrator ^ Administrator||001025|20240410114348

OBX|14|NM|^ ^ ^ NOR.Ct ^ Norovirus Ct ^ STAT-

DX|NOR|NA|||||F|||||administrator ^ Administrator||001025|20240410114348

OBX|15|NM|^ ^ ^ NOR.EndPoint ^ Norovirus End Point ^ STAT-

DX|NOR|NA|||||F|||||administrator ^ Administrator||001025|20240410114348

OBX|16|CE|^ ^ ^ IC ^ IC ^ STAT-

DX|IC|10828004 ^ POSITIVE ^ SCT|||||F|||||administrator ^ Administrator||001025|20240410

OBX|17|NM|^ ^ ^IC.Ct^IC Ct^STAT-

OBX|18|NM|^ ^ ^|C.EndPoint^IC End Point^STAT-

DX	IC	344162.56					F				administrator ^ Administrator	001025	20240410114348
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```
MSH|^~\&|DiagCORE000001035||MYLIS||20240411155350||OUL^R22^OUL_R22|M2024041115535000001|P|2.5|||||UNICODE UTF-8
```

PID | 1 | | mix4

SPM|1|540635646||980^Para-Pak C&S^STAT-DX|||||P

OBR	1			GI2 Mini BV			20240411081834	20240411093418									F
-----	---	--	--	-------------	--	--	----------------	----------------	--	--	--	--	--	--	--	--	---

ORC | SC

OBX|1|CE|97312-3 ^ Campylobacter coli+jejuni+upsaliensis

DNA ^ LN ^ CAM ^ Campylobacter ^ STAT-

DX|CAM|10828004^POSITIVE^SCT|||||F||||administrator^Administrator||001078|20240411093418

OBX|2|NM|^ ^ ^CAM.Ct ^ Campylobacter Ct ^ STAT-

DX CAM 31.54					F				administrator^Administrator	001078 20240411093418
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OBX|3|NM|^ ^ ^CAM.EndPoint^Campylobacter End Point^STAT-

DX CAM 262588.52					F				administrator^Administrator	001078 20240411093418
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OBX|4|CE|97313-1 ^ Salmonella sp DNA ^ LN ^ SAL ^ Salmonella ^ STAT-

DX|SAL|260385009 ^ NEGATIVE ^ SCT|||||F||||administrator ^ Administrator||001078|20240411093418

OBX|5|NM|^ ^ ^SAL.Ct^Salmonella Ct^STAT-

DX	SAL	NA				F				administrator ^ Administrator	001078	20240411093418
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OBX|6|NM|^ ^ ^SAL.EndPoint^Salmonella End Point^STAT-

DX	SAL	NA					F				administrator ^ Administrator		001078	20240411093418
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OBX|7|CE|80679-4 ^ Escherichia coli Stx1+Stx2 toxin stx1+stx2 genes ^ LN ^ STEC ^ Shiga-like toxin
E. coli (STEC) ^ STAT-

DX|STEC|260385009^NEGATIVE^SCT|||||F||||administrator^Administrator||001078|2024
0411093418

OBX|8|NM|^ ^ ^STEC.Ct^ Shiga-like toxin E. coli (STEC) Ct^ STAT-

DX	STEC	NA					F				administrator ^ Administrator		001078	20240411093418
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OBX|9|NM|^ ^ ^STEC.EndPoint^ Shiga-like toxin E. coli (STEC) End Point^ STAT-

DX	STEC	NA					F				administrator ^ Administrator	001078	20240411093418
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OBX|10|CE|70242-3 ^ Shigella species+EIEC invasion plasmid antigen H (ipaH)
 gene ^ LN ^ SHIGE ^ Shigella ^ STAT-
 DX|SHIGE|260385009 ^ NEGATIVE ^ SCT||||F||||administrator ^ Administrator||001078|202
 40411093418
 OBX|11|NM| ^ ^ ^ SHIGE.Ct ^ Shigella Ct ^ STAT-
 DX|SHIGE|NA||||F||||administrator ^ Administrator||001078|20240411093418
 OBX|12|NM| ^ ^ ^ SHIGE.EndPoint ^ Shigella End Point ^ STAT-
 DX|SHIGE|NA||||F||||administrator ^ Administrator||001078|20240411093418
 OBX|13|CE|92692-3 ^ Norovirus genogroup I+II RNA ^ LN ^ NOR ^ Norovirus ^ STAT-
 DX|NOR|260385009 ^ NEGATIVE ^ SCT||||F||||administrator ^ Administrator||001078|2024
 0411093418
 OBX|14|NM| ^ ^ ^ NOR.Ct ^ Norovirus Ct ^ STAT-
 DX|NOR|NA||||F||||administrator ^ Administrator||001078|20240411093418
 OBX|15|NM| ^ ^ ^ NOR.EndPoint ^ Norovirus End Point ^ STAT-
 DX|NOR|NA||||F||||administrator ^ Administrator||001078|20240411093418
 OBX|16|CE| ^ ^ ^ IC ^ IC ^ STAT-
 DX|IC|10828004 ^ POSITIVE ^ SCT||||F||||administrator ^ Administrator||001078|20240411
 093418
 OBX|17|NM| ^ ^ ^ IC.Ct ^ IC Ct ^ STAT-
 DX|IC|31.84||||F||||administrator ^ Administrator||001078|20240411093418
 OBX|18|NM| ^ ^ ^ IC.EndPoint ^ IC End Point ^ STAT-
 DX|IC|271587.96||||F||||administrator ^ Administrator||001078|20240411093418

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