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LIS Interface Specification

QIAstat-Dx[®] Meningitis/Encephalitis (ME) Panel



IVD

REF

691621

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Purpose and Scope

Purpose

The purpose of this document is to specify the exchange information of QIAstat-Dx ME Panel (Cat. no. 691621) 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 ME Panel Assay Definition File (ADF) version 2.1 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
ME	Meningitis/Encephalitis
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 name of the assay is coded as ME in the HL7 field OBR 4.1 Universal Service Identifier.

Example

OBR|1|||ME|||20230207162740|20230207174816|||||||||||||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
CSF (Cerebrospinal fluid)	430

Example

SPM|1|523011006||430^CSF^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
<i>Streptococcus pneumoniae</i>	SPNEU
<i>Neisseria meningitidis</i>	NMEN

Alternate test name OBX 3.5	Alternate test identifier OBX 3.4
<i>Streptococcus agalactiae</i>	SAGAL
<i>Listeria monocytogenes</i>	LMONO
<i>Haemophilus influenza</i>	HINF
<i>Escherichia coli</i> K1	ECOLIK1
<i>Streptococcus pyogenes</i>	SPYO
Enterovirus	ENT
<i>Cryptococcus neoformans/gattii</i>	CRYPT

Example

OBX|1|CE|99094-5 ^ Streptococcus pneumoniae DNA ^ LN ^ SPNEU ^ Streptococcus pneumoniae ^ STAT-DX|SPNEU|260385009 ^ NEGATIVE ^ SCT| || || |F| || |administrator ^ Administrator| |001063|20230207174816

Note: In the case of positive detection of *Streptococcus pyogenes*, “*Streptococcus pyogenes* (see IFU)” and “SPYO (see IFU)” will be reported as OBX 3.5 and OBX 3.4, respectively. This is to prompt the user to read the Instructions for Use, where a limitation states that “*Streptococcus pyogenes* is an extremely rare cause of community-acquired meningitis/encephalitis infections in the U.S. and a positive assay result for this analyte should be supported by additional culture evidence”. Examples for both negative and positive detection of *Streptococcus pyogenes* are provided at the end of this document.

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
Streptococcus pneumoniae DNA	99094-5	https://loinc.org/99094-5/
Neisseria meningitidis DNA	99092-9	https://loinc.org/99092-9/
Streptococcus agalactiae DNA	99093-7	https://loinc.org/99093-7/
Listeria monocytogenes DNA	99091-1	https://loinc.org/99091-1/
Haemophilus influenzae DNA	99090-3	https://loinc.org/99090-3/
Escherichia coli K1 DNA	99089-5	https://loinc.org/99089-5/
Streptococcus pyogenes DNA	99095-2	https://loinc.org/99095-2/
Enterovirus RNA	29591-5	https://loinc.org/29591-5/
Cryptococcus gattii+neoformans DNA	99088-7	https://loinc.org/99088-7/

Example

OBX|1|CE|99094-5 ^ Streptococcus pneumoniae DNA ^ LN ^ SPNEU ^ Streptococcus pneumoniae ^ STAT-DX|SPNEU|260385009 ^ NEGATIVE ^ SCT|||||F||||administrator ^ Administrator||001063|20230207174816

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|4|CE|99092-9 ^ Neisseria meningitidis DNA ^ LN ^ NMEN ^ Neisseria meningitidis ^ STAT-
DX|NMEN|260385009 ^ NEGATIVE ^ SCT|||||F||||administrator ^ Administrator||001063|20230207
174816 OBX|5|NM| ^ ^ ^ NMEN.Ct ^ Neisseria meningitidis Ct ^ STAT-
DX|NMEN|NA|||||F||||administrator ^ Administrator||001063|20230207174816
OBX|6|NM| ^ ^ ^ NMEN.EndPoint ^ Neisseria meningitidis End Point ^ STAT-
DX|NMEN|NA|||||F||||administrator ^ Administrator||001063|20230207174816

Example positive value

OBX|7|CE|99093-7 ^ Streptococcus agalactiae DNA ^ LN ^ SAGAL ^ Streptococcus agalactiae ^ STAT-
DX|SAGAL|10828004 ^ POSITIVE ^ SCT|||||F||||administrator ^ Administrator||001063|2023020717
4816 OBX|8|NM| ^ ^ ^ SAGAL.Ct ^ Streptococcus agalactiae Ct ^ STAT-
DX|SAGAL|32.69|||||F||||administrator ^ Administrator||001063|20230207174816
OBX|9|NM| ^ ^ ^ SAGAL.EndPoint ^ Streptococcus agalactiae End Point ^ STAT-
DX|SAGAL|278195.80|||||F||||administrator ^ Administrator||001063|20230207174816

Example invalid value

OBX|10|CE|99091-1 ^ Listeria monocytogenes DNA ^ LN ^ LMONO ^ Listeria monocytogenes ^ STAT-
DX|LMONO|
373068000 ^ UNDETERMINED ^ SCT|||||F||||administrator ^ Administrator||001063|202302071748
16 OBX|11|NM| ^ ^ ^ LMONO.Ct ^ Listeria monocytogenes Ct ^ STAT-
DX|LMONO|NA|||||F||||administrator ^ Administrator||001063|20230207174816
OBX|12|NM| ^ ^ ^ LMONO.EndPoint ^ Listeria monocytogenes End Point ^ STAT-
DX|LMONO|NA|||||F||||administrator ^ Administrator||001063|20230207174816

Examples

The following is an example of a negative result:

```
MSH|^~\&|DiagCORE000001276||MYLIS||20241204132132||OUL^R22^OUL_R22|M20241
2041321320071|P|2.5|||||UNICODE UTF-8PID|1||4SPM|1|542450826||430^CSF^STAT-
DX|||||POBR|1|||ME|||20241204115811|20241204131736|||||||||||||FORC|SCOBX
|1|CE|29591-5^Enterovirus RNA^LN^ENT^Enterovirus^STAT-
DX|ENT|260385009^NEGATIVE^SCT|||||F||||administrator^Administrator||001475|20241
204131736OBX|2|NM|^ ^ ^ENT.Ct^Enterovirus Ct^STAT-
DX|ENT|NA|||||F||||administrator^Administrator||001475|20241204131736OBX|3|NM|^
^ ^ENT.EndPoint^Enterovirus End Point^STAT-
DX|ENT|NA|||||F||||administrator^Administrator||001475|20241204131736OBX|4|CE|990
89-5^Escherichia coli K1 DNA^LN^ECOLIK1^Escherichia coli K1^STAT-
DX|ECOLIK1|260385009^NEGATIVE^SCT|||||F||||administrator^Administrator||001475|2
0241204131736OBX|5|NM|^ ^ ^ECOLIK1.Ct^Escherichia coli K1 Ct^STAT-
DX|ECOLIK1|NA|||||F||||administrator^Administrator||001475|20241204131736OBX|6|N
M|^ ^ ^ECOLIK1.EndPoint^Escherichia coli K1 End Point^STAT-
DX|ECOLIK1|NA|||||F||||administrator^Administrator||001475|20241204131736OBX|7|CE
|99090-3^Haemophilus influenzae DNA^LN^HINF^Haemophilus influenzae^STAT-
DX|HINF|260385009^NEGATIVE^SCT|||||F||||administrator^Administrator||001475|2024
1204131736OBX|8|NM|^ ^ ^HINF.Ct^Haemophilus influenzae Ct^STAT-
DX|HINF|NA|||||F||||administrator^Administrator||001475|20241204131736OBX|9|NM|^
^ ^HINF.EndPoint^Haemophilus influenzae End Point^STAT-
DX|HINF|NA|||||F||||administrator^Administrator||001475|20241204131736OBX|10|CE|9
9091-1^Listeria monocytogenes DNA^LN^LMONO^Listeria monocytogenes^STAT-
DX|LMONO|260385009^NEGATIVE^SCT|||||F||||administrator^Administrator||001475|20
241204131736OBX|11|NM|^ ^ ^LMONO.Ct^Listeria monocytogenes Ct^STAT-
DX|LMONO|NA|||||F||||administrator^Administrator||001475|20241204131736OBX|12|N
M|^ ^ ^LMONO.EndPoint^Listeria monocytogenes End Point^STAT-
DX|LMONO|NA|||||F||||administrator^Administrator||001475|20241204131736OBX|13|C
E|99092-9^Neisseria meningitidis DNA^LN^NMEN^Neisseria meningitidis^STAT-
DX|NMEN|260385009^NEGATIVE^SCT|||||F||||administrator^Administrator||001475|202
41204131736OBX|14|NM|^ ^ ^NMEN.Ct^Neisseria meningitidis Ct^STAT-
DX|NMEN|NA|||||F||||administrator^Administrator||001475|20241204131736OBX|15|NM
|^ ^ ^NMEN.EndPoint^Neisseria meningitidis End Point^STAT-
DX|NMEN|NA|||||F||||administrator^Administrator||001475|20241204131736OBX|16|CE|
```


99093-7 ^ Streptococcus agalactiae DNA ^ LN ^ SAGAL ^ Streptococcus agalactiae ^ STAT-
 DX|SAGAL|260385009 ^ NEGATIVE ^ SCT|||||F|||||administrator ^ Administrator||001475|202
 41204131736OBX|17|NM|^ ^ ^ SAGAL.Ct ^ Streptococcus agalactiae Ct ^ STAT-
 DX|SAGAL|NA|||||F|||||administrator ^ Administrator||001475|20241204131736OBX|18|NM
 | ^ ^ ^ SAGAL.EndPoint ^ Streptococcus agalactiae End Point ^ STAT-
 DX|SAGAL|NA|||||F|||||administrator ^ Administrator||001475|20241204131736OBX|19|CE|
 99094-5 ^ Streptococcus pneumoniae DNA ^ LN ^ SPNEU ^ Streptococcus pneumoniae ^ STAT-
 DX|SPNEU|260385009 ^ NEGATIVE ^ SCT|||||F|||||administrator ^ Administrator||001475|202
 41204131736OBX|20|NM|^ ^ ^ SPNEU.Ct ^ Streptococcus pneumoniae Ct ^ STAT-
 DX|SPNEU|NA|||||F|||||administrator ^ Administrator||001475|20241204131736OBX|21|NM
 | ^ ^ ^ SPNEU.EndPoint ^ Streptococcus pneumoniae End Point ^ STAT-
 DX|SPNEU|NA|||||F|||||administrator ^ Administrator||001475|20241204131736OBX|22|CE|
 99095-2 ^ Streptococcus pyogenes DNA ^ LN ^ SPYO ^ Streptococcus pyogenes ^ STAT-
 DX|SPYO|260385009 ^ NEGATIVE ^ SCT|||||F|||||administrator ^ Administrator||001475|2024
 1204131736OBX|23|NM|^ ^ ^ SPYO.Ct ^ Streptococcus pyogenes Ct ^ STAT-
 DX|SPYO|NA|||||F|||||administrator ^ Administrator||001475|20241204131736OBX|24|NM|
 ^ ^ ^ SPYO.EndPoint ^ Streptococcus pyogenes End Point ^ STAT-
 DX|SPYO|NA|||||F|||||administrator ^ Administrator||001475|20241204131736OBX|25|CE|9
 9088-7 ^ Cryptococcus gattii+neoformans DNA ^ LN ^ CRYPT ^ Cryptococcus
 neoformans/gattii ^ STAT-
 DX|CRYPT|260385009 ^ NEGATIVE ^ SCT|||||F|||||administrator ^ Administrator||001475|202
 41204131736OBX|26|NM|^ ^ ^ CRYPT.Ct ^ Cryptococcus neoformans/gattii Ct ^ STAT-
 DX|CRYPT|NA|||||F|||||administrator ^ Administrator||001475|20241204131736OBX|27|NM
 | ^ ^ ^ CRYPT.EndPoint ^ Cryptococcus neoformans/gattii End Point ^ STAT-
 DX|CRYPT|NA|||||F|||||administrator ^ Administrator||001475|20241204131736OBX|28|CE|
 ^ ^ ^ IC ^ IC ^ STAT-
 DX|IC|10828004 ^ POSITIVE ^ SCT|||||F|||||administrator ^ Administrator||001475|20241204
 131736OBX|29|NM|^ ^ ^ IC.Ct ^ IC Ct ^ STAT-
 DX|IC|28.07|||||F|||||administrator ^ Administrator||001475|20241204131736OBX|30|NM|
 ^ ^ ^ IC.EndPoint ^ IC End Point ^ STAT-
 DX|IC|524360.32|||||F|||||administrator ^ Administrator||001475|20241204131736

The following is an example of a positive result in SPYO:

MSH| ^ ~&|DiagCORE000001276||MYLIS||20241204132132||OUL ^ R22 ^ OUL_R22|M20241
 2041321320071|P|2.5|||||UNICODE UTF-8PID|1||4SPM|1|542450826||430 ^ CSF ^ STAT-
 DX|||||POBR|1||ME||20241204115811|20241204131736|||||||FORC|SCOBX

|1|CE|29591-5^Enterovirus RNA^LN^ENT^Enterovirus^STAT-
 DX|ENT|260385009^NEGATIVE^SCT|||||F||||administrator^Administrator||001475|20241
 204131736OBX|2|NM|^ ^ ^ENT.Ct^Enterovirus Ct^STAT-
 DX|ENT|NA|||||F||||administrator^Administrator||001475|20241204131736OBX|3|NM|^ ^
 ^ ^ENT.EndPoint^Enterovirus End Point^STAT-
 DX|ENT|NA|||||F||||administrator^Administrator||001475|20241204131736OBX|4|CE|990
 89-5^Escherichia coli K1 DNA^LN^ECOLIK1^Escherichia coli K1^STAT-
 DX|ECOLIK1|260385009^NEGATIVE^SCT|||||F||||administrator^Administrator||001475|2
 0241204131736OBX|5|NM|^ ^ ^ECOLIK1.Ct^Escherichia coli K1 Ct^STAT-
 DX|ECOLIK1|NA|||||F||||administrator^Administrator||001475|20241204131736OBX|6|N
 M|^ ^ ^ECOLIK1.EndPoint^Escherichia coli K1 End Point^STAT-
 DX|ECOLIK1|NA|||||F||||administrator^Administrator||001475|20241204131736OBX|7|CE
 |99090-3^Haemophilus influenzae DNA^LN^HINF^Haemophilus influenzae^STAT-
 DX|HINF|260385009^NEGATIVE^SCT|||||F||||administrator^Administrator||001475|2024
 1204131736OBX|8|NM|^ ^ ^HINF.Ct^Haemophilus influenzae Ct^STAT-
 DX|HINF|NA|||||F||||administrator^Administrator||001475|20241204131736OBX|9|NM|^ ^
 ^ ^HINF.EndPoint^Haemophilus influenzae End Point^STAT-
 DX|HINF|NA|||||F||||administrator^Administrator||001475|20241204131736OBX|10|CE|9
 9091-1^Listeria monocytogenes DNA^LN^LMONO^Listeria monocytogenes^STAT-
 DX|LMONO|260385009^NEGATIVE^SCT|||||F||||administrator^Administrator||001475|20
 241204131736OBX|11|NM|^ ^ ^LMONO.Ct^Listeria monocytogenes Ct^STAT-
 DX|LMONO|NA|||||F||||administrator^Administrator||001475|20241204131736OBX|12|N
 M|^ ^ ^LMONO.EndPoint^Listeria monocytogenes End Point^STAT-
 DX|LMONO|NA|||||F||||administrator^Administrator||001475|20241204131736OBX|13|C
 E|99092-9^Neisseria meningitidis DNA^LN^NMEN^Neisseria meningitidis^STAT-
 DX|NMEN|260385009^NEGATIVE^SCT|||||F||||administrator^Administrator||001475|202
 41204131736OBX|14|NM|^ ^ ^NMEN.Ct^Neisseria meningitidis Ct^STAT-
 DX|NMEN|NA|||||F||||administrator^Administrator||001475|20241204131736OBX|15|NM
 | ^ ^ ^NMEN.EndPoint^Neisseria meningitidis End Point^STAT-
 DX|NMEN|NA|||||F||||administrator^Administrator||001475|20241204131736OBX|16|CE|
 99093-7^Streptococcus agalactiae DNA^LN^SAGAL^Streptococcus agalactiae^STAT-
 DX|SAGAL|260385009^NEGATIVE^SCT|||||F||||administrator^Administrator||001475|202
 41204131736OBX|17|NM|^ ^ ^SAGAL.Ct^Streptococcus agalactiae Ct^STAT-
 DX|SAGAL|NA|||||F||||administrator^Administrator||001475|20241204131736OBX|18|NM
 | ^ ^ ^SAGAL.EndPoint^Streptococcus agalactiae End Point^STAT-
 DX|SAGAL|NA|||||F||||administrator^Administrator||001475|20241204131736OBX|19|CE|
 99094-5^Streptococcus pneumoniae DNA^LN^SPNEU^Streptococcus pneumoniae^STAT-
 DX|SPNEU|260385009^NEGATIVE^SCT|||||F||||administrator^Administrator||001475|202
 41204131736OBX|20|NM|^ ^ ^SPNEU.Ct^Streptococcus pneumoniae Ct^STAT-
 DX|SPNEU|NA|||||F||||administrator^Administrator||001475|20241204131736OBX|21|NM
 | ^ ^ ^SPNEU.EndPoint^Streptococcus pneumoniae End Point^STAT-
 DX|SPNEU|NA|||||F||||administrator^Administrator||001475|20241204131736OBX|22|CE|
 99095-2^Streptococcus pyogenes DNA^LN^SPYO (see IFU)^Streptococcus pyogenes (see
 IFU)^STAT-DX|SPYO (see
 IFU)|10828004^POSITIVE^SCT|||||F||||administrator^Administrator||001475|2024120413
 1736OBX|23|NM|^ ^ ^SPYO (see IFU).Ct^Streptococcus pyogenes (see IFU) Ct^STAT-DX|SPYO
 (see
 IFU)|32.69|||||F||||administrator^Administrator||001475|20241204131736OBX|24|NM|^ ^
 ^ ^SPYO.EndPoint^Streptococcus pyogenes (see IFU) End Point^STAT-DX|SPYO (see
 IFU)|278195.80|||||F||||administrator^Administrator||001475|20241204131736
 OBX|25|CE|99088-7^Cryptococcus gattii+neoformans DNA^LN^CRYPT^Cryptococcus

neoformans/gattii ^ STAT-

DX|CRYPT|260385009 ^ NEGATIVE ^ SCT|||||F|||||administrator ^ Administrator||001475|20241204131736OBX|26|NM|^ ^ ^ CRYPT.Ct ^ Cryptococcus neoformans/gattii Ct ^ STAT-

DX|CRYPT|NA|||||F|||||administrator ^ Administrator||001475|20241204131736OBX|27|NM|^ ^ ^ CRYPT.EndPoint ^ Cryptococcus neoformans/gattii End Point ^ STAT-

DX|CRYPT|NA|||||F|||||administrator ^ Administrator||001475|20241204131736OBX|28|CE|^ ^ ^ IC ^ IC ^ STAT-

DX|IC|10828004 ^ POSITIVE ^ SCT|||||F|||||administrator ^ Administrator||001475|20241204131736OBX|29|NM|^ ^ ^ IC.Ct ^ IC Ct ^ STAT-

DX|IC|28.07|||||F|||||administrator ^ Administrator||001475|20241204131736OBX|30|NM|^ ^ ^ IC.EndPoint ^ IC End Point ^ STAT-

DX|IC|524360.32|||||F|||||administrator ^ Administrator||001475|20241204131736

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