

Xpert® Xpress GBS, US-IVD Laboratory Information System Guidance

REF XPRSGBS-10

ADF: **Xpert Xpress GBS US-IVD**

Version 2*

Purpose: To provide information for enabling a Laboratory Information System (LIS) interface for the Xpert® Xpress GBS test on GeneXpert® Systems.

Contents: 1. Host Communication in GeneXpert System
2. Example Result Messages
 2.1.1.ASTM
 2.1.2.HL7

If you need further assistance, please contact Cepheid Technical Support at <https://www.cepheid.com/en/about/contact-us> or email techsupport@cepheid.com.

**Please Note: Xpert Xpress GBS, US-IVD (XPRSGBS-10) is Launching with Version 2. There is no Version 1 for that Catalog Number.*

1 Host Communication in GeneXpert® System

1.1 Consult your LIS System Administrator:

Before making changes to your GeneXpert LIS interface settings, consult your LIS System Administrator

1.2 Enable Host Communication:

If the GeneXpert system is not already configured for LIS host communication, follow the instructions in your GeneXpert System’s User Guide: “Configuring Host Communications for a LIS.”

1.3 Assay Host Test Code and Result Code Configuration:

Assay Host Test Code and Result Code must be defined in the GeneXpert system.

Note: When defining Host Test Codes and Result Codes, consider if your organization needs to use different Codes for different versions of Cepheid tests so that the test versions can be distinguished in your LIS.

1.4 Suggested Assay Host Test Codes

ADF Name / Assay Name	ADF Version	Assay Host Test Code	Analyte Name	Result Code	Possible Result Values
Xpert Xpress GBS US-IVD	2	¹ GBS	GBS	² N.A.	POSITIVE
					PRESUMPTIVE NEGATIVE
					INVALID
					ERROR
					NO RESULT

¹**Note:** As a Single-Result Assay, the Assay Host Test Code will be the same as the Upload and Download Code.

²**Note:** Result Code is not applicable for Single-Result Assay

2 Example Messages

These example messages can be used by an LIS interface analyst to understand the structure and content of Xpert Xpress GBS test results.

2.1 Example Result Messages

2.1.1 Example ASTM Messages

INVALID

```
H|@^|\GXM-07284374338||GeneXpert PC^GeneXpert^6.5||||LIS|P|1394-97|20221120145951
P|1||||
O|1|Xpress_GBS_V2_INVALID#2||^G|B|R|20231018041923|||||||ORH|||||||F
R|1|^G|B|^X|p|e|r|t|X|p|r|e|s|G|B|S|U|S|-|I|V|D|^2|^|^I|N|V|A|L|I|D|^|||||F|<None>|20231018041923|20231018050114|CPHD-J07QJ3L^724586^638684^0^10804^
R|2|^G|B|^S|^P|^C|^P|^A|^S|^S|^|||
R|3|^G|B|^S|^S|^P|^C|^C|^t|^33.1|||
R|4|^G|B|^S|^S|^P|^C|^E|^n|^d|^P|^t|^236.0|||
R|5|^G|B|^S|^S|^S|^A|^C|^F|^A|^I|^L|^|||
R|6|^G|B|^S|^S|^S|^A|^C|^C|^t|^39.0|||
R|7|^G|B|^S|^S|^S|^A|^C|^E|^n|^d|^P|^t|^192.0|||
R|8|^G|B|^S|^S|^G|B|^S|^I|^N|V|A|L|I|D|^|||
R|9|^G|B|^S|^S|^G|B|^S|^C|^t|^0.0|||
R|10|^G|B|^S|^S|^G|B|^S|^E|^n|^d|^P|^t|^2.0|||
L|1|N
```

ERROR

```
H|@^|\GXM-80870148183||GeneXpert PC^GeneXpert^6.5||||LIS|P|1394-97|20221120150152
P|1||||
O|1|Xpress_GBS_V2_ERROR#2||^G|B|R|20231018040803|||||||ORH|||||||F
R|1|^G|B|^S|^X|p|e|r|t|X|p|r|e|s|G|B|S|U|S|-|I|V|D|^2|^|^E|R|R|O|R|^A|^|||||F|<None>|20231018040803|20231018042315|CPHD-J07QJ3L^724585^210075850^0^10804^
C|1||Error^5006^Post-run analysis error^Error 5006: [SPC] probe check failed. Probe check value of 258 for reading number 1 was above the maximum of
147^20231018042315|N
C|2||Error^5006^Post-run analysis error^Error 5006: [SPC] probe check failed. Probe check value of 250 for reading number 3 was above the maximum of
147^20231018042315|N
```

C|3||Error^5006^Post-run analysis error^Error 5006: [SAC] probe check failed. Probe check value of 675 for reading number 1 was above the maximum of 219^20231018042315|N
C|4||Error^5006^Post-run analysis error^Error 5006: [SAC] probe check failed. Probe check value of 698 for reading number 3 was above the maximum of 219^20231018042315|N
R|2|^G^S^S^P^C^|NO RESULT^||
R|3|^G^S^S^P^C^Ct|^0.0||
R|4|^G^S^S^P^C^EndPt|^0.0||
R|5|^G^S^S^S^A^C^|NO RESULT^||
R|6|^G^S^S^S^A^C^Ct|^0.0||
R|7|^G^S^S^S^A^C^EndPt|^0.0||
R|8|^G^S^S^G^S^|NO RESULT^||
R|9|^G^S^S^G^S^Ct|^0.0||
R|10|^G^S^S^G^S^EndPt|^0.0||
L|1|N

GBS POSITIVE

H|@^\|GXM-61165330715||GeneXpert PC^GeneXpert^6.5||||LIS||P|1394-97|20221120150116
P|1||||
O|1|Xpress_GBS_V2_POSITIVE#2|^G^S^R|20231018041706||||||ORH|||||||F
R|1|^G^S^Xpert Xpress GBS US-IVD^2^^|POSITIVE^||||F||<None>|20231018041706|20231018044931|CPHD-
J07QJ3L^724585^210075699^0^10804^
R|2|^G^S^S^P^C^|NA^||
R|3|^G^S^S^P^C^Ct|^0.0||
R|4|^G^S^S^P^C^EndPt|^2.0||
R|5|^G^S^S^S^A^C^|NA^||
R|6|^G^S^S^S^A^C^Ct|^0.0||
R|7|^G^S^S^S^A^C^EndPt|^-1.0||
R|8|^G^S^S^G^S^|POS^||
R|9|^G^S^S^G^S^Ct|^24.9||
R|10|^G^S^S^G^S^EndPt|^219.0||
L|1|N

GBS PRESUMPTIVE NEGATIVE

H|@^\GXM-18031380150||GeneXpert PC^GeneXpert^6.5||||LIS||P|1394-97|20221120150032
P|1||||
O|1|Xpress_GBS_V2_NEGATIVE#2||^GBS|R|20231018041829||||||ORH|||||||F
R|1|^GBS^Xpert Xpress GBS US-IVD^2^^|PRESUMPTIVE NEGATIVE^||||F||<None>|20231018041829|20231018045959|CPHD-
J07QJ3L^724586^210069259^0^10804^
R|2|^GBS^^SPC^|PASS^|||
R|3|^GBS^^SPC^Ct|^33.2|||
R|4|^GBS^^SPC^EndPt|^250.0|||
R|5|^GBS^^SAC^|PASS^|||
R|6|^GBS^^SAC^Ct|^28.1|||
R|7|^GBS^^SAC^EndPt|^392.0|||
R|8|^GBS^^GBS^|NEG^|||
R|9|^GBS^^GBS^Ct|^0.0|||
R|10|^GBS^^GBS^EndPt|^-1.0|||
L|1|N

NO RESULT

H|@^\GXM-43411275648||GeneXpert PC^GeneXpert^6.5||||LIS||P|1394-97|20221120145837
P|1||||
O|1|Xpress_GBS_V2_NO_RESULT#2||^GBS|R|20231018054525||||||ORH|||||||F
R|1|^GBS^Xpert Xpress GBS US-IVD^2^^|NO RESULT^||||F||<None>|20231018054525|20231018054619|CPHD-J07QJ3L^724586^652096^0^10804^
R|2|^GBS^^SPC^|NO RESULT^|||
R|3|^GBS^^SPC^Ct|^0.0|||
R|4|^GBS^^SPC^EndPt|^0.0|||
R|5|^GBS^^SAC^|NO RESULT^|||
R|6|^GBS^^SAC^Ct|^0.0|||
R|7|^GBS^^SAC^EndPt|^0.0|||
R|8|^GBS^^GBS^|NO RESULT^|||
R|9|^GBS^^GBS^Ct|^0.0|||
R|10|^GBS^^GBS^EndPt|^0.0|||
L|1|N

2.1.2 Example HL7 Messages

INVALID

```
MSH|^~\&|GeneXpert PC^GeneXpert^6.5||LIS||20221120150733||ORU^R32^ORU_R30|GXM-38376235265|P|2.5
PID|1|||||||
ORC|RE|1|||||||20231018041923
OBR|1|||GBS|||||||||||||F
TQ1|||||||20231018041923|20231018050114|R
OBX|1|ST|&GBS&Xpert Xpress GBS US-IVD&2|&|INVALID^|||||F|||||^<None>||~10804~0~638684~724586~CPHD-J07QJ3L
OBX|2|ST|&GBS|SPC&|PASS^|
OBX|3|ST|&GBS|SPC&Ct|^33.1|
OBX|4|ST|&GBS|SPC&EndPt|^236.0|
OBX|5|ST|&GBS|SAC&|FAIL^|
OBX|6|ST|&GBS|SAC&Ct|^39.0|
OBX|7|ST|&GBS|SAC&EndPt|^192.0|
OBX|8|ST|&GBS|GBS&|INVALID^|
OBX|9|ST|&GBS|GBS&Ct|^0.0|
OBX|10|ST|&GBS|GBS&EndPt|^2.0|
SPM|1|Xpress_GBS_V2_INVALID#2^||ORH|||||P
```

ERROR

```
MSH|^~\&|GeneXpert PC^GeneXpert^6.5||LIS||20221120150940||ORU^R32^ORU_R30|GXM-16811188632|P|2.5
PID|1|||||||
ORC|RE|1|||||||20231018040803
OBR|1|||GBS|||||||||||||F
TQ1|||||||20231018040803|20231018042315|R
OBX|1|ST|&GBS&Xpert Xpress GBS US-IVD&2|&|ERROR^|||||F|||||^<None>||~10804~0~210075850~724585~CPHD-J07QJ3L
NTE|1|L|Error^5006^Post-run analysis error^Error 5006: [SPC] probe check failed. Probe check value of 258 for reading number 1 was above the maximum of 147^20231018042315
NTE|2|L|Error^5006^Post-run analysis error^Error 5006: [SPC] probe check failed. Probe check value of 250 for reading number 3 was above the maximum of 147^20231018042315
NTE|3|L|Error^5006^Post-run analysis error^Error 5006: [SAC] probe check failed. Probe check value of 675 for reading number 1 was above the maximum of 219^20231018042315
NTE|4|L|Error^5006^Post-run analysis error^Error 5006: [SAC] probe check failed. Probe check value of 698 for reading number 3 was above the maximum of 219^20231018042315
```

OBX|2|ST|&GBS|SPC&|NO RESULT^||
OBX|3|ST|&GBS|SPC&Ct|^0.0||
OBX|4|ST|&GBS|SPC&EndPt|^0.0||
OBX|5|ST|&GBS|SAC&|NO RESULT^||
OBX|6|ST|&GBS|SAC&Ct|^0.0||
OBX|7|ST|&GBS|SAC&EndPt|^0.0||
OBX|8|ST|&GBS|GBS&|NO RESULT^||
OBX|9|ST|&GBS|GBS&Ct|^0.0||
OBX|10|ST|&GBS|GBS&EndPt|^0.0||
SPM|1|Xpress_GBS_V2_ERROR#2^||ORH|||||P

GBS POSITIVE

MSH|^~\&|GeneXpert PC^GeneXpert^6.5||LIS||20221120150902||ORU^R32^ORU_R30|GXM-87801175073|P|2.5
PID|1|||||||
ORC|RE|1|||||||20231018041706
OBR|1||GBS|||||||||||||F
TQ1|||||||20231018041706|20231018044931|R
OBX|1|ST|&GBS&Xpert Xpress GBS US-IVD&2|&|POSITIVE^|||||F||||^<None>||~10804~0~210075699~724585~CPHD-J07QJ3L
OBX|2|ST|&GBS|SPC&|NA^||
OBX|3|ST|&GBS|SPC&Ct|^0.0||
OBX|4|ST|&GBS|SPC&EndPt|^2.0||
OBX|5|ST|&GBS|SAC&|NA^||
OBX|6|ST|&GBS|SAC&Ct|^0.0||
OBX|7|ST|&GBS|SAC&EndPt|^-1.0||
OBX|8|ST|&GBS|GBS&|POS^||
OBX|9|ST|&GBS|GBS&Ct|^24.9||
OBX|10|ST|&GBS|GBS&EndPt|^219.0||
SPM|1|Xpress_GBS_V2_POSITIVE#2^||ORH|||||P

GBS PRESUMPTIVE NEGATIVE

MSH|^~\&|GeneXpert PC^GeneXpert^6.5||LIS||20221120150830||ORU^R32^ORU_R30|GXM-25323218444|P|2.5
PID|1|||||||
ORC|RE|1|||||||20231018041829
OBR|1||GBS|||||||||||||F
TQ1|||||||20231018041829|20231018045959|R

OBX|1|ST|&GBS&Xpert Xpress GBS US-IVD&2|&|PRESUMPTIVE NEGATIVE^|||||F|||||^<None>||~10804~0~210069259~724586~CPHD-J07QJ3L
OBX|2|ST|&GBS|SPC&|PASS^||
OBX|3|ST|&GBS|SPC&Ct|^33.2||
OBX|4|ST|&GBS|SPC&EndPt|^250.0||
OBX|5|ST|&GBS|SAC&|PASS^||
OBX|6|ST|&GBS|SAC&Ct|^28.1||
OBX|7|ST|&GBS|SAC&EndPt|^392.0||
OBX|8|ST|&GBS|GBS&|NEG^||
OBX|9|ST|&GBS|GBS&Ct|^0.0||
OBX|10|ST|&GBS|GBS&EndPt|^-1.0||
SPM|1|Xpress_GBS_V2_NEGATIVE#2^||ORH|||||P

NO RESULT

MSH|^~\&|GeneXpert PC^GeneXpert^6.5||LIS||20221120150559||ORU^R32^ORU_R30|GXM-52237156788|P|2.5
PID|1|||||
ORC|RE|1|||||20231018054525
OBR|1||GBS|||||F
TQ1|||||20231018054525|20231018054619|R
OBX|1|ST|&GBS&Xpert Xpress GBS US-IVD&2|&|NO RESULT^|||||F|||||^<None>||~10804~0~652096~724588~CPHD-J07QJ3L
OBX|2|ST|&GBS|SPC&|NO RESULT^||
OBX|3|ST|&GBS|SPC&Ct|^0.0||
OBX|4|ST|&GBS|SPC&EndPt|^0.0||
OBX|5|ST|&GBS|SAC&|NO RESULT^||
OBX|6|ST|&GBS|SAC&Ct|^0.0||
OBX|7|ST|&GBS|SAC&EndPt|^0.0||
OBX|8|ST|&GBS|GBS&|NO RESULT^||
OBX|9|ST|&GBS|GBS&Ct|^0.0||
OBX|10|ST|&GBS|GBS&EndPt|^0.0||
SPM|1|Xpress_GBS_V2_NO_RESULT#2^||ORH|||||P