

Xpert® HBV Viral Load Laboratory Information System Guidance

REF GXHBV-VL-CE-10 / GXHBV-VL-CN-10

ADF: **Xpert HBV Viral Load** **Version 2**

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

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

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® HBV Viral Load	2	¹ HBVVL	HBV	² N.A.	NOT DETECTED
					DETECTED
					DETECTED > 1.00E09 IU/mL
					DETECTED <10 IU/mL
					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® HBV Viral Load test results.

2.1 Example Result Messages

2.1.1 Example ASTM Messages: Xpert® HBV Viral Load

INVALID

```
H|@^\|GXM-64278603857||BCH 120000833^GeneXpert^6.5|||||LIS||P|1394-97|20240529083739
P|1||||
O|1|HBV_Invalid#4||^HBVVL|R|20240517054825|||||||ORH|||||||F
R|1|^HBVVL^Xpert HBV Viral Load^2^^|INVALID^|IU/mL|10.00 to
100000000.00|A||F||<None>|20240517054825|20240517064536|WinDev2006Eval^910757973^746690^1007139710^18405^20250309
R|2|^HBVVL^Xpert HBV Viral Load^2^^LOG|^|IU/mL|1.00 to
9.00|A||F||<None>|20240517054825|20240517064536|WinDev2006Eval^910757973^746690^1007139710^18405^20250309
R|3|^HBVVL^HBV^|INVALID^|||
R|4|^HBVVL^HBV^Ct|^0.0|||
R|5|^HBVVL^HBV^EndPt|^1.0|||
R|6|^HBVVL^HBV^Delta Ct|^|||
R|7|^HBVVL^IQS-H^|FAIL^|||
R|8|^HBVVL^IQS-H^Ct|^0.0|||
R|9|^HBVVL^IQS-H^EndPt|^1.0|||
R|10|^HBVVL^IQS-L^|FAIL^|||
R|11|^HBVVL^IQS-L^Ct|^0.0|||
R|12|^HBVVL^IQS-L^EndPt|^1.0|||
L|1|N
```

DETECTED > 1.00E09 IU/mL

H|@^\|GXM-85058318458||BCH 120000833^GeneXpert^6.5||||LIS||P|1394-97|20240529083740
P|1||||
O|1|HBV_more than 10E9#1||^HBVVL|R|20240517043205|||||||ORH|||||||F
R|1|^HBVVL^Xpert HBV Viral Load^2^^|DETECTED^|IU/mL|10.00 to
1000000000.00|>||F||<None>|20240517043205|20240517052908|WinDev2006Eval^755920^718507^1201899158^18704^20250525
R|2|^HBVVL^Xpert HBV Viral Load^2^^LOG|^|IU/mL|1.00 to
9.00|>||F||<None>|20240517043205|20240517052908|WinDev2006Eval^755920^718507^1201899158^18704^20250525
R|3|^HBVVL^HBV^|POS^||
R|4|^HBVVL^HBV^Ct|^8.3||
R|5|^HBVVL^HBV^EndPt|^518.0||
R|6|^HBVVL^HBV^Delta Ct|^16.4||
R|7|^HBVVL^IQS-H^|PASS^||
R|8|^HBVVL^IQS-H^Ct|^19.5||
R|9|^HBVVL^IQS-H^EndPt|^259.0||
R|10|^HBVVL^IQS-L^|PASS^||
R|11|^HBVVL^IQS-L^Ct|^31.3||
R|12|^HBVVL^IQS-L^EndPt|^438.0||
L|1|N

DETECTED

H|@^\|GXM-52884836211||BCH 120000833^GeneXpert^6.5||||LIS||P|1394-97|20240529083742
P|1||||
O|1|HBV_Detected||^HBVVL|R|20240517043137|||||||ORH|||||||F
R|1|^HBVVL^Xpert HBV Viral Load^2^^|^137.56|IU/mL|10.00 to
1000000000.00|N||F||<None>|20240517043137|20240517052818|WinDev2006Eval^755920^801735^1201899166^18704^20250525
R|2|^HBVVL^Xpert HBV Viral Load^2^^LOG|^2.14|IU/mL|1.00 to
9.00|N||F||<None>|20240517043137|20240517052818|WinDev2006Eval^755920^801735^1201899166^18704^20250525
R|3|^HBVVL^HBV^|POS^||
R|4|^HBVVL^HBV^Ct|^31.4||

R|5|^^^HBVVL^^^HBV^EndPt|^437.0|||
R|6|^^^HBVVL^^^HBV^Delta Ct|^^-6.8|||
R|7|^^^HBVVL^^^IQS-H^|PASS^|||
R|8|^^^HBVVL^^^IQS-H^Ct|^19.5|||
R|9|^^^HBVVL^^^IQS-H^EndPt|^261.0|||
R|10|^^^HBVVL^^^IQS-L^|PASS^|||
R|11|^^^HBVVL^^^IQS-L^Ct|^31.1|||
R|12|^^^HBVVL^^^IQS-L^EndPt|^389.0|||
L|1|N

DETECTED <10 IU/mL

H|@^\GXM-65153760227||BCH 120000833^GeneXpert^6.5|||||LIS||P|1394-97|20240529083743
P|1||||
O|1|HBV_less than 10#1||^^^HBVVL|R|20240517043027|||||||ORH|||||||F
R|1|^^^HBVVL^Xpert HBV Viral Load^2^^|DETECTED^|IU/mL|10.00 to
100000000.00|<|F||<None>|20240517043027|20240517052717|WinDev2006Eval^910757974^805627^1201899165^18704^20250525
R|2|^^^HBVVL^Xpert HBV Viral Load^2^^LOG|^|IU/mL|1.00 to
9.00|<|F||<None>|20240517043027|20240517052717|WinDev2006Eval^910757974^805627^1201899165^18704^20250525
R|3|^^^HBVVL^^^HBV^|POS^|||
R|4|^^^HBVVL^^^HBV^Ct|^35.9|||
R|5|^^^HBVVL^^^HBV^EndPt|^341.0|||
R|6|^^^HBVVL^^^HBV^Delta Ct|^^-11.3|||
R|7|^^^HBVVL^^^IQS-H^|PASS^|||
R|8|^^^HBVVL^^^IQS-H^Ct|^19.5|||
R|9|^^^HBVVL^^^IQS-H^EndPt|^249.0|||
R|10|^^^HBVVL^^^IQS-L^|PASS^|||
R|11|^^^HBVVL^^^IQS-L^Ct|^30.8|||
R|12|^^^HBVVL^^^IQS-L^EndPt|^436.0|||
L|1|N

NOT DETECTED

H|@^\|GXM-38238038615||BCH 120000833^GeneXpert^6.5||||LIS||P|1394-97|20240529083744
P|1||||
O|1|HBV_Negative|^H^HBVVL|R|20240517042932|||||||ORH|||||||F
R|1|^H^HBVVL^Xpert HBV Viral Load^2^^|NOT DETECTED^|IU/mL|10.00 to
1000000000.00|A||F||<None>|20240517042932|20240517052616|WinDev2006Eval^910757973^890930^1201899164^18704^20250525
R|2|^H^HBVVL^Xpert HBV Viral Load^2^^LOG|^|IU/mL|1.00 to
9.00|A||F||<None>|20240517042932|20240517052616|WinDev2006Eval^910757973^890930^1201899164^18704^20250525
R|3|^H^HBVVL^H^HBV^|NEG^|||
R|4|^H^HBVVL^H^HBV^Ct|^0.0|||
R|5|^H^HBVVL^H^HBV^EndPt|^0.0|||
R|6|^H^HBVVL^H^HBV^Delta Ct|^|||
R|7|^H^HBVVL^H^IQS-H^|PASS^|||
R|8|^H^HBVVL^H^IQS-H^Ct|^20.2|||
R|9|^H^HBVVL^H^IQS-H^EndPt|^235.0|||
R|10|^H^HBVVL^H^IQS-L^|PASS^|||
R|11|^H^HBVVL^H^IQS-L^Ct|^31.3|||
R|12|^H^HBVVL^H^IQS-L^EndPt|^438.0|||
L|1|N

ERROR

H|@^\|GXM-30501610102||BCH 120000833^GeneXpert^6.5||||LIS||P|1394-97|20240529083745
P|1||||
O|1|HBV_ERROR|^H^HBVVL|R|20240517042827|||||||ORH|||||||F
R|1|^H^HBVVL^Xpert HBV Viral Load^2^^|ERROR^|IU/mL|10.00 to
1000000000.00|A||F||<None>|20240517042827|20240517043156|WinDev2006Eval^910757973^746690^1201899168^18704^20250525
R|2|^H^HBVVL^Xpert HBV Viral Load^2^^LOG|^|IU/mL|1.00 to
9.00|A||F||<None>|20240517042827|20240517043156|WinDev2006Eval^910757973^746690^1201899168^18704^20250525
C|1||Error^2096^Operation terminated^Error 2096: Assay-Specific Termination Error #1: 11, 30, 0, 0^20240517043140|N
R|3|^H^HBVVL^H^HBV^|NO RESULT^|||

R|4|^^^HBVVL^^^HBV^Ct|^0.0|||
R|5|^^^HBVVL^^^HBV^EndPt|^0.0|||
R|6|^^^HBVVL^^^HBV^Delta Ct|^|||
R|7|^^^HBVVL^^^IQS-H^|NO RESULT^|||
R|8|^^^HBVVL^^^IQS-H^Ct|^0.0|||
R|9|^^^HBVVL^^^IQS-H^EndPt|^0.0|||
R|10|^^^HBVVL^^^IQS-L^|NO RESULT^|||
R|11|^^^HBVVL^^^IQS-L^Ct|^0.0|||
R|12|^^^HBVVL^^^IQS-L^EndPt|^0.0|||
L|1|N

NO RESULT

H|^@\|GXM-17147503340|BCH 120000833^GeneXpert^6.5|||||LIS|P|1394-97|20240529083746
P|1||||
O|1|HBV_NO RESULT|^|^HBVVL|R|20240517042807|||||||ORH|||||||F
R|1|^^^HBVVL^Xpert HBV Viral Load^2^^|NO RESULT^|IU/mL|10.00 to
100000000.00|A|F|<None>|20240517042807|20240517043535|WinDev2006Eval^910757973^760486^1201899167^18704^20250525
R|2|^^^HBVVL^Xpert HBV Viral Load^2^^LOG|^|IU/mL|1.00 to
9.00|A|F|<None>|20240517042807|20240517043535|WinDev2006Eval^910757973^760486^1201899167^18704^20250525
R|3|^^^HBVVL^^^HBV^|NO RESULT^|||
R|4|^^^HBVVL^^^HBV^Ct|^0.0|||
R|5|^^^HBVVL^^^HBV^EndPt|^0.0|||
R|6|^^^HBVVL^^^HBV^Delta Ct|^|||
R|7|^^^HBVVL^^^IQS-H^|NO RESULT^|||
R|8|^^^HBVVL^^^IQS-H^Ct|^0.0|||
R|9|^^^HBVVL^^^IQS-H^EndPt|^0.0|||
R|10|^^^HBVVL^^^IQS-L^|NO RESULT^|||
R|11|^^^HBVVL^^^IQS-L^Ct|^0.0|||
R|12|^^^HBVVL^^^IQS-L^EndPt|^0.0|||

2.1.2 Example HL7 Messages: Xpert® HBV Viral Load

INVALID

```
MSH|^~\&|BCH 120000833^GeneXpert^6.5||LIS||20240529084531||ORU^R32^ORU_R30|GXM-41263226562|P|2.5
PID|1|||||
ORC|RE|1|||||20240517054825
OBR|1|||HBVVL|||||F
TQ1|||||20240517054825|20240517064536|R
OBX|1|ST|&HBVVL&Xpert HBV Viral Load&2|&|INVALID^|IU/mL|10.00-
100000000.00|A||F||||^<None>||20250309~18405~1007139710~746690~910757973~WinDev2006Eval
OBX|2|ST|&HBVVL&Xpert HBV Viral Load&2|&LOG|^|IU/mL|1.00-
9.00|A||F||||^<None>||20250309~18405~1007139710~746690~910757973~WinDev2006Eval
OBX|3|ST|&HBVVL|HBV&|INVALID^|
OBX|4|ST|&HBVVL|HBV&Ct|^0.0|
OBX|5|ST|&HBVVL|HBV&EndPt|^1.0|
OBX|6|ST|&HBVVL|HBV&Delta Ct|^|
OBX|7|ST|&HBVVL|IQS-H&|FAIL^|
OBX|8|ST|&HBVVL|IQS-H&Ct|^0.0|
OBX|9|ST|&HBVVL|IQS-H&EndPt|^1.0|
OBX|10|ST|&HBVVL|IQS-L&|FAIL^|
OBX|11|ST|&HBVVL|IQS-L&Ct|^0.0|
OBX|12|ST|&HBVVL|IQS-L&EndPt|^1.0|
SPM|1|HBV_Invalid#4^|ORH|||||P
```

DETECTED > 1.00E09 IU/mL

```
MSH|^~\&|BCH 120000833^GeneXpert^6.5||LIS||20240529084533||ORU^R32^ORU_R30|GXM-15228544705|P|2.5
PID|1|||||
ORC|RE|1|||||20240517043205
OBR|1|||HBVVL|||||F
TQ1|||||20240517043205|20240517052908|R
```


OBX|1|ST|&HBVVL&Xpert HBV Viral Load&2|&|DETECTED^|IU/mL|10.00-1000000000.00|>||F|||||^<None>||20250525~18704~1201899158~718507~755920~WinDev2006Eval
OBX|2|ST|&HBVVL&Xpert HBV Viral Load&2|&LOG|^|IU/mL|1.00-9.00|>||F|||||^<None>||20250525~18704~1201899158~718507~755920~WinDev2006Eval
OBX|3|ST|&HBVVL|HBV&|POS^||
OBX|4|ST|&HBVVL|HBV&Ct|^8.3||
OBX|5|ST|&HBVVL|HBV&EndPt|^518.0||
OBX|6|ST|&HBVVL|HBV&Delta Ct|^16.4||
OBX|7|ST|&HBVVL|IQS-H&|PASS^||
OBX|8|ST|&HBVVL|IQS-H&Ct|^19.5||
OBX|9|ST|&HBVVL|IQS-H&EndPt|^259.0||
OBX|10|ST|&HBVVL|IQS-L&|PASS^||
OBX|11|ST|&HBVVL|IQS-L&Ct|^31.3||
OBX|12|ST|&HBVVL|IQS-L&EndPt|^438.0||
SPM|1|HBV_more than 10E9#1^||ORH|||||||P

DETECTED

MSH|^~\&|BCH 120000833^GeneXpert^6.5||LIS||20240529084534||ORU^R32^ORU_R30|GXM-12463085834|P|2.5
PID|1|||||||
ORC|RE|1|||||||20240517043137
OBR|1|||HBVVL|F
TQ1|||||20240517043137|20240517052818|R
OBX|1|ST|&HBVVL&Xpert HBV Viral Load&2|&|^137.56|IU/mL|10.00-1000000000.00|N||F|||||^<None>||20250525~18704~1201899166~801735~755920~WinDev2006Eval
OBX|2|ST|&HBVVL&Xpert HBV Viral Load&2|&LOG|^2.14|IU/mL|1.00-9.00|N||F|||||^<None>||20250525~18704~1201899166~801735~755920~WinDev2006Eval
OBX|3|ST|&HBVVL|HBV&|POS^||
OBX|4|ST|&HBVVL|HBV&Ct|^31.4||
OBX|5|ST|&HBVVL|HBV&EndPt|^437.0||
OBX|6|ST|&HBVVL|HBV&Delta Ct|^-6.8||

OBX|7|ST|&HBVVL|IQS-H&|PASS^||
OBX|8|ST|&HBVVL|IQS-H&Ct|^19.5||
OBX|9|ST|&HBVVL|IQS-H&EndPt|^261.0||
OBX|10|ST|&HBVVL|IQS-L&|PASS^||
OBX|11|ST|&HBVVL|IQS-L&Ct|^31.1||
OBX|12|ST|&HBVVL|IQS-L&EndPt|^389.0||
SPM|1|HBV_Detected^||ORH|||||P

DETECTED <10 IU/mL

MSH|^~\&|BCH 120000833^GeneXpert^6.5||LIS||20240529084535||ORU^R32^ORU_R30|GXM-78844014651|P|2.5
PID|1|||||||
ORC|RE|1|||||20240517043027
OBR|1|||HBVVL|||||||F
TQ1|||||20240517043027|20240517052717|R
OBX|1|ST|&HBVVL&Xpert HBV Viral Load&2|&|DETECTED^|IU/mL|10.00-
100000000.00|<||F|||||^<None>||20250525~18704~1201899165~805627~910757974~WinDev2006Eval
OBX|2|ST|&HBVVL&Xpert HBV Viral Load&2|&LOG|^|IU/mL|1.00-
9.00|<||F|||||^<None>||20250525~18704~1201899165~805627~910757974~WinDev2006Eval
OBX|3|ST|&HBVVL|HBV&|POS^||
OBX|4|ST|&HBVVL|HBV&Ct|^35.9||
OBX|5|ST|&HBVVL|HBV&EndPt|^341.0||
OBX|6|ST|&HBVVL|HBV&Delta Ct|^-11.3||
OBX|7|ST|&HBVVL|IQS-H&|PASS^||
OBX|8|ST|&HBVVL|IQS-H&Ct|^19.5||
OBX|9|ST|&HBVVL|IQS-H&EndPt|^249.0||
OBX|10|ST|&HBVVL|IQS-L&|PASS^||
OBX|11|ST|&HBVVL|IQS-L&Ct|^30.8||
OBX|12|ST|&HBVVL|IQS-L&EndPt|^436.0||
SPM|1|HBV_less than 10#1^||ORH|||||P

NOT DETECTED

MSH|^~\&|BCH 120000833^GeneXpert^6.5||LIS||20240529084536||ORU^R32^ORU_R30|GXM-82033721724|P|2.5
PID|1|||||
ORC|RE|1|||||20240517042932
OBR|1|||HBVVL|||||F
TQ1|||||20240517042932|20240517052616|R
OBX|1|ST|&HBVVL&Xpert HBV Viral Load&2|&|NOT DETECTED^|IU/mL|10.00-
1000000000.00|A|||F|||^<None>||20250525~18704~1201899164~890930~910757973~WinDev2006Eval
OBX|2|ST|&HBVVL&Xpert HBV Viral Load&2|&LOG|^|IU/mL|1.00-
9.00|A|||F|||^<None>||20250525~18704~1201899164~890930~910757973~WinDev2006Eval
OBX|3|ST|&HBVVL|HBV&|NEG^||
OBX|4|ST|&HBVVL|HBV&Ct|^0.0||
OBX|5|ST|&HBVVL|HBV&EndPt|^0.0||
OBX|6|ST|&HBVVL|HBV&Delta Ct|^||
OBX|7|ST|&HBVVL|IQS-H&|PASS^||
OBX|8|ST|&HBVVL|IQS-H&Ct|^20.2||
OBX|9|ST|&HBVVL|IQS-H&EndPt|^235.0||
OBX|10|ST|&HBVVL|IQS-L&|PASS^||
OBX|11|ST|&HBVVL|IQS-L&Ct|^31.3||
OBX|12|ST|&HBVVL|IQS-L&EndPt|^438.0||
SPM|1|HBV_Negative^||ORH|||||P

ERROR

MSH|^~\&|BCH 120000833^GeneXpert^6.5||LIS||20240529084538||ORU^R32^ORU_R30|GXM-02027411500|P|2.5
PID|1|||||
ORC|RE|1|||||20240517042827
OBR|1|||HBVVL|||||F
TQ1|||||20240517042827|20240517043156|R
OBX|1|ST|&HBVVL&Xpert HBV Viral Load&2|&|ERROR^|IU/mL|10.00-
1000000000.00|A|||F|||^<None>||20250525~18704~1201899168~746690~910757973~WinDev2006Eval

OBX|2|ST|&HBVVL&Xpert HBV Viral Load&2|&LOG|^|IU/mL|1.00-
9.00|A|||F||||^<None>||20250525~18704~1201899168~746690~910757973~WinDev2006Eval
NTE|1|L|Error^2096^Operation terminated^Error 2096: Assay-Specific Termination Error #1: 11, 30, 0, 0^20240517043140
OBX|3|ST|&HBVVL|HBV&|NO RESULT^| |
OBX|4|ST|&HBVVL|HBV&Ct|^0.0| |
OBX|5|ST|&HBVVL|HBV&EndPt|^0.0| |
OBX|6|ST|&HBVVL|HBV&Delta Ct|^| |
OBX|7|ST|&HBVVL|IQS-H&|NO RESULT^| |
OBX|8|ST|&HBVVL|IQS-H&Ct|^0.0| |
OBX|9|ST|&HBVVL|IQS-H&EndPt|^0.0| |
OBX|10|ST|&HBVVL|IQS-L&|NO RESULT^| |
OBX|11|ST|&HBVVL|IQS-L&Ct|^0.0| |
OBX|12|ST|&HBVVL|IQS-L&EndPt|^0.0| |
SPM|1|HBV_ERROR^|ORH|||P

NO RESULT

MSH|^~\&|BCH 120000833^GeneXpert^6.5||LIS||20240529084539||ORU^R32^ORU_R30|GXM-23187044080|P|2.5
PID|1|||F||| |
ORC|RE|1|||20240517042807
OBR|1||HBVVL|||F
TQ1|||20240517042807|20240517043535|R
OBX|1|ST|&HBVVL&Xpert HBV Viral Load&2|&|NO RESULT^|IU/mL|10.00-
100000000.00|A|||F||||^<None>||20250525~18704~1201899167~760486~910757973~WinDev2006Eval
OBX|2|ST|&HBVVL&Xpert HBV Viral Load&2|&LOG|^|IU/mL|1.00-
9.00|A|||F||||^<None>||20250525~18704~1201899167~760486~910757973~WinDev2006Eval
OBX|3|ST|&HBVVL|HBV&|NO RESULT^| |
OBX|4|ST|&HBVVL|HBV&Ct|^0.0| |
OBX|5|ST|&HBVVL|HBV&EndPt|^0.0| |
OBX|6|ST|&HBVVL|HBV&Delta Ct|^| |
OBX|7|ST|&HBVVL|IQS-H&|NO RESULT^| |

OBX|8|ST|&HBVVL|IQS-H&Ct|^0.0||
OBX|9|ST|&HBVVL|IQS-H&EndPt|^0.0||
OBX|10|ST|&HBVVL|IQS-L&|NO RESULT^||
OBX|11|ST|&HBVVL|IQS-L&Ct|^0.0||
OBX|12|ST|&HBVVL|IQS-L&EndPt|^0.0||
SPM|1|HBV_NO RESULT^||ORH|||||P