



October 2019

Re: Special instructions for BCR-ABL Ultra customers

Dear Valued Customer:

Cepheid is releasing an updated assay definition file (ADF) for Xpert<sup>®</sup> BCR-ABL Ultra, which must be used with software versions: Dx 5.1 or above, or Xpertise<sup>™</sup> 6.6 or above.

**Attention:** If your LIS system uses the test name in the mapped test code, then your **LIS Administrator** will need to update the test codes in the LIS system.

The new ADF will **not** replace the current ADF in the system and will **not** be automatically LIS-enabled upon import.

Specifically, the test name has changed and this may affect your current LIS mapped assay host test codes.

#### Changes

- On the GeneXpert<sup>®</sup> System, you will need to create new test codes for the new ADF (after updating the software and installing the new ADF)
- The test result is changing – please see page 2 for an example of the change
- The LIS traces are changing – please see pages 3 to 6 for examples of this change

If you need further assistance, please contact Cepheid Technical Support by submitting a case online at <http://www.cepheid.com/us/support/support/contact-support-online>.

If you prefer, you can contact your local Technical Support office. This information is available at [www.cepheid.com](http://www.cepheid.com) or [www.cepheidinternational.com](http://www.cepheidinternational.com) under the SUPPORT tab. Select the Contact Us option.

Thank you for your continued business and interest in our products. We appreciate the partnership we have formed and will continue to strive to bring you the highest quality systems and tests in the industry.

Sincerely,

Cepheid



### Example results:

RESULT RANGE: % BCR-ABL/ABL /S	GXBCRABL-CE-10 or RBCRABL-10 using GX Dx 4.4a-4.8	GXBCRABL-10 or GXBCRABL-US-10 using GX Dx 5.1 and higher
>55%	BCR-ABL has been detected at a level of XX% (IS)	POSITIVE [Above upper LoQ]
0.0030-55%	BCR-ABL has been detected at a level of X.XX% (IS)	POSITIVE [X.XX% (IS) and MR X.XX]
<0.0030%	BCR-ABL has been detected at a level of X.XX% (IS)	POSITIVE [Below LoD;>MR4.52/<0.0030% (IS)]
N/A	BCR-ABL was not detected at a detection limit of X.XXXXX% (IS)	NEGATIVE [Sufficient ABL transcript]
N/A	BCR ABL Invalid	INVALID [Insufficient ABL transcript]
N/A	BCR ABL Invalid	INVALID [Too high BCR-ABL and ABL transcripts]
N/A	BCR ABL Invalid	INVALID [Too high ABL transcript]
N/A	BCR ABL Invalid	INVALID [Too high BCR-ABL transcript]

### CE-IVD and US-IVD LIS Trace Example

Product Codes: GXBCRABL-10 and GXBCRABL-US-10

ADF Name: Xpert BCR-ABL Ultra G2

Version: 1

```
H|@^|URM-QrS3u1WA-08||GeneXpert PC^GeneXpert^5.1||||LIS||P|1394-
97|20190926113731
.P|1||||^|
.O|1|condition_5_1|^|bcrabl|R|20190920132100|||||ORH|||||F
.R|1|^|bcrabl^Xpert BCR-ABL Ultra G2^1^^|NEGATIVE [Sufficient ABL
transcript]^|0.0030 to 55.00||F||Krupa
shridhar|20190920132100|20190920150548|Cepheid7670ZV1^701731^611655^1142
62188^08699^20901224
.R|2|^|bcrabl^Xpert BCR-ABL Ultra G2^1^^MR|^|0.0030 to 55.00||F||krupa
shridhar|20190920132100|20190920150548|Cepheid7670ZV1^701731^611655^1142
62188^08699^20901224
.R|3|^|bcrabl|^|BCR-ABL^|NEG^||
.R|4|^|bcrabl|^|BCR-ABL^Ct|^0.0||
.R|5|^|bcrabl|^|BCR-ABL^EndPt|^13.0||
.R|6|^|bcrabl|^|BCR-ABL^Delta Ct|^||
.R|7|^|bcrabl|^|ABL^|PASS^||
.R|8|^|bcrabl|^|ABL^Ct|^15.7||
.R|9|^|bcrabl|^|ABL^EndPt|^425.0||
.R|10|^|bcrabl|^|ABL^Delta Ct|^||
.L|1|N.
```



H|@^\|URM-kpQ3u1WA-01||GeneXpert PC^GeneXpert^5.1||||LIS||P|1394-97|20190926113722  
.P|1||||^|  
.O|1|Condition 1||^|bcrab|R|20190920131708||||||ORH||||||F  
.R|1|^|bcrab|^Xpert BCR-ABL Ultra G2^1^^|**POSITIVE [Above upper LoQ]**^||0.0030 to 55.00|||F||krupa  
shridhar|20190920131708|20190920150209|Cepheid7670ZV1^700039^613556^114262193^08699^20901224  
.R|2|^|bcrab|^Xpert BCR-ABL Ultra G2^1^^MR|^||0.0030 to 55.00|||F||krupa  
shridhar|20190920131708|20190920150209|Cepheid7670ZV1^700039^613556^114262193^08699^20901224  
.R|3|^|bcrab|^|BCR-ABL^|POS^|||  
.R|4|^|bcrab|^|BCR-ABL^Ct|^9.8|||  
.R|5|^|bcrab|^|BCR-ABL^EndPt|^718.0|||  
.R|6|^|bcrab|^|BCR-ABL^Delta Ct|^^-0.7|||  
.R|7|^|bcrab|^|ABL^|PASS^|||  
.R|8|^|bcrab|^|ABL^Ct|^9.2|||  
.R|9|^|bcrab|^|ABL^EndPt|^411.0|||  
.R|10|^|bcrab|^|ABL^Delta Ct|^|||  
.L|1|N.

Product Codes: GXBCRABL-10 and GXBCRABL-US-10  
ADF Name: Xpert BCR-ABL Ultra G2  
Version: 1

H|@^\|URM-ahR3u1WA-04||GeneXpert PC^GeneXpert^5.1||||LIS||P|1394-97|20190926113726  
.P|1||||^|  
.O|1|condition\_3\_2||^|bcrab|R|20190920131903||||||ORH||||||F  
.R|1|^|bcrab|^Xpert BCR-ABL Ultra G2^1^^|**POSITIVE [0.011% (IS) and MR3.96]**^0.011% (IS)|0.0030 to 55.00|||F||krupa  
shridhar|20190920131903|20190920150352|Cepheid7670ZV1^700039^604297^114262192^08699^20901224  
.R|2|^|bcrab|^Xpert BCR-ABL Ultra G2^1^^MR|^3.96% (IS)|0.0030 to 55.00|||F||krupa  
shridhar|20190920131903|20190920150352|Cepheid7670ZV1^700039^604297^114262192^08699^20901224  
.R|3|^|bcrab|^|BCR-ABL^|POS^|||  
.R|4|^|bcrab|^|BCR-ABL^Ct|^26.3|||  
.R|5|^|bcrab|^|BCR-ABL^EndPt|^644.0|||  
.R|6|^|bcrab|^|BCR-ABL^Delta Ct|^^-14.1|||  
.R|7|^|bcrab|^|ABL^|PASS^|||  
.R|8|^|bcrab|^|ABL^Ct|^12.1|||  
.R|9|^|bcrab|^|ABL^EndPt|^425.0|||  
.R|10|^|bcrab|^|ABL^Delta Ct|^|||



.L|1|N.

H|@^|\URM-WGS3u1WA-06||GeneXpert PC^GeneXpert^5.1||||LIS||P|1394-97|20190926113728

.P|1||||^|

.O|1|condition\_3\_4|^|bcrab|R|20190920132000|||||ORH|||||F

.R|1|^|bcrab|^Xpert BCR-ABL Ultra G2^1^^|**POSITIVE [Below LoD;**

**>MR4.52/<0.0030% (IS)]**^0.0030|% (IS)|0.0030 to 55.00||F||krupa

shridhar|20190920132000|20190920150515|Cepheid7670ZV1^701731^603743^1142

62190^08699^20901224

.R|2|^|bcrab|^Xpert BCR-ABL Ultra G2^1^^MR|^4.52|% (IS)|0.0030 to 55.00||F||krupa

shridhar|20190920132000|20190920150515|Cepheid7670ZV1^701731^603743^1142

62190^08699^20901224

.R|3|^|bcrab|^|BCR-ABL^|POS^|||

.R|4|^|bcrab|^|BCR-ABL^Ct|^29.7|||

.R|5|^|bcrab|^|BCR-ABL^EndPt|^232.0|||

.R|6|^|bcrab|^|BCR-ABL^Delta Ct|^16.5|||

.R|7|^|bcrab|^|ABL^|PASS^|||

.R|8|^|bcrab|^|ABL^Ct|^13.2|||

.R|9|^|bcrab|^|ABL^EndPt|^423.0|||

.R|10|^|bcrab|^|ABL^Delta Ct|^|||

.L|1|N.

Product Codes: GXBCRABL-10 and GXBCRABL-US-10

ADF Name: Xpert BCR-ABL Ultra G2

Version: 1

H|@^|\URM-xhT3u1WA-11||GeneXpert PC^GeneXpert^5.1||||LIS||P|1394-97|20190926113734

.P|1||||^|

.O|1|condition\_7|^|bcrab|R|20190920132227|||||ORH|||||F

.R|1|^|bcrab|^Xpert BCR-ABL Ultra G2^1^^|**INVALID [Too high ABL**

**transcript]**^|0.0030 to 55.00||F||krupa

shridhar|20190920132227|20190920150718|Cepheid7670ZV1^701732^619188^1142

62183^08699^20901224

.R|2|^|bcrab|^Xpert BCR-ABL Ultra G2^1^^MR|^|0.0030 to 55.00||F||krupa

shridhar|20190920132227|20190920150718|Cepheid7670ZV1^701732^619188^1142

62183^08699^20901224

.R|3|^|bcrab|^|BCR-ABL^|INVALID^|||

.R|4|^|bcrab|^|BCR-ABL^Ct|^24.2|||

.R|5|^|bcrab|^|BCR-ABL^EndPt|^636.0|||

.R|6|^|bcrab|^|BCR-ABL^Delta Ct|^|||

.R|7|^|bcrab|^|ABL^|FAIL^|||

.R|8|^|bcrab|^|ABL^Ct|^7.9|||

.R|9|^|bcrab|^|ABL^EndPt|^205.0|||

.R|10|^|bcrab|^|ABL^Delta Ct|^|||

.L|1|N.

H|@^\|URM-R9S3u1WA-09||GeneXpert PC^GeneXpert^5.1||||LIS||P|1394-97|20190926113732  
.P|1||||^|  
.O|1|condition\_5\_2|^|bcrab|R|20190920132123|||||ORH|||||F  
.R|1|^|bcrab|^Xpert BCR-ABL Ultra G2^1|^|INVALID [Insufficient ABL transcript]^|0.0030 to 55.00||F||krupa  
shridhar|20190920132123|20190920150613|Cepheid7670ZV1^701732^609809^114262185^08699^20901224  
.R|2|^|bcrab|^Xpert BCR-ABL Ultra G2^1|^MR|^|0.0030 to 55.00||F||krupa  
shridhar|20190920132123|20190920150613|Cepheid7670ZV1^701732^609809^114262185^08699^20901224  
.R|3|^|bcrab|^|BCR-ABL|^|INVALID^|  
.R|4|^|bcrab|^|BCR-ABL^Ct|^0.0||  
.R|5|^|bcrab|^|BCR-ABL^EndPt|^6.0||  
.R|6|^|bcrab|^|BCR-ABL^Delta Ct|^|  
.R|7|^|bcrab|^|ABL|^|FAIL^|  
.R|8|^|bcrab|^|ABL^Ct|^26.8||  
.R|9|^|bcrab|^|ABL^EndPt|^90.0||  
.R|10|^|bcrab|^|ABL^Delta Ct|^|  
.L|1|N.

Product Codes: GXBCRABL-10 and GXBCRABL-US-10  
ADF Name: Xpert BCR-ABL Ultra G2  
Version: 1

H|@^\|URM-dPT3u1WA-10||GeneXpert PC^GeneXpert^5.1||||LIS||P|1394-97|20190926113733  
.P|1||||^|  
.O|1|condition\_6|^|bcrab|R|20190920132207|||||ORH|||||F  
.R|1|^|bcrab|^Xpert BCR-ABL Ultra G2^1|^|INVALID [Too high BCR-ABL and ABL transcripts]^|0.0030 to 55.00||F||krupa  
shridhar|20190920132207|20190920150657|Cepheid7670ZV1^701732^609452^114262186^08699^20901224  
.R|2|^|bcrab|^Xpert BCR-ABL Ultra G2^1|^MR|^|0.0030 to 55.00||F||krupa  
shridhar|20190920132207|20190920150657|Cepheid7670ZV1^701732^609452^114262186^08699^20901224  
.R|3|^|bcrab|^|BCR-ABL|^|INVALID^|  
.R|4|^|bcrab|^|BCR-ABL^Ct|^7.8||  
.R|5|^|bcrab|^|BCR-ABL^EndPt|^517.0||  
.R|6|^|bcrab|^|BCR-ABL^Delta Ct|^|  
.R|7|^|bcrab|^|ABL|^|FAIL^|  
.R|8|^|bcrab|^|ABL^Ct|^7.3||  
.R|9|^|bcrab|^|ABL^EndPt|^-35.0||  
.R|10|^|bcrab|^|ABL^Delta Ct|^|  
.L|1|N.

