



July 29, 2019

**IMPORTANT PRODUCT NOTICE**

Xpert® HCV Viral Load

Part Number	Batch Number	Lot Number	Expiration Date
GXHCV-VL-CE-10	1000151328	32901	2020-03-15
GXHCV-VL-IN-10	1000151455	32902	2020-03-15
GXHCV-VL-CE-10	1000151573	32903	2020-03-15

Attention Cepheid Customer,

Cepheid is writing to provide important information regarding the Xpert® HCV Viral Load assay.

ISSUE:	<p>Customer complaints reported to Cepheid have shown an increase of ‘5007’ probe check (high) errors for above mentioned batches of Xpert® HCV Viral Load.</p> <p>Further investigation has determined that the lot specific parameters embedded within the cartridge (batch) lot barcode were incorrectly set which could result in increased probe check errors.</p>
IMPACT:	<p>The error code ‘5007’ probe check (high) is reported early in the instrument’s test sequence, and therefore no patient result will be generated or displayed.</p> <p>The error message may trigger the user to retest using the remainder of the sample prepared. The re-test procedure is listed in Section 16.2 (‘Retest Procedure’) of the package insert (PN 301-3019).</p> <p>If further sampling is required, then recollect sample per Section 11.0 (‘Specimen Collection, Storage, and Transport’) of the package insert.</p>
ACTION:	<p>Cepheid will provide replacement product for any product from these lots, currently in your inventory. You should document (see Response Form), stop using and then dispose of any remaining product from this lot that is in your inventory.</p> <p>To receive your replacement product, please provide information on the Response Form acknowledging receipt of this letter and send this form to the Cepheid customer service/order management group with whom you regularly place orders for Xpert® assays; refer to the table for applicable contact information. Alternatively, Response Forms can be emailed to <a href="mailto:CFQ@cepheid.com">CFQ@cepheid.com</a> or FAX +33 563 825 301.</p> <p><b>Replacement product should ship to you within 3-5 business days following receipt of the Response Form.</b></p>



Please share this information with your laboratory staff and retain this notification as part of your laboratory Quality System documentation. If you have forwarded any of the affected product(s) listed above to another laboratory, please provide them a copy of this letter.

Please complete and return the enclosed Response Form within 10 days so we are assured you have received this important communication.

If you have any questions regarding this notice, please refer to the table for applicable contact information.

We apologize for the inconvenience that this caused your laboratory.

Sincerely,

Sophie Pernice  
Senior Director, Quality Systems and Regulatory Compliance  
Cepheid AB  
Röntgenvägen 5, 171 54 Solna  
Sweden

Region	Telephone	Technical Support Email	Order Management Email
US	+ 1 888 838 3222	techsupport@cepheid.com	ordermanagement@cepheid.com
Australia and New Zealand	+ 1800 107 884 (AU) + 0800 001 028 (NZ)	techsupportANZ@cepheid.com	cepheid.ANZ@cepheid.com
Brazil and Latin America	+ 55 11 3524 8373	latamsupport@cepheid.com	americas_ex-us@Cepheid.com
China	+ 86 021 5406 5387	techsupportchina@cepheid.com	katherine.foo@cepheid.com
France	+ 33 563 825 319	support@cepheideurope.com	ordersdirect@cepheid.com
Germany	+ 49 69 710 480 480	support@cepheideurope.com	kundenservice@cepheid.com
India, Bangladesh, Bhutan, Nepal, and Sri Lanka	+ 91 11 48353010	techsupportindia@cepheid.com	ordermanagement@cepheid.com
Italy	+ 39 800 902 567	support@cepheideurope.com	ordersitaly@cepheid.com
Japan	+ 0120 95 4886	support@japan.cepheid.com	toru.chiku@cepheid.com
South Africa	+ 27 861 22 76 35	support@cepheideurope.com	order.sa@cepheid.com
United Kingdom	+ 44 3303 332 533	support@cepheideurope.com	sales@cepheideurope.co.uk
Belgium, Netherlands, and Luxembourg	+33 563 825 319	support@cepheideurope.com	orders@cepheidbenelux.com
Other European, Middle East, and African countries	+ 33 563 825 319 + 971 4 253 3218	support@cepheideurope.com	orderspartners@cepheideurope.com ordershbdc@cepheidhbdc.com





**CUSTOMER RESPONSE FORM**  
Xpert® HCV Viral Load

Part Number	Batch Number	Lot Number	Expiration Date
GXHCV-VL-CE-10	1000151328	32901	2020-03-15
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GXHCV-VL-CE-10	1000151573	32903	2020-03-15

<b>Customer Site Name:</b>	
<b>Ship to Address:</b>	
<b>Phone Number:</b>	
<b>E-mail:</b>	

**Please select one choice:**

I acknowledge receipt of this letter and I am not requesting any replacement product.

Or:

I acknowledge receipt of this letter, certify that I have Xpert® HCV Viral Load, catalog GXHCV-VL-CE-10 or GXHCV-VL-IN-10:

Batch 1000151328 (Lot 32901).  
Batch 1000151455 (Lot 32902).  
Batch 1000151573 (Lot 32903), and I am requesting replacement product.

**Quantity Cartridges On-hand:** \_\_\_\_\_ GXHCV-VL-CE-10 Batch 1000151328 (Lot 32901)  
**Quantity Cartridges On-hand:** \_\_\_\_\_ GXHCV-VL-IN-10 Batch 1000151455 (Lot 32902)  
**Quantity Cartridges On-hand:** \_\_\_\_\_ GXHCV-VL-CE-10 Batch 1000151573 (Lot 32903)

**Product Disposal Attestation:** I attest that I will dispose of any remaining Xpert® HCV Viral Load of the following batches: Batch 1000151328 (Lot 32901); Batch 1000151455 (Lot 32902); Batch 1000151573 (Lot 32903).

**Print Name:** \_\_\_\_\_ **Print Title:** \_\_\_\_\_

**Signature:** \_\_\_\_\_ **Date:** \_\_\_\_\_

Please return completed Response Form to  
Cepheid by email: [CFQ@cepheid.com](mailto:CFQ@cepheid.com) or  
FAX +33 563 825 301.

