

**URGENT FIELD SAFETY NOTICE**

Xpert® HIV-1 Viral Load, Catalog GXHIV-VL-CE-10 lot 1000034821 (cartridge lot 14001) and GXHIV-VL-CE-10 lot 1000036280 (cartridge lot 14002)  
Device Destruction Required

September 16, 2016

Dear Valued Customer:

You may have received a previous letter regarding this field safety notice, dated September 6, 2016. Please note that this notification contains the same content as the previous notification with the addition of the header that is required by the European Commission.

Thank you for using the Xpert® HIV-1 Viral Load assay. According to our records, you have received Xpert® HIV-1 Viral Load, Catalog GXHIV-VL-CE-10 lot 1000034821 (cartridge lot 14001) and/or GXHIV-VL-CE-10 lot 1000036280 (cartridge lot 14002). Cepheid has received reports that some of our customers have experienced cartridge performance issues that manifest as abnormal PCR amplification curve patterns, which can yield invalid results (the most common outcome), or much less commonly, inaccurate quantification of HIV-1 RNA when using this test and its intended use specimen types. Cepheid will provide replacement product for GXHIV-VL-CE-10 lot 1000034821 (cartridge lot 14001) and/or GXHIV-VL-CE-10 lot 1000036280 (cartridge lot 14002) currently in your inventory. You should document (see below) and then dispose of any remaining product from these lots that are in your inventory.

To receive your replacement product, please provide information on page 2 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; see table below. Replacement product should ship to you within 3-5 business days following receipt of this form.

Upon request, Cepheid Technical Support (see contact information below) is available to analyze the GeneXpert® data files (gxx files) for tests that you performed using these lots of product if you have questions about the accuracy of your results.

Please accept our apology for this event. We have implemented additional operational processes to prevent this from occurring again and remain committed to providing you with the highest quality products possible.

Sincerely,

Jason Affourtit  
Executive Director, Worldwide Technical Support  
Cepheid  
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US	+ 1 888 838 3222	techsupport@cepheid.com	ordermanagement@cepheid.com
Australia and New Zealand	+ 1800 107 884 + 0800 001 028	techsupportANZ@cepheid.com	katherine.foo@cepheid.com
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