



Nov 11<sup>th</sup>, 2019

URGENT FIELD SAFETY NOTICE

Xpert® HIV-1 Viral Load assay

Part Number	Batch Number	Lot Number	Expiration Date
GXHIV-VL-CE-10	Not applicable	Not applicable	Not applicable

Attention Cepheid Customer,

Cepheid is initiating a field action for the product listed above. This letter contains important information that needs your immediate attention.

ISSUE:	As part of Cepheid’s Post Market Surveillance activities and in the context of continuous improvement of our products, Cepheid is updating the Package Insert of the Xpert® HIV-1 Viral Load assay to give more precise recommendations for potential false results due to mutations / deletions / insertions in the primer / probe binding sites. Cepheid recently received a notification from a customer about a discrepant HIV-1 viral load measurement that showed no detectable virus, whereas a parallel measurement with an alternate methodology indicated the presence of a viral load. The error rate from the date of product launch for such miss or under quantification still remains very rare with a rate less than 0,0013%.
IMPACT:	The impact of lack of detection due to miss/under quantification is limited as the Xpert® HIV-1 Viral Load test is intended for use as an aid in assessing viral response to antiretroviral treatment. Xpert HIV-1 VL results indicating viral suppression may require further testing using alternative technologies with different genomic targets in circumstances where poor medication adherence, accompanying laboratory data or other clinical information raise concerns of underlying viremia.
ACTION:	In the limitation section 17 of our Package Insert, Cepheid is proposing the following additional clarification:  “The assay targets a single conserved part of the LTR region with a combination of several oligonucleotides designed to accommodate polymorphisms in the genome. Rare mutations, base changes, deletions or inserts, within the LTR region of the HIV-1 VL assay may affect primer and/or probe binding resulting in under-quantification or lack of detection of virus. Users are advised to consider these events when evaluating HIV-1 viral load results; Xpert HIV-1 VL results indicating viral suppression may require further testing using alternative technologies with different genomic targets in circumstances where poor medication adherence, accompanying laboratory data or other clinical information raise concerns of underlying viremia. The laboratory is also advised to perform method correlation studies if HIV testing methods change from one technology to another as differences between platforms and technologies may result in variable HIV viral load results.”
RESOLUTION:	The Package Insert of the product Xpert® HIV-1 Viral Load will be updated (in the next revision) in order to include the above paragraph included in the limitation section. Also, in the spirit of






	further continuous innovation, Cepheid is targeting to put on the market a dual target assay for HIV Viral Load in 2020.
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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. Also please note that all relevant competent authorities were notified of this action.

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,

  
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