

September 15, 2017

**MEDICAL DEVICE FIELD ACTION**

## Xpert EV® assay

Part Number	Batch Number	Lot Number
GXEV-100N-10	1000045409	06802

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:	Customers have reported a higher than expected number of invalid test results when using the product listed above per the package insert.
IMPACT:	Patient results are not reported for invalid tests and the test report is designated as “invalid”.
ACTION:	Stop using the product listed above. Dispose of any remaining product in your inventory and Cepheid will provide replacement product.  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. Replacement product should ship to you within 3-5 business days following receipt of the Response Form.
RESOLUTION:	Cepheid has implemented additional operational controls to prevent this from reoccurring and remains committed to providing you with the highest quality products possible.

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,

Somesh Lalithraj  
Director, Quality Systems & Regulatory Compliance  
Cepheid  
904 Caribbean Drive, Sunnyvale, CA 94089



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 and Netherlands	+33 563 825 3319	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 ordershdbc@cepheidhdbc.com



**Please complete the Response Form acknowledging receipt of this letter:**

<b>Customer 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.
- I acknowledge receipt of this letter, certify that I have Xpert® EV, catalog GXEV-100N-10 batch 1000045409 (lot 06802). I am requesting replacement product.

**Quantity Cartridges On-hand:** \_\_\_\_\_ GXEV-100N-10 batch 1000045409 (lot 06802)

**Product Disposal Attestation:** I attest that I will dispose of any remaining Xpert® EV, catalog GXEV-100N-10 batch 1000045409 (lot 06802).

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

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

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

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

