

IMPORTANT PRODUCT NOTICE

Xpert® EV

Part Number	Batch Number	Lot Number	Expiration Date
GXEV-100N-10	1000408741	22001	March 26, 2023

Dear Cepheid Customer,

We are writing to inform you that Cepheid has initiated a field action for the product listed above. Cepheid has become aware that some customers received Xpert® EV kits from batch 1000408741 Lot 22001 containing cartridges with a component that may cause low sample-processing control/internal control (SPC/IC) endpoints (displayed as 'CIC' in the GeneXpert Dx View Results window under the Analyte Name in the legend). This may result in false negative or non-determinate/invalid test results and a delay in obtaining a diagnostic test result.

Cepheid recommends that you discontinue the use of GXEV-100N-10 Lot 22001. Document the quantity you have in inventory by completing the attached Customer Response Form, then dispose of any remaining affected product. Customer Response Forms can be emailed to CFQ@cepheid.com or faxed to (408) 716-3143. We ask that you return the enclosed Customer Response Form within 10 days, so we are assured you have received this important communication.

If you have already used the impacted product and had a discrepant or non-determinate result, please contact Cepheid Technical Support at the emails/phone numbers listed in the table on page 2 to register a complaint. Any positive test result received should be considered valid.

Cepheid currently does not have replacement product in our inventory; however, we will notify you when replacement product becomes available.

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.

If you have any questions regarding this notice, please refer to the table on page 2 for applicable contact information.

We apologize for the inconvenience that this may have caused your laboratory.

Sincerely,



Somesh Lalithraj
Vice President, Global Quality



Region	Telephone	Technical Support Email
US	+ 1 888 838 3222 Press 2	techsupport@cepheid.com
Australia and New Zealand	+ 1 800 130 821 + 0800 001 028	techsupportANZ@cepheid.com
Belgium, Netherlands and Luxembourg	+ 33 563 825 319	support@cepheideurope.com
France	+ 33 563 825 319	support@cepheideurope.com
Italy	+ 39 800 902 567	support@cepheideurope.com
Spain	+ 34 919 90 67 62	support@cepheideurope.com
South Africa	+ 27 861 22 76 35	support@cepheideurope.com
Other European, Middle East, and African Countries	+ 33 563 825 319 + 971 4 253 3218	support@cepheideurope.com
Other Countries Not Listed	+ 1 408 400 8495	techsupport@cepheid.com

Contact information for other Cepheid offices is available on our website www.cepheid.com under the SUPPORT tab. Select the Contact Us option.





Please return only completed Customer Response Form to Cepheid by email CFQ@cepheid.com or FAX (408) 716-3143

CUSTOMER RESPONSE FORM

Xpert® EV

Part Number	Batch Number	Lot Number	Expiration Date
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Customer Name:	
Ship to Address:	
Phone Number:	
E-mail:	

Please select one choice:

I acknowledge receipt of this letter and I do not have Xpert® EV kits from Lot # 22001 in inventory.

Or:

I acknowledge receipt of this letter, confirm I have Xpert® EV kits from Lot # 22001 in inventory.

Quantity Cartridges in Inventory: _____ GXEV-100N-10 Lot # 22001

Product Disposal Attestation: I attest that I will dispose of any remaining Xpert® EV kits Lot # 22001.

Print Name: _____

Print Title: _____

Signature: _____

Date: _____

