

March 26, 2024

Urgent FIELD SAFETY NOTICE
Xpert® Carba-R

Legal Manufacturer	Single Registration Number (SRN)	Unique Device Identifier (UDI)	Part Number	Batch Number	Lot Number	Expiration Date
Cepheid	US-MF-00001097902020	07332940006518	GXCARBARP-CE-10	1001208183	10808	09-Mar-2025

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:	Cepheid has received customer complaints for false positive New Delhi Metallo-beta-lactamase (NDM) patient test results with Xpert® Carba-R (GXCARBARP-CE-10 batch 1001208183 lot 10808) kits.
IMPACT:	False positive patient test results can result in unnecessary contact precautions leading to non-infectious adverse events and side effects from inappropriate antibiotic treatment.
ACTION:	<p>Please dispose of any GXCARBARP-CE-10 kits from batch 1001208183 lot 10808 in your inventory and Cepheid will provide replacement kits with the quantity requested. The replacement should ship within 5 business days following receipt of the completed response form.</p> <p>Cepheid asks that you acknowledge receipt of this Important Product Notice by completing the attached Customer Response Form and either emailing the completed form to CFQ@cepheid.com or faxing it to +1 (408) 716-3143. Cepheid will not send a reply or confirmation of received response forms.</p> <p>As with all questionable positive or questionable negative results, please continue to report to Cepheid Technical Support for investigation.</p>
RESOLUTION:	Cepheid has identified the source of the contaminant referenced in the customer complaints and has implemented countermeasures and actions to prevent this issue from recurring.

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 on the following page for applicable contact information. We apologize for the inconvenience that this caused your laboratory.

Sincerely,



Somesh Lalithraj
Vice President, Global Quality

Date

Region	Telephone	Technical Support Email
France	+ 33 563 825 319	support@cepheideurope.com
Germany	+ 49 69 710 480 480	support@cepheideurope.com
Italy	+ 39 800 902 567	support@cepheideurope.com
United Kingdom	+ 44 3303 332 533	support@cepheideurope.com
Belgium and Netherlands	+33 563 825 3319	support@cepheideurope.com
Other European, Middle East, and African countries	+ 33 563 825 319 + 971 4 253 3218	support@cepheideurope.com



CUSTOMER RESPONSE FORM
Xpert® Carba-R

Legal Manufacturer	Single Registration Number (SRN)	Unique Device Identifier (UDI)	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 am not requesting any replacement product.

Or:

☐ I acknowledge receipt of this letter, certify that I have Xpert® Carba-R catalog GXCARBARP-CE-10 batch 1001208183 (lot 10808). I am requesting replacement product.

Quantity Cartridges On-hand: _____ GXCARBARP-CE-10 batch 1001208183 (lot 10808)

Product Disposal Attestation: I attest that I will dispose of any remaining Xpert® Carba-R, catalog GXCARBARP-CE-10 batch 1001208183 (lot 10808)

Print Name: _____

Print Title: _____

Signature: _____

Date: _____

