

Important Product Notice
Xpert® Carba-R

Legal Manufacturer	Single Registration Number (SRN)	Unique Device Identifier (UDI)	Part Number	Batch Number	Lot Number	Expiration Date
Cepheid AB	SE-MF-000002020	07332940001049	GXCARBAR-CE-10	1001493704	13801	24-01-2027

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 become aware that customers in Malaysia received Xpert® Carba-R tests with the unregistered P/N GXCARBAR-CE-10 instead of the registered P/N GXCARBARP-CE-10.
IMPACT:	Use of GXCARBAR-CE-10 does not generate invalid results, and there is no difference between the two catalog numbers other than the IMP/IMP1 analyte name. If you receive indeterminate results, you should repeat the test.
ACTION:	<p>Please ensure that any remaining inventory of GXCARBAR-CE-10 is promptly removed from use and disposed of in accordance with your institution’s procedures.</p> <p>Additionally, please remove the Assay Definition File (ADF) for GXCARBAR-CE-10 from your system by following these instructions for the GeneXpert® Dx System (PC-based software):</p> <p>Prerequisites</p> <ul style="list-style-type: none"> • No tests running • Logged in as Administrator (Cepheid-Admin or equivalent) [https://web-support.cepheid.com/Documents/301-Training-Materials/301-8343-Rev-C-GX-Dx-Reference-Guide.pdf] <p>Steps</p> <ol style="list-style-type: none"> 1. Open GeneXpert® Dx Software 2. From the Main Menu, select: Define Assays 3. A list of installed assays (ADFs) will appear. 4. Select the assay you want to remove. 5. Choose one of the following (depending on options available): Delete (permanent) 6. Confirm action when prompted 7. After removal, the assay will no longer appear in Create Test. <p>You can find the information above in the <i>GeneXpert Dx System Operator Manual</i>, section 2.16.3, Deleting Assay Definition Files.</p>





	Please take appropriate action and notify relevant clinical teams as needed. The Customer Response Form can be emailed to CFQ@cepheid.com or faxed to +1 (408) 716-3143. Your response will be received at the email address above. Cepheid does not send replies or confirmation emails related to your response. The replacement product should ship to you within 5–10 business days following receipt of the Customer Response Form.
RESOLUTION:	Cepheid is actively investigating the cause of the issue and is working to avoid recurrence in the future.

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 with 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 below, which contains the contact information for Cepheid Technical Support.

We apologize for any inconvenience this may have caused your laboratory.

Sincerely,

Somesh Lalithraj

Somesh Lalithraj (04/06/2026 18:07:46 PDT)

Somesh Lalithraj
Senior Vice President Quality, Regulatory and Clinical Affairs

Region	Telephone	Technical Support Email
Malaysia	+65 60115728	techsupport.apac@cepheid.com





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

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 a product replacement.

Or:

I acknowledge receipt of this letter, and I am requesting product for replacement and/or retesting purposes.

Quantity Cartridges Requested: _____ GXCARBAP-CE-10

Reminder 1 kit = 10 cartridges

Product Disposal Attestation: I attest that I will dispose of any remaining Xpert® Carba-R catalog GXCARBAR-CE-10 batch 1001493704 lot 13801.

Print Name: _____

Print Title: _____

Signature: _____

Date: _____

