

May 30, 2024

URGENT FIELD SAFETY NOTICE

Xpert® MTB/RIF Ultra

Legal Manufacturer	Single Registration Number (SRN)	Unique Device Identifier (UDI)	Part Number	Batch Number	Lot Number	Expiration Date
Cepheid AB	SE-MF-000002020	07332940002138	GXMTB/RIF-ULTRA-50	1000714555	39116	28-Jul-2024

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 conducted a routine post-market stability study for GXMTB/RIF-ULTRA-50 kit batch 1000714555 lot 39116, which failed to meet the half-time stability criteria.
IMPACT:	A false negative test result with a positive patient sample may occur. This could lead to transmission of disease and/or disease progression. To date, there have been no customer complaints for false negative test results with GXMTB/RIF-ULTRA-50 lot 39116.
ACTION:	Please dispose of GXMTB/RIF-ULTRA-50 lot 39116 you have in inventory. Cepheid will provide replacement product. The replacement should ship within 5 business days following receipt of the completed response form. If you have previously received or receive a negative test result with GXMTB/RIF-ULTRA-50 lot 39116, and the patient shows clinical signs/symptoms of MTB, re-test with a cartridge from a different lot or an alternative test/method, if available. Xpert® MTB/RIF Ultra is intended as an aid in the diagnosis of pulmonary tuberculosis when used in conjunction with clinical and other laboratory findings. As with all questionable positive or questionable negative results, please continue to report to Cepheid Technical Support for investigation. 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.
RESOLUTION:	Cepheid has begun the investigation to determine 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 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

Somesh Lalithraj (Jun 2, 2024 21:57 PDT)

Somesh Lalithraj
Vice President, Global Quality

Region/Country	Telephone	Technical Support Email
Latin America	+0800 941 4610	latamsupport@cepheid.com
European and African Countries	+ 27 870 06 15 50 + 33 563 825 319	support@cepheideurope.com



CUSTOMER RESPONSE FORM
Xpert® MTB/RIF Ultra

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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® MTB/RIF Ultra catalog GXMTB/RIF-ULTRA-50 batch 1000714555 lot 39116. I am requesting replacement product.

Quantity Cartridges On-hand: _____ GXMTB/RIF-ULTRA-50 batch 1000714555 lot 39116

Product Disposal Attestation: I attest that I will dispose of any remaining Xpert® MTB/RIF Ultra catalog GXMTB/RIF-ULTRA-50 batch 1000714555 lot 39116

Print Name: _____

Print Title: _____

Signature: _____

Date: _____

