



October 20, 2017

IMPORTANT PRODUCT NOTICE

Xpert® MRSA

Part Number	Batch Number	Lot Number	Expiration Date
GXMRSA-100N-10	1000054536	20712	October 7, 2018

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 reports that some of our customers have experienced a higher number of invalid results than would typically be expected when using this test and its intended use specimen types.
IMPACT:	As in all Xpert® assays, when the test is determined to be invalid, no patient results are reported and the report designation is “invalid”. There is no impact to valid results.
ACTION:	Cepheid will provide replacement product currently in your inventory. You should document (see Response Form), stop using and then dispose of any remaining product from this lot that is in your inventory. Please provide information on the Response Form acknowledging receipt of this letter, number of replacement product requested, if any, and email 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.

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,

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Cepheid
904 Caribbean Drive, Sunnyvale, CA 94089

Region	Telephone	FAX	Technical Support Email	Order Management Email
US	+ 1 888 838 3222	(408) 716-2550	techsupport@cepheid.com	claims@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	claims@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 ordershbc@cepheidhbc.com



CUSTOMER RESPONSE FORM

Xpert® MRSA

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.
- I acknowledge receipt of this letter, certify that I have Xpert® MRSA, catalog GXMRSA-100N-10 batch 1000054536 (lot 20712). I am requesting replacement product.

Quantity Cartridges On-hand: _____ GXMRSA-100N-10 batch 1000054536 (lot 20712)

Product Disposal Attestation: I attest that I will dispose of any remaining Xpert® MRSA, catalog GXMRSA-100N-10 batch 1000054536 (lot 20712).

Print Name: _____ **Print Title:** _____

Signature: _____ **Date:** _____

