December 7, 2017

IMPORTANT PRODUCT NOTICE

Xpert® GBS Part Number GXGBS-100N-10

Batch Number	Lot Number	Expiration Date
1000038939	08006	December 24, 2017
1000038940	08007	January 21, 2018
1000041037	08008	February 25, 2018
1000043701	08009	March 4, 2018
1000046139	08010	April 15, 2018
1000048542	08011	April 29, 2018
1000047891	08012	May 13, 2018
1000056857	08401	August 19, 2018
1000050712	08402	July 8, 2018
1000053616	08403	July 8, 2018

Batch Number	Lot Number	Expiration Date
1000054880	08404	July 8, 2018
1000054881	08405	July 8, 2018
1000059274	08406	July 8, 2018
1000062024	08407	July 8, 2018
1000062025	08408	July 8, 2018
1000063189	08409	July 8, 2018
1000064921	08410	December 2, 2018
1000064922	09201	December 16, 2018
1000067405	09202	January 20, 2019

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 customers have experienced a higher number of pressure abort (E2008) errors than would be typically expected when using this test and its intended use specimen types.
IMPACT:	A pressure abort (E2008) error will delay the GBS test result and may require repeat testing. The error typically occurs within 30 minutes of the test start. As with all Xpert® assays, when the test has an error, no patient results are reported, and the report is designated as “invalid”. There is no impact to valid test results.
ACTION:	Cepheid recommends that laboratory staff be in the vicinity of the testing to be alerted to any errors that may occur. This will save time in the event that repeat testing is required. Coordination between clinicians and the testing laboratory is important to not delay administration of antibiotics while results are pending. Per the Xpert GBS Package Insert 300-8907 revision D, Interpretation of Results, NO RESULT: - In the event of an "ERROR" result (maximum pressure abort or probe check failure), immediately perform retest or run the second swab, or initiate alternate methods. "ERROR” results may happen within first 30 minutes of the test. - When performing intrapartum testing, repeat testing may not be feasible and will depend on practices and policies within each facility. Coordination between clinicians and the testing laboratory is important to not delay administration of antibiotics while results are pending.

	The Xpert GBS Package Insert 300-8907 revision D, Reasons to Repeat the Assay or Initiate Alternate Procedures, provides three (3) options for retesting: - If there is fluid in the cartridge S chamber, use a transfer pipette to transfer all the fluid to the S chamber of a new cartridge, and then rerun the test. - If there is no fluid, use sterile tweezers to transfer the swab to a new cartridge, and then rerun the test. - Alternatively, prepare a new cartridge using the second swab, and then rerun the test. Cepheid will provide replacement cartridges for tests that resulted in higher than expected pressure abort (E2008) errors. Please contact Technical Support representing your geographic area. Please provide information on the Response Form acknowledging receipt of this letter. Forms can be emailed to CFQ@cepheid.com or FAX +1 (408) 716-3143.
RESOLUTION:	Cepheid has implemented corrective action for newly manufactured GXGBS-100N-10 lots to prevent the higher than expected pressure abort (E2008) errors.

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,

Eric Salle
Senior Manager, EMENA Regulatory Compliance / Quality Systems
Vira Solelh
81470 Maurens-Scopont – France

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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
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France	+ 33 563 825 319	support@cepheideurope.com	ordersdirect@cepheid.com
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CUSTOMER RESPONSE FORM

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Customer Name:	
Ship to Address:	
Phone Number:	
E-mail:	

Please select:

I acknowledge receipt of this letter and understand the Actions detailed.

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

Signature: _____ **Date:** _____

Please return completed Response Form to Cepheid by email: CFQ@cepheid.com or FAX +1 (408) 716-3143.

904 Caribbean Drive Sunnyvale, CA 94089 USA WWW.CEPHEID.COM