



June 15, 2020

MEDICAL DEVICE FIELD ACTION

Dear Valued Luminex Customer,

Luminex has identified an instrument failure mode with the VERIGENE® Processor SP that may result in a VERIGENE® Blood Culture Gram Positive (BC-GP) or Gram Negative (BC-GN) false negative call. This failure mode will not affect other VERIGENE assays. Luminex has developed a software solution that will both identify and alert users to this issue. Luminex has updated this software out of an abundance of caution as the occurrence of this failure mode is extremely infrequent. Luminex Global Support Services will be contacting you within the next three business days to confirm your mailing address to ship your software update via USB and provide you information regarding the installation process. Once this update has been completed, you will need to email a screen shot of the updated software, as well as a completed Notice of Destruction for this USB (that will come with the USB), back to Global Support Services at support@luminexcorp.com to complete the upgrade process.

Since the initial launch of the VERIGENE Blood Culture-Gram Positive and Gram Negative Tests in 2012 and 2014, respectively, more than 45 published clinical studies with more than 6,000 total patients studied have demonstrated the clinical and cost-effectiveness of both of these assays. In addition, more than one million blood culture tests have been shipped since Luminex acquired these tests from Nanosphere. Luminex is taking the action to correct this issue as a result of the first reported false negative associated with this very rare instrument error.

Until this updated software is installed, it is important, and part of good laboratory practice, that you follow the specific guidelines indicated in the current VERIGENE Blood Culture Gram Positive (BC-GP) and Gram Negative (BC-GN) Package Inserts. Specifically, “Not Detected” test results from a positive blood culture bottle should be evaluated further. The sub-culturing of blood cultures is necessary, per the intended use sections within the Package Inserts in the VERIGENE Blood Culture Kits. For your information, below is the referenced language contained in the Package Inserts:

VERIGENE Blood Culture Kits (BC-GP/BC-GN), which are performed using the sample-to-result VERIGENE System, are qualitative multiplexed in vitro diagnostic tests for the simultaneous detection and identification of selected gram-positive/gram-negative bacteria and resistance markers. These tests are performed directly on blood culture media using blood culture bottles identified as positive by a continuous monitoring blood culture system and which contain gram-positive/gram-negative bacteria as determined by Gram stain.

These assays are indicated for use in conjunction with other clinical lab findings to aid in the diagnosis of bacterial, bloodstream infections, however, are not to be used to monitor infections.

Sub-culturing of positive blood cultures is necessary to recover organisms for antimicrobial susceptibility testing (AST), for identification of organisms not detected by BC-GP/BC-GN assays, to detect mixed infections that may not be detected by the assays (BC-GP/BC-GN), for association of antimicrobial resistance marker genes to a specific organism, or for epidemiological typing.

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VERIGENE Blood Culture Portfolio

Product Name	Part Number	Package Insert
VERIGENE Gram-Positive Blood Culture Test Kit (BC-GP)	20-005-018	89-30000-00-782 Rev A
VERIGENE Gram-Negative Blood Culture Test Kit (BC-GN)	20-005-021	89-30000-00-776 Rev A
VERIGENE Gram-Negative Blood Culture Test Kit (BC-GNv2) APAC Region Only	20-005-026	027-00051-01 Rev B

At Luminex, we consistently strive to meet or exceed your expectations and apologize for any inconvenience this situation may cause you. We appreciate your understanding as we take action to ensure patient and customer satisfaction. Please contact Luminex Global Support Services with any questions or concerns.

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