



October 14, 2020

CUSTOMER ADVISORY NOTIFICATION

Dear Valued Luminex Customer,

According to our records, you have ordered and may have used our portfolio of VERIGENE® Assays in your laboratory. Through post-market surveillance activities, we have identified an increase in the No Call rate for these products under certain circumstances. Our investigation has identified that the likelihood of a No Call for the assays below increases when test cartridges are left on the Processor SP for an extended time following completion of assay preparation.

Affected VERIGENE Assay Products

Product Name	Part Number
VERIGENE Respiratory Pathogens Flex Nucleic Acid Test Kit (RP Flex)	20-005-024
VERIGENE Clostridium difficile Nucleic Acid Test Kit (CDF)	20-005-022

In addition to this same increase in the No Call rate, for the following products, we have also observed a slight increase in the likelihood of a False Positive result for the products listed below when test cartridges are left on the Processor SP for an extended time following completion of assay preparation.

Affected VERIGENE Assay Products

Product Name	Part Number
VERIGENE Gram-Positive Blood Culture Test Kit (BC-GP)	20-005-018
VERIGENE Gram-Negative Blood Culture Test Kit (BC-GN)	20-005-021
VERIGENE Gram-Negative Blood Culture Test Kit (BC-GNv2) APAC Region Only	20-005-026
VERIGENE Enteric Pathogens Nucleic Acid Test Kit (EP)	20-005-023

To address both of these issues, we are currently working on a software solution aimed at further optimizing the washing and drying steps in the sample preparation process. This software update should minimize the frequency and likelihood of No Call results, as well as False Positive results, for all assays. Until this solution is finalized and implemented, you should remove test cartridges from the VERIGENE® SP Processor immediately following completion of assay preparation, and then process these cartridges on the VERIGENE Reader as soon as possible to obtain test results. While this is common practice for many customers already, doing so should minimize the occurrence of No Call results for the products listed below.

We will contact you with more details on the software solution as soon as possible.

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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.

Luminex Global Support Services
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