



complexity simplified.

March 18, 2021

Dear Valued Luminex Customer,

During a recent internal investigation, Luminex identified rare instances of VERIGENE® SP Amplification (AMP) Heaters failing to meet dimensional specifications. Should this occur, it is possible that the VERIGENE® Enteric Pathogens Nucleic Acid Test Kit (Part No. 20-005-023) could provide a false-negative result for *Vibrio parahaemolyticus*, *Salmonella*, and/or *Shigella* spp.

We recommend that all VERIGENE Enteric Pathogen customers review your QC data to ensure a passing result for all targets. If a false negative is observed for any of the targets within the past twelve months, please contact Luminex Global Support Services at [support@luminexcorp.com](mailto:support@luminexcorp.com) so that we can arrange for the replacement of your AMP Heater. Please note, until the current AMP Heater is replaced, there is a low possibility of receiving a false negative when running the VERIGENE Enteric Pathogens Nucleic Acid Test Kit.

To help confirm that your VERIGENE SP AMP Heater meets the proper dimensional specifications, if easily accessible, please locate the TSB Log on the back of each SP unit and verify that 15 is marked off. If it is, no further action is required. Alternatively, if the review of your QC data for the past twelve months and your three previous incoming lot validations show no false negatives for *Vibrio parahaemolyticus*, *Salmonella*, and/or *Shigella* spp., no further action is required.

**Affected VERIGENE Assay Product**

Product Name	Part Number
VERIGENE Enteric Pathogens Nucleic Acid Test Kit	20-005-023

We ask that you complete and return the attached acknowledgment letter so that we can confirm that your AMP Heater either meets dimensional specifications or requires replacement. Please accept our sincerest apologies for any inconvenience this situation may cause you. We appreciate your understanding as we take action to maintain the highest standards in patient safety and customer satisfaction.

Luminex Global Support Services  
1-877-785-2323 (U.S. and Canada)  
+1-512-381-4397 (Outside U.S. and Canada)  
[support@luminexcorp.com](mailto:support@luminexcorp.com)

CAN-0271

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**VERIGENE® AMP Heater Acknowledgement Letter**

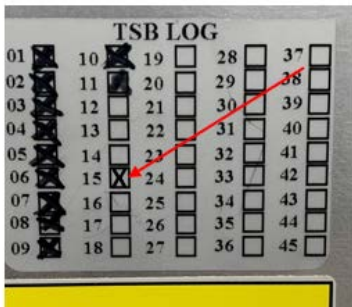
Please complete the information below.

Institution Name: \_\_\_\_\_

Address: \_\_\_\_\_

Total Number of VERIGENE SP Processors: \_\_\_\_\_

- I. I was able to locate the TSB LOG on the back of the VERIGENE SP Processor and confirm that 15 is checked.



VERIGENE SP Processor Serial Number	Box Number 15 Checked (Yes or No)

*If the back of your VERIGENE SP Processor is inaccessible, you were unable to locate the TSB Log, or Box 15 is unchecked, please continue to section II.*

- II. I have reviewed my internal QC data for the VERIGENE Enteric Pathogens Nucleic Acid Test Kit (Part No. 20-005-023) and:

- I have not observed any false negatives in my Quality Control runs.
- I have observed a false negative result and will be contacting Luminex Global Support Service (contact information on the prior page) to help determine the next steps for replacement.

Please sign and date in the space provided below and return to Luminex Global Support Services at [support@luminexcorp.com](mailto:support@luminexcorp.com).

Signature: \_\_\_\_\_

Date: \_\_\_\_\_