July 24, 2020

URGENT: MEDICAL DEVICE FIELD ACTION

Amplification Well Temperature Verification Fixture (FA-0005-01)
Elution Well Temperature Verification Fixture (FA-0006-01)
Sample Well Temperature Verification Fixture (FA-0007-01)
Hybridization Cartridge Temperature Verification Fixture (FA-0008-01)
Z-Axis Calibration Gauge (FA-0013-01)
VERIGENE® Reader Alignment Slide (FA-0014-01)

Dear Field Service Personnel,

Purpose of this Letter

Luminex has determined that three (3) separate test fixtures used by field service engineers to service the VERIGENE® Systems were procured from unapproved sources and, in some cases, were manufactured using unvalidated processes. The fixtures are: 1) Temperature Verification Fixtures (which consist of the first four fixtures identified above); 2) Z-Axis Calibration Gauges, and; 3) VERIGENE Reader Alignment Slides.

Reason for the Voluntary Recall

Following its acquisition of Nanosphere, Luminex needed additional test fixtures to support the needs of our larger service organization calibration and verification tools were purchased in a manner that was outside of our normal procurement processes. These test fixtures were provided to Luminex's service organization, as well as third-party distributor field service engineers, and were subsequently used in the field to service VERIGENE instruments. Purchasing outside our normal processes, even from an otherwise-approved supplier, is prohibited and CANNOT happen in the future.

Risk to Health

This recall is related to non-compliance through not following procedures, and is not related to patient/user safety. Internal testing has shown that the test fixtures function correctly and that there is no impact to the VERIGENE Systems.

Actions to be Taken

Due to nonconformance with Luminex's Quality System, the exact location of all test fixtures needs to be verified, and affected test fixtures will need to be removed from the field over the next several weeks. All of the test fixtures in the scope of this voluntary recall must be returned as soon as possible, but in any event, by NO LATER THAN September 18, 2020.

Luminex Corporation
12212 Technology Blvd., Austin, TX 78727 USA
T 1.877.785.2323 (US) 1.512.381.4397 (OUS/CANADA) F 512.219.5114 E support@luminexcorp.com
www.luminexcorp.com

PLEASE NOTE: No other Luminex products are involved in this field action.

Type of Action by the Company:

As an immediate action, please follow the enclosed steps for Voluntary Recall in their entirety in order to locate the affected fixtures.

Enclosed is an Acknowledgment and Receipt form. This form must be completed and returned, even if you do not have any of the affected test fixtures. Luminex Global Support Services can assist you in completing this form and process. This information is essential in order to maintain recall effectiveness information required by the US FDA.

Please contact Luminex Global Support Services with any questions or concerns you may have.

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

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STEPS FOR VOLUNTARY RECALL

Amplification Well Temperature Verification Fixture (FA-0005-01)
Elution Well Temperature Verification Fixture (FA-0006-01)
Sample Well Temperature Verification Fixture (FA-0007-01)
Hybridization Cartridge Temperature Verification Fixture (FA-0008-01)
Z-Axis Calibration Gauge (FA-0013-01)
VERIGENE® Reader Alignment Slide (FA-0014-01)

The Acknowledgment and Receipt Form attached to this letter must be completed and returned.

1. **Complete Acknowledgment and Receipt Form.** Complete the enclosed Acknowledgment and Receipt form, even if you do not have any affected product on hand, following the instructions in this notice. Luminex Global Support Services can assist you in completing the form.

2. **Return the Acknowledgement and Receipt Form to Luminex.** Attach a signed, completed copy of the Acknowledgement and Receipt Form in an email, and send it to support@luminexcorp.com on or before August 8, 2020**.**

   Optional notification method: Place a signed original copy of the Acknowledgment and Receipt Form in an envelope, and mail it on or before August 8, 2020 to:

   Luminex Corporation
   Attn: Luminex Global Support Services team
   12201 Technology Boulevard
   Suite 130
   Austin, TX 78727
   USA

PRODUCT RECALL

Acknowledgment and Receipt Form

PLEASE FILL OUT AND RETURN

Amplification Well Temperature Verification Fixture (FA-0005-01)
Elution Well Temperature Verification Fixture (FA-0006-01)
Sample Well Temperature Verification Fixture (FA-0007-01)
Hybridization Cartridge Temperature Verification Fixture (FA-0008-01)
Z-Axis Calibration Gauge (FA-0013-01)
VERIGENE® Reader Alignment Slide (FA-0014-01)

Manufacturer's Product Number/Catalog Number: See above

I have read and understand the recall instructions provided in **CAN-0262 URGENT: MEDICAL DEVICE RECALL** letter dated July 24, 2020? Yes ☐ No ☐

Do you have any of the listed part numbers below? Yes ☐ No ☐

If yes, please complete the table below.

Part Number	Description	List ID # below: Fixture 1	List ID # below: Fixture 2
FA-0005-01	*Amplification Well Temperature Verification Fixture*		
FA-0006-01	*Elution Well Temperature Verification Fixture*		
FA-0007-01	*Sample Well Temperature Verification Fixture*		
FA-0008-01	*Hybridization Cartridge Temperature Verification Fixture*		
FA-0013-01	*Z-Axis Calibration Gauge*		
FA-0014-01	*VERIGENE Reader Alignment Slide**		

*Please note if the Luminex logo is/is not on the slide.

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DATE:_____

COMPANY NAME:_____

CONTACT NAME:_____

ADDRESS:_____

CITY: _____ STATE/PROVINCE: _____

COUNTRY: _____

ZIP CODE/POSTAL CODE: _____

TEL NO:_____FAX NO.:_____

EMAIL ADDRESS:_____

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