August xx, 2019

URGENT: FIELD SAFETY NOTICE
xTAG® RVP FAST v2 (Respiratory Viral Panel Fast v2)

Dear Valued Luminex Customer,

Luminex monitors the performance of its primers and probes in all of its respiratory *in vitro* diagnostic device (IVD) products. This includes our assays that are intended to detect Influenza A and/or B viruses, and Respiratory Syncytial Virus (RSV) subtypes A and B. Since circulating viral strains mutate and their prevalence fluctuates from season to season, we perform our respiratory product biosurveillance analysis at the conclusion of each flu season utilizing GISAID and GenBank databases. The *in silico* review of these databases through October 2018 revealed a high prevalence of sequence variation for particular xTAG® RVP FAST v2 assay targets as compared to their assay design. Empirical testing using synthetic DNA (gBlocks) containing the mutations was noted to impact detection at LoD in the following targets: Influenza A Matrix (H3 subtype), Influenza B (Victoria lineage), and Respiratory Syncytial Virus (RSV) A. As a result, the sensitivity of the targets containing these mismatches may be impacted in low titer specimens when using the **xTAG® RVP FAST v2 (Respiratory Viral Panel Fast v2) Assay (I040C0413).**

A false negative result may occur when detecting and subtyping Influenza A (H3) and detecting RSV A in patient specimens. However, the assay will continue to detect Influenza A, Influenza B, RSV B and all other targets in accordance with the products' performance claims.

This issue does not create any immediate health hazards, as the impact of a false negative result is limited in the overall population as infections are most often self-limited, resolving without treatment other than supportive care.
However, lowered test sensitivity for Influenza A, particularly H3 subtype has the potential to lead to a delayed diagnosis and delayed use of antiviral medications, which need to be administered soon after symptom onset for maximal clinical efficacy. This has the potential to lead to increased morbidity in vulnerable patients (e.g. elderly, transplant recipients, chronic heart and/or lung disease, etc.)

As a result of our biosurveillance review, we have initiated a field safety corrective action to retrieve or correct the following lots of xTAG® RVP FAST v2 kits:

Product	Catalogue Number	Lot Number
xTAG® RVP FAST v2 (Respiratory Viral Panel Fast v2)	I040C0413	IK040C-1050
	I040C0413	IK040C-1051
	I040C0413	IK040C-1052
	I040C0413	IK040C-1053
	I040C0413	IK040C-1054
	I040C0413	IK040C-1055

PLEASE NOTE: NO OTHER LUMINEX PRODUCTS ARE INVOLVED IN THIS RECALL.

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If you decide that you no longer wish to use xTAG® RVP FAST v2 (Respiratory Viral Panel Fast v2) Assay, please follow Option 1 on the Steps in Voluntary Recall/Field Correction page.

Option #1 – Discontinue use of the xTAG® RVP FAST v2 (Respiratory Viral Panel Fast v2) and destroy any units that are in inventory.

Option #2 – Continue using xTAG® RVP FAST v2 (Respiratory Viral Panel Fast v2) with new use limitations. The new limitations will require the customer to use an alternated test method for testing and reporting results for Influenza A (H3) subtyping and RSV A. Please note that the instructions for use will not be updated at this time.

Please be informed that all of the xTAG® RVP FAST v2 (Respiratory Viral Panel Fast v2) kits are placed on inventory and regulatory hold and will only be available to existing customers that choose to proceed with Option #2. Additionally, Luminex is anticipating the discontinuation of this product in the next 12 months.

This recall is being made with the knowledge of the EU Competent Authority. Please inform any member of your laboratory interacting with the device or the corresponding test results of this product performance condition. In addition, please pass this notice on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred. Please refer to Appendix A for the Intended Use/Indications for Use of xTAG® RVP FAST v2 (Respiratory Viral Panel Fast v2).

If you wish to follow up on previous patient results obtained by xTAG® RVP FAST v2 (Respiratory Viral Panel Fast v2) contact Luminex Global Support Services.

Although no adverse events have been reported, adverse reaction or quality problems experienced with the use of this product may be reported to the National Competent Authority.

We appreciate your assistance with this matter. Please call the Luminex Global Support Services Team if you have any questions or concerns.

Luminex Global Support Services
+1-512-381-4397 (Outside U.S. and Canada)
CAN-0244, Rev A

_____

Ronald D. Dunn
Vice President, Global Regulatory & Clinical Affairs
Luminex Corporation

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Luminex®

STEPS IN VOLUNTARY RECALL / FIELD CORRECTION

OPTION 1

The Acknowledgment and Receipt Form attached to this letter must be completed and returned even if you do not have any xTAG® RVP FAST v2 (Respiratory Viral Panel Fast v2) on hand.

1. **Segregate Recalled Product**. Please immediately remove all affects lots of xTAG® RVP FAST v2 (Respiratory Viral Panel Fast v2) from your inventory that are unused and unexpired (regardless of location) and segregate these lots in a secure location for destruction.

2. **Complete Acknowledgment and Receipt Form.** Complete and return the enclosed Acknowledgment and Receipt Form by email (support@luminexcorp.com) or mail (even if you do not have any product on hand), following the directions on this page and the Acknowledgment and Receipt Form. Luminex Global Support Services can assist you in completing the form, if needed.

3. **Please destroy the product and provide confirmation in the Acknowledgment and Receipt Form on or before August xx, 2019. Luminex will replace any unused products and handle any customer concerns on a case-by-case basis. Please inform Luminex Global Support Services if you destroyed product and need a replacement(s).**

OPTION 2

If you have xTAG® RVP FAST v2 (Respiratory Viral Panel Fast v2) and wish to continue using the product for testing, please **Complete Acknowledgment and Receipt Form.**

Complete and return the enclosed Acknowledgment and Receipt Form by email (support@luminexcorp.com) or mail, following the directions on this page and the Acknowledgment and Receipt Form. Luminex Global Support Services can assist you in completing the form, if needed.

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PRODUCT RECALL

Acknowledgment and Receipt Form – Option 1

PLEASE FILL OUT AND RETURN

RECALL PRODUCT: xTAG® RVP FAST v2 (Respiratory Viral Panel Fast v2)

Manufacturer's Product Number/Catalog Number: I040C0413

Serial/ Lot Numbers: IK040C-1050, IK040C-1051, IK040C-1052, IK040C-1053, IK040C-1054, IK040C-1055

I have read and understand the recall instructions provided in CAN-0244 **URGENT: FIELD SAFETY NOTICE** letter dated **August xx, 2019**: Yes ☐ No ☐

Any adverse events associated with recalled product? Yes ☐ No ☐

If yes, please explain:

_____

_____

☐ We do not have any stock of the above on hand.

☐ We have _____of the above units in inventory and all of the above units have been destroyed.

COMPANY NAME:_____

CONTACT NAME:_____

ADDRESS:_____

CITY: _____ STATE/PROVINCE: _____

ZIP CODE/POSTAL CODE: _____

TEL NO:_____FAX NO.:_____

EMAIL ADDRESS:_____

SIGNATURE:_____

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DATE:_____

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PRODUCT RECALL

Acknowledgment and Receipt Form – Option 2

PLEASE FILL OUT AND RETURN

RECALL PRODUCT: xTAG® RVP FAST v2 (Respiratory Viral Panel Fast v2)

Manufacturer's Product Number/Catalog Number: I040C0413

Serial/ Lot Numbers: IK040C-1050, IK040C-1051, IK040C-1052, IK040C-1053, IK040C-1054, IK040C-1055

I have read and understand the recall instructions provided in CAN-0244 **URGENT: FIELD SAFETY NOTICE** letter dated **August xx, 2019**: Yes ☐ No ☐

Any adverse events associated with recalled product? Yes ☐ No ☐

If yes, please explain:

_____

_____

☐ **We will continue using xTAG® RVP FAST v2 (Respiratory Viral Panel Fast v2) and will not use the product for testing and reporting results for Influenza A (H3) and RSV A. We will use an alternate method to test for these targets.**

COMPANY NAME:_____

CONTACT NAME:_____

ADDRESS:_____

CITY: _____ STATE/PROVINCE: _____

ZIP CODE/POSTAL CODE: _____

TEL NO:_____FAX NO.:_____

EMAIL ADDRESS:_____

SIGNATURE:_____

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DATE:_____

Appendix A

The xTAG® Respiratory Viral Panel Fast v2 (RVP FAST v2) is a qualitative nucleic acid multiplex test intended for the simultaneous detection and identification of multiple respiratory virus nucleic acids in nasopharyngeal swabs, nasal aspirates and bronchioalveolar lavages from individuals suspected of respiratory tract infections. The virus types and subtypes detected by xTAG® RVP FAST v2 are listed below in Table 1. The detection and identification of specific viral nucleic acids from individuals exhibiting signs and symptoms of respiratory infection aids in the diagnosis of respiratory viral infection when used in conjunction with other clinical and laboratory findings.

TABLE 1. **Respiratory Viruses Detected by xTAG® RVP FAST v2**

Virus	Type/Subtype
Influenza A	H1
	H3
	2009 H1N1
Influenza B	
Respiratory Syncytial Virus	
Coronavirus	229E
	OC43
	NL63
	HKU1
Parainfluenza virus	Parainfluenza 1
	Parainfluenza 2
	Parainfluenza 3
	Parainfluenza 4
Human Metapneumovirus	
Enterovirus/Rhinovirus	
Adenovirus	
Human Bocavirus	

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