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February 15, 2019

Luminex Corporation
12212 Technology Blvd
Austin, TX 78727

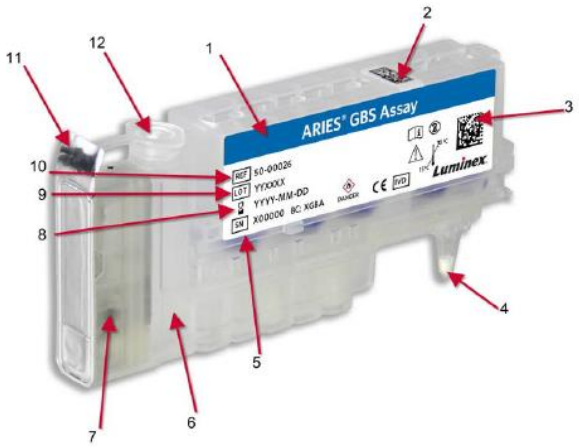
cc: Chairman Medical Board and/or relevant Head of Department

URGENT: MEDICAL DEVICE RECALL / FIELD SAFETY NOTICE

ARIES® HSV 1&2 Assay (PN 50-10017 and PN 50-10031)
ARIES® *Bordetella* Assay (PN 50-10037)
ARIES® Flu A/B & RSV Assay (PN 50-10020)
ARIES® GBS Assay (PN 50-10021)
ARIES® Group A Strep Assay (PN 50-10041)
ARIES® *C. difficile* Assay (PN 50-10018)
ARIES® Extraction Kit (PN 50-10026)

Dear Valued Luminex Customer,

Luminex recently identified a manufacturing defect in the back seal (see Figure 1, Item 11) of our ARIES® cassettes. Specifically, the seal integrity may not meet requirements for some cassettes manufactured between 9/18/2018 and 1/15/2019, and shipped between 9/28/2018 through 1/17/2019, in the lots listed in Table 1 below. The back seal plays a role in maintaining performance until the labeled expiration date. As a result, there is a remote possibility that an invalid or false negative result could occur when using the affected ARIES® Assay Lots.



1. Assay type	7. Side cassette
2. Cassette barcode (top)	8. Cassette expiration date
3. Cassette barcode (side)	9. Cassette lot number
4. PCR tube	10. Cassette part number
5. Cassette serial number	11. Back seal
6. Sample chamber	12. Cassette cap

Figure 1: ARIES® Cassette Example

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Product/lot numbers affected by the back seal defect can be found In Table 1 below.

Table 1

Product[1]	Product Number	Lot Number
ARIES® HSV 1&2 Assay	50-10017	AA7308 AA7485 AA7545 AA7625 AA7630 AA7636 AA7945 AA7985
ARIES® HSV 1&2 Assay (CE-IVD)	50-10031	AA7465
ARIES® *Bordetella* Assay	50-10037	AA7125 AA7310 AA7548 AA7633
ARIES® Flu A/B & RSV Assay	50-10020	AA7127 AA7206 AA7312 AA7549 AA7635
ARIES® GBS Assay	50-10021	AA7546 AA7629
ARIES® Group A Strep Assay	50-10041	AA7313 AA7526 AA7605 AA7631 AA7645
ARIES® *C. difficile* Assay	50-10018	AA7306 AA7311 AA7627 AA7634
ARIES® Extraction Kit*	50-10026	AA7126 AA7307 AA7385 AA7525 AA7547 AA7628 AA7666

*****The intended use for Extraction Cassettes (PN 50-10026) is to extract nucleic acid from human biological specimens and universal transport media (UTM). The ARIES® Extraction Cassette contains a Sample Processing Control (SPC), and has not been validated for use with any specific analytical test method. Given this intended use, false negative and invalid results are not a potential outcome. However, extraction efficiency may be reduced due to potential loss of volume of the reagents.

As an immediate action, Luminex is requesting that customers discontinue use of, and discard, the products listed above immediately. Please contact Luminex Global Support Services to obtain replacement material or if you have questions regarding previously tested results.

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

[1] See CAN-0233 Attachment (Table 4) for product specific Intended Uses.

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Enclosed is an Acknowledgment and Receipt form. You must complete and return this form even if you do not have any remaining product. Luminex Global Support Services can assist you in completing this form. This information is essential in order to maintain recall effectiveness information required by US FDA and the national competent authority.

This recall is being made with the knowledge of the US Food and Drug Administration, Regulatory Agencies within affected regions, and your competent authority, as applicable. This notice should be passed on to all who need to be aware within your organization. Distributors must notify end user customers.

Although no adverse events have been reported, adverse reactions or quality problems experienced with the use of this product may be reported to Luminex, the distributor or local representative, the national Competent Authority, or FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax, as applicable.

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
1-877-785-2323 (U.S. and Canada)
+1-512-381-4397 (Outside U.S. and Canada)
support@luminexcorp.com
CAN-0233

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

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VOLUNTARY RECALL STEPS

The Acknowledgment and Receipt Form attached to this letter must be completed and returned even if you do not have any of the following product on hand:

ARIES® HSV 1&2 Assay (PN 50-10017 and PN 50-10031)
ARIES® *Bordetella* Assay (PN 50-10037)
ARIES® Flu A/B & RSV Assay (PN 50-10020)
ARIES® GBS Assay (PN 50-10021)
ARIES® Group A Strep Assay (PN 50-10041)
ARIES® *C. difficile* Assay (PN 50-10018)
ARIES® Extraction Kit (PN 50-10026)

1. **Segregate Recalled Product**. Please immediately remove all affected lots of the above listed products from your inventory and segregate this product in a secure location for destruction.

2. **Complete Acknowledgment and Receipt Form.** Complete and return the enclosed Acknowledgment and Receipt Form (Pages 5 and 6) 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.

3. **Please destroy the segregated product and provide confirmation in the Acknowledgment and Receipt Form (Table 3).** 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).

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PRODUCT RECALL

ACKNOWLEDGMENT AND RECEIPT FORM

PLEASE FILL OUT THIS FORM AND RETURN BY FEBRUARY 28, 2019

DATE: _____

COMPANY NAME: _____

CONTACT NAME: _____

CORPORATE TITLE: _____

ADDRESS: _____

CITY: _____ STATE/PROVINCE: _____

COUNTRY:_____ ZIP CODE/POSTAL CODE: _____

TEL NO: _____ FAX NO: _____

RECALL:

Table 2

Product Name	Product Number	Lot Number	UDI
ARIES® HSV 1&2 Assay	50-10017	AA7308, AA7485 AA7545, AA7625 AA7630, AA7636 AA7945, AA7985	00840487100295
ARIES® HSV 1&2 Assay (CE-IVD)	50-10031	AA7465	N/A
ARIES® *Bordetella* Assay	50-10037	AA7125, AA7310, AA7548, AA7633	00840487101452
ARIES® Flu A/B & RSV Assay	50-10020	AA7127, AA7206 AA7312, AA7549 AA7635	00840487100158
ARIES® GBS Assay	50-10021	AA7546, AA7629	00840487100165
ARIES® Group A Strep Assay	50-10041	AA7313, AA7526 AA7605, AA7631 AA7645	00840487101469
ARIES® *C. difficile* Assay	50-10018	AA7306, AA7311 AA7627, AA7634	00840487100059
ARIES® Extraction Kit*	50-10026	AA7126, AA7307 AA7385, AA7525 AA7547, AA7628 AA7666	00840487100073

I have read and understand the recall letter **[CAN 0233]: URGENT MEDICAL DEVICE RECALL / FIELD SAFETY NOTICE** letter date **February 15, 2019** and agree to discontinue use of the product(s) listed immediately: Yes ☐ No ☐

Have you observed any adverse events associated with recalled product? Yes ☐ No ☐

If yes, please explain (provide associated product number and lot number):

_____

_____

If you have product remaining, please use the Table 3 below to check the appropriate box(es) for the Product/Lot Number of remaining material. In addition, please use the space provided to record quantities for all material destroyed. If you do not have any remaining product, please check the below statement and check the "N/A" box just above Table 3.

☐ We do not have any stock of the above products on hand. All stock has been consumed.

☐ N/A

Table 3

Product Name	Product Number	Lot Number / Quantity of Kit(s) Destroyed
ARIES HSV 1&2 Assay	☐ 50-10017	☐ AA7308 _____ ☐ AA7485 _____ ☐ AA7545 _____ ☐ AA7625 _____ ☐ AA7630 _____ ☐ AA7636 _____ ☐ AA7945 _____ ☐ AA7985 _____
ARIES HSV 1&2 Assay (CE-IVD)	☐ 50-10031	☐ AA7465 _____
ARIES *Bordetella* Assay	☐ 50-10037	☐ AA7125 _____ ☐ AA7310 _____ ☐ AA7548 _____ ☐ AA7633 _____
ARIS Flu A/B & RSV Assay	☐ 50-10020	☐ AA7127 _____ ☐ AA7206 _____ ☐ AA7312 _____ ☐ AA7549 _____ ☐ AA7635 _____
ARIES GBS Assay	☐ 50-10021	☐ AA7546 _____ ☐ AA7629 _____
ARIES Group A Strep Assay	☐ 50-10041	☐ AA7313 _____ ☐ AA7526 _____ ☐ AA7605 _____ ☐ AA7631 _____ ☐ AA7645 _____
ARIES *C. difficile* Assay	☐ 50-10018	☐ AA7306 _____ ☐ AA7311 _____ ☐ AA7627 _____ ☐ AA7634 _____
ARIES Extraction Kit*	☐ 50-10026	☐ AA7126 _____ ☐ AA7307 _____ ☐ AA7385 _____ ☐ AA7525 _____ ☐ AA7547 _____ ☐ AA7628 _____ ☐ AA7666 _____

PLEASE RETURN COMPLETED FORM BY FEBRUARY 28, 2019

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CAN-0233 Attachment – Product Specific Intended Use Statements

Table 4

Product Name	Product Number	Intended Use
ARIES® HSV 1&2 Assay	50-10017	The ARIES® HSV 1&2 Assay is a real-time polymerase chain reaction (PCR) based qualitative *in vitro* diagnostic test for the direct detection and differentiation of Herpes Simplex Virus 1 and 2 (HSV 1 and HSV 2) DNA in cutaneous or mucocutaneous lesion specimens from symptomatic patients. The test is indicated for use as an aid in diagnosis of HSV infection in symptomatic patients. The ARIES® HSV 1&2 Assay is indicated for use on the ARIES® Systems. **WARNING:** The ARIES® HSV 1&2 Assay is not FDA cleared for use with cerebrospinal fluid (CSF). The assay is not intended to be used for prenatal screening.
ARIES® HSV 1&2 Assay (CE-IVD)	50-10031	The ARIES® HSV 1&2 Assay (EU) is a real-time polymerase chain reaction (PCR) based qualitative *in vitro* diagnostic test for the direct detection and typing of herpes simplex virus (HSV 1&2) DNA in cutaneous or mucocutaneous lesion specimens from symptomatic patients or in CSF from patients suspected of HSV infections of the central nervous system (CNS). The test is indicated for use with symptomatic individuals to aid in the diagnosis of HSV infections. Negative CSF results do not preclude HSV 1 and HSV 2 infection and should not be used as the sole basis for diagnosis, treatment, or other patient management decisions. The assay is not intended to be used for prenatal screening. The ARIES® HSV 1&2 Assay (EU) is indicated for use with ARIES® Systems.
ARIES® *Bordetella* Assay	50-10037	The ARIES® *Bordetella* Assay is a real-time polymerase chain reaction (PCR) based qualitative in vitro diagnostic test for the direct detection and identification of *Bordetella pertussis* (*B. pertussis*) and *Bordetella parapertussis* (*B. parapertussis*) nucleic acid in nasopharyngeal swab (NPS) specimens obtained from individuals suspected of having a respiratory tract infection attributable to *B. pertussis* or *B. parapertussis*. The ARIES® *Bordetella* Assay targets the *B. pertussis* toxin promoter and the *B. parapertussis* IS1001 insertion element in the genomes. When clinical factors suggest that *B. pertussis* or *B. parapertussis* may not be the cause of respiratory infection, other clinically appropriate investigation(s) should be carried out in accordance with published guidelines. Negative results for the ARIES® *Bordetella* Assay do not preclude *B. pertussis* or *B. parapertussis* infection and positive results do not rule out co-infections with other respiratory pathogens. The direct detection and identification of *B. pertussis* and *B. parapertussis* nucleic acids from symptomatic patients aids in the diagnosis of *B. pertussis* and *B. parapertussis* respiratory infection in conjunction with other clinical findings and epidemiological information. The ARIES® *Bordetella* Assay is indicated for use with the ARIES® Systems.

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Table 4 (cont'd)

Product Name	Product Number	Intended Use
ARIES® Flu A/B & RSV Assay	50-10020	The ARIES® Flu A/B & RSV Assay is a polymerase chain reaction (PCR) based qualitative *in vitro* diagnostic test for the direct detection and differentiation of influenza A virus, influenza B virus, and respiratory syncytial virus (RSV) nucleic acid in nasopharyngeal swab (NPS) specimens from patients with signs and symptoms of respiratory tract infection in conjunction with clinical and laboratory findings. The test is intended for use as an aid in the differential diagnosis of Influenza A, Influenza B, and RSV in humans and is not intended to detect Influenza C. Negative results do not preclude influenza virus or RSV infection and should not be used as the sole basis for diagnosis, treatment, or other management decisions. Conversely, positive results do not rule-out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. The use of additional laboratory testing (e.g. bacterial culture, immunofluorescence, X-ray findings) and clinical presentation must be taken into consideration in order to obtain the final diagnosis of respiratory viral infection. Performance characteristics for Influenza A were established during the 2014-2015 and the 2015-2016 influenza seasons when influenza A/H3N2 and A/H1N1 pandemic were the predominant influenza A viruses in circulation. When other Influenza A viruses are emerging, performance characteristics may vary. If infection with a novel Influenza A virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent influenza viruses and sent to state or local health departments for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens. The ARIES® Flu A/B & RSV Assay is indicated for use with the ARIES® Systems.
ARIES® GBS Assay	50-10021	The ARIES® GBS Assay, performed on ARIES® Systems, is a real-time polymerase chain reaction (RT-PCR) based qualitative in vitro diagnostic test. The ARIES® GBS Assay is designed to detect Group B *Streptococcus* (GBS) nucleic acid from 18-24 hour Lim broth enrichments of vaginal-rectal swab specimens obtained from pregnant women. The ARIES® GBS Assay is intended for use as a method for detection of GBS colonization in antepartum women. It is not intended to diagnose or monitor treatment of a GBS infection. The ARIES® GBS Assay does not provide susceptibility results. Culture isolates are needed for performing susceptibility testing as recommended for penicillin-allergic women.

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Table 4 (Cont'd)

Product Name	Product Number	Intended Use
ARIES® Group A Strep Assay	50-10041	The ARIES® Group A Strep Assay is a real-time polymerase chain reaction (PCR) based qualitative in vitro diagnostic test for the direct detection of *Streptococcus pyogenes* (Group A β-hemolytic *Streptococcus*) in throat swab specimens from patients with signs and symptoms of pharyngitis. The ARIES® Group A Strep Assay can be used as an aid in the diagnosis of Group A Streptococcal pharyngitis. The assay is not intended to monitor treatment for Group A *Streptococcus* infections. The ARIES® Group A Strep Assay is indicated for use with ARIES® Systems.
ARIES® *C. difficile* Assay	50-10018	The ARIES® *C. difficile* Assay is a real-time polymerase chain reaction (PCR) based qualitative *in vitro* diagnostic test for the direct detection of toxigenic *Clostridium difficile* (*C. difficile*) nucleic acid in unpreserved, unformed (liquid or soft) stool specimens obtained from patients suspected of having *Clostridium difficile* infection (CDI). The test targets the *C. difficile* toxin A gene (*tcdA*) and toxin B gene (*tcdB*) and is indicated for use as an aid in the diagnosis of *C. difficile* infection (CDI). The ARIES® *C. difficile* Assay is indicated for use with ARIES® Systems.
ARIES® Extraction Kit	50-10026	The ARIES® Extraction Kit is intended to extract nucleic acid from human biological specimens and universal transport media (UTM). The ARIES Extraction Cassette contains a Sample Processing Control (SPC). The ARIES Extraction Kit has not been validated for use with any specific analytical test method. The ARIES Extraction Kit is indicated for use on the ARIES System.