



(July 28, 2022)

URGENT: MEDICAL DEVICE RECALL

ARIES[®] SARS-CoV-2, ARIES[®] *Bordetella* and ARIES[®] HSV Assays

Dear Customer,

The purpose of this letter is to advise you that Luminex is voluntarily recalling specific lots of ARIES[®] SARS-CoV-2, ARIES[®] *Bordetella*, and ARIES[®] HSV Assays listed in the table below.

We have received complaints regarding higher than usual levels of invalids. You are receiving this letter because our records indicate that you purchased at least one of these products listed in the table below. Our investigation identified the automated extraction may be impaired in these cassettes. We are not aware of any adverse events associated with these products.

We recommend that you **discard any remaining inventory** and review the results generated with these specific kits and lots. If you have experienced a high frequency of invalid results, please contact Luminex Technical Support Services at support@luminexcorp.com at your earliest convenience to discuss next steps and **arrange for replacements**.

Product Name	Part Number	Lot Number	Expiration Date
ARIES [®] SARS-CoV-2 Assay (CE-IVD)	50-10051	AB5147A	09/14/2022
		AB5062A	06/04/2022
		AB5082A	09/08/2022
		AB5121A	09/09/2022
ARIES [®] <i>Bordetella</i> Assay (CE-IVD)	50-10037	AB5059A	11/23/2022
ARIES [®] HSV 1&2 Assay (IVD)	50-10017	AB5145A	12/30/2022

Luminex has reviewed its procedures and has updated them to include safeguards to avoid reoccurrence of this issue.

Please contact Luminex Technical Support Services to discuss any questions you have. We offer our sincerest apologies for any inconvenience this situation may have caused.



Luminex Technical Support Services

Contact Information:

1-877-785-2323 (U.S. and Canada)

+1-512-381-4397 (Outside U.S. and Canada)

support@luminexcorp.com

CAN-0303 Rev. A

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.