DiaSorin The Diagnostic Specialist

DiaSorin Molecular

URGENT FIELD SAFETY NOTIFICATION LETTER

Date: 12 May 2020

Dear Valued Customer:

DiaSorin Molecular LLC is informing its potentially impacted customers of an internally observed issue associated with the use of the Multi-Assay Suite (MAS) feature in the LIAISON® MDX Studio Software (LMS) Version 2.0. The problem is specific to the MAS feature of LMS 2.0 when running Simplexa™ HSV 1 & 2 Direct (MOL2150) with Simplexa™ VZV Direct (MOL3650) or Simplexa™ VZV Swab Direct (MOL3655) together on the same Direct Amplification Disc.

The MAS feature incorrectly applies the thresholds of the first loaded assay to the analytes coupled with the same dye in the second assay. HSV-2 and VZV are the only two analytes sharing the same dye, which may potentially result in a false negative HSV-2 result or a false positive VZV result, only when a signal ends its amplification between both thresholds:

- If the VZV barcode is scanned first, the VZV threshold will be used to evaluate the HSV-2 results. The VZV threshold is higher and thus there is a potential for a weak HSV-2 to be missed, giving a false negative result. HSV-1 results will not be affected.
- If the HSV barcode is scanned first, the HSV-2 threshold will be used to evaluate the VZV results. The HSV-2 threshold is lower and thus there is a potential for a VZV sample to give a false positive result.

All of the amplification curves remain reliable and there is no need to run samples again. Re-analysis of affected runs is sufficient.

DiaSorin Molecular has not received any customer or field notifications or complaints regarding this issue. An analysis was done to review all runs archived from Clinical Trials and some customer databases. Based on this analysis, the risk of a false result was determined to be low because in all cases, the positive signals crossed both thresholds.

Please be advised that as referenced in the Instructions for Use, the evaluation of "results from this test must be considered in conjunction with the clinical history, epidemiological data and other laboratory information available to the clinician evaluating the patient and negative results do not rule out infections of the CNS and should not be used as the sole basis for treatment or other patient management decisions."

Please immediately discontinue use of the MAS feature. This issue will be corrected in the LIAISON® MDX Studio Software Version 2.1. The new version is expected in June 2020, a member of our team will contact you to coordinate the installation of the software repair at your convenience.

Please forward this communication to all required individuals within your organization.

DiaSorin Molecular is committed to providing high quality, safe and effective products. We sincerely apologize for any inconvenience this error may have caused. If you would like assistance with evaluating runs or if you have any questions, please contact DiaSorin Molecular Technical Services at +1-562-240-6500, option 3 or by email at ts.molecular@DiaSorin.com.

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Product: LIAISON® MDX Studio Software Version 2.0	Reference No.: FA20-01

RETURN TO FAX NO:	(562) 240-6526 ATTN: Technical Services
RETURN BY EMAIL TO:	technicalinfo.molecular@diasorin.com
RETURN BY MAIL TO:	DiaSorin Molecular LLC ATTN: Technical Services 11331 Valley View St. Cypress, CA 90630

I acknowledge receipt of the DiaSorin Molecular LLC notification for the LIAISON® MDX Studio Software Version 2.0 issue.

NAME including contact information (phone and email)	
INSTITUTION:	
ADDRESS:	
DATE:	