



The Diagnostic Specialist

DIASORIN CUSTOMER NOTIFICATION LETTER

Date: January 22, 2014

Dear Valued Customer:

Our records indicate you have received one or more LIAISON® EBV IgM kits, catalog number 310500, lot numbers 028031X and/or 028031X/1.

Through internal testing, DiaSorin has confirmed that the kit lot identified has a potential to produce false negative results. You may or may not have observed this phenomenon.

As a precautionary measure, we recommend that you destroy all remaining inventory of LIAISON® EBV IgM kits, catalog number 310500, lot numbers 028031X and 028031X/1. DiaSorin will be providing free-of-charge replacement product.

Based on internal test results and a health risk assessment, review of past patient results is not considered necessary as the result should not be used alone but in conjunction with other EBV serological markers to determine disease state.

DiaSorin has identified the affected component and has taken appropriate corrective action to prevent recurrence. Please keep this notice for your records and disseminate this information within your institution, as required.

Please complete the bottom portion of this letter and return as confirmation that you have received this notification and for processing any necessary free-of-charge replacement product.

We apologize for any inconvenience this may cause and thank you for your cooperation.

If you have any questions regarding this notice please contact Product Support at 1-800-328-1482.

Product: LIAISON® EBV IgM

Affected Kit Lots: 028031X and 028031X/1

Catalog Number: 310500

RETURN TO FAX NO: (651) 351-5669
ATTN: Lori Pfeifer, Product Support

RETURN BY MAIL TO: DiaSorin Inc.
ATTN: Lori Pfeifer, Product Support
DiaSorin Inc.
1951 NORTHWESTERN AVE.
STILLWATER, MINNESOTA 55082-0285

I have been notified and have destroyed the indicated kit lot number.

OF KITS DESTROYED: _____

OF REPLACEMENT KITS REQUESTED: _____

NAME including contact information (phone and email): _____

INSTITUTION: _____

ADDRESS: _____

DATE: _____