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**PRODUCT UPDATE – LIAISON MEASLES IgG (PN 318810) Lot number 159026**

The DiaSorin LIAISON Measles IgG assay uses chemiluminescent immunoassay (CLIA) technology on the LIAISON® Analyzer family for the qualitative determination of IgG antibodies to measles virus in human serum. It is intended to be used as an aid in the determination of serological status to measles virus.

CDC reports that from January 1 to July 3, 2019, there have been 1,109 individual cases of measles confirmed in 28 states (1). This is the greatest number of cases reported in the U.S. since 1992.

Increased testing and communication with Public Health, CDC, clinicians and laboratorians has prompted a review of the optimal specificity and sensitivity for Measles IgG assays in this new environment of lower vaccination in specific populations and ongoing community exposure.

Re-exposure to the measles virus induces a strong anamnestic immune response with a rapid boosting of IgG antibodies, which prevents clinical disease (2), suggesting lower positive IgG responses may provide appropriate protection.

Unnecessary quarantine post exposure is given as the reason for a sensitive Measles IgG assay by Public Health at both the state and county level.

Consensus is that an assay for Measles IgG should be as sensitive as practicable to avoid unnecessary vaccination or unnecessary quarantine of those exposed to measles and thus reduce the overall individual and public health economic impact of Measles outbreaks in the community.

DiaSorin has reassessed the comparator data in light of these new needs and lowered the cut-off and equivocal zone for the assay to increase the agreement for positive results with the comparator assay. This will be implemented with a new lot number. There have been no changes to assay formulation or performance.

Information for the new cut-off has been provided against the current international standard for Measles Antibody (WHO Third International Standard for Anti-Measles, NIBSC code: 97/648).

It is expected that laboratories tracking population positivity and negativity rates will see increased positivity and decreased negativity with implementation of this new lot.

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**ASSAY INSTRUCTIONS FOR USE (IFU) CHANGES****12. INTERPRETATION OF RESULTS**

- The optimal cut-off value has been changed to reflect greater sensitivity to the presence of Measles IgG antibodies.
- The new cut-off value discriminating between the presence and the absence of Measles virus IgG is 15.0 AU/mL.
- Samples with Measles virus IgG concentrations below 13.5 AU/mL should be graded negative.
- Samples with Measles virus IgG concentrations ranging between 13.5 and 16.5 AU/mL should be graded equivocal.
- Samples with Measles virus IgG concentrations equal to or above 16.5 AU/mL should be graded positive.

**14. SPECIFIC PERFORMANCE CHARACTERISTICS**

- Reference to WHO standard. The cut-off value of LIAISON® Measles IgG immunoassay equates to 175 mIU/mL WHO Third International Standard for Anti-Measles, NIBSC code: 97/648. This data is for information only and should be considered as indicative.

**15. COMPARATOR METHOD**

- Comparator data is against a commercially available ELISA method.

- 1) Centers for Disease Control and Prevention  
<https://www.cdc.gov/measles/cases-outbreaks.html>
  - 2) S.C. REDD, L.E. MARKOWITZ et al.  
Measles vaccine, in Vaccines, S.A. Plotkin, W.A. Orenstein eds., W.B. Saunders, Philadelphia, p. 222-266 (1999).
  - 3) Centers for Disease Control and Prevention  
Prevention of Measles, Rubella, Congenital Rubella Syndrome, and Mumps, 2013: Summary Recommendations of the Advisory Committee on Immunization Practices (ACIP) Recommendations and Reports, June 14, 2013 / 62(RR04);1-34
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