URGENT FIELD SAFETY NOTICE

Product description: Human IgM Kit for use on SPAPLUS, Product codes NK012.S and NK012.10S
FSCA Identifier 12580
Type of Action - Advisory

14th October 2013

Dear Customer,

Details of affected devices: This issue affects the Human IgM Kits for use on SPAPLUS, product codes NK012.S and NK012.10S – All lots.

Description of the problem: We recently became aware of a sample that gave an inappropriately low IgM result using the SPAPLUS Human IgM Kit. Further investigations identified that this sample was subject to antigen excess effect; even though it's true value was below the claimed level of 56.4g/L.

The antigen excess capacity of this product has been reviewed and has been confirmed as correct. Investigations have suggested that this sample contained predominantly monoclonal IgM and we believe that this particular type of IgM reacted aberrantly with the antibody and subsequently yielded this spurious result. To date this is the only report of this nature for the Human IgM Kit and thus we believe this to be a very rare event.

In developing immunoglobulin assays The Binding Site always try to ensure we minimise the potential occurrences of antigen excess. However, as with all immunoglobulin assays it cannot be completely eliminated and in rare cases very high immunoglobulin concentrations, especially monoclonal samples, may give false low results.

Actions to be taken: The Binding Site recommend, that for any patient whose IgM value does not concur with their clinical history or other test results that the sample be re-assayed at different dilutions to identify the true value.

We have updated the instructions for use to highlight this aspect of the products performance. Please refer to limitations section 10.4 of the IgM package insert SIN144 Version 2nd October 2013.

Transmission of this Field Safety Notice: Please transfer this notice to other organisations on which this advice has an impact.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of corrective action.

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