

	Immediate Action Required
✓	Action Required
	Information Only

## Important Notice

**Product code and description:** NK012.S - Human IgM Kit for use on SPAPLUS  
**Lot:** 413849  
**Reference:** GLB121124  
**Date:** 15/10/2018  
**Issue:** Validation of assay calibration

**Dear Customer,**

The Binding Site (TBS) has become aware that some customers have experienced challenges when validating the calibration of the IgM SPAPLUS assay kit, NK012.S lot 413849. This is indicated by kit control values reporting outside the specified ranges. TBS investigations have shown when the high and low controls (NL012.S lot 434220 and NH012.S lot 434219) return results within their specified ranges, the assay calibration can be accepted and results may be reported.

**The Binding Site would like to advise the following to allow continuity of testing where customers are facing calibration validation issues:**

1. For kit NK012.S lot 413849, please load reagents on-board the analyser and leave for a minimum of 18 hours prior to running the calibration and validating the curve. The SPAPLUS analyser holds the assay reagent (SN090 lot 434221 and NA012.S lot 443205) in a temperature controlled reagent carousel; please leave the reagents on-board the analyser until empty (following stability advice in the insert Section 6).
2. Customers are **advised that once the calibration is established and validated, the reagents must remain** on the instrument until the reagent is consumed including when re-running the calibration. Investigations on NK012.S lot 413849 have shown that inversion of the reagent vials prior to re-calibration can contribute to kit control values reporting outside the specified ranges.
3. Control vials and the calibrator set are held in the sample handling area of the analyser. When not in use, the control vials and calibrator set should be removed from the instrument, be capped to avoid evaporation and be stored at 2-8°C in the refrigerator.
4. If a control measurement is out of range when assayed with a stored curve the assay must be recalibrated. If on recalibration the control values measured with the new curve are still out of range, the instrument and the assay parameters should be checked before repeating the assay.
5. In our laboratories we have found that following the above advice allows continued and safe running of the IgM assay, if calibration issues are still experienced when following this advice please do not hesitate to contact a Binding Site representative.

Please be aware that this advice only applies to NK012.S lot 413849. For other assay kits run on the SPAPLUS analyser please assay as per the insert and SPAPLUS operation manual.

**Details of affected devices:**

Product	Lot number	Expiry
NK012.S - Human IgM Kit for use on SPAPLUS	413849	01/2019

**Advice on action to be taken by the user:**

- Follow advice provided in the Important Notice.
- Return your completed TSWS18 E-back form to your local Binding Site representative.

**Associated Document(s):**

- *TSWS18 E-Back Form*

**Transmission of this Important information: (if appropriate)**

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

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

Should you require any further information please contact

Your local Binding Site Representative

or

Technical Support Group

UK: +44(0) 1214569696

Technical.support@bindingsite.com

Please contact your TBS representative if calibration issues for the assay persist.

Kind Regards,