

✓	Immediate Action Required
	Action Required
	Information Only

Urgent Field Safety Notice

Product code and description: NK012.S - Human IgM Kit for use on SPAPLUS
Lot: 407483
Reference: GLB119739
Date: Wednesday, 25 July 2018
Issue: Kit accuracy issue

Dear Customer,

The Binding Site have identified that the kit (NK012.S lot 407483) demonstrates a reduction in accuracy within the same day of running the calibration curve.

Investigations at The Binding Site indicate that after running the calibration curve the recovery of the kit control results decrease by approximately 12% within the same day. Samples have been shown to be similarly affected. On the day after running the assay calibration curve the control results may be out of range. If the kit control results are outside of the stated acceptable range, then patient sample results should not be reported as indicated in the kit IFU. As stated in the kit IFU (section 1) for this assay, test results are to be used in conjunction with other clinical and laboratory findings.

The impact on assay accuracy is limited, however as a precautionary action The Binding Site is requesting that the affected kit lot (NK012.S lot 407483) is no longer used and is disposed of locally.

Details of affected devices:

Product	Lot number	Expiry
Human IgM Kit for use on SPAPLUS (NK012.S)	407483	01/2019

Advice on action to be taken by the user:

- Immediately quarantine and dispose all of NK012.S lot 407483 kits in your organisation.
- Return your completed TSWS18 E-back form to your local Binding Site representative. A witness signature of the kit disposal is required on the E-back form.

Associated Document(s):

- *TSWS18 E-Back Form*

Transmission of this Important information:

This notice needs to be passed on to 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.co.uk

Kind Regards,



Colin Booth

Director of Regulatory and Quality