	Immediate Action Required
✓	Action Required
	Information Only

Field Safety Notice

Product code and description:	**NK012.OPT - Optilite IgM Kit**
Reference:	GLB125990
Date:	29 July 2019
Issue:	Validation of assay calibration

Dear Customer,

Evidence found from an in-house study at The Binding Site (TBS) has shown that some users may experience difficulties when attempting to validate the calibration of the Optilite IgM Kit lot 420256. This is indicated by kit control values reporting outside the specified ranges. TBS investigations have shown that when the high and low controls (NQ012.1 lot 446965 and NQ012.2 lot 446965) return results within their specified ranges, the assay calibration can be accepted and results may be reported.

TBS are therefore providing the advice shown below and have taken the decision to reduce the expiry date of the affected kits from January 2020 to September 13th, 2019. The decision to reduce the shelf life should allow remaining kits held by customers to be used and provide time to transition to a new kit lot.

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

1. For kit NK012.OPT lot 420256, please load reagents on-board the analyser and leave overnight, or alternatively for a minimum of 18 hours, prior to running the calibration and validating the curve. The Optilite analyser holds the assay reagent (R012.OPT lot 446963) 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.OPT lot 420256 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 and calibrator vials are held in the sample handling area of the analyser. When not in use, the control and calibrator vials should be removed from the instrument, be capped to avoid evaporation and be stored at 2-8˚C in the refrigerator.

4. To validate the calibration curve, the control materials must be tested a minimum of once a day and should return results within ±15% of the concentration(s) as stated on the accompanying QC certificate. 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 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 Optilite IgM assay, if calibration issues are still experienced when following this advice please do not hesitate to contact a Binding Site representative.

Details of affected devices:

Product	Lot number(s)/ software version	Original Expiry Date	New Expiry Date
NK012.OPT Optilite IgM Kit	420256	01/2020	13th September 2019

Advice on action to be taken by the user:

- Follow advice provided in this Urgent Medical Device Correction notice
- Follow the amended kit expiry and discard any remaining kits on this date.
- 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:

- 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 transfer this notice to other organisations on which this action has an impact.
- 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

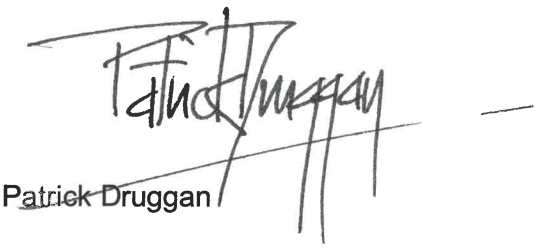
Technical Support Group

UK: +44(0) 1214569696

Technical.support@bindingsite.com

On behalf of the Binding Site group, please accept our apologies for any inconvenience caused as a result of this issue.

Yours Sincerely



Patrick Druggan

Head of Regulatory Affairs