

✓	Immediate Action Required
	Action Required
	Information Only

Urgent Field Safety Notice

Product code and description: NK044.OPT - Optilite C-Reactive Protein Reagent
Reference: GLB123189 – AE035
Date: 19 February 2019
Issue: Deterioration of product
Action Required: Immediate termination of use and disposal

Dear Customer,

This Urgent Field Safety Notice has been issued by The Binding Site to inform you of an observed deterioration of the CRP NK044.OPT reagent material, lot number 417670. The Binding Site has made the decision to remove the affected product lot from the market.

Summary of Issue:

Investigations have confirmed that there has been a deterioration of the affected reagent lot and that the issue may present in two ways:

- a) 2-3 hours after running and validating the initial calibration curve for the assay, the reported results for samples with CRP levels of approximately 20mg/L or lower may be up to -25% from their true value. This issue should be identified by the occurrence of QC failures for the low control, when the controls are subsequently run. Samples with higher CRP levels and the high control have not been shown to be affected by this.
- b) Sample values determined from using the last 20 tests from affected reagent vials may be significantly elevated, up to a 200% increase from the true value. This has been shown to more significantly affect samples with lower levels of CRP (see table 1 below). Samples with true levels of CRP above 55mg/L are minimally affected by the issue.

Table 1. The most extreme observed impact of the issue for the last 20 tests of an affected vial

True sample target value (mg/L)	Most extreme value observed (mg/L)	Percentage away from target		
		Across last 20 tests	Range for last 11-20 tests	Range for last 1-10 tests
7.1	21.2	Up to + 200% increase	-6% to 130%	124% to 200%
21.9	35.6	Up to + 63% increase	-17% to 44%	16% to 63%
56	69	Up to + 23% increase	-	-

The values provided in the table are the most extreme observed from recent investigations. The impact of the issue is understood to be variable and progressive through time, therefore, previous testing results would be likely to be less affected.

The Binding Site recognises that the performance of affected vials is not acceptable. However, the use of CRP levels, at affected concentrations, is known to be a crude test and is not used in isolation to pinpoint a specific action. Furthermore, the biological variation of CRP, CV_i (within subject coefficient of variation) is reported to be 42% and the RCV (Reference Change Value) for the assay is calculated to be 120%. The occurrence of the observed level of falsely elevated results may occasionally lead to increased frequency in patient follow up and repeated testing but would be unlikely to impact on patient treatment.

Details of affected devices:

Product	Lot number	Expiry
Optilite C-Reactive Protein Reagent NK044.OPT	417670	30/06/2019

Advice on action to be taken by the user:

- Please discontinue using this product immediately and remove any remaining affected reagents from the Optilite instrument.
- Please dispose of any remaining product at your facility following local regulations.
- The Binding Site considers the issue is unlikely to impact on medical management, however, we recommend that the above information is discussed with your medical director so that the potential impact of the issue is considered on a local level.
- Please return your completed and signed E-Back Form TSWS18 (attached) to Technical.support@bindingsite.com or to your local Binding Site representative within one week of receiving this notification. A witness signature of the kit disposal is required on the E-Back form.

Associated Document(s):

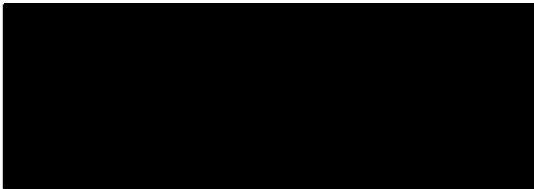
- *TSWS18 E-Back Form*

Transmission of this Important information:

- This notice needs to be distributed to all those who need to be aware of the matter within your organisation.
- Please transfer this notice to any 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 recommended actions.

The Binding Site thank you in advance for your help and support in completing the required actions that have been outlined above and sincerely apologise any inconvenience that may be caused.

Kind Regards,



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