

# Urgent Field Safety Notice



**Product code and description:** ZK044.L.R – MININEPH™ Human C-Reactive Protein Kit  
**Reference:** GLB128972  
**Date:** 12 December 2019  
**Issue:** Deterioration in assay performance  
**Action Required:** Immediate termination of use

## Summary of Issue:

The Binding Site has identified that the quality control samples supplied with ZK044.L.R lot 415776 are reporting above their specified acceptance ranges. Investigation by The Binding Site has indicated that there is an approximately 90% likelihood of one or both the QC results reporting out of the above specified range. This indicates that affected kit assay performance has deteriorated since product release. The Binding Site has therefore decided to remove the affected kits from the field.

It is expected that sample results are affected to the same extent as the kit QCs. As stated in the instructions for use, where QC results report outside of the acceptance ranges, patient sample results should not be reported.

## Details of affected device:

Product	Lot number	Expiry
MININEPH™ Human C-Reactive Protein Kit	415776	31/05/2020

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

- Please discontinue using this product immediately.
- Please dispose of any remaining product at your facility following local regulations.
- Please return your completed and signed E-back form TSWS18 (attached) to [Technical.support@bindingsite.com](mailto:Technical.support@bindingsite.com) or to your local Binding Site Representative within one week of receiving this notification. Please note, a witness signature of the kit disposal is required on the E-back form.

**Associated Document:**

- *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.

The Binding Site thank you in advance for your help and support in completing the actions outlined above and sincerely apologise for any inconvenience 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](mailto:Technical.support@bindingsite.com)