✓	Immediate Action Required
	Action Required
	Information Only

Urgent Field Safety Notice

Product code and description:	MK016 - VaccZyme™ Human Anti-Haemophilus Influenzae type b Enzyme Immunoassay Kit
Reference:	GLB124438/GLB125869/AE040
Date:	12 August 2019
Issue:	Positive Bias on Quality Controls and Samples
Action Required:	Immediate termination of use and disposal

Dear Customer,

This Urgent Field Safety Notice is issued by The Binding Site to inform you of an observed deterioration of the assay performance since product release of MK016, lot numbers 413170 & 435314. The Binding Site has made the decision to remove the affected product lots from the market.

Summary of Issue:

A positive bias has been identified on the affected lots. The degree of bias varies depending on the assay method used, with approximately 25% positive bias by a manual method, and approximately 45% positive bias using automated methods. Both patient samples and Quality Control materials are affected, however the issue presents inconsistently across individual plates. Patient samples results may therefore be affected even where Quality Control results are within acceptable ranges. Table 1 shows the mean biases observed with Quality Control materials using manual and automated methods.

Table 1 – Quality Control Biases observed with MK016 lots 413170 & 435314

	Manual Method	Automated Method
High Control	+1.98 %	+22 %
Low Control	+27 %	+49 %

The Binding Site considers that the issue is unlikely to impact on medical management. Falsely elevated results, incorrectly indicating a protective level of anti-Hib antibody, are considered unlikely given the degree of positive bias observed, the intended use of the device, and the limitations included in the device labelling. The Human Anti-Haemophilus Influenzae type b Enzyme Immunoassay is a supporting test alongside assessment of responses to protein and polysaccharide antigens in the assessment of immunodeficiency, and should be used as an aid in diagnosis only, however, we recommend that the information contained within this notice is discussed with your medical director so that the potential impact of the issue is considered on a local level.

Details of affected devices:

Product	Lot numbers	Expiry
MK016 VaccZyme™ Human Anti-Haemophilus Influenzae type b Enzyme Immunoassay Kit	413170 435314	31/12/2019

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.
- 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. Please note, 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 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,

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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