



Urgent Field Safety Notice

Immediate Action Required

Axis-Shield Liquid Stable (LS) 2-Part HOMOCYSTEINE REAGENT

Dear Healthcare Professional,

This Field Safety Notice contains important information concerning the Axis-Shield Liquid Stable (LS) 2-Part HOMOCYSTEINE REAGENT. Please review the information below to determine impact to your organisation then follow the recommended course of action provided to help facilitate our Product Recall of affected lots.

Date Issued 20 March 2015

Product Axis-Shield Liquid Stable (LS) 2-Part HOMOCYSTEINE REAGENT

Affected Lots

Part Number	Lot Number	Expiration Date
FHBC100	802899574	2015-05-06
FHRWR100	802899249	2015-05-06
FHRWR1000	802899248	2015-05-06
FHRWR200	802899989	2015-05-06
FHRWR200	802899250	2015-05-06
FHRWCN1	802900104	2015-07-31

Reason for Recall Axis-Shield Liquid Stable (LS) 2-Part HOMOCYSTEINE REAGENT lots listed above show deterioration in assay performance manifesting itself by under recovery of Homocysteine in Controls and Patient Samples.

The cause of this deterioration has been attributed to a loss of reductant activity in Reagent 1.

Detection It is recommended that control materials with values for homocysteine in both the normal and abnormal ranges are tested to validate reagent performance. Under recovery will be detected if Axis-Shield Homocysteine controls (part number FHCY200) are used to confirm assay validity. These controls will fail low to the specification detailed within Instructions for Use (IFU).

Patient Impact Testing performed at Axis-Shield demonstrates that the affected lots are at the limit of acceptable clinical performance. This observation was consistent across the reportable range of the assay. For this reason, **do not continue to use affected Reagent lots**. Test data generated to date will be acceptable where validity control specifications have been met.

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Required Action We request that you take the following action at this time:

- Do not use the affected Reagent lots referenced in this safety notice.
- In the event you are currently using or have inventory of one of the lots listed, immediately contact our Product Support Department to arrange for replacement material.
- Please complete the attached Acknowledgement Form within **10 working days** and return it to Axis-Shield Product Support Department on fax number +44 (0) 1382 422 088, or via e-mail; **MDL-AXD-Product-Support@alere.com**
- Please ensure this safety notice has been distributed and reviewed by all appropriate personnel within your organisation.
- **If you have forwarded or distributed affected lots to another organisation, please inform them of this Product Recall and provide a copy of this safety notice to them.**
- Please retain a copy of this safety notice for your laboratory records.

**Additional
Information**

Axis-Shield sincerely regrets and apologises for any inconvenience this issue may have caused. Competent Authorities are being advised of this issue. If you have any issues or concerns please contact Axis-Shield via e-mail; **MDL-AXD-Product-Support@alere.com**



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RPBL1155/R1
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Immediate Action Required - Acknowledgement Form

Axis-Shield Liquid Stable (LS) 2-Part HOMOCYSTEINE REAGENT

In order to comply with Competent Authority Regulations it is important that you complete this acknowledgement form **within 10 working days** and return it to Axis-Shield Product Support Department on fax number +44 (0) 1382 422 088, or via e-mail; **MDL-AXD-Product-Support@alere.com**

Customer Details:

Organisation			
Department			
Title			
Print Name			
Signature			
Date			
Address			
City		Phone	
Postal Code/ZIP		Country	
E-mail		Fax	

Affected Lots:

Part Number	Lot Number	Expiration Date	Remaining Inventory Available for Return (units)
FHBC100	802899574	2015-05-06	
FHRWR100	802899249	2015-05-06	
FHRWR1000	802899248	2015-05-06	
FHRWR200	802899989	2015-05-06	
FHRWR200	802899250	2015-05-06	
FHRWCN1	802900104	2015-07-31	

Questions:

Questions:	Y/N
<ul style="list-style-type: none"> Did you read and understand the attached Urgent Field Safety Notice for Axis-Shield Liquid Stable (LS) 2-Part HOMOCYSTEINE REAGENT? 	
<ul style="list-style-type: none"> Have you followed the instructions and implemented the required actions detailed in this Field Safety Notice? If no please indicate the reason in the comments section below. 	
<ul style="list-style-type: none"> If affected lots have been forwarded or distributed to another organisation, have they been informed of this Product Recall and provided with a copy of this Safety Notice? 	

Comments:

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