

# Urgent Field Safety Notice

## Liquid Stable (LS) 2-Part Homocysteine Reagent

### Immediate Action Required

Date Issued

16<sup>th</sup> SEPTEMBER 2019

### Product

Product Name	Part Number	Lot Number(s)	Expiry Date	UDI Number
Liquid Stable (LS) 2-Part Homocysteine Reagent	FHBC100	902924530	2020-05-26	05055845400282
		902925703	2020-08-14	
	FHRWR100	902924526	2020-05-26	05055845400169
		902925702	2020-08-14	
	FHRWR200	902924829	2020-06-26	05055845400176

### Explanation

Dear valued customer,

The purpose of this letter is to inform you that Axis-Shield is initiating a voluntary product correction of the Liquid Stable (LS) 2-Part Homocysteine Reagent product, part numbers as listed above. The Liquid Stable (LS) 2-Part Homocysteine Reagent is intended for *in vitro* quantitative determination of total homocysteine in human serum and plasma. The product can assist in the diagnosis and treatment of patients suspected of having hyperhomocysteinemia and homocystinuria. The correction is limited to the lots above, no other lot numbers in the field are impacted at this time.

All lots listed above demonstrate a potential performance issue as detected by an under-recovery of sample results during routine testing. Our internal stability testing using these reagent lots has shown the reagents will report results of samples tested at lower values than expected during shelf life.

Our root cause investigation is underway and has linked the under-recovery to the reducing reagent, Reagent 1, in these reagent kits.

### Patient Impact

This issue will be detected when the test is run as intended. Quality Control materials will demonstrate low values out of range, which invalidate the assay run and mitigate reporting of falsely low patient results. If quality control procedures are not performed per the instructions for use, this issue may result in falsely low patient results being reported.

**Necessary  
Actions**

- **Immediately discontinue use of** the affected lots listed and switch to the alternate material lot(s) you may have available in your laboratory.
- **Immediately destroy** any remaining inventory of the affected lots listed according to your laboratory procedures.
- **Complete and return the accompanying verification form**
- **Immediately order replacement material(s) if you do not have unaffected material available.**
- **Please retain this letter** for your laboratory records.

**To Prevent  
Occurrence**

- **New replacements lots should be used.**

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**Contact  
Information**

We sincerely regret any inconvenience this may have caused your laboratory. If you, or any of the healthcare providers you serve, have any questions regarding this information, please contact us:

For Questions regarding this information	For Questions regarding replacement orders
Axis-Shield Product Support Department Fax: +(44) 1382 422 088 e-mail: <b>MDL-AXD-Product-Support@alere.com</b>	Axis-Shield Logistics Department Tel: +(44) 1382 422 000 Fax: +(44) 1382 422 088 email: <b>MDL-AXD-Sales-Team@alere.com</b> Web: <a href="http://www.axis-shield.com">www.axis-shield.com</a>

**General  
Information**

- Further advice or information is not expected in follow-up FSN.
- The Competent (Regulatory) Authority of your country has been informed about this communication.

## Field Safety Notice Customer Reply Form

# IMMEDIATE ACTION REQUIRED

Please complete this form, even if you have no impacted materials remaining.

Please complete and return this form within **10 working days** to

Axis-Shield Product Support Department

Fax: +(44) 1382 422 088 or e-mail: [MDL-AXD-Product-Support@alere.com](mailto:MDL-AXD-Product-Support@alere.com)

### 1. Field Safety Notice (FSN) information

FSN Reference number	078289
FSN Date	16 <sup>th</sup> SEPTEMBER 2019
Product/ Device name	Axis-Shield Liquid Stable (LS) 2-Part HOMOCYSTEINE REAGENT

### 2. RECIPIENT ACTION to be taken

The following has been verified (please Check ):

#### FSN INFORMATION

<input type="checkbox"/>	I confirm receipt of the FSN and that I read and understood its content.		
<input type="checkbox"/>	I performed all actions requested by the FSN.		
<input type="checkbox"/>	The information and required actions have been brought to the attention of all relevant users and executed.		
<input type="checkbox"/>	All areas where the affected material could be located have been checked.		

#### DEVICE INFORMATION

<input type="checkbox"/>	I have discontinued use of any affected material		Date performed (DD/MM/YY):
<input type="checkbox"/>	Quantity Discarded/ To Be Replaced (Kits)	Qty:      Lot/Serial Number:	Date performed (DD/MM/YY):
<input type="checkbox"/>	No affected devices are available for return/ destruction		
<input type="checkbox"/>	I do not have any affected devices.		
<input type="checkbox"/>	I require further information. Please contact me.		

### 3. RECIPIENT DETAILS

ORGANISATION:			
STREET ADDRESS:			COUNTRY:
CITY:			POSTAL CODE/ZIP:
<b>I HAVE READ, UNDERSTOOD AND IMPLEMENTED THE REQUIRED ACTIONS</b>			
TITLE:		DEPARTMENT:	
PRINT NAME:		DATE	
SIGNATURE:			
EMAIL:			