

09 May 2019

Field Safety Notice

FSN1901

**Recalibration of Seralite®- FLC Serum test Kits, Product Code SKL10025****Product**

<b>Seralite®- FLC Serum test kits:</b>	<b>Lot</b>	<b>Expiry Date</b>
	SS180301	December 2019
	SS180401	February 2020

Dear Valued Customer,

The purpose of this letter is to inform you of a recalibration for Seralite®- FLC Serum test kits, lot numbers SS180301 and SS180401.

**Description of Issue:**

The lot numbers of for Seralite®- FLC Serum test kits listed have shown slight positive drift over time. Quality control results have been confirmed as acceptable, though at the upper end of the acceptance range when using the using FLC LFD Controls, product Code FG-SKL40004-LS, lot number LC180002.

As a precautionary measure, recalibration barcodes have been produced for use with these Seralite®- FLC Serum test kits.

This recalibration has no impact upon the expiry dates of the Seralite®- FLC Serum test kits.

Root cause and longer term corrective action for this issue is under investigation. However, as an interim control, the corrective action will be to use an updated barcode with the listed Seralite®- FLC Serum test kits.

**Actions to be taken:**

For kits in the field, the replacement barcodes should be used in place of the barcodes attached to the individual devices.

- A sheet of 25 new barcodes will be supplied for use with each SS180301 and SS180401 kit.

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- A new barcode should be used for each device in the kit, ensuring that it is correct for the kit lot number: SS180301 or SS180401.
- Immediately prior to use, upon opening the device foil, a replacement bar code should be placed on top of the existing barcode.
- The device should be scanned and read in accordance with the ADxLR5 User Guide, document number IFU014.

The Medicines and Healthcare products Regulatory Agency (MHRA) has been informed of this field safety notification.

This notice needs to be passed onto all who need to be aware within your organisation, or any organisation where the listed lot numbers of the Seralite®- FLC Serum test kits have been transferred to. If you have any queries, please contact our Customer Services Department on +44(0)1904 406080 or [customersupport@abingdonhealth.com](mailto:customersupport@abingdonhealth.com).

You should complete and return the accompanying Acknowledgement Form in regard to inventory you have received and / or is in stock.

We appreciate your immediate attention to the matter and apologise for any inconvenience it may have caused.

Yours sincerely,



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## Attachment: Acknowledgement Form

**Recalibration of Seralite®- FLC Serum test Kits, Product Code SKL10025**
**1. Customer Information**

Customer Account Number: ----- Organisation Name: -----  
 Address: -----  
 City and Postal Code: -----  
 Contact Name: -----  
 Contact Title: -----  
 Phone Number: -----

**2. Product Information:**

<u>Seralite®- FLC Serum test kits:</u>	<u>Lot</u>	<u>Expiry Date</u>
	SS180301	December 2019
	SS180401	February 2019

**3. Questions:**

	Yes	No
1. Did you read the enclosed Field Safety Notice regarding Recalibration of Seralite®- FLC Serum test Kits, Product Code SKL10025		
2. Have you implemented the actions as indicated in the Field Safety Notice as necessary? If no, please indicate the reason in the Comments section.		
Comments:		

Signature: ----- Date: -----

This form must be completed and returned to Abingdon Health Ltd.:

email: info@abingdonhealth.com