

	Immediate Action Required
✓	Action Required
	Information Only

Field Safety Notice

Product code and description: LK018.P - Freelite® Human Lambda Free kit for use on the Siemens BN ProSpec®

Lot : 467939

Reference: TBS Identifier – GLB149962/AE061

Date: 26 October 2022

Issue: Potential for invalid calibration curves

Dear Binding Site Customer,

This notice has been issued by The Binding Site (TBS) to inform you of the potential occurrence of calibrator 6 exceeding the optical limit of the Siemens BN ProSpec® analyser when using this product (refer to Table 1 for the affected product details).

Summary of Issue:

Following a number of customer reports and internal testing, we have identified that the kit listed in Table 1 may exceed the optical limit of the analyser when generating a calibration curve. When this occurs, a value of '0' will be reported for calibrator point 6 meaning that a full calibration curve cannot be generated, causing the software to reject the calibration curve.

Generation of acceptable curves using this lot is dependent on each individual instrument and therefore not all end users are affected by the issue. Where acceptable curves have been generated and sample testing performed with this lot, a review of previous results is not required. The most recent curves generated by TBS internally also demonstrate the issue and we are therefore unable to fully support continued use of the affected kit lot in the field.

TBS recognise that the issue may cause a delay to testing due to the frequency of calibration failures or inability to achieve valid curves. TBS has assessed the clinical risk as negligible as sample results cannot be generated or reported in the absence of a valid curve. However, TBS have taken the decision to withdraw this kit lot due to the limited ability to investigate product performance and to prevent further customer dissatisfaction.

Table 1. Details of affected device:

Product	Lot number	Expiry
LK018.P - Freelite® Human Lambda Free kit for use on the Siemens BN ProSpec® UDI: 05051700006453	467939	30/SEP/23

Advice on action to be taken by the user:

- Please dispose of the affected product at your facility following local regulations and contact your local TBS representative regarding provision of alternative kit lots.
- 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 as acknowledgment of carrying out the disposal.

Associated Document(s):

- *TSWS18 E-Back Form*

Transmission of this Important information:

- This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.
- Please maintain awareness of this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

The Binding Site would like to thank you in advance for your help and support in completing the actions outlined above and sincerely apologise for any inconvenience caused.

Kind Regards

Ned Merrick

Chief Quality & Regulatory Officer and Quality & Regulatory Director

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

Field Correction E-back Form

Field Safety Notice

Product code and description: LK018.P - Freelite® Human Lambda Free kit for use on the Siemens BN ProSpec®

Lot: 467939

Reference: GLB149962/AE061

Date: 28 October 2022

Issue: Potential for invalid calibration curves

A Field Safety Notice has been issued under Reference GLB149962/AE061 which details the required actions for TBS Kit LK018.P Lot 467939. Please complete, date and sign the below, confirming that you have received and acknowledged the information and advice issued in the notice.

Lot Number	467939
Number of current product stock <i>(on date notification received)</i>	
Stock check date <i>(dd/mm/yy)</i>	
Number of kits disposed	
	Performed by:
Print Name:	
Sign:	
Position:	
Organisation:	
Date:	

Please return completed E-back form to **technical.support@bindingsite.com** or your local Binding Site Representative.

