Asnières, January 22, 2026

For the attention of the Head of Laboratory

Reference : RIS-25-0064

FIELD SAFETY NOTICE

Product	Reference	Lot	UDI	Action
STA LIATEST FREE PROTEIN S 6	00516	271 971	(01)03607450005165(11)241001(17)260131(10)271971(241)00516	destruction
		272 304	(01)03607450005165(11)241114(17)260228(10)272304(241)00516	destruction
		272 529	(01)03607450005165(11)241218(17)260331(10)272529(241)00516	destruction
		272 859	(01)03607450005165(11)250221(17)260531(10)272859(241)00516	destruction
		273 018	(01)03607450005165(11)250306(17)260630(10)273018(241)00516	destruction
		273 426	(01)03607450005165(11)250430(17)260831(10)273426(241)00516	new precalibration barcode
		273 635	(01)03607450005165(11)250604(17)260930(10)273635(241)00516	new precalibration barcode
STA LIATEST FREE PROTEIN S 2	00527	272 860	(01)03607450005271(11)250221(17)260228(10)272860(241)00527	destruction
		273 019	(01)03607450005271(11)250306(17)260331(10)273019(241)00527	destruction
		273 427	(01)03607450005271(11)250430(17)260531(10)273427(241)00527	new precalibration barcode
		273 636	(01)03607450005271(11)250604(17)260630(10)273636(241)00527	new precalibration barcode

Dear customer,

According to our traceability records, you have received one or more kits of STA LIATEST FREE PROTEIN S 2 (REF 00527) and/or 6 (REF 00516).
Stago has identified a risk of underestimating the levels of quality controls and normal samples in several lots. In accordance with the provisions of our quality policy, we are recalling the lots listed above.

Additional information and instructions follow.

✓ **Description :**

Following customer complaints about STA Liatest Free Protein S 6 Lot 271971, Stago confirmed out-of-range results for the STA Liatest Control N (REF 00526) and an underestimation of the free protein S level in normal patient plasmas. The defect only affects normal-range values.

The root cause investigations revealed an issue linked to a lot of one of the biological raw material components whose effects on results become apparent gradually over time.

Example for this lot **271971** :
STA Liatest Control N range (57-89)% : found at 49.7%
STA Liatest Control P range (21-35)% : found at 24.6%

According to our risk analysis, the potential risk associated with this underestimation would be an error in classifying protein S deficiency: a patient with type II deficiency (qualitative defects) could be incorrectly classified as type I or III (quantitative defects). However, the risk remains negligible, given the rarity of type II deficiencies and the fact that this classification has no impact on patient care.

Consequently, it seems unnecessary to recheck the results obtained with this lot. However, during a future check-up as part of the follow-up of patients with protein S deficiency, it may be relevant to control the antigenic level of free protein S.

Please note that no adverse patient impact has been reported by users to date.

The incriminated lot of raw material was also used in the manufacture of other STA LIATEST FREE PROTEIN S 2 and 6 lots which do not currently exhibit the same performance issues as with Lot 271971. Nevertheless, out of an abundance of caution, we are recalling all affected lots as a precautionary measure.

✓ **Actions required :**

If you currently have one or more kits of STA LIATEST FREE PROTEIN S 2 and/or 6 :

- **For lots with a short expiration date (REF 00516: Lots 271971, 272304, 272529, 272859, 273018 and REF 00527: Lots 272860, 273019),** we ask you to discontinue their use and dispose of them in accordance with your local regulation.

- **For lots with a later expiration date (REF 00516: Lots 273426, 273635 and REF 00527: Lots 273427, 273636),** we ask you :

    - If the initial flyer has already been loaded into the instrument:
        - No longer use the initial pre-calibration settings.
        - Replace them with those provided with the new pre-calibration barcodes attached, according to the procedure described in Appendix 1 of this letter.
    - If the initial flyer has not yet been loaded into the instrument:
        - Do not use it and proceed to load the lot using the new pre-calibration barcodes provided in the attachment.

We also ask you to complete, sign, and return the attached Acknowledgement Form to confirm receipt of this letter.

The Competent Administrative Authority of the country of origin (France) has been informed.

For additional information, please contact your local contact.

We apologize in advance for any inconvenience caused to your laboratory and thank you for your continued trust. Please be assured that the quality of Stago products is at the heart of our concerns and drives our continued focus.

Yours sincerely,

FIELD SAFETY NOTICE

APPENDIX 1 – PROCEDURE FOR REVIEWING STA LIATEST FREE PROTEIN S 2 (00527) and 6 (00516) PRE-CALIBRATION BARCODES ON STAGO INSTRUMENTS

ON STA-R MAX

Refer to section ***8.7.3 Delete a lot*** in the reference manual.
Then, reload the selected lot and scan the new pre-calibration barcode in front of the reader. Check that the displayed parameters A0, A1, A2, A3 match those on the new pre-calibration barcode. Run the controls.

WARNING
This procedure will delete the calibration for the removed lot of STA LIATEST FREE PROTEIN S 2 (00527) and 6 (00516).

ON STA COMPACT MAX

Simulate a lot change :

1. Request the product drawer to open.
   - Displaying the product loading screen : cursor in the identity field and message “Please indicate the product identity” displayed.
2. Manually enter the identity of reagent 1 (Buffer) for STA Liatest Free Protein S according to the packaging used:
   a. **12232** for reference 00527 STA Liatest Free Protein S 2
   b. **12222** for reference 00516 STA Liatest Free Protein S 6
3. The product name, volume, and stability will appear automatically.
4. The cursor moves to the input field for the volume. If necessary, correct the volume and stability, then confirm by pressing Enter.
5. Enter the **last three digits of the lot number** and confirm by pressing Enter.
6. Place the R1 vial in a position corresponding to its diameter.
7. Since a lot change is detected, scan the **new** “pre-calibration barcode” in front of the reader, then click Confirm.
8. Load reagent 2 by scanning the vial’s barcode.
   ➔ Note the pre-calibration from the previous pre-calibration barcode is still active in the Calibration menu.
9. In the Calibration / Test Free PS menu, click **[Calibrate a lot] and select a lot different** from STA-Liatest Free PS (old lot shown in gray) to “deactivate” the original pre-calibration for the lot concerned by the new pre-calibration barcode. Click **[Confirm]**.
10. Then click again on **[Calibrate a lot] and select the lot with the new pre-calibration barcode** to import the new pre-calibration. Click **[Confirm]**.
11. Check that the A0, A1, A2, and A3 values on the new pre-calibration barcode match the equation displayed on the screen.
12. Run the controls.