Stago

Asnières, 20th July 2026

For the attention of the Head of Laboratory

Reference : RC-26-0004

FIELD SAFETY NOTICE

STA®- Staclot® Protein S (ref. 0746) lot 273074

UDI : (01)3607450007466(11)250331(17)270331(10)273074(241)00746

Dear customer,

Based on our traceability records, you have received one or more kits of **STA- Staclot Protein S (ref. 0746) lot 273074**. You are therefore affected by this Safety Notice. In accordance with the ANSM, our french Competent Administrative Authority, and the provisions set out in our quality policy, we are proceeding with its withdrawal.

Please find below additional information.

✓ **Description of the issue:**

Following customer complaints regarding Quality Controls (QCs) out of the upper limit of the acceptable range at the end of the analytical series when using STA Staclot Protein S lot 273074, Stago investigated and confirmed a positive QC values drift within the 4-hour stability period of the STA Staclot Protein S reagent.

Based on our internal tests, QCs can be found at the upper limit of the Stago ranges about 1h30 minutes after calibration. Consequently, this lot may require a higher recalibration frequency, which could modify the organization of your laboratory. As expected, recalibration brings the QC results back within the ranges.

Investigations to identify the cause of the issue are ongoing.

✓ **Risk assessment:**

According to our risk analysis and internal tests, as long as the analytical series are validated by CQ within the sales ranges at the beginning and at the end, there is no risk for patient results.

Under these conditions, the results previously issued with this batch do not need to be reviewed.

✓ **Actions required :**

Considering the inconvenience caused by this recalibration frequency and in accordance with ANSM, we ask you to:

- **Stop using STA Staclot Protein S lot 273074 and dispose of all remaining kits according to local regulations.**

- **Return to us the enclosed answer coupon by email, duly completed and signed, certifying that you have read this letter.**

Your Competent Administrative Authority has been informed regarding this issue.

For additional information, please contact your local contact.

We apologize for any inconvenience caused to your laboratory. Please rest assured that maintaining the quality of Stago products remains our highest priority and is subject to continual review and improvement.

Yours sincerely,