

Asnières, December 21<sup>st</sup>, 2010

Reference: RC 101213-01

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**BATCH WITHDRAWAL CONCERNING THE REAGENT**  
**STA NEOPLASTIN R 15 (ROCHE REF. 03263347 140), Lot 624171**

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Dear Madam, Dear Sir,

You have ordered and received in your laboratory some kits of STA Neoplastin R 15ml lot 624171 (Roche Ref. 03263347 140).

As part of our quality policy, we are issuing a batch withdrawal.

Please find below the information regarding this issue.

✓ **Identification and description of the defect:**

Following a distributor complaint, Diagnostica Stago has investigated and confirmed that the results of normal and abnormal control plasmas (STA Preciclot Plus I & II, expressed in %) obtained with STA Neoplastin R 15 lot 624171 are systematically found in the lower part of the assigned ranges.

Results of normal and abnormal control plasmas expressed in clotting times are correctly recovered inside the assigned ranges. STA Preciclot Plus III is correctly recovered in the assigned ranges both in clotting times and in percentages.

The defect is detected with QC plasmas and has no clinical impact on patient samples. Therefore, when the QC is recovered within the assigned ranges, the patient results are not to be called into question.

✓ **Actions:**

**Despite the absence of clinical consequence related to this issue, Diagnostica Stago is asking you as a precaution:**

- to stop using this lot of STA Neoplastin R 624171 (Roche Ref. 03263347 140),
- to follow the instruction given by Roche Diagnostics regarding these kits.

For complementary information, please contact Roche Diagnostics

Please receive our apologies for the inconvenience that you might encounter in your laboratory.

We thank you in advance for your confidence.

Sincerely yours,