For submission to the Head of Laboratory

(CITY), October 17th 2017

Reference: RC-17-0019

URGENT – FIELD SAFETY NOTICE
Néoplastine® CI Plus ② (ref. 00374)
Néoplastine® CI Plus ⑤ (ref. 00375)
STA - Néoplastine® CI ⑤ (ref. 00605)
STA - Néoplastine® CI Plus ⑤ (ref. 00606)
See list on appendix

Dear Madam, Dear Sir,

According to our records, you have received in your laboratory one or several kits of reagent (lots listed on appendix).

This letter contains specific instructions for use of these lots and further information about the defect.

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

Following a customer complaint, Stago has investigated and confirmed a defect of homogeneity within lot, for lots listed in the appendix.

Some reagents vials will give prolonged Prothrombin Time (decreased PT %) and it will affect both Quality Control and patients plasmas.
The defect is easy to detect since **the Quality Control values are outside their ranges in time and/or in percentage**.

The root cause investigations have found the issue is a vial manufacturing problem which can result in an inconsistent seal of the vial and therefore may compromise the contents.
Internal investigations have shown that the occurrence of the defect within lot is low (average of 2% of the vials). On a defective vial, clotting times are longer with an average of 13% on a normal plasma and 26% on abnormal plasma.

If Quality Control are tested on each vial of reagent and if results are found within their ranges, there is no clinical risk for the patient.
Otherwise, as patient results are interpreted in a global clinical context, we leave at your discretion the decision to review previous patient results on a case by case basis.

✓ **Actions :**

If you have in your laboratory, any of the lots among those listed in the appendix, we are asking you to:

- **If it is not already done, run a Quality Control test at every change of vial.**
- **Return to your local distributor, by fax or e-mail, the enclosed form completed and confirming that you have read this letter.**

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

Your Competent Administrative Authority has also been informed regarding this issue.

For additional information, please contact your local distributor.

Please accept our apologies for this inconvenience. We thank you in advance for your support.

Yours sincerely,