Asnières, 2025, December 05

To the Head of Laboratory

Reference : RC-25-0052

FIELD SAFETY NOTICE

Asserachrom HPIA (ref 00615) lot 271288

UDI : (01)03607450006155(11)240531(17)260531(10)271288(241)00615

Dear customer,

Our traceability records indicate that you have received one or more Asserachrom HPIA kits (ref. 00615) from lot 271288. Therefore we are bringing this Safety Notice to your attention concerning a defect present in certain Reagent 1 (Coated Strip) strips. Pursuant to our quality policy, we are initiating the withdrawal process.

For further details, please refer to the information below.

✓ **Defect description and identification:**

After receiving customer complaints, Stago investigated and confirmed that some strips of Reagent 1 from Asserachrom HPIA lot 271288 had a coloring defect. Due to this defect, every well in the impacted strip produces negative results. Kit reference R6 and Control 2 (R7b) will produce low optical density (OD) readings, similar to those of Control 1 (R7a). As a result, these values will not meet the requirements specified in the assigned value sheet for the lot and must not be used in your laboratory.

Our risk analysis indicates that if the operator fails to detect the defect, there is a possibility of falsely determining that anti-heparin-PF4 antibodies are absent in patients suspected of having heparin-induced thrombocytopenia (HIT). This error could result in restarting heparin therapy that was previously stopped. Nonetheless, the overall risk is minimal, as the defect can be readily detected and test results are consistently interpreted within the framework of clinical context and platelet kinetics.

Given these conditions, it is unnecessary to review all past results; instead, each negative result should be reassessed considering clinical context (such as heparin use in cardiac surgery, trauma, platelet count trends, and signs of type II heparin-induced thrombocytopenia, including thrombosis, skin lesions, or allergic reactions after a heparin bolus.).

✓ **Actions required :**

Please follow these steps:

- **Stop using Lot 271288 and Dispose of all remaining product according to local regulations.**
- **Please complete, sign, and return the attached Acknowledgement Form to confirm receipt of this letter.**

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The Competent Administrative Authority in the country of origin (France) has been duly notified.

Your Competent Administrative Authority has also been notified about this issue.

For further information, please reach out to your local representative.

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,

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