

**FIELD SAFETY NOTICE**

**HEMOSIL PT-FIBRINOGEN HS PLUS, PART No. 0008469810,  
LOTS MANUFACTURED PRIOR TO JUNE 2014**

November 21, 2014

Dear Valued HemosIL PT-Fibrinogen HS PLUS Customer:

This notification is intended to advise your facility regarding a performance issue identified with some vials from product lots of **HemosIL PT-Fibrinogen HS PLUS, PN 0008469810, manufactured prior to June 2014.**

Specifically, some vials in these older lots exhibit a yellow / brownish color after reconstitution (yellow color or darker) instead of the typical white to off-white color. Vials exhibiting this yellow / brownish color were observed to cause prolonged prothrombin (PT) clotting times as discussed on the next page. Following is a list of in-date lots sold worldwide with the potential for affected vials:

<b>HemosIL PT-Fibrinogen HS PLUS, PN 0008469810 – Potentially Affected In-Date Lots –</b>	
<b>Lot No.</b>	<b>Expiration Date</b>
N1122175	11/30/2014
N1222324	12/31/2014
N0132936	1/31/2015
N0333382	3/31/2015
N0233302	2/28/2015
E0333382	3/31/2015
N0333626	3/31/2015
N0433932	4/30/2015
N0634953	6/30/2015
N0735317	5/31/2015
N0735599	7/31/2015
N0836106	8/31/2015
N0936197	9/30/2015
N0148094	12/31/2015
N0248652	2/29/2016
N0349325	12/31/2015
N0249017	2/29/2016
N0449790	4/30/2016
N0440009	4/30/2016

- **Issue Description and Result Impact**

This issue is attributed to higher levels of residual moisture in some vials, which contributes to the yellow/brownish color at reconstitution and the resultant prolonged PT clotting time results.

Vials exhibiting this yellow / brownish color were observed to cause prolonged clotting times, with several reports of controls being outside of the established ranges.

**IMPORTANT:** If an affected vial is used with a patient sample, a significant shift in INR greater than 10% could occur with the potential to alter medical treatment.

- **Mandatory Customer Actions**

- If you observe any yellow / brownish color after reconstitution, **do not use the affected vial. Discard the vial and reconstitute another vial.**

**NOTE:** The yellow/brownish color is detectable after reconstitution, not with the lyophilized cakes.

- Only use a vial if the reconstituted color is the typical white to off-white color.
- The picture below shows examples of unaffected and affected reconstituted vials:

**Unaffected Vials (White Color)**

**Affected Vials (Yellow Color)**



- **Mandatory Customer Actions (Continued)**

- Run quality controls at least once every 8 hour shift in accordance with good laboratory practice and insert sheet instructions.
- Share this information with your laboratory staff and follow your internal procedures.
- Forward this notification to all affected locations within your facility.
- Retain a copy of this notification for your records.

CORRECTIVE ACTION TAKEN: Corrective action has been implemented starting with Lot N0640734 (June 2014) to prevent further occurrences of excess moisture in vials of HemosIL PT-Fibrinogen HS PLUS, PN 0008469810.

Please contact your local representative with any questions.

We appreciate your prompt attention to this important notification.

Sincerely,

Carol Marble  
Regulatory Affairs Director