



IMPORTANT PRODUCT CORRECTION
CARRYOVER ISSUE WITH HEMOSIL SYNTHASIL APTT REAGENT
ON ACL TOP FAMILY
ALL MODELS: ACL TOP, ACL TOP CTS, ACL TOP 700, ACL TOP 700 CTS,
ACL TOP 700 LAS, ACL TOP 500 CTS AND ACL TOP 300 CTS

July 2013

Dear Valued ACL TOP Family Customer:

This notification is intended to advise your facility regarding a potential carryover issue identified on the ACL TOP Family that causes shortened APTT results. The ACL TOP Family consists of the following models:

ACL TOP
ACL TOP CTS
ACL TOP 700
ACL TOP 700 CTS
ACL TOP 700 LAS
ACL TOP 500 CTS
ACL TOP 300 CTS

Issue Description and Result Impact

Our investigation of recent customer complaints determined that an ACL TOP Family instrument can experience carryover that causes shortened APTT clotting times on patient and/or quality control results when a HemosIL SynthASil APTT reagent (PN 0020006800) is located in the same reagent rack as certain other HemosIL reagents. The carryover is introduced during the liquid height check that is performed upon rack insertion and is dependent on material position, the order of rack insertion, and the sequence in which the assays are performed.

The extent of the shortened clotting times varies from instrument to instrument and is not reproducible on all instruments. In certain instances, this issue has manifested itself as a downward shift in APTT clotting times of greater than 10 seconds.

Important Workaround Instructions

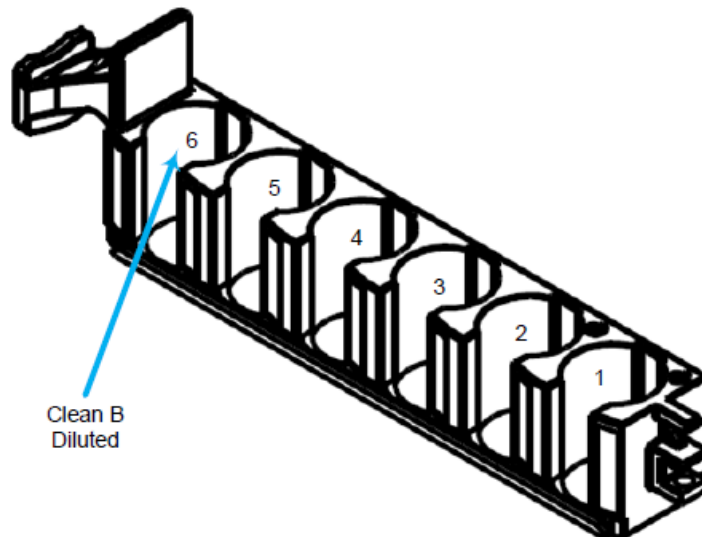
Our testing has confirmed that the following workaround addresses the potential carryover that causes shortened APTT results for HemosIL SynthASil (PN 0020006800).

1. Do not place HemosIL SynthASil reagent vials (APTT Reagent and/or Calcium Chloride) in a reagent rack containing any one of the following reagents:

- HemosIL RecombiPlasTin 2G PN 0020002950 and 0020003050
- HemosIL Fibrinogen-C PN 0020003900 and 0020301100
- HemosIL Q.F.A. Thrombin (Bovine) PN 0020301700 and 0020301800
- HemosIL Thrombin Time PN 0009758515
- HemosIL Liquid Antithrombin (Factor Xa vial only) PN 0020030100, 0020300400, 0020002500
- HemosIL Heparin (Factor Xa vial only) PN 0020009400
- HemosIL Liquid Heparin (Factor Xa vial only) PN 0020300100
- HemosIL Liquid Anti Xa (Factor Xa vial only) PN 0020302600

The HemosIL SynthASil reagent vials (APTT Reagent and/or Calcium Chloride) need to be in a separate reagent rack from the above reagents.

2. In addition, place a vial of Dilute HemosIL Clean B (PN 0009832700) in position 6 (front most position) of any rack containing the above listed reagents. By placing the Dilute Clean B in the front position, the height check on the Dilute Clean B will be performed last. The probe contact with the Dilute Clean B during the height check will prevent the potential for carryover.



It is not necessary to place a vial of Dilute Clean B in the rack containing the HemosIL SynthASil reagents.

3. Instrumentation Laboratory is actively working on a software mitigation to address this issue. Until available, please use the workaround described above.

Please contact your local representative with any questions.

We appreciate your prompt attention to this important notification.

Sincerely,

A black rectangular redaction box covering the signature area.