SIEMENS

Urgent Field Safety Notice

067D0200-01

May 2008

ADVIA® 120 and ADVIA 2120 Hematology Systems

Perox Sheath Filter Changes

Our records indicate that you may have received ADVIA® 120/2120 Perox Sheath Filters, PN 518-3148-05, lot number H7MN95519.

Unlike the previous lots of filters that have a yellow end cap, lot H7MN95519 has no part number on the filter package and a colorless end cap on the filter. This makes the 0.8 micron Perox filters indistinguishable from the 0.22 micron RBC/ Baso filters. Installing the Perox filter on the RBC/Baso side can result in an increased background count.

Please check your inventory for the incompletely labeled Perox filter packages. The packages are marked with "0.8 micron pore size". If you have any of these filter packages, immediately label, with indelible marker, the word "PEROX" on the bag **and** the filter.

If you have any filters that are unidentifiable, please discard them and contact your local service provider to report your no-charge replacement needs.

Siemens Healthcare Diagnostics is correcting the unlabeled Perox filter packages to include PN 518-3148-05, the quantity, the date, and a "Perox" label on the filter body. We will be returning to the yellow end cap in the future.

As an added precaution, we are changing the instructions for replacing the RBC/Baso filter.

- After the new filter is installed, following the five reagent primes, you **must** run a background count to ensure the count is acceptable.
- In a future release, the Operator's Guide will be revised to include this extra step.

If the Perox filter was installed incorrectly, out of specification background counts would signal any impact on test results. If background counts are not elevated, patient results would not be affected. Since checking background counts is part of the daily startup procedure, there may be a need to retest some patients whose results are borderline low when a filter change is performed after daily startup. *We recommend that you discuss the content of this letter with your laboratory director regarding the need to perform repeat testing on results previously reported.*

Complete the attached *Completion Notification Form* indicating that you have read and understood this notice, and submit the form to your branch representative **within 7 days**.

We apologize for the inconvenience that this may have caused. Contact your technical support provider or distributor if you need assistance or have further questions.

Siemens Healthcare Diagnostics Inc.

511 Benedict Avenue
Tarrytown, NY 10591

www.siemens.com/diagnostics

SIEMENS

Completion Notification

Urgent Field Safety Notice – 067D0200-01

To signify compliance to this notification *ADVIA 120 and 2120 Perox Filter Changes* (067D0200-01, Rev. A), please sign and date the completed form and submit the signed copy of this form to the following person:

Attention (Branch Representative): _____

Fax Number (Branch Fax Number): _____

_____

System Serial Number (s)

_____

Customer _____

Branch _____

Account Number _____

Country _____

Date when notice 067D0200-01 was received. _____

Signature: _____

Printed Name: _____

Title: _____