



September 20, 2010

## URGENT: FIELD SAFETY NOTICE

### Synchron® CX4/5/7 CE, CX4/5/7 Delta and CX9 ALX Clinical Systems

Dear Beckman Coulter Customer:

Beckman Coulter has confirmed software limitations which affect **only manually-loaded** reagent cartridges on the CX instruments listed above:

#### ISSUE 1:

- Any manually-loaded reagent cartridge with a lot expiration date of December 2011 or later will incorrectly display a reagent status of "Reagent Expired" with approximately 13,000 "Days Usable". CX PRO and CX3 systems are not affected.
- Example:

REAGENT STATUS					
LOC	CHEM	LOT #	AVAIL	DAYS USABLE	STATUS
1	CHOL	A12345	315	⇒ 13740	⇒ Reagent Expired
2					

#### IMPACT 1:

- Sample results generated from a reagent cartridge which was manually-loaded with a lot expiration date of December 2011 or later will be flagged with the instrument code "R" (Reagent Expired).

#### REQUIRED ACTION 1:

- If a reagent cartridge with a lot expiration date of December 2011 or later needs to be manually-loaded, an expiration date before December 2011 (e.g., November 2011) must be entered in the instrument software. The true reagent lot expiration date must then be tracked manually. A template example has been provided for your convenience (see attachment); or you may record this information per your current laboratory practices.

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**ISSUE 2:**

- Any manually-loaded reagent cartridge with a lot expiration date before December 2011 will not exhibit a status of "Reagent Expired" on the reagent status screen even if the reagent lot has expired.
- The "Days Usable" displayed on the reagent status screen for a manually-loaded reagent cartridge which expires before December 2011, will indicate the number of days left of reagent on-board stability only. CX PRO and CX3 systems are not affected.

**Example:**

- A specific manually-loaded reagent lot is due to expire in 2 weeks (14 days).
- The specified on-board reagent stability for that reagent is 30 days (stated in the Chemistry Information Sheet).
- Since the days left until expiration are fewer than the on-board reagent stability, the system should display the "Days Usable" 14 days.
- The software limitation causes the system to incorrectly display the "Days Usable" 30 days.

**IMPACT 2:**

- The days remaining of reagent on-board stability for manually-loaded reagent cartridges could exceed the reagent lot expiration date and the instrument software would indicate an incorrect number of days usable. Expired reagent could remain in-use if the remaining days of on-board stability exceed the days until lot expiration.

**REQUIRED ACTION 2:**

- Manually track the reagent lot expiration dates and reagent cartridge serial numbers for all manually-loaded reagent cartridges. A template example has been provided for your convenience (see attachment).

Please share this information with your laboratory staff and retain this notification as part of your laboratory Quality System documentation. Complete and return the enclosed response form within 10 days so we can be assured that you have received this important notification.

If you need assistance or have any questions regarding this notification, contact your local Beckman Coulter representative. We sincerely apologize for any inconvenience that this may have caused your laboratory.

Thank you for your continued support of Beckman Coulter products.

Sincerely,



Group Manager, Corporate Quality and Regulatory Affairs  
Attachment: Tracking sheet template

Enclosed: Manual Load Tracking Worksheet

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