October 22, 2015

URGENT FIELD SAFETY NOTICE – FSN 26319

Access CEA Reagent Kit

For use with the Access Family of Immunoassay Systems*

REF	LOT	
33200	595027 595029	15-FEB-16 28-FEB-16

* The Access Family of Immunoassay Systems includes the Access 2, UniCel DxI 800 and UniCel DxI 600, UniCel DxC 600i, and the UniCel DxC 880i, UniCel DxC 860i, UniCel DxC 680i, and UniCel DxC 660i systems.

Attention Beckman Coulter Customer:

Beckman Coulter is initiating a field safety corrective action for the product listed above. This letter contains important information that needs your immediate attention.

ISSUE:	• Beckman Coulter has determined that the Access CEA reagent packs (P/N 33200) of the lots listed above were filled incorrectly. These packs contain insufficient quantity of reagents in one of the pack wells.

IMPACT:	• The impact is dependent upon the instrument and software version installed at the time the reagent lot was in use:
	  • Access 2 systems running software version 3.3.1 or lower, and Access 2i systems running software version 6.1 or lower with these reagent lots:
	  ○ The instrument may have generated incorrect results of 0.0 ng/mL when using an affected pack.
	  ○ All other results greater than 0.0 ng/mL are not affected by this issue and are correct.
	  • Access 2 systems running software version 3.4.2 and Access 2i systems running software version 6.2.2 or higher with these lots:
	  ○ The affected packs would have been detected by process monitoring with a result flag QSD (indicates reagent dispense is insufficient), and the pack would have been disabled by the instrument.
	  ○ No patient result would have been generated.
	  • UniCel DxI systems running any software version:
	  ○ The packs would have been detected by reagent pack monitoring with a result flag QSD, and the pack would have been disabled by the instrument.
	  ○ No patient result would have been generated.

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ACTION:	**To all customers that received the affected lots listed above:** • Discard the Access CEA reagent pack lots listed above. **To Access 2 customers with software version 3.3.1 or lower and Access 2i customers with software version 6.1 or lower ONLY:** • Review your patient results that were reported as 0.0 ng/mL and did not match the clinical status of the patients. • At the discretion of your Laboratory Director, notify clinicians that it is possible the Access CEA sample results reported by your laboratory were affected by this issue.
RESOLUTION:	• The affected Access CEA reagent pack lots are no longer being distributed.

The national competent authority has been informed of this field safety corrective action.

Please share this information with your laboratory staff and retain this notification as part of your laboratory Quality System documentation. If you have forwarded any of the affected products listed above to another laboratory, please provide them a copy of this letter.

Please complete and return the enclosed Response Form within 10 days so we are assured you have received this important communication.

If you have any questions regarding this notice, please contact the Customer Support Hotline at 00353 1407 3082 or techsupportie@beckman.com.

To request replacement material, please contact your local Beckman Coulter Customer Service Representative on +353 (0) 1407 3081 or bcieorders@beckman.com.

We apologize for the inconvenience that this caused your laboratory.

Yours sincerely,

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Enclosed: Vigilance Response Form