October 24, 2016

**URGENT MEDICAL DEVICE RECALL**

Access Ostase Calibrator Kit and Access Ostase QC Kit

For use with the Access Family of Immunoassay Systems*

| REF | LOT | |
|---|---|---|
| B83876 Access Ostase Calibrators | 623207 | 18-Feb-2017 |
| | 626000 | 12-May-2017 |
| B83877 Access Ostase QC | 623208 | 18-Feb-2017 |
| | 626001 | 12-May-2017 |
| 37305 Access Ostase Calibrators | 628294 | 12-Oct-2016 |
| | 628296 | 16-Nov-2016 |
| 37309 Access Ostase QC | 628297 | 16-Nov-2016 |

** 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 an urgent medical device recall (field action) for the products listed above. This letter contains important information that needs your immediate attention.

**ISSUE:**

Beckman Coulter has determined that the Access Ostase Calibrator and QC lots listed above do not meet their expiration date claims within our 10% criteria. For the lots listed above, we determined that REF B83876 and B83877 have 68 days of stability and REF 37305 and 37309 have 51 days of stability. The table below summarizes the revised expiration dates for the affected lot numbers.

| REF | Lot Number | New Expiration Date |
|---|---|---|
| B83876 | 623207 | 7-Jul-2016 |
| | 626000 | 28-Sep-2016 |
| B83877 | 623208 | 7-Jul-2016 |
| | 626001 | 28-Sep-2016 |
| 37305 | 628294 | 9-Sep-2016 |
| | 628296 | 14-Oct-2016 |
| 37309 | 628297 | 14-Oct-2016 |

- For 37305/37309, the instability could cause patient results to be overestimated by as much as 16% at the original expiration dates.
- For B83876/B83877, the instability could cause patient results to be overestimated by as much as 16% as of October 17, 2016.

| | |
|---|---|
| **IMPACT:** | • Access Ostase Calibrator and QC instability could result in falsely elevated patient results or QC failures.<br>• A falsely elevated Ostase result could be interpreted as falling above the normal range when it is actually within the normal range. This could subject patients to additional diagnostic testing that is not necessary.<br>• A falsely elevated Ostase result could imply a higher bone alkaline phosphatase level when compared with a prior true result. Consequently, a physician could incorrectly assume that the bisphosphonate therapy (e.g. Fosamax, Boniva) for osteoporosis has been ineffective.<br>• QC failures could delay reporting patient results. |
| **ACTION:** | • Discard all of the Access Ostase Calibrator and Access Ostase QC kits listed in this letter.<br>• At the discretion of your laboratory director, consider a review of all results generated after the new expiration dates outlined in the Issue section. |
| **RESOLUTION:** | • Beckman Coulter has discontinued shipping orders of the Access Ostase Calibrator and QC kit lot numbers that are listed in this letter. |

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.

You may request replacement product or credit by contacting your local Beckman Coulter Representative.

If you have any questions regarding this notice, please contact our Customer Technical Support Center:

- From our website: http://www.beckmancoulter.com
- By phone: call 1-800-854-3633 in the United States and Canada.
- Outside the United States and Canada, contact your local Beckman Coulter representative.

We apologize for the inconvenience that this caused your laboratory.

Sincerely,

[redacted]
Director, Regulatory Affairs

*Enclosure: Response Form*