

**URGENT FIELD SAFETY NOTICE****Access Immunoassay Systems*
Ostase Calibrator, QC and Reagent Kits**

Attention Access Ostase Customer,

Beckman Coulter is initiating a voluntary recall for the products listed below. This letter contains important information that needs your immediate attention.

Part Number	Lot Number	Expiration Date	Lot Number	Expiration Date
REF 37305 Access Ostase Calibrator	013489	11/30/2010	111530	09/30/2011
	013490	01/31/2011	113463	10/31/2011
	015210	02/28/2011	114259	10/31/2011
	018854	03/31/2011	114260	11/30/2011
	020419	05/31/2011	115484	12/31/2011
	022834	06/30/2011	116658	01/31/2012
	109632	07/31/2011		
REF 37309 Access Ostase QC	009091	10/10/2010	109636	09/30/2011
	013491	10/31/2010	113465	10/31/2011
	013492	11/30/2010	113969	10/31/2011
	014488	12/31/2010	114261	11/30/2011
	015211	02/28/2011	115485	12/31/2011
	018855	03/31/2011	116660	01/31/2012
	020420	04/30/2011	118211	02/28/2012
	021285	05/31/2011		
REF 37300 Access Ostase Reagent	011167	04/30/2011	017561	09/30/2011
	014486	7/31/2011		

* Includes the Access, Access 2, UniCel Dxl 800, UniCel Dxl 600, SYNCHRON LXi 725, UniCel DxC 600i, and the UniCel DxC 880i, 860i, 680i, and 660i Integrated Systems

ISSUE

- The Access Ostase Calibrator and QC lots above do not meet expiration date claims. As a result, quality control and patient sample results may be falsely elevated by up to 14%.
- Our investigation indicates that the cause of the stability failure may be a raw material used in the manufacture of all of the Calibrator and QC lots listed in the table above.
- The Access Ostase Reagent Kit lots listed above were quality control tested and released using Access Ostase Calibrator and QC lots that contain the implicated raw material.

IMPACT

- A falsely elevated Ostase result may be interpreted as above the normal range when it is actually within the normal range, potentially causing patients to undergo additional unnecessary diagnostic testing.
- A falsely elevated Ostase result may suggest a higher bone alkaline phosphatase level when compared with a prior true result, when no increase in bone turnover has actually occurred. In this case, it could be falsely assumed that treatment has not been effective in patients taking bisphosphonate therapy (e.g. Fosamax[†], Boniva[†]) for osteoporosis.
- Calibration failures resulting from this issue could delay test results.

* Fosamax is a trademark of Merck & Co., Inc.

† Boniva is a trademark of Roche Therapeutics Inc.



ACTION

- Discontinue use of the Access Ostase Calibrator, QC, and Reagent lots identified above and discard all remaining inventory.
- Consider a review of all results where a false elevation in the result would have resulted in crossing a clinical decision threshold.
- If you have received feedback from clinicians questioning the reported Ostase results obtained with the identified lots, consider the need for further diagnostic testing. As stated in the Instructions for Use for the Access Ostase Reagent, results should be interpreted in light of the total clinical presentation of the patient, including: symptoms, clinical history, data from additional tests, and other appropriate information.

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 a copy of the letter to them.

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

To receive credit for unused product, please contact your local Beckman Coulter Representative.

If you have any questions regarding this notice, please contact your local Beckman Coulter Representative.

We apologize for the inconvenience this has caused your laboratory.

Sincerely,

A handwritten signature in black ink that reads 'Scott Cundy'.

Scott Cundy
VP, Quality and Regulatory Affairs

Enclosure: Response Form

Beckman Coulter, the stylized logo, Access, UniCel, DxI, and SYNCHRON LX are trademarks of Beckman Coulter, Inc., and are registered with the USPTO. Ostase is a trademark of Hybritech Incorporated, and is registered with the USPTO. Hybritech Incorporated is a subsidiary of Beckman Coulter, Inc.



Ostase Calibrator, QC and Reagent Kits Questions and Answers

1. How was this issue discovered?

This issue was discovered through an internal evaluation of calibrator stability which showed that lots 111530, 113463, 114259, and 114260 do not meet stability claims. Further investigation into the instability of these particular lots has led us to believe that it may be due to a raw material used in the manufacture of all Calibrator and QC lots listed in the table on page 1.

2. Will my laboratory be able to detect the issue through QC testing?

This stability issue affects both Access Ostase Calibrator and Access Ostase QC; therefore, this issue may not always be detected by quality control results shifting out of range. However, if you are using another vendor's quality control material or a patient based quality control material, a shift may be detected.

3. Should I be concerned about my patient results?

If patient results were generated while using any of the Access Ostase Calibrator, QC or Reagent lot numbers on page 1, it is possible that results were falsely elevated. We recommend that you consider a review of all results obtained with these lots where a false elevation would have resulted in crossing a clinical decision threshold. In this case, your laboratory may want to consider advising the clinician that the reported Ostase results may have been falsely elevated so that they may evaluate whether diagnosis or treatment decisions should be revisited.

4. What is the impact on other Access Ostase Calibrator and QC lots?

This product correction only affects Access Ostase Calibrator and QC lots listed in the table on page 1. To our knowledge, only those Access Ostase Calibrator and QC lots listed on page 1 are affected by this problem

5. What is the impact on other Access Ostase Reagent lots?

This product correction only affects Access Ostase Reagent lot numbers 011167, 014486 and 017561. In addition, a Product Corrective Action letter (PCA #17154) was sent on June 13, 2011, identifying Access Ostase Reagent lot 021281 as having a stability issue. All Access Ostase Reagent lots identified in both of these letters have expired. We have performed quality control testing using unaffected calibrator and QC on all Access Ostase Reagent lots with expiration dates after September 30, 2011 and have confirmed no impact to these lots.