

October 27, 2006

**URGENT: PRODUCT CORRECTIVE ACTION**  
**Access® Immunoassay Systems Thyroglobulin Antibody Reagent Kit**

Part Number	Lot Numbers	Expiration Dates
<b>33890</b> <b>Access Thyroglobulin Antibody</b>	<b>518729</b>	<b>10/31/06</b>
	<b>520617</b>	<b>12/31/06</b>
	<b>612764</b>	<b>12/31/06</b>
	<b>613481</b>	<b>3/31/07</b>
	<b>614541</b>	<b>5/31/07</b>
	<b>616787</b>	<b>8/31/07</b>

Used on: Access® and Access® 2 Immunoassay Systems  
UniCel® Dxi 800 Access® Immunoassay System  
And SYNCHRON LX®i 725 Clinical System

Dear Access Thyroglobulin Antibody Customer,

Beckman Coulter has received customer feedback reports regarding low end imprecision affecting both S0 calibrators and patient samples, which can lead to inaccurate low level patient results when using the Access Thyroglobulin Antibody assay. Until further notification, please discontinue use of the referenced lot numbers. We recommend that you perform Thyroglobulin Antibody testing using an alternate method. Beckman Coulter is currently investigating a solution to this issue. This investigation will take a minimum of eight weeks. There will be further communication once a resolution is reached.

The Access Thyroglobulin Antibody assay has a total imprecision claim of less than 10% at concentrations greater than 50 IU/mL. Initial internal testing demonstrates that the precision claims as outlined in the directional insert are being met. If your laboratory is performing quality control testing below this level, please evaluate this low level control based upon historical performance. If there is any evidence of imprecision which exceeds the historical performance, please evaluate patient results in context of the clinical presentation.

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 that we may maintain our records.

We sincerely apologize for any inconvenience that this may have caused your laboratory. If you need assistance or have any questions regarding this Product Corrective Action, please contact the Customer Technical Support at 1-800-854-3633 in the United States and Canada, or contact your local Beckman Coulter Representative. Thank you for your continued support of Beckman Coulter products.

Sincerely,

  
Regulatory Affairs Manager—Corporate  
Enclosure: Response Form

PCA-C-D-1003