



# Urgent Field Safety Notice

## Product Correction

Immediate Action Required

<b>Date Issued</b>	15 March 2011
<b>Product</b>	<b>Shear Valve Assembly</b> <b>Part Numbers: 8921204902 &amp; 8921167602</b>
<b>Explanation</b>	<p>We have identified an issue with the Shear Valve Assembly, used on CELL-DYN 3200, CELL-DYN 3500, CELL-DYN 3700, and CELL-DYN Ruby analyzers.</p> <p>A nylon washer, used on the Shear Valve Assembly, may have an undersized outer diameter that can potentially get caught within an adjacent drive plate opening. This issue may not appear on all instruments. When the nylon washer gets caught, the analyzer will generate "Shear Valve Position" faults or "RBC Diluent Syringe Overpressure" SIMs. If you receive one of the error messages listed above, please follow the procedure in the Operator's Manual Section 10. The procedure may temporarily resolve the issue but the part still needs to be replaced by Field Service.</p> <p>We are in the process of completing replacement of the affected parts. Your local Abbott Diagnostics Field Service Representative will contact you to schedule an appointment that is convenient for your laboratory. If you have not yet heard from your Abbott Representative and the issue occurs, please contact Abbott immediately so that we may arrange a visit as soon as possible.</p>
<b>Patient Impact</b>	There is a potential for delay in generating results. There is no impact to analytical patient results.
<b>Necessary Actions</b>	<p>Please review the letter and inform your Laboratory Manager of the pending action.</p> <p>Complete and return the Customer Reply Form.</p> <p>Please save a copy of this letter for your records.</p>
<b>Contact Information</b>	If you or any of the health care providers you serve have any questions regarding this information, U.S. customers should call Customer Support at 1-877-4ABBOTT. Customers outside the U.S., please contact your local hematology customer support representative.