Second Notice November 8, 2013

September 12, 2013

URGENT PRODUCT CORRECTION

Coulter LH 750 Hematology Analyzer, PN 6605632 and A85570
Coulter LH 780 Hematology Analyzer, PN 723585 and A90728

Attention Beckman Coulter Customer,

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

ISSUE:	An internal investigation indicates that specific lots of check valves used in several locations within the LH 750 and LH 780 analyzers may fail. This failure may result in an air or liquid leak at the connection to the Vacuum Overflow Tank waste line or at the Backwash Tank drain line.
IMPACT:	• There is a remote risk of reporting erroneous results for all parameters on control and patient samples if the Backwash Tank fails to refill after manual aspiration. **This risk is limited to the samples analyzed using the manual aspiration mode.** The error message "Backwash Tank Not Full" will occur when the backwash system's diluent supply is depleted. The "Backwash Tank Not Full" message will cause the analyzer to stop processing samples. • There is a remote risk for a leak of biohazardous waste if the check valve fails at the Vacuum Overflow Tank waste line.
ACTION:	• If you experience a "Backwash Tank Not Full" error message, review manual mode sample results since the last acceptable QC run. System safeguards that assist with detection of erroneous results include Startup, QC, system messages and flagging (e.g., R), delta checks, flagging from limit sets (H, L, a, c), definitive messages and decision rules that would trigger further review. • Avoid physical contact with a possible leak by continuing to use personal protective equipment as recommended in the Instructions for Use and by national regulations.
RESOLUTION:	Your service representative will contact you to schedule an on-site visit for check valve inspection and replacement of any affected valves.

Share this information with your laboratory staff and retain this notification as part of your laboratory's Quality System documentation. If you have forwarded 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.

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