June 29, 2017

URGENT FIELD SAFETY NOTICE

PRODUCT	REF	SOFTWARE VERSION
COULTER LH 750 Analyzer	6605632, A85570, A68807	All
COULTER LH 780 Analyzer	723585, A90728, A68808	
COULTER LH500 Analyzer	178832, 178833, 178834, A91062, A90994	
COULTER HmX CP Analyzers	6605522, 6605523, 6605524	
COULTER HmX AL Analyzers	6605525, 6605526, 6605527, A85566, A85564	

Dear Beckman Coulter Customer,

Beckman Coulter is initiating a field safety corrective action for the products listed above. This letter contains important information that needs your immediate attention regarding a documentation update to clarify the limitations and system messages related to the Differential blast detection and flagging.

ISSUE:	Beckman Coulter has determined that additional clarification for the Blast Suspect messages is necessary. In rare situations, the LH 750, LH 780, LH 500 and HmX Analyzers may not flag or detect blasts in some blood samples. This is due to limitations in the available technology as well as the properties of blasts in certain samples.
IMPACT:	If these limitations are not clearly understood or are misinterpreted, in rare situations there could be a delay in the recognition, diagnosis and treatment of conditions associated with blasts in the peripheral blood.
ACTION:	Please refer to the following modified information for both the Suspect messages and Limitations sections for the Differential: Blasts are detected, but not enumerated, by internal algorithms using acquired events, histogram and dataplot patterns, and sophisticated statistical methods for all available data for the sample analyzed. A standard trigger value or limit corresponding to enumeration on peripheral smear cannot be established because: • Laboratories differ in their desired sensitivity to abnormal flagging and messaging. • Laboratories differ in their definition of blasts. • Mature and immature abnormal cell types may sometimes be identified as blasts. • Blasts can be rare events. Blasts can represent a mixed population of cells often associated with specimen abnormalities that alter the white cells population's pattern distribution in dataplots and histograms away from a normal distribution pattern. The presence of blast cells may trigger other available Suspect messages but not all blood samples that contain blasts will report a Suspect message.

	A blast Suspect message is not diagnostic. The user must not rely upon instrument results alone to replace the need for manual microscopic review of abnormal blood samples, if indicated by other clinical and laboratory features of the patient. Further diagnostic procedure and clinical evaluations must be evaluated for diagnosis. Additionally, refer to your Instructions for Use data review sections for complete information on all available messaging and flagging options on the system.
RESOLUTION:	Please utilize this notification as additional labeling concerning limitations for Blast Suspect messaging.

The national competent authority has been informed of this field safety corrective action.

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 product(s) listed above to another laboratory, please provide them with 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.

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

- Via our website, http://www.beckmancoulter.com/customersupport/support

We apologize for the inconvenience that this caused your laboratory.

Sincerely,

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Enclosures: Response Form