

June 9, 2008

URGENT: FIELD SAFETY NOTICE
COULTER® GEN•S and LH SlideMakers
All software revisions

Dear Beckman Coulter Customer,

Beckman Coulter has become aware of a potential issue with the COULTER GEN•S and LH Slidemaker.

Background	<ul style="list-style-type: none">• The operator has the option to configure the type of Sample Identification information that is printed on the label that is applied to the glass slide prepared by the SlideMaker.• One option is to print the same bar-code that the Analyzer has read from the primary sample tube.
Issue	<ul style="list-style-type: none">• If the primary tube bar-code contains a lower case alpha character, !, \, ', ~, {, or }, the SlideMaker printer does not recognize these characters.• If the barcode on the slide label is read by a device outside of the analyzer or SlideMaker, the slide could be mis-identified.• Depending on the application or software used with the scanner, the barcode results will not match the human readable.<ul style="list-style-type: none">○ As an example, if a sample ID is 123AbC, the lower case letter could be omitted and the sample ID may appear as 123AC.• The text (human readable portion of the printed label) appears identical to the tube Sample ID.
Action	<ul style="list-style-type: none">• Only use upper case alpha characters in the Sample Identifier.• If you must use lower case alpha characters in the Sample Identifier, configure the SlideMaker Slide labels without a bar-code.

Please share this information with your laboratory staff and retain this notification as part of your laboratory Quality System documentation. Please complete and return the enclosed response form within 10 days so we may maintain our records.

If you have any questions regarding this letter, contact your local Beckman Coulter Representative. We sincerely apologize for any inconvenience that this may have caused your laboratory. Thank you for your continued support of Beckman Coulter products.

Sincerely,



Group Manager, Corporate Regulatory Affairs

Enc: Response Form

PCA-M-F-1026