November 21, 2017

URGENT FIELD SAFTEY NOTICE – FSN 30696

REF	Part Numbers
iQ200 Series Urine Microscopy Analyzer with Barcode Reader Model NFT-2100	800-3046, 800-3047, 800-3052, 800-3053, 800-3802, 800-3803, 800-3900, 800-3920, 800-3925, 800-3931, 800-3933, 800-3934, 800-3935, 800-3937, 800-3950, 800-3951, 800-3042, 800-3043, 800-3044, 800-3049, 800-3050, 800-7190, 800-7713, 800-7714, 800-7715, 800-7101, 800-7102, 800-3938, 800-7157

Attention Beckman Coulter Customer,

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

ISSUE:	Iris International has determined that the iQ200 Series Urine Microscopy Analyzer with Barcode Reader (Model NFT-2100), may intermittently exhibit the following: ▪ Failure to read the urine sample dilution barcode label where it defaults to a dilution factor of 1:1 and does not apply the correct dilution factor. ▪ Failure to read body fluid dilution barcode label where the rack is rejected and no results are generated.
IMPACT:	When the iQ Series Analyzer fails to read the urine sample dilution barcode label, erroneous results with incorrect concentrations and inaccurate particle counts for any formed particles will be generated. ▪ Incorrect patient results will be observed as an unexpected discrepancy between instrument results and the patient's clinical picture. ▪ The greatest impact could be a delay in recognition of Hematuria**.**
ACTION:	1. Anytime a dilution has been made, the laboratory must verify that the dilution factor is correct before release of final results. 2. If Auto-Release is used, the printing option should always be enabled for result release (follow the instructions in the Operator's Manual P/N 300-4321 (International) or P/N 300-4320 (North America). a. Document samples that are being diluted. b. Look at the printout for those samples and verify the dilution code before release of the results from the LIS. c. If dilution code is incorrect, reject the result and re-run the sample according to your laboratory protocol.

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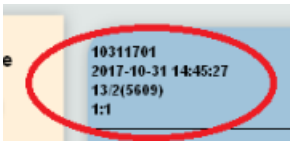
	3. If Auto-Release is not used: a. Verify that the dilution factor is correct on the specimen screen as shown below:  b. If the displayed dilution factor is incorrect, delete results and create a manual order for the specimen with the correct dilution factor (following the instructions in the iQ200 Operator's manual, P/N 300-4321 (International) or P/N 300-4320 (North America), Chapter 7 (Manual Orders) and rerun. 4. In the case of manual entries, dilution barcode entries are not dependent on the barcode reader. Dilution factors can be verified during the manual entry process, prior to running the sample, and do not need to be verified as described in scenarios 2 and 3 above. (iQ200 Operator's manual, P/N 300-4321 (International) or P/N 300-4320 (North America), Chapter 7 (Manual Orders).
RESOLUTION:	Beckman Coulter is working on a resolution to correct and prevent recurrence of this issue.

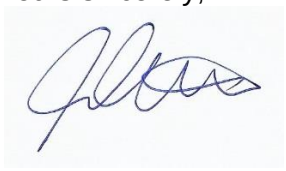
Please share this information with your laboratory staff and retain this notification as part of your laboratory Quality System documentation. If you have forwarded any of the affected product(s) listed above to another laboratory, please provide them a copy of this letter.

Complete and return the enclosed response form within 10 days so that we are assured you have received this important communication.

If you have any questions regarding this notice, please contact the Customer Support Hotline at 0845 600 1345 or techsupportuk@beckman.com.

We apologize for the inconvenience that this has caused your laboratory.

Yours sincerely,



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Enclosed: Vigilance Response Form