October 23, 2019

FIELD SAFETY CORRECTIVE ACTION NOTIFICATION

Product	Part Number
iQ200 Series Urine Microscopy Analyzer	All part numbers
iChemVELOCITY Urine Chemistry System	All part numbers

Attention Beckman Coulter Customer,
Copy: Chairman Medical Board/Head of Departments of Affected consignees

*Applicable to affected consignees in Singapore only

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

ISSUE:	Customers have reported incidents where two sets of results report the same Specimen Identifier (Specimen ID) with different results, different Medical Record Number (MRN) and different patient identification (demographics). The potential cause of this misidentification could be of an external source (ex. LIS, Use Error). The iQ200 and iChemVELOCITY do not alert the user when the same Specimen ID is associated with different MRN or patient demographics. There is no evidence that would indicate that the iQ200 and/or iChemVELOCITY is the cause of the misidentification. One possible scenario on how this could occur is as follows: A laboratory receives an outpatient sample from ABC Laboratory for Jane Doe that has a barcode number of 0000012345 and also receives a second sample from the ED Emergency Department for John Smith that also has a barcode number of 0000012345. In this example, results from Jane Doe may be reported under John Smith or vice-versa.
IMPACT:	Results with the incorrect Specimen ID can be reported to the physician.
ACTION:	Follow the actions below to reduce the potential for this issue: • Follow good laboratory practice (GLP) and ensure that a unique identification system is in place. • Ensure that specimens are labeled with a unique Specimen ID and manual orders utilize a unique Specimen ID. • Do not reuse barcode numbers that identify different specimens. If barcode numbers must be reused, ensure results have been released from the LIS and the instrument Work List has been cleared.

	• Clear all Manual Orders immediately after results are released, even if barcodes are used for subsequent runs (See iQ200 or iChemVELOCITY IFU, Chapter 7, Manual Orders). • Verify the Specimen ID on the result printout against original specimen ID before releasing the result.
RESOLUTION:	Beckman Coulter is in the process of developing a software update to alert users if Specimen IDs are re-used, projected for release in 2020.

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 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 Beckman Coulter Customer Support Center:

- From our website: http://www.beckmancoulter.com
- Outside of the United States and Canada, contact your local Beckman Coulter Representative.

We apologize for the inconvenience that this caused your laboratory.

Sincerely,

[redacted]

Roger Janczak
Vice President, Quality and Regulatory Affairs

Enclosure: Response Form