Iris®
Diagnostics Division

January 13, 2016

URGENT MEDICAL DEVICE RECALL

iChemVELOCITY Automated Urine Chemistry System using iChemVELOCITY Urine Chemistry Strips

REF 800-7212; 800-7212-001; 800-7204; 800-7204-FJR

Attention Iris International Customer,

Iris International is initiating a field action for the products listed above. This letter contains important information that needs your immediate attention.

ISSUE:	Iris International has become aware of loose or missing analyte pads being found in the several locations (strip vial, strip provider module, strip conveyor system or waste container) that are undetectable by the iChemVELOCITY System.
IMPACT:	• If affected strips are used to assay patient samples, the issue has the potential to cause erroneous pH results and false negative results for the following tests; nitrite, glucose, blood, bilirubin, urobilinogen, protein, leukocyte esterase, ketones, and ascorbic acid. • There is no impact to the measurement of color, clarity and specific gravity.
ACTION:	• When loading strips, observe for loose or missing analyte pads; if loose or missing pads are observed, discard the vial and do not use the strips from that vial. • In addition to regularly scheduled maintenance, the lab should determine a schedule to periodically check the strip provider module, strip conveyor system, and waste container for pads that may have fallen off during processing. • Furthermore, if pads are found in the strip provider module, strip conveyor system or waste container, contact service to rule out any instrument operational issue. • For product replacement of affected vials, please contact your local support representative. • A retrospective review of results may be clinically warranted for those samples that were tested with strips that were subsequently known to have missing pads. Consult your Laboratory Director to determine if further retrospective review of results is clinically warranted with particular consideration to situations in which inconsistencies appear to exist between clinical conditions, results of other lab tests, or other urine analytes.
RESOLUTION:	Corrections have been implemented within manufacturing to address this issue and design improvements are being further evaluated.

FA-15048

9772 Eton Avenue
Chatsworth,
California 91311

P: 1.800.222.7000
www.beckmancoulter.com

Share this information with your laboratory staff. 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.

Beckman Coulter will be managing the logistics of this notice.

If you have any questions or concerns regarding this notice, please contact your local support representative:

- Via our website, at http://www.beckmancoulter.com
- By phone, call 800 854-3633 in the United States and Canada

We apologize for the inconvenience to your laboratory.

Sincerely,

Marwan Fathallah
Vice President, Quality Assurance and Regulatory Affairs
Enclosure: Response Form

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A Division of
IRIS International, Inc.

9172 Eton Avenue
Chatsworth
California 91311

P 818 527 7000
www.beckmancoulter.com