November 7th, 2019

URGENT MEDICAL DEVICE RECALL

Product	Part Number
iChemVELOCITY Urine Chemistry System	All Part Numbers

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:	As a result of an internal investigation, Beckman Coulter has become aware of an issue affecting Specific Gravity (SG) chemistry settings for the iChemVELOCITY Urine Chemistry Systems that prevents the trigger of a chemistry system flag "S3" and may result in erroneous Specific Gravity results. • The S3 value flag is generated when the instrument is unable to measure the Specific Gravity of the sample due to an interference in the sample or a hardware failure. • The S3 value flag triggers chemistry system flags that are designed to require operator review prior to release of results. • The iChemVELOCITY Instructions for Use (IFU) incorrectly states that for S3, "The Specific Gravity result is >1.060. This is a normal condition." The IFU does not state that S3 value flag is generated when the instrument is unable to measure the Specific Gravity of the sample due to an interference in the sample or a hardware failure.
IMPACT:	Erroneous Specific Gravity results may be reported from the laboratory which may trigger unnecessary or inappropriate additional testing. • **<u>If your SG chemistry settings are affected:</u>** • Specific Gravity results that cannot be measured due to interference or hardware failures are not held for review and are incorrectly released as SG>1.060 • The operator will not be able to differentiate between results that have been correctly measured and reported as SG>1.060 and those that were unable to be measured, but report as SG>1.060 • **<u>If your SG chemistry settings are not affected:</u>** The sample results will be flagged as "S3" and when the operator consults the IFU, which states "The Specific Gravity result is >1.060. This is a normal condition". The customer could potentially report an incorrect result as SG>1.060.

	In both scenarios, physicians may believe that the sample is more concentrated than it is and fail to interpret other results i.e. urine drug screen or urine pregnancy test in the context of a possibly dilute sample. In the absence of a history of radiographic contrast material or mannitol (diuretic) administration, a SG>1.060 result is physiologically unlikely.
ACTION:	To recognize that SG chemistry settings are affected (S3 flag has been disabled in your instrument), refer to the IFU, Chapter 9, Setup, Settings Screen and follow the instructions provided below: • From the Instrument screen, select **Logon**. • **Do not go Off line** to display settings. • Select **Settings**. Warning screen(s) will display indicating that settings cannot be changed, but can be displayed. • Select **OK > Chemistry > SG > Edit > Edit Map**. The SPGR Map Settings screen is displayed. • Use the vertical scrollbar and review all the Input values on the SPGR Map Settings screen. o If one of the SG Input values is S3, then your SG chemistry settings are affected. Your instrument has been set up to prevent the trigger of the S3 flag. ▪ You will not be able to differentiate between a measured result of >1.060 and a non-measured result i.e. instrument unable to measure specific gravity. ▪ Follow the instructions below. o If there are no S3 Input values, then your chemistry settings are not affected and your instrument will trigger the S3 flag. ▪ Any S3 flag that is obtained must be handled per your lab protocol. ▪ Follow the instructions below. **<u>Instructions</u>** • Review results to determine if samples report an SG result of >1.060 or an SG result of S3 • If the SG result is >1.060 or S3, test samples for SG using an alternate method* determined by your laboratory • If persistent SG results are >1.060 or persistent S3 results are seen, contact your local Beckman Coulter Representative • Report any adverse reactions or quality problems experienced with the use of this product to Beckman Coulter (contact information is at the end of this letter) and you may also report to the United States Food and Drug Administration (Visit www.fda.gov/medwatch, or call 1-800-FDA-1088). **Note that SG results measured by refractometry methods may differ from SG results measured by reagent strip methods. For specimens containing x-ray or radiographic contrast media, the reagent strip method can be used because the reagent strip method for SG is not affected by nonionic large molecular weight solutes. The reagent strip method can also be used to measure SG in specimens containing mannitol (diuretic).*

RESOLUTION:	• This Urgent Medical Device Recall letter serves as a temporary labeling update for this issue. • The iChemVELOCITY's Instructions For Use (IFU) will be updated. • Beckman Coulter has a service tool in development which will be utilized by field service personnel to restore to factory settings as required. • Beckman Coulter will contact you when the tool is available, projected starting the 1st quarter of 2020.

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 other laboratories, please provide them a copy of this letter.

So that we are assured you have received this important communication, please respond within 10 days in one of the following ways:

- Electronically, if you received this communication via email.
- Manually, complete and return the enclosed Response Form.

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

- Via our website: http://www.beckmancoulter.com Support > Request Instrument Support.
- By phone: call 800-526-7694 in the United States and Canada.
- Outside the United States and Canada, contact your local Beckman Coulter Representative.

We apologize for the inconvenience that this caused your laboratory.

Sincerely,

Amalia Colon
Director of Quality Assurance

Enclosure: Response Form