

October 23, 2019

FIELD SAFETY CORRECTIVE ACTION NOTIFICATION

Product	Part Number
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:	<p>As a result of an internal investigation, Beckman Coulter has become aware of an issue affecting Specific Gravity chemistry settings for the iChemVELOCITY Urine Chemistry System that prevents the trigger of a chemistry system flag “S3” and may result in erroneous Specific Gravity (SG) results.</p> <ul style="list-style-type: none"> • 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:	<p>Erroneous Specific Gravity results may be reported from the laboratory which may trigger unnecessary or inappropriate patient treatment.</p> <p>For affected instruments:</p> <ul style="list-style-type: none"> • 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
ACTION:	<p>For all results held in the Work List or released to the Laboratory Information System (LIS):</p> <ul style="list-style-type: none"> • Review results to determine if samples report an SG result of >1.060 or an SG result of S3

	<ul style="list-style-type: none">• If the SG result is >1.060 or S3, test samples for SG using an alternate method determined by your laboratory• Use the SG results from the alternate test method to change the SG results onboard the instrument, if the Detailed Audit Trail feature is enabled or change the SG results at the LIS• If persistent SG results are >1.060 or persistent S3 results are seen, contact your local Beckman Coulter Representative
RESOLUTION:	<ul style="list-style-type: none">• This Urgent Field Safety Notice serves as a temporary labeling update for this issue.• The iChemVELOCITY's Instructions For Use (IFU) will be updated.• Beckman Coulter has a software upgrade in progress which is projected to be available starting the 1st quarter of 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.

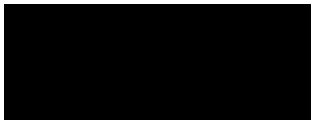
Please complete and return the enclosed Response Form within 10 days so we are assured you have received this important communication.

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

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

We apologize for the inconvenience that this caused your laboratory.

Sincerely,



Roger Janczak
Vice President, Quality and Regulatory Affairs

Enclosure: Response Form

Beckman Coulter, the stylized logo and the Beckman Coulter product and service names mentioned herein are trademarks or registered trademarks of Beckman Coulter, Inc. in the United States and other countries.