



November 14, 2022

URGENT MEDICAL DEVICE RECALL

IRISpec CA/CB/CC

REF	LOT
800-7211	565-22 and higher

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:	<ul style="list-style-type: none"> Beckman Coulter has become aware of an increase in customer complaints generated for intermittent IRISpec CB glucose control false positive results when used in conjunction with iChemVELOCITY Urine Chemistry Strips PN 800-7212. If a QC run fails, the system will not allow the operator to run patient samples. The QC run should be repeated and be successful before running patient samples ([iChemVELOCITY Urine Chemistry System Instructions For Use (IFU) P/N 301-7146BE, Chapter 4; Quality Control). This issue affects IRISpec CB control lot numbers 565-22 and higher when analyzed with iChemVELOCITY Urine Chemistry Strips (PN 800-7212) lot numbers 7212554M and higher. There is no impact to patient results, IRISpec CA or CC controls.
IMPACT:	<p>The following outcomes may occur:</p> <ul style="list-style-type: none"> Delay in diagnosis and appropriate treatment may occur. IRISpec CB control may intermittently recover false positive results for Glucose.
ACTION:	<ul style="list-style-type: none"> <u>If IRISpec CB controls pass</u> (QC results are within QC acceptance criteria): <ul style="list-style-type: none"> Continue to process patient samples per IFU (P/N 301-7146BE) <u>If IRISpec CB controls fail</u> (QC results are outside QC acceptance criteria): <ul style="list-style-type: none"> Refer to Addendum A below for troubleshooting No retrospective review of QC or patient sample results is necessary.
RESOLUTION:	Further investigation is taking place to prevent re-occurrence.



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 listed above to another laboratory, 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 your local support representative:

- From our website: <http://www.beckmancoulter.com>
- Via phone, call 800-526-7694 in the United States and Canada.
- Contact your Local Beckman Coulter Representative

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

We apologize for any inconvenience that this caused your laboratory.

Sincerely,

DocuSigned by:

Medha Avisetti



Signer Name: Medha Avisetti
Signing Reason: I approve this document
Signing Time: 14-Nov-2022 | 12:46:47 PM PST

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Medha Avisetti
Vice President, QRA Hematology, UA, LS, CDSS & GQM

Enclosure: Response Form

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Addendum A

Reference: iChemVELOCITY Urine Chemistry System – Instructions For Use (PN 301-7146 Rev BE)

IRISpec CB controls failure troubleshooting steps:

NOTE: If the QC run passes at any point, normal instrument operation can resume. If QC fails, continue to the next step.

1	Repeat the QC run using the same lot number (controls and strips, if available).
2	Repeat the QC run using an unopened bottle of controls (same lot, if available).
3	Repeat the QC run using a new control lot number (if available).
4	Run a Reflectance CalChek (PN 800-7703) <ul style="list-style-type: none"> - If the CalChek is successful, repeat the QC run. - If the CalChek fails or if the QC fails again, contact Technical Services or your distributor to obtain phone support
5	If troubleshooting fails to resolve the issue: <ul style="list-style-type: none"> • Follow your laboratory's protocol to bring your backup system online