



July 10, 2024

URGENT MEDICAL DEVICE RECALL

IRISpec CA/CB/CC

REF	LOT
800-7211	432-24 and higher
800-7702	432-24 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 for intermittent IRISpec CB glucose control failure, resulting in false positive results when used in conjunction with iChemVELOCITY Urine Chemistry Strips PNs 800-7204 and 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 pass successfully before running patient samples. This issue affects IRISpec CB control lot numbers 432-24 and higher when analyzed with iChemVELOCITY Urine Chemistry Strips PN 800-7204 lot numbers 7204661M and higher; and 800-7212 lot numbers 7212706M and higher. 									
IMPACT:	<p>The following outcomes may occur:</p> <ul style="list-style-type: none"> Delay of patient results released to the physician. There is no impact to the accuracy of patient results, IRISpec CA, or IRISpec CC controls. 									
ACTION:	<ul style="list-style-type: none"> Beckman Coulter has updated its control ranges to move the negative Glucose control from IRISpec CB to IRISpec CC. Update the CB and CC control ranges for Glucose as indicated in Table 1 below. For instructions, refer to Addendum A: "Updating the QC ranges for Glucose in the Analyzer". <p>Table 1:</p> <table border="1"> <thead> <tr> <th>Product Name and Analyte</th> <th>Current Acceptable result range</th> <th>Revised Acceptable result range</th> </tr> </thead> <tbody> <tr> <td>IRISpec CB Glucose (800-7211 & 800-7702)</td> <td>Negative</td> <td>N/A</td> </tr> <tr> <td>IRISpec CC Glucose (800-7211)</td> <td>N/A</td> <td>Negative</td> </tr> </tbody> </table>	Product Name and Analyte	Current Acceptable result range	Revised Acceptable result range	IRISpec CB Glucose (800-7211 & 800-7702)	Negative	N/A	IRISpec CC Glucose (800-7211)	N/A	Negative
Product Name and Analyte	Current Acceptable result range	Revised Acceptable result range								
IRISpec CB Glucose (800-7211 & 800-7702)	Negative	N/A								
IRISpec CC Glucose (800-7211)	N/A	Negative								



	<ul style="list-style-type: none"> • The above Glucose ranges supersede the ranges listed in the IRISpec CB control Instructions For Use (IFU) PN C36362.AC, C36361.AC and the assay sheet C39722.AC and C39721.AC. Use only the specifications in this letter. • No retrospective review of QC or patient sample results is necessary. • Beckman Coulter recommends posting this Recall Notification Letter on/or near the analyzer.
RESOLUTION:	<ul style="list-style-type: none"> • As an interim action, an update on the Glucose control range is being implemented via this letter. • This letter serves as a labeling update for this issue until further notice. • 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(s) 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 Customer Support Center or your local representative;

- From our website: <http://www.beckmancoulter.com>
- By phone: Call 800-526-7694 in the United States and Canada.
 - Outside 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 the inconvenience that this caused your laboratory.

Sincerely,

DocuSigned by:
Jennifer Chau
 Signer Name: Jennifer Chau
Signing Reason: I approve this document
Signing Time: 10-Jul-2024 | 3:07:42 PM PDT
CC3CD3A8EA284A8CB13031EA135AA19D

Jennifer Chau
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, (Appendix A) (PN 300 4449FH)

iChemVELOCITY Urine Chemistry System – Instructions For Use, (Appendix A) (PN 301-7146BE)

DxU 810c Iris Urine Chemistry System – Instructions For Use, (Appendix A) (PN C49355AA)

Updating the QC ranges for Glucose in the Analyzer.	
1	Go Off-line NOTE: QC range updates require admin level operator access.
2	From the Consumable window, select Chemistry QC.
3	On the first Chemistry QC Screen, verify the test strip information is correct.
4	Select Next until you reach the CB Control Screen.
5	<p>Verify that the name of the control material, lot ID, and expiration date are correct prior to QC range updates. Implement the revised quality control ranges listed in Table 1 above for the IRISpec CB and CC Glucose ONLY.</p> <p>NOTE: The lower and upper limits must be selected by using the drop-down arrows. Color and format may differ depending on your analyzer.</p> <p>From the CB Control Screen for Glucose:</p> <ol style="list-style-type: none"> 1. Select N/A 2. A “Warning!” pop-up will be displayed: “Selecting N/A disables QC results which verify system performance. The urine chemistry system will not provide QC results for the selected analyte. There is a potential for erroneous results if patient samples are processed with untested QC.” 3. Select OK 4. Select Next to move to IRISpec CC control. <p>From the CC Control Screen for Glucose:</p> <ol style="list-style-type: none"> 1. Determine if Glucose is N/A or Negative. 2. If Glucose is Negative for Lower and Upper limit, no changes are needed. 3. If Glucose is N/A, then unselect N/A. 4. Using the Drop-down, select Negative for the Lower Limit. 5. Using the Drop-down, select Negative for the Upper Limit.



Example: Updated CB N/A GLU Range

Chemistry QC

Control Name (Position 9):

Lot ID:

Expiration:

Chemistry	Lower Limits	Upper Limits	N/A
Blood	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>
Bilirubin	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>
Urobilinogen	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>
Ketone	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>
Glucose	Negative	Negative	<input checked="" type="checkbox"/>
Protein	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>
Nitrite	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>
Leukocytes	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>
pH	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>
Specific Gravity	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>
Color	<input type="text"/>	<input type="text"/>	<input checked="" type="checkbox"/>
Clarity	<input type="text"/>	<input type="text"/>	<input checked="" type="checkbox"/>
Ascorbic Acid	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>

Prev Next OK Cancel

Example: Updated CC Negative GLU Range

DXU-PC - VNC Viewer

Chemistry QC

Control Name (Position 10):

Lot ID:

Expiration:

Chemistry	Lower Limits	Upper Limits	N/A
Blood	<input type="text"/>	<input type="text"/>	<input checked="" type="checkbox"/>
Bilirubin	<input type="text"/>	<input type="text"/>	<input checked="" type="checkbox"/>
Urobilinogen	<input type="text"/>	<input type="text"/>	<input checked="" type="checkbox"/>
Ketone	<input type="text"/>	<input type="text"/>	<input checked="" type="checkbox"/>
Glucose	Negative	Negative	<input type="checkbox"/>
Protein	<input type="text"/>	<input type="text"/>	<input checked="" type="checkbox"/>
Nitrite	<input type="text"/>	<input type="text"/>	<input checked="" type="checkbox"/>
Leukocytes	<input type="text"/>	<input type="text"/>	<input checked="" type="checkbox"/>
pH	<input type="text"/>	<input type="text"/>	<input checked="" type="checkbox"/>
Specific Gravity	<input type="text"/>	<input type="text"/>	<input checked="" type="checkbox"/>
Color	<input type="text"/>	<input type="text"/>	<input checked="" type="checkbox"/>
Clarity	<input type="text"/>	<input type="text"/>	<input checked="" type="checkbox"/>
Ascorbic Acid	20 mg/dL +	40 mg/dL ++	<input type="checkbox"/>

Prev Next OK Cancel

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|---|---|
| 6 | After implementing the new ranges for IRISpec CB and CC Glucose only, select OK to return to the Consumable window.
NOTE: IRISpec CA control is not impacted. No IRISpec CA QC range update is needed. |
| 7 | Select OK to exit the Consumable window. |
| 8 | Select Maintenance > Restart > follow the prompts and log back in |