




August 17, 2023

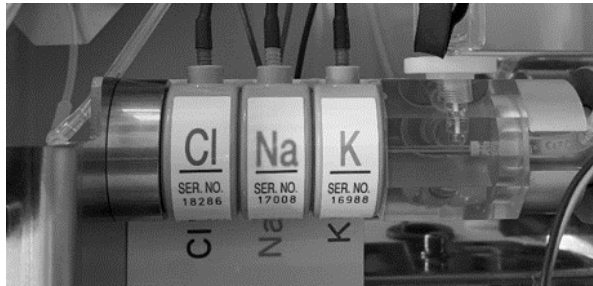

IMPORTANT PRODUCT NOTICE

K (Potassium) ELECTRODE for AU/DxC AU Beckman Coulter analyzers
(AU480, AU680, AU5800 and DxC 700 AU)

REF	LOT	Serial Number (S/N)	
MU919500	22303	29540 – 29560 29562 – 29671 29673 – 29829 29831 – 29929 29931 – 29984 29986 – 30091 30093 – 30192	2024-03-01

Dear Beckman Coulter Customer,

Beckman Coulter is sending this letter regarding the K (Potassium) electrode REF MU919500 used for potassium testing on the ISE unit. Test results are not affected.

ISSUE:	<ul style="list-style-type: none"> Beckman Coulter has determined that K electrodes with the lot number and serial numbers listed in the table above were filled with an incorrect inner liquid.
IMPACT:	<ul style="list-style-type: none"> When a defective K electrode is used in the AU/DxC AU Beckman Coulter analyzers, calibration failures may occur resulting in the need to replace the electrode and repeat calibration and QC checks. There is no impact to patient results. Patient results generated after calibration and QC have passed are accurate. The worst-case health hazard in this case is that there is a possible delay in reporting patient results.
ACTION:	<ul style="list-style-type: none"> Check the serial number (S/N) on the label of any K electrodes currently installed on your instruments: <div data-bbox="480 1430 1373 1803" style="border: 1px solid black; padding: 5px; margin: 10px 0;"> <p style="text-align: center;">Electrode Label</p> <div style="display: flex; justify-content: space-around;">   </div> </div> <ul style="list-style-type: none"> ○ If the S/N of the K electrodes is listed above: <ul style="list-style-type: none"> ▪ Stop using the K electrode.



	<ul style="list-style-type: none"> ▪ Dispose of the K electrode according to your laboratory protocol. ▪ Replace the K electrode with one S/N that is <u>not</u> listed above. <ul style="list-style-type: none"> ▪ Refer to the “Replace the Na, K, or CL Electrode” procedure in the instrument Instructions for Use (IFU). ▪ Perform ISE calibration and QC according to the IFU, if you remove or replace an electrode. <ul style="list-style-type: none"> • Check the S/N on the box label of any K electrodes in your inventory: <div data-bbox="646 569 1214 1188" data-label="Image" style="text-align: center; border: 1px solid black; padding: 5px;"> <p>Electrode Box Label</p> </div> <ul style="list-style-type: none"> ○ If the S/N of the K electrodes is listed above, dispose of the K electrode according to your laboratory protocol. • No retrospective review of results is necessary.
RESOLUTION:	<ul style="list-style-type: none"> • Beckman Coulter has discontinued shipment of the affected lot.

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 our Customer Support Center:

- From our website: <http://www.beckmancoulter.com>
- For customers in other geographies, contact your local Beckman Coulter Representative for replacement.



We apologize for any inconvenience that this caused your laboratory.

Sincerely,

DocuSigned by:

Signer Name: Alyssa Yarbrough
Signing Reason: I approve this document
Signing Time: 17-Aug-2023 | 4:48:54 PM PDT
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Alyssa Yarbrough
Director, Quality and Regulatory Affairs

Enclosure: Response Form