



April 16, 2025

URGENT SAFETY NOTICE

AU480 and AU680 Clinical Chemistry Analyzers

Analyzer	REF	UDI	Serial Numbers
AU480	B11810	14987666540664	From 10155 to 2025021482
	B12183	14987666540671	
	B80091	16954701010015	
	B96692	14987666542965	
	B96693	14987666542972	
	C02654	14987666543283	
	C02655	14987666543290	
	C02845	16954701010022	
	C41919	14987666544174	
	C41920	14987666544181	
	N3659700	14987666535257	
	N3659800	14987666535264	
	N3659900	14987666535271	
	N3660000	14987666535288	
	N3660100	14987666535547	
	N3660200	14987666535554	
	N3660300	14987666535752	
	N3660400	14987666535769	
	N3660500	14987666536032	
	N3660600	14987666536049	
	N3660800	14987666536063	
	N3912400	14987666537084	
	N3912500	14987666537091	
	N3150700, N3151000, N3151300, N3151400, N3151500, N3151600, N3151900,	Due to the age of the device and the fact that it has exceeded its storage period, the UDI number is not available.	
AU680	B12185	14987666540732	From 10436 to 2022087656
	B12186	14987666540688	
	B12187	14987666540701	
	B12188	14987666540725	
	B96694	14987666542989	
	B96695	14987666542996	
	B96696	14987666543009	
	C02656	14987666543306	




	C02657	14987666543313	
	N3147700	15099590346249	
	N3662000	14987666535301	
	N3662100	14987666535318	
	N3662200	14987666535325	
	N3662700	14987666535615	
	N3663000	14987666535646	
	N3910200	14987666535790	
	N3910400	14987666535813	
	N3910500	14987666535820	
	N3910600	14987666535912	
	N3910800	14987666535936	
	N3910900	4987666535946	
	N3911200	14987666535974	
	N3911700	14987666536575	
	N3911900	14987666536599	
	N3147100, N3147200, N3147300, N3147400, N3147600, N3148100, N3149400, N3149800	Due to the age of the device and the fact that it has exceeded its storage period, the UDI number is not available.	

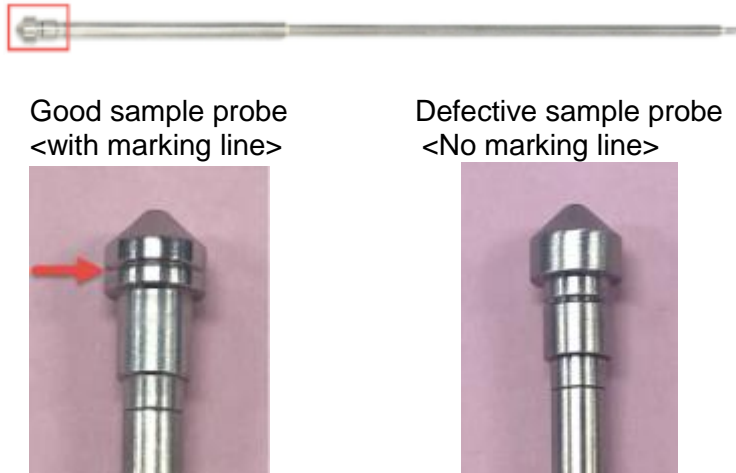
(SRN): US-MF-000010288

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 identified that using MU993400 sample probes with lot numbers from 178713114 to 179433670 on AU480 and AU680 clinical chemistry analyzers. There is remote probability of false low test results due to sample dispensing issues. 
IMPACT:	<ul style="list-style-type: none"> There is a remote possibility that affected sample probes may cause false low results for assays with sample volume between 1.0 - 2.0 uL



	<p>(Max. 34% error at 1.0 uL and 7% error at 1.6 uL sample dispensing volume).</p> <ul style="list-style-type: none"> In a worst case scenario, there is a remote possibility of delayed recognition or treatment.
ACTION:	<ul style="list-style-type: none"> Check the analyzers, which meet the condition below, as they may include a defective sample probe. <ul style="list-style-type: none"> Analyzers whose Serial No. is from 2023070718 to 2025021482. Analyzers whose sample probe has been replaced since July 1, 2023. For analyzers that meet either of the above criteria, remove the sample probe from the instrument in accordance with IFU Section 6, Maintenance / As needed Maintenance/Replace a Sample or Reagent Probe. And then, check the groove on the head of the removed sample probe. (see Fig.-1) <ul style="list-style-type: none"> If it has "a marking line", please continue to use. If it does not have "a marking line", please replace the sample probe with a probe not included in the impacted sample probe LOT numbers. <p>Fig.-1</p>  <ul style="list-style-type: none"> Analyzers that do not fall into the above condition can be used as is. Please check your stock of sample probes as follows: <ul style="list-style-type: none"> Check the outer box label of your sample probes. If you have MU993400 sample probes with LOT numbers from 178713114 to 179433670, please dispose of the impacted probe to ensure it is not used and contact your BEC representative for a replacement (see Fig.-2). <p>Note: Also check the sample probes included in the maintenance kits for AU480 (PN: B66751) and AU680 (PN: B66752) (see Fig.-</p>



	<p>3). Contact your BEC representative for a replacement if impacted probes are identified.</p> <p>Fig.-2</p>  <p>Fig.-3</p>  <ul style="list-style-type: none"> • If all the results of the actions above show only defective sample probes on your analyzers and in stock, stop measuring the assay items which sample volume is 2.0 uL or less and contact your BEC representative for a replacement. • Beckman Coulter recommends that customers who have replaced probes on your analyzers per this letter should share the content of this letter with your laboratory and/or medical director to assess if a retrospective review of the patient results is needed.
<p>RESOLUTION:</p>	<ul style="list-style-type: none"> • Beckman Coulter has discontinued shipment of the affected lots of sample probes. • New lots numbers of sample probes are not affected.

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 Customer Support Center:

Beckman Coulter, Inc.
250 S. Kreamer Boulevard
Brea, CA 92821, USA

Telephone: (800) 854-3633
Internet:
www.beckmancoulter.com

FA-001346





From our website: <http://www.beckmancoulter.com>

For customers in other geographies, contact your local Beckman Coulter Representative for replacement.

We apologize for the inconvenience that this caused your laboratory.

Sincerely,

Signed by:

 Signer Name: Jennifer Chau
Signing Reason: I approve this document
Signing Time: 16-Apr-2025 | 12:32:38 PM PDT
CC3CD3A8EA284A8CB13031EA135AA19D

Jennifer Chau
Vice President, U.S. Quality Operations

Enclosure: Response Form

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