Fisher Diagnostics a division of
Thermo Fisher Scientific Inc.
8365 Valley Pike
Middletown, VA (USA)
22645-1905
Phone: (800) 528-0494
Fax: (540) 869-8132

October 27, 2026

URGENT- FIELD SAFETY NOTICE
(FSCA 02-26-M)
ACTION REQUIRED

Infinity™ Ammonia Reagent for Beckman Coulter AU Chemistry Analyzers (OSR61154)

Dear Valued Customer,

The purpose of this letter is to advise you that Fisher Diagnostics, a division of Fisher Scientific Company, LLC, a part of Thermo Fisher Scientific, Inc., is conducting a field safety corrective action for the in-vitro diagnostic products listed below (Table 1). Our records indicate that you have purchased units of the affected products. Please read the following information carefully.

Table 1: Product List

Product Description	Catalog Number	Lot Number	Expiration Date (YYYY-MM-DD)	UDI
Infinity™ Ammonia Reagent for Beckman Coulter AU Chemistry Analyzers	OSR61154	2915	2028-03-01	00845275000016
Infinity™ Ammonia Reagent for Beckman Coulter AU Chemistry Analyzers	OSR61154	2916	2028-03-01	00845275000016
Infinity™ Ammonia Reagent for Beckman Coulter AU Chemistry Analyzers	OSR61154	9511	2028-02-01	00845275000016
Infinity™ Ammonia Reagent for Beckman Coulter AU Chemistry Analyzers	OSR61154	9510	2028-02-01	00845275000016
Infinity™ Ammonia Reagent for Beckman Coulter AU Chemistry Analyzers	OSR61154	0644	2027-12-01	00845275000016
Infinity™ Ammonia Reagent for Beckman Coulter AU Chemistry Analyzers	OSR61154	0645	2027-12-01	00845275000016
Infinity™ Ammonia Reagent for Beckman Coulter AU Chemistry Analyzers	OSR61154	0614	2027-11-01	00845275000016
Infinity™ Ammonia Reagent for Beckman Coulter AU Chemistry Analyzers	OSR61154	0613	2027-11-01	00845275000016
Infinity™ Ammonia Reagent for Beckman Coulter AU Chemistry Analyzers	OSR61154	2016	2027-10-01	00845275000016
Infinity™ Ammonia Reagent for Beckman Coulter AU Chemistry Analyzers	OSR61154	5301	2027-10-01	00845275000016
Infinity™ Ammonia Reagent for Beckman Coulter AU Chemistry Analyzers	OSR61154	9901	2027-08-01	00845275000016
Infinity™ Ammonia Reagent for Beckman Coulter AU Chemistry Analyzers	OSR61154	2525	2027-08-01	00845275000016
Infinity™ Ammonia Reagent for Beckman Coulter AU Chemistry Analyzers	OSR61154	7602	2027-07-01	00845275000016
Infinity™ Ammonia Reagent for Beckman Coulter AU Chemistry Analyzers	OSR61154	7603	2027-07-01	00845275000016

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Product Description	Catalog Number	Lot Number	Expiration Date (YYYY-MM-DD)	UDI
Infinity™ Ammonia Reagent for Beckman Coulter AU Chemistry Analyzers	OSR61154	4111	2027-05-01	00845275000016
Infinity™ Ammonia Reagent for Beckman Coulter AU Chemistry Analyzers	OSR61154	2393	2027-05-01	00845275000016
Infinity™ Ammonia Reagent for Beckman Coulter AU Chemistry Analyzers	OSR61154	7411	2027-03-01	00845275000016
Infinity™ Ammonia Reagent for Beckman Coulter AU Chemistry Analyzers	OSR61154	6624	2027-03-01	00845275000016
Infinity™ Ammonia Reagent for Beckman Coulter AU Chemistry Analyzers	OSR61154	3223	2027-02-01	00845275000016
Infinity™ Ammonia Reagent for Beckman Coulter AU Chemistry Analyzers	OSR61154	3231	2027-02-01	00845275000016
Infinity™ Ammonia Reagent for Beckman Coulter AU Chemistry Analyzers	OSR61154	7779	2027-01-01	00845275000016
Infinity™ Ammonia Reagent for Beckman Coulter AU Chemistry Analyzers	OSR61154	7780	2027-01-01	00845275000016
Infinity™ Ammonia Reagent for Beckman Coulter AU Chemistry Analyzers	OSR61154	0206	2026-12-01	00845275000016
Infinity™ Ammonia Reagent for Beckman Coulter AU Chemistry Analyzers	OSR61154	0209	2026-12-01	00845275000016

INTENDED PURPOSE

Infinity™ Ammonia Reagent for Beckman Coulter AU Chemistry Analyzers (OSR61154) is used for the quantitative determination of Ammonia (NH3) concentrations in human plasma for use on the Beckman Coulter AU Chemistry Analyzers.

Calibration of this ammonia procedure is accomplished by use of the Infinity™ Ammonia Standard provided in the kit. The Standard has been manufactured gravimetrically using material traceable to an in-house certified material. Single-point standard at 59 µmol/L. Calibration frequency 7 days; recalibration required on reagent lot change or observed shift in control values. Measuring range 10–600 µmol/L; expected values 18–72 µmol/L (US) / 7–72 µmol/L (EU). Total precision <5% CV.

REASON FOR FIELD ACTION AND DESCRIPTION OF THE ISSUE

Fisher Diagnostics is initiating a field safety corrective action for the product **Infinity™ Ammonia Reagent for Beckman Coulter AU Chemistry Analyzers** because we have received complaints from customers reporting approximately **6% to 15% low calibration bias** after switching ammonia standard lots and attributed the bias to the calibrators. This observed issue applies to customers who purchased the product listed in Table 1. This issue may lead to prognostic misclassification for mortality thresholds, a delay in the initiation of time-sensitive treatment measures, and/or errors in clinical treatment decisions; this may cause development of serious patient harm.

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RISK TO HEALTH / IMPACT ON PATIENT RESULTS

Health hazard evaluation performed by a medical officer determined there is a likely probability of Serious Adverse Health consequences in the population at greatest risk using the device. Results reported with the affected Standard lots may be falsely low. Consult your laboratory Medical Director on whether previously reported results require evaluation, especially results for neonatal, pediatric, and acute liver failure patients that were just below a clinical decision threshold. For questions, contact Thermo Fisher Scientific Technical Support at Techsupport_diagnostics_mtn@thermofisher.com.

ACTIONS BEING TAKEN BY THE MANUFACTURER

Fisher Diagnostics is investigating the root cause of the low calibration bias observed when using the product and will take necessary actions to prevent a recurrence of this issue.

ACTIONS TO BE TAKEN BY THE CUSTOMER

1. Determine if you have inventory of the affected lot of **Infinity™ Ammonia Reagent for Beckman Coulter AU Chemistry Analyzers** as listed in Table 1.
2. Discontinue use and dispose of the material in accordance with local, regional, and national regulations.
3. Contact Techsupport_diagnostics_mtn@thermofisher.com for any additional support.
4. This Field Safety Notice needs to be passed to anyone within your organization or any organization where the potentially affected lots have been transferred.
5. Retain a copy of this letter for your laboratory records.
6. Please complete the Field Safety Notice Response Form attached to this notification within 10 days of the date of this letter and return as instructed.

If you have any additional questions regarding this notice, contact Fisher Diagnostics technical support by Toll Free 1800-528-0494 or by email: techsupport_diagnostics_mtn@thermofisher.com

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We appreciate your immediate attention to this Field Safety Notice. Please distribute this information immediately to any staff that may be impacted by this issue. We apologize for any inconvenience this may have caused and appreciate your understanding as we take action to ensure customer safety and satisfaction.

Sincerely,

Mark Chamberlain
Vice President, Quality & Regulatory Affairs
Specialty Diagnostics Group

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URGENT- Field Safety Notice RESPONSE FORM
(FSCA 02-26-M)

Infinity™ Ammonia Reagent for Beckman Coulter AU Chemistry Analyzers (OSR61154)

☐ I confirm I have read, understood, and have taken action or determined no action is needed at our location according to the attached Field Safety Notice instructions.

☐ I am a user of the affected product and I understand that this notice applies to the medical device listed in the Table below.

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Infinity™ Ammonia Reagent for Beckman Coulter AU Chemistry Analyzers	OSR61154	0645	2027-12-01	00845275000016
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Infinity™ Ammonia Reagent for Beckman Coulter AU Chemistry Analyzers	OSR61154	0613	2027-11-01	00845275000016
Infinity™ Ammonia Reagent for Beckman Coulter AU Chemistry Analyzers	OSR61154	2016	2027-10-01	00845275000016
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Infinity™ Ammonia Reagent for Beckman Coulter AU Chemistry Analyzers	OSR61154	9901	2027-08-01	00845275000016
Infinity™ Ammonia Reagent for Beckman Coulter AU Chemistry Analyzers	OSR61154	2525	2027-08-01	00845275000016
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Infinity™ Ammonia Reagent for Beckman Coulter AU Chemistry Analyzers	OSR61154	7780	2027-01-01	00845275000016
Infinity™ Ammonia Reagent for Beckman Coulter AU Chemistry Analyzers	OSR61154	0206	2026-12-01	00845275000016
Infinity™ Ammonia Reagent for Beckman Coulter AU Chemistry Analyzers	OSR61154	0209	2026-12-01	00845275000016

Do you have any knowledge of adverse medical events associated with the products listed in this Medical Device Field Safety Notice?

☐ Yes ☐ No

If yes, please explain and contact Techsupport_diagnostics_mtn@thermofisher.com

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PLEASE RETURN COMPLETED AND SIGNED FORM TO EMAIL WITHIN 10 DAYS UPON RECEIPT to Techsupport_diagnostics_mtn@thermofisher.com

Name/Title:	
Date:	
Company/Institute:	
Phone:	
Email:	
Signature:	

It is important that your organization takes action as detailed in this letter and also replies without delay by using this response form.
Your reply is evidence, which Thermo Fisher Scientific and Regulatory Authorities need to monitor the progress.