Immunalysis Corporation
829 Towne Center Drive
Pomona, CA 91767, United States

Field Safety Notice

Date Issued May 9, 2025

Product

Product Description	Part Number (PN)	Lot number (LN)	Expiration Date	Global Trade Identification Number (GTIN)	UDI
Multi-Drug Calibrator Level 1, 15 mL Kit	10000-15	E53694	6/30/2025	00840937108895	01008409371088951720250630 10E53694
Multi-Drug Calibrator Level 1, 15 mL Kit	10000-15	E53934	8/31/2025	00840937108895	01008409371088951720250831 10E53934
Multi-Drug Calibrator Level 1, 15 mL Kit	10000-15	E54585	9/30/2025	00840937108895	01008409371088951720250930 10E54585
Multi-Drug Calibrator Level 1, 25 mL Kit	10000-25	E53694	6/30/2025	00840937108901	01008409371089011720250630 10E53694
Multi-Drug Calibrator Level 1, 25 mL Kit	10000-25	E53934	8/31/2025	00840937108901	01008409371089011720250831 10E53934
Multi-Drug Calibrator Level 2, 15 mL Kit	10001-15	E54586	9/30/2025	00840937108918	01008409371089181720250930 10E54586
Multi-Drug Calibrator Level 2, 15 mL Kit	10001-15	E53695	6/30/2025	00840937108918	01008409371089181720250630 10E53695
Multi-Drug Calibrator Level 2, 15 mL Kit	10001-15	E53935	8/31/2025	00840937108918	01008409371089181720250831 10E53935
Multi-Drug Calibrator Level 2, 25 mL Kit	10001-25	E53695	6/30/2025	00840937108925	01008409371089251720250630 10E53695
Multi-Drug Calibrator Level 3, 15 mL Kit	10002-15	E53696	6/30/2025	00840937108932	01008409371089321720250630 10E53696
Multi-Drug Calibrator Level 3, 15 mL Kit	10002-15	E54115	8/31/2025	00840937108932	01008409371089321720250831 10E54115
Multi-Drug Calibrator Level 3, 25 mL Kit	10002-25	E53696	6/30/2025	00840937108949	01008409371089491720250630 10E53696
Multi-Drug Calibrator Level 3, 25 mL Kit	10002-25	E54115	8/31/2025	00840937108949	01008409371089491720250831 10E54115
Multi-Drug Calibrator Level 4, 15 mL Kit	10003-15	E53697	6/30/2025	00840937108956	01008409371089561720250630 10E53697
Multi-Drug Calibrator Level 4, 15 mL Kit	10003-15	E54076	8/31/2025	00840937108956	01008409371089561720250831 10E54076

Quality record references: FCA-00000390

Multi-Drug Calibrator Level 4, 25 mL Kit	10003-25	E53697	6/30/2025	00840937108963	01008409371089631720250630 10E53697
Multi-Drug Control Set 1 (15 mL)	3000-15	EK23796	6/30/2025	00840937107935	01008409371079351720250630 10EK23796
Multi-Drug Control Set 1 (15 mL)	3000-15	EK23985	8/31/2025	00840937107935	01008409371079351720250831 10EK23985
Multi-Drug Control Set 1 (15 mL)	3000-15	EK24153	9/30/2025	00840937107935	01008409371079351720250930 10EK24153
Multi-Drug Control Set 1 (15 mL)	3000-15	EK24235	9/30/2025	00840937107935	01008409371079351720250930 10EK24235
Multi-Drug Control Set 1 (25 mL)	3000-25	EK23985	8/31/2025	00840937107942	01008409371079421720250831 10EK23985

Explanation

This letter is to inform you that Abbott has identified a performance issue with Multi-Drug Calibrator / Control products (lots listed above). During our routine monitoring of analyte stability amongst the listed products, it was discovered that the Oxazepam analyte, which is the calibrator for the Benzodiazepine assay(s) (314UR-0025, 314UR-0060W, 314UR-0100, 314UR-0500), exceeded the maximum allowable shift at 2 - 8˚C storage at timepoints beyond 6 months. This means that for impacted lots, the Oxazepam expiry is 6 months less than what is indicated on the product label.

Impact on Patient Results or Operator Safety

There is a potential for the analyte values for Oxazepam aged greater than 6 months amongst the listed lots to display increased variance when run on test instruments.

- A result shift in the Oxazepam analyte could cause a Control failure or a False (+) result or a False (-) result in the Benzodiazepine assay.

All other analytes present in these products continue to perform acceptably up to the expiration listed on the product packaging.

Necessary Actions

- Discontinue use of the listed impacted lots for Benzodiazepine Assay testing or any other use of the Oxazepam analyte values.
- Any remaining inventory of these lots should not be used for Benzodiazepine Assay testing or any other use of the Oxazepam analyte values, although the use of analyte data for other non-Oxazepam analytes is unimpacted.
- The impacted lots may continue to be used for assays other than Benzodiazepine.
- For lots not on the impacted list, they are usable as-is, based on the listed expiration date for all analytes, including Oxazepam.
- Complete and return the “Customer Reply – Field Safety Notice – Acknowledgement form” to provide customer verification.
- If you have forwarded the products listed above to other laboratories, please inform them of this Field Safety Notice and provide a copy of this letter to them.
- Please retain this letter for your laboratory records.

Contact Information	If you have experienced any patient or user injury associated with this Field Safety Notice, please immediately report the event to Pomona Applications Group (email: application@immunalysis.com; Phone number: 909-482-0840; Fax: 909-482-0850). It is important that your organization takes the actions detailed in the Field Safety Notice and confirms that you have received the Field Safety Notice. Your organization's reply is the evidence Abbott needs to monitor the progress of the product actions.

Immunalysis Corporation
829 Towne Center Drive
Pomona, CA 91767, United States

Abbott

Customer Reply

Field Safety Notice – Acknowledgement form

1. Actions to be taken by Customer:

a) We acknowledge receipt of the Immunalysis Corporation Field Safety Notice dated May 9, 2025.

b) We confirm that all areas where the product could be located have been checked.

c) **SELECT ALL STATEMENTS THAT APPLY**

The following has been verified:

☐ We do not have any affected product.

☐ Affected product was redistributed to another facility. The contact information for that facility is: _____.

☐ We have affected product. We will continue testing all other analytes except Oxazepam. We will not be disposing of the affected product.

☐ We have affected product. We elect to dispose of the affected product. The Total quantity that we have received of this lot(s) is entered below. What we have entered below is what we seek replacement for.

Product Description	Part Number (PN)	Lot number (LN)	Total Quantity to be disposed and replaced*
Multi-Drug Calibrator Level 1, 15 mL Kit	10000-15	E53694	
Multi-Drug Calibrator Level 1, 15 mL Kit	10000-15	E53934	
Multi-Drug Calibrator Level 1, 15 mL Kit	10000-15	E54585	
Multi-Drug Calibrator Level 1, 25 mL Kit	10000-25	E53694	
Multi-Drug Calibrator Level 1, 25 mL Kit	10000-25	E53934	
Multi-Drug Calibrator Level 2, 15 mL Kit	10001-15	E54586	
Multi-Drug Calibrator Level 2, 15 mL Kit	10001-15	E53695	
Multi-Drug Calibrator Level 2, 15 mL Kit	10001-15	E53935	
Multi-Drug Calibrator Level 2, 25 mL Kit	10001-25	E53695	
Multi-Drug Calibrator Level 3, 15 mL Kit	10002-15	E53696	
Multi-Drug Calibrator Level 3, 15 mL Kit	10002-15	E54115	
Multi-Drug Calibrator Level 3, 25 mL Kit	10002-25	E53696	
Multi-Drug Calibrator Level 3, 25 mL Kit	10002-25	E54115	
Multi-Drug Calibrator Level 4, 15 mL Kit	10003-15	E53697	
Multi-Drug Calibrator Level 4, 15 mL Kit	10003-15	E54076	
Multi-Drug Calibrator Level 4, 25 mL Kit	10003-25	E53697	
Multi-Drug Control Set 1 (15 mL)	3000-15	EK23796	
Multi-Drug Control Set 1 (15 mL)	3000-15	EK23985	
Multi-Drug Control Set 1 (15 mL)	3000-15	EK24153	
Multi-Drug Control Set 1 (15 mL)	3000-15	EK24235	
Multi-Drug Control Set 1 (25 mL)	3000-25	EK23985	

2. Customer Contact details:

DATE*:

AUTHORIZED SIGNATURE* PRINT NAME OF CONTACT INDIVIDUAL*:

TITLE: DEPARTMENT:

INSTITUTION*: ACCOUNT NUMBER, if known:

ADDRESS*:

CITY*: STATE*: PHONE*:

POSTAL CODE*: COUNTRY*:

EMAIL:

***Mandatory Field**

3. Return acknowledgement to sender

DISTRIBUTORS: PLEASE POPULATE THE EMAIL AND FAX FIELDS BELOW WITH YOUR CONTACT INFORMATION TO FACILITATE RETURN OF CUSTOMER COMPLETED FORM TO YOU

Email	
Fax	
Deadline for returning this form	Please complete and return this form within **10 business days** of receipt