URGENT FIELD SAFETY NOTICE R003/26

Oxalate Reagent B - Product Code: 591-2

Oxalate Kit – Product Code 591-D

19th August 2026

Dear Customer,

Trinity Biotech is notifying you of a quality issue relating to Oxalate Reagent B Lot 2500711 and Oxalate Kit Lot 2502503 containing this reagent lot. Our records indicate that you may have received one or more of these affected products.

Following investigation of a product performance issue affecting the identified lot, Trinity Biotech is issuing this Field Safety Notice for affected product.

Device	Unique Device Identifier (UDI)	Product Code	Affected Serial or lot number range
Oxalate Reagent B	05391516742191	591-2	2500711
Oxalate Kit	05391516742245	591-D	2502503

Please review this notice carefully and complete the actions outlined below.

Background:

Oxalate Reagent B is a component of the Oxalate kit 591-C/-D. Trinity Biotech Oxalate reagents are for the quantitative, enzymatic determination of oxalate in urine at 590 nm.

The Oxalate assay works by the enzymatic method described below. It is based on the oxidation of oxalate by oxalate oxidase followed by measurement of hydrogen peroxide (H2O2) produced during the reaction by a peroxidase-catalyzed reaction. The procedure is specific for oxalate.

Trinity Biotech has determined that Oxalate Reagent B Lot 2500711 exhibits performance variability outside established acceptance criteria when compared with previously approved reagent lots. Investigation of the affected lot identified vial-to-vial variability that may lead to a negative bias and under-recovery of oxalate results.

Testing has confirmed that the issue is confined to Oxalate Reagent B Lot 2500711 and Oxalate Kit Lot 2502503 containing this reagent lot. The assessment of all other currently marketed Oxalate Reagent B lots indicate they continue to meet performance specifications.

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Trinity Biotech Manufacturing Limited
Registered in Ireland. Registration number 239206
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Accordingly, Trinity Biotech is implementing this Field Safety Notice and will replace all affected product (Oxalate Reagent B Lot 2500711 and Oxalate Kit Lot 2502503) remaining within the distribution chain.

An investigation into the root cause of this issue has been initiated and any corrective and/or preventive actions will be implemented as appropriate to prevent the recurrence of this issue.

Clinical Impact:

Performance variability identified within Oxalate Reagent B Lot 2500711, between individual vials, may result in a negative bias and the underestimation of elevated oxalate concentrations. The performance variability reported was identified when results were compared to previous lots of Oxalate Reagent B.

Users should evaluate the need for retrospective review of previously reported results based on their laboratory's established procedures, risk assessment, and applicable local requirements.

Actions to be taken by the Manufacturer

- Trinity Biotech is replacing Oxalate Reagent B Lot 2500711 and Oxalate Kit Lot 2502503 containing this reagent lot. Affected customers are being notified and requested to identify and segregate existing stock. Replacement product will be supplied, and appropriate corrective and preventative actions are being implemented to address the issue.

Actions to be taken by the customer/end user

- Immediately identify and segregate all inventory of Oxalate Reagent B Lot 2500711 and Oxalate Kit Lot 2502503 containing Oxalate Reagent B Lot 2500711. Dispose of the affected inventory in accordance with your facility's established procedures.
- Complete and return the Customer Reply Form, confirm current stock levels of affected product.
- Acknowledgement of this notice is required. Please review, complete, sign and return the attached Customer Reply Form in accordance with the directions on the form (accompanying this notification).
- Please ensure all employees in your facility or those contracted by your facility are made aware of this notification and the recommended actions.
- Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Trinity Biotech confirms that the Competent (Regulatory) Authority of your country has been informed about this communication.

Patient safety is our highest priority. As such, we are committed to transparent communication to ensure that you have timely, relevant information for managing your testing programme.

If you have any questions or concerns regarding this notification, please contact your local representative.

Sincerely,

S.Bevan

Sharon Bevan
Vice President Quality Assurance & Regulatory Affairs

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02. R003-26 Oxalate FSN Customer letter

Final Audit Report 2026-08-19

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