FIELD SAFETY NOTICE (FSN)

Correction to EGFR Variant Coverage and Limit of Detection

1. FSN Reference
FSN No.: 101398
Date: 2026-04-30
Affected Product: ctDNA EGFR Mutation Analysis Kit (CTEGFR-48)
Affected Lots: All

2. Attention
This notice is addressed to all users of the ctDNA EGFR Mutation Analysis Kit, including laboratory personnel, clinicians, and distributors.

3. Description of the Issue
EntroGen has identified, through post-market surveillance and internal verification, that the EGFR exon 19 deletion variant c.2254_2277del (p.Ser752_Ile759del) is not reliably detected by the assay.

Further verification identified one additional variant c.2253_2276del24 (p.Ser752_Ile759del) in the same sequence region that is not reliably detected, and one variant c.2252_2276delinsA (p.T751_I759delinsN) for which the limit of detection (LOD) is higher than previously documented.

4. Risk to Patient / User
Failure to detect affected variants may result in a false negative result, which could impact clinical decision-making, including potential exclusion from appropriate targeted therapy.
The risk is limited to the specific variants described above. No broader impact on other EGFR variants has been identified.

The affected variants are of low prevalence within the tested population; however, when present, failure to detect these variants may result in a false negative outcome and impact clinical decision-making.

5. Actions Taken by the Manufacturer
- Removal of affected variants from the list of reported detectable mutations
- Revision of the LOD for the affected variant

- Update of the Instructions for Use (IFU) and associated documentation to reflect accurate performance characteristics

6. Actions Required by the Customer

- Review this notice carefully
- Discontinue reliance on detection of the affected variants listed above
- Ensure that all relevant personnel are informed of this update
- Replace existing IFU documentation with the updated version upon availability

7. Distribution of This Notice

Please ensure that this Field Safety Notice is distributed to all relevant personnel within your organization and any organizations to which the product has been supplied.

8. Contact Information

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9. Acknowledgement of Receipt

Please confirm receipt of this notice by replying to this email (sent to support@entrogen.com).

We apologize for any inconvenience caused and appreciate your cooperation in ensuring patient safety and proper use of our products.

EntroGen, Inc.