Thermo Fisher Scientific
Frederick manufacturing Facility
7335 Executive Way
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www.thermofisher.com

URGENT FIELD SAFETY NOTICE:
Oncomine™ Dx Express Test Panel

Product Name	Catalog Number	UDI	Lot Number	Expiration Date
Oncomine™ Dx Express Test Panel	A50871	(01)10190302017305(17)230619(10)2558058	2558058	19-Jun-23
		(01)10190302017305(17)240730(10)2652678	2652678	30-Jul-24
		(01)10190302017305(17)240730(10)2727921	2727921	30-Jul-24
		(01)10190302017305(17)250630(10)2887516	2887516	30-Jun-25
		(01)10190302017305(17)260430(10)2976520	2976520	30-Apr-26
		(01)10190302017305(17)250830(10)3089734	3089734	30-Aug-25
		(01)10190302017305(17)261030(10)3108423	3108423	30-Oct-26
		(01)10190302017305(17)250830(10)3089736	3089736	30-Aug-25
		(01)10190302017305(17)270530(10)3283776	3283776	30-May-27
		(01)10190302017305(17)261130(10)3155329	3155329	30-Nov-26
		(01)10190302017305(17)230330(10)2468955	2468955	30-Mar-23
		(01)10190302017305(17)260530(10)3335701US	3335701US	30-May-26

Date: 22 MAY 2026

Institution: BIOMARKETING SERVICES (M) SDN

Dear Valued Customer:

We are writing to inform you of a Field Safety Corrective Action related to the Oncomine™ Dx Express Test Panel, (SKU A50871). This issue impacts all distributed lots (see table above for affected lot details). The panel kit is utilized in the workflow of the Oncomine™ Dx Express Test.

Reason for the Field Safety Corrective Action:
During internal testing, we determined that the Oncomine™ Dx Express Test Panel may have reduced sensitivity for detecting the FGFR3 c.746C>G p.S249C (COSM715) variant when present in a sample at low variant allelic frequencies (VAFs). This is likely due to a sequence-related effect that can inhibit amplification of the mutant allele, which may result in false-negative results for this specific variant when present at low VAFs. This limitation is most relevant for bladder cancer samples, where the FGFR3 p.S249C mutation is more prevalent.

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Device Intended Use:
The Ion Torrent Oncomine® Dx Express Test (ODxET) is a qualitative in vitro diagnostic test that utilizes targeted next-generation sequencing (NGS) technology to detect deletions, insertions, and substitutions from cfTNA extracted from plasma samples or from DNA and RNA extracted from formalin-fixed, paraffin-embedded (FFPE) tumor tissue samples. ODxET is performed using the Ion Torrent Genexus Dx System.

ODxET is intended to provide clinically relevant tumor mutation profiling information to be used by qualified healthcare professionals in accordance with professional guidelines, as an aid in therapy management of cancer patients with solid malignant neoplasms. Please note that it is not conclusive or prescriptive for the labeled use of any specific therapeutic product.

Actions Required:

- Review all prior patient results generated using the affected panel lots and assess the potential impact on reported results, specifically related to the risk of false-negative results of the FGFR3 c.746C>G (p.S249C) variant.

- Complete and return the attached Customer Response Sheet. Please ensure all relevant personnel within your organization are informed of this Field Safety Corrective Action. If affected product has been distributed outside your facility, promptly notify those recipients.

Recommendations:

- Increase tumor content in FFPE samples where feasible, particularly for bladder cancer specimens.

- Consider confirmatory or orthogonal testing for FGFR3 p.S249C, particularly for bladder cancer samples where results generated using the Oncomine™ Dx Express Test are negative.

We have conducted an internal investigation and are implementing corrective actions to prevent the recurrence of this issue.

We apologize for any inconvenience caused and appreciate your cooperation. If you have any technical questions or concerns, please contact our Technical Support at 800-955-6288 (option 4) or via email at techsupport@thermofisher.com

Sincerely,


Electronically signed by: Kelly Mitchell-Haloskey
Reason: Author of the GxP document
Date: May 22, 2026 14:58:24 EDT

Kelly Mitchell-Haloskey
Sr. Manager, Quality
Life Sciences Solutions
Thermo Fisher Scientific

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FIELD SAFETY CORRECTIVE ACTION CUSTOMER RESPONSE SHEET
Acknowledgement and Receipt Form
(Customer response is required)

Product Name	Catalog Number	Lot Number	Number of Units Remaining in Inventory

Customer Name and Address:

_____

_____

I have read and understand the instructions provided in the letter dated 22 MAY 2026 ☐YES ☐ NO

Any adverse events associated with impacted product? ☐YES ☐ NO

If yes, please explain:

I have shipped this lot to other facilities:	☐ YES	☐ NO
If "YES," I have notified those facilities of this FSCA:	☐ YES	☐ NO
If "YES," describe the method of notification:		
Number of customers/facilities notified:		
Date notified:		

Customer Signature of Receipt: _____ Date: _____

Submit the sheet by emailing a scanned copy to techsupport@thermofisher.com and Kelly.mitchell-haloskey@thermofisher.com

For any technical questions or concerns please contact our Technical Support at 1-800-955-6288 or via email at techsupport@thermofisher.com

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