Thermo Fisher Scientific
Frederick manufacturing Facility
7335 Executive Way
Frederick, MD, 21704
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URGENT: Field Safety Notice

Product Name	UDI	Catalog Number	Lot Number	Expiration Date
Oncomine® Dx Express Test Panel	(01)10190302017305(17) 250630(10)2887516	A50871	2887516	06/30/2025
Oncomine® Dx Express Test Panel	(01)10190302017305(17) 240730(10)2727921	A50871	2727921	07/30/2024
Oncomine® Dx Express Test Panel	(01)10190302017305(17) 240730(10)2652678	A50871	2652678	07/30/2024
Oncomine® Dx Express Test Panel	(01)10190302017305(17) 230619(10)2558058	A50871	2558058	07/30/2023
Oncomine® Dx Express Test Panel	(01)10190302017305(17) 230330(10)2468955	A50871	2468955	03/30/2023

Date: XX JUN 2024

Customer Name
Device Name
Street Address
City, State, Zip Code

Subject: Field Safety Corrective Action - Oncomine® Dx Express Test Panel (CE-IVD)

We are writing to inform you of an issue related to the Oncomine® Dx Express Test Panel (CE-IVD), finished good A50871. This issue impacts all distributed lots (see table above with lot details). The panel kit is utilized in the workflow of the Ion Torrent Oncomine® Dx Express Test.

Reason for Corrective Action: During our internal testing, it was discovered that the current ODxET Panel lacks sufficient coverage for five RET SNVs (listed below) on one of the RET amplicons. These SNV variants are listed in Appendix B of the product's instructions for use (IFU) as variants detected by the assay. Due to a panel primer design issue, these five variants cannot be effectively detected. This can result in false negative calls on these variants.

Please note that the primer design issue does not affect any other RET variants listed in the IFU. This notification specifically pertains to the five variants mentioned below.

Gene	AA change	Nucleotide Change	Variant ID
RET	p.E921K	c.2761G>A	COSM20889
RET	p.S922P	c.2764T>C	COSM26636
RET	p.M918L	c.2752A>C	COSM5945760
RET	p.M918T	c.2753T>C	COSM965
RET	p.M918V	c.2752A>G	OM3420

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

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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.

Action Required:

- We kindly request that you review all previous analyses of patient samples considering that these listed RET variants will likely not have been covered and assess the impact accordingly.

- We ask that you determine if your current inventory of the panel kit can still be used in your workflow considering the removal of the affected 5 RET SNVs. Please note that the primer design issue does not affect any other RET variants listed in the IFU. This notification specifically pertains to the five variants mentioned above.

- If you decide not to use the impacted kits, we request that you dispose of all affected units in accordance with the instructions provided in the safety data sheets (if applicable) and all relevant laws and regulations.

- To facilitate the corrective action process, please complete the attached Customer Response Sheet and return it to us. Additionally, it is essential that you notify all affected users within your facility. If you have shipped any of the affected lots to external customers or facilities, you must promptly inform them of this Field Safety Corrective Action.

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. You may request your replacement by sending an email to: EMEA.Complaints.LSG@thermofisher.com or by calling: 00 800 5345 5345 option 1.

Thank you for your prompt attention to this matter.

Sincerely,

Kelly M Haloskey
Sr. Manager, Quality
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 <enter date>. ☐YES ☐ NO

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

If yes, please explain:

I confirm the following:	☐ Continued use of the impacted lots currently in our inventory; We have confirmed the design issue will not affect our workflow
	☐ Remaining inventory will be discarded; Credit my account
	☐ No request

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 EMEA.Complaints.LSG@thermofisher.com and LSGFRD-QualitySystems@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

Ship-To Order Number: «Order Number»

Thermo Fisher Scientific Reference Number: PR 796743