invivoscribe®
Improving Lives with Precision Diagnostics®
+1 858.224.6600 Fax +1 858.224.6601
support@invivoscribe.com

Urgent Field Safety Notice

LymphoTrack® Dx *IGH* FR1/2/3 Assay Panel – MiSeq™ and LymphoTrack Dx *IGH* FR3 Assay Panel – MiSeq
Field Safety Corrective Action (FSCA)-identifier: 3014173060-07-18-23-003-C
Field Safety Corrective Action (FSCA): Device Destruction

Date: 2023 August 18

Attention: Invivoscribe Customers

Details on affected devices:
A nonconformity was discovered in a specific lot of raw material used to formulate *IGH* FR3 master mixes, provided with both the LymphoTrack Dx *IGH* FR1/2/3 Assay Panel – MiSeq (Catalog #: 91210139) and the LymphoTrack Dx *IGH* FR3 Assay Panel – MiSeq (Catalog #: 91210119), rendering the *IGH* FR3 VH4 primer non-functional. A full list of impacted products, including specific lot numbers is detailed in the table below.

Catalog Number	Description	Lot Number	Product web page	Impacted Reagent Part Number	Impacted Reagent Description	Impacted Reagent Lot Number
91210119	LymphoTrack Dx *IGH* FR3 Assay Panel - MiSeq	P0002310 P0002475 010551 010802	https://catalog.invivoscribe.com/product/lymphotrack-dx-igh-fr3-assay-panel-miseq/	21210929CE	IGH FR3 MiSeq 22	P0000150
				21210939CE	IGH FR3 MiSeq 23	P0000152
				21210949CE	IGH FR3 MiSeq 25	P0000154
				21210959CE	IGH FR3 MiSeq 27	P0000156
91210139	LymphoTrack Dx *IGH* FR1/2/3 Assay Panel - MiSeq	P0001051 P0001052 011324	https://catalog.invivoscribe.com/product/lymphotrack-dx-igh-fr1-2-3-assay-panel-miseq/	21210929CE	IGH FR3 MiSeq 22	P0000150
				21210939CE	IGH FR3 MiSeq 23	P0000152
				21210949CE	IGH FR3 MiSeq 25	P0000154
				21210959CE	IGH FR3 MiSeq 27	P0000156

Description of the problem:
The impacted master mix lots, when used to amplify clinical samples, will not produce amplification of the VH4 region. In the event of a clonal *IGH* FR3 VH4 region, the lack of *IGH* FR3 VH4 region amplification due to the defective primer would result in non-detection. This non-detection could result in a false negative result if the clonal event is not detected by the other frameworks.

However, if the impacted framework 3 products were used per the products' instructions for use and reported in the context of all 3 frameworks, the non-functioning *IGH* FR3 VH4 primer would likely not alter the clonality result since *IGH* FR1 and *IGH* FR2 master mixes would be expected to capture and detect the missing *IGH* FR3 VH4 rearrangements in almost all cases.

The *IGH* FR1 and *IGH* FR2 master mixes contain primers located upstream of the VH4 region in *IGH* FR3, which would be likely to identify a clonal sequence in the VH4 region. Thus, the VH4 rearrangements that are missed by the impacted *IGH* FR3 master mixes can still be detected by *IGH* FR1 and or *IGH* FR2 master mixes. As indicated in the table above, 4 of the 24 *IGH* FR3 master mixes included with the kit (indices 22, 23, 25 and 27) contain the nonconforming material.

Please note if the end-users were to only test specimen with the impacted LymphoTrack Dx *IGH* FR3 Assay Panel – MiSeq or only with the *IGH* FR3 reagents included with the impacted LymphoTrack Dx *IGH* FR1/2/3 Assay Panel – MiSeq, *IGH* VH4 rearrangements would not be detected.

+1 858.224.6600 Fax +1 858.224.6601
support@invivoscribe.com

This oligo defect does not impact any other rearrangement type; all other rearrangement types would still be detected as expected.

Advise on action to be taken by the user:
Please complete the attached Filed Action Form and email to support@invivoscribe.com within 7 days. This form requires the following actions :

- confirm receipt of the Field Safety Notice.
- confirm the Field Safety Notice was provided to all affected parties
- discontinue use and destroy any remaining defective material
- provide confirmation that all remaining defective product was destroyed
- determine whether any adverse events occurred due to this product defect
- indicate whether replacement product(s) are requested

Transmission of this Field Safety Notice:
This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Contact reference person:
James Thom
Invivoscribe, Inc.
10222 Barnes Canyon Road
Building 1
San Diego, CA 92121 USA
support@invivoscribe.com

The undersigned confirms that this notice has been provided to the appropriate Regulatory Agencies.

Invivoscribe is committed to providing our customers with the highest quality product possible and is taking corrective actions to prevent recurrence. We sincerely regret any inconvenience this may cause. If you require additional assistance or have any questions, please contact our support team at support@invivoscribe.com. We thank you for being a loyal customer.

James Thom
Manager, Quality Assurance