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Urgent Field Safety Notice

LymphoTrack® Dx *IGH* FR3 Assay Kit A – MiSeq™ (Catalog #: 91210109)
LymphoTrack® Dx *IGH* FR3 Assay Panel – MiSeq™ (Catalog #: 91210119)
LymphoTrack® Dx *IGH* FR1/2/3 Assay Kit A – MiSeq™ (Catalog #: 91210129)
LymphoTrack® Dx *IGH* FR1/2/3 Assay Panel – MiSeq™ (Catalog #: 91210139)

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, rendering the *IGH* FR3 VH7 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
91210109	LymphoTrack Dx *IGH* FR3 Assay Kit A - MiSeq	P0000888 P0001257 P0002263	https://catalog.invivoscribe.com/product/lymphotrack-dx-igh-fr3-assay-kit-a-miseq/	21210739CE	IGH FR3 MiSeq 02	N0001376
				21210749CE	IGH FR3 MiSeq 03	N0001378
				21210759CE	IGH FR3 MiSeq 04	N0001380
				21210769CE	IGH FR3 MiSeq 05	N0001382
				21210779CE	IGH FR3 MiSeq 06	N0001384
				21210789CE	IGH FR3 MiSeq 07	N0001386
				21210799CE	IGH FR3 MiSeq 08	N0001388
91210119	LymphoTrack Dx *IGH* FR3 Assay Panel - MiSeq	P0000096 P0000889 P0001013 P0001884 P0001961	https://catalog.invivoscribe.com/product/lymphotrack-dx-igh-fr3-assay-panel-miseq/	21210739CE	IGH FR3 MiSeq 02	N0001376
				21210749CE	IGH FR3 MiSeq 03	N0001378
				21210759CE	IGH FR3 MiSeq 04	N0001380
				21210769CE	IGH FR3 MiSeq 05	N0001382
				21210779CE	IGH FR3 MiSeq 06	N0001384
				21210789CE	IGH FR3 MiSeq 07	N0001386
				21210799CE	IGH FR3 MiSeq 08	N0001388
				21210809CE	IGH FR3 MiSeq 09	N0001390
				21210819CE	IGH FR3 MiSeq 10	N0001392
				21210829CE	IGH FR3 MiSeq 11	N0001394
				21210839CE	IGH FR3 MiSeq 12	N0001396

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Catalog Number	Description	Lot Number	Product web page	Impacted Reagent Part Number	Impacted Reagent Description	Impacted Reagent Lot Number
91210129	LymphoTrack Dx *IGH* FR1/2/3 Assay Kit A - MiSeq	P0000091 P0000935 P0001551 P0002078 P0002246	https://catalog.invivoscribe.com/product/lymphotrack-dx-igh-fr1-2-3-assay-kit-a-miseq/	21210739CE	IGH FR3 MiSeq 02	N0001376
				21210749CE	IGH FR3 MiSeq 03	N0001378
				21210759CE	IGH FR3 MiSeq 04	N0001380
				21210769CE	IGH FR3 MiSeq 05	N0001382
				21210779CE	IGH FR3 MiSeq 06	N0001384
				21210789CE	IGH FR3 MiSeq 07	N0001386
				21210799CE	IGH FR3 MiSeq 08	N0001388
91210139	LymphoTrack Dx *IGH* FR1/2/3 Assay Panel - MiSeq	N0001993 P0000220 P0000908 P0001111	https://catalog.invivoscribe.com/product/lymphotrack-dx-igh-fr1-2-3-assay-panel-miseq/	21210739CE	IGH FR3 MiSeq 02	N0001376
				21210749CE	IGH FR3 MiSeq 03	N0001378
				21210759CE	IGH FR3 MiSeq 04	N0001380
				21210769CE	IGH FR3 MiSeq 05	N0001382
				21210779CE	IGH FR3 MiSeq 06	N0001384
				21210789CE	IGH FR3 MiSeq 07	N0001386
				21210799CE	IGH FR3 MiSeq 08	N0001388
				21210809CE	IGH FR3 MiSeq 09	N0001390
				21210819CE	IGH FR3 MiSeq 10	N0001392
				21210829CE	IGH FR3 MiSeq 11	N0001394
				21210839CE	IGH FR3 MiSeq 12	N0001396

Description of the problem:

The impacted master mix lots, when used to amplify clinical samples, will not produce amplification of the VH7 region. In the event of a clonal *IGH* FR3 VH7 region, the lack of *IGH* FR3 VH7 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 (FR3) products were used per the products' instructions for use and reported in the context of all 3 frameworks, the non-functioning *IGH* FR3 VH7 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 VH7 rearrangements in almost all cases.

The *IGH* FR1 and *IGH* FR2 master mixes contain primers located upstream of the VH7 region in *IGH* FR3, which would be likely to identify a clonal sequence in the VH7 region. Thus, the VH7 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, *IGH* FR3 master mixes included with the kit contain the nonconforming material.

Please note if the end-users were to only test specimen with the impacted LymphoTrack Dx *IGH* FR3 Assay – MiSeq or only with the *IGH* FR3 reagents included with the impacted LymphoTrack Dx *IGH* FR1/2/3 Assay – MiSeq, *IGH* VH7 rearrangements would not be detected.

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

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Advise on action to be taken by the user:
Please complete the attached Field Action Form and email your distributor within 7 days. This form requires the following actions :

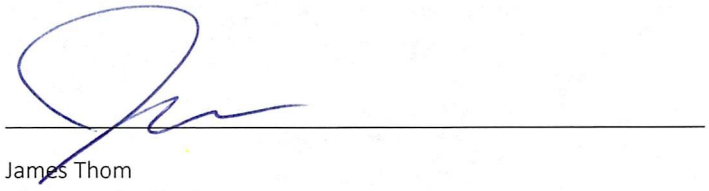
- confirm receipt of the Field Safety Notice.
- confirm the Field Safety Notice was provided to all affected parties
- discontinue use and destroy any remaining defective material
- provide confirmation that all remaining defective product was destroyed
- determine whether any adverse events occurred 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