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Urgent Field Safety Notice

LymphoTrack® Dx *IGHV* Leader Somatic Hypermutation Assay Kit A – MiSeq™ (Catalog #: 91210059)
LymphoTrack® Dx *IGHV* Leader Somatic Hypermutation Assay Panel – MiSeq™ (Catalog #: 91210069)
LymphoTrack® Dx *TRG* Assay Panel – MiSeq™ (Catalog #: 92270009)
Field Safety Corrective Action (FSCA)-identifier: FAA-001
Field Safety Corrective Action (FSCA): Device Destruction

Date: 2024 May 16

Attention: Invivoscribe Customers

Details on Affected Devices:

LymphoTrack Dx *IGHV* Leader Somatic Hypermutation Assays – MiSeq
A nonconformity was discovered in specific lots of the LymphoTrack Dx *IGHV* Leader Somatic Hypermutation Assay Kit A – MiSeq (Catalog #: 91210059) and LymphoTrack Dx *IGHV* Leader Somatic Hypermutation Assay Panel – MiSeq (Catalog #: 91210069) resulting in impaired detection of VH3 clonal rearrangements present in samples amplified with the *IGH* Leader MiSeq Index 08 Master Mix. This nonconformity also renders these products unable to detect VH5 rearrangements in samples amplified with the *IGH* Leader MiSeq Index 12. The impacted *IGH* Leader Index 08 and Index 12 Master Mixes will not produce the expected amplification of the VH3 and VH5 regions, respectively. In the event of a clonal rearrangement in the VH3 and/or VH5 region, the lack of VH3 and/or VH5 region amplification would result in non-detection. All other rearrangement types would still be detected as expected.

LymphoTrack Dx *TRG* Assay Panel - MiSeq
A nonconformity was discovered in specific lots of the LymphoTrack Dx *TRG* Assay Panel – MiSeq (Catalog #: 92270009), rendering the product unable to detect Vg9 clonal rearrangements present in samples amplified with the *TRG* MiSeq Index 13 Master Mix provided within the LymphoTrack Dx *TRG* Assay Panel – MiSeq (Catalog #: 92270009). The impacted master mix lots will not produce amplification of the Vg9 region. In the event of a clonal *TRG* rearrangement in the Vg9 region, the lack of *TRG* Vg9 region amplification would result in non-detection. All other rearrangement types would still be detected as expected.

Description of the Problem:

LymphoTrack Dx *IGHV* Leader Somatic Hypermutation Assays – MiSeq
The LymphoTrack Dx *IGHV* Leader Somatic Hypermutation Assays contain multiple primers in the VH3 region of the *IGH* locus. However, the *IGH* Leader MiSeq Index 08 Master Mix (Component Part #: 21210319CE, Lot #: N0000437) is missing one VH3 primer which significantly contributes to the identification of clonal VH3 sequences. Similarly, the impacted *IGH* Leader MiSeq Index 12 Master Mix (Component Part #: 21210359CE, Lot #: 011418) is missing one primer located in the VH5 region of the *IGH* locus which would likely be required for the identification of a clonal VH5 sequence. As indicated in Table 1.0, only the *IGH* Leader Indices 08 and/or 12 Master Mixes are affected; the other *IGH* Leader MiSeq Master Mixes included with the kit will detect VH3 and VH5 rearrangements. A false result from a non-detected VH3 and/or VH5 rearrangement could result in an adverse event if the false result impacted patient treatment decisions.

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LymphoTrack Dx *TRG* Assay Panel – MiSeq

The impacted *TRG* MiSeq Index 13 Master Mix lot (Component Part #: 22270139CE, Lot #: 010179), when used to amplify clinical samples, will not produce amplification for the Vg9 region, resulting in non-detection of a clonal rearrangement present in the *TRG* Vg9 region. As indicated in Table 1.0, only *TRG* MiSeq 13 master mix is affected; the other 23 *TRG* MiSeq master mixes included with the kit will detect Vg9 rearrangements. The false result from a non-detected Vg9 clonal rearrangement could result in an adverse event if the false result impacted patient treatment decision.

Table 1.0 Impacted products

Catalog #	Product Description	Kit Lot Number	Master Mix Part Number	Master Mix Description	Master Mix Lot Number
91210059	LymphoTrack Dx *IGHV* Leader Somatic Hypermutation Assay Kit A - MiSeq	N0000647 N0000870	21210319CE	*IGH* Leader MiSeq 08	N0000437
91210069	LymphoTrack Dx *IGHV* Leader Somatic Hypermutation Assay Panel - MiSeq	N0000646 N0000813	21210319CE	*IGH* Leader MiSeq 08	N0000437
		013445 013901 014890 015054	21210359CE	*IGH* Leader MiSeq 12	011418
92270009	LymphoTrack Dx *TRG* Assay Panel - MiSeq	012343 013204 013631	22270139CE	*TRG* MiSeq 13	010179

Required Actions:

Please complete the attached Field Action Form and email to your distributor or support@invivoscribe.com within 5 business days.

This form requires the following actions:

- Confirm receipt of this Field Safety Notice.
- Disseminate the Field Safety Notice to affected parties.
- Discontinue use and destroy any remaining defective:
  - *IGH* Leader SHM MiSeq Index 08 Master Mixes.
  - *IGH* Leader SHM MiSeq Index 12 Master Mixes.
  - *TRG* MiSeq 13 Master Mixes
- Provide confirmation that all remaining defective products were destroyed along with any request for replacement product(s).
- Inform Invivoscribe of any known false negative results from non-detected Vg9, VH3 and/or VH5 clonal rearrangements. Retesting residual clinical sample against a different Master Mix may be performed, if necessary

Please note, all other Master Mix components provided with the impacted assays are not affected and may continue to be used.

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Transmission of this Field Safety Notice:

This notice needs to be provided to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred. Please maintain awareness of 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 Technical Support team at support@invivoscribe.com. We thank you for being a loyal customer.

James Thom
Manager, Quality Assurance

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Field Action Form

Customer

Organization _____ Date _____

Country _____

Please confirm receipt of the Field Safety Notice.
☐ Received ☐ Not Received

Please confirm the Field Safety Notice was provided to all affected parties.
☐ Yes ☐ No

Was all remaining defective product destroyed?
☐ Yes ☐ No

How many LymphoTrack Dx *IGHV* Leader Somatic Hypermutation Assay Kit A - MiSeq (Catalog #: 91210059) or LymphoTrack Dx *IGHV* Leader Somatic Hypermutation Assay Panel - MiSeq kits (Catalog #: 91210069) did you receive?

How many patients were tested with the impacted *IGH* MiSeq Index 08 Master Mix?

How many patients were tested with the impacted *IGH* MiSeq Index 12 Master Mix?

How many LymphoTrack Dx *TRG* Assay Panel – MiSeq (Catalog #: 92270009) kits did you receive?

How many patients were tested with the impacted *TRG* MiSeq Index 13 Master Mix?

Are you aware of any adverse events due to this product defect? (i.e., Are you aware of any specific incidents where results of impacted product have negatively impacted patient management?)
☐ Yes ☐ No

Is replacement product requested?
☐ Yes ☐ No

Within 5 business days, please email a completed copy of this form to your distributor or if you are a direct customer of Invivoscribe please email this form to support@invivoscribe.com.