



TITLE: FIELD SAFETY NOTICE TEMPLATE
RESPONSIBLE DEPARTMENT: RAQS MANAGEMENT
STATUS: CURRENT

DOCUMENT No. F-GP010-002
ISSUED: 10TH NOV 2017
VERSION: 2

Urgent Field Safety Notice

Commercial name of the affected product: Holotype HLA 24/11 - Configuration A1 & CE v2
FSCA-identifier (e.g. date): QMS-449
Type of action: advice of action to be taken by the user

Date: 22nd Nov 2019

Attention: to whom it may concern

Details on affected devices:

reference number: H-62
Lot number: 0000404953
Number of product: 15



DK_Shipments.xlsx

Description of the problem:

A manufacturing oversight was recently identified by our Quality Department relating to the incorrect expiration date being indicated on our product label. This may result in expired product being used.

Using an expired product may contribute to increased ambiguities caused by incorrect fragment sizes. This can be easily detected by checking the QC metrics of the genotyping result in the software, HLA Twin, which are flagged for the user.

This has no consequences on the health of patients, but it may cause a slight delay in treatment management and inconvenience for the user.

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Advise on corrective actions to be taken by the user:

Check the listed products in the attachment and identify whether any of these were used or not. If any were used, identify the date when they were used. Take the necessary actions based on the following options:

1. If the laboratory has used the listed products after the corrected expiry, you may have experienced the effects described above. Please contact Omixon through the email to support@omixon.com discuss how we can compensate for any inconveniences caused.
2. If the laboratory has used listed products before the corrected expiry, you have no action to take.
3. If the laboratory has not used listed products and the corrected expiry is after 31th Dec 2019, the product will be used before the corrected expiry.
4. If the laboratory has not used listed products and the corrected expiry is before 31th Dec 2019, Omixon will send replacement parts immediately.

Please notify Omixon via support@omixon.com about your actions taken in order to handle replacement of the affected products and/or compensation.

Please acknowledge upon receipt that you are aware of the content of this Field Safety Notice by sending back attached 'Acknowledgement of FSN_QMS_449' document completed, signed and dated.

Transmission of this Field Safety Notice: (if appropriate)

This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred. Please transfer this notice to other organizations on which this action has an impact.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Contact reference person:

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Peter Meintjes
CEO
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1117 Budapest
Hungary
support@omixon.com

The undersigned confirms that this notice has been notified the appropriate Regulatory Agency.

Signature

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