Omixon Biocomputing Ltd.
1117 Budapest
Fehérvári út 50-52.
Hungary
Web: **www.omixon.com**

Urgent Field Safety Notice

Commercial name of the affected products:

REF no.	Product name	Primer lot
H52.1	Holotype HLA 24/7 - Configuration A1 & CE v2	**P5.1/013**

FSCA-identifier (e.g. date): QMS-340
Type of action: Preventative advice given by the manufacturer regarding the use of the device

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Date: 7th May, 2019

Attention: to whom it may concern

As a responsible vendor selling RUO products in North America and CE-IVD products in Europe, Omixon would like to make all of our customers aware of a recent observation from our customers that occurred five times, classified as a Class III Major Complaint under the Omixon's Quality Management System. This Complaint concerns the experience of caps being loose on any one of the primer reagent tubes in the Primer Component box of Holotype HLA. The loose caps may or may not result in a possible decreased reagent volume in the affected tubes. The loose caps can be easily identified upon receipt of product by visual inspection.

Details on affected device:

REF no.	Product name	Primer lot
H52.1	Holotype HLA 24/7 - Configuration A1 & CE v2	**P5.1/013**

Description of the problem:

A small number of caps have been reported of being loose on any one of the primer reagent tubes in the Primer Component box of Holotype HLA. The loose caps may or may not result in a possible decreased reagent volume in the affected tubes. Upon further investigation at Omixon's manufacturing site, the frequency of the issue was identified at approximately 10% and corrective measures have been taken to eliminate it immediately for all future LOT numbers.

It is a degradation of the product characteristics (lower volume might be in primer tube as stated on label) which has no health consequence on the patients, but it may cause a slight delay in treatment and inconvenience.

Advice on action to be taken by the user:

Should you experience the above described problem, please notify your Omixon sales representative in order to issue a replacement of the affected component boxes.

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Please aknowledge upon receipt that you are aware of the content of this Field Safety Notice by sending back attached 'Acknowledgement of FSN_QMS_340' document filled, signed and dated.

Transmission of this Field Safety Notice:

This notice should be communicated to all who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

Please communicate this notice to other organisations on which this action has an impact.

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

Contact reference person:

Peter Meintjes
CEO
Omixon Biocomputing Ltd
Fehérvári út 50-52.
1117 Budapest
Hungary
support@omixon.com

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

Signature