OMIXON BIOCOMPUTING LTD.
H-1117 BUDAPEST, KAPOSVÁR UTCA 14-18.

Urgent Field Safety Notice

Manufacturer: Omixon Biocomputing Ltd
SRN: HU-MF-000003018
Commercial name of the affected product: Holotype HLA assay kit configurations

Basic UDI-DI/EUDAMED DI Code	Devices	Device Model	Device Name	Risk class	Date	State
B-05999565780128	1	H23	Holotype HLA 96/5 - Configuration A & CE v2	IVD Annex II List B	2023-07-11	Registered
B-05999565780104	1	H24	Holotype HLA 96/5 - Configuration B & CE v2	IVD Annex II List B	2023-07-11	Registered
B-05999565780777	1	H26	Holotype HLA 96/5 - Configuration C & CE v2	IVD Annex II List B	2023-07-11	Registered
B-05999565780678	1	H32.1	Holotype HLA 96/7 – Configuration A & CE v2	IVD Annex II List B	2023-07-11	Registered
B-05999565780036	1	H34.1	Holotype HLA 96/7 - Configuration B & CE v2	IVD Annex II List B	2023-07-11	Registered
B-05999565780012	1	H38	Holotype HLA 96/7 - Configuration C & CE v2	IVD Annex II List B	2023-07-11	Registered
B-05999565780265	1	H52.1	Holotype HLA 24/7 - Configuration A1 & CE v2	IVD Annex II List B	2023-07-11	Registered
B-05999565780241	1	H56	Holotype HLA 24/7 - Configuration A2 & CE v2	IVD Annex II List B	2023-07-11	Registered
B-05999565780227	1	H58	Holotype HLA 24/7 - Configuration A3 & CE v2	IVD Annex II List B	2023-07-11	Registered
B-05999565780203	1	H60	Holotype HLA 24/7 - Configuration A4 & CE v2	IVD Annex II List B	2023-07-11	Registered
B-05999565780401	1	H62	Holotype HLA 24/11 - Configuration A1 & CE v2	IVD Annex II List B	2023-07-11	Registered
B-05999565780388	1	H64	Holotype HLA 24/11 - Configuration A2 & CE v2	IVD Annex II List B	2023-07-11	Registered
B-05999565780364	1	H66	Holotype HLA 24/11 - Configuration A3 & CE v2	IVD Annex II List B	2023-07-11	Registered
B-05999565780340	1	H68	Holotype HLA 24/11 - Configuration A4 & CE v2	IVD Annex II List B	2023-07-11	Registered
B-05999565780173	1	H72	Holotype HLA 96/11 - Configuration A & CE v2	IVD Annex II List B	2023-07-11	Registered
B-05999565780142	1	H76	Holotype HLA 96/11 - Configuration B & CE v2	IVD Annex II List B	2023-07-11	Registered
B-05999565780791	1	H78	Holotype HLA 96/11 - Configuration C & CE v2	IVD Annex II List B	2023-07-11	Registered

used with Promega GoTaq 2X Long PCR Master Mix which is an accessory

UDI: see screenshot above for Holotype HLA assay kit
FSCA-identifier (e.g. date): QMS-960/974
Type of action:
Preventive advice was given by the manufacturer due to amplification errors reported by our users.

Date: 31th July 2024

Attention: to whom it may concern

Details on affected devices:

Promega GoTaq 2X Long PCR Master Mix (PN: AX676A) lot 581844.

Description of the problem:

Our customers have reported amplification errors when using our Holotype HLA products with a specific lot 581844 of Promega GoTaq 2X Long PCR Master Mix (PN: AX676A), the reagent used as an accessory for the amplification step of Holotype HLA protocol.

This amplification error can have a negative impact on performance in several ways: customers have observed lower PCR yields, random PCR failures of single or multiple loci, and an increased rate of DRB4 failures independent of the Holotype kit lots. Investigation has shown that the problem occurs randomly within lot 581844 and appears to be a storage issue.

QMS-974 risk
Potential failure mode/hazard: missing results for one or more loci
Potential effect of failure mode/primary hazard: delay in reporting results
Possible causes of failure: most probably Promega enzyme performance
Detection methods: amplicon quantitation, gel electrophoresis
Severity: 5
Occurrence: 4
Detectability: 4
RPN: 80 which is above the risk acceptability threshold (50)

QMS-960 risk
Potential failure mode/hazard: increased dropout rate for DRB4 locus
Potential effect of failure mode/primary hazard: increased incorrect result reported
Possible causes of failure: most probably Promega enzyme performance
Detection methods: LD (linkage disequilibrium) feature in the Omixon HLA TWIN sw
Severity: 6
Occurrence: 3
Detectability: 4
RPN: 72 which is above the risk acceptability threshold (50)

Advise on action to be taken by the user:

Until you receive a replacement product from a different lot, we strongly recommend testing each individual Promega tube to confirm that it is performing as intended. Any failed tubes should be reported to Omixon immediately so that we can arrange for replacement of used Promega and Primer tubes.

Transmission of this Field Safety Notice:

This notice must be distributed to all those who need to know within your organization or to any organization to which the potentially affected devices have been transferred. (If appropriate)

Please distribute this notice to other organizations affected by this action. (If appropriate)

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

Please acknowledge upon receipt that you are aware of the content of this Field Safety Notice by sending a response email to support@omixon.com

Contact reference person:

Dr. Attila Bérces
CEO

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

Signature