

Urgent Field Safety Notice

Olerup SSP HLA A typing kits:

A*01 Lots: 41V, 35X, 83Y

A*24 Add-on Lot 32Y

May 04 ; 2016

Type of action: Advice by manufacturer – review of previous results

Attention: Update of interpretation tables Olerup SSP A*01 and A*24 Add-on typing kits.

Details on affected devices:

In listed product/lots the kit of A*01, the A*01:04N allele is not amplified by primer-mix 5 as stated in product documentation. This concerns the following products: A*01 Lots: 41V, 35X, 83Y

The primer causing the false negative reaction is also present in the kit A*24 Add-on Lot 32Y.

Description of the problem:

The false negative amplification for the A*01 kit yields a revised reactivity pattern for the A*01:04N allele that is identical to A*01:01 alleles. The false negative amplification in the kit A*24 add-on creates a kit that cannot separate the A*24:11N from the A*24:02:01G alleles¹⁾.

Advise on action to be taken by the user:

Affected A*01 kits:

Review of interpretation of HLA-A typing results retrieved from the listed A*01 kits/lots to identify results that include A*01:01 alleles. Those typings should be re-typed to ensure correct HLA-type.

*Customers that have made typings using the affected A*01 kits yielding results that include A*01:01 alleles are asked to confirm numbers to Olerup and will be provided with the corresponding number of Olerup HLA-A*01 add-on kits for retyping. The A*01 add-on kit specifically resolve this HLA typing ambiguity i.e. separates the A*01 alleles from A*01:04N allele.*

Unused affected A*01 kits should be discarded.

*The customers who have unused affected A*01 tests/kits on the shelf, are asked to discard these and confirm numbers to Olerup SSP AB. The tests will be replaced with the corresponding number of updated A*01 kits.*

¹⁾ 24:02:01:01-24:11N, 24:13:01-24:13:02, 24:17-24:50, 24:54-24:56, 24:58-24:63, 24:66-24:91, 24:93, 24:95-24:113, 24:115-24:137, 24:139-24:187, 24:189-24:210, 24:212-24:221, 24:223-24:227, 24:229-24:290, 24:292-24:294Q

Affected A*24 add-on kit:

HLA-A typing results retrieved from the listed A*24 Add-on kit/lot should be re-typed to ensure correct HLA-type.

Unused affected A*24 add-on tests should be discarded.

*The customers should confirm number of discarded A*24 add-on tests Olerup SSP AB.*

*All distributed A*24 add-on tests will be replaced by the corresponding number of updated A*24 add-on kits.*

We kindly ask for confirmation of receipt and understanding of this information to be sent back to vigilance@olerup.com or your distributor. A form that can be used for this is attached.

Transmission of this Field Safety Notice:

This notice needs to be passed on all those who need to be aware within your organization or to any organization where the affected lots have been transferred.

Contact reference person: Daniel Malica
Head Quality Assurance
Olerup SSP AB
vigilance@olerup.com
Mobile:+46 73 9737888

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



Daniel Malica
Head Quality Assurance
Olerup SSP AB



Confirmation form

To:
Daniel Malica
Head Quality Assurance Olerup SSP AB
vigilance@olerup.com
Fax: +468-717 88 18

I hereby confirm that we have received and understood the **Field Safety Notice** issued for Olerup SSP

Olerup SSP HLA A- typing kits: A*01 Lots: 41V, 35X, 83Y
A*24 Add-on Lot 32Y

I furthermore confirm that the kits listed below had been scrapped and will not be used.

Confirmation of scrapped kits

Product A*01 / A*24 Add-on	Lot number 41V/35 X/ 83Y/32Y	Kit size 6/12/24	With/without Taq	Number of scrapped tests	Number of Add-on needed for retyping A*01 results

Name: _____

Signature: _____

Title: _____

Date: _____

Company: _____

Country: _____

Please note: To be returned by June 6, 2016