101.411-24/06 – including *Taq* polymerase 101.411-24/06u – without *Taq* polymerase

Lot No.: **59R** 

## Olerup SSP® HLA-A\*01

Product number: 101.411-24/06– including *Taq* pol.

101.411-24u/06u - without *Taq* pol.

Lot number: 59R

Expiry date: 2015-August-01

Number of tests: 24 test – Product No. 101.411-24

6 tests - Product No. 101.411-06

Number of wells per test: 48

### CHANGES COMPARED TO THE PREVIOUS HLA-A\*01 LOT (06N):

Well	5'-primer	3'-primer	rationale
7	-	-	Exchanged positive control primer pair.
9	Added	Added	Exchanged positive control primer pair,
			primer pair added for the A*01:103 allele.
17	-	Added	3'-primer added for the A*01:101 allele.
22	Added	Added	3'-primer added for the A*01:107 allele.
26	Added	Added	Primer pair added for the A*01:104 allele.
27	-	Added	3'-primer added for the A*01:109 allele.
28	Exchanged	Added	3'-primer added for the A*01:109 allele,
			exchanged 5'-primer for improved specificity
			of amplification.
29	-	Added	3'-primer added for the A*01:101 allele.
30	Exchanged	Added	3'-primer added for the A*01:100 allele,
			exchanged 5'-primer for improved specificity
			of amplification.
33	Exchanged	Exchanged	Exchanged primer pair for increased allelic
			resolution, exchanged positive control
			primer pair.
35	-	Added	3'-primer added for the A*01:100 allele.
39	Added	Added	Primer pair added for the A*01:113 allele.
40	Added	Added	Primer pair added for the A*01:113 allele.
43	-	Added	3'-primer added for the A*01:107 allele.
46	-	-	Exchanged positive control primer pair, for
			decreased tendencies of primer oligomer
			formation.

THE NUMBER OF WELLS is unchanged.

#### **ALLELE COVERAGE:**

A\*01:01 to A\*01:113, i.e. all the currently recognized HLA-A\*01 alleles, will be amplified by the primers in the HLA-A\*01 SSP kit; <a href="https://www.ebi.ac.uk/imgt/hla">www.ebi.ac.uk/imgt/hla</a>, 2012-July-12, release 3.9.0.



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The HLA-A\*01 kit enables separation of the confirmed HLA-A\*01 alleles as listed in the IMGT/HLA database<sup>1,2</sup>. An HLA allele is listed as confirmed by IMGT/HLA if it has been sequenced by more than a single laboratory or from multiple sources.

The HLA- A\*01 kit also enables identification of polymorphisms in exons outside of the region encoding the peptide binding domain and of null and alternatively expressed alleles.

The A\*01:27N and 01:103 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 9.

The A\*01:32 and 01:104 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 26.

The A\*01:47 and 01:49 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 35.

The A\*01:50 and 01:62 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 38.

The A\*01:53N and 01:54 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 36.

The A\*01:65 and 01:92 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 37.

The HLA-A\*01 subtyping kit cannot distinguish the silent mutations in the A\*01:01:01:01, 01:01:02-01:01:22, 01:01:24-01:01:31, 01:01:33-01:01:37 and 01:01:39-01:01:47 alleles or in the A\*01:69:01-01:69:02 alleles.

<sup>1</sup>This lot of the HLA-A\*01 subtyping kit cannot distinguish the A\*01:72 allele from the A\*01:01:01:01, 01:01:02-01:01:22, 01:01:24-01:01:31, 01:01:33-01:01:37, 01:01:39-01:01:47, 01:67-01:68, 01:70-01:71, 01:74-01:79, 01:82, 01:84-01:86, 01:88, 01:90-01:91, 01:93-01:94, 01:96-01:97, 01:99, 01:102, 01:105-01:106, 01:108 and 01:110-01:112 alleles.

<sup>2</sup>The A\*01:69:01-01:69:02 and the A\*03:18, 11:01:04, 11:08, 11:23, 11:44 and 11:94 alleles give rise to identical amplification patterns with the HLA-A\*01 primer set. These alleles can be distinguished by the HLA-A low resolution and/or the HLA-A\*03 and HLA-A\*11 kits.

#### RESOLUTION IN HLA-A\*01 HOMO- AND HETEROZYGOTES:

The A\*01:72 allele cannot be distinguished from the A\*01:01:01:01, 01:01:02-01:01:22, 01:01:24-01:01:31, 01:01:33-01:01:37, 01:01:39-01:01:47, 01:67-01:68, 01:70-01:71, 01:74-01:79, 01:82, 01:84-01:86, 01:88, 01:90-01:91, 01:93-01:94, 01:96-01:97, 01:99, 01:102, 01:105-01:106, 01:108 and 01:110-01:112 alleles. The A\*01:01,01:01, A\*01:01,01:02 and A\*01:02,01:02 genotypes give rise to unique amplification patterns with regard to other confirmed HLA-A\*01 alleles.

# INFLUENCE ON THE INTERPRETATION OF HLA-A\*01 SUBTYPINGS BY NON-HLA-A\*01 ALLELES:

None frequently occurring.

#### MODIFICATIONS MADE DUE TO COMMENTS FROM CUSTOMERS:

No comments received.

