

Olerup SSP® HLA-A*23

Product number:	101.421-06 – including <i>Taq</i> polymerase
Lot number:	71K
Expiry date:	2013-June-01
Number of tests:	6
Number of wells per test:	24
Storage - pre-aliquoted primers:	dark at -20°C
- PCR Master Mix:	-20°C
- Adhesive PCR seals	RT
- Product Insert	RT

This Product Description is only valid for Lot No. 71K.

CHANGES COMPARED TO THE PREVIOUS OLERUP SSP® HLA-A*23 LOT

The HLA-A*23 specificity and interpretation tables have been updated for the HLA-A alleles described since the previous *Olerup SSP®* HLA-A*23 lot was made (Lot No. 31G).

The amplification patterns for some rare HLA-A*23 alleles only differ by the length of the specific PCR products.

The primers of the wells detailed below have been exchanged, added or modified compared to the previous lot.

Well	5'-primer	3'-primer	rationale
3	-	Added	Primer added for the A*23:25 allele.
4	Added	Added	Primer pair added for the A*23:28 allele.
7	Added	Added	Primer pair added for the A*23:22 allele.
8	-	Added	Primer added for the A*23:26 allele.
10	-	Added	Primer added for the A*23:23 allele.
13	-	Added	Primers added for the A*23:24 and A*23:30 alleles.
15	Modified	Modified	Improved specificity of primer pair.
19	Added	Added	Primer pair added for the A*23:27 allele.
20	Added	Added	Primer pair added for the A*23:29 allele.
22	-	Added	Primer added for the A*23:31 allele.

Change in revision R01 compared to R00:

1. Primer mix 21 does not amplify the A*23:05 allele. Furthermore, for many A*23 alleles it is not known whether they are amplified by this primer mix due to lack of nucleotide sequence information. This has been changed in the specificity and amplification tables.

PRODUCT DESCRIPTION

HLA-A*23 SSP subtyping

CONTENT

The primer set contains 5'- and 3'-primers for identifying the A*23:01 to A*23:31 alleles.

PLATE LAYOUT

Each test consists of 24 PCR reactions in a 24 well cut PCR plate.

1	2	3	4	5	6	7	8
9	10	11	12	13	14	15	16
17	18	19	20	21	22	23	24

The 24 well cut PCR plate is marked with 'HLA-A*23' in silver/gray ink.

Well No. 1 is marked with the Lot Number '71K'.

A faint row of numbers is seen between wells 1 and 2 or wells 7 and 8 of the PCR trays. These stem from the manufacture of the trays, and should be disregarded.

The PCR plates are covered with a PCR-compatible foil.

Please note: When removing each 24 well PCR plate, make sure that the remaining plates stay covered. Use a scalpel or a similar instrument to carefully cut the foil between the plates.

INTERPRETATION

The interpretation of HLA-A*23 SSP subtypings will be influenced three A*01, fourteen A*02, two A*03, the A*11:21N, most A*24, the A*25:11, the A*26:16, the A*29:07, several A*30, two A*31, two A*32, two A*33 and four A*68 alleles when present on the other haplotype. In addition, the B*18:27 allele will be amplified by primer mixes 1, 3, 10, 14 and 15.

UNIQUELY IDENTIFIED ALLELES

All the HLA-A*23 alleles, i.e. **A*23:01 to A*23:31 alleles**, recognized by the HLA Nomenclature Committee in October 2010¹ will give rise to unique amplification patterns by the primers in the HLA-A*23 subtyping kit.

The HLA-A*23 subtyping kit cannot distinguish the A*23:01:01-23:01:05 alleles or the A*23:03:01-23:03:02 alleles.

The A*23:08N and 23:22 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 7.

The A*23:09 and 23:26 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 8.

The A*23:10 and 23:23 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 10.

The A*23:15 and 23:27 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 19.

The A*23:16 and 23:29 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 20.

Lot No.: **71K**

Lot-specific information

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The A*23:18 and 23:28 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 4.

The A*23:19Q and 23:31 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 22.

¹HLA-A alleles listed on the IMGT/HLA web page 2010-October-15, release 3.2.0, www.ebi.ac.uk/imgt/hla.

RESOLUTION IN HOMO- AND HETEROZYGOTES

A total of 36 alleles generate 24 amplification patterns that can be combined in 300 homozygous and heterozygous combinations. 156 of these genotypes do not give rise to unique amplification patterns. The different lengths of the specific PCR products were not considered in these calculations.

++++-----	-----	-++++-----	*23:03:01, *23:18 = *23:18, *23:25
+++-+-----	-----	-++++-----	*23:03:01, *23:06 = *23:06, *23:25
+++-----	-----	-++++-----	*23:03:01, *23:07N = *23:07N, *23:25
+++-----+	-----	-++++-----	*23:03:01, *23:08N = *23:08N, *23:25
+++-----+	-----	-++++-----	*23:03:01, *23:09 = *23:09, *23:25
+++-----	+-----	-++++-----	*23:03:01, *23:05 = *23:05, *23:25
+++-----	-+-----	-++++-----	*23:03:01, *23:10 = *23:10, *23:25
+++-----	---+-----	-++++-----	*23:03:01, *23:11N = *23:11N, *23:25
+++-----	----+-----	-++++-----	*23:03:01, *23:12 = *23:12, *23:25
+++-----	-----+	-++++-----	*23:02, *23:03:01 = *23:02, *23:25 = *23:03:01, *23:30 = *23:24, *23:25 = *23:25, *23:30
+++-----	-----++	-++++-----	*23:03:01, *23:14 = *23:14, *23:25
+++-----	-----	+-----	*23:03:01, *23:13 = *23:13, *23:25
+++-----	-----	-++++-----	*23:03:01, *23:15 = *23:15, *23:25
+++-----	-----	-++++-----	*23:03:01, *23:16 = *23:16, *23:25
+++-----	-----	-++++-----	*23:03:01, *23:19Q = *23:19Q, *23:25
+++-----	-----	-++++-----	*23:03:01, *23:20 = *23:20, *23:25
+++-----	-----	-++++-----	*23:03:01, *23:21 = *23:21, *23:25
+++-----	-----	-++++-----	*23:01:01, *23:03:01 = *23:01:01, *23:25 = *23:03:01, *23:17 = *23:03:01, *23:25 = *23:17, *23:25 = *23:25, *23:25
+++-----	-----+	-++++-----	*23:02, *23:18 = *23:18, *23:24 = *23:18, *23:30
+++-----	-----	-++++-----	*23:01:01, *23:18 = *23:17, *23:18 = *23:18, *23:18
+++-----	-----+	-++++-----	*23:02, *23:06 = *23:06, *23:24 = *23:06, *23:30
+++-----	-----	-++++-----	*23:01:01, *23:06 = *23:06, *23:06 = *23:06, *23:17
+++-----	-----+	-++++-----	*23:02, *23:07N = *23:07N, *23:24 = *23:07N, *23:30
+++-----	-----	-++++-----	*23:01:01, *23:07N = *23:07N, *23:07N = *23:07N, *23:17
+++-----	-----+	-++++-----	*23:02, *23:08N = *23:08N, *23:24 = *23:08N, *23:30
+++-----	-----	-++++-----	*23:01:01, *23:08N = *23:08N, *23:08N = *23:08N, *23:17
+++-----	-----+	-++++-----	*23:02, *23:09 = *23:09, *23:24 = *23:09, *23:30
+++-----	-----	-++++-----	*23:01:01, *23:09 = *23:09, *23:09 = *23:09, *23:17
+++-----	+-----	-++++-----	*23:02, *23:05 = *23:05, *23:24 = *23:05, *23:30
+++-----	+-----	-++++-----	*23:01:01, *23:05 = *23:05, *23:05 = *23:05, *23:17
+++-----	-+-----	-++++-----	*23:02, *23:10 = *23:10, *23:24 = *23:10, *23:30
+++-----	-+-----	-++++-----	*23:01:01, *23:10 = *23:10, *23:10 = *23:10, *23:17
+++-----	---+-----	-++++-----	*23:02, *23:11N = *23:11N, *23:24 = *23:11N, *23:30
+++-----	---+-----	-++++-----	*23:01:01, *23:11N = *23:11N, *23:11N = *23:11N, *23:17
+++-----	----++	-++++-----	*23:02, *23:12 = *23:12, *23:24 = *23:12, *23:30
+++-----	----+-----	-++++-----	*23:01:01, *23:12 = *23:12, *23:12 = *23:12, *23:17
+++-----	-----+	-++++-----	*23:02, *23:04 = *23:04, *23:24 = *23:04, *23:30
+++-----	-----+++	-++++-----	*23:02, *23:14 = *23:14, *23:24 = *23:14, *23:30
+++-----	-----+	+-----	*23:02, *23:13 = *23:13, *23:24 = *23:13, *23:30
+++-----	-----+	-++++-----	*23:02, *23:15 = *23:15, *23:24 = *23:15, *23:30

Lot No.: **71K**

Lot-specific information

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++-----	-----+---	-+---+---	*23:02, *23:16 = *23:16, *23:24 = *23:16, *23:30
++-----	-----+---	-+---+---	*23:02, *23:19Q = *23:19Q, *23:24 = *23:19Q, *23:30
++-----	-----+---	-+---+---	*23:02, *23:20 = *23:20, *23:24 = *23:20, *23:30
++-----	-----+---	-+---+---	*23:02, *23:21 = *23:21, *23:24 = *23:21, *23:30
++-----	-----+---	-+---+---	*23:01:01, *23:02 = *23:01:01, *23:24 = *23:01:01, *23:30 =
			*23:02, *23:17 = *23:02, *23:24 = *23:02, *23:30 = *23:17, *23:24
			= *23:17, *23:30 = *23:24, *23:30 = *23:30, *23:30
++-----	-----+---	-+---+---	*23:01:01, *23:04 = *23:04, *23:17
++-----	-----+---	-+---+---	*23:01:01, *23:14 = *23:14, *23:14 = *23:14, *23:17
++-----	-----+---	-+---+---	*23:01:01, *23:13 = *23:13, *23:13 = *23:13, *23:17
++-----	-----+---	-+---+---	*23:01:01, *23:15 = *23:15, *23:15 = *23:15, *23:17
++-----	-----+---	-+---+---	*23:01:01, *23:16 = *23:16, *23:16 = *23:16, *23:17
++-----	-----+---	-+---+---	*23:01:01, *23:19Q = *23:17, *23:19Q = *23:19Q, *23:19Q
++-----	-----+---	-+---+---	*23:01:01, *23:20 = *23:17, *23:20 = *23:20, *23:20
++-----	-----+---	-+---+---	*23:01:01, *23:21 = *23:17, *23:21 = *23:21, *23:21
++-----	-----+---	-+---+---	*23:01:01, *23:01:01 = *23:01:01, *23:17

*23:01:01 = *23:01:01-23:01:05
*23:03:01 = *23:03:01-23:03:02
*23:08N = *23:08N and 23:22
*23:09 = *23:09 and 23:26
*23:10 = *23:10 and 23:23
*23:15 = *23:15 and 23:27
*23:16 = *23:16 and 23:29
*23:18 = *23:18 and 23:28
*23:19Q = *23:19Q and 23:31

SPECIFICITY TABLE

HLA-A*23 SSP subtyping

Specificities and sizes of the PCR products of the 24 primer mixes used for HLA-A*23 SSP subtyping

Primer Mix	Size of spec. PCR product ¹	Size of control band ²	Amplified HLA-A*23 alleles ³	Other amplified HLA Class I alleles ⁴
1⁶	210 bp	800 bp	*23:01:01-23:01:05, 23:03:01-23:31	*02:17:01-02:17:02, 02:108, 02:110, 02:268, 24:13:01-24:13:02, 24:18, 24:24, 24:94, 29:07, 31:29, B*18:27
2	160 bp	1070 bp	*23:01:01-23:02, 23:05-23:31	*02:19, 02:36-02:37, 02:54, 02:255, 24:02:01:01-24:02:40, 24:04-24:09N, 24:11N, 24:13:01-24:15, 24:17, 24:19-24:20, 24:24-24:32, 24:34-24:64, 24:66-24:74, 24:76-24:93, 24:95-24:109, 24:111-24:124, 24:126-24:137, 24:139-24:155N, 33:19, 68:26, 68:65
3^{5,8}	125 bp, 270 bp	800 bp	*23:03:01-23:03:02, 23:25	*24:21:01, 29:07, 31:29, B*18:27
4^{5,9}	90 bp, 200 bp	1070 bp	*23:18, 23:28	*24:77
5	230 bp	800 bp	*23:06	*31:36
6	470 bp	1070 bp	*23:07N	*01:04N, 03:21N, 11:21N, 24:11N
7^{5,10}	95 bp, 205 bp	800 bp	*23:08N, 23:22	*02:82N
8^{7,11}	135 bp, 215 bp	1070 bp	*23:09, 23:26	*01:02, 01:20, 24:129
9	235 bp	1070 bp	*23:05	*24:25
10¹²	135 bp, 230 bp	800 bp	*23:10, 23:23	*24:10 ^w , 24:46, B*18:27
11	200 bp	800 bp	*23:11N	
12	190 bp	1070 bp	*23:12	*24:30, 24:42, 25:11, 32:08
13^{5,13}	90 bp, 210 bp	800 bp	*23:02, 23:24, 23:30	*24:06, 24:87, 24:138
14	245 bp	1070 bp	*23:04	*02:17:01-02:17:02, 02:108, 02:110, 02:268, 24:03:01-24:03:02, 24:10, 24:18, 24:22, 24:33, 24:94, 24:125, 24:138, 29:07, 31:29, B*18:27
15	210 bp	1070 bp	*23:14	*24:13:02, B*18:27
16¹⁴	175 bp, 205 bp	800 bp	*23:14	*02:17:01 ^w -02:17:02 ^w , 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, 24:139-24:155N, 26:16, 33:19, 68:45
17	225 bp	1070 bp	*23:13	*03:72, 24:07, 24:19, 24:24, 24:112, 24:131, 30:01:01-30:01:04, 30:11:01-30:11:02, 30:14L-30:20, 30:23-30:26, 30:30-30:31, 30:35-30:43, 68:45
18⁵	110 bp	1070 bp	*23:01:01-23:01:05, 23:02 ^w , 23:04-23:13, 23:14 ^w , 23:15-23:23, 23:25-23:31	*02:40, 02:51, 02:130, 24:24, 32:28, 33:32, 68:51 ^w
19^{5,15}	120 bp, 260 bp	800 bp	*23:15, 23:27	
20¹⁶	130 bp, 230 bp	800 bp	*23:16, 23:29	*24:128
21⁵	90 bp	800 bp	*23:01:01-23:01:05, 23:02 [?] -23:04 [?] , 23:06-23:07N, 23:08N [?] , 23:09, 23:10 [?] -23:16 [?] , 23:18 [?] -23:25 [?] , 23:26, 23:27 [?] -23:31 [?]	
22^{5,6,17}	90 bp, 290 bp	1070 bp	*23:19Q, 23:31	*24:17, 24:41, 24:62, 24:106, 29:07, 31:29
23⁷	170 bp	1070 bp	*23:20	
24	180 bp	800 bp	*23:21	

¹Alleles are assigned by the presence of specific PCR product(s). However, the sizes of the specific PCR products may be helpful in the interpretation of HLA-A*23 SSP typings.

When the primers in a primer mix can give rise to specific PCR products of more than one length this is indicated if the size difference is 20 base pairs or more. Size differences shorter than 20 base pairs are not given. For high resolution SSP kits the respective lengths of the specific PCR product(s) of the alleles amplified by these primer mixes are given.

Nonspecific amplifications, i.e. a ladder or a smear of bands, may sometimes be seen. GC-rich primers have a higher tendency of giving rise to nonspecific amplifications than other primers.

PCR fragments longer than the control bands may sometimes be observed. Such bands should be disregarded and do not influence the interpretation of the SSP typings.

PCR fragments migrating faster than the control bands, but slower than a 400 bp fragment may be seen in some gel read-outs. Such bands can be disregarded and do not influence the interpretation of the SSP typings.

Some primers may give rise to primer oligomer artifacts. Sometimes this phenomenon is an inherit feature of the primer pair(s) of a primer mix. More often it is due to other factors such as too low amount of DNA in the PCR reactions, taking too long time in setting up the PCR reactions, working at elevated room temperature or using thermal cyclers that are not pre-heated.

²The internal positive control primer pairs amplify segments of the human growth hormone gene. The two different control primer pairs give rise to either an internal positive control band of 1070 base pairs, for most

wells, or a band of 800 base pairs, for some wells.

Well number 1 contains the primer pair giving rise to the shorter, 800 bp, internal positive control band in order to help in the correct orientation of the HLA-A*23 subtyping.

In addition, wells number 3, 5, 7, 10, 11, 13, 16, 19 to 21 and 24 contain the primer pair giving rise to the shorter, 800 bp, internal positive control band in order to allow kit identification.

In the presence of a specific amplification the intensity of the control band often decreases.

³For several HLA-A alleles 1st or 4th exon nucleotide sequences are not available. In these instances it is not known whether some of the primers of the SSP sets are completely matched with the target sequences or not. We assume that unknown sequences in these regions are conserved within allelic groups.

The A*23:08N and 23:22 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 7.

The A*23:09 and 23:26 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 8.

The A*23:10 and 23:23 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 10.

The A*23:15 and 23:27 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 19.

The A*23:16 and 23:29 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 20.

The A*23:18 and 23:28 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 4.

The A*23:19Q and 23:31 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 22.

⁴Due to the sharing of sequence motifs between HLA-A alleles non-HLA-A*23 alleles will be amplified by primer mixes 1 to 10, 12 to 18, 20 and 22. In addition, the B*18:27 allele will be amplified by primer mixes 1, 3, 10, 14 and 15.

⁵Short specific PCR fragments are less intense and not as sharp as longer specific bands.

⁶Primer mixes 1 and 22 may yield less PCR product than the other A*23 primer mixes.

⁷Primer mix 8 and 23 may give rise to nonspecific amplifications.

⁸Primer mix 3: Specific PCR fragment of 125 bp in the A*23:03:01-23:03:02 and the A*24:21:01, 29:07 and 31:29 and the B*18:27 alleles. Specific PCR fragment of 270 bp in the A*23:25 allele.

⁹Primer mix 4: Specific PCR fragment of 90 bp in the A*23:18 and 23:28 and the A*24:77 alleles. Specific PCR fragment of 200 bp in the A*23:28 and the A*24:77 alleles.

¹⁰Primer mix 7: Specific PCR fragment of 95 bp in the A*23:08Nn and the A*02:82N alleles. Specific PCR fragment of 205 bp in the A*23:22 allele.

¹¹Primer mix 8: Specific PCR fragment of 135 bp in the A*23:26 allele. Specific PCR fragment of 215 bp in the A*23:09 and the A*01:02, 01:20 and 24:129 alleles.

¹²Primer mix 10: Specific PCR fragment of 135 bp in the A*23:23 and in the B*18:27 alleles. Specific PCR fragment of 230 bp in the A*23:10 and in the A*24:10^w and 24:46 alleles.

¹³Primer mix 13: Specific PCR fragment of 90 bp in the A*23:30 allele. Specific PCR fragment of 210 bp in the A*23:02 and 23:24 and in the A*24:06, 24:87 and 24:138 alleles.

¹⁴Primer mix 16: Specific PCR fragment of 175 bp in the A*23:14 and in the A*24:02:16, 24:06, 24:13:01-24:13:02, 24:18, 24:22, 24:54, 24:87, 24:107 and 24:133 alleles. Specific PCR fragment of 205 bp in the A*24:05, 24:24, 24:130, 26:16 and 68:45 alleles. Specific PCR fragment of 175 and 205 bp in the A*24:02:01:01-24:02:15, 24:02:17-24:04, 24:07-24:11N, 24:17, 24:19-24:21:02, 24:23, 24:25-24:50, 24:55-24:56, 24:58-24:63, 24:66-24:86N, 24:88-24:90N, 24:93, 24:95-24:106, 24:108-24:113, 24:131-24:132N, 24:115-24:129, 24:134-24:137, 24:139-24:155N and 33:19 alleles.

¹⁵Primer mix 19: Specific PCR fragment of 120 bp in the A*23:15 allele. Specific PCR fragment of 260 bp in the A*23:27 allele.

¹⁶Primer mix 20: Specific PCR fragment of 130 bp in the A*23:29 and in the A* 24:128 alleles. Specific PCR fragment of 230 bp in the A*23:16 allele.

¹⁷Primer mix 22: Specific PCR fragment of 90 bp in the A*23:31 and in the A*24:17, 24:41, 24:62, 24:106, 29:07 and 31:29 alleles. Specific PCR fragment of 290 bp in the A*23:19Q allele.

‘w’, may be weakly amplified.

‘?’, nucleotide sequence information not available for the primer matching sequence.

INTERPRETATION TABLE

HLA-A*23 SSP subtyping

Amplification patterns of the A*23:01 to A*23:31 alleles

	Well ¹¹											
	1	2	3	4	5	6	7	8	9	10	11	12
Length of spec.	210	160	125	90	230	470	95	135	235	135	200	190
PCR product(s)			270	200			205	215		230		
Length of int.	800	1070	800	1070	800	1070	800	1070	1070	800	800	1070
pos. control ¹												
5'-primer(s) ²	368	453	368	98	144	3 rd I	98	98	28	368	160	144
	5'-gTT ^{3'}	5'-AAA ^{3'}	5'-gTT ^{3'}	5'-CTC ^{3'}	5'-gCC ^{3'}	5'-ATA ^{3'}	5'-CTC ^{3'}	5'-CTC ^{3'}	5'-TCg ^{3'}	5'-gTT ^{3'}	5'-ACg ^{3'}	5'-gCC ^{3'}
				678			564					
				5'-AgA ^{3'}			5'-TgA ^{3'}					
3'-primer(s) ³	539	570	453	256	331	621	262	193	92	463	317	292
	5'-TCA ^{3'}	5'-CCg ^{3'}	5'-TCg ^{3'}	5'-CTg ^{3'}	5'-CTC ^{3'}	5'-ggg ^{3'}	5'-TgC ^{3'}	5'-CgA ^{3'}	5'-AAC ^{3'}	5'-gCT ^{3'}	5'-ggA ^{3'}	5'-gTg ^{3'}
			595	728			616	271		559		
			5'-CCg ^{3'}	5'-CCT ^{3'}			5'-CgT ^{3'}	5'-CAT ^{3'}		5'-CCg ^{3'}		
Well No.	1	2	3	4	5	6	7	8	9	10	11	12
HLA-A allele												
*23:01:01-23:01:05	1	2										
*23:02		2										
*23:03:01-23:03:02	1		3									
*23:04	1											
*23:05	1	2							9			
*23:06	1	2			5							
*23:07N	1	2				6						
*23:08N, 23:22 ⁴	1	2					7					
*23:09, 23:26 ⁵	1	2						8				
*23:10, 23:23 ⁶	1	2								10		
*23:11N	1	2									11	
*23:12	1	2										12
Well No.	1	2	3	4	5	6	7	8	9	10	11	12

INTERPRETATION TABLE

HLA-A*23 SSP subtyping

Amplification patterns of the A*23:01 to A*23:31 alleles

Well ¹¹												
13	14	15	16	17	18	19	20	21	22	23	24	
90	245	210	175	225	110	120	130	90	90	170	180	Length of spec.
210			205			260	230		290			PCR product(s)
800	1070	1070	800	1070	1070	800	800	800	1070	1070	800	Length of int.
												pos. control ¹
368	368	368	98	98	453	98	228	920	368	678	98	5'-primer(s) ²
5' -gTT 3'	5' -gTT 3'	5' -gTT 3'	5' -CTC 3'	5' -CTC 3'	5' -AAA 3'	5' -CTC 3'	5' -ATg 3'	5' -CCA 3'	5' -gTT 3'	5' -AgA 3'	5' -CTC 3'	
			368			493	379					
			5' -gTT 3'			5' -CTg 3'	5' -ACA 3'					
419	570	538	259	282	524	316	317	971	418	806	238	3'-primer(s) ³
5' -CgC 3'	5' -CAC 3'	5' -CAG 3'	5' -gTT 3'	5' -gAC 3'	5' -CAC 3'	5' -gAA 3'	5' -ggA 3'	5' -CAG 3'	5' -gTC 3'	5' -CTA 3'	5' -CCT 3'	
530			502	282		570	570		619			
5' -CCA 3'			5' -CTT 3'	5' -gAC 3'		5' -CCg 3'	5' -CCg 3'		5' -gTT 3'			
539			539									
5' -TCC 3'			5' -TCT 3'									
13	14	15	16	17	18	19	20	21	22	23	24	Well No.
												HLA-A allele
					18			21				*23:01:01-23:01:05
13					w			?				*23:02
								?				*23:03:01-23:03:02
	14				18			?				*23:04
					18							*23:05
					18			21				*23:06
					18			21				*23:07N
					18			?				*23:08N, 23:22 ⁴
					18			21				*23:09, 23:26 ⁵
					18			?				*23:10, 23:23 ⁶
					18			?				*23:11N
					18			?				*23:12
13	14	15	16	17	18	19	20	21	22	23	24	Well No.

Lot No.: **71K**

Lot-specific information

www.olerup-ssp.com

Length of spec.	210	160	125	90	230	470	95	135	235	135	200	190
PCR product(s)			270	200			205	215		230		
Well No.	1	2	3	4	5	6	7	8	9	10	11	12
*23:13	1	2										
*23:14	1	2										
*23:15, 23:27 ⁷	1	2										
*23:16, 23:29 ⁸	1	2										
*23:17	1	2										
*23:18, 23:28 ⁹	1	2		4								
*23:19Q, 23:31 ¹⁰	1	2										
*23:20	1	2										
*23:21	1	2										
*23:24	1	2										
*23:25	1	2	3									
*23:30	1	2										
*01:02, 01:20								8				
*01:04N, 03:21N, 11:21N						6						
*02:17:01-02:17:02	1											
*02:19, 02:36-02:37, 02:54, 02:255, 24:14-24:15, 24:51- 24:53, 24:57, 24:64, 24:92, 24:114, 68:26, 68:65		2										
*02:40, 02:51, 02:130, 32:28, 33:32												
*02:82N							7					
*02:108, 02:110, 02:268, 24:94	1											
*03:72, 30:01:01-30:01:04, 30:11:01-30:11:02, 30:14L- 30:20, 30:23-30:26, 30:30- 30:31, 30:35-30:43												
*24:02:01:01-24:02:40, 24:04- 24:05, 24:08-24:09N, 24:20, 24:26-24:29, 24:31-24:32, 24:34-24:40N, 24:43-24:45N, 24:47-24:50, 24:54-24:56, 24:58-24:61, 24:63, 24:66- 24:74, 24:76, 24:78-24:86N, 24:88-24:91, 24:93, 24:95- 24:105, 24:107-24:109, 24:111, 24:113, 24:115-24:124, 24:126- 24:127, 24:130, 24:132N- 24:137, 24:139-24:155N, 33:19		2										
Well No.	1	2	3	4	5	6	7	8	9	10	11	12

Lot No.: **71K**

Lot-specific information

www.olerup-ssp.com

90	245	210	175	225	110	120	130	90	90	170	180	Length of spec. PCR product(s)
210			205			260	230		290			Well No.
13	14	15	16	17	18	19	20	21	22	23	24	
				17	18			?				*23:13
		15	16		w			?				*23:14
					18	19		?				*23:15, 23:27 ⁷
					18		20	?				*23:16, 23:29 ⁸
					18							*23:17
					18			?				*23:18, 23:28 ⁹
					18			?	22			*23:19Q, 23:31 ¹⁰
					18			?		23		*23:20
					18			?			24	*23:21
13								?				*23:24
					18			?				*23:25
13					18			?				*23:30
												*01:02, 01:20
												*01:04N, 03:21N, 11:21N
	14		w									*02:17:01-02:17:02
												*02:19, 02:36-02:37, 02:54, 02:255, 24:14-24:15, 24:51- 24:53, 24:57, 24:64, 24:92, 24:114, 68:26, 68:65
					18							*02:40, 02:51, 02:130, 32:28, 33:32
												*02:82N
	14											*02:108, 02:110, 02:268, 24:94
					17							*03:72, 30:01:01-30:01:04, 30:11:01-30:11:02, 30:14L- 30:20, 30:23-30:26, 30:30- 30:31, 30:35-30:43
			16									*24:02:01:01-24:02:40, 24:04- 24:05, 24:08-24:09N, 24:20, 24:26-24:29, 24:31-24:32, 24:34-24:40N, 24:43-24:45N, 24:47-24:50, 24:54-24:56, 24:58-24:61, 24:63, 24:66- 24:74, 24:76, 24:78-24:86N, 24:88-24:91, 24:93, 24:95- 24:105, 24:107-24:109, 24:111, 24:113, 24:115-24:124, 24:126- 24:127, 24:130, 24:132N- 24:137, 24:139-24:155N, 33:19
13	14	15	16	17	18	19	20	21	22	23	24	Well No.

Lot No.: **71K**

Lot-specific information

www.olerup-ssp.com

Length of spec.	210	160	125	90	230	470	95	135	235	135	200	190
PCR product(s)			270	200			205	215		230		
Well No.	1	2	3	4	5	6	7	8	9	10	11	12
*24:03:01-24:03:02, 24:22, 24:33, 24:125												
*24:06, 24:87		2										
*24:07, 24:19, 24:112, 24:131		2										
*24:10										w		
*24:11N		2				6						
*24:13:01	1	2										
*24:13:02	1	2										
*24:17, 24:41, 24:62, 24:106		2										
*24:18	1											
*24:21:01			3									
*24:21:02, 24:23, 24:75, 24:110, 26:16												
*24:24	1	2										
*24:25		2							9			
*24:30, 24:42		2										12
*24:46		2								10		
*24:77		2		4								
*24:128		2										
*24:129		2						8				
*24:138												
*25:11, 32:08												12
*29:07, 31:29	1		3									
*31:36					5							
*68:45												
*68:51												
B*18:27	1		3							10		
Well No.	1	2	3	4	5	6	7	8	9	10	11	12

¹The internal positive control primer pairs amplify segments of the human growth hormone gene. The two different control primer pairs give rise to either an internal positive control band of 1070 base pairs, for most Wells, or a band of 800 base pairs, for some Wells.

Well number 1 contains the primer pair giving rise to the shorter, 800 bp, internal positive control band in order to help in the correct orientation of the HLA-A*23 subtyping. .

In addition, wells number 3, 5, 7, 10, 11, 13, 16, 19 to 21 and 24 contain the primer pair giving rise to the shorter, 800 bp, internal positive control band in order to allow kit identification.

²The nucleotide position, in the 1st, 2nd, 3rd or 4th exons or 3rd intron matching the specificity-determining 3'-end of the primer is given. Nucleotide numbering as on the www.ebi.ac.uk/imgt/hla web site. The sequence of the 3 terminal nucleotides of the primer is given.

³The nucleotide position, in the 2nd, 3rd or 4th exons, matching the specificity-determining 3'-end of the primer is given in the anti-sense direction. Nucleotide numbering as on the www.ebi.ac.uk/imgt/hla web site. The sequence of the 3 terminal nucleotides of the primer is given.

Lot No.: **71K**

Lot-specific information

www.olerup-ssp.com

90	245	210	175	225	110	120	130	90	90	170	180	Length of spec.
210			205			260	230		290			PCR product(s)
13	14	15	16	17	18	19	20	21	22	23	24	Well No.
	14		16									*24:03:01-24:03:02, 24:22, 24:33, 24:125
13			16									*24:06, 24:87
			16	17								*24:07, 24:19, 24:112, 24:131
	14		16									*24:10
			16									*24:11N
			16									*24:13:01
		15	16									*24:13:02
			16						22			*24:17, 24:41, 24:62, 24:106
	14		16									*24:18
			16									*24:21:01
			16									*24:21:02, 24:23, 24:75, 24:110, 26:16
			16	17	18							*24:24
			16									*24:25
			16									*24:30, 24:42
			16									*24:46
			16									*24:77
			16				20					*24:128
			16									*24:129
13	14											*24:138
												*25:11, 32:08
	14								22			*29:07, 31:29
												*31:36
			16	17								*68:45
					w							*68:51
	14	15										B*18:27
13	14	15	16	17	18	19	20	21	22	23	24	Well No.

⁴The A*23:08N and 23:22 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 7.

⁵The A*23:09 and 23:26 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 8.

⁶The A*23:10 and 23:23 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 10.

⁷The A*23:15 and 23:27 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 19.

⁸The A*23:16 and 23:29 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 20.

⁹The A*23:18 and 23:28 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 4.

¹⁰The A*23:19Q and 23:31 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 22.

Lot No.: **71K**

Lot-specific information

www.olerup-ssp.com

¹¹Primer mix 3: Specific PCR fragment of 125 bp in the A*23:03:01-23:03:02 and the A*24:21:01, 29:07 and 31:29 and the B*18:27 alleles. Specific PCR fragment of 270 bp in the A*23:25 allele.
Primer mix 4: Specific PCR fragment of 90 bp in the A*23:18 and 23:28 and the A*24:77 alleles.
Specific PCR fragment of 200 bp in the A*23:28 and the A*24:77 alleles.
Primer mix 7: Specific PCR fragment of 95 bp in the A*23:08Nn and the A*02:82N alleles. Specific PCR fragment of 205 bp in the A*23:22 allele.
Primer mix 8: Specific PCR fragment of 135 bp in the A*23:26 allele. Specific PCR fragment of 215 bp in the A*23:09 and the A*01:02, 01:20 and 24:129 alleles.
Primer mix 10: Specific PCR fragment of 135 bp in the A*23:23 and in the B*18:27 alleles. Specific PCR fragment of 230 bp in the A*23:10 and in the A*24:10^w and 24:46 alleles.
Primer mix 13: Specific PCR fragment of 90 bp in the A*23:30 allele. Specific PCR fragment of 210 bp in the A*23:02 and 23:24 and in the A*24:06, 24:87 and 24:138 alleles.
Primer mix 16: Specific PCR fragment of 175 bp in the A*23:14 and in the A*24:02:16, 24:06, 24:13:01-24:13:02, 24:18, 24:22, 24:54, 24:87, 24:107 and 24:133 alleles. Specific PCR fragment of 205 bp in the A*24:05, 24:24, 24:130, 26:16 and 68:45 alleles. Specific PCR fragment of 175 and 205 bp in the A*24:02:01:01-24:02:15, 24:02:17-24:04, 24:07-24:11N, 24:17, 24:19-24:21:02, 24:23, 24:25-24:50, 24:55-24:56, 24:58-24:63, 24:66-24:86N, 24:88-24:90N, 24:93, 24:95-24:106, 24:108-24:113, 24:131-24:132N, 24:115-24:129, 24:134-24:137, 24:139-24:155N and 33:19 alleles.
Primer mix 19: Specific PCR fragment of 120 bp in the A*23:15 allele. Specific PCR fragment of 260 bp in the A*23:27 allele.
Primer mix 20: Specific PCR fragment of 130 bp in the A*23:29 and in the A* 24:128 alleles. Specific PCR fragment of 230 bp in the A*23:16 allele.
Primer mix 22: Specific PCR fragment of 90 bp in the A*23:31 and in the A*24:17, 24:41, 24:62, 24:106, 29:07 and 31:29 alleles. Specific PCR fragment of 290 bp in the A*23:19Q allele.
'w', may be weakly amplified.
'?', nucleotide sequence information not available for the primer matching sequence.

CELL LINE VALIDATION SHEET																				
HLA-A*23 SSP subtyping kit																				
				Well																
				1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	
				Lot No.:	200853601	200853602	201079603	201079623	200853605	200853606	201079607	201079608	200853609	201079610	200853611	200853612	201079613	200853614	201079615	200853616
	IHWC cell line	A*	A*																	
1	9001 SA	*24:02		-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+
2	9280 LK707	*02:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
3	9011 E4181324	*01:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
4	9275 GU373	*30:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
5	9009 KAS011	*01:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
6	9353 SM	*02:01	*26:03	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
7	9020 QBL	*26:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
8	9025 DEU	*31:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
9	9026 YAR	*26:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
10	9107 LKT3	*24:02		-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+
11	9051 PITOUT	*29:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
12	9052 DBB	*02:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
13	9004 JESTHOM	*02:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
14	9071 OLGA	*31:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
15	9075 DKB	*24:02		-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+
16	9037 SWEIG007	*29:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
17	9282 CTM3953540	*03:01	*80:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
18	9257 32367	*33:03	*74:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
19	9038 BM16	*02:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
20	9059 SLE005	*02:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
21	9064 AMALA	*02:17		+	-	-	-	-	-	-	-	-	-	-	-	-	+	-	-	W
22	9056 KOSE	*02:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
23	9124 IHL	*02:01	*34:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
24	9035 JBUSH	*32:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
25	9049 IBW9	*33:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
26	9285 WT49	*02:05		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
27	9191 CH1007	*24:10	*29:01	-	-	-	-	-	-	-	-	-	W	-	-	-	+	-	+	-
28	9320 BEL5GB	*02:01	*29:02	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
29	9050 MOU	*29:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
30	9021 RSH	*30:01	*68:02	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
31	9019 DUCAF	*30:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
32	9297 HAG	*02:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
33	9098 MT14B	*31:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
34	9104 DHIF	*31:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
35	9302 SSTO	*32:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
36	9024 KT17	*02:06	*11:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
37	9065 HHKB	*03:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
38	9099 LZL	*02:17		+	-	-	-	-	-	-	-	-	-	-	-	-	+	-	-	W
39	9315 CML	*01:01	*03:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
40	9134 WHONP199	*02:07	*30:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
41	9055 H0301	*03:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
42	9066 TAB089	*02:07		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
43	9076 T7526	*02:06	*02:07	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
44	9057 TEM	*66:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
45	9239 SHJO	*23:01	*24:02	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+
46	9013 SCHU	*03:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
47	9045 TUBO	*02:16	*03:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
48	9303 TER-ND	*02:01	*11:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

CELL LINE VALIDATION SHEET											
HLA-A*23 SSP subtyping kit											
				Well							
				17	18	19	20	21	22	23	24
				201079617	200853618	201079619	201079620	200853621	201079622	201079623	200963924
			Lot No.:								
	IHWC cell line	A*	A*								
1	9001 SA	*24:02		-	-	-	-	-	-	-	-
2	9280 LK707	*02:01		-	-	-	-	-	-	-	-
3	9011 E4181324	*01:01		-	-	-	-	-	-	-	-
4	9275 GU373	*30:01		+	-	-	-	-	-	-	-
5	9009 KAS011	*01:01		-	-	-	-	-	-	-	-
6	9353 SM	*02:01	*26:03	-	-	-	-	-	-	-	-
7	9020 QBL	*26:01		-	-	-	-	-	-	-	-
8	9025 DEU	*31:01		-	-	-	-	-	-	-	-
9	9026 YAR	*26:01		-	-	-	-	-	-	-	-
10	9107 LKT3	*24:02		-	-	-	-	-	-	-	-
11	9051 PITOUT	*29:02		-	-	-	-	-	-	-	-
12	9052 DBB	*02:01		-	-	-	-	-	-	-	-
13	9004 JESTHOM	*02:01		-	-	-	-	-	-	-	-
14	9071 OLGA	*31:01		-	-	-	-	-	-	-	-
15	9075 DKB	*24:02		-	-	-	-	-	-	-	-
16	9037 SWEIG007	*29:02		-	-	-	-	-	-	-	-
17	9282 CTM3953540	*03:01	*80:01	-	-	-	-	-	-	-	-
18	9257 32367	*33:03	*74:01	-	-	-	-	-	-	-	-
19	9038 BM16	*02:01		-	-	-	-	-	-	-	-
20	9059 SLE005	*02:01		-	-	-	-	-	-	-	-
21	9064 AMALA	*02:17		-	-	-	-	-	-	-	-
22	9056 KOSE	*02:01		-	-	-	-	-	-	-	-
23	9124 IHL	*02:01	*34:01	-	-	-	-	-	-	-	-
24	9035 JBUSH	*32:01		-	-	-	-	-	-	-	-
25	9049 IBW9	*33:01		-	-	-	-	-	-	-	-
26	9285 WT49	*02:05		-	-	-	-	-	-	-	-
27	9191 CH1007	*24:10	*29:01	-	-	-	-	-	-	-	-
28	9320 BEL5GB	*02:01	*29:02	-	-	-	-	-	-	-	-
29	9050 MOU	*29:02		-	-	-	-	-	-	-	-
30	9021 RSH	*30:01	*68:02	+	-	-	-	-	-	-	-
31	9019 DUCAF	*30:02		-	-	-	-	-	-	-	-
32	9297 HAG	*02:01		-	-	-	-	-	-	-	-
33	9098 MT14B	*31:01		-	-	-	-	-	-	-	-
34	9104 DHIF	*31:01		-	-	-	-	-	-	-	-
35	9302 SSTO	*32:01		-	-	-	-	-	-	-	-
36	9024 KT17	*02:06	*11:01	-	-	-	-	-	-	-	-
37	9065 HHKB	*03:01		-	-	-	-	-	-	-	-
38	9099 LZL	*02:17		-	-	-	-	-	-	-	-
39	9315 CML	*01:01	*03:01	-	-	-	-	-	-	-	-
40	9134 WHONP199	*02:07	*30:01	+	-	-	-	-	-	-	-
41	9055 H0301	*03:01		-	-	-	-	-	-	-	-
42	9066 TAB089	*02:07		-	-	-	-	-	-	-	-
43	9076 T7526	*02:06	*02:07	-	-	-	-	-	-	-	-
44	9057 TEM	*66:01		-	-	-	-	-	-	-	-
45	9239 SHJO	*23:01	*24:02	-	+	-	-	+	-	-	-
46	9013 SCHU	*03:01		-	-	-	-	-	-	-	-
47	9045 TUBO	*02:16	*03:01	-	-	-	-	-	-	-	-
48	9303 TER-ND	*02:01	*11:01	-	-	-	-	-	-	-	-

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-A*23 SSP

Product number: 101.421-06 – including *Taq* polymerase
Lot number: 71K
Expiry date: 2013-June-01
Number of tests: 6
Number of wells per test: 24

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2008-536-01	9	2008-536-09	17	2010-796-17
2	2008-536-02	10	2010-796-10	18	2008-536-18
3	2010-796-03	11	2008-536-11	19	2010-796-19
4	2010-796-04	12	2008-536-12	20	2010-796-20
5	2008-536-05	13	2010-796-13	21	2008-536-21
6	2008-536-06	14	2008-536-14	22	2010-796-22
7	2010-796-07	15	2010-796-15	23	2010-796-23
8	2010-796-08	16	2008-536-16	24	2009-639-24

The specificity of each primer solution of the kit has been tested against 48 well characterized IHWC cell line DNAs.

No DNAs carrying the alleles to be amplified by primer solutions 3 to 5, 9, 11, 13, 15, 19, 20 and 23 to 24 were available. The specificities of the primers in primer solutions 3, 13, 15 and 19 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer. In primer solutions 4, 5, 9 and 23 to 24 it was only possible to test the 5'-primers, the 3'-primers were not possible to test. In primer solutions 11 and 20 it was only possible to test the 3'-primers, the 5'-primers was not possible to test. In primer solutions 3, 7, 8, 13, 19 and 22 one or two 3'-primers were not possible to test, and in primer solution 19 one 5'-primer was not possible to test. Additional primers in primer solutions 7, 10 and 16 were tested by separately adding one additional 5'-primer and/or one additional 3'-primer.

Results: No false positive or false negative amplifications were obtained.

Date of approval: 2011-January-21

Approved by:

Production Quality Control

Lot No.: **71K**

Lot-specific information

www.olerup-ssp.com

Declaration of Conformity

Product name: *Olerup* SSP® HLA-A*23
Product number: 101.421-06
Lot number: 71K

Intended use: HLA-A*23 high resolution histocompatibility testing

Manufacturer: *Olerup* SSP AB
Franzengatan 5
SE-112 51 Stockholm, Sweden
Phone: +46-8-717 88 27
Fax: +46-8-717 88 18

We, *Olerup* SSP AB, hereby declare that this product, to which this Declaration of Conformity relates is in conformity with the following Standard(s) and other normative document(s) ISO 9001:2008 and ISO 13485:2003, following the provisions of the 98/79/EC Directive on *in vitro* diagnostic medical devices, Annex II List B, conformity assessed using Annex IV, as transposed into the national laws of the Member States of the European Union.

The Technical Documentation File is maintained at *Olerup* SSP AB, Franzengatan 5, SE-112 51 Stockholm, Sweden.

Notified Body: Lloyd's Register Quality Assurance Limited, Hiramford, Middlemarch Office Village, Siskin Drive, Coventry CV3 4FJ, United Kingdom. (Notified Body number: 0088.)

Stockholm, Sweden
2012-August-20

Ann-Cathrin Jareman
Head of QA and Regulatory Affairs

Lot No.: **71K**

Lot-specific information

www.olerup-ssp.com

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