

Lot No.: **21G**

Lot-specific Information

Olerup SSP[®] HLA-A*01

Product number: 101.411-24u/06u– without *Taq* pol.
Lot number: 21G
Expiry date: 2011-September-01
Number of tests: 24 test – Product No. 101.411-24u
6 tests – Product No. 101.411-06u
Number of wells per test: 30
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. 21G.

CHANGES COMPARED TO THE PREVIOUS *OLERUP SSP*[®] HLA-A*01 Lot

The HLA-A*01 specificity and interpretation tables have been updated for the HLA-A alleles described since the previous *Olerup SSP*[®] HLA-A*01 lot was made (**Lot No. 94E**).

Three wells have been added to the HLA-A*01 kit,
wells **25 to 30**.

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

Well	5'-primer	3'-primer	rationale
24	-	Modified	Increased specificity of primer pair.
25	New	New	Primer pair added for the A*0131N allele.
26	New	New	Primer pair added for the A*0132 allele.
27	New	New	Primer pair added for the A*0133 allele.
28	New	New	Primer pair added for the A*0134N allele.
29	New	New	Primer pair added for the A*0135 allele.
30	New	New	Primer pair added for the A*0137 allele.

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PRODUCT DESCRIPTION

HLA-A*01 SSP subtyping

CONTENT

The primer set contains 5'- and 3'-primers for identifying the A*0101 to A*0137 alleles.

PLATE LAYOUT

Each test consists of 30 PCR reactions in a 32 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
25	26	27	28	29	30	empty	empty

The 32 well cut PCR plate is marked with 'HLA-A*01'.

Well No. 1 is marked with '21G' in silver/gray ink.

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 heat-sealed with a PCR-compatible foil.

Please note: When removing each 32 well PCR plate, make sure that the remaining plates stay sealed. Use a scalpel or a similar instrument to carefully cut the foil between the plates.

INTERPRETATION

The interpretation of HLA-A*01 SSP subtypings will be influenced by five A*02 alleles, the A*03 alleles, the A*11 alleles, the A*2307N allele, six A*24 alleles, the A*2632 allele, most A*30 alleles, two A*31 alleles, the A*3204 allele, the A*3313 allele, five A*34 alleles, the A*36, the A*7410 allele and the A*8001 allele when present on the other haplotype.

UNIQUELY IDENTIFIED ALLELES

All the HLA-A*01 allele¹, i.e. **A*0101 to A*0137**, recognized by the HLA Nomenclature Committee in July 2009¹ will give rise to unique amplification patterns by the primers in the HLA-A*01 subtyping kit.

The HLA-A*01 subtyping kit cannot distinguish the A*01010101, A*010102 to A*010105 alleles.

¹HLA-A alleles listed on the IMGT/HLA web page 2009-July-17, release 2.26.0, www.ebi.ac.uk/imgt/hla.

RESOLUTION IN HOMO- AND HETEROZYGOTES

The 35 HLA-A*01 alleles generate 36 amplification patterns that can be combined in 666 homozygous and heterozygous combinations. 258 of these genotypes do not give rise to unique amplification patterns. The different lengths of the specific PCR

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products generated by primer mixes 8, 10, 11, 16, 20 and 23 were not considered in these calculations.

+++-----+ ------ -+---+--- ------	0107,0120 = 0120,0123
+++-----+ ------ -+---+--- ------	0102,0107 = 0102,0123
+++-----+ +----- -+----- ------	0102,0108 = 0102,0127N
+++----- -+----- -+---+--- ------	0111N,0120 = 0120,0128
+++----- -+----- -+----- ------	0102,0111N = 0102,0128
++-+-----+ ------ -+----- ------	0103,0107 = 0103,0123
++-+----- -+----- -+----- ------	0103,0111N = 0103,0128
++-+-----+ ------ -+----- ------	0104N,0107 = 0104N,0123
++-+-----+ +----- -+----- ------	0104N,0108 = 0104N,0127N
++-+----- -+----- -+----- ------	0104N,0111N = 0104N,0128
++-+----- ------ -+----- ------	0101,0104N = 0104N,0104N
++-+-----+ ------ -+----- ------	0107,0109 = 0109,0123
++-+-----+ +----- -+----- ------	0108,0109 = 0109,0127N
++-+----- -+----- -+----- ------	0109,0111N = 0109,0128
++-+----- ------ -+----- ------	0101,0109 = 0109,0109
++-+-----+ ------ -+----- ------	0106,0107 = 0106,0123
++-+-----+ +----- -+----- ------	0106,0108 = 0106,0127N
++-+-----+ -+----- -+----- ------	0106,0111N = 0106,0128
++-+-----+ ------ -+----- ------	0101,0106 = 0106,0106
++-+-----+ +-----+ -+----- ------	01010102N,0108 =
	01010102N,0127N
++-+-----+ +----- -+----- ------	0107,0108 = 0107,0127N =
	0108,0123 = 0123,0127N
++-+-----+ -+----- -+---+--- ------	0107,0110 = 0110,0123
++-+-----+ -+----- -+----- ------	0107,0129 = 0123,0129
++-+-----+ -+-----+ -+----- ------	01010102N,0111N =
	01010102N,0128
++-+-----+ -+----- -+----- ------	0107,0111N = 0111N,0123 =
	0123,0128
++-+-----+ -----+--- -+---+---+ ------	0107,0119 = 0119,0123
++-+-----+ -----+--- -+-----+ ------	0107,0112 = 0112,0123
++-+-----+ -----+--- -+---+--- ------	0107,0121 = 0121,0123
++-+-----+ -----+--- -+----- ------	0107,0117 = 0117,0123
++-+-----+ -----+--- -+----- ------	0107,0114 = 0114,0123
++-+-----+ -----+--- -+----- ------	0101,01010102N =
	01010102N,01010102N =
	01010102N,0107 =
	01010102N,0115N =
	01010102N,0123 =
	0107,0115N = 0115N,0123
++-+-----+ ------ ++-+----- ------	0107,0116N = 0116N,0123
++-+-----+ ------ -+---+--- ------	0107,0130 = 0123,0130
++-+-----+ ------ -+---+--- ------	0107,0118N = 0118N,0123
++-+-----+ ------ -+---+--- ------	0107,0126 = 0123,0126
++-+-----+ ------ -+---+--- ------	0107,0122N = 0122N,0123
++-+-----+ ------ -+---+--- ------	0107,0124 = 0123,0124
++-+-----+ ------ -+---+--- ------	0107,0125 = 0123,0125
++-+-----+ ------ -+-----+ ------	0107,0131N = 0123,0131N
++-+-----+ ------ -+----- -+-----	0107,0132 = 0123,0132
++-+-----+ ------ -+----- -+-----	0107,0133 = 0123,0133

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++-----+ -+----- -+----- ----+--	0107,0134N = 0123,0134N
++-----+ -+----- -+----- ----+--	0107,0135 = 0123,0135
++-----+ -+----- -+----- ----+--	0107,0137 = 0123,0137
++-----+ -+----- -+----- ----+--	0101,0107 = 0101,0123 =
	0107,0123 = 0123,0123
++----- ++----- -+----- -+-----	0108,0110 = 0110,0127N
++----- ++----- -+----- -+-----	0108,0129 = 0127N,0129
++----- ++----- -+----- -+-----	0108,0113 = 0113,0127N
++----- ++----- -+----- -+-----	0108,0111N = 0108,0128 =
	0111N,0127N = 0127N,0128
++----- +-----+----- -+----- -+-----	0108,0121 = 0121,0127N
++----- +-----+----- -+----- -+-----	0108,0117 = 0117,0127N
++----- +-----+----- -+----- -+-----	0108,0115N = 0115N,0127N
++----- +-----+----- -+----- -+-----	0108,0116N = 0116N,0127N
++----- +-----+----- -+----- -+-----	0108,0130 = 0127N,0130
++----- +-----+----- -+----- -+-----	0108,0118N = 0118N,0127N
++----- +-----+----- -+----- -+-----	0108,0126 = 0126,0127N
++----- +-----+----- -+----- -+-----	0108,0122N = 0122N,0127N
++----- +-----+----- -+----- -+-----	0108,0124 = 0124,0127N
++----- +-----+----- -+----- -+-----	0108,0125 = 0125,0127N
++----- +-----+----- -+----- -+-----	0108,0131N = 0127N,0131N
++----- +-----+----- -+----- -+-----	0108,0132 = 0127N,0132
++----- +-----+----- -+----- -+-----	0108,0133 = 0127N,0133
++----- +-----+----- -+----- -+-----	0108,0134N = 0127N,0134N
++----- +-----+----- -+----- -+-----	0108,0135 = 0127N,0135
++----- +-----+----- -+----- -+-----	0108,0137 = 0127N,0137
++----- +-----+----- -+----- -+-----	0101,0108 = 0101,0127N =
	0108,0127N = 0127N,0127N
++----- -+----- -+----- -+-----	0110,0111N = 0110,0128
++----- -+----- -+----- -+-----	0111N,0129 = 0128,0129
++----- -+-----+----- -+-----+-----	0110,0112 = 0110,0119 =
	0119,0129
++----- -+-----+----- -+-----+-----	0110,0121 = 0121,0129
++----- -+-----+----- -+-----+-----	0101,0110 = 0110,0110 =
	0110,0126 = 0110,0129 =
	0126,0129
++----- -+-----+----- -+-----+-----	0101,0129 = 0129,0129
++----- -+-----+----- -+-----+-----	0111N,0119 = 0119,0128
++----- -+-----+----- -+-----+-----	0111N,0112 = 0112,0128
++----- -+-----+----- -+-----+-----	0111N,0121 = 0121,0128
++----- -+-----+----- -+-----+-----	0101,0113 = 0111N,0113 =
	0111N,0117 = 0113,0117 =
	0117,0128
++----- -+-----+----- -+-----+-----	0113,0113 = 0113,0128
++----- -+-----+----- -+-----+-----	0111N,0114 = 0114,0128
++----- -+-----+----- -+-----+-----	0111N,0115N = 0115N,0128
++----- -+-----+----- -+-----+-----	0111N,0116N = 0116N,0128
++----- -+-----+----- -+-----+-----	0111N,0130 = 0128,0130
++----- -+-----+----- -+-----+-----	0111N,0118N = 0118N,0128
++----- -+-----+----- -+-----+-----	0111N,0126 = 0126,0128
++----- -+-----+----- -+-----+-----	0111N,0122N = 0122N,0128
++----- -+-----+----- -+-----+-----	0111N,0124 = 0124,0128
++----- -+-----+----- -+-----+-----	0111N,0125 = 0125,0128

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++-----	--+-----	-+-----	+-----	0111N,0131N = 0128,0131N
++-----	--+-----	-+-----	-+-----	0111N,0132 = 0128,0132
++-----	--+-----	-+-----	--+---	0111N,0133 = 0128,0133
++-----	--+-----	-+-----	---+--	0111N,0134N = 0128,0134N
++-----	--+-----	-+-----	-----+	0111N,0135 = 0128,0135
++-----	--+-----	-+-----	-----+	0111N,0137 = 0128,0137
++-----	--+-----	-+-----	-----	0101,0111N = 0101,0128 =
++-----	-----+--	-+-----	-----	0111N,0111N = 0111N,0128
++-----	-----+--	-+-----	-----	0101,0119 = 0112,0121 =
++-----	-----+--	-+-----	-----	0112,0126 = 0119,0121 =
++-----	-----+--	-+-----	-----	0119,0125 = 0119,0126
++-----	-----+--	-+-----	-----	0101,0112 = 0112,0125
++-----	-----+--	-+-----	-----	0101,0121 = 0121,0121 =
++-----	-----+--	-+-----	-----	0121,0126
++-----	-----+--	-+-----	-----	0101,0117 = 0117,0117
++-----	-----+--	-+-----	-----	0101,0115N = 0115N,0115N
++-----	-----+--	-+-----	-----	0101,0116N = 0116N,0116N
++-----	-----+--	-+-----	-----	0101,0130 = 0118N,0124 =
++-----	-----+--	-+-----	-----	0118N,0130 = 0124,0130 =
++-----	-----+--	-+-----	-----	0130,0130
++-----	-----+--	-+-----	-----	0101,0118N = 0118N,0118N
++-----	-----+--	-+-----	-----	0101,0126 = 0126,0126
++-----	-----+--	-+-----	-----	0101,0122N = 0122N,0122N
++-----	-----+--	-+-----	-----	0101,0124 = 0124,0124
++-----	-----+--	-+-----	-----	0101,0125 = 0125,0125
++-----	-----+--	-+-----	+-----	0101,0131N = 0131N,0131N
++-----	-----+--	-+-----	-+-----	0101,0132 = 0132,0132
++-----	-----+--	-+-----	--+---	0101,0133 = 0133,0133
++-----	-----+--	-+-----	---+--	0101,0134N = 0134N,0134N
++-----	-----+--	-+-----	-----+	0101,0135 = 0135,0135
++-----	-----+--	-+-----	-----+	0101,0137 = 0137,0137
-+-----	-----+--	-+-----	-----	0112,0119 = 0114,0119 =
-+-----	-----+--	-+-----	-----	0119,0119
-+-----	-----+--	-+-----	-----	0112,0112 = 0112,0114

0101 = 01010101, 010102-010105

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SPECIFICITY TABLE

HLA-A*01 SSP subtyping

Specificities and sizes of the PCR products of the 30 primer mixes used for HLA-A*01 SSP subtyping

Primer Mix	Size of spec. PCR product ¹	Size of control band ²	Amplified HLA-A*01 alleles	Other amplified HLA-A alleles ³
1	235 bp	800 bp	*01010101-0102, 0104N, 0106, 0107, 0109-0111N, 0113, 0115N-0118N, 0121-0135, 0137	*0318, 110101-1103, 1105-1125, 1129-1134, 1136-1144, 3604
2⁴	145 bp	1070 bp	*01010101-010105, 0103, 0104N, 0106-0117, 0118N ^w , 0119, 0121-0123, 0124 ^w , 0125-0135, 0137	*3601-3604
3⁴	120 bp	800 bp	*0102, 0120	
4	305 bp	1070 bp	*0103	*1126, 2632, 3313, 3603, 7410
5	470 bp	1070 bp	*0104N	*0321N, 1121N, 2307N, 2411N
6	210 bp	1070 bp	*0109	
7	215 bp	800 bp	*0106	*0305, 0342, 112401-1125, 1131, 1135, 9256, 300101-3003, 3007-3016, 3018-3020, 3022-3027N, 3103, 3104, 3402-3404, 3407, 3408, 8001
8^{4,7}	110 bp, 180 bp	1070 bp	*01010102N, 0107, 0123	
9	235 bp	1070 bp	*0108, 0127N	
10⁸	155 bp, 270 bp	800 bp	*0110, 0129	*1114 ^w , 3026, 8001 ^w
11^{4,9}	135 bp, 275 bp	800 bp	*0111N, 0113, 0128	
12^{4,6}	85 bp	800 bp		*3601-3604

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13	205 bp	1070 bp	*0112, 0119, 0121	*0302, 0307 ^w , 0310, 0331, 0332, 0342 ^w , 1131 ^w , 1135 ^w , 9256 ^w , 2492, 3004 ^w , 3006 ^w , 3009 ^w , 3017 ^w , 3103 ^w , 3104 ^w
14⁴	120 bp	1070 bp	*0113, 0117	
15	235 bp	1070 bp	*0112, 0114, 0119	*03010101- 030105, 030107- 0317, 0319-0339, 0341-0347, 0350, 0351, 0355, 1104, 1127, 1135, 9256, 2492, 300101- 3004, 3006-3013, 3015-3020, 3022- 3027N, 3103, 3104, 3204, 3402- 3404, 3407, 3408, 3601, 3602
16^{5,10}	180 bp, 235 bp	1070 bp	*01010102N, 0115N	
17	210 bp	1070 bp	*0116N	
18⁴	135 bp	1070 bp	*01010101-0104N, 0106, 0108-0112, 0114-0127N, 0129-0135, 0137	*3601-3604
19⁵	170 bp	1070 bp	*0118N, 0130	*2422
20^{4,11}	65 bp, 425 bp	800 bp	*0110, 0119, 0121, 0126	
21	255 bp	1070 bp	*0120	*0219, 0236, 0237, 0254, 2414, 2493
22	590 bp	1070 bp	*0122N	
23^{5,12}	155 bp, 175 bp	1070 bp	*0124, 0130	*2422
24	215 bp	1070 bp	*0112, 0119, 0125	*0302, 0310, 0331, 0332, 110101- 110103, 110105- 1107, 1109-1122, 1127, 1129, 1130, 1132-1134, 1136- 1143, 2492
25⁴	90 bp	1070 bp	*0131N	
26	450 bp	1070 bp	*0132	

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27	160 bp	1070 bp	*0133	
28^{4,5}	95 bp	1070 bp	*0134N	*240203
29	155 bp	800 bp	*0135	
30	145 bp	1070 bp	*0137	

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*01 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 inherent 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*01 subtyping.

In addition, wells number 3, 7, 10 to 12, 20 and 29 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.

³Due to the sharing of sequence motifs between HLA-A alleles a few non-HLA-A*01 alleles will be amplified by primer mixes 1, 2, 4, 5, 7, 10, 12, 13, 15, 18, 19, 21, 23, 24 and 28.

⁴Short specific PCR fragments are less intense and not as sharp as longer specific bands.

⁵Primer mixes 16, 19, 23 and 28 may give rise to non-specific amplifications.

⁶Primer mix 12 might faintly amplify the A*0227, A*110101-110202, 1104-1107, 1109-1113, 1115-1119 and 1121N-1132 alleles.

⁷Primer mix 8: Specific PCR fragment of 110 bp in the A*0107 and 0123 alleles. Specific PCR fragment of 180 bp in the A*01010102N allele.

⁸Primer mix 10: Specific PCR fragment of 155 bp in the A*0110 and in the A*1114^w, 3026, 8001^w alleles. Specific PCR fragment of 270 bp in the A*0129 allele.

⁹Primer mix 11: Specific PCR fragment of 135 bp in the A*0113 and 0128 alleles. Specific PCR fragment of 275 bp in the A*0111N allele.

¹⁰Primer mix 16: Specific PCR fragment of 180 bp in the A*01010102N allele. Specific PCR fragment of 235 bp in the A*0115N allele.

¹¹Primer mix 20: Specific PCR fragment of 65 bp in the A*0110, A*0121 and A*0126 alleles. Specific PCR fragment of 425 bp in the A*0119 allele.

¹²Primer mix 23: Specific PCR fragment of 155 bp in the A*0124 allele. Specific PCR fragment of 175 bp in the A*0130 and *2422 alleles.

'w', might be weakly amplified.

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INTERPRETATION TABLE																
HLA-A*01 SSP subtyping																
Amplification patterns of the A*0101 to 0137 alleles																
	Well⁵															
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
Length of spec.	235	145	120	305	470	210	215	110	235	155	135	85	205	120	235	180
PCR product								180		270	275					235
Length of int.	800	1070	800	1070	1070	1070	800	1070	1070	800	800	800	1070	1070	1070	1070
pos. control¹																
5'-primer(s)²	363 5'-ATA	98 5'-CTT	123 5'-AgT	341 5'-ggA	3 rd I 5'-ATA	171 5'-TTA	363 5'-ATA	203 5'-gAA	363 5'-ATA	113 5'-CCC	203 5'-gAA	527 5'-TgC	363 5'-ATA	203 5'-gAA	363 5'-ATA	203 5'-gAA
										413 5'-CCg	363 5'-ATA					363 5'-ATA
3'-primer(s)³	559 5'-CCg	203 5'-TCT	203 5'-TCT	362 5'-TCA	621 5'-ggg	341 5'-CgT	539 5'-TCA	270 5'-ACA	553 5'-CTA	341 5'-CgT	299 5'-CCA	570 5'-CAC	527 5'-CCA	282 5'-gAC	559 5'-CgT	341 5'-CgT
	559 5'-CCg							341 5'-CgT	559 5'-CCA	527 5'-CCC	597 5'-TTA			282 5'-gAC	559 5'-CgT	557 5'-gC
Well No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
HLA-A allele⁴																
*01010101, 010102-010105	1	2														
*01010102N	1	2						8								16
*0102	1		3													
*0103		2		4												
*0104N	1	2			5											
*0106	1	2					7									
*0107	1	2						8								
*0108		2							9							
*0109	1	2				6										
*0110	1	2								10						
*0111N	1	2									11					
*0112		2											13		15	
*0113	1	2									11			14		
*0114		2													15	
*0115N	1	2														16
*0116N	1	2														
Well No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16

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HLA-A*01 SSP subtyping														
Amplification patterns of the A*0101 to 0137 alleles														
Well5														
17	18	19	20	21	22	23	24	25	26	27	28	29	30	
210	135	170	65	255	590	155	215	90	450	160	95	155	145	Length of spec. PCR product
			425			175								
1070	1070	1070	800	1070	1070	1070	1070	1070	1070	1070	1070	800	1070	Length of int. pos. control¹
363	203	215	203	355	3 rd I	89	363	203	3 rd I	98	650	363	650	5'-primer(s)²
5'-ATA	5'-gAA	5'-gCC	5'-gAA	5'-CCg	5'-ATA	5'-gAA	5'-ATA	5'-gAA	5'-ATA	5'-CTT	5'-CCC	5'-ATA	5'-CCC	
		413	521			413								
		5'-CCA	5'-ggC			5'-CCA								
531	299	341	346	570	750	203	539	251	622	218	705	476	755	3'-primer(s)³
5'-TCC	5'-TCg	5'-CgT	5'-AgC	5'-CCg	5'-Tg	5'-TCT	5'-TCT	5'-CCT	5'-ggT	5'-gCT	5'-TCT	5'-CCA	5'-CCA	
		545	545			545								
		5'-AgA	5'-AgA			5'-AgA								
17	18	19	20	21	22	23	24	25	26	27	28	29	30	Well No.
														HLA-A allele⁴
	18													*01010101, 010102-010105
	18													*01010102N
	18													*0102
	18													*0103
	18													*0104N
	18													*0106
	18													*0107
	18													*0108
	18													*0109
	18		20											*0110
	18													*0111N
	18						24							*0112
	18													*0113
	18													*0114
	18													*0115N
17	18													*0116N
17	18	19	20	21	22	23	24	25	26	27	28	29	30	Well No.

Lot No.: **21G**

Lot-specific Information

Length of spec.	235	145	120	305	470	210	215	110	235	155	135	85	205	120	235	180
PCR product								180		270	275					235
Well No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
*0117	1	2												14		
*0118N	1	w														
*0119		2											13		15	
*0120			3													
*0121	1	2											13			
*0122N	1	2														
*0123	1	2						8								
*0124	1	w														
*0125	1	2														
*0126	1	2														
*0127N	1	2							9							
*0128	1	2									11					
*0129	1	2								10						
*0130	1	2														
*0131N	1	2														
*0132	1	2														
*0133	1	2														
*0134N	1	2														
*0135	1	2														
*0137	1	2														
*0219, 0236, 0237, 0254, 2414, 2493																
*03010101-030105, 030107-030110, 0303N, 0304, 0306, 0308, 0309, 0311N- 0317, 0319, 0320, 0322-0330, 0333- 0339, 0341, 0343- 0347, 0350, 0351, 0355, 3204															15	
*0302, 0310, 0331, 0332, 2492													13		15	
*0305, 300101- 3003, 3007, 3008, 3010-3013, 3015, 3016, 3018-3020, 3022-3025, 3027N, 3402-3404, 3407, 3408								7							15	
Well No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16

Lot No.: **21G**

Lot-specific Information

210	135	170	65	255	590	155	215	90	450	160	95	155	145	Length of spec. PCR product
			425			175								
17	18	19	20	21	22	23	24	25	26	27	28	29	30	Well No.
	18													*0117
	18	19												*0118N
	18		20				24							*0119
	18			21										*0120
	18		20											*0121
	18				22									*0122N
	18													*0123
	18					23								*0124
	18						24							*0125
	18		20											*0126
	18													*0127N
	18													*0128
	18													*0129
	18	19				23								*0130
	18							25						*0131N
	18								26					*0132
	18									27				*0133
	18										28			*0134N
	18											29		*0135
	18												30	*0137
				21										*0219, 0236, 0237, 0254, 2414, 2493
														*03010101-030105, 030107-030110, 0303N, 0304, 0306, 0308, 0309, 0311N- 0317, 0319, 0320, 0322-0330, 0333- 0339, 0341, 0343- 0347, 0350, 0351, 0355, 3204
							24							*0302, 0310, 0331, 0332, 2492
														*0305, 300101- 3003, 3007, 3008, 3010-3013, 3015, 3016, 3018-3020, 3022-3025, 3027N, 3402-3404, 3407, 3408
17	18	19	20	21	22	23	24	25	26	27	28	29	30	Well No.

Lot No.: **21G**

Lot-specific Information

Length of spec.	235	145	120	305	470	210	215	110	235	155	135	85	205	120	235	180
PCR product								180		270	275					235
Well No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
*0307, 3004, 3006, 3017													w		15	
*0318, 110104, 1108, 1123, 1144	1															
*0321N					5										15	
*0342, 1135, 9256, 3009, 3103, 3104							7						w		15	
*110101-110103, 110105-1103, 1105-1107, 1109-1113, 111501-1120, 1122, 1129, 1130, 1132-1134, 1136-1143	1															
*1104, 1127															15	
*1114	1									w						
*1121N	1				5											
*112401-1125	1						7									
*1126, 2632, 3313, 7410				4												
*1131	1						7						w			
*2307N, 2411N					5											
*240203																
*2422																
*3014L							7									
*3026							7			10					15	
*3601, 3602		2										12			15	
*3603		2		4								12				
*3604	1	2										12				
*8001							7			w						
HLA-A allele ⁴																
Well No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16

Lot No.: **21G**

Lot-specific Information

210	135	170	65	255	590	155	215	90	450	160	95	155	145	Length of spec. PCR product
			425			175								Well No.
17	18	19	20	21	22	23	24	25	26	27	28	29	30	
														*0307, 3004, 3006, 3017
														*0318, 110104, 1108, 1123, 1144
														*0321N
														*0342, 1135, 9256, 3009, 3103, 3104
							24							*110101-110103, 110105-1103, 1105- 1107, 1109-1113, 111501-1120, 1122, 1129, 1130, 1132- 1134, 1136-1143
							24							*1104, 1127
							24							*1114
							24							*1121N
														*112401-1125
														*1126, 2632, 3313, 7410
														*1131
														*2307N, 2411N
											28			*240203
		19				23								*2422
														*3014L
														*3026
	18													*3601, 3602
	18													*3603
	18													*3604
														*8001
														HLA-A allele ⁴
17	18	19	20	21	22	23	24	25	26	27	28	29	30	Well No.

Lot No.: 21G

Lot-specific Information

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*01 subtyping.

In addition, wells number 3, 7, 10 to 12, 20 and 29 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.

²The nucleotide position, in the 1st, 2nd or 3rd exon or the 2nd 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 or 3rd exon, 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.

⁴The nucleotide sequence of the A*0105N allele has been shown to be identical to A*0104N.

⁵Primer mix 8: Specific PCR fragment of 110 bp in the A*0107 and 0123 alleles. Specific PCR fragment of 180 bp in the A*01010102N allele.

Primer mix 10: Specific PCR fragment of 155 bp in the A*0110 and in the A*1114^w, 3026 and 8001^w alleles. Specific PCR fragment of 270 bp in the A*0129 allele.

Primer mix 11: Specific PCR fragment of 135 bp in the A*0113 and 0128 alleles. Specific PCR fragment of 275 bp in the A*0111N allele.

Primer mix 16: Specific PCR fragment of 180 bp in the A*01010102N allele. Specific PCR fragment of 235 bp in the A*0115N allele.

Primer mix 20: Specific PCR fragment of 65 bp in the A*0110, A*0121 and A*0126 alleles. Specific PCR fragment of 425 bp in the A*0119 allele.

Primer mix 23: Specific PCR fragment of 155 bp in the A*0124 allele. Specific PCR fragment of 175 bp in the A*0130 and *2422 alleles.

'w', might be faintly amplified.

Lot No.: **21G**

Lot-specific Information

CELL LINE VALIDATION SHEET																				
HLA-A*01 SSP subtyping kit																				
				Prod. No.:	Well															
					1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
					200962901	200962902	200962903	200962904	200962905	200962906	200962907	200962908	200962909	200962910	200962911	200962912	200962913	200962914	200962915	200962916
	IHWC cell line	A*																		
1	9001 SA	*2402			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2	9280 LK707	*0201			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
3	9011 E4181324	*0101			+	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
4	9275 GU373	*3001			-	-	-	-	-	-	+	-	-	-	-	-	-	-	+	-
5	9009 KAS011	*0101			+	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
6	9353 SM	*0201	*2603		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
7	9020 QBL	*2601			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
8	9025 DEU	*3101			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
9	9026 YAR	*2601			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
10	9107 LKT3	*2402			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
11	9051 PITOUT	*2902			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
12	9052 DBB	*0201			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
13	9004 JESTHOM	*0201			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
14	9071 OLGA	*3101			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
15	9075 DKB	*2402			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
16	9037 SWEIG007	*2902			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
17	9282 CTM3953540	*0301	*8001		-	-	-	-	-	-	+	-	-	W	-	-	-	-	+	-
18	9257 32367	*3303	*7401		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
19	9038 BM16	*0201			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
20	9059 SLE005	*0201			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
21	9064 AMALA	*0217			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
22	9056 KOSE	*0201			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
23	9124 IHL	*0201	*3401		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
24	9035 JBUSH	*3201			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
25	9049 IBW9	*3301			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
26	9285 WT49	*0205			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
27	9191 CH1007	*2410	*2901		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
28	9320 BEL5GB	*0201	*2902		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
29	9050 MOU	*2902			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
30	9021 RSH	*3001	*6802		-	-	-	-	-	-	-	+	-	-	-	-	-	-	+	-
31	9019 DUCAF	*3002			-	-	-	-	-	-	+	-	-	-	-	-	-	-	+	-
32	9297 HAG	*0201			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
33	9098 MT14B	*3101			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
34	9104 DHIF	*3101			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
35	9302 SSTO	*3201			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
36	9024 KT17	*0206	*1101		+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
37	9065 HHKB	*0301			-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	-
38	9099 LZL	*0217			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
39	9315 CML	*0101	*0301		+	+	-	-	-	-	-	-	-	-	-	-	-	-	+	-
40	9134 WHONP199	*0207	*3001		-	-	-	-	-	-	+	-	-	-	-	-	-	-	+	-
41	9055 H0301	*0301			-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	-
42	9066 TAB089	*0207			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
43	9076 T7526	*0207			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
44	9057 TEM	*6601			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
45	9239 SHJO	*2301	*2402		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
46	9013 SCHU	*0301			-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	-
47	9045 TUBO	*0216	*0301		-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	-
48	9303 TER-ND	*0201	*1101		+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
49	9366 DAUDI	*0102	*6601		+	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-

Lot No.: **21G**

Lot-specific Information

CELL LINE VALIDATION SHEET																	
HLA-A*01 SSP subtyping kit																	
			Prod. No.:	Well													
				17	18	19	20	21	22	23	24	25	26	27	28	29	30
				200962917	200962918	200962919	200962920	200962921	200962922	200962923	200962924	200962925	200962926	200962927	200962928	200962929	200962930
	IHWC cell line	A*															
1	9001 SA	*2402		-	-	-	-	-	-	-	-	-	-	-	-	-	-
2	9280 LK707	*0201		-	-	-	-	-	-	-	-	-	-	-	-	-	-
3	9011 E4181324	*0101		-	+	-	-	-	-	-	-	-	-	-	-	-	-
4	9275 GU373	*3001		-	-	-	-	-	-	-	-	-	-	-	-	-	-
5	9009 KAS011	*0101		-	+	-	-	-	-	-	-	-	-	-	-	-	-
6	9353 SM	*0201	*2603	-	-	-	-	-	-	-	-	-	-	-	-	-	-
7	9020 QBL	*2601		-	-	-	-	-	-	-	-	-	-	-	-	-	-
8	9025 DEU	*3101		-	-	-	-	-	-	-	-	-	-	-	-	-	-
9	9026 YAR	*2601		-	-	-	-	-	-	-	-	-	-	-	-	-	-
10	9107 LKT3	*2402		-	-	-	-	-	-	-	-	-	-	-	-	-	-
11	9051 PITOUT	*2902		-	-	-	-	-	-	-	-	-	-	-	-	-	-
12	9052 DBB	*0201		-	-	-	-	-	-	-	-	-	-	-	-	-	-
13	9004 JESTHOM	*0201		-	-	-	-	-	-	-	-	-	-	-	-	-	-
14	9071 OLG A	*3101		-	-	-	-	-	-	-	-	-	-	-	-	-	-
15	9075 DKB	*2402		-	-	-	-	-	-	-	-	-	-	-	-	-	-
16	9037 SWEIG007	*2902		-	-	-	-	-	-	-	-	-	-	-	-	-	-
17	9282 CTM3953540	*0301	*8001	-	-	-	-	-	-	-	-	-	-	-	-	-	-
18	9257 32367	*3303	*7401	-	-	-	-	-	-	-	-	-	-	-	-	-	-
19	9038 BM16	*0201		-	-	-	-	-	-	-	-	-	-	-	-	-	-
20	9059 SLE005	*0201		-	-	-	-	-	-	-	-	-	-	-	-	-	-
21	9064 AMALA	*0217		-	-	-	-	-	-	-	-	-	-	-	-	-	-
22	9056 KOSE	*0201		-	-	-	-	-	-	-	-	-	-	-	-	-	-
23	9124 IHL	*0201	*3401	-	-	-	-	-	-	-	-	-	-	-	-	-	-
24	9035 JBUSH	*3201		-	-	-	-	-	-	-	-	-	-	-	-	-	-
25	9049 IBW9	*3301		-	-	-	-	-	-	-	-	-	-	-	-	-	-
26	9285 WT49	*0205		-	-	-	-	-	-	-	-	-	-	-	-	-	-
27	9191 CH1007	*2410	*2901	-	-	-	-	-	-	-	-	-	-	-	-	-	-
28	9320 BEL5GB	*0201	*2902	-	-	-	-	-	-	-	-	-	-	-	-	-	-
29	9050 MOU	*2902		-	-	-	-	-	-	-	-	-	-	-	-	-	-
30	9021 RSH	*3001	*6802	-	-	-	-	-	-	-	-	-	-	-	-	-	-
31	9019 DUCAF	*3002		-	-	-	-	-	-	-	-	-	-	-	-	-	-
32	9297 HAG	*0201		-	-	-	-	-	-	-	-	-	-	-	-	-	-
33	9098 MT14B	*3101		-	-	-	-	-	-	-	-	-	-	-	-	-	-
34	9104 DHIF	*3101		-	-	-	-	-	-	-	-	-	-	-	-	-	-
35	9302 SSTO	*3201		-	-	-	-	-	-	-	-	-	-	-	-	-	-
36	9024 KT17	*0206	*1101	-	-	-	-	-	-	-	+	-	-	-	-	-	-
37	9065 HHKB	*0301		-	-	-	-	-	-	-	-	-	-	-	-	-	-
38	9099 LZL	*0217		-	-	-	-	-	-	-	-	-	-	-	-	-	-
39	9315 CML	*0101	*0301	-	+	-	-	-	-	-	-	-	-	-	-	-	-
40	9134 WHONP199	*0207	*3001	-	-	-	-	-	-	-	-	-	-	-	-	-	-
41	9055 H0301	*0301		-	-	-	-	-	-	-	-	-	-	-	-	-	-
42	9066 TAB089	*0207		-	-	-	-	-	-	-	-	-	-	-	-	-	-
43	9076 T7526	*0207		-	-	-	-	-	-	-	-	-	-	-	-	-	-
44	9057 TEM	*6601		-	-	-	-	-	-	-	-	-	-	-	-	-	-
45	9239 SHJO	*2301	*2402	-	-	-	-	-	-	-	-	-	-	-	-	-	-
46	9013 SCHU	*0301		-	-	-	-	-	-	-	-	-	-	-	-	-	-
47	9045 TUBO	*0216	*0301	-	-	-	-	-	-	-	-	-	-	-	-	-	-
48	9303 TER-ND	*0201	*1101	-	-	-	-	-	-	-	+	-	-	-	-	-	-
49	9366 DAUDI	*0102	*6601	-	+	-	-	-	-	-	-	-	-	-	-	-	-

Lot No.: **21G**

Lot-specific Information

CERTIFICATE OF ANALYSIS

Olerup SSP[®] HLA-A*01 SSP

Product number: 101.411-24u/06u – without *Taq* pol.
Lot number: 21G
Expiry date: 2011-September-01
Number of tests: 24 test – Product No. 101.411-24u
6 tests – Product No. 101.411-06u
Number of wells per test: 30

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2009-629-01	11	2009-629-11	21	2009-629-21
2	2009-629-02	12	2009-629-12	22	2009-629-22
3	2009-629-03	13	2009-629-13	23	2009-629-23
4	2009-629-04	14	2009-629-14	24	2009-629-24
5	2009-629-05	15	2009-629-15	25	2009-629-25
6	2009-629-06	16	2009-629-16	26	2009-629-26
7	2009-629-07	17	2009-629-17	27	2009-629-27
8	2009-629-08	18	2009-629-18	28	2009-629-28
9	2009-629-09	19	2009-629-19	29	2009-629-29
10	2009-629-10	20	2009-629-20	30	2009-629-30

The specificity of each primer solution of the kit has been tested against 49 well characterized IHWC cell line DNAs.

No DNAs carrying the alleles to be amplified by primer solutions 6, 8 to 11, 14, 19 to 23 and 25 to 30 were available. The specificities of primers in primer solutions 8, 10, 11, 14, 19 to 21 and 23 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer. In primer solution 6 and it was only possible to test the 3'-primer, the 5'-primer was not possible to test. In primer solutions 9, 22 and 25 to 30 it was only possible to test the 5'-primers, the 3'-primers were not possible to test. Additional primers in primer solutions 15 and 16 were tested by separately adding one 5'-primer respectively one 3'-primer. In primer solutions 8, 10, 11, 16, 19 and 20 one or the 3'-primers was not possible to test.

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

Date of approval: 2009-October-14

Approved by:

Quality Control, Supervisor

Lot No.: **21G**

Lot-specific Information

Declaration of Conformity

Product name: *Olerup* SSP® HLA-A*01
Product number: 101.411-24u/06u
Lot number: 21G

Intended use: HLA-A*01 high resolution histocompatibility testing

Manufacturer: *Olerup* SSP AB
Hasselstigen 1
SE-133 33 Saltsjöbaden, 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, as transposed into the national laws of the Member States of the European Union.

The Technical Documentation File is maintained at *Olerup* SSP AB, Hasselstigen 1, SE-133 33 Saltsjöbaden, Sweden.

The Authorized Representative located within the Community is: *Olerup* SSP AB.

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

Saltsjöbaden, Sweden
2009-October-14

Olle Olerup
Managing Director

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