

Olerup SSP[®] HLA-A*30

Product number:	101.429-12 – including <i>Taq</i> polymerase 101.429-12u – without <i>Taq</i> polymerase
Lot number:	38E
Expiry date:	2010-April-01
Number of tests:	12
Number of wells per test:	21
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. 38E.

CHANGES COMPARED TO THE PREVIOUS OLERUP SSP[®] HLA-A*30 LOT

The HLA-A*30 specificity and interpretation tables have been updated for the HLA-A alleles described since the previous *Olerup SSP[®]* HLA-A*30 lot was made (Lot No. X40).

Five wells have been added to the HLA-A*30 kit,
wells **17 to 21**.

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

Well	5'-primer	3'-primer	rationale
2	-	Added	Primer added for the A*3023 allele
3	-	Modified	Increased yield of specific PCR product.
8	Removed	Removed	One primer pair moved to well 17.
17	Added	Added	Primer pair moved from well 8
18	Added	Added	Primer pair added for the A*3020 allele.
19	Added	Added	Primer pair added for the A*3022 allele.
20	Added	Added	Primer pair added for the A*3023 allele.
21	Added	Added	Primer pair added for the A*3024 allele.

Changes in revision R01 compared to R00:

1. The A*3008 allele is weakly amplified by primer mix 7.

PRODUCT DESCRIPTION

HLA-A*30 SSP subtyping

CONTENT

The primer set contains 5'- and 3'-primers for identifying the A*3001 to A*3024 alleles.

PLATE LAYOUT

Each test consists of 21 PCR reactions in a 24 well cut PCR plate. Wells 22 to 24 are empty.

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

The 24 well cut PCR plate is marked with 'HLA-A*30'.

Well No. 1 is marked with '38E'.

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*30 SSP subtypings will be influenced by three A*01, the A*0252, four A*24, two A*26, the A*2914, most A*31, the A*3207 and the A*6806 alleles when present on the other haplotype.

UNIQUELY IDENTIFIED ALLELES

All the HLA-A*30 alleles, i.e. **A*3001 to A*3024 alleles**, recognized by the HLA Nomenclature Committee in April 2008¹ will give rise to unique amplification patterns by the primers in the HLA-A*30 subtyping kit.

The HLA-A*30 kit cannot distinguish the A*300101 and A*300102 alleles, the A*300201 to A*300204 or the A*301101 and A*301102 alleles.

¹HLA-B alleles listed on the IMGT/HLA web page 2008-April-08, release 2.21.0, www.ebi.ac.uk/imgt/hla.

RESOLUTION IN HOMO- AND HETEROZYGOTES

The 22 HLA-A*30 alleles can be combined in 253 homozygous and heterozygous combinations. Seventy of these genotypes do not give rise to unique amplification patterns.

++++-----	+++-----	+-----	3003,3018 = 3011,3012
++++-----	+--+-----	+-----	3003,3016 = 3011,3013
++++-----	+--+-----	+-----	3001,3003 = 3002,3011
+++-----	+++-----	+-----	3012,3016 = 3013,3018
+++-----	+++-----	+-----	3001,3012 = 3002,3018
+++-----	+--+-----	+-----	3001,3013 = 3002,3016 = 3013,3016
++-+-	+--+-----	+-----	3004,3011 = 3011,3017 = 3011,3019
++-+-	+--+-----	+-----	3001,3006 = 3006,3019
++-+-	+--+-----	+-----	3008,3017 = 3008,3019
++-+-	+++-----	+-----	3004,3018 = 3017,3018 = 3018,3019
++-+-	+--+-----	+-----	3004,3016 = 3016,3017 = 3016,3019
++-+-	+--+-----	+-----	3004,3014L = 3014L,3017 = 3014L,3019
++-+-	+--+-----	+-----	3004,3015 = 3015,3017 = 3015,3019
++-+-	+--+-----	++---	3004,3020 = 3017,3020 = 3019,3020
++-+-	+--+-----	+--+	3004,3023 = 3017,3023 = 3019,3023
++-+-	+--+-----	+----+	3004,3024 = 3017,3024 = 3019,3024
++-+-	+--+-----	+-----	3001,3004 = 3001,3017 = 3001,3019 =
			3004,3019 = 3017,3019 = 3019,3019
++-----	+--+-----	+-----	3001,3016 = 3016,3016
++-----	+--+-----	+-----	3001,3014L = 3014L,3014L
++-----	+--+-----	+-----	3001,3015 = 3015,3015
++-----	+--+-----	++---	3001,3020 = 3020,3020
++-----	+--+-----	+--+	3001,3023 = 3023,3023
++-----	+--+-----	+----+	3001,3024 = 3024,3024
+--+-----	+--+-----	-----	3002,3006 = 3004,3007 = 3006,3007
+--+-----	+--+-----	-----	3002,3010 = 3010,3010
+--+-----	+--+-----	-----	3002,3013 = 3013,3013
-----+	+--+-----	-----	3004,3006 = 3006,3006
-----+	+--+-----	+-----	3004,3017 = 3017,3017

SPECIFICITY TABLE

HLA-A*30 SSP subtyping

Specificities and sizes of the PCR products of the 21 primer mixes used for HLA-A*30 SSP subtyping

Primer Mix	Size of spec. PCR product ¹	Size of control band ²	Amplified HLA-A*30 alleles	Other amplified HLA-A alleles ³
1	165 bp	800 bp	300101-3003, 3007-3016, 3018-3020, 3022-3024	0252
2	205 bp	800 bp	300101-300102, 3008, 301101-301102, 3014L-3016, 3018-3020, 3023, 3024	
3	205 bp	800 bp	300201-3003, 3007, 3010, 3012, 3013, 3022	
4	155 bp	1070 bp	3003, 301101-301102	0102, 0120
5⁵	150, 245 bp	1070 bp	3004, 3006, 3017, 3019	0252 ^{weakly} , 2466 ^{weakly} , 6806
6^{4,6}	80, 185 bp	1070 bp	3006, 3007	
7	200 bp	1070 bp	3008 ^{weakly}	
8⁴	85 bp	800 bp	3010	
9	180 bp	1070 bp	300101-300204, 3004, 3006, 3007, 3009, 3010, 3012-3020, 3023, 3024	
10⁷	150 bp	1070 bp	3012, 3018	0107, 2619, 2914, 310102-3107, 3109-3122
11	215 bp	800 bp	300101-3004, 3006, 3009-3020, 3023, 3024	0102 ^{weakly} , 2424, 2467, 2616, 3207
12	145 bp	1070 bp	3009	
13	155 bp	1070 bp	300101-300204, 3004, 3006-3010, 3013-3017, 3019, 3020, 3023, 3024	
14	210 bp	1070 bp	3013, 3016	
15	240 bp	800 bp	3014L	
16	265 bp	1070 bp	3015	

17	225 bp	1070 bp	300101-300102, 301101-301102, 3014L-3020, 3023, 3024	2419
18	210 bp	800 bp	3020	
19	160 bp	1070 bp	3022	
20	210 bp	800 bp	3023	
21	185 bp	1070 bp	3024	

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*30 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 length 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*30 subtyping.

In addition, wells number 2, 3, 8, 11, 15, 18 and 20 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 non-HLA-A*30 alleles will be amplified by primer mixes 1, 4, 5, 10, 11 and 17.

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

⁵Primer mix 5: Specific PCR fragment of 150 bp in the A*3004, 3006, 3017 and A*0252^{weakly}, 2466^{weakly} and 6806 alleles. Specific PCR fragment of 245 bp in the A*3019 allele.

⁶Primer mix 6: Specific PCR fragment of 80 bp in the A*3006 allele. Specific PCR fragment of 185 bp in the A*3007 allele.

⁷Primer mix 10 may give rise to nonspecific amplifications.

INTERPRETATION TABLE												
HLA-A*30 SSP subtyping												
Amplification patterns of the A*3001 to 3024 alleles												
	Well⁵											
	1	2	3	4	5	6	7	8	9	10	11	12
Length of spec.	165	205	205	155	150	80	200	85	180	150	215	145
PCR product					245	185						
Length of int.	800	800	800	1070	1070	1070	1070	800	1070	1070	800	1070
pos. control ¹												
5'-primer(s) ²	414	363	363	123	123	123	78	367	98	127	98	418
	5'-gAA ^{3'}	5'-ATA ^{3'}	5'-ATA ^{3'}	5'-AgT ^{3'}	5'-AgT ^{3'}	5'-AgT ^{3'}	5'-TCT ^{3'}	5'-TgC ^{3'}	5'-CTC ^{3'}	5'-ggg ^{3'}	5'-CTC ^{3'}	5'-AgC ^{3'}
					414							
					5'-gAA ^{3'}							
3'-primer(s) ³	538	526	526	238	325	163	238	411	238	238	270	524
	5'-CAA ^{3'}	5'-CCA ^{3'}	5'-CCg ^{3'}	5'-CCC ^{3'}	5'-gTg ^{3'}	5'-CgC ^{3'}	5'-CCT ^{3'}	5'-TCA ^{3'}	5'-CCT ^{3'}	5'-CCT ^{3'}	5'-ACA ^{3'}	5'-CAC ^{3'}
					524	265						
					5'-CAT ^{3'}	5'-CCC ^{3'}						
Well No.	1	2	3	4	5	6	7	8	9	10	11	12
HLA-A allele ⁴												
*300101-300102	1	2							9		11	
*300201-300204	1		3						9		11	
*3003	1		3	4							11	
*3004					5				9		11	
*3006					5	6			9		11	
*3007	1		3			6			9			
*3008	1	2					w					
*3009	1								9		11	12
*3010	1		3					8	9		11	
*301101-301102	1	2		4							11	
*3012	1		3						9	10	11	
*3013	1		3						9		11	
*3014L	1	2							9		11	
*3015	1	2							9		11	
*3016	1	2							9		11	
*3017					5				9		11	
*3018	1	2							9	10	11	
*3019	1	2			5				9		11	
*3020	1	2							9		11	
*3022	1		3									
*3023	1	2							9		11	
*3024	1	2							9		11	
Well No.	1	2	3	4	5	6	7	8	9	10	11	12

INTERPRETATION TABLE									
HLA-A*30 SSP subtyping									
Amplification patterns of the A*3001 to 3024 alleles									
Well⁵									
13	14	15	16	17	18	19	20	21	
155	210	240	265	225	210	160	210	185	Length of spec.
									PCR product
1070	1070	800	1070	1070	800	1070	800	1070	Length of int.
									pos. control ¹
123	123	363	363	98	123	123	363	634	5'-primer(s) ²
5'-AgT ^{3'}	5'-AgT ^{3'}	5'-ATA ^{3'}	5'-ATA ^{3'}	5'-CTC ^{3'}	5'-AgT ^{3'}	5'-AgT ^{3'}	5'-ATA ^{3'}	5'-CAg ^{3'}	
238	292	563	586	282	294	240	530	777	3'-primer(s) ³
5'-CCT ^{3'}	5'-gTg ^{3'}	5'-Cgg ^{3'}	5'-CAC ^{3'}	5'-gAC ^{3'}	5'-CgT ^{3'}	5'-ggA ^{3'}	5'-CCT ^{3'}	5'-gCA ^{3'}	
13	14	15	16	17	18	19	20	21	Well No.
									HLA-A allele ⁴
13				17					*300101-300102
13									*300201-300204
									*3003
13									*3004
13									*3006
13									*3007
13									*3008
13									*3009
13									*3010
				17					*301101-301102
									*3012
13	14								*3013
13		15		17					*3014L
13			16	17					*3015
13	14			17					*3016
13				17					*3017
				17					*3018
13				17					*3019
13				17	18				*3020
						19			*3022
13				17			20		*3023
13				17				21	*3024
13	14	15	16	17	18	19	20	21	Well No.

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Lot-specific information

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Length of spec.	165	205	205	155	150	80	200	85	180	150	215	145
PCR product					245	185						
Well No.	1	2	3	4	5	6	7	8	9	10	11	12
*0102				4							w	
*0107, 2619, 2914, 310102-3107, 3109- 3122									10			
*0120				4								
*0252	1				w							
*2419												
*2424, 2467, 2616, 3207									11			
*2466					w							
*6806					5							
HLA-A allele ⁴												
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*30 subtyping.

In addition, wells number 2, 3, 8, 11, 15, 18 and 20 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 2nd or 3rd exons, matching the specificity-determining 3'-end of the primer is given. Nuclotide 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 exons, matching the specificity-determining 3'-end of the primer is given in the anti-sense direction. Nuclotide 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.: **38E**

Lot-specific information

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155	210	240	265	225	210	160	210	185	Length of spec. PCR product
13	14	15	16	17	18	19	20	21	Well No.
									*0102
									*0107, 2619, 2914, 310102-3107, 3109- 3122
									*0120
									*0252
				17					*2419
									*2424, 2467, 2616, 3207
									*2466
									*6806
									HLA-A allele ⁴
13	14	15	16	17	18	19	20	21	Well No.

⁴The sequence of the A*3005 allele has been shown to be identical to A*3004.

A*3021 has been renamed to A*301102.

⁵Primer mix 5: Specific PCR fragment of 150 bp in the A*3004, 3006, 3017 and A*0252^{weakly}, 2466^{weakly} and 6806 alleles. Specific PCR fragment of 245 bp in the A*3019 allele.

Primer mix 6: Specific PCR fragment of 80 bp in the A*3006 allele. Specific PCR fragment of 185 bp in the A*3007 allele.

CELL LINE VALIDATION SHEET																				
HLA-A*30 SSP subtyping kit																				
				Lot No.:	Well															
					1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
					200617101	200843302	200843303	200617104	200730405	200617106	200617107	200843308	200617109	200617110	200617111	200730412	200617113	200617114	200617115	200617116
	IHC cell line	A*	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	9007 DEM	*0201			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
9	9026 YAR	*2601			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
10	9107 LKT3	*2402			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
11	9051 PITOUT	*2902			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
12	9052 DBB	*0201			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
13	9067 BTB	*0201			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
14	9071 OLGA	*3101			-	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-
15	9075 DKB	*2402			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
16	9037 SWEIG007	*2902			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
17	9008 WILJON	*2501			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
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		-	-	-	-	-	-	-	-	-	-	-	-	+	-	-	-

Lot No.: **38E**

Lot-specific information

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CELL LINE VALIDATION SHEET									
HLA-A*30 SSP subtyping kit									
					Well				
					17	18	19	20	21
				Lot No.:	200843317	200843318	200843319	200843320	200843321
	IHWC cell line	A*	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	9007 DEM	*0201			-	-	-	-	-
9	9026 YAR	*2601			-	-	-	-	-
10	9107 LKT3	*2402			-	-	-	-	-
11	9051 PITOUT	*2902			-	-	-	-	-
12	9052 DBB	*0201			-	-	-	-	-
13	9067 BTB	*0201			-	-	-	-	-
14	9071 OLGA	*3101			-	-	-	-	-
15	9075 DKB	*2402			-	-	-	-	-
16	9037 SWEIG007	*2902			-	-	-	-	-
17	9008 WILJON	*2501			-	-	-	-	-
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		-	-	-	-	-

CERTIFICATE OF ANALYSIS

Olerup SSP[®] HLA-A*30

Product number: 101.429-12 – including *Taq* polymerase
101.429-12u – without *Taq* polymerase
Lot number: 38E
Expiry date: 2010-April-01
Number of tests: 12
Number of wells per test: 21

Well specifications:

Well No.	Production No.	Well No.	Production No.
1	2006-171-01	12	2007-304-12
2	2008-433-02	13	2006-171-13
3	2008-433-03	14	2006-171-14
4	2006-171-04	15	2006-171-15
5	2007-304-05	16	2006-171-16
6	2006-171-06	17	2008-433-17
7	2006-171-07	18	2008-433-18
8	2008-433-08	19	2008-433-19
9	2006-171-09	20	2008-433-20
10	2006-171-10	21	2008-433-21
11	2006-171-11		

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 5 to 8, 12 and 14 to 16, and 18 to 21 were available. The specificities of the primers in primer 5, 6, 7, 12, 14 and 19 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer. In primer solution 6 it was only possible to the 5'-primer and one of the 3'-primers, one 3'-primer was not possible to test. In primer solutions 15, 16, 18 and 20 it was only possible to test the 5'-primers, the 3'-primers were not possible to test. In primer solution 8 it was only possible to test the 3'-primer, the 3'-primer was not possible to test.

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

Date of approval: 2009-September-04

Approved by:

Quality Control, Supervisor

Declaration of Conformity

Product name: *Olerup* SSP® HLA-A*30
Product number: 101.429-12, 101.429-12u
Lot number: 38E

Intended use: HLA-A*30 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 9001:2000 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, 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-September-04

Olle Olerup
Managing Director

HLA-A*30
101.429-12 – including *Taq* polymerase
101.429-12u – without *Taq* polymerase

Product Insert

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Lot-specific information

www.olerup.com

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Product Insert

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Lot No.: **38E**

Lot-specific information

www.olerup.com

HLA-A*30
101.429-12 – including *Taq* polymerase
101.429-12u – without *Taq* polymerase

Product Insert

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Lot No.: **38E**

Lot-specific information

www.olerup.com

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