

Olerup SSP[®] HLA-A*31

Product number:	101.430-12 – including <i>Taq</i> polymerase
Lot number:	84G
Expiry date:	2012-March-01
Number of tests:	12
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. 84G.

CHANGES COMPARED TO THE PREVIOUS *OLERUP SSP*[®] HLA-A*31 LOT

The HLA-A*31 specificity and interpretation tables have been updated for the HLA-A alleles described since the previous *Olerup SSP*[®] HLA-A*31 lot was made (Lot No. 24F).

One well has been added to the HLA-A*31 kit,
well **24**.

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

Well	5'-primer	3'-primer	rationale
5	Added	Added	New primer pair for the A*3126 allele.
7	Modified	-	Increased yield of specific PCR product.
8	Added	Added	New primer pairs for the A*3124 and A*3127 alleles.
11	Added	-	New primer for the A*3126 allele.
12	-	Modified	Modified 3'-primer for improved specificity.
14	Added	Added	New primer pair for the A*3124 allele.
15	Added	Added	New primer pair for the A*3125 allele.
17	Added	Added	New primer pair for the A*3125 allele.
18	-	Modified	Modified 3'-primer for improved specificity.
22	-	Added	New primer for the A*3127 allele.
24	New	New	New primer pair for the A*3128 allele.

PRODUCT DESCRIPTION

HLA-A*31 SSP subtyping

CONTENT

The primer set contains 5'- and 3'-primers for identifying the A*3101 to A*3128 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*31’ in silver/gray ink.

Well No. 1 is marked with the Lot Number ‘84G’.

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*31 SSP subtypings will be influenced by two A*01, nine A*02, three A*03, six A*11, most A*23, five A*24, the A*2619, most A*29, three A*30, the A*32, the A*33, most A*34, the A*6606, three A*68, the A*74 and the A*8001 alleles when present on the other haplotype.

UNIQUELY IDENTIFIED ALLELES

All the HLA-A*31 alleles, i.e. **A*3101 to A*3128 alleles**, recognized by the HLA Nomenclature Committee in January 2010¹ will give rise to unique amplification patterns by the primers in the HLA-A*31 subtyping kit.

The HLA-A*31 subtyping kit cannot separate the A*310102 to A*310106 alleles.

¹HLA-A alleles listed on the IMGT/HLA web page 2010-January-15, release 2.28.0, www.ebi.ac.uk/imgt/hla.

RESOLUTION IN HOMO- AND HETEROZYGOTES

The 28 HLA-A*31 alleles can be combined in 406 homozygous and heterozygous combinations. 116 of these genotypes do not give rise to unique amplification patterns. The different sizes of the PCR products generated by primer mixes 5, 8, 11, 14, 15, 17 and 22 have not been considered in these calculations.

+++++--	+---+---	-----	3103, 3107 = 3103, 3108
+++++--	+---+---	-----	3104, 3107 = 3104, 3108
+++----	+---+---	-----	3106, 3107 = 3106, 3108
+++----	++++---	-----	3107, 3126 = 3108, 3126
+++----	+---+---	-----	3105, 3107 = 3105, 3108
+++----	+---+---	-----	3107, 3124 = 3108, 3124
+++----	+---+---	-----	3107, 3127 = 3108, 3127
+++----	+---+---	-----	3107, 3109 = 3108, 3109
+++----	+++----	-----	3107, 3111 = 3108, 3111
+++----	+++----	-----	3107, 3112 = 3108, 3112
+++----	+++----	-----	3107, 3113 = 3108, 3113
+++----	+++----	-----	3107, 3114N = 3108, 3114N
+++----	+++----	-----	3107, 3125 = 3108, 3125
+++----	+++----	-----	3107, 3115 = 3108, 3115
+++----	+++----	-----	3107, 3116 = 3108, 3116
+++----	+++----	-----	3107, 3117 = 3108, 3117
+++----	+++----	-----	3107, 3118 = 3108, 3118
+++----	+++----	-----	3107, 3119 = 3108, 3119
+++----	+++----	-----	3107, 3120 = 3108, 3120
+++----	+++----	-----	3107, 3122 = 3108, 3122
+++----	+++----	-----	3107, 3123 = 3108, 3123
+++----	+++----	-----	3107, 3128 = 3108, 3128
+++----	+++----	-----	3101, 3107 = 3101, 3108 = 3102, 3107 = 3102, 3108 = 3102, 3110
+++----	+++----	-----	3107, 3121 = 3108, 3121
+++----	+++----	-----	3107, 3107 = 3107, 3108 = 3107, 3110 = 3108, 3110
+++----	+++----	-----	3101, 3102 = 3102, 3102
+++----	+++----	-----	3103, 3112 = 3103, 3126 = 3104, 3126
+++----	+++----	-----	3103, 3103 = 3103, 3104 = 3103, 3106
+++----	+++----	-----	3104, 3104 = 3104, 3106
+++----	+++----	-----	3101, 3126 = 3112, 3126 = 3126, 3126
+++----	+++----	-----	3101, 3105 = 3105, 3105
+++----	+++----	-----	3114N, 3127 = 3122, 3124 = 3124, 3127
+++----	+++----	-----	3101, 3124 = 3109, 3114N = 3109, 3124 = 3114N, 3124 = 3124, 3124
+++----	+++----	-----	3101, 3127 = 3109, 3122 = 3109, 3127 = 3122, 3127 = 3127, 3127
+++----	+++----	-----	3101, 3109 = 3109, 3109
+++----	+++----	-----	3101, 3111 = 3111, 3111
+++----	+++----	-----	3101, 3112 = 3112, 3112
+++----	+++----	-----	3101, 3113 = 3113, 3113
+++----	+++----	-----	3101, 3114N = 3114N, 3114N
+++----	+++----	-----	3101, 3125 = 3115, 3117 = 3115, 3125 = 3117, 3125 = 3125, 3125
+++----	+++----	-----	3101, 3115 = 3115, 3115
+++----	+++----	-----	3101, 3116 = 3116, 3116

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Lot-specific information

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+-----	+---+---	+-----	3101, 3117 = 3117, 3117
+-----	+---+---	-+-----	3101, 3118 = 3118, 3118
+-----	+---+---	--+-----	3101, 3119 = 3119, 3119
+-----	+---+---	---+-----	3101, 3120 = 3120, 3120
+-----	+---+---	-----+--	3101, 3122 = 3122, 3122
+-----	+---+---	-----+-	3101, 3123 = 3123, 3123
+-----	+---+---	-----++	3101, 3128 = 3128, 3128

3101 = 310102-310106

SPECIFICITY TABLE

HLA-A*31 SSP subtyping

Specificities and sizes of the PCR products of the 24 primer mixes used for HLA-A*31 SSP subtyping

Primer Mix	Size of spec. PCR product ¹	Size of control band ²	Amplified HLA-A*31 alleles	Other amplified HLA-A alleles ³
1	155 bp	800 bp	*310102-3107, 3109-3128	*0107, 9285, 2619, 2914, 3012, 3018
2	215 bp	800 bp	*3102, 3107, 3108	*2482, 3308
3	155 bp	800 bp	*3103, 3104	*3402-3404, 3406-3408, 6606
4 ⁵	165 bp	1070 bp	*3103, 3104, 3106	*0106, 9214, 0305, 0342, 112401-1125, 1131, 1135, 29010101-2904, 2906-2922, 3026, 3318, 3402-3404, 3407, 3408, 680801, 680802, 8001
5 ⁷	135 bp, 285 bp	1070 bp	*3103, 3126	*1143, 3313
6	165 bp	800 bp	*3105	*230301, 2903, 3213, 3310
7	505 bp	1070 bp	*3107, 3108, 3110	*0281, 0287, 9212, 9224, 9229, 230101, 230102, 230301-2313, 2315-2325, 241301, 2418, 2424, 2494, 2913, 320101-320104, 3203-3209, 3211Q-3221
8 ⁸	155 bp, 220 bp	1070 bp	*3109, 3124, 3127	
9 ^{4,5}	75 bp	1070 bp	*310102-3102, 3105, 3107-3128	*0265, 9252, 230301, 320101-3203, 3205-3221, 330101-330103, 330301-3317, 3320-3329, 7401-7414N
10	160 bp	1070 bp	*3111	
11 ⁹	135 bp, 215 bp	1070 bp	*3112, 3126	

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12	245 bp	1070 bp	*310102-3106, 3109, 3111- 3120, 3122- 3128	*1143, 2919, 330101- 330103, 330301-3312, 3314-3316, 3318- 3329, 6829
13⁴	85 bp	1070 bp	*3113	
14¹⁰	150 bp, 470 bp	800 bp	*3114N, 3124	
15¹¹	150 bp, 225 bp	1070 bp	*3115, 3125	
16	165 bp	1070 bp	*3116	*2912
17¹²	150 bp, 235 bp	1070 bp	*3117, 3125	
18	200 bp	1070 bp	*3118	
19⁴	110 bp	1070 bp	*3119	*0352
20	325 bp	1070 bp	*3120	
21	180 bp	1070 bp	*3121	*0107, 9285
22¹³	155 bp, 190 bp	1070 bp	*3122, 3127	
23	200 bp	1070 bp	*3123	
24⁶	220 bp	1070 bp	*3128	

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*31 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*31 subtyping.

In addition, wells number 2, 3, 6 and 14 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*31 alleles will be amplified by primer mixes 1 to 7, 9, 12, 16, 19 and 21.

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

⁵Primer mixes 4 and 9 may give a lower yield of specific PCR product than the other HLA-A*31 primer mixes.

⁶Primer mix 24 may give rise to nonspecific amplifications.

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⁷Primer mix 5: Specific PCR product of 135 bp in the A*3126 allele. Specific PCR product of 285 bp in the A*3103 and in the A*1143 and A*3313 alleles.

⁸Primer mix 8: Specific PCR product of 155 bp in the A*3124 and A*3127 alleles. Specific PCR product of 220bp in the A*3109 allele.

⁹Primer mix 11: Specific PCR product of 135 bp in the A*3126 allele. Specific PCR product of 215 bp in the A*3112 allele.

¹⁰Primer mix 14: Specific PCR product of 150 bp in the A*3124 allele. Specific PCR product of 470bp in the A*3114N allele.

¹¹Primer mix 15: Specific PCR product of 150 bp in the A*3125 allele. Specific PCR product of 225 bp in the A*3115 allele.

¹²Primer mix 17: Specific PCR product of 150 bp in the A*3125 allele. Specific PCR product of 235 bp in the A*3117 allele.

¹³Primer mix 22: Specific PCR product of 155 bp in the A*3127 allele. Specific PCR product of 190 bp in the A*3122 allele.

INTERPRETATION TABLE

HLA-A*31 SSP subtyping

Amplification patterns of the A*3101 to A*3128 alleles

	Well ⁵											
	1	2	3	4	5	6	7	8	9	10	11	12
Length of spec. PCR product(s)	155	215	155	165	135	165	505	155	75	160	135	245
Length of int. pos. control ¹	800	800	800	1070	1070	800	1070	1070	1070	1070	1070	1070
5'-primer ²	127	97	423	413	97	448	317	97	413	448	362	97
	5' -ggg 3'	5' -TCA 3'	5' -gCT 3'	5' -CCg 3'	5' -TCA 3'	5' -CCT 3'	5' -gCT 3'	5' -TCA 3'	5' -CCA 3'	5' -CCT 3'	5' -gAA 3'	5' -TCA 3'
					445			448			445	
					5' -TCC 3'			5' -CCT 3'			5' -TCC 3'	
3'-primer ³	238	270	538	539	341	570	538	214	448	565	538	299
	5' -CCT 3'	5' -ACT 3'	5' -CAA 3'	5' -TCA 3'	5' -CgT 3'	5' -CCg 3'	5' -CAA 3'	5' -CCA 3'	5' -CAA 3'	5' -CAg 3'	5' -CAA 3'	5' -CCA 3'
	245				538			278				
	5' -ACg 3'				5' -CAA 3'			5' -ggC 3'				
								559				
								5' -CCg 3'				
Well No.	1	2	3	4	5	6	7	8	9	10	11	12
HLA-A allele ⁴												
*310102-310106	1								9			12
*3102	1	2							9			12
*3103	1		3	4	5							12
*3104	1		3	4								12
*3105	1					6			9			12
*3106	1			4								12
*3107	1	2					7		9			
*3108		2					7		9			
*3109	1							8	9			12
*3110	1						7		9			
*3111	1								9	10		12
*3112	1								9		11	12
*3113	1								9			12
*3114N	1								9			12
*3115	1								9			12
*3116	1								9			12
*3117	1								9			12
*3118	1								9			12
*3119	1								9			12
*3120	1								9			12
*3121	1								9			
*3122	1								9			12
*3123	1								9			12
Well No.	1	2	3	4	5	6	7	8	9	10	11	12

INTERPRETATION TABLE												
HLA-A*31 SSP subtyping												
Amplification patterns of the A*3101 to A*3128 alleles												
Well ⁵												
13	14	15	16	17	18	19	20	21	22	23	24	
85	150	150	165	150	200	110	325	180	155	200	220	Length of spec. PCR product(s)
	470	225		235					190			
1070	800	1070	1070	1070	1070	1070	1070	1070	1070	1070	1070	Length of int. pos. control ¹
413	448	98	98	98	413	488	302	98	98	652	97	5'-primer ²
5' -CCA 3' 5' -CCT 3' 5' -CAC 3' 5' -CAC 3' 5' -CAC 3' 5' -CCA 3' 5' -ggT 3' 5' -ggA 3' 5' -CTT 3' 5' -CAC 3' 5' -CTg 3' 5' -TCA 3'												
	3rd I	448		448								
	5' -ATA 3' 5' -CCT 3'			5' -CCT 3'								
456	559	281	221	292	571	559	346	238	214	811	277	3'-primer ³
5' -TCg 3' 5' -CCg 3' 5' -AgC 3' 5' -ACA 3' 5' -gTT 3' 5' -CCT 3' 5' -CgT 3' 5' -AgC 3' 5' -CCT 3' 5' -CCA 3' 5' -CAT 3' 5' -ggT 3'												
	621	559		559					245			
	5' -ggg 3' 5' -CCT 3'			5' -CCT 3'					5' -ACg 3'			
13	14	15	16	17	18	19	20	21	22	23	24	Well No.
												HLA-A allele ⁴
												*310102-310106
												*3102
												*3103
												*3104
												*3105
												*3106
												*3107
												*3108
												*3109
												*3110
												*3111
												*3112
13												*3113
	14											*3114N
		15										*3115
			16									*3116
				17								*3117
					18							*3118
						19						*3119
							20					*3120
								21				*3121
									22			*3122
										23		*3123
13	14	15	16	17	18	19	20	21	22	23	24	Well No.

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Lot-specific information

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Length of spec.	155	215	155	165	135	165	505	155	75	160	135	245
PCR product(s)					285			220			215	
Well No.	1	2	3	4	5	6	7	8	9	10	11	12
*3124	1							8	9			12
*3125	1								9			12
*3126	1				5				9		11	12
*3127	1							8	9			12
*3128	1								9			12
*0106, 9214, 0305, 0342, 112401- 1125, 1131, 1135, 29010101-290205, 2904, 2906-2911, 2915-2918, 2920- 2922, 3026, 680801, 680802, 8001				4								
*0107, 9285	1											
*0265, 9252, 3202, 3210, 3317, 7401- 7414N									9			
*0281, 0287, 9212, 9224, 9229, 230101, 230102, 230302-2313, 2315- 2325, 241301, 2418, 2424, 2494, 3204							7					
*0352												
*1143					5							12
*230301, 3213						6	7		9			
*2482		2										
*2619, 3012, 3018	1											
*2903				4		6						
*2912				4								
*2913				4			7					
*2914	1			4								
*2919, 3318				4								12
*320101-320104, 3203, 3205-3209, 3211Q, 3212, 3214- 3221							7		9			
*330101-330103, 330301-3307, 3309, 3311, 3312, 3314-3316, 3320- 3329									9			12
*3308		2							9			12
Well No.	1	2	3	4	5	6	7	8	9	10	11	12

Lot No.: **84G**

Lot-specific information

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85	150	150	165	150	200	110	325	180	155	200	220	Length of spec. PCR product(s)
13	14	15	16	17	18	19	20	21	22	23	24	Well No.
	470	225		235					190			
	14											*3124
		15		17								*3125
									22			*3126
											24	*3127
												*3128
								21				*0106, 9214, 0305, 0342, 112401- 1125, 1131, 1135, 29010101-290205, 2904, 2906-2911, 2915-2918, 2920- 2922, 3026, 680801, 680802, 8001
												*0107, 9285
												*0265, 9252, 3202, 3210, 3317, 7401- 7414N
												*0281, 0287, 9212, 9224, 9229, 230101, 230102, 230302-2313, 2315- 2325, 241301, 2418, 2424, 2494, 3204
						19						*0352
												*1143
												*230301, 3213
												*2482
												*2619, 3012, 3018
												*2903
			16									*2912
												*2913
												*2914
												*2919, 3318
												*320101-320104, 3203, 3205-3209, 3211Q, 3212, 3214- 3221
												*330101-330103, 330301-3307, 3309, 3311, 3312, 3314-3316, 3320- 3329
												*3308
13	14	15	16	17	18	19	20	21	22	23	24	Well No.

Length of spec.	155	215	155	165	135	165	505	155	75	160	135	245
PCR product(s)					285			220			215	
Well No.	1	2	3	4	5	6	7	8	9	10	11	12
*3310						6			9			12
*3313					5				9			
*3319, 6829												12
*3402-3404, 3407, 3408			3	4								
*3406, 6606			3									
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*31 subtyping.

In addition, wells number 2, 3, 6 and 14 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 2nd, 3rd or 4th exons or the 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.

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Lot-specific information

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85	150	150	165	150	200	110	325	180	155	200	220	Length of spec. PCR product(s)
13	14	15	16	17	18	19	20	21	22	23	24	Well No.
	470	225		235					190			*3310
												*3313
												*3319, 6829
												*3402-3404, 3407, 3408
												*3406, 6606
												HLA-A allele ⁴
13	14	15	16	17	18	19	20	21	22	23		Well No.

⁴The sequence of the A*310101 allele has been shown to be identical to A*310102.

⁵Primer mix 5: Specific PCR product of 135 bp in the A*3126 allele. Specific PCR product of 285 bp in the A*3103 and in the A*1143 and A*3313 alleles.

Primer mix 8: Specific PCR product of 155 bp in the A*3124 and A*3127 alleles. Specific PCR product of 220bp in the A*3109 allele.

Primer mix 11: Specific PCR product of 135 bp in the A*3126 allele. Specific PCR product of 215 bp in the A*3112 allele.

Primer mix 14: Specific PCR product of 150 bp in the A*3124 allele. Specific PCR product of 470bp in the A*3114N allele.

Primer mix 15: Specific PCR product of 150 bp in the A*3125 allele. Specific PCR product of 225 bp in the A*3115 allele.

Primer mix 17: Specific PCR product of 150 bp in the A*3125 allele. Specific PCR product of 235 bp in the A*3117 allele.

Primer mix 22: Specific PCR product of 155 bp in the A*3127 allele. Specific PCR product of 190 bp in the A*3122 allele.

CELL LINE VALIDATION SHEET																				
HLA-A*31 SSP subtyping kit																				
				Well																
				1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	
				Lot No.:	200969701	200969702	200969703	200969704	200969705	200969706	200969707	200969708	200969709	200969710	200969711	200969712	200969713	200969714	200969715	200969716
	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	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	-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-
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	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

CELL LINE VALIDATION SHEET												
HLA-A*31 SSP subtyping kit												
				Prod. No.:	Well							
					17	18	19	20	21	22	23	24
					200969717	200969718	200969719	200969720	200969721	200969722	200969723	200969724
	IHC 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	-	-	-	-	-	-	-	-
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*31 SSP

Product number: 101.430-12 – including *Taq* polymerase
Lot number: 84G
Expiry date: 2012-March-01
Number of tests: 12
Number of wells per test: 24

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2009-697-01	9	2009-697-09	17	2009-697-17
2	2009-697-02	10	2009-697-10	18	2009-697-18
3	2009-697-03	11	2009-697-11	19	2009-697-19
4	2009-697-04	12	2009-697-12	20	2009-697-20
5	2009-697-05	13	2009-697-13	21	2009-697-21
6	2009-697-06	14	2009-697-14	22	2009-697-22
7	2009-697-07	15	2009-697-15	23	2009-697-23
8	2009-697-08	16	2009-697-16	24	2009-697-24

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 2, 5, 6, 8, 10, 11 and 13 to 24 were available. The specificities of the primers in primer solutions 2, 5, 6, 8, 14 and 21 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer. In primer solutions 10, 13, 15 to 18, 20, 22 and 22 to 24 it was only possible to test the 5'-primer, the 3'-primer was not possible to test. In primer solutions 11 and 19 it was only possible to test the 3'-primer, the 5'-primer was not possible to test. In primer solution 5, one 5'-primer was not possible to test, and in primer solutions 1, 8 and 14 one or two 3'-primers were not possible to test.

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

Date of approval: 2010-April-01

Approved by:

Quality Control, Supervisor

Lot No.: **84G**

Lot-specific information

www.olerup-ssp.com

Declaration of Conformity

Product name: *Olerup* SSP® HLA-A*31
Product number: 101.430-12
Lot number: 84G

Intended use: HLA-A*31 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, 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
2010-April-01

Olle Olerup
Managing Director

Lot No.: **84G**

Lot-specific information

www.olerup-ssp.com

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Fax: +43-1-710 15 00 10

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Olerup Inc., 901 S. Bolmar St., Suite R, West Chester, PA 19382

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Fax: 610-344-7989

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