

## Olerup SSP<sup>®</sup> HLA-A\*31

Product number:	101.430-12 – including <i>Taq</i> polymerase
Lot number:	24F
Expiry date:	2010-November-01
Number of tests:	12
Number of wells per test:	23
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. 24F.**

### CHANGES COMPARED TO THE PREVIOUS *OLERUP SSP*<sup>®</sup> 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*<sup>®</sup> HLA-A\*31 lot was made (Lot No. Y30).

Two wells have been added to the HLA-A\*31 kit,  
wells **22 to 23**.

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

Well	5'-primer	3'-primer	rationale
1	-	Added	New 3'-primer for the A*3122 allele.
18	Exchanged	Exchanged	Exchanged primer pair to decrease formation of primer dimers.
22	New	New	New primer pair for the A*3122 allele.
23	New	New	New primer pair for the A*3123 allele.

Changes in revision R01 compared to R00:

1. Length of specific PCR product generated by primer mix 18 corrected to 200 bp.

## PRODUCT DESCRIPTION

### HLA-A\*31 SSP subtyping

#### CONTENT

The primer set contains 5'- and 3'-primers for identifying the A\*3101 to A\*3123 alleles.

#### PLATE LAYOUT

Each test consists of 23 PCR reactions in a 24 well cut PCR plate. Wells 24 is empty.

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

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 ‘24F’.

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, eight A\*02, the A\*0305, five A\*11, most A\*23, four A\*24, the A\*2619, most A\*29, three A\*30, most A\*32, the A\*33, most A\*34, the A\*6606, two 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\*3123 alleles**, recognized by the HLA Nomenclature Committee in October 2008<sup>1</sup> 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 and A\*310103 alleles.

<sup>1</sup>HLA-A alleles listed on the IMGT/HLA web page 2008-October-10, release 2.23.0, [www.ebi.ac.uk/imgt/hla](http://www.ebi.ac.uk/imgt/hla).

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Lot-specific information

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### RESOLUTION IN HOMO- AND HETEROZYGOTES

The 23 HLA-A\*31 alleles can be combined in 276 homozygous and heterozygous combinations. Eighty of these genotypes do not give rise to unique amplification patterns.

+++++--+	+---+-----	-----	3103,3107 = 3103,3108
+++++--+	+---+-----	-----	3104,3107 = 3104,3108
+++---+-	+---+-----	-----	3106,3107 = 3106,3108
++----++	+---+-----	-----	3105,3107 = 3105,3108
++----++	+---+-----	-----	3107,3109 = 3108,3109
++----+-	++-+-----	-----	3107,3111 = 3108,3111
++----+-	++-+-----	-----	3107,3112 = 3108,3112
++----+-	+---+-----	-----	3107,3113 = 3108,3113
++----+-	+---+-----	-----	3107,3114 <sup>N</sup> = 3108,3114 <sup>N</sup>
++----+-	+---+-----	-----	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
++----+-	+---+-----	-----	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
+----++--	---+-----	-----	3103,3103 = 3103,3104 =
			3103,3106
+---+-----	---+-----	-----	3104,3104 = 3104,3106
+-----+--	+---+-----	-----	3101,3105 = 3105,3105
+-----+--	+---+-----	-----	3101,3109 = 3109,3109
+-----+--	++-+-----	-----	3101,3111 = 3111,3111
+-----+--	++-+-----	-----	3101,3112 = 3112,3112
+-----+--	++-+-----	-----	3101,3113 = 3113,3113
+-----+--	++-+-----	-----	3101,3114 <sup>N</sup> = 3114 <sup>N</sup> ,3114 <sup>N</sup>
+-----+--	++-+-----	-----	3101,3115 = 3115,3115
+-----+--	++-+-----	-----	3101,3116 = 3116,3116
+-----+--	+---+-----	+-----	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 = 310102-310103

## SPECIFICITY TABLE

### HLA-A\*31 SSP subtyping

Specificities and sizes of the PCR products of the 23 primer mixes used for HLA-A\*31 SSP subtyping

Primer Mix	Size of spec. PCR product <sup>1</sup>	Size of control band <sup>2</sup>	Amplified HLA-A*31 alleles	Other amplified HLA-A alleles <sup>3</sup>
1	155 bp	800 bp	310102-3107, 3109-3123	0107, 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	165 bp	1070 bp	3103, 3104, 3106	0106, 9214, 0305, 112401-1125, 1131, 1135, 29010101-2904, 2906-2918, 3026, 3318, 3402-3404, 3407, 3408, 6808, 8001
5	285 bp	1070 bp	3103	3313
6	165 bp	800 bp	3105	230301, 2903, 3213, 3310
7	500 bp	1070 bp	3107, 3108, 3110	0281, 0287, 9212, 9224, 9229, 2301, 230301-2313, 2315-2319Q, 241301, 2424, 2494, 2913, 320101-320103, 3203, 3205-3209, 3211Q-3217
8	220 bp	1070 bp	3109	
9 <sup>5</sup>	75 bp	1070 bp	310102-3102, 3105, 3107-3123	0265, 9252, 230301, 320101-3203, 3205-3217, 3301, 330301-3317, 3320-3322, 7401-7413
10	160 bp	1070 bp	3111	
11	215 bp	1070 bp	3112	
12	245 bp	1070 bp	310102-3106, 3109, 3111-3120, 3122, 3123	3301, 330301-3312, 3314-3316, 3318-3322, 6829
13 <sup>5</sup>	85 bp	1070 bp	3113	
14	470 bp	800 bp	3114N	

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<b>15</b>	225 bp	1070 bp	3115	
<b>16</b>	165 bp	1070 bp	3116	2912
<b>17</b>	235 bp	1070 bp	3117	
<b>18<sup>4</sup></b>	200 bp	1070 bp	3118	
<b>19<sup>5</sup></b>	110 bp	1070 bp	3119	
<b>20</b>	325 bp	1070 bp	3120	
<b>21</b>	180 bp	1070 bp	3121	0107
<b>22</b>	190 bp	1070 bp	3122	
<b>23</b>	200 bp	1070 bp	3123	

<sup>1</sup>Alleles 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 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.

<sup>2</sup>The 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.

<sup>3</sup>Due 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 and 21.

<sup>4</sup>Primer mix 18 may give rise to nonspecific amplifications.

<sup>5</sup>Short specific PCR fragments are less intense and not as sharp as longer specific bands.

<b>INTERPRETATION TABLE</b>												
<b>HLA-A*31 SSP subtyping</b>												
<b>Amplification patterns of the A*3101 to A*3123 alleles</b>												
	<b>Well</b>											
	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>6</b>	<b>7</b>	<b>8</b>	<b>9</b>	<b>10</b>	<b>11</b>	<b>12</b>
<b>Length of spec.</b>	155	215	155	165	285	165	500	220	75	160	215	245
<b>PCR product</b>												
<b>Length of int.</b>	<b>800</b>	<b>800</b>	<b>800</b>	1070	1070	<b>800</b>	1070	1070	1070	1070	1070	1070
<b>pos. control<sup>1</sup></b>												
<b>5'-primer<sup>2</sup></b>	127	97	423	413	97	448	317	97	413	448	362	97
	5'-ggg <sup>3'</sup>	5'-TCA <sup>3'</sup>	5'-gCT <sup>3'</sup>	5'-CCg <sup>3'</sup>	5'-TCA <sup>3'</sup>	5'-CCT <sup>3'</sup>	5'-gCT <sup>3'</sup>	5'-TCA <sup>3'</sup>	5'-CCA <sup>3'</sup>	5'-CCT <sup>3'</sup>	5'-gAA <sup>3'</sup>	5'-TCA <sup>3'</sup>
<b>3'-primer<sup>3</sup></b>	238	270	538	539	341	570	538	278	448	565	538	299
	5'-CCT <sup>3'</sup>	5'-ACT <sup>3'</sup>	5'-CAA <sup>3'</sup>	5'-TCA <sup>3'</sup>	5'-CgT <sup>3'</sup>	5'-CCg <sup>3'</sup>	5'-CAA <sup>3'</sup>	5'-ggC <sup>3'</sup>	5'-CAA <sup>3'</sup>	5'-CAg <sup>3'</sup>	5'-CAA <sup>3'</sup>	5'-CCA <sup>3'</sup>
	245											
	5'-ACg <sup>3'</sup>											
<b>Well No.</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>6</b>	<b>7</b>	<b>8</b>	<b>9</b>	<b>10</b>	<b>11</b>	<b>12</b>
<b>HLA-A allele<sup>4</sup></b>												
<b>*310102-310103</b>	1								9			12
<b>*3102</b>	1	2							9			12
<b>*3103</b>	1		3	4	5							12
<b>*3104</b>	1		3	4								12
<b>*3105</b>	1					6			9			12
<b>*3106</b>	1			4								12
<b>*3107</b>	1	2					7		9			
<b>*3108</b>		2					7		9			
<b>*3109</b>	1							8	9			12
<b>*3110</b>	1						7		9			
<b>*3111</b>	1								9	10		12
<b>*3112</b>	1								9		11	12
<b>*3113</b>	1								9			12
<b>*3114N</b>	1								9			12
<b>*3115</b>	1								9			12
<b>*3116</b>	1								9			12
<b>*3117</b>	1								9			12
<b>*3118</b>	1								9			12
<b>*3119</b>	1								9			12
<b>*3120</b>	1								9			12
<b>*3121</b>	1								9			
<b>*3122</b>	1								9			12
<b>*3123</b>	1								9			12
<b>Well No.</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>6</b>	<b>7</b>	<b>8</b>	<b>9</b>	<b>10</b>	<b>11</b>	<b>12</b>

<b>INTERPRETATION TABLE</b>											
<b>HLA-A*31 SSP subtyping</b>											
<b>Amplification patterns of the A*3101 to A*3123 alleles</b>											
<b>Well</b>											
13	14	15	16	17	18	19	20	21	22	23	
85	470	225	165	235	200	110	325	180	190	200	Length of spec.
											PCR product
1070	800	1070	1070	1070	1070	1070	1070	1070	1070	1070	Length of int.
											pos. control <sup>1</sup>
413	3 <sup>rd</sup> I	98	98	98	413	488	302	98	98	652	5'-primer <sup>2</sup>
5'-CCA <sup>3'</sup>	5'-ATA <sup>3'</sup>	5'-CAC <sup>3'</sup>	5'-CAC <sup>3'</sup>	5'-CAC <sup>3'</sup>	5'-CCA <sup>3'</sup>	5'-ggT <sup>3'</sup>	5'-ggA <sup>3'</sup>	5'-CTT <sup>3'</sup>	5'-CAC <sup>3'</sup>	5'-CTg <sup>3'</sup>	
456	620	281	221	292	571	559	346	238	245	811	3'-primer <sup>3</sup>
5'-TCg <sup>3'</sup>	5'-CCA <sup>3'</sup>	5'-AgC <sup>3'</sup>	5'-ACA <sup>3'</sup>	5'-gTT <sup>3'</sup>	5'-CCT <sup>3'</sup>	5'-CgT <sup>3'</sup>	5'-AgC <sup>3'</sup>	5'-CCT <sup>3'</sup>	5'-ACg <sup>3'</sup>	5'-CAT <sup>3'</sup>	
13	14	15	16	17	18	19	20	21	22	23	Well No.
											HLA-A allele <sup>4</sup>
											*310102-310103
											*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	Well No.

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Length of spec.	155	215	155	165	285	165	500	220	75	160	215	245
PCR product												
Well No.	1	2	3	4	5	6	7	8	9	10	11	12
*0106, 9214, 0305, 112401-1125, 1131, 1135, 29010101-290203, 2904, 2906-2911, 2915-2918, 3026, 6808, 8001				4								
*0107	1											
*0265, 9252, 3202, 3210, 3317, 7401-7413									9			
*0281, 0287, 9212, 9224, 9229, 2301, 230302-2313, 2315-2319Q, 241301, 2424, 2494							7					
*230301						6	7		9			
*2482		2										
*2619, 3012, 3018	1											
*2903				4		6						
*2912				4								
*2913				4			7					
*2914	1			4								
*320101-320103, 3203, 3205-3209, 3211Q, 3212, 3214-3217							7		9			
*3213						6	7		9			
*3301, 330301-3307, 3309, 3311, 3312, 3314-3316, 3320-3322									9			12
*3308		2							9			12
*3310						6			9			12
*3313					5				9			
*3318				4								12
*3319, 6829												12
*3402-3404, 3407, 3408			3	4								
*3406, 6606			3									
HLA-A allele <sup>4</sup>												
Well No.	1	2	3	4	5	6	7	8	9	10	11	12



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85	470	225	165	235	200	110	325	180	190	200	Length of spec. PCR product
13	14	15	16	17	18	19	20	21	22	23	Well No.
											*0106, 9214, 0305, 112401 1125, 1131, 1135, 29010101-290203, 2904, 2906-2911, 2915-2918, 3026, 6808, 8001
								21			*0107
											*0265, 9252, 3202, 3210, 3317, 7401-7413
											*0281, 0287, 9212, 9224, 9229, 2301, 230302-2313, 2315-2319Q, 241301, 2424, 2494
											*230301
											*2482
											*2619, 3012, 3018
											*2903
			16								*2912
											*2913
											*2914
											*320101-320103, 3203, 3205-3209, 3211Q, 3212, 3214-3217
											*3213
											*3301, 330301-3307, 3309, 3311, 3312, 3314-3316, 3320-3322
											*3308
											*3310
											*3313
											*3318
											*3319, 6829
											*3402-3404, 3407, 3408
											*3406, 6606
											HLA-A allele <sup>4</sup>
13	14	15	16	17	18	19	20	21	22	23	Well No.

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<sup>1</sup>The 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.

<sup>2</sup>The nucleotide position, in the 2<sup>nd</sup> or 3<sup>rd</sup> exons or the 3<sup>rd</sup> intron, matching the specificity-determining 3'-end of the primer is given. Nucleotide numbering as on the [www.ebi.ac.uk/imgt/hla](http://www.ebi.ac.uk/imgt/hla) web site. The sequence of the 3 terminal nucleotides of the primer is given.

<sup>3</sup>The nucleotide position, in the 2<sup>nd</sup> or 3<sup>rd</sup> 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](http://www.ebi.ac.uk/imgt/hla) web site. The sequence of the 3 terminal nucleotides of the primer is given.

<sup>4</sup>The sequence of the A\*310101 allele has been shown to be identical to A\*310102.

CELL LINE VALIDATION SHEET																				
HLA-A*31 SSP subtyping kit																				
				Lot No.:	Well															
					1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
					200852701	200510702	200510703	200510704	200510705	200510706	200510707	200510708	200510709	200510710	200510711	200510712	200510713	200738814	200738815	200738816
	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		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

CELL LINE VALIDATION SHEET											
HLA-A*31 SSP subtyping kit											
				Prod. No.:	Well						
					17	18	19	20	21	22	23
					200738817	200852718	200738819	200852720	200852721	200852722	200852723
	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	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\*31 SSP

Product number: 101.430-12 – including *Taq* polymerase  
Lot number: 24F  
Expiry date: 2010-November-01  
Number of tests: 12  
Number of wells per test: 23

#### Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2008-527-01	9	2005-107-09	17	2007-388-17
2	2005-107-02	10	2005-107-10	18	2008-527-18
3	2005-107-03	11	2005-107-11	19	2007-388-19
4	2005-107-04	12	2005-107-12	20	2008-527-20
5	2005-107-05	13	2005-107-13	21	2008-527-21
6	2005-107-06	14	2007-388-14	22	2008-527-22
7	2005-107-07	15	2007-388-15	23	2008-527-23
8	2005-107-08	16	2007-388-16		

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 23 were available. The specificities of the primers in primer solutions 2, 5, 6 and 21 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer. In primer solutions 8, 10, 13 to 18, 20, 22 and 23 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.

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

**Date of approval:** 2009-May-27

**Approved by:**

Quality Control, Supervisor

## Declaration of Conformity

**Product name:** *Olerup* SSP® HLA-A\*31  
**Product number:** 101.430-12  
**Lot number:** 24F

**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 9001:2000 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-May-27

Olle Olerup  
Managing Director



Lot No.: **24F**

Lot-specific information

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