

Lot No.: **78F**

Lot-specific information

## **Olerup SSP<sup>®</sup> HLA-A\*30**

**Product number:** 101.429-12u – without *Taq* polymerase  
**Lot number:** 78F  
**Expiry date:** 2011-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. 78F.**

### **CHANGES COMPARED TO THE PREVIOUS *OLERUP SSP<sup>®</sup>* 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<sup>®</sup>* HLA-A\*30 lot was made (Lot No. 38E).

Three wells have been added to the HLA-A\*30 kit,  
wells **22 to 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
3	-	Added	Primer added for the A*3027N allele.
7	Added	Added	Primer pair added for the A*3028 allele.
22	New	New	New primer pair for the A*3027N allele.
23	New	New	Primer pair added for the A*3026 allele.
24	New	New	Primer pair added for the A*3025 allele.

Changes in revision R02 compared to R01:

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

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## PRODUCT DESCRIPTION

### HLA-A\*30 SSP subtyping

#### CONTENT

The primer set contains 5'- and 3'-primers for identifying the A\*3001 to A\*3028 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\*30' in silver/gray ink.

Well No. 1 is marked with '78F'.

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, the A\*0343, the A\*2309, four A\*24, two A\*26, the A\*2914, most A\*31, the A\*3207, two A\*68 and the A\*8001 alleles when present on the other haplotype.

#### UNIQUELY IDENTIFIED ALLELES

All the HLA-A\*30 alleles, i.e. **A\*3001 to A\*3028 alleles**, recognized by the HLA Nomenclature Committee in January 2009<sup>1</sup> 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.

<sup>1</sup>HLA-B alleles listed on the IMGT/HLA web page 2009-January-16, release 2.24.0, [www.ebi.ac.uk/imgt/hla](http://www.ebi.ac.uk/imgt/hla).

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**RESOLUTION IN HOMO- AND HETEROZYGOTES**

The 28 HLA-A\*30 alleles can be combined in 351 homozygous and heterozygous combinations. Ninety-five of these genotypes do not give rise to unique amplification patterns. The different lengths of the specific PCR products generated by primer mixes 5 and 6 were not considered in these calculations.

++++----- ++----- +----- 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 = 3019, 3028  
++---+- +++---+- +----- 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  
++-----+ +++---+- +----- 3008, 3018 = 3018, 3028  
++-----+ +-+---+- +----- 3008, 3016 = 3016, 3028  
++-----+ +-+---+- +----- 3008, 3014L = 3014L, 3028  
++-----+ +-+---+- +----- 3008, 3015 = 3015, 3028  
++-----+ +-+---+- ++----- 3008, 3020 = 3020, 3028  
++-----+ +-+---+- +-+----- 3008, 3023 = 3023, 3028  
++-----+ +-+---+- +-+----- 3008, 3024 = 3024, 3028  
++-----+ +-+---+- +-----+ 3008, 3026 = 3026, 3028  
++-----+ +-+---+- +----- 3001, 3008 = 3001, 3028  
++-----+ +-+---+- +----- 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  
+-+---+- +-+---+- -----+ 3002, 3027N = 3027N, 3027N  
+-+---+- +-+---+- -----+ 3002, 3025 = 3025, 3025  
-+---+- +-+---+- +-----+ 3004, 3026 = 3017, 3026  
-----+ +-+---+- ----- 3004, 3006 = 3006, 3006  
-----+ +-+---+- +----- 3004, 3017 = 3017, 3017

3001 = 300101-300102  
3002 = 300201-300204  
3011 = 301101-301102

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## SPECIFICITY TABLE

### HLA-A\*30 SSP subtyping

Specificities and sizes of the PCR products of the 24 primer mixes used for HLA-A\*30 SSP subtyping

Primer Mix	Size of spec. PCR product <sup>1</sup>	Size of control band <sup>2</sup>	Amplified HLA-A*30 alleles	Other amplified HLA-A alleles <sup>3</sup>
1	165 bp	<b>800 bp</b>	300101-3003, 3007-3016, 3018-3020, 3022-3025, 3027, 3038	0252, 0343
2	205 bp	<b>800 bp</b>	300101-300102, 3008, 301101-301102, 3014L-3016, 3018-3020, 3023, 3024, 3026	
3	210 bp	<b>800 bp</b>	300201-3003, 3007, 3010, 3012, 3013, 3022, 3025, 3027N	8001 <sup>weakly</sup>
4	155 bp	1070 bp	3003, 301101-301102	0102, 0120
5 <sup>5</sup>	150, 245 bp	1070 bp	3004, 3006, 3017, 3019	0252 <sup>weakly</sup> , 2466 <sup>weakly</sup> , 6806
6 <sup>4,6</sup>	80, 185 bp	1070 bp	3006, 3007	
7	200 bp	1070 bp	3008 <sup>weakly</sup> , 3028	
8 <sup>4</sup>	85 bp	<b>800 bp</b>	3010	
9	180 bp	1070 bp	300101-300204, 3004, 3006, 3007, 3009, 3010, 3012-3020, 3023-3028	
10 <sup>7</sup>	150 bp	1070 bp	3012, 3018	0107, 2619, 2914, 310102-3107, 3109-3124
11	215 bp	<b>800 bp</b>	300101-3004, 3006, 3009-3020, 3023-3028	0102 <sup>weakly</sup> , 0120 <sup>weakly</sup> , 2309 <sup>weakly</sup> , 2424, 2467, 2616, 3207, 6845
12	145 bp	1070 bp	3009	
13	155 bp	1070 bp	300101-300204, 3004, 3006-3010, 3013-3017, 3019, 3020, 3023-3028	

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<b>14</b>	210 bp	1070 bp	3013, 3016
<b>15</b>	240 bp	<b>800 bp</b>	3014L
<b>16</b>	265 bp	1070 bp	3015
<b>17</b>	225 bp	1070 bp	300101-300102, 2419, 6845 301101-301102, 3014L-3020, 3023, 3024, 3026
<b>18</b>	210 bp	<b>800 bp</b>	3020
<b>19</b>	160 bp	1070 bp	3022
<b>20</b>	210 bp	<b>800 bp</b>	3023
<b>21</b>	185 bp	1070 bp	3024
<b>22</b>	215 bp	<b>800 bp</b>	3027N
<b>23</b>	155 bp	1070 bp	3026
<b>24<sup>7</sup></b>	200 bp	1070 bp	3025

<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\*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

<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\*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.

<sup>3</sup>Due 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.

<sup>4</sup>Short specific PCR fragments are less intense and not as sharp as longer specific bands.

<sup>5</sup>Primer mix 5: Specific PCR fragment of 150 bp in the A\*3004, 3006, 3017 and A\*0252<sup>weakly</sup>, 2466<sup>weakly</sup> and 6806 alleles. Specific PCR fragment of 245 bp in the A\*3019 allele.

<sup>6</sup>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.

<sup>7</sup>Primer mixes 10 and 24 may give rise to nonspecific amplifications.

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<b>INTERPRETATION TABLE</b>												
<b>HLA-A*30 SSP subtyping</b>												
<b>Amplification patterns of the A*3001 to 3028 alleles</b>												
	<b>Well<sup>5</sup></b>											
	1	2	3	4	5	6	7	8	9	10	11	12
Length of spec.	165	205	210	155	150	80	200	85	180	150	215	145
PCR product					245	185						
Length of int.	<b>800</b>	<b>800</b>	<b>800</b>	1070	1070	1070	1070	<b>800</b>	1070	1070	<b>800</b>	1070
pos. control <sup>1</sup>												
5'-primer(s) <sup>2</sup>	414	363	363	123	123	123	78	367	98	127	98	418
	5'-gAA <sup>3'</sup>	5'-ATA <sup>3'</sup>	5'-ATA <sup>3'</sup>	5'-AgT <sup>3'</sup>	5'-AgT <sup>3'</sup>	5'-AgT <sup>3'</sup>	5'-TCT <sup>3'</sup>	5'-TgC <sup>3'</sup>	5'-CTC <sup>3'</sup>	5'-ggg <sup>3'</sup>	5'-CTC <sup>3'</sup>	5'-AgC <sup>3'</sup>
					414							
					5'-gAA <sup>3'</sup>							
3'-primer(s) <sup>3</sup>	538	526	526	238	325	163	238	411	238	238	270	524
	5'-CAA <sup>3'</sup>	5'-CCA <sup>3'</sup>	5'-CCg <sup>3'</sup>	5'-CCC <sup>3'</sup>	5'-gTg <sup>3'</sup>	5'-CgC <sup>3'</sup>	5'-CCT <sup>3'</sup>	5'-TCA <sup>3'</sup>	5'-CCT <sup>3'</sup>	5'-CCT <sup>3'</sup>	5'-ACA <sup>3'</sup>	5'-CAC <sup>3'</sup>
			535		524	265	526					
			5'-CTA <sup>3'</sup>		5'-CAT <sup>3'</sup>	5'-CCC <sup>3'</sup>	5'-CCg <sup>3'</sup>					
Well No.	1	2	3	4	5	6	7	8	9	10	11	12
HLA-A allele <sup>4</sup>												
*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

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<b>INTERPRETATION TABLE</b>												
<b>HLA-A*30 SSP subtyping</b>												
<b>Amplification patterns of the A*3001 to 3028 alleles</b>												
<b>Well<sup>5</sup></b>												
13	14	15	16	17	18	19	20	21	22	23	24	
155	210	240	265	225	210	160	210	185	215	155	200	Length of spec. PCR product
1070	1070	800	1070	1070	800	1070	800	1070	800	1070	1070	Length of int. pos. control <sup>1</sup>
123	123	363	363	98	123	123	363	634	363	413	123	5'-primer(s) <sup>2</sup>
5'-AgT <sup>3'</sup>	5'-AgT <sup>3'</sup>	5'-ATA <sup>3'</sup>	5'-ATA <sup>3'</sup>	5'-CTC <sup>3'</sup>	5'-AgT <sup>3'</sup>	5'-AgT <sup>3'</sup>	5'-ATA <sup>3'</sup>	5'-CAG <sup>3'</sup>	5'-ATA <sup>3'</sup>	5'-CCg <sup>3'</sup>	5'-AgT <sup>3'</sup>	
238	292	563	586	282	294	240	530	777	535	526	282	3'-primer(s) <sup>3</sup>
5'-CCT <sup>3'</sup>	5'-gTg <sup>3'</sup>	5'-Cgg <sup>3'</sup>	5'-CAC <sup>3'</sup>	5'-gAC <sup>3'</sup>	5'-CgT <sup>3'</sup>	5'-ggA <sup>3'</sup>	5'-CCT <sup>3'</sup>	5'-gCA <sup>3'</sup>	5'-CTA <sup>3'</sup>	5'-CCA <sup>3'</sup>	5'-gAC <sup>3'</sup>	
13	14	15	16	17	18	19	20	21	22	23	24	Well No. HLA-A allele <sup>4</sup>
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	22	23	24	Well No.

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Length of spec.	165	205	210	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
*3025	1		3						9		11	
*3026		2							9		11	
*3027N	1		3						9		11	
*3028	1						7		9		11	
*0102, 0120				4							w	
*0107, 2619, 2914, 310102-3107, 3109- 3124										10		
*0252	1				w							
*0343	1											
*2309											w	
*2419												
*2424, 2467, 2616, 3207											11	
*2466					w							
*6806					5							
*6845											11	
*8001			w									
HLA-A allele <sup>4</sup>												
Well No.	1	2	3	4	5	6	7	8	9	10	11	12

<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\*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.

<sup>2</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. Nuclotide 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. Nuclotide 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.



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155	210	240	265	225	210	160	210	185	215	155	200	Length of spec. PCR product
13	14	15	16	17	18	19	20	21	22	23	24	Well No.
13											24	*3025
13				17						23		*3026
13									22			*3027N
13												*3028
												*0102, 0120
												*0107, 2619, 2914, 310102-3107, 3109- 3124
												*0252
												*0343
												*2309
				17								*2419
												*2424, 2467, 2616, 3207
												*2466
												*6806
				17								*6845
												*8001
												HLA-A allele <sup>4</sup>
13	14	15	16	17	18	19	20	21	22	23	24	Well No.

<sup>4</sup>The sequence of the A\*3005 allele has been shown to be identical to A\*3004.

A\*3021 has been renamed to A\*301102.

<sup>5</sup>Primer mix 5: Specific PCR fragment of 150 bp in the A\*3004, 3006, 3017 and A\*0252<sup>weakly</sup>, 2466<sup>weakly</sup> 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.

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CELL LINE VALIDATION SHEET																				
HLA-A*30 SSP subtyping kit																				
				Well																
				1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	
				Lot No.:	200617101	200843302	200958603	200617104	200730405	200617106	200958607	200843308	200617109	200617110	200617111	200730412	200617113	200617114	200617115	200617116
	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	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	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	-

Lot No.: 78F

Lot-specific information

CELL LINE VALIDATION SHEET												
HLA-A*30 SSP subtyping kit												
				Well								
				17	18	19	20	21	22	23	24	
				Lot No.:	200843317	200843318	200843319	200843320	200843321	200958622	200958623	200958624
	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	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		-	-	-	-	-	-	-	-	-
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45	9239 SHJO	*2301	*2402	-	-	-	-	-	-	-	-	-
46	9013 SCHU	*0301		-	-	-	-	-	-	-	-	-
47	9045 TUBO	*0216	*0301	-	-	-	-	-	-	-	-	-
48	9303 TER-ND	*0201	*1101	-	-	-	-	-	-	-	-	-

Lot No.: **78F**

Lot-specific information

## CERTIFICATE OF ANALYSIS

### **Olerup SSP<sup>®</sup> HLA-A\*30**

**Product number:** 101.429-12u – without *Taq* polymerase  
**Lot number:** 78F  
**Expiry date:** 2011-March-01  
**Number of tests:** 12  
**Number of wells per test:** 24

#### **Well specifications:**

Well No.	Production No.	Well No.	Production No.
1	2006-171-01	13	2006-171-13
2	2008-433-02	14	2006-171-14
3	2009-586-03	15	2006-171-15
4	2006-171-04	16	2006-171-16
5	2007-304-05	17	2008-433-17
6	2006-171-06	18	2008-433-18
7	2009-586-07	19	2008-433-19
8	2008-433-08	20	2008-433-20
9	2006-171-09	21	2008-433-21
10	2006-171-10	22	2009-586-22
11	2006-171-11	23	2009-586-23
12	2007-304-12	24	2009-586-24

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 6, 7, 12, 14 to 16, and 18 to 24 were available. The specificities of the primers in primer 6, 7, 12, 14, 19, 23 and 24 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer. In primer solution 6 it was only possible to test the 5'-primer and one of the 3'-primers, one 3'-primer was not possible to test. In primer solutions 15, 16, 18, 20 and 22 it was only possible to test the 5'-primers, the 3'-primers were not possible to test. In primer solution 21 it was only possible to test the 3'-primer, the 5'-primer was not possible to test. In addition, one 5'-primer in primer solution 5 was tested by adding an additional 3'-primer, one 3'-primer in this solution was not possible to test.

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

**Date of approval:** 2009-September-11

**Approved by:**

**Quality Control, Supervisor**

Lot No.: **78F**

Lot-specific information

## Declaration of Conformity

**Product name:** *Olerup* SSP® HLA-A\*30  
**Product number:** 101.429-12u  
**Lot number:** 78F

**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-11

Olle Olerup  
Managing Director

Lot No.: **78F**

Lot-specific information

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Lot No.: **78F**

Lot-specific information

**ADDRESSES:**

**Manufacturer:**

**Olerup SSP AB**, Hasselstigen 1, SE-133 33 Saltsjöbaden, Sweden.

**Tel:** +46-8-717 88 27

**Fax:** +46-8-717 88 18

**E-mail:** [info-ssp@olerup.com](mailto:info-ssp@olerup.com)

**Web page:** <http://www.olerup.com>

**Distributed by:**

**Olerup GmbH**, Löwengasse 47 / 6, AT-1030 Vienna, Austria.

**Tel:** +43-1-710 15 00

**Fax:** +43-1-710 15 00 10

**E-mail:** [support-at@olerup.com](mailto:support-at@olerup.com)

**Web page:** <http://www.olerup.com>

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

**Tel:** 1-877-OLERUP1

**Fax:** 610-344-7989

**E-mail:** [info.us@olerup.com](mailto:info.us@olerup.com)

**Web page:** <http://www.olerup.com>

For information on *Olerup* SSP distributors worldwide, contact **Olerup GmbH**.