

Lot No.: **48G**

Lot-specific Information

Olerup SSP[®] HLA-A*32

Product number: 101.431-12u – without *Taq* polymerase
Lot number: 48G
Expiry date: 2011-October-01
Number of tests: 12
Number of wells per test: 16
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. 48G.

CHANGES COMPARED TO THE PREVIOUS *OLERUP SSP[®]* HLA-A*32 LOT

The HLA-A*32 specificity and interpretation tables have been updated for the HLA-A alleles described since the previous *Olerup SSP[®]* HLA-A*32 lot was made (**Lot No. 99E**).

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	-	Modified	Increased yield of specific PCR product.
6	Added	Added	New primer pair for the A*3220 allele.
7	-	Added	New primer pair for the A*3217 allele.
8	Added	Added	New primer pair for the A*3219N allele.
10	-	Added	New primer pair for the A*3217 allele.
11	Added	Added, modified	New primer pair for the A*3220 allele, modified 3'-primer for increased specificity.
14	Added	Added, modified	New primer pair for the A*3218 allele, modified 3'-primer for increased specificity.
15	Added	Added	New primer pair for the A*3218 allele.

Lot No.: **48G**

Lot-specific Information

Lot No.: **48G**

Lot-specific Information

PRODUCT DESCRIPTION

HLA-A*32 SSP subtyping

CONTENT

The primer set contains 5'- and 3'-primers for identifying the A*3201 to A*3220 alleles.

PLATE LAYOUT

Each test consists of 16 PCR reactions in a 16 well cut PCR plate.

1	2	3	4	5	6	7	8
9	10	11	12	13	14	15	16

The 16 well cut PCR plate is marked with 'HLA-A*32' in silver/gray ink.

Well No. 1 is marked with the Lot No. '48G'.

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 16 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*32 SSP subtypings will be influenced by most A*01, eleven A*02, most A*03, most A*23, five A*24, the A*2503, two A*26, four A*29, most A*30, six A*31, the A*3310, the A*3408, the A*36, A*6845 and most A*74 alleles when present on the other haplotype.

UNIQUELY IDENTIFIED ALLELES

All the HLA-A*32 alleles, i.e. **A*3201 to A*3220 alleles**, recognized by the HLA Nomenclature Committee in October 2009¹ will give rise to unique amplification patterns by the primers in the HLA-A*32 subtyping kit.

The A*32 subtyping kit cannot distinguish the A*320101 to A*320103 alleles.

¹HLA-A alleles listed on the IMGT/HLA web page 2009-October-19, release 2.27.0, www.ebi.ac.uk/imgt/hla.

Lot No.: **48G**

Lot-specific Information

RESOLUTION IN HOMO- AND HETEROZYGOTES

The 20 HLA-A*32 alleles can be combined in 210 homozygous and heterozygous combinations. 132 of these genotypes do not give rise to unique amplification patterns. The different sizes of the specific PCR fragments generated by primer mixes 6, 8, 11, 12, 13 and 15 were not considered in these calculations.

++++-----	+-----	3202, 3207 = 3202, 3219N
++++-----	+----+---	3202, 3211Q = 3202, 3215
++++-----	+-----	3201, 3202 = 3202, 3206
++-+-----	+-----	3206, 3207 = 3206, 3219N
++-+-----	+--+-----	3206, 3210 = 3206, 3216
++-+-----	+----+---	3206, 3211Q = 3206, 3215
++-+-----	+-----	3201, 3206 = 3206, 3206
++-+-----	+-----	3203, 3207 = 3203, 3219N
++-+-----	+--+-----	3203, 3210 = 3203, 3216
++-+-----	+----+---	3203, 3211Q = 3203, 3215
++-+-----	+-----	3201, 3203 = 3203, 3203
++-+-----	+--+-----	3207, 3220 = 3219N, 3220
++-+-----	+-----	3204, 3207 = 3204, 3219N
++-+-----	++++-----	3210, 3220 = 3216, 3220
++-+-----	+--+-----	3211Q, 3220 = 3215, 3220
++-+-----	+--+-----	3201, 3220 = 3204, 3209 = 3204, 3220 = 3209, 3220 = 3220, 3220
++-+-----	+--+-----	3204, 3210 = 3204, 3216
++-+-----	+----+---	3204, 3211Q = 3204, 3215
++-+-----	++++-----	3207, 3217 = 3217, 3219N
++-+-----	+-----	3205, 3207 = 3205, 3219N
++-+-----	++-+-----	3210, 3217 = 3216, 3217
++-+-----	++-+-----	3211Q, 3217 = 3215, 3217
++-+-----	++-+-----	3201, 3217 = 3205, 3208 = 3205, 3217 = 3208, 3217 = 3217, 3217
++-+-----	+--+-----	3205, 3210 = 3205, 3216
++-+-----	+----+---	3205, 3211Q = 3205, 3215
++-+-----	+-----	3201, 3205 = 3205, 3205
++-+-----	++++-----	3207, 3208 = 3208, 3219N
++-+-----	+--+-----	3207, 3209 = 3209, 3219N
++-+-----	+--+-----	3207, 3210 = 3207, 3216 = 3210, 3219N = 3216, 3219N
++-+-----	+----+---	3207, 3211Q = 3211Q, 3219N = 3215, 3219N
++-+-----	+-----++-	3207, 3218 = 3218, 3219N
++-+-----	+-----+--	3207, 3212 = 3212, 3219N
++-+-----	+-----+--	3207, 3213 = 3213, 3219N
++-+-----	+-----++	3207, 3214 = 3214, 3219N
++-+-----	+-----	3201, 3207 = 3201, 3219N = 3207, 3219N = 3219N, 3219N
++-+-----	++-+-----	3208, 3210 = 3208, 3216
++-+-----	++-+-----	3208, 3211Q = 3208, 3215
++-+-----	++-+-----	3201, 3208 = 3208, 3208
++-+-----	++++-----	3209, 3210 = 3209, 3216

Lot No.: **48G**

Lot-specific Information

++-----	+--+-----	3209, 3211Q = 3209, 3215
++-----	+--+-----	3201, 3209 = 3209, 3209
++-----	+---+-----	3210, 3211Q = 3210, 3215 = 3211Q, 3216 = 3215, 3216
++-----	+---+---+	3210, 3218 = 3216, 3218
++-----	+---+---+	3210, 3212 = 3212, 3216
++-----	+---+---+	3210, 3213 = 3213, 3216
++-----	+---+---+	3210, 3214 = 3214, 3216
++-----	+---+-----	3201, 3210 = 3201, 3216 = 3210, 3216 = 3216, 3216
++-----	+---+---+	3211Q, 3218 = 3215, 3218
++-----	+---+---+	3211Q, 3212 = 3212, 3215
++-----	+---+---+	3211Q, 3213 = 3213, 3215
++-----	+---+---+	3211Q, 3214 = 3214, 3215
++-----	+---+-----	3201, 3211Q = 3201, 3215 = 3211Q, 3211Q = 3211Q, 3215
++-----	+---+---+	3201, 3218 = 3212, 3213 = 3212, 3218 = 3213, 3218 = 3218, 3218
++-----	+---+---+	3201, 3212 = 3212, 3212
++-----	+---+---+	3201, 3213 = 3213, 3213
++-----	+---+---+	3201, 3214 = 3214, 3214

3201 = 320101-320103

Lot No.: **48G**

Lot-specific Information

SPECIFICITY TABLE

HLA-A*32 SSP subtyping

Specificities and sizes of the PCR products of the 16 primer mixes used for HLA-A*32 SSP subtyping

Primer Mix	Size of spec. PCR product ¹	Size of control band ²	Amplified HLA-A*32 alleles	Other amplified HLA-A alleles ³
1	200 bp	800 bp	*320101-3206, 3208-3214, 3216-3220	*01010101-010108, 0103, 0104N, 0106- 0119, 0121-0142, 0144, 0145, 0245, 025601, 025602, 03010101- 030103, 030105-0311N, 0313-0322, 0325-0329, 0331-0335, 0337-0358, 0360-0362, 9203, 9295, 3121, 3601-3604, 7401- 7403, 7405-7414N
2	510 bp	1070 bp	*320101- 320103, 3203- 3209, 3211Q- 3220	*0281, 0287, 9212, 9224, 9229, 230101, 230102, 230301-2313, 2315-2322, 241301, 2418, 2424, 2494, 2913, 3107, 3108, 3110
3⁴	130bp	1070 bp	*3202	*2905, 3124
4^{4,5}	115 bp	800 bp	*3202, 3206	
5	165 bp	800 bp	*3203	
6^{4,6}	120, 520 bp	1070 bp	*3204, 3220	*2418
7⁴	135 bp	800 bp	*3205, 3217	*2913
8⁷	165, 215 bp	1070 bp	*3207, 3219N	*0102 ^w , 0120 ^w , 2309 ^w , 2424, 2467, 2616, 300101-3004, 3006, 3009-3020, 3023-3030, 6845
9	180 bp	1070 bp	*320101-3203, 3205-3220	*2913
10	150 bp	800 bp	*3208, 3217	*2913
11^{4,8}	120, 165 bp	1070 bp	*3209, 3220	
12^{4,9}	130, 195 bp	1070 bp	*3210, 3216	
13¹⁰	150, 200	1070 bp	*3211Q, 3215	*0255, 0324, 2503,

Lot No.: **48G**

Lot-specific Information

	bp			2620, 3408
14	215 bp	1070 bp	*3212, 3218	*2906
15¹¹	165, 220 bp	1070 bp	*3213, 3218	*230301, 2903, 3105, 3310
16	220 bp	1070 bp	*3214	

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*32 SSP typings.

When the primers in a primer mix can give rise to specific PCR products of more than one length this is indicated if the size difference is 20 base pairs or more. Size differences shorter than 20 base pairs are not given. For high resolution SSP kits the respective lengths of the specific PCR product(s) of the alleles amplified by these primer mixes are given.

Nonspecific amplifications, i.e. a ladder or a smear of bands, may sometimes be seen. GC-rich primers have a higher tendency of giving rise to nonspecific amplifications than other primers.

PCR fragments longer than the control bands may sometimes be observed. Such bands should be disregarded and do not influence the interpretation of the SSP typings.

PCR fragments migrating faster than the control bands, but slower than a 400 bp fragment may be seen in some gel read-outs. Such bands can be disregarded and do not influence the interpretation of the SSP typings.

Some primers may give rise to primer oligomer artifacts. Sometimes this phenomenon is an inherent feature of the primer pair(s) of a primer mix. More often it is due to other factors such as too low amount of DNA in the PCR reactions, taking too long time in setting up the PCR reactions, working at elevated room temperature or using thermal cyclers that are not pre-heated.

²The internal positive control primer pairs amplify segments of the human growth hormone gene. The two different control primer pairs give rise to either an internal positive control band of 1070 base pairs, for most wells, or a band of 800 base pairs, for some wells.

Well number 1 contains the primer pair giving rise to the shorter, 800 bp, internal positive control band in order to help in the correct orientation of the HLA-A*01 subtyping.

In addition, wells number 4, 5, 7 and 10 contain the primer pair giving rise to the shorter, 800 bp, internal positive control band in order to allow kit identification.

In the presence of a specific amplification the intensity of the control band often decreases.

³Due to the sharing of sequence motifs between HLA-A alleles a few non-HLA-A*32 alleles will be amplified by primer mixes 1 to 3, 6 to 10 and 13 to 15.

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

⁵Primer mix 4 has a tendency of giving rise to non-specific amplifications.

⁶Primer mix 6: Specific PCR fragment of 120 bp in A*3220 allele. Specific PCR fragment of 520 bp in the A*3204 and the A*2418 alleles.

⁷Primer mix 8: Specific PCR fragment of 165 bp in A*3219N allele. Specific PCR fragment of 215 bp in the A*3207 and the A*2424, 2467, 2616, 300101-3004, 3006, 3009-3020, 3023-3030 and 6845 alleles.

⁸Primer mix 11: Specific PCR fragment of 120 bp in A*3220 allele. Specific PCR fragment of 165 bp in the A*3209 allele.

⁹Primer mix 12: Specific PCR fragment of 130 bp in A*3210 allele. Specific PCR fragment of 195 bp in the A*3216 allele.

¹⁰Primer mix 13: Specific PCR fragment of 150 bp in A*3211Q allele. Specific PCR fragment of 200 bp in the A*3215 and A*0255, 0324, 2503, 2620 and 3408 alleles.

¹¹Primer mix 15: Specific PCR fragment of 165 bp in A*3213 and the 230301, 2903, 3105 and 3310 alleles. Specific PCR fragment of 220 bp in the A*3218 allele.

'w', might be weakly amplified.

Lot No.: **48G**

Lot-specific Information

INTERPRETATION TABLE								
HLA-A*32 SSP subtyping								
Amplification patterns of the A*3201 to A*3220 alleles								
	Well ⁴							
	1	2	3	4	5	6	7	8
Length of spec.	200	510	130	115	165	120	135	165
PCR product(s)						520		215
Length of int.	800	1070	1070	800	800	1070	800	1070
pos. control ¹								
5'-primer(s) ²	98	317	448	448	180	101	180	98
	5' -CTT 3'	5' -gCT 3'	5' -CCT 3'	5' -CCT 3'	5' -TTT 3'	5' -CAT 3'	5' -TTT 3'	5' -CTC 3'
						317		448
						5' -gCT 3'		5' -CCT 3'
3'-primer(s) ³	256	538	539	524	302	180	265	270
	5' -CTg 3'	5' -CAA 3'	5' -TCT 3'	5' -CAT 3'	5' -ggT 3'	5' -TCA 3'	5' -CCC 3'	5' -ACA 3'
	256	555				555	282	573
	5' -CTg 3'	5' -CCA 3'				5' -CCA 3'	5' -gAC 3'	5' -AgT 3'
Well No.	1	2	3	4	5	6	7	8
HLA-A allele								
*320101-320103	1	2						
*3202	1		3	4				
*3203	1	2			5			
*3204	1	2				6		
*3205	1	2					7	
*3206	1	2		4				
*3207		2						8
*3208	1	2						
*3209	1	2						
*3210	1							
*3211Q	1	2						
*3212	1	2						
*3213	1	2						
*3214	1	2						
*3215		2						
*3216	1	2						
*3217	1	2					7	
*3218	1	2						
*3219N	1	2						8
*3220	1	2				6		
Well No.	1	2	3	4	5	6	7	8

Lot No.: **48G**

Lot-specific Information

INTERPRETATION TABLE								
HLA-A*32 SSP subtyping								
Amplification patterns of the A*3201 to A*3220 alleles								
Well ⁴								
9	10	11	12	13	14	15	16	
180	150	120	130	150	215	165	220	Length of spec. PCR product(s)
		165	195	200		220		
1070	800	1070	1070	1070	1070	1070	1070	Length of int. pos. control ¹
180	180	101	448	102	139	139	124	5'-primer(s) ²
5' -TTT 3'	5' -TTT 3'	5' -CAT 3'	5' -CCT 3'	5' -ACA 3'	5' -TCg 3'	5' -TCg 3'	5' -gCC 3'	
		448		448	448	448		
		5' -CCT 3'		5' -CCT 3'	5' -CCT 3'	5' -CCT 3'		
317	282	180	539	259	317	317	302	3'-primer(s) ³
5' -ggA 3'	5' -gAC 3'	5' -TCA 3'	5' -TCC 3'	5' -gTT 3'	5' -ggA 3'	5' -ggA 3'	5' -ggC 3'	
	292	571	602	559	616	570		
	5' -gTg 3'	5' -CCg 3'	5' -TCA 3'	5' -CTC 3'	5' -CgC 3'	5' -CCg 3'		
9	10	11	12	13	14	15	16	Well No.
								HLA-A allele
9								*320101-320103
9								*3202
9								*3203
								*3204
9								*3205
9								*3206
9								*3207
9	10							*3208
9		11						*3209
9			12					*3210
9				13				*3211Q
9					14			*3212
9						15		*3213
9							16	*3214
9				13				*3215
9			12					*3216
9	10							*3217
9					14	15		*3218
9								*3219N
9		11						*3220
9	10	11	12	13	14	15	16	Well No.

Lot No.: **48G**

Lot-specific Information

Length of spec.	200	510	130	115	165	120	135	165
PCR product						520		215
Well No.	1	2	3	4	5	6	7	8
*01010101-010108, 0103, 0104N, 0106-0119, 0121-0142, 0144, 0145, 0245, 025601, 025602, 03010101-030103, 030105-0311N, 0313-0322, 0325-0329, 0331-0335, 0337-0358, 0360-0362, 9203, 9295, 3121, 3601-3604, 7401-7403, 7405-7414N	1							
*0102, 0120								w
*0255, 0324, 2503, 2620, 3408								
*0281, 0287, 9212, 9224, 9229, 230101, 230102, 230302-2308N, 2310-2313, 2315-2322, 241301, 2494, 3107, 3108, 3110		2						
*230301		2						
*2309		2						w
*2418		2				6		
*2424		2						8
*2467, 2616, 300101-3004, 3006, 3009-3020, 3023-3030, 6845								8
*2903, 3105, 3310								
*2905, 3124			3					
*2906								
*2913		2					7	
HLA-A allele								
Well No.	1	2	3	4	5	6	7	8

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*32 subtyping.

In addition, wells number 4, 5, 7 and 10 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 or 3rd exon, matching the specificity-determining 3'-end of the primer is given. Nucleotide numbering as on the www.ebi.ac.uk/imgt/hla web site. The sequence of the 3 terminal nucleotides of the primer is given.

³The nucleotide position, in the 2nd or 3rd exon, matching the specificity-determining 3'-end of the primer is given in the anti-sense direction. Nucleotide numbering as on the www.ebi.ac.uk/imgt/hla web site. The sequence of the 3 terminal nucleotides of the primer is given.

Lot No.: **48G**

Lot-specific Information

180	150	120	130	150	215	165	220	Length of spec. PCR product
9	10	11	12	13	14	15	16	Well No.
								*01010101-010108, 0103, 0104N, 0106-0119, 0121-0142, 0144, 0145, 0245, 025601, 025602, 03010101-030103, 030105- 0311N, 0313-0322, 0325-0329, 0331-0335, 0337-0358, 0360- 0362, 9203, 9295, 3121, 3601- 3604, 7401-7403, 7405-7414N
								*0102, 0120
				13				*0255, 0324, 2503, 2620, 3408
								*0281, 0287, 9212, 9224, 9229, 230101, 230102, 230302-2308N, 2310-2313, 2315-2322, 241301, 2494, 3107, 3108, 3110
						15		*230301
								*2309
								*2418
								*2424
								*2467, 2616, 300101-3004, 3006, 3009-3020, 3023-3030, 6845
						15		*2903, 3105, 3310
								*2905, 3124
					14			*2906
9	10							*2913
								HLA-A allele
9	10	11	12	13	14	15	16	Well No.

⁴Primer mix 6: Specific PCR fragment of 120 bp in A*3220 allele. Specific PCR fragment of 520 bp in the A*3204 and the A*2418 alleles.

Primer mix 8: Specific PCR fragment of 165 bp in A*3219N allele. Specific PCR fragment of 215 bp in the A*3207 and the A*2424, 2467, 2616, 300101-3004, 3006, 3009-3020, 3023-3030 and 6845 alleles.

Primer mix 11: Specific PCR fragment of 120 bp in A*3220 allele. Specific PCR fragment of 165 bp in the A*3209 allele.

Primer mix 12: Specific PCR fragment of 130 bp in A*3210 allele. Specific PCR fragment of 195 bp in the A*3216 allele.

Primer mix 13: Specific PCR fragment of 150 bp in A*3211Q allele. Specific PCR fragment of 200 bp in the A*3215 and A*0255, 0324, 2503, 2620 and 3408 alleles.

Primer mix 15: Specific PCR fragment of 165 bp in A*3213 and the 230301, 2903, 3105 and 3310 alleles. Specific PCR fragment of 220 bp in the A*3218 allele.

'w', might be weakly amplified.

Lot No.: **48G**

Lot-specific Information

CELL LINE VALIDATION SHEET																			
HLA-A*32 SSP subtyping kit																			
				Well															
				1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
				Lot No.:															
				200965601	200850302	200850303	200850304	200965605	200965606	200965607	200965608	200850309	200965610	200965611	200850312	200850313	200965614	200965615	200850316
	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	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

Lot No.: **48G**

Lot-specific Information

CERTIFICATE OF ANALYSIS

Olerup SSP[®] HLA-A*32 SSP

Product number: 101.431-12u – without *Taq* polymerase
Lot number: 48G
Expiry date: 2011-October-01
Number of tests: 12
Number of wells per test: 16

Well specifications:

Well No.	Production No.	Well No.	Production No.
1	2009-656-01	9	2008-503-09
2	2008-503-02	10	2009-656-10
3	2008-503-03	11	2009-656-11
4	2008-503-04	12	2008-503-12
5	2009-656-05	13	2008-503-13
6	2009-656-06	14	2009-656-14
7	2009-656-07	15	2009-656-15
8	2009-656-08	16	2008-503-16

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 3 to 5, 7 and 10 to 16 were available. The specificities of the primers in primer solutions 3 to 5, 7 and 10 to 15 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer.

In primer solution 16 it was only possible to test the 3'-primer, the 5'-primer was not possible to test.

Additional primers in primer solutions 2, 6 and 8 were tested by separately adding one 5' –primer, respectively one 3'-primer.

In primer solution 1, 8, 10, 12 and 13 one of the 3'-primers was not possible to test. In primer solutions 6 and 15 one of the 5'-primers was not possible to test, and in primer solutions 11 and 14 one 5'-primer and one 3'-primer were not possible to test.

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

Date of approval: 2009-November-08

Approved by:

Quality Control, Supervisor

Lot No.: **48G**

Lot-specific Information

Declaration of Conformity

Product name: *Olerup* SSP® HLA-A*32
Product number: 101.431-12u
Lot number: 48G

Intended use: HLA-A*32 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
2009-November-08

Olle Olerup

Lot No.: **48G**

Lot-specific Information

Lot No.: **48G**

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

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

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

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

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