

Lot No.: **99E**

Lot-specific Information

## **Olerup SSP<sup>®</sup> HLA-A\*32**

Product number: 101.431-12u – without *Taq* polymerase  
Lot number: 99E  
Expiry date: 2010-August-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. 99E.**

### **CHANGES COMPARED TO THE PREVIOUS *OLERUP SSP<sup>®</sup>* 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<sup>®</sup>* HLA-A\*32 lot was made (**Lot No. Y13**).

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	-	Modified	Increased specificity of specific primer pair.
4	-	Modified	Increased specificity of specific primer pair.
12	-	New and modified	New primer for the A*3216 allele, and changed primer to increase specificity.

Lot No.: **99E**

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\*3216 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'.

Well No. 1 is marked with the Lot No. '99E'.

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, nine A\*02, the A\*03, most A\*23, four A\*24, the A\*2503, two A\*26, four A\*29, most A\*30, five A\*31, the A\*3310, the A\*3408, the A\*36 and the A\*74 alleles when present on the other haplotype.

#### UNIQUELY IDENTIFIED ALLELES

All the HLA-A\*32 alleles, i.e. **A\*3201 to A\*3216 alleles**, recognized by the HLA Nomenclature Committee in July 2008<sup>1</sup> 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.

<sup>1</sup>HLA-A alleles listed on the IMGT/HLA web page 2008-July-11, release 2.22.0, [www.ebi.ac.uk/imgt/hla](http://www.ebi.ac.uk/imgt/hla).

Lot No.: **99E**

Lot-specific Information

**RESOLUTION IN HOMO- AND HETEROZYGOTES**

The 16 HLA-A\*32 alleles can be combined in 136 homozygous and heterozygous combinations. Forty-eight of these genotypes do not give rise to unique amplification patterns. The different sizes of the specific PCR fragments generated by primer mixes 12 and 13 were not considered in these calculations.

++++-----	+-----	3202,3211Q = 3202,3215
++-+-----	+---+-----	3206,3210 = 3206,3216
++-+-----	+---+-----	3206,3211Q = 3206,3215
++-+-----	+---+-----	3203,3210 = 3203,3216
++-+-----	+---+-----	3203,3211Q = 3203,3215
++-----	+-----	3204,3210 = 3204,3216
++-----	+-----	3204,3211Q = 3204,3215
++-----	+-----	3205,3210 = 3205,3216
++-----	+-----	3205,3211Q = 3205,3215
++-----	+-----	3207,3210 = 3207,3216
++-----	++-+-----	3208,3210 = 3208,3216
++-----	++-+-----	3208,3211Q = 3208,3215
++-----	++-+-----	3209,3210 = 3209,3216
++-----	++-+-----	3209,3211Q = 3209,3215
++-----	++-+-----	3210,3211Q = 3210,3215
		= 3211Q,3216 = 3215,3216
++-----	+---+-----	3210,3212 = 3212,3216
++-----	+---+-----	3210,3213 = 3213,3216
++-----	+---+-----	3210,3214 = 3214,3216
++-----	+---+-----	3210,3216 = 3216,3216
++-----	+-----	3211Q,3212 = 3212,3215
++-----	+-----	3211Q,3213 = 3213,3215
++-----	+-----	3211Q,3214 = 3214,3215
++-----	+-----	3211Q,3211Q = 3211Q,3215

Lot No.: **99E**

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 <sup>1</sup>	Size of control band <sup>2</sup>	Amplified HLA-A*32 alleles	Other amplified HLA-A alleles <sup>3</sup>
<b>1</b>	200 bp	<b>800 bp</b>	320101-3206, 3208-3214, 3216	01010101-010105, 0103, 0104N, 0106-0119, 0121-0130, 0245, 0256, 9203, 03010101-030103, 030105-0311N, 0313- 0322, 0325-0329, 0331- 0339, 3121, 3601-3604, 7401-7403, 7405-7412N
<b>2</b>	510 bp	1070 bp	320101-320103, 3203-3209, 3211Q-3216	0281, 0287, 9212, 9224, 9229, 2301, 230301- 2313, 2315-2319Q, 241301, 2418, 2424, 2913, 3107, 3108, 3110
<b>3<sup>4</sup></b>	130bp	1070 bp	3202	2905
<b>4<sup>4,5</sup></b>	115 bp	<b>800 bp</b>	3202, 3206	
<b>5</b>	165 bp	<b>800 bp</b>	3203	
<b>6</b>	520 bp	1070 bp	3204	2418
<b>7<sup>4</sup></b>	125 bp	<b>800 bp</b>	3205	
<b>8</b>	215 bp	1070 bp	3207	2424, 2467, 2616, 300101-3004, 3006, 3009-3020, 3023-3025
<b>9</b>	180 bp	1070 bp	320101-3203, 3205-3216	2913
<b>10</b>	155 bp	<b>800 bp</b>	3208	
<b>11</b>	165 bp	1070 bp	3209	
<b>12<sup>4,6</sup></b>	130, 195 bp	1070 bp	3210, 3216	
<b>13<sup>7</sup></b>	150, 200 bp	1070 bp	3211Q, 3215	0255, 0324, 2503, 2620, 3408
<b>14</b>	210 bp	1070 bp	3212	2906
<b>15</b>	165 bp	1070 bp	3213	230301, 2903, 3105, 3310
<b>16</b>	220 bp	1070 bp	3214	

Lot No.: **99E**

### Lot-specific Information

<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\*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 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\*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.

<sup>3</sup> Due 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, 8 and 9, 13 to 15.

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

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

<sup>6</sup> Primer mix 12: Specific PCR fragment of 130 bp in A\*3210 allele. Specific PCR fragment of 195 bp in the A\*3216 allele.

<sup>7</sup> 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.

Lot No.: **99E**

Lot-specific Information

<b>INTERPRETATION TABLE</b>								
<b>HLA-A*32 SSP subtyping</b>								
<b>Amplification patterns of the A*3201 to A*3216 alleles</b>								
	<b>Well<sup>4</sup></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>
Length of spec.	200	510	130	115	165	520	125	215
PCR product(s)								
Length of int.	<b>800</b>	<b>1070</b>	<b>1070</b>	<b>800</b>	<b>800</b>	<b>1070</b>	<b>800</b>	<b>1070</b>
pos. control <sup>1</sup>								
5'-primer(s) <sup>2</sup>	<b>98</b>	<b>317</b>	<b>448</b>	<b>448</b>	<b>180</b>	<b>317</b>	<b>180</b>	<b>98</b>
	5'-CTT <sup>3'</sup>	5'-gCT <sup>3'</sup>	5'-CCT <sup>3'</sup>	5'-CCT <sup>3'</sup>	5'-TTT <sup>3'</sup>	5'-gCT <sup>3'</sup>	5'-TTT <sup>3'</sup>	5'-CTC <sup>3'</sup>
3'-primer(s) <sup>3</sup>	<b>256</b>	<b>538</b>	<b>539</b>	<b>524</b>	<b>302</b>	<b>555</b>	<b>265</b>	<b>270</b>
	5'-CTg <sup>3'</sup>	5'-CAA <sup>3'</sup>	5'-TCT <sup>3'</sup>	5'-CAT <sup>3'</sup>	5'-ggT <sup>3'</sup>	5'-CCA <sup>3'</sup>	5'-CCC <sup>3'</sup>	5'-ACA <sup>3'</sup>
		<b>555</b>						
		5'-CCA <sup>3'</sup>						
Well No.	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>6</b>	<b>7</b>	<b>8</b>
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						
*01010101-010105, 0103, 0104N, 0106-0119, 0121-0130, 0245, 0256, 9203, 03010101-030103, 030105- 0311N, 0313-0322, 0325-0329, 0331- 0339, 3121, 3601-3604, 7401-7403, 7405-7412N	1							
Well No.	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>6</b>	<b>7</b>	<b>8</b>

Lot No.: **99E**

Lot-specific Information

INTERPRETATION TABLE								
HLA-A*32 SSP subtyping								
Amplification patterns of the A*3201 to A*3216 alleles								
Well <sup>4</sup>								
9	10	11	12	13	14	15	16	
180	155	165	130	150	210	165	220	Length of spec.
			195	200				PCR product(s)
1070	<b>800</b>	1070	1070	1070	1070	1070	1070	Length of int.
								pos. control <sup>1</sup>
180	180	448	448	102	448	448	124	5'-primer(s) <sup>2</sup>
5'-TTT <sup>3'</sup>	5'-TTT <sup>3'</sup>	5'-CCT <sup>3'</sup>	5'-CCT <sup>3'</sup>	5'-ACA <sup>3'</sup>	5'-CCT <sup>3'</sup>	5'-CCT <sup>3'</sup>	5'-ggC <sup>3'</sup>	
				448				
				5'-CCT <sup>3'</sup>				
317	292	571	539	259	616	570	302	3'-primer(s) <sup>3</sup>
5'-ggA <sup>3'</sup>	5'-gTg <sup>3'</sup>	5'-CCg <sup>3'</sup>	5'-TCC <sup>3'</sup>	5'-gTT <sup>3'</sup>	5'-CgC <sup>3'</sup>	5'-CCg <sup>3'</sup>	5'-ggC <sup>3'</sup>	
			618	559				
			5'-TCA <sup>3'</sup>	5'-CTC <sup>3'</sup>				
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
								*01010101-010105, 0103, 0104N, 0106-0119, 0121-0130, 0245, 0256, 9203, 03010101-030103, 030105- 0311N, 0313-0322, 0325-0329, 0331 0339, 3121, 3601-3604, 7401-7403, 7405-7412N
9	10	11	12	13	14	15	16	Well No.

Lot No.: **99E**

Lot-specific Information

Length of spec.	200	510	130	115	165	520	125	215
PCR product								
Well No.	1	2	3	4	5	6	7	8
*0255, 0324, 2503, 2620, 3408								
*0281, 0287, 9212, 9224, 9229, 2301, 230302-2313, 2315-2319Q, 241301, 3107, 3108, 3110		2						
*230301		2						
*2418		2				6		
*2424		2						8
*2467, 2616, 300101-3004, 3006, 3009-3020, 3023-3025								8
*2903, 3105, 3310								
*2905			3					
*2906								
*2913		2						
HLA-A allele								
Well No.	1	2	3	4	5	6	7	8

<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\*01 subtyping.

In addition, wells number 3, 7, 10 to 12 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>2</sup>The nucleotide position, in the 1<sup>st</sup>, 2<sup>nd</sup> or 3<sup>rd</sup> exon or the 2<sup>nd</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> 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](http://www.ebi.ac.uk/imgt/hla) web site. The sequence of the 3 terminal nucleotides of the primer is given.



Lot No.: **99E**

Lot-specific Information

180	155	165	130	150	210	165	220	Length of spec. PCR product
9	10	11	12	13	14	15	16	Well No.
			195	200				
				13				*0255, 0324, 2503, 2620, 3408
								*0281, 0287, 9212, 9224, 9229, 2301, 230302-2313, 2315-2319Q, 241301, 3107, 3108, 3110
						15		*230301
								*2418
								*2424
								*2467, 2616, 300101-3004, 3006, 3009-3020, 3023-3025
						15		*2903, 3105, 3310
								*2905
								*2906
9					14			*2913
								HLA-A allele
9	10	11	12	13	14	15	16	Well No.

<sup>4</sup>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.

Lot No.: **99E**

Lot-specific Information

<b>CELL LINE VALIDATION SHEET</b>																			
<b>HLA-A*32 SSP subtyping kit</b>																			
				<b>Well</b>															
				1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
				Lot No.:															
				200850301	200850302	200850303	200850304	200850305	200850306	200850307	200850308	200850309	200850310	200850311	200850312	200850313	200850314	200850315	200850316
	<b>IHWC cell line</b>	<b>A*</b>	<b>A*</b>																
1	9001 SA	*2402		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2	9280 LK707	*0201		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
3	9011 E4181324	*0101		+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
4	9275 GU373	*3001		-	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-
5	9009 KAS011	*0101		+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
6	9353 SM	*0201	*2603	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
7	9020 QBL	*2601		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
8	9007 DEM	*0201		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
9	9026 YAR	*2601		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
10	9107 LKT3	*2402		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
11	9051 PITOUT	*2902		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
12	9052 DBB	*0201		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
13	9067 BTB	*0201		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
14	9071 OLGA	*3101		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
15	9075 DKB	*2402		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
16	9037 SWEIG007	*2902		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
17	9008 WILJON	*2501		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
18	9257 32367	*3303	*7401	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
19	9038 BM16	*0201		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
20	9059 SLE005	*0201		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
21	9064 AMALA	*0217		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
22	9056 KOSE	*0201		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
23	9124 IHL	*0201	*3401	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
24	9035 JBUSH	*3201		+	+	-	-	-	-	-	-	+	-	-	-	-	-	-	-
25	9049 IBW9	*3301		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
26	9285 WT49	*0205		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
27	9191 CH1007	*2410	*2901	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
28	9320 BEL5GB	*0201	*2902	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
29	9050 MOU	*2902		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
30	9021 RSH	*3001	*6802	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-
31	9019 DUCAF	*3002		-	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-
32	9297 HAG	*0201		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
33	9098 MT14B	*3101		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
34	9104 DHIF	*3101		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
35	9302 SSTO	*3201		+	+	-	-	-	-	-	-	+	-	-	-	-	-	-	-
36	9024 KT17	*0206	*1101	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
37	9065 HHKB	*0301		+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
38	9099 LZL	*0217		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
39	9315 CML	*0101	*0301	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
40	9134 WHONP199	*0207	*3001	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-
41	9055 H0301	*0301		+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
42	9066 TAB089	*0207		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
43	9076 T7526	*0207		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
44	9057 TEM	*6601		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
45	9239 SHJO	*2301	*2402	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
46	9013 SCHU	*0301		+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
47	9045 TUBO	*0216	*0301	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
48	9303 TER-ND	*0201	*1101	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

Lot No.: **99E**

Lot-specific Information

## CERTIFICATE OF ANALYSIS

### **Olerup SSP<sup>®</sup> HLA-A\*32 SSP**

**Product number:** 101.431-12u – without *Taq* polymerase  
**Lot number:** 99E  
**Expiry date:** 2010-August-01  
**Number of tests:** 12  
**Number of wells per test:** 16

#### **Well specifications:**

Well No.	Production No.	Well No.	Production No.
1	2008-503 -01	9	2008-503-09
2	2008-503-02	10	2008-503-10
3	2008-503-03	11	2008-503-11
4	2008-503-04	12	2008-503-12
5	2008-503-05	13	2008-503-13
6	2008-503-06	14	2008-503-14
7	2008-503-07	15	2008-503-15
8	2008-503-08	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 2 to 7 and 10 to 16 were available. The specificities of the primers in primer solutions 3 to 7, 12, 13 and 15 tested by separately adding one additional 5'-primer, respectively one additional 3'-primer. In primer solutions 10, 11, and 14 it was only possible to test the 5'-primers, the 3'-primers were not possible to test. In primer solution 2 and 16 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**

Lot No.: **99E**

Lot-specific Information

## Declaration of Conformity

**Product name:** *Olerup* SSP<sup>®</sup> HLA-A\*32  
**Product number:** 101.431-12u  
**Lot number:** 99E

**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 9001:2000 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

Lot No.: **99E**

Lot-specific Information

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