

Lot No.: **40F**

Lot-specific information

Olerup SSP[®] HLA-A*26

Product number: 101.424-12u – without *Taq* polymerase
Lot number: 40F
Expiry date: 2011-January-01
Number of tests: 12
Number of wells per test: 30
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. 40F.

CHANGES COMPARED TO THE PREVIOUS *OLERUP SSP*[®] HLA-A*26 LOT

The HLA-A*26 specificity and interpretation tables have been updated for the HLA-A alleles described since the previous *Olerup SSP*[®] HLA-A*26 lot was made (Lot No. 03E).

Three wells have been added to the HLA-A*26 kit,
wells **28 to 30**.

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

Well	5'-primer	3'-primer	rationale
5	Removed	Removed	Primer pair moved to well 30.
25	-	Exchanged	New 3'-primer to improve yield of specific PCR product
28	New	New	New primer pair for the A*2636 allele.
29	New	New	New primer pair for the A*2637 allele.
30	Moved	Moved	Primer pair from well 5.

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PRODUCT DESCRIPTION

HLA-A*26 SSP subtyping

CONTENT

The primer set contains 5'- and 3'-primers for identifying the A*2601 to A*2637 alleles.

PLATE LAYOUT

Each test consists of 27 PCR reactions in a 32 well cut PCR plate. Wells 31 and 32 are empty.

1	2	3	4	5	6	7	8
9	10	11	12	13	14	15	16
17	18	19	20	21	22	23	24
25	26	27	28	29	30	empty	empty

The 32 well PCR plate is marked with 'HLA-A*26' in silver/gray ink.

Well No. 1 is marked with the Lot Number '40F'.

The PCR plates are covered with a PCR-compatible foil.

Please note: When removing each 32 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*26 SSP subtypings will be influenced by five A*01, several A*02, the A*0309, most A*11, the A*2310, six A*24, the A*25, two A*30, two A*31, the A*3313, the A*34, the A*3603, the A*4301, the A*66, the A*68, the A*6901, two A*74 and the A*8001 allele when present on the other haplotype.

UNIQUELY IDENTIFIED ALLELES

All the HLA-A*26 alleles, i.e. **A*2601 to A*2637**, recognized by the HLA Nomenclature Committee in October 2008¹ will give rise to unique amplification patterns by the primers in the HLA-A*26 subtyping kit.

The HLA-A*26 subtyping kit cannot distinguish the A*260101 to A*260106 alleles or the A*260701 and A*260702 alleles.

¹HLA-A alleles listed on the IMGT/HLA web page 2008-October-10, release 2.23.0, www.ebi.ac.uk/imgt/hla.

RESOLUTION IN HOMO- AND HETEROZYGOTES

The 37 HLA-A*26 alleles can be combined in 703 homozygous and heterozygous combinations. 204 of these genotypes do not give rise to unique amplification patterns. The different sizes of the specific PCR products generated by the primers in wells 6, 9, 10, 12, 18 and 30 have not been considered in these calculations.

+++---+--	-----	-----	-----	2602,2605 = 2602,2627
+++-----	-+-----	-----	-----	2602,2607 = 2602,2620
++-+-----	--+-----	-----	----+--	2601,2606 = 2606,2636
++-+-----	-----	-+-----	----+--	2601,2621 = 2621,2636

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++-+-----	-----	-----	---+--	2601,2603 = 2603,2636
++-+++-	-----	-----	-----	2604,2605 = 2604,2627
++-+-----	-+-----	-----	-----	2604,2607 = 2604,2620
++-+++++	---+-----	-----	-----	2605,2628 = 2627,2628
++-++++-	-----	-----	-----	2605,2608 = 2608,2627
++-++-+	+---+-----	-----	-----	2605,2618 = 2618,2627
++-++-+	---+-----	-----	-----	2605,2614 = 2614,2627
++-++-+	-----	-----	-----	2605,2611N = 2611N,2627
++-++-+	+-----	-----	-----+	2605,2629 = 2627,2629
++-++-+	+-----	-----	-----	2605,2612 = 2612,2627
++-++-+	-+-----	-----	-----	2605,2620 = 2607,2627 = 2620,2627
++-++-+	---+-----	-----	-----	2605,2616 = 2616,2627
++-++-+	-----+-----	-----	-----	2605,2617 = 2617,2627
++-++-+	-----+-----	-----	-----	2605,2610 = 2610,2627
++-++-+	-----++	-----	-----+	2605,2633 = 2627,2633
++-++-+	-----++	-----	-----	2605,2613 = 2613,2627
++-++-+	-----	+-----	-----	2605,2609 = 2609,2627
++-++-+	-----	---+-----	-----	2605,2622 = 2622,2627
++-++-+	-----	---+-----	-----	2605,2623 = 2623,2627
++-++-+	-----	---+-----	-----	2605,2624 = 2624,2627
++-++-+	-----	-----+-----	-----	2605,2625N = 2625N,2627
++-++-+	-----	-----+-----	-----	2605,2626 = 2626,2627
++-++-+	-----	-----+-----	-----	2605,2632 = 2627,2632
++-++-+	-----	-----	-+-----	2605,2634 = 2627,2634
++-++-+	-----	-----	---+-----	2605,2635 = 2627,2635
++-++-+	-----	-----	---+-----	2605,2636 = 2627,2636
++-++-+	-----	-----	---+-----	2605,2637 = 2627,2637
++-++-+	-----	-----	-----+	2605,2615 = 2615,2627
++-++-+	-----	-----	-----	2601,2605 = 2601,2627 = 2605,2627 = 2627,2627
++-+++++	+---+-----	-----	-----	2608,2618 = 2612,2628 = 2618,2628
++-+++++	-+---+-----	-----	-----	2607,2628 = 2620,2628
++-+++++	---+-----	-----	-----	2601,2628 = 2608,2614 = 2608,2628 = 2611N,2628 = 2614,2628 = 2616,2628 = 2628,2628
++-++++-	-+-----	-----	-----	2607,2608 = 2608,2620
++-++++-	-----	-----	-----	2601,2608 = 2608,2608
++-+++++	+---+-----	-----	-----	2607,2618 = 2618,2620
++-+++++	+---+-----	-----	-----+	2614,2629 = 2615,2618 = 2618,2629
++-+++++	+---+-----	-----	-----	2601,2618 = 2611N,2618 = 2612,2614 = 2612,2618 = 2614,2618 = 2616,2618 = 2618,2618
++-+++++	-+---+-----	-----	-----	2607,2614 = 2614,2620
++-+++++	-+-----	-----	-----	2607,2611N = 2611N,2620
++-+++++	---+-----	-----	-----	2601,2614 = 2611N,2614 = 2611N,2616 = 2614,2614 = 2614,2616
++-+++++	-----	-----	-----	2601,2611N = 2611N,2611N

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++-----	++-----	-----	-----+	2607,2629 = 2620,2629
++-----	++-----	-----	-----	2607,2612 = 2612,2620
++-----	+-----++	-----	-----+	2612,2633 = 2613,2629 = 2629,2633
++-----	+-----	-----	-----+	2601,2629 = 2612,2615 = 2612,2629 = 2615,2629
++-----	+-----	-----	-----	2601,2612 = 2612,2612
++-----	-+-----	-----	-----	2607,2616 = 2616,2620
++-----	-+-----	-----	-----	2607,2617 = 2617,2620
++-----	-+-----	-----	-----	2607,2610 = 2610,2620
++-----	-+-----++	-----	-----+	2607,2633 = 2620,2633
++-----	-+-----++	-----	-----	2607,2613 = 2613,2620
++-----	-+-----	+-----	-----	2607,2609 = 2609,2620
++-----	-+-----	--+-----	-----	2607,2622 = 2620,2622
++-----	-+-----	---+-----	-----	2607,2623 = 2620,2623
++-----	-+-----	----+-----	-----	2607,2624 = 2620,2624
++-----	-+-----	-----+--	-----	2607,2625N = 2620,2625N
++-----	-+-----	-----+-	-----	2607,2626 = 2620,2626
++-----	-+-----	-----+--	-----	2607,2632 = 2620,2632
++-----	-+-----	-----+--	-----	2607,2634 = 2620,2634
++-----	-+-----	-----+--	-----	2607,2635 = 2620,2635
++-----	-+-----	-----+--	-----	2607,2636 = 2620,2636
++-----	-+-----	-----+--	-----	2607,2637 = 2620,2637
++-----	-+-----	-----+--	-----	2607,2615 = 2615,2620
++-----	-+-----	-----	-----	2601,2607 = 2601,2620 = 2607,2620 = 2620,2620
++-----	--+-----++	-----	-----+	2615,2619 = 2619,2633
++-----	--+-----++	-----	-----	2601,2619 = 2613,2619
++-----	---+-----	-----	-----	2601,2616 = 2616,2616
++-----	----+-----	-----	-----	2601,2617 = 2617,2617
++-----	-----+--	-----	-----	2601,2610 = 2610,2610
++-----	-----++	-----	-----+	2601,2633 = 2613,2615 = 2613,2633 = 2615,2633 = 2633,2633
++-----	-----++	-----	-----	2601,2613 = 2613,2613
++-----	-----	--+-----	-----	2601,2622 = 2622,2622
++-----	-----	---+-----	-----	2601,2623 = 2623,2623
++-----	-----	----+-----	-----	2601,2624 = 2624,2624
++-----	-----	-----+--	-----	2601,2625N = 2625N,2625N
++-----	-----	-----+-	-----	2601,2626 = 2626,2626
++-----	-----	-----+--	-----	2601,2632 = 2632,2632
++-----	-----	-----+--	-----	2601,2635 = 2635,2635
++-----	-----	-----+--	-----	2601,2636 = 2636,2636
++-----	-----	-----+--	-----	2601,2637 = 2637,2637
++-----	-----	-----+--	-----	2601,2615 = 2615,2615
+--+-----	--+-----++	-----	---+--	2603,2619 = 2606,2619
+--+-----	--+-----	+-----	---+--	2606,2621 = 2606,2631
+--+-----	-----	+-----	---+--	2603,2621 = 2603,2631 = 2621,2621 = 2621,2631

2601 = 260101-260106
2607 = 260701-260701

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SPECIFICITY TABLE

HLA-A*26 SSP subtyping

Specificities and sizes of the PCR products of the 30 primer mixes used for HLA-A*26 SSP subtyping.

Primer Mix	Size of spec. PCR product ¹	Size of control band ²	Amplified HLA-A*26 alleles	Other amplified HLA-A alleles ³
1	180 bp	800 bp	260101-260106, 2603, 2605, 260701-2608, 2610-2628, 2630-2633, 2635-2637	9235, 250101-2505, 4301, 6601, 6604-6608
2⁴	80 bp	800 bp	260101-2602, 2604, 2608-2618, 2620, 2622-2629, 2632-2637	3313
3	140 bp	1070 bp	2602	
4	255 bp	800 bp	2603, 2606, 2621, 2630	020102, 020605, 0250, 9222, 0309, 1106, 1118, 2428, 2489, 3013, 3016, 6805, 6815, 6820, 7406
5	180 bp	1070 bp	2604	
6^{4,6}	80, 160 bp	1070 bp	2605, 2627	
7	150 bp	800 bp	2608, 2628	2504
8	135 bp	1070 bp	2611N, 2614, 2618, 2628	3103, 3104, 3403, 3406
9⁷	145, 190 bp	1070 bp	2612, 2618, 2629	3103 ^{weakly} , 3104 ^{weakly} , 3406 ^{weakly} , 6606 ^{weakly}
10^{4,8}	85, 260 bp	1070 bp	260701-260702, 2620	9246
11	140 bp	800 bp	2606, 2619	3103
12⁹	135, 240 bp	1070 bp	2614, 2616, 2618, 2628	0102, 0120, 2404, 3103, 3104, 3403, 3406
13	255 bp	1070 bp	2617	
14	145 bp	1070 bp	2610	0238, 9201, 2310, 2410, 2446
15⁴	100 bp	800 bp	2613, 2619, 2633	0113, 0117, 110101-1111, 1113-1116, 1120-1127, 1129-1137, 2502, 340101-

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				3406, 3408, 6601, 6604, 6606-6608
16	430 bp	1070 bp	2613, 2619, 2633	0234-023503, 025601-025602, 0262, 0278, 9203, 2419, 340101-3408, 6601, 6602, 6604, 6606-6608, 680101-680202, 6806-6814, 6816-6819, 6821-6830, 6832-6835, 6837-6843, 6901
17	175 bp	1070 bp	2609	2506, 3103, 3104, 340101-3408
18^{4,13}	125, 205 bp	800 bp	2621, 2631	
19	245 bp	800 bp	2622	0238, 9201
20	210 bp	1070 bp	2623	
21⁴	115 bp	1070 bp	2624	
22⁴	100 bp	1070 bp	2625N	
23	165 bp	1070 bp	2626	
24	305 bp	1070 bp	2632	0103, 1126, 3313, 3603, 7410
25	360 bp	1070 bp	2630	9235, 3104, 6602, 6603
26	175 bp	1070 bp	2634	
27	275 bp	1070 bp	2635	
28^{4,5}	90 bp	1070 bp	2603, 2606, 2621, 2636	1106, 8001
29	330 bp	1070 bp	2637	
30^{4,11}	125, 235 bp	1070 bp	2615, 2629, 2633	

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*26 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

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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*26 subtyping.

In addition, wells number 2, 4, 7, 11, 15, 18 and 19 contain the primer pair giving rise to the shorter, 800 bp, internal positive control band in order to allow kit identification.

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

³Due to the sharing of sequence motifs between HLA-A alleles non-HLA-A*26 alleles will be amplified by primer mixes 1, 2, 4, 7, 8 to 12 and 14 to 17, 19, 24, 25 and 28.

⁴Specific PCR fragments shorter than 125 base pairs have a lower intensity and are less sharp than longer PCR bands.

⁵Primer mix 28 may yield less intense specific PCR products than the other A*26 primer mixes.

⁶Primer mix 6: Specific PCR fragment of 80 bp in the A*2605 allele. Specific PCR fragment of 160 bp in the A*2627 allele.

⁷Primer mix 9: Specific PCR fragment of 145 bp in the A*2612 and A*2618 and weakly in the A*3103, A*3104, A*3406 and A*6606 alleles. Specific PCR fragment of 190 bp in the A*2629 allele.

⁸Primer mix 10: Specific PCR fragment of 85 bp in the A*260701-260702 alleles. Specific PCR fragment of 260 bp in the A*2620 and in the A*9246 allele.

⁹Primer mix 12: Specific PCR fragment of 135 bp in the A*2614, A*2618 and A*2628 and the A*3103, A*3104, A*3403 and A*3406 alleles. Specific PCR fragment of 240 bp in the A*2616 and the A*0102, A*0120 and A*2404 alleles.

¹⁰Primer mix 18: Specific PCR fragment of 125 bp in the A*2631 allele. Specific PCR fragment of 205 bp in the A*2621 allele.

¹¹Primer mix 30: Specific PCR fragment of 125 bp in the A*2615 and A*2629 allele. Specific PCR fragment of 235 bp in the A*2633 allele.

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INTERPRETATION TABLE																
HLA-A*26 SSP subtyping																
Amplification patterns of the A*2601 to 2637 alleles																
	Well⁴															
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
Length of spec.	180	80	140	255	180	80	150	135	145	85	140	135	255	145	100	430
PCR product						160			190	260		240				
Length of int.	800	800	1070	800	1070	1070	800	1070	1070	1070	800	1070	1070	1070	800	1070
pos. control¹																
5'-primer(s)²	418	261	418	78	423	261	423	423	423	78	243	98	346	453	282	28
	5'-Agg ^{3'}	5'-AAC ^{3'}	5'-AgA ^{3'}	5'-TCC ^{3'}	5'-gCT ^{3'}	5'-AAC ^{3'}	5'-gCT ^{3'}	5'-gCT ^{3'}	5'-gCT ^{3'}	5'-TCT ^{3'}	5'-CCT ^{3'}	5'-CTC ^{3'}	5'-gTA ^{3'}	5'-AAA ^{3'}	5'-CAG ^{3'}	5'-TCg ^{3'}
						423				257	416	423				
						5'-gCT ^{3'}				5'-Cgg ^{3'}	5'-gCg ^{3'}	5'-gCT ^{3'}				
3'-primer(s)³	559	299	517	292	560	299	524	517	527	299	341	299	559	559	341	282
	5'-CCg ^{3'}	5'-TCg ^{3'}	5'-CgT ^{3'}	5'-gTg ^{3'}	5'-ACA ^{3'}	5'-TCT ^{3'}	5'-CAC ^{3'}	5'-CgC ^{3'}	5'-CCA ^{3'}	5'-TCg ^{3'}	5'-CgT ^{3'}	5'-TCg ^{3'}	5'-CCg ^{3'}	5'-CCg ^{3'}	5'-CgT ^{3'}	5'-gAC ^{3'}
						542	538	519	570		517	517				290
						5'-CTT ^{3'}	5'-CTg ^{3'}	5'-ggA ^{3'}	5'-CCg ^{3'}		5'-CgT ^{3'}	5'-CgC ^{3'}				5'-gAA ^{3'}
								524				524				
								5'-CAC ^{3'}				5'-CAC ^{3'}				
Well No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
HLA-A allele																
*260101-260106	1	2														
*2602		2	3													
*2603	1			4												
*2604		2			5											
*2605	1					6										
*2606				4							11					
*260701-260702	1									10						
*2608	1	2					7									
*2609		2														
*2610	1	2												14		
*2611N	1	2						8								
*2612	1	2							9							
*2613	1	2													15	16
*2614	1	2						8				12				
*2615	1	2														
*2616	1	2										12				
*2617	1	2											13			
*2618	1	2						8	9			12				
*2619	1										11				15	16
*2620	1	2								10						
*2621	1			4												
Well No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16

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INTERPRETATION TABLE														
HLA-A*26 SSP subtyping														
Amplification patterns of the A*2601 to 2637 alleles														
Well⁴														
17	18	19	20	21	22	23	24	25	26	27	28	29	30	
175	125	245	210	115	100	165	305	360	175	275	90	330	125	Length of spec.
	205												235	PCR product
1070	800	800	1070	1070	1070	1070	1070	1070	1070	1070	1070	1070	1070	Length of int.
														pos. control ¹
423	257	355	392	652	280	652	341	341	423	106	292	28	98	5'-primer(s) ²
5'-gCT ^{3'}	5'-CCC ^{3'}	5'-CCg ^{3'}	5'-CgA ^{3'}	5'-Tg ^{3'}	5'-CCC ^{3'}	5'-CTg ^{3'}	5'-ggA ^{3'}	5'-ggC ^{3'}	5'-gCT ^{3'}	5'-CCA ^{3'}	5'-CTC ^{3'}	5'-TCg ^{3'}	5'-CTA ^{3'}	
	423													
	5'-gCT ^{3'}													
559	341	559	559	728	341	776	362	418	559	341	341	186	180	3'-primer(s) ³
5'-CgT ^{3'}	5'-CgT ^{3'}	5'-CCg ^{3'}	5'-CCg ^{3'}	5'-CCT ^{3'}	5'-CgT ^{3'}	5'-CAA ^{3'}	5'-TCA ^{3'}	5'-gTC ^{3'}	5'-CCA ^{3'}	5'-CgT ^{3'}	5'-CgT ^{3'}	5'-TCC ^{3'}	5'-TCC ^{3'}	
	589												290	
	5'-CTT ^{3'}												5'-gAA ^{3'}	
17	18	19	20	21	22	23	24	25	26	27	28	29	30	Well No.
														HLA-A allele
														*260101-260106
														*2602
											28			*2603
														*2604
														*2605
											28			*2606
														*260701-260702
														*2608
17														*2609
														*2610
														*2611N
														*2612
														*2613
														*2614
													30	*2615
														*2616
														*2617
														*2618
														*2619
														*2620
	18										28			*2621
17	18	19	20	21	22	23	24	25	26	27	28	29	30	Well No.

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Length of spec.	180	80	140	255	180	80	150	135	145	85	140	135	255	145	100	430
PCR product						160			190	260		240				
Well No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
*2622	1	2														
*2623	1	2														
*2624	1	2														
*2625N	1	2														
*2626	1	2														
*2627	1	2				6										
*2628	1	2					7	8				12				
*2629		2							9							
*2630	1			4												
*2631	1															
*2632	1	2														
*2633	1	2													15	16
*2634		2														
*2635	1	2														
*2636	1	2														
*2637	1	2														
*0102, 0120, 2404												12				
*0103, 3603, 7410																
*0113, 0117, 110101- 1105, 1107-1111, 1113-1116, 1120- 1125, 1127, 1129- 1137															15	
*020102, 020605, 0250, 9222, 0309, 1118, 2428, 2489, 3013, 3016, 6805, 6815, 6820, 7406				4												
*0234-023503, 025601-025602, 0262, 0278, 9203, 2419, 680101- 680202, 6806-6814, 6816-6819, 6821- 6830, 6832-6835, 6837-6843. 6901																16
*0238, 9201														14		
*9235	1															
*9246										10						
*1106				4											15	
*1126															15	
*2310, 2410, 2446														14		
Well No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16

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175	125	245	210	115	100	165	305	360	175	275	90	330	125	Length of spec.
	205												235	PCR product
17	18	19	20	21	22	23	24	25	26	27	28	29	30	Well No.
		19												*2622
			20											*2623
				21										*2624
					22									*2625N
						23								*2626
														*2627
														*2628
													30	*2629
								25						*2630
	18													*2631
							24							*2632
													30	*2633
									26					*2634
										27				*2635
											28			*2636
												29		*2637
							24							*0102, 0120, 2404
														*0103, 3603, 7410
														*0113, 0117, 110101-1105, 1107-1111, 1113-1116, 1120-1125, 1127, 1129-1137
														*020102, 020605, 0250, 9222, 0309, 1118, 2428, 2489, 3013, 3016, 6805, 6815, 6820, 7406
														*0234-023503, 025601-025602, 0262, 0278, 9203, 2419, 680101-680202, 6806-6814, 6816-6819, 6821-6830, 6832-6835, 6837-6843, 6901
			19											*0238, 9201
								25						*9235
											28			*9246
														*1106
							24							*1126
														*2310, 2410, 2446
17	18	19	20	21	22	23	24	25	26	27	28	29	30	Well No.

Lot No.: **40F**

Lot-specific information

Length of spec.	180	80	140	255	180	80	150	135	145	85	140	135	255	145	100	430
PCR product						160			190	260		240				
Well No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
*250101-250102, 2503, 2505, 4301, 6605	1															
*2502	1														15	
*2504	1						7									
*2506																
*3103								8	w		11	12				
*3104								8	w			12				
*3313		2														
*340101-3402, 3404, 3405, 3408															15	16
*3403								8				12			15	16
*3406								8	w			12			15	16
*3407																16
*6601, 6604, 6607, 6608	1														15	16
*6602																16
*6603																
*6606	1								w						15	16
*8001																
HLA-A allele																
Well No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16

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*26 subtyping. .

In addition, wells number 2, 4, 7, 11, 15, 18 and 19 contain the primer pair giving rise to the shorter, 800 bp, internal positive control band in order to allow kit identification.

²The nucleotide position, in the 1st, 2nd, 3rd or 4th exons, matching the specificity-determining 3'-end of the primer is given. Nuclotide numbering as on the www.ebi.ac.uk/imgt/hla web site. The sequence of the 3 terminal nucleotides of the primer is given.

³The nucleotide position, in the 2nd, 3rd or 4th exons, matching the specificity-determining 3'-end of the primer is given in the anti-sense direction. Nuclotide 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.: **40F**

Lot-specific information

175	125	245	210	115	100	165	305	360	175	275	90	330	125	Length of spec.
	205												235	PCR product
17	18	19	20	21	22	23	24	25	26	27	28	29	30	Well No.
														*250101-250102, 2503, 2505, 4301, 6605
														*2502
														*2504
17														*2506
17														*3103
17								25						*3104
							24							*3313
17														*340101-3402, 3404, 3405, 3408
17														*3403
17														*3406
17														*3407
														*6601, 6604, 6607, 6608
								25						*6602
								25						*6603
														*6606
											28			*8001
														HLA-A allele
17	18	19	20	21	22	23	24	25	26	27	28	29	30	Well No.

⁴Primer mix 6: Specific PCR fragment of 80 bp in the A*2605 allele. Specific PCR fragment of 160 bp in the A*2627 allele.

Primer mix 9: Specific PCR fragment of 145 bp in the A*2612 and A*2618 and weakly in the A*3103, A*3104, A*3406 and A*6606 alleles. Specific PCR fragment of 190 bp in the A*2629 allele.

Primer mix 10: Specific PCR fragment of 85 bp in the A*260701-260702 alleles. Specific PCR fragment of 260 bp in the A*2620 and in the A*9246 allele.

Primer mix 12: Specific PCR fragment of 135 bp in the A*2614, A*2618 and A*2628 and the A*3103, A*3104, A*3403 and A*3406 alleles. Specific PCR fragment of 240 bp in the A*2616 and the A*0102, A*0120 and A*2404 alleles.

Primer mix 18: Specific PCR fragment of 125 bp in the A*2631 allele. Specific PCR fragment of 205 bp in the A*2621 allele.

Primer mix 30: Specific PCR fragment of 125 bp in the A*2615 and A*2629 allele. Specific PCR fragment of 235 bp in the A*2633 allele.

Lot No.: 40F

Lot-specific information

CELL LINE VALIDATION SHEET																					
HLA-A*26 SSP subtyping kit																					
				Prod. No.:	Well																
					1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	
					200627501	200627502	200627503	200627504	200854305	200627506	200627507	200627508	200627509	200627510	200627511	200627512	200627513	200627514	200627515	200627516	
	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	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.: **40F**

Lot-specific information

CELL LINE VALIDATION SHEET																		
HLA-A*26 SSP subtyping kit																		
				Well														
				17	18	19	20	21	22	23	24	25	26	27	28	29	30	
				Prod. No.:	200627517	200627518	200627519	200627520	200627521	200627522	200627523	200627524	200854325	200840426	200840427	200854328	200854329	200854330
	IHCW 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	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.: **40F**

Lot-specific information

CERTIFICATE OF ANALYSIS

Olerup SSP[®] HLA-A*26 SSP

Product number: 101.424-12u – without *Taq* polymerase
Lot number: 40F
Expiry date: 2011-January-01
Number of tests: 12
Number of wells per test: 30

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2006-275-01	11	2006-275-11	21	2006-275-21
2	2006-275-02	12	2006-275-12	22	2006-275-22
3	2006-275-03	13	2006-275-13	23	2006-275-23
4	2006-275-04	14	2006-275-14	24	2006-275-24
5	2008-543-05	15	2006-275-15	25	2008-543-25
6	2006-275-06	16	2006-275-16	26	2008-404-26
7	2006-275-07	17	2006-275-17	27	2008-404-27
8	2006-275-08	18	2006-275-18	28	2008-543-28
9	2006-275-09	19	2006-275-19	29	2008-543-29
10	2006-275-10	20	2006-275-20	30	2008-543-30

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 to 13, 18 to 23 and 26 to 30 were available. The specificities of the primers in primer solutions 7, 9, 10 and 19 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer. In primer solutions 6 and 8 one of the 3'-primers was not possible to test. In primer solutions 11 and 18 one of the 5'-primers was not possible to test. In primer solutions 13, 20, 22 and 27 it was only possible to test the 3'-primer. In primer solutions 21, 23, 26, 29 and 30 it was only possible to test the 5'-primers. Additional primers in primer solution 12 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer.

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

Date of approval: 2009-May-25

Approved by:

Quality Control, Supervisor

Lot No.: **40F**

Lot-specific information

Declaration of Conformity

Product name: *Olerup* SSP® HLA-A*26
Product number: 101.424-12u
Lot number: 40F

Intended use: HLA-A*26 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-25

Olle Olerup
Managing Director

Lot No.: **40F**

Lot-specific information

Lot No.: **40F**

Lot-specific information

Lot No.: **40F**

Lot-specific information

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Fax: +46-8-717 88 18

E-mail: info-ssp@olerup.com

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

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Tel: +43-1-710 15 00

Fax: +43-1-710 15 00 10

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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**.