

Lot No.: **98F**

Lot-specific information

Olerup SSP[®] HLA-B*37

Product number: 101.541-06u – without *Taq* polymerase
Lot number: 98F
Expiry date: 2011-July-01
Number of tests: 6
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. 98F.

CHANGES COMPARED TO THE PREVIOUS *OLERUP SSP[®]* HLA-B*37 LOT.

The HLA-B*37 specificity and interpretation tables have been updated for the HLA-B alleles described since the previous *Olerup SSP[®]* HLA-B*37 lot was made (**Lot No. 53E**).

The primers of the wells detailed below has been exchanged or modified.

Well	5'-primer	3'-primer	rationale
8	-	Exchanged	Exchanged 3'-primer for increased specificity of specific primer pair.
9	Exchanged	Exchanged	Exchanged primer pair for the B*3708 allele.
10	Removed, added	Removed, added	Primer pair for the B*3708 allele removed, new primer pair for the B*3714 allele.

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PRODUCT DESCRIPTION

HLA-B*37 SSP typing

CONTENT

The primer set contains 5'- and 3'-primers for identifying the B*3701 to B*3714 alleles.

PLATE LAYOUT

Each HLA-B*37 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 PCR plate is marked with 'HLA-B*37'.

Well No. 1 is marked with the Lot No. '98F'.

The PCR plates are heat-sealed with a PCR-compatible foil.

Please note: When removing each 16 well PCR plate, make sure that the remaining plates stay sealed. Use a scalpel or a similar instrument to carefully cut the foil between the plates.

INTERPRETATION

The interpretation of HLA-B*37 SSP subtypings will be influenced by most B*07, the B*08, the B*1323, eight B*15, the B*18, the B*27, the B*35, the B*37, the B*3817, three B*39, the B*40, the B*41, the B*42, several B*44, the B*45, the B*4614, B*47, three B*48, the B*49, the B*50, four B*51, the B*5303, the B*5402, two B*55, two B*56, the B*5709, the B*7301, the B*78 and B*82 alleles when present on the other haplotype. In addition, the Cw*0768 allele will be amplified by primer mix 1 and the Cw*0223 allele will be amplified by primer mix 8.

UNIQUELY IDENTIFIED ALLELES

All the HLA-B*37, i.e. **B*3701 to B*3714**, recognized by the HLA Nomenclature Committee in May 2009¹ will be amplified by the primers in the HLA-B*37 SSP kit. The HLA-B*37 subtyping kit cannot distinguish the B*370101 to B*370105 alleles.

¹HLA-B alleles listed on the IMGT/HLA web page 2009-May-11, release 2.25.2, www.ebi.ac.uk/imgt/hla.

RESOLUTION IN HOMO- AND HETEROZYGOTES

The fourteen HLA-B*37 alleles can be combined in 105 homozygous and heterozygous combinations. Seventeen of these genotypes do not give rise to unique amplification patterns. The different lengths of the specific PCR products in lanes 3 and 4 were not considered in these calculations.

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+----+----  +---+-----  3701,3713 = 3703N,3704 = 3703N,3713 =
                                 3704,3713 = 3713,3713
+----+----  +---+-----  3701,3703N = 3703N,3703N
    
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+---+-----	----+-----	3701,3704 = 3704,3704
+---+---+	----+-----	3701,3706 = 3706,3706
+-----+--	-++-----	3705,3714 = 3714,3714
+-----+--	----+---+	3705,3711 = 3711,3711
-----+---	---+-----+	3709,3709 = 3709,3712

3701 = 370101 to 370105

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SPECIFICITY TABLE

HLA-B*37 SSP subtyping

Specificities and sizes of the PCR products of the 16 primer mixes used for HLA-B*37 SSP subtyping

Primer Mix	Size of spec. PCR product ¹	Size of control band ²	Amplified HLA-B*37 alleles	Other amplified HLA-B alleles ³
1	210 bp	800 bp	*370101-370105, 3703N-3706, 3708, 3710, 3711, 3713, 3714	Cw*0768
2⁴	95 bp	1070 bp	*3702	*2701-270510, 2708, 2710, 2712, 2713, 2715-2718, 2723, 2725, 2726, 2728, 2729, 2731, 2736-2740, 2742, 2744, 2745, 2750, 4704, 4705
3⁶	200 bp, 235 bp	1070 bp	*3703N, 3713	
4⁷	200 bp, 255 bp	1070 bp	*3704, 3713	*1818
5	210 bp	1070 bp	*370101-3704, 3706-3709, 3712, 3713	*0727, 3817
6⁴	145 bp	1070 bp	*3705, 3711, 3714 ^w	*0765, 0832, 1546, 1553, 180101-1808, 1810-1815, 1817N-1833, 350101-350801, 350803-3524, 3527-3545, 3547, 3548, 3550-3572, 3574-3595, 3597, 3599, 391901, 391902, 400101-4011, 401401-4016, 4018, 4020, 4022N-4040, 4042-4045, 4048-4075, 4077-4092, 4094, 4095, 4101-4104, 4105 ^w , 4106-4108, 4409, 4446, 4501-

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				4509, 4702, 4703 ^w , 5001, 5002, 5004, 5606, 7801-7806, 9506, 9543
7⁴	135 bp	1070 bp	*3706	*47010101, 47010102, 4705
8⁴	120 bp	1070 bp	*3707	*070201-071802, 0720- 0724, 0726-0732, 0734-0739, 0741-0747, 0749N, 0750, 0752, 0754-0759, 0761-0772, 0775, 0776, 4015, 4016, 4023, 4032, 4805, 4808, 4815, 9538, Cw*0223
9⁴	80 bp	1070 bp	*3708	*0727, 3817, 5303
10⁴	145 bp	1070 bp	*3714	
11	215 bp	1070 bp	*3709	*0704, 0719, 0725, 080101-0805, 0807, 0808N, 0810, 0811, 0814, 0815, 0817- 0819N, 0821-0824, 0826-0838, 3587, 4102, 4104, 4201, 4202, 420501-4210
12	205 bp	1070 bp	*370101-3707, 3709-3714	*1323, 1571, 1812, 2701-2721, 2724-2736, 2738-2746, 2750, 3563, 400101-4007, 4009, 4011, 4013- 4016, 4018-4020, 4022N-4024, 4026- 4039, 4042-4048, 4050-4057, 4059-4067, 4070-4096, 4101-4108, 4415, 4418, 4455, 4501-4509, 490101- 4905, 5001, 5002, 5004
13⁵	255 bp	800 bp	*3710	*1323, 1809, 2701, 4047, 4096, 4415, 4455, 4902
14	245 bp	1070 bp	*3711	*1571, 180101-1803, 1805-1808, 1810-1815, 1817N-1824, 1826- 1833, 2708, 2712,

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				2718, 2726, 2733, 2740, 2744, 3550, 3563, 3584, 3931, 400101-400104, 400106-4009, 4011, 401401-4016, 4018, 4020, 4022N-4036, 4038, 4039, 4042- 4046, 4048, 4050- 4057, 4059-4075, 4077-4095, 4101-4104, 4106-4108, 4202, 4209, 4501-4509, 4614, 5001, 5002, 5004, 5402, 5516, 7301
15⁴	135 bp	1070 bp	*3711	*0765, 0832, 180101- 1808, 1810-1815, 1817N-1833, 350101- 350202, 350301- 350801, 350803-3518, 352001-3524, 3528- 3545, 3548, 3550- 3555, 3557-3562, 3564-3572, 3574-3595, 3597, 3599, 391901, 391902, 5606, 7801- 7805
16	170 bp	1070 bp	*3709, 3712	*0704, 0719, 0725, 080101-0805, 0807- 0812, 0815-0819N, 0821-0824, 0826, 0827, 0829-0838, 1551, 1583, 3538, 3587, 4101-4108, 4201, 4202, 4204- 4210, 4414, 4417, 4451, 4462, 4509, 5108, 5120, 5136, 5144N, 5520, 5613, 5709, 8201, 8202

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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-B*37 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-B*37 SSP subtyping.

In addition, well number 13 contains 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-B alleles non-HLA-B*37 alleles will be amplified by primer mixes 2, 4 to 9 and 11 to 16. In addition, the Cw*0768 allele will be amplified by primer mix 1 and the Cw*0223 allele will be amplified by primer mix 8.

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

⁵Primer mix 13 has a tendency of giving rise to primer oligomer formation.

⁶Primer mix 3: Specific PCR fragment of 200 bp in the B*3713 allele. Specific PCR fragment of 235 bp in the B*3703N allele.

⁷Primer mix 4: Specific PCR fragment of 200 bp in the B*3713 allele. Specific PCR fragment of 255 bp in the B*3704 and B*1818 alleles.

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INTERPRETATION TABLE								
HLA-B*37 SSP subtyping								
Amplification patterns of the HLA-B*3701 to *3714 alleles								
	Well⁴							
	1	2	3	4	5	6	7	8
Length of spec.	210	95	200	200	210	145	135	120
PCR product(s)			235	255				
Length of int.	800	1070	1070	1070	1070	1070	1070	1070
pos. control¹								
5'-primer(s)²	368	363	142	368	142	206	206	527
	5'-gTC 3'	5'-AAT 3'	5'-TCT 3'	5'-gTC 3'	5'-TCT 3'	5'-gAA 3'	5'-gAA 3'	5'-TgA 3'
			368			206		
			5'-gTC 3'			5'-gAC 3'		
3'-primer(s)³	538	418	337	527	311	311	301	605
	5'-gTC 3'	5'-gTC 3'	5'-CTA 3'	5'-CCT 3'	5'-ggg 3'	5'-ggT 3'	5'-gTC 3'	5'-gCT 3'
			527	583	311			
			5'-CCT 3'	5'-gTg 3'	5'-ggg 3'			
Well No.	1	2	3	4	5	6	7	8
HLA-B allele								
*370101-370105	1				5			
*3702		2			5			
*3703N	1		3		5			
*3704	1			4	5			
*3705	1					6		
*3706	1				5		7	
*3707					5			8
*3708	1				5			
*3709					5			
*3710	1							
*3711	1					6		
*3712					5			
*3713	1		3	4	5			
*3714	1					w		
*070201-0703, 070501-071802, 0720-0724, 0726, 0728-0732, 0734-0739, 0741-0747, 0749N, 0750, 0752, 0754-0759, 0761-0764, 0766-0772, 0775, 0776, 9538, 4805, 4808, 4815, Cw*0223								8
*0704								8
Well No.	1	2	3	4	5	6	7	8

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HLA-B*37 SSP subtyping								
Amplification patterns of the HLA-B*3701 to *3714 alleles								
Well ⁴								
9	10	11	12	13	14	15	16	
80	145	215	205	255	245	135	170	Length of spec. PCR product(s)
1070	1070	1070	1070	800	1070	1070	1070	Length of int. pos. control ¹
261	206	363	97	97	97	206	409	5'-primer(s) ²
5'-AAC 3'	5'-gAC 3'	5'-AgC 3'	5'-TCC 3'	5'-TCC 3'	5'-TCC 3'	5'-gAC 3'	5'-ggC 3'	
301	311	538	259	309	302	302	538	3'-primer(s) ³
5'-gTC 3'	5'-ggT 3'	5'-gTC 3'	5'-CTC 3'	5'-gTg 3'	5'-ggC 3'	5'-ggC 3'	5'-gTC 3'	
			259					
			5'-CTC 3'					
9	10	11	12	13	14	15	16	Well No.
								HLA-B allele
			12					*370101-370105
			12					*3702
			12					*3703N
			12					*3704
			12					*3705
			12					*3706
			12					*3707
9								*3708
		11	12				16	*3709
			12	13				*3710
			12		14	15		*3711
			12				16	*3712
			12					*3713
	10		12					*3714
								*070201-0703, 070501-071802, 0720-0724, 0726, 0728-0732, 0734-0739, 0741-0747, 0749N, 0750, 0752, 0754-0759, 0761-0764, 0766-0772, 0775, 0776, 9538, 4805, 4808, 4815, Cw*0223
		11					16	*0704
9	10	11	12	13	14	15	16	Well No.

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Length of spec.	210	95	200	200	210	145	135	120
PCR product(s)			235	255				
Well No.	1	2	3	4	5	6	7	8
*0719, 0725, 080101-0805, 0807, 0808N, 0810, 0811, 0815, 0817-0819N, 0821-0824, 0826, 0827, 0829-0831, 0833-0838, 4201, 420501-4208, 4210								
*0727					5			8
*0765						6		8
*0809, 0812, 0816, 1551, 1583, 4204, 4414, 4417, 4451, 4462, 5108, 5120, 5136, 5144N, 5520, 5613, 5709, 8201, 8202								
*0814, 0828								
*0832, 3587						6		
*1323, 4047, 4096, 4415, 4455, 4902								
*1546, 1553, 9506, 9543, 350203, 3519, 3527, 3547, 3556, 4010, 4040, 4049, 4058, 4409, 4446, 4702, 7806						6		
*1571, 2733, 4046, 4093								
*180101-1803, 1805-1808, 1810, 1811, 1813-1815, 1817N, 1819-1824, 1826-1833, 3550, 3584						6		
*1804, 1825, 350101-350202, 350301-350801, 350803-3518, 352001-3524, 3528-3537, 3539-3545, 3548, 3551-3555, 3557-3562, 3564-3572, 3574-3583, 3585, 3586, 3588-3595, 3597, 3599, 391901, 391902, 5606, 7801-7805						6		
*1809								
*1812						6		
*1818				4		6		
*2701		2						
*2702-270510, 2710, 2713, 2715-2717, 2725, 2728, 2729, 2731, 2736, 2738, 2739, 2742, 2745, 2750		2						
*2706, 2707, 2709, 2711, 2714, 2719-2721, 2724, 2727, 2730, 2732, 2734, 2735, 2741, 2743, 2746, 4013, 4019, 4076, 4418, 490101, 490102, 4903-4905								
*2708, 2712, 2718, 2726, 2740, 2744		2						
*2723, 2737, 4704		2						
Well No.	1	2	3	4	5	6	7	8

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80	145	215	205	255	245	135	170	Length of spec. PCR product(s)
9	10	11	12	13	14	15	16	Well No.
		11					16	*0719, 0725, 080101-0805, 0807, 0808N, 0810, 0811, 0815, 0817-0819N, 0821-0824, 0826, 0827, 0829-0831, 0833-0838, 4201, 420501-4208, 4210
9								*0727
						15		*0765
							16	*0809, 0812, 0816, 1551, 1583, 4204, 4414, 4417, 4451, 4462, 5108, 5120, 5136, 5144N, 5520, 5613, 5709, 8201, 8202
		11						*0814, 0828
		11				15	16	*0832, 3587
			12	13				*1323, 4047, 4096, 4415, 4455, 4902
								*1546, 1553, 9506, 9543, 350203, 3519, 3527, 3547, 3556, 4010, 4040, 4049, 4058, 4409, 4446, 4702, 7806
			12		14			*1571, 2733, 4046, 4093
					14	15		*180101-1803, 1805-1808, 1810, 1811, 1813-1815, 1817N, 1819-1824, 1826-1833, 3550, 3584
						15		*1804, 1825, 350101-350202, 350301-350801, 350803-3518, 352001-3524, 3528-3537, 3539-3545, 3548, 3551-3555, 3557-3562, 3564-3572, 3574-3583, 3585, 3586, 3588-3595, 3597, 3599, 391901, 391902, 5606, 7801-7805
				13				*1809
			12		14	15		*1812
					14	15		*1818
			12	13				*2701
			12					*2702-270510, 2710, 2713, 2715-2717, 2725, 2728, 2729, 2731, 2736, 2738, 2739, 2742, 2745, 2750
			12					*2706, 2707, 2709, 2711, 2714, 2719-2721, 2724, 2727, 2730, 2732, 2734, 2735, 2741, 2743, 2746, 4013, 4019, 4076, 4418, 490101, 490102, 4903-4905
			12		14			*2708, 2712, 2718, 2726, 2740, 2744
								*2723, 2737, 4704
9	10	11	12	13	14	15	16	Well No.

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Length of spec.	210	95	200	200	210	145	135	120
PCR product(s)			235	255				
Well No.	1	2	3	4	5	6	7	8
*3538						6		
*3563, 400101-400104, 400106-4007, 4009, 4011, 401401-401403, 4018, 4020, 4022N, 4024, 4026-4031, 4033-4036, 4038, 4039, 4042-4045, 4048, 4050-4057, 4059-4067, 4070-4075, 4077-4092, 4094, 4095, 4501-4508, 5001, 5002, 5004						6		
*3817					5			
*3931, 4614, 5402, 5516, 7301								
*400105, 4037						6		
*4008, 4025, 4068, 4069						6		
*4015, 4016, 4023, 4032						6		8
*4101, 410301, 410302, 4106-4108, 4509						6		
*4102, 4104						6		
*4105						w		
*4202, 4209								
*47010101, 47010102							7	
*4703						w		
*4705		2					7	
*5303								
<i>Cw</i> *0768	1							
HLA-B allele								
Well No.	1	2	3	4	5	6	7	8

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80	145	215	205	255	245	135	170	Length of spec. PCR product(s)
9	10	11	12	13	14	15	16	Well No.
						15	16	*3538
			12		14			*3563, 400101-400104, 400106-4007, 4009, 4011, 401401-401403, 4018, 4020, 4022N, 4024, 4026-4031, 4033-4036, 4038, 4039, 4042-4045, 4048, 4050-4057, 4059-4067, 4070-4075, 4077 4092, 4094, 4095, 4501-4508, 5001, 5002, 5004
9								*3817
					14			*3931, 4614, 5402, 5516, 7301
			12					*400105, 4037
					14			*4008, 4025, 4068, 4069
			12		14			*4015, 4016, 4023, 4032
			12		14		16	*4101, 410301, 410302, 4106-4108, 4509
		11	12		14		16	*4102, 4104
			12				16	*4105
		11			14		16	*4202, 4209
								*47010101, 47010102
								*4703
								*4705
9								*5303
								Cw*0768
								HLA-B allele
9	10	11	12	13	14	15	16	Well No.

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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-B*37 SSP subtyping.

In addition, well number 13 contains 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 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.

⁴Primer mix 3: Specific PCR fragment of 200 bp in the B*3713 allele. Specific PCR fragment of 235 bp in the B*3703N allele.

Primer mix 4: Specific PCR fragment of 200 bp in the B*3713 allele. Specific PCR fragment of 255 bp in the B*3704 and B*1818 alleles.

'w', might be weakly amplified.

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CELL LINE VALIDATION SHEET																			
HLA-B*37 SSP primer set																			
				Well															
				Prod. No.:															
				1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
				200845701	200845702	200845703	200845704	200845705	200845706	200845707	200960808	200960809	200960810	200845711	200960812	200845713	200960814	200845715	200845716
	IHC cell line		B*																
1	9001 SA		*0702	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-
2	9280 LK707		*5201	*7301	-	-	-	-	-	-	-	-	-	-	-	-	+	-	-
3	9011 E4181324		*52011		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
4	9275 GU373		*1510	*5301	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
5	9009 KAS011		*3701		+	-	-	-	+	-	-	-	-	-	-	-	-	-	-
6	9353 SM		*3901	*5101	-	-	-	-	-	-	-	-	-	-	+	-	-	-	-
7	9020 QBL		*1801		-	-	-	-	-	+	-	-	-	-	-	-	+	+	-
8	9025 DEU		*3501		-	-	-	-	-	+	-	-	-	-	-	-	-	+	-
9	9026 YAR		*3801		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
10	9107 LKT3		*5401		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
11	9051 PITOUT		*4403		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
12	9052 DBB		*5701		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
13	9004 JESTHOM		*2705		-	+	-	-	-	-	-	-	-	-	+	-	-	-	-
14	9071 OLGA		*1501	*1520	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
15	9075 DKB		*4001		-	-	-	-	-	+	-	-	-	-	+	-	+	-	-
16	9037 SWEIG007		*4002		-	-	-	-	-	+	-	-	-	-	+	-	+	-	-
17	9282 CTM3953540		*0801	*5501	-	-	-	-	-	-	-	-	-	+	-	-	-	-	+
18	9257 32367		*1401	*5601	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
19	9038 BM16		*1801		-	-	-	-	-	+	-	-	-	-	-	-	+	+	-
20	9059 SLE005		*4001		-	-	-	-	-	+	-	-	-	-	+	-	+	-	-
21	9064 AMALA		*1501		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
22	9056 KOSE		*3503		-	-	-	-	-	+	-	-	-	-	-	-	-	+	-
23	9124 IHL		*4002	*5602	-	-	-	-	-	+	-	-	-	-	+	-	+	-	-
24	9035 JBUSH		*3801		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
25	9049 IBW9		*1402		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
26	9285 WT49		*5801		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
27	9191 CH1007		*0705	*5101	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-
28	9320 BEL5GB		*4402	*4403	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
29	9050 MOU		*4403		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
30	9021 RSH		*4201		-	-	-	-	-	-	-	-	-	+	-	-	-	-	+
31	9019 DUCAF		*1801		-	-	-	-	-	+	-	-	-	-	-	-	+	+	-
32	9297 HAG		*4102		-	-	-	-	-	+	-	-	-	+	+	-	+	-	+
33	9098 MT14B		*4001		-	-	-	-	-	+	-	-	-	-	+	-	+	-	-
34	9104 DHIF		*3801		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
35	9302 SSTO		*4402		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
36	9024 KT17		*1501	*3501	-	-	-	-	-	+	-	-	-	-	-	-	-	+	-
37	9065 HHKB		*0702		-	-	-	-	-	-	-	+	-	-	-	-	-	-	-
38	9099 LZL		*1501		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
39	9315 CML		*0801	*2705	-	+	-	-	-	-	-	-	-	+	+	-	-	-	+
40	9134 WHONP199		*1302	*4601	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
41	9055 H0301		*1402		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
42	9066 TAB089		*4601		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
43	9076 T7526		*4601		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
44	9057 TEM		*3801		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
45	9239 SHJO		*4201	*5001	-	-	-	-	-	+	-	-	-	+	+	-	+	-	+
46	9013 SCHU		*0702		-	-	-	-	-	-	-	+	-	-	-	-	-	-	-
47	9045 TUBO		*5101		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
48	9303 TER-ND		*3501	*4403	-	-	-	-	-	+	-	-	-	-	-	-	-	+	-

Lot No.: **98F**

Lot-specific information

CERTIFICATE OF ANALYSIS

Olerup SSP[®] HLA-B*37 SSP

Product number: 101.541-06u – without *Taq* polymerase
Lot number: 98F
Expiry date: 2011-July-01
Number of tests: 6
Number of wells per test: 16

Well specifications:

Well No.	Production No.	Well No.	Production No.
1	2008-457-01	9	2009-608-09
2	2008-457-02	10	2009-608-10
3	2008-457-03	11	2005-457-11
4	2008-457-04	12	2009-608-12
5	2008-457-05	13	2008-457-13
6	2008-457-06	14	2009-608-14
7	2008-457-07	15	2008-457-15
8	2009-608-08	16	2008-457-16

The specificity of each primer solution of the HLA-B*37 primer set has been tested against 48 well characterized IHWC cell line DNAs.

No DNAs carrying the allele to be amplified by primer solutions 3, 4, 9 and 10 were available. The specificities of the primers in primer solutions 4, 9 and 10 were tested by separately adding one additional 3'-primer, respectively one additional 5'-primer.

In primer solution 3 it was only possible to test the 5'-primer by separately adding one additional 3'-primer, the 3'-primer was not possible to test. In primer solution 4 one 3'-primer was not possible to test.

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

Date of approval: 2009-July-25

Approved by:

Quality Control, Supervisor

Lot No.: **98F**

Lot-specific information

Declaration of Conformity

Product name: *Olerup* SSP® HLA-B*37
Product number: 101.541-06u
Lot number: 98F

Intended use: HLA-B*37 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 13485:2008, 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-July-25

Olle Olerup
Managing Director

Lot No.: **98F**

Lot-specific information

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