

Lot No.: **53E**

Lot-specific information

Olerup SSP[®] HLA-B*37

Product number: 101.541-06u – without *Taq* polymerase
Lot number: 53E
Expiry date: 2010-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. 53E.

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. X71**).

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

Well	5'-primer	3'-primer	rationale
1	Modified	-	Increased specificity of specific primer pair.
3	Added	Added	Primer pair added for the B*3713 allele.
4	Modified	Added	Primer added for the B*3713 allele.
5	-	Modified	Primer modified for the B*370102 allele.
6	Modified	-	Increased specificity of specific primer pair.
8	Exchanged	-	Increased specificity of specific primer pair.
15	Modified	-	Increased specificity of specific primer pair.

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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*3713 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 'B*37'.

Well No. 1 is marked with the Lot No. '53E'.

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, many B*15, the B*18, the B*27, the B*35, three B*38, 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, the B*51, the B*53, 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.

UNIQUELY IDENTIFIED ALLELES

All the HLA-B*37, i.e. **B*3701 to B*3713**, recognized by the HLA Nomenclature Committee in April 2008¹ 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*370104 alleles.

¹HLA-B alleles listed on the IMGT/HLA web page 2008-April-08, release 2.21.0, www.ebi.ac.uk/imgt/hla.

RESOLUTION IN HOMO- AND HETEROZYGOTES

The thirteen HLA-B*37 alleles can be combined in 91 homozygous and heterozygous combinations. Thirteen of these genotypes do not give rise to unique amplification patterns.

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

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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	370101-370104, 3703N-3706, 3708, 3710, 3711, 3713	
2 ⁴	95 bp	1070 bp	3702	2701-270402, 270502-270510, 2708, 2710, 2712, 2713, 2715-2718, 2723, 2725, 2726, 2728, 2729, 2731, 2736-2740, 2742, 4704, 4705
3 ⁶	200, 235 bp	1070 bp	3703N, 3713	
4 ⁷	200, 255 bp	1070 bp	3704, 3713	1818
5	210 bp	1070 bp	370101-3704, 3706-3709, 3712, 3713	0727, 3817
6 ⁴	145 bp	1070 bp	3705, 3711	0832, 1546, 1553, 9506, 9543, 180101-1808, 1810-1815, 1817N-1829, 350101-350801, 350803-3524, 3527-3545, 3547, 3548, 3550-3572, 3574-3588, 391901-391902, 400101-4011, 401401-4016, 4018, 4020, 4022N-4040, 4042-4045, 4048-4075, 4077-4088, 4101-4104, 4105 ^{weakly} , 4106-4108, 4409, 4446, 4501-4508, 4702, 4703 ^{weakly} , 5001, 5002, 5004, 5606, 7801-7805
7 ⁴	135 bp	1070 bp	3706	47010101-47010102, 4705

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8⁴	125 bp	1070 bp	3707	070201-0724, 0726-0732, 0734-0741, 0743-0747, 0749N, 0750, 0752, 0754-0759, 0761-0764, 0806, 0820, 9538, 4015, 4016, 4023, 4032, 4805, 4808, 4815
9	205 bp	1070 bp	3708	180101-1803, 1805-1811, 1813-1815, 1817N-1824, 1826-1829, 2723, 3550, 3584, 3931, 4008, 4025, 4068, 4202, 4209, 5402, 5516, 7301
10⁴	80 bp	1070 bp	3708	0832, 1502, 1508, 151101-151103, 1513, 1515, 1521, 1531, 1544, 1555, 1576, 1588, 1589, 9512, 9521, 9539, 9543, 9544, 1829, 350101-350201, 3503-350902, 3511, 3512, 351401-3515, 3517-352001, 3521-3524, 3526, 3527, 3529-3548, 3550-3562, 3564-356802, 3570-3572, 3574-3579, 3581-3588, 3806, 3807, 391901, 4008, 4025, 4068, 4406, 4412, 510101-510102, 510104-512402, 5126-5138, 5140-5146, 5148-5155, 530101-5316, 5606, 7801-7804
11	215 bp	1070 bp	3709	0704, 0719, 0725, 080101-0805, 0807, 0808N, 0810, 0811, 0814, 0815, 0817-0819N, 0821-0824, 0826-0836, 3587, 4102, 4104, 4201,

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12	205 bp	1070 bp	370101-3707, 3709-3713	4202, 420501-4209 1571, 1812, 2701- 270402, 270502-2721, 2724-2736, 2738-2742, 3563, 400101-4007, 4009, 4011, 4013- 4016, 4018-4020, 4022N-4024, 4026- 4039, 4042-4048, 4050-4057, 4059-4067, 4070-4088, 4101-4108, 4415, 4418, 4455, 4501-4508, 4614, 4901-4905, 5001, 5002, 5004
13⁵	255 bp	800 bp	3710	1809, 2701, 4047, 4415, 4455, 4902
14	245 bp	1070 bp	3711	1571, 180101-1803, 1805-1808, 1810-1815, 1817N-1824, 1826- 1829, 2708, 2712, 2718, 2726, 2733, 2740, 3550, 3563, 3584, 3931, 400101- 400104, 400106-4009, 4011, 401401-4016, 4018, 4020, 4022N- 4036, 4038, 4039, 4042-4046, 4048, 4050-4057, 4059-4088, 4101-4108, 4202, 4209, 4501-4508, 4614, 5001, 5002, 5004, 5402, 5516, 7301
15⁴	135 bp	1070 bp	3711	0832, 180101-1808, 1810-1815, 1817N- 1829, 350101-350801, 350803-3518, 352001- 3524, 3528-3545, 3548, 3550-3555, 3557-3562, 3564-3572, 3574-3588, 391901- 391902, 5606, 7801- 7805
16	170 bp		3709, 3712	0704, 0719, 0725, 080101-0805, 0807- 0812, 0815-0819N,

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	0821-0824, 0826, 0827, 0829-0836, 1551, 1583, 3538, 3587, 4101-4108, 4201, 4202, 4204- 4209, 4414, 4417, 4451, 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 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.

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 and 4 to 16.

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 *3713 alleles								
	Well⁴							
	1	2	3	4	5	6	7	8
Length of spec.	210	95	200	200	210	145	135	125
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	610
	5'-gTC ^{3'}	5'-gTC ^{3'}	5'-CTA ^{3'}	5'-CCT ^{3'}	5'-ggg ^{3'}	5'-ggT ^{3'}	5'-gTC ^{3'}	5'-CTC ^{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								
*370101-370104	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			
*070201-0703, 070501-071802, 0720-0724, 0726, 0728-0732, 0734-0741, 0743-0747, 0749N, 0750, 0752, 0754-0759, 0761-0764, 0806, 0820, 9538, 4805, 4808, 4815								8
*0704, 0719								8
Well No.	1	2	3	4	5	6	7	8

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INTERPRETATION TABLE								
HLA-B*37 SSP subtyping								
Amplification patterns of the HLA-B*3701 to *3713 alleles								
Well ⁴								
9	10	11	12	13	14	15	16	
205	80	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
97	222	363	97	97	97	135	409	5'-primer(s) ²
5'-TCC ^{3'}	5'-CCA ^{3'}	5'-AgC ^{3'}	5'-TCC ^{3'}	5'-TCC ^{3'}	5'-TCC ^{3'}	5'-gAC ^{3'}	5'-ggC ^{3'}	
259	259	538	259	309	302	302	538	3'-primer(s) ³
5'-gTT ^{3'}	5'-gTT ^{3'}	5'-gTC ^{3'}	5'-CTC ^{3'}	5'-gTg ^{3'}	5'-ggC ^{3'}	5'-ggC ^{3'}	5'-gTC ^{3'}	
9	10	11	12	13	14	15	16	Well No.
								HLA-B allele
			12					*370101-370104
			12					*3702
			12					*3703N
			12					*3704
			12					*3705
			12					*3706
			12					*3707
9	10							*3708
		11	12				16	*3709
			12	13				*3710
			12		14	15		*3711
			12				16	*3712
			12					*3713
								*070201-0703, 070501-071802, 0720-0724, 0726, 0728-0732, 0734-0741, 0743-0747, 0749N, 0750, 0752, 0754-0759, 0761-0764, 0806, 0820, 9538, 4805, 4808, 4815
		11					16	*0704, 0719
9	10	11	12	13	14	15	16	Well No.

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Length of spec.	210	95	200	200	210	145	135	125
PCR product(s)			235	255				
Well No.	1	2	3	4	5	6	7	8
*0725, 080101-0805, 0807, 0808N, 0810, 0811, 0815, 0817-0819N, 0821-0824, 0826, 0827, 0829-0831, 0833-0836, 4201, 420501-4208								
*0727					5			8
*0809, 0812, 0816, 1551, 1583, 4204, 4414, 4417, 4451, 5520, 5613, 5709, 8201, 8202								
*0814, 0828								
*0832, 3587					6			
*1502, 1508, 151101-151103, 1513, 1515, 1521, 1531, 1544, 1555, 1576, 1588, 1589, 9512, 9521, 9539, 9544, 350802, 3526, 3546, 3806, 3807, 4406, 4412, 510101-510102, 510104-5107, 510901-5119, 5121-512402, 5126-5135, 5137, 5138, 5140-5143, 5145, 5146, 5148-5155, 530101-5316								
*1546, 1553, 9506, 4010, 4040, 4049, 4058, 4409, 4446, 4702					6			
*1571, 2733, 4046, 4076, 4614								
*9543, 3519, 3527, 3547, 3556					6			
*180101-1803, 1805-1808, 1810, 1811, 1813-1815, 1817N, 1819-1824, 1826-1828						6		
*1804, 1825, 350202, 3510, 3513, 3516, 352002, 3528, 3569, 3580, 391902, 7805					6			
*1809								
*1812					6			
*1818				4		6		
*1829, 3550, 3584					6			
*2701		2						
*2702-270402, 270502-270510, 2710, 2713, 2715-2717, 2725, 2728, 2729, 2731, 2736, 2738, 2739, 2742		2						
Well No.	1	2	3	4	5	6	7	8

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205	80	215	205	255	245	135	170	Length of spec. PCR product(s)
9	10	11	12	13	14	15	16	Well No.
		11					16	*0725, 080101-0805, 0807, 0808N, 0810, 0811, 0815, 0817-0819N, 0821- 0824, 0826, 0827, 0829-0831, 0833- 0836, 4201, 420501-4208 *0727
							16	*0809, 0812, 0816, 1551, 1583, 4204, 4414, 4417, 4451, 5520, 5613, 5709, 8201, 8202 *0814, 0828
	10	11				15	16	*0832, 3587
	10							*1502, 1508, 151101-151103, 1513, 1515, 1521, 1531, 1544, 1555, 1576, 1588, 1589, 9512, 9521, 9539, 9544, 350802, 3526, 3546, 3806, 3807, 4406, 4412, 510101-510102, 510104-5107, 510901-5119, 5121-512402, 5126-5135, 5137, 5138, 5140-5143, 5145, 5146, 5148-5155, 530101-5316 *1546, 1553, 9506, 4010, 4040, 4049, 4058, 4409, 4446, 4702 *1571, 2733, 4046, 4076, 4614
			12		14			*9543, 3519, 3527, 3547, 3556 *180101-1803, 1805-1808, 1810, 1811, 1813-1815, 1817N, 1819-1824, 1826- 1828 *1804, 1825, 350202, 3510, 3513, 3516, 352002, 3528, 3569, 3580, 391902, 7805 *1809
				13				*1812
			12		14	15		*1818
9					14	15		*1829, 3550, 3584
9	10				14	15		*2701
			12	13				*2702-270402, 270502-270510, 2710, 2713, 2715-2717, 2725, 2728, 2729, 2731, 2736, 2738, 2739, 2742
			12					
9	10	11	12	13	14	15	16	Well No.

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Length of spec.	210	95	200	200	210	145	135	125
PCR product(s)			235	255				
Well No.	1	2	3	4	5	6	7	8
*2706, 2707, 2709, 2711, 2714, 2719-2721, 2724, 2727, 2730, 2732, 2734, 2735, 2741, 4013, 4019, 4418, 4901, 4903-4905								
*2708, 2712, 2718, 2726, 2740		2						
*2723		2						
*2737, 4704		2						
*350101-350201, 3503-350801, 350803-350902, 3511, 3512, 351401-3515, 3517, 3518, 352001, 3521-3524, 3529-3537, 3539-3545, 3548, 3551-3555, 3557-3562, 3564-356802, 3570-3572, 3574-3579, 3581-3583, 3585, 3586, 3588, 391901, 5606, 7801-7804						6		
*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, 4077-4088, 4501-4508, 5001, 5002, 5004						6		
*3817					5			
*3931								
*400105, 4037						6		
*4008, 4025, 4068						6		
*4015, 4016, 4023, 4032						6		8
*4047, 4415, 4455, 4902								
*4069						6		
*4101, 410301-410302, 4106-4108						6		
*4102, 4104						6		
*4105						w		
*4202, 4209								
*47010101-47010102							7	
*4703						w		
*4705		2					7	
*5108, 5120, 5136, 5144N								
*5402, 5516, 7301								
HLA-B allele								
Well No.	1	2	3	4	5	6	7	8

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205	80	215	205	255	245	135	170	Length of spec. PCR product(s)
9	10	11	12	13	14	15	16	Well No.
			12					*2706, 2707, 2709, 2711, 2714, 2719-2721, 2724, 2727, 2730, 2732, 2734, 2735, 2741, 4013, 4019, 4418, 4901, 4903-4905
			12		14			*2708, 2712, 2718, 2726, 2740
9								*2723
								*2737, 4704
	10					15		*350101-350201, 3503-350801, 350803-350902, 3511, 3512, 351401-3515, 3517, 3518, 352001, 3521-3524, 3529-3537, 3539-3545, 3548, 3551-3555, 3557-3562, 3564-356802, 3570-3572, 3574-3579, 3581-3583, 3585, 3586, 3588, 391901, 5606, 7801-7804
	10					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, 4088, 4501-4508, 5001, 5002, 5004
								*3817
9					14			*3931
			12					*400105, 4037
9	10				14			*4008, 4025, 4068
			12		14			*4015, 4016, 4023, 4032
			12	13				*4047, 4415, 4455, 4902
					14			*4069
			12		14		16	*4101, 410301-410302, 4106-4108
		11	12		14		16	*4102, 4104
			12		14		16	*4105
9		11			14		16	*4202, 4209
								*47010101-47010102
								*4703
								*4705
	10						16	*5108, 5120, 5136, 5144N
9					14			*5402, 5516, 7301
								HLA-B allele
9	10	11	12	13	14	15	16	Well No.

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Lot-specific information

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																
					1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	
					Prod. No.:	200845701	200845702	200845703	200845704	200845705	200845706	200845707	200845708	200845709	200845710	200845711	200845712	200845713	200845714	200845715	200845716
		IHWC 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	9007	DEM	*5701		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
9	9026	YAR	*3801		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
10	9107	LKT3	*5401		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
11	9051	PITOUT	*4403		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
12	9052	DBB	*5701		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
13	9067	BTB	*2705		-	+	-	-	-	-	-	-	-	-	-	+	-	-	-	-	-
14	9071	OLGA	*1501	*1520	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
15	9075	DKB	*4001		-	-	-	-	-	+	-	-	-	-	-	+	-	+	-	-	-
16	9037	SWEIG007	*4002		-	-	-	-	-	+	-	-	-	-	-	+	-	+	-	-	-
17	9008	WILJON	*1801		-	-	-	-	-	+	-	-	+	-	-	-	-	+	+	-	-
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.: **53E**

Lot-specific information

CERTIFICATE OF ANALYSIS

Olerup SSP[®] HLA-B*37 SSP

Product number: 101.541-06u – without *Taq* polymerase
Lot number: 53E
Expiry date: 2010-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	2008-457-09
2	2008-457-02	10	2008-457-10
3	2008-457-03	11	2005-457-11
4	2008-457-04	12	2008-457-12
5	2008-457-05	13	2008-457-13
6	2008-457-06	14	2008-457-14
7	2008-457-07	15	2008-457-15
8	2008-457-08	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 and 13 were available. The specificities of the primers in primer solutions 4, 13 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.

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

Date of approval: 2009-May-27

Approved by:

Quality Control, Supervisor

Lot No.: **53E**

Lot-specific information

Declaration of Conformity

Product name: *Olerup* SSP® HLA-B*37
Product number: 101.541-06u
Lot number: 53E

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-May-27

Olle Olerup
Managing Director

Lot No.: **53E**

Lot-specific information

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