

Lot No.: **97F**

Lot-specific information

Olerup SSP[®] HLA-B*13

Product number: 101.515-12u – without *Taq* polymerase
Lot number: 97F
Expiry date: 2011-July-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. 97F.

CHANGES COMPARED TO THE PREVIOUS *OLERUP SSP*[®] HLA-B*13 LOT

The HLA-B*13 specificity and interpretation tables have been updated for the HLA-B alleles described since the previous *Olerup SSP*[®] HLA-B*13 lot was made (Lot No. 96E).

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	-	Added	Primer added for the B*1322 and B*1324 alleles.
6	Modified	-	Modified 5'-primer for increased yield of specific PCR product.
15	Added	Added	Primer pair added for the B*1322 and B*1323 alleles, and exchanged positive control primer pair.

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PRODUCT DESCRIPTION

HLA-B*13 SSP subtyping

CONTENT

The primer set contains 5'- and 3'-primers for identifying the B*1301 to B*1324 alleles.

PLATE LAYOUT

Each test consists of 16 PCR reactions in a 16 well 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-B*13' in silver/gray ink.

Well No. 1 is marked with the Lot No. '97F'.

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*13 subtypings will be influenced by several B*07, most B*08, most B*15, the B*18, several B*27, most B*35, two B*37, the B*38, most B*39, the B*40, the B*41, the B*42, several B*44, the B*45, the B*46, the B*4702, the B*48, the B*49, the B*50, several B*51, two B*52, most B*53, the B*54, the B*55, the B*56, most B*57, most B*58, the B*59, the B*67, the B*7301, the B*81 and the B*82 alleles when present on the other haplotype. In addition, the Cw*0206 allele will be amplified by primer mix 12 and the Cw*0334 allele will be amplified by primer mix 3.

UNIQUELY IDENTIFIED ALLELES

All the HLA-B*13 alleles, i.e. **B*1301 to B*1324**, recognized by the HLA Nomenclature Committee in May 2009¹ will give rise to unique amplification patterns by the primers in the HLA-B*13 subtyping kit.

The HLA-B*13 kit cannot distinguish the B*130201 to B*130205 alleles.

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

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RESOLUTION IN HOMO- AND HETEROZYGOTES

The 23 HLA-B*13 alleles can be combined in 276 homozygous and heterozygous combinations. 124 of these genotypes do not give rise to unique amplification patterns. The different lengths of the specific PCR products generated by primer mixes 5, 8, 10, 13, 15 and 16 were not considered in these calculations.

+++++---+	-----	1307N,1316 = 1318,1320 = 1318,1324
+++++---	+-----	1308Q,1320 = 1308Q,1324
+++++---	-+-----	1309,1320 = 1309,1324
+++++---	-----+---	1319,1320 = 1319,1324
+++++---	-----+--	1302,1322 = 1314,1320 = 1314,1322 = 1314,1324 = 1316,1322 = 1316,1323
+++++---	-----+---	1315,1320 = 1315,1324 = 1316,1317
+++++---	-----	1301,1316 = 1302,1320 = 1302,1324 = 1316,1320 = 1316,1324
+++++---	-----+--	1307N,1314 = 1318,1323
+++++---	-----+---	1307N,1315 = 1317,1318
+++++---	-----	1301,1318 = 1302,1307N = 1307N,1318
+++++---	-+-----	1302,1321 = 1309,1313 = 1309,1321
+++++---	-----++	1314,1317 = 1315,1323
+++++---	-----+--	1301,1314 = 1302,1323 = 1314,1323
+++++---	-----+---	1301,1315 = 1302,1317 = 1315,1317
+++-+---	-----	1303,1307N = 1307N,1320 = 1307N,1324
+++-+---	-+-----	1303,1321 = 1320,1321 = 1321,1324
+++-+---	---+-----	1310,1320 = 1310,1324
+++-+---	----+-----	1311,1320 = 1311,1324
+++-+---	-----+---	1303,1313 = 1313,1320 = 1313,1324
+++-+---	-----+--	1301,1322 = 1303,1323 = 1320,1322 = 1320,1323 = 1322,1323 = 1323,1324
+++-+---	-----+---	1303,1317 = 1317,1320 = 1317,1324
+++-+---	-----	1301,1303 = 1301,1320 = 1301,1324 = 1303,1320 = 1320,1320 = 1320,1324
+++-----	-----	1301,1307N = 1307N,1307N
+++-----	-+-----	1301,1321 = 1313,1321 = 1321,1321
+++-----	-----+---	1301,1313 = 1313,1313
+++-----	-----+--	1301,1323 = 1323,1323
+++-----	-----+---	1301,1317 = 1317,1317
++-++---	-----	1303,1318 = 1316,1318
++-++---	+-----	1303,1308Q = 1308Q,1316
++-++---	-+-----	1303,1309 = 1309,1316
++-++---	----+-----	1303,1319 = 1312,1316 = 1316,1319
++-++---	-----+--	1303,1314 = 1314,1316
++-++---	-----+---	1303,1315 = 1315,1316
++-++---	-----	1302,1303 = 1302,1316 = 1303,1316 = 1316,1316
++-+-----	-----+---	1312,1318 = 1318,1319
++-+-----	-----	1302,1318 = 1318,1318
++-+-----	+-----	1308Q,1312 = 1308Q,1319
++-+-----	+-----	1302,1308Q = 1308Q,1308Q

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+++----- -+---+---	1309,1312 = 1309,1319
+++----- -----+-+	1312,1314 = 1314,1319
+++----- -----+---+	1312,1315 = 1315,1319
+++----- -----+---	1302,1312 = 1302,1319 = 1312,1319 = 1319,1319
+++----- -----+--	1302,1314 = 1314,1314
+++----- -----++	1302,1315 = 1315,1315
+--+----- -----+--	1303,1322 = 1322,1322 = 1322,1324
+--+----- -----	1303,1324 = 1324,1324

1302 = 130201 - 130205

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SPECIFICITY TABLE

HLA-B*13 SSP subtyping

Specificities and sizes of the PCR products of the 16 primer mixes used for HLA-B*13 SSP subtyping

Primer Mix	Size of spec. PCR product ¹	Size of control band ²	Amplified HLA-B*13 alleles	Other amplified HLA Class I alleles ³
1	140 bp	800 bp	1301-1304, 1306- 1308Q, 1310-1324	4460
2^{4,5}	95 bp	800 bp	1301- 130205, 1307N- 1311, 1313- 1321, 1323	4091
3	245 bp	1070 bp	1301, 1307N, 1313, 1317, 1320-1324	0712, 0714, 071801, 071802, 2719, 2730, 3515, 3533, 3588, 4004, 4030, 4034, 4059, 4064, 4068, 4416, 4421, 446401, 446402, 4817, 5713, Cw*0334
4	245 bp	1070 bp	130201- 130205, 1308Q, 1309, 1314- 1316, 1318, 1319	2714, 40060101-400602, 4044, 4053, 4070, 4075, 4083, 4086, 4093, 4095, 4096, 5110, 5116, 5131, 5134, 5208, 5509, 5522, 5524, 7301
5^{4,8}	125 bp, 150 bp, 180 bp	800 bp	1303, 1316, 1320, 1322, 1324	1542, 1573, 1586, 3560, 3917, 4071, 4410, 4415, 4418, 4501, 4504-4508, 4611, 4618, 490101-4903, 5001, 5002, 5004, 5115, 5162, 5401-5403, 5405N, 5407, 5408N, 5410, 5412, 5413, 5417, 550101- 5503, 5505, 5507, 5509-5512, 5515, 5516, 5518, 5519, 5521, 5522, 5524-5526, 5529-5531, 5533, 5534, 5601, 5602, 5604, 5607, 5608, 5610, 5613, 5614, 5616, 5617, 5619N, 5620, 5623, 5624, 5901, 5904, 8201, 8202
6⁴	105 bp	1070 bp	1304	1504, 1516, 1567, 1595, 9537,

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				9555, 3537, 390601, 390602, 3933, 3934, 4086, 4502, 4509, 4904, 4905, 511301, 511302, 5137, 5163, 5214, 5414, 5513, 5523, 5532, 5622, 5903, 7301
7^{6,7}	190 bp	1070 bp	1306	0734, 080101-0806, 0808N-0810, 0812, 0813, 0815-0820, 0822-0824, 0826, 0827, 0829-0836, 0838, 1542, 1583, 1586, 1826, 3560, 3587, 3712, 380101, 380201-3807, 3809-3819, 39010101-39010102L, 390103-390602, 3908-3914, 3916, 3918-3920, 3922-3924, 3926-3928, 3930, 3931, 3934-3937, 3939, 3941, 3942, 3944-3946, 3948, 4039, 4051, 4101-410302, 4105-4108, 4201, 4202, 4204-4208, 4210, 4618, 5121, 5136, 5401, 5402, 5404, 5405N, 5407, 5408N, 5410-5413, 5417, 550101-5505, 5507, 5510-5513, 5515-5521, 5525, 5526, 5528-5534, 5610, 5612, 5623, 5820, 5901-5903, 670101-6702
8^{6,7,9}	185 bp, 225 bp	1070 bp	1307N, 1318	1504, 9537, 3933, 5105, 5129, 5154, 5161, 5410, 5509, 5521
9	230 bp	1070 bp	1308Q	
10^{4,10}	105 bp , 210 bp	800 bp	1309, 1321	070501-0706, 0732, 0734, 0740, 0753, 0769, 080102, 0806, 0820, 1553, 9550, 2707, 2708, 2711, 2712, 2718, 2720, 2724, 2726, 2727, 2733, 2740, 2742-2744, 350902, 3518, 3531, 3563, 3584, 3588, 3590, 400101-4016, 4018-4040, 4042-4096, 4101-4104, 4106-4108, 4409, 4431, 4446, 4501-4509, 4610, 4702, 480101, 480102, 480301-4807, 4809-4811, 4813, 4815, 4816, 4818, 4819, 5001, 5002, 5004, 510109, 5110, 512402, 5411, 5504, 5508, 7301, 8101-8104N
11	280 bp	800 bp	1304, 1310	0709, 0711, 0717, 0828, 0835, 0837, 15010101-1508,

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				151101-1516, 1518-1521, 1523-1529, 1531-1536, 1538- 1540, 1543, 1544, 1546, 1547, 1549-1557, 1560-1562, 1564- 1572, 1574-1576, 1578-1582, 1584, 1585, 1587-1589, 1591- 1598, 9501-9529, 9531, 9532, 9534-9536, 9538-9549N, 9551-9560, 180101-1815, 1817N-1825, 1827-1833, 2741, 350101-350107, 3505, 3507- 350803, 3510, 3511, 351401- 3517, 3519-3521, 3523-3530, 3532, 3535, 3537, 3540N- 3543, 3545-3554, 3557, 3558, 3561-3564, 3566-3569, 3571, 3572, 3576-3580, 3582, 3586, 3589-3594, 3597, 3599, 3907, 3943, 4003, 4020, 4038, 4052, 4059, 4060, 4209, 4417, 4443, 4509, 460101-4610, 4612- 4617, 4802, 4814, 4904, 4905, 5137, 5145, 5163, 530101- 5303, 5305, 5306, 5308-5318, 5406, 5409, 5414, 5514, 5523, 5532, 5603, 5609, 5618, 570101-570103, 5706, 5708, 5710, 5711, 5713-5716, 5718, 5719, 580101-5802, 5804- 5807, 5809-5819, 5821
12⁴	90 bp	1070 bp	1311	1573, 3917, 4048, 4071, 5162, 5602, 5604, 5610, Cw*0206
13^{4,11}	90 bp, 180 bp	800 bp	1312, 1319	
14⁴	130 bp	1070 bp	1313, 1321	4091
15^{4,12}	105 bp, 245 bp	800 bp	1314, 1322, 1323	1573, 1809, 2701, 3710, 380201-3804, 3808, 3815, 3818, 4047, 4048, 4096, 4415, 4455, 4902
16^{4,13}	90 bp, 205 bp	1070 bp	1315, 1317	3546, 5162

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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*13 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*13 subtyping.

In addition, wells number 2, 5, 10, 11, 13 and 15 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-B alleles some non-HLA-B*13 alleles will be amplified by primer mixes 1, 3 to 8 and 10 to 12, 15 and 16. In addition, the Cw*0206 allele will be amplified by primer mix 12 and the Cw*0334 allele will be amplified by primer mix 3.

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

⁵Primer mix 2 may give rise to a weak band of about 400 bp. This band should be disregarded when interpreting HLA-B*13 SSP subtypings.

⁶Primer mixes 5 may give a lower yield of specific PCR product than the other HLA-B*13 primer mixes.

⁷Primer mixes 7 and 8 have a weak tendency of nonspecific amplifications.

⁸Primer mix 5: Specific PCR fragment of 125 bp in the B*1322, 1324 and the B*1586, 3560, 4508, 4618, 490102, 5401, 5402, 5405N, 5407, 5408N, 5410, 5412, 5413, 5417, 5502, 5507, 5510, 5512, 5516, 5518, 5519, 5522, 5526, 5530, 5534, 5610, 5619N and 5623 alleles. Specific PCR fragment of 150 bp in the B*1316 and 1320 alleles. Specific PCR fragment of 125 and 150 bp in the B*1542, 550101-550104, 5503, 5505, 5509, 5511, 5515, 5521, 5524, 5525, 5529, 5531 and 5533 alleles. Specific PCR fragments of 125 and 180 bp in the B*1303, 4071, 4410, 4415, 4418, 4501, 4504-4507, 4611, 490102, 5115, 5403, 5601, 5602, 5604, 5607, 5608, 5613, 5614, 5616, 5617, 5620, 5624, 5904, 8201 and 8202 alleles. Specific PCR fragments of 125, 150 and 180 bp in the B* 1573, 490101, 4902, 4903, 5001, 5002, 5004 and 5162 alleles. All bands may not always be visible.

⁹Primer mix 8: Specific PCR fragment of 185 bp in the B*1307N allele. Specific PCR fragment of 225 bp in the B*1318 and the B*1504, 9537, 3933, 5105, 5129, 5154, 5161, 5410, 5509 and 5521 alleles.

¹⁰Primer mix 10: Specific PCR fragment of 105 bp in the B*1321 and the B*070501-0706, 0732, 0734, 0740, 0753, 0769, 080102, 0806, 0820, 9550, 2707, 2711, 2720, 2724, 2727, 2743, 350902, 3518, 3531, 3588, 4010, 4012, 4013, 401403, 4019, 4021, 4047, 4058, 4076, 4088, 4096, 4431, 480101, 480102, 480301-4807, 4809-4811, 4813, 4815, 4816, 4818, 4819, 510109, 5110, 512402, 5411, 5504, 5508 and 8101-8104N alleles. Specific PCR fragment of 210 bp in the B*1309 and the B*1553, 2708, 2712, 2718, 2726, 2740, 2742, 2744, 3563, 3584, 3590, 4003, 4009, 4018, 4020, 4024, 4031-4033, 4042, 4044, 4052, 4059, 4060, 4071, 407201, 4077, 4087, 4089, 4095, 4101-4104, 4106, 4107, 4409, 4446, 4501-4509, 4610, 4702, 5001, 5002, 5004 and 7301 alleles. Specific PCR fragments of 105 and 210 bp in the B*2733, 400101-400204, 4004-4008, 4011, 401401, 401402, 4015, 4016, 4022, 4023, 4025, 4027,

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4029, 4030, 4034-4040, 4043, 4045, 4046, 4048, 4049-4051, 4053-4057, 4061-4070, 407202-4075, 4078-4086, 4088, 4090-4094 and 4108 alleles.

¹¹Primer mix 13: Specific PCR fragment of 90 bp in the B*1319 allele. Specific PCR fragment of 180 bp in the B*1312 allele.

¹²Primer mix 15: Specific PCR fragment of 105 bp in the B*1322 and the B*1573 and 4048 alleles. Specific PCR fragment of 245 bp in the B*1314 and 1323 and B*1809, 2701, 3710, 380201-3804, 3808, 3815, 3818, 4047, 4096, 4415, 4455 and 4902 alleles.

¹³Primer mix 16: Specific PCR fragment of 90 bp in the B*1317 and B*3546 alleles. Specific PCR fragment of 205 bp in the B*1315 and B*5162 alleles.

'w', may be weakly amplified.

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INTERPRETATION TABLE								
HLA-B*13 SSP subtyping								
Amplification patterns of the B*1301 to *1324 alleles								
	Well⁵							
	1	2	3	4	5	6	7	8
Length of spec.	140	95	245	245	125	105	190	185
PCR product(s)					150			225
					180			
Length of int.	800	800	1070	1070	800	1070	1070	1070
pos. control¹								
5'-primer(s)²	209	506	355	357	420	357	412	106
	5'-ggC 3'	5'-gCT 3'	5'-TCA 3'	5'-Tgg 3'	5'-TTA 3'	5'-Tgg 3'	5'-ATA 3'	5'-CCA 3'
								357
								5'-Tgg 3'
3'-primer(s)³	309	559	559	559	506	419	559	251
	5'-gTg 3'	5'-CTC 3'	5'-CTC 3'	5'-CTC 3'	5'-TgC 3'	5'-Cgg 3'	5'-CgT 3'	5'-CCC 3'
					527	419		539
					5'-CCT 3'	5'-CgA 3'		5'-TCC 3'
					559			
					5'-CAg 3'			
Well No.	1	2	3	4	5	6	7	8
HLA-B allele⁴								
*1301	1	2	3					
*130201-130205	1	2		4				
*1303	1				5			
*1304	1					6		
*1306	1						7	
*1307N	1	2	3					8
*1308Q	1	2		4				
*1309		2		4				
*1310	1	2						
*1311	1	2						
*1312	1							
*1313	1	2	3					
*1314	1	2		4				
*1315	1	2		4				
*1316	1	2		4	5			
*1317	1	2	3					
*1318	1	2		4				8
Well No.	1	2	3	4	5	6	7	8

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INTERPRETATION TABLE								
HLA-B*13 SSP subtyping								
Amplification patterns of the B*1301 to *1324 alleles								
Well ⁵								
9	10	11	12	13	14	15	16	
230	105	280	90	90	130	105	90	Length of spec. PCR product(s)
	210			180		245	205	
1070	800	800	1070	800	1070	800	1070	Length of int. pos. control ¹
357	142	419	369	268	419	97	144	5'-primer(s) ²
5' -Tgg 3'	5' -TCA 3'	5' -gTC 3'	5' -TAC 3'	5' -Agg 3'	5' -gTA 3'	5' -TCC 3'	5' -gCA 3'	
	412			420		103	420	
	5' -ATA 3'			5' -TTA 3'		5' -CCT 3'	5' -TTA 3'	
						420		
						5' -TTA 3'		
548	311	Intron	420	317	506	309	193	3'-primer(s) ³
5' -ggC 3'	5' -ggT 3'	5' -TAT 3'	5' -gCT 3'	5' -ggA 3'	5' -TgA 3'	5' -gTg 3'	5' -CgT 3'	
	477			559		486	583	
	5' -gCg 3'			5' -CCC 3'		5' -gCC 3'	5' -gTg 3'	
9	10	11	12	13	14	15	16	Well No. HLA-B allele ⁴
								*1301
								*130201-130205
								*1303
		11						*1304
								*1306
								*1307N
9								*1308Q
	10							*1309
		11						*1310
			12					*1311
				13				*1312
					14			*1313
						15		*1314
							16	*1315
								*1316
							16	*1317
								*1318
9	10	11	12	13	14	15	16	Well No.

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Length of spec.	140	95	245	245	125	105	190	185
PCR product(s)					150			225
					180			
Well No.	1	2	3	4	5	6	7	8
*1319	1	2		4				
*1320	1	2	3		5			
*1321	1	2	3					
*1322	1		3		5			
*1323	1	2	3					
*1324	1		3		5			
*070501-0706, 0732, 0740, 0753, 0769, 9550, 2707, 2708, 2711, 2712, 2718, 2720, 2724, 2726, 2727, 2733, 2740, 2742-2744, 350902, 3518, 3531, 3584, 400101-400204, 4005, 4007-4016, 4018, 4019, 4021-4029, 4031-4033, 4035-4037, 4040, 4042, 4043, 4045, 4046, 4049, 4050, 4054-4058, 4061-4063, 4065-4067, 4069, 407201-4074, 4076-4082, 4084, 4085, 4087-4090, 4092, 4094, 4104, 4409, 4431, 4446, 4503, 4702, 480101, 480102, 480301-4807, 4809-4811, 4813, 4815, 4816, 4818, 4819, 510109, 512402, 5508, 8101-8104N								
*0709, 0711, 0717, 0828, 0837, 15010101-1503, 1505-1508, 151101-1515, 1518-1521, 1523-1529, 1531-1536, 1538-1540, 1543, 1544, 1546, 1547, 1549-1552, 1554-1557, 1560-1562, 1564-1566, 1568-1572, 1574-1576, 1578-1582, 1584, 1585, 1587-1589, 1591-1594N, 1596-1598, 9501-9529, 9531, 9532, 9534-9536, 9538-9549N, 9551-9554, 9556-9560, 180101-1808, 1810-1815, 1817N-1825, 1827-1833, 2741, 350101-350107, 3505, 3507-350803, 3510, 3511, 351401, 351402, 3516, 3517, 3519-3521, 3523-3530, 3532, 3535, 3540N-3543, 3545, 3547-3554, 3557, 3558, 3561, 3562, 3564, 3566-3569, 3571, 3572, 3576-3580, 3582, 3586, 3589, 3591-3594, 3597, 3599, 3907, 3943, 4209, 4417, 4443, 460101-4609, 4612-4617, 4802, 4814, 5145, 530101-5303, 5305, 5306, 5308-5318, 5406, 5409, 5514, 5603, 5609, 5618, 570101-570103, 5706, 5708, 5710, 5711, 5714-5716, 5718, 5719, 580101-5802, 5804-5807, 5809-5819, 5821								
*0712, 0714, 071801, 071802, 2719, 2730, 3533, 4416, 4421, 446401, 446402, 4817, <i>Cw*0334</i>			3					
Well No.	1	2	3	4	5	6	7	8

Lot No.: **97F**

Lot-specific information

230	105	280	90	90	130	105	90	Length of spec.
	210			180		245	205	PCR product(s)
9	10	11	12	13	14	15	16	Well No.
				13				*1319
								*1320
	10			14				*1321
						15		*1322
				15				*1323
								*1324
	10							*070501-0706, 0732, 0740, 0753, 0769, 9550, 2707, 2708, 2711, 2712, 2718, 2720, 2724, 2726, 2727, 2733, 2740, 2742-2744, 350902, 3518, 3531, 3584, 400101-400204, 4005, 4007-4016, 4018, 4019, 4021-4029, 4031-4033, 4035-4037, 4040, 4042, 4043, 4045, 4046, 4049, 4050, 4054 4058, 4061-4063, 4065-4067, 4069, 407201-4074, 4076-4082, 4084, 4085, 4087-4090, 4092, 4094, 4104, 4409, 4431, 4446, 4503, 4702, 480101, 480102, 480301-4807, 4809-4811, 4813, 4815, 4816, 4818, 4819, 510109, 512402, 5508, 8101-8104N
		11						*0709, 0711, 0717, 0828, 0837, 15010101-1503, 1505-1508, 151101-1515, 1518-1521, 1523-1529, 1531-1536, 1538-1540, 1543, 1544, 1546, 1547, 1549-1552, 1554-1557, 1560-1562, 1564-1566, 1568-1572, 1574-1576, 1578-1582, 1584, 1585, 1587-1589, 1591-1594N, 1596-1598, 9501 9529, 9531, 9532, 9534-9536, 9538-9549N, 9551 9554, 9556-9560, 180101-1808, 1810-1815, 1817N-1825, 1827-1833, 2741, 350101-350107, 3505, 3507-350803, 3510, 3511, 351401, 351402, 3516, 3517, 3519-3521, 3523-3530, 3532, 3535, 3540N-3543, 3545, 3547-3554, 3557, 3558, 3561, 3562, 3564, 3566-3569, 3571, 3572, 3576-3580, 3582, 3586, 3589, 3591-3594, 3597, 3599, 3907, 3943, 4209, 4417, 4443, 460101-4609, 4612-4617, 4802, 4814, 5145, 530101-5303, 5305, 5306, 5308-5318, 5406, 5409, 5514, 5603, 5609, 5618, 570101-570103, 5706, 5708, 5710, 5711, 5714-5716, 5718, 5719, 580101-5802, 5804-5807, 5809-5819, 5821
								*0712, 0714, 071801, 071802, 2719, 2730, 3533, 4416, 4421, 446401, 446402, 4817, Cw*0334
9	10	11	12	13	14	15	16	Well No.

Lot No.: **97F**

Lot-specific information

Well No.	1	2	3	4	5	6	7	8
Length of spec.	140	95	245	245	125	105	190	185
PCR product(s)					150			225
					180			
Well No.	1	2	3	4	5	6	7	8
*0734, 080102, 0806, 0820, 4039, 4051, 4101-410302, 4106-4108, 5411, 5504							7	
*080101, 080103-0805, 0808N-0810, 0812, 0813, 0815-0819N, 0822-0824, 0826, 0827, 0829-0834, 0836, 0838, 1583, 1826, 3587, 3712, 380101, 3805-3807, 3809-3814, 3816, 3817, 3819, 39010101-39010102L, 390103-3905, 3908-3914, 3916, 3918-3920, 3922-3924, 3926-3928, 3930, 3931, 3935-3937, 3939, 3941, 3942, 3944-3946, 3948, 4105, 4201, 4202, 4204-4208, 4210, 5121, 5136, 5404, 5517, 5520, 5528, 5612, 5820, 5902, 670101-6702							7	
*0835							7	
*1504						6		8
*1516, 1567, 1595, 3537, 4904, 4905, 5137, 5163, 5414, 5523, 9555						6		
*1542, 1586, 3560, 4618, 5401, 5402, 5405N, 5407, 5408N, 5412, 5413, 5417, 550101-5503, 5505, 5507, 5510-5512, 5515, 5516, 5518, 5519, 5525, 5526, 5529-5531, 5533, 5534, 5623, 5901					5		7	
*1553, 3563, 3590, 4003, 4020, 4038, 4052, 4060, 4610								
*1573					5			
*1809								
*2701, 3710, 3808, 4455								
*2714, 5116, 5131, 5134, 5208				4				
*3515, 5713			3					
*3546								
*3588, 4004, 4030, 4034, 4064, 4068			3					
*380201-3804, 3815, 3818							7	
*390601, 390602, 3934, 5513, 5903						6	7	
*3917, 5602, 5604					5			
*3933, 9537						6		8
*40060101-400602, 4044, 4053, 4070, 4075, 4083, 4093, 4095, 5110				4				
*4047								
*4048								
Well No.	1	2	3	4	5	6	7	8

Lot No.: **97F**

Lot-specific information

9	10	11	12	13	14	15	16	Well No.
230	105	280	90	90	130	105	90	Length of spec.
	210			180		245	205	PCR product(s)
9	10	11	12	13	14	15	16	Well No.
	10							*0734, 080102, 0806, 0820, 4039, 4051, 4101-410302, 4106-4108, 5411, 5504
								*080101, 080103-0805, 0808N-0810, 0812, 0813, 0815-0819N, 0822-0824, 0826, 0827, 0829, 0834, 0836, 0838, 1583, 1826, 3587, 3712, 380101, 3805-3807, 3809-3814, 3816, 3817, 3819, 39010101-39010102L, 390103-3905, 3908, 3914, 3916, 3918-3920, 3922-3924, 3926-3928, 3930, 3931, 3935-3937, 3939, 3941, 3942, 3944-3946, 3948, 4105, 4201, 4202, 4204-4208, 4210, 5121, 5136, 5404, 5517, 5520, 5528, 5612, 5820, 5902, 670101-6702
		11						*0835
		11						*1504
		11						*1516, 1567, 1595, 3537, 4904, 4905, 5137, 5163, 5414, 5523, 9555
								*1542, 1586, 3560, 4618, 5401, 5402, 5405N, 5407, 5408N, 5412, 5413, 5417, 550101-5503, 5505, 5507, 5510-5512, 5515, 5516, 5518, 5519, 5525, 5526, 5529-5531, 5533, 5534, 5623, 5901
	10	11						*1553, 3563, 3590, 4003, 4020, 4038, 4052, 4060, 4610
			12			15		*1573
		11				15		*1809
						15		*2701, 3710, 3808, 4455
								*2714, 5116, 5131, 5134, 5208
		11						*3515, 5713
		11					16	*3546
	10							*3588, 4004, 4030, 4034, 4064, 4068
						15		*380201-3804, 3815, 3818
								*390601, 390602, 3934, 5513, 5903
			12					*3917, 5602, 5604
								*3933, 9537
	10							*40060101-400602, 4044, 4053, 4070, 4075, 4083, 4093, 4095, 5110
	10					15		*4047
	10		12			15		*4048
9	10	11	12	13	14	15	16	Well No.

Lot No.: **97F**

Lot-specific information

Length of spec.	140	95	245	245	125	105	190	185
PCR product(s)					150			225
					180			
Well No.	1	2	3	4	5	6	7	8
*4059			3					
*4071					5			
*4086, 7301				4		6		
*4091		2						
*4096				4				
*4410, 4418, 4611, 490101, 490102, 4903, 5115, 5403, 5601, 5607, 5608, 5613, 5614, 5616, 5617, 5619N, 5620, 5624, 5904, 8201, 8202					5			
*4415, 4902					5			
*4460	1							
*4501, 4504-4508, 5001, 5002, 5004					5			
*4502						6		
*4509						6		
*5105, 5129, 5154, 5161								8
*511301, 511302, 5214, 5622						6		
*5162					5			
*5410, 5521					5		7	8
*5509				4	5			8
*5522, 5524				4	5			
*5532						6	7	
*5610					5		7	
<i>Cw*0206</i>								
Well No.	1	2	3	4	5	6	7	8

Lot No.: **97F**

Lot-specific information

230	105	280	90	90	130	105	90	Length of spec. PCR product(s)
	210			180		245	205	
9	10	11	12	13	14	15	16	Well No.
	10	11						*4059
	10		12					*4071
	10							*4086, 7301
	10				14			*4091
	10					15		*4096
								*4410, 4418, 4611, 490101, 490102, 4903, 5115, 5403, 5601, 5607, 5608, 5613, 5614, 5616, 5617, 5619N, 5620, 5624, 5904, 8201, 8202
						15		*4415, 4902
								*4460
	10							*4501, 4504-4508, 5001, 5002, 5004
	10							*4502
	10	11						*4509
								*5105, 5129, 5154, 5161
								*511301, 511302, 5214, 5622
			12				16	*5162
								*5410, 5521
								*5509
								*5522, 5524
		11						*5532
			12					*5610
			12					Cw*0206
9	10	11	12	13	14	15	16	Well No.

Lot No.: 97F

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*13 subtyping.

In addition, wells number 2, 5, 10, 11, 13 and 15 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 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 2nd or 3rd exon or the 3rd intron, 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.

⁴The sequence of the B*1305 allele has been shown to be identical to B*1304.

⁵Primer mix 5: Specific PCR fragment of 125 bp in the B*1322, 1324 and the B*1586, 3560, 4508, 4618, 490102, 5401, 5402, 5405N, 5407, 5408N, 5410, 5412, 5413, 5417, 5502, 5507, 5510, 5512, 5516, 5518, 5519, 5522, 5526, 5530, 5534, 5610, 5619N and 5623 alleles. Specific PCR fragment of 150 bp in the B*1316 and 1320 alleles. Specific PCR fragment of 125 and 150 bp in the B*1542, 550101-550104, 5503, 5505, 5509, 5511, 5515, 5521, 5524, 5525, 5529, 5531 and 5533 alleles. Specific PCR fragments of 125 and 180 bp in the B*1303, 4071, 4410, 4415, 4418, 4501, 4504-4507, 4611, 490102, 5115, 5403, 5601, 5602, 5604, 5607, 5608, 5613, 5614, 5616, 5617, 5620, 5624, 5904, 8201 and 8202 alleles. Specific PCR fragments of 125, 150 and 180 bp in the B* 1573, 490101, 4902, 4903, 5001, 5002, 5004 and 5162 alleles. All bands may not always be visible.

Primer mix 8: Specific PCR fragment of 185 bp in the B*1307N allele. Specific PCR fragment of 225 bp in the B*1318 and the B*1504, 9537, 3933, 5105, 5129, 5154, 5161, 5410, 5509 and 5521 alleles.

Primer mix 10: Specific PCR fragment of 105 bp in the B*1321 and the B*070501-0706, 0732, 0734, 0740, 0753, 0769, 080102, 0806, 0820, 9550, 2707, 2711, 2720, 2724, 2727, 2743, 350902, 3518, 3531, 3588, 4010, 4012, 4013, 401403, 4019, 4021, 4047, 4058, 4076, 4088, 4096, 4431, 480101, 480102, 480301-4807, 4809-4811, 4813, 4815, 4816, 4818, 4819, 510109, 5110, 512402, 5411, 5504, 5508 and 8101-8104N alleles. Specific PCR fragment of 210 bp in the B*1309 and the B*1553, 2708, 2712, 2718, 2726, 2740, 2742, 2744, 3563, 3584, 3590, 4003, 4009, 4018, 4020, 4024, 4031-4033, 4042, 4044, 4052, 4059, 4060, 4071, 407201, 4077, 4087, 4089, 4095, 4101-4104, 4106, 4107, 4409, 4446, 4501-4509, 4610, 4702, 5001, 5002, 5004 and 7301 alleles. Specific PCR fragments of 105 and 210 bp in the B*2733, 400101-400204, 4004-4008, 4011, 401401, 401402, 4015, 4016, 4022, 4023, 4025, 4027, 4029, 4030, 4034-4040, 4043, 4045, 4046, 4048, 4049-4051, 4053-4057, 4061-4070, 407202-4075, 4078-4086, 4088, 4090-4094 and 4108 alleles.

Primer mix 13: Specific PCR fragment of 90 bp in the B*1319 allele. Specific PCR fragment of 180 bp in the B*1312 allele.

Primer mix 15: Specific PCR fragment of 105 bp in the B*1322 and the B*1573 and 4048 alleles. Specific PCR fragment of 245 bp in the B*1314 and 1323 and B*1809, 2701, 3710, 380201-3804, 3808, 3815, 3818, 4047, 4096, 4415, 4455 and 4902 alleles.

Primer mix 16: Specific PCR fragment of 90 bp in the B*1317 and B*3546 alleles. Specific PCR fragment of 205 bp in the B*1315 and B*5162 alleles.

'w', may be weakly amplified.

Lot No.: **97F**

Lot-specific information

CELL LINE VALIDATION SHEET																				
HLA-B*13 SSP subtyping kit																				
				Prod. No.:	Well															
					1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
					200617501	200617502	200617503	200617504	200960705	200960706	200617507	200960708	200617509	200849810	200617511	200960712	200960713	200960714	200960715	200960716
	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	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.: **97F**

Lot-specific information

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-B*13 SSP

Product number: 101.515-12u – without *Taq* polymerase
Lot number: 97F
Expiry date: 2011-July-01
Number of tests: 12
Number of wells per test: 16

Well specifications:

Well No.	Production No.	Well No.	Production No.
1	2006-175-01	9	2006-175-09
2	2006-175-02	10	2008-498-10
3	2006-175-03	11	2006-175-11
4	2006-175-04	12	2009-607-12
5	2009-607-05	13	2009-607-13
6	2009-607-06	14	2009-607-14
7	2006-175-07	15	2009-607-15
8	2009-607-08	16	2009-607-16

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 9, 13, 14 and 16 were available. The specificities of the primers in primer 14 and 16 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer. In primer solution 9, it was only possible to test the 5'-primers, the 3'-primers were not possible to test. In primer solution 13, one 5'-primer and one 3'-primer was not possible to test. Additional primers in primer solutions 8 and 15 were tested by separately adding one 5'-primer and/or one 3'-primer. In primer solution 8, 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.: **97F**

Lot-specific information

Declaration of Conformity

Product name: *Olerup* SSP® HLA-B*13
Product number: 101.515-12u
Lot number: 97F

Intended use: HLA-B*13 high resolution histocompatibility testing

Manufacturer: *Olerup* SSP AB
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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, 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

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