

Lot No.: **41F**

Lot-specific information

***Olerup SSP*[®] HLA-B*54**

Product number: 101.569-06u – without *Taq* polymerase
Lot number: 41F
Expiry date: 2010-December-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. 41F.

CHANGES COMPARED TO THE PREVIOUS *OLERUP SSP*[®] HLA-B*54 LOT

The HLA-B*54 specificity and interpretation tables have been updated for the HLA-B alleles described since the previous *Olerup SSP*[®] HLA-B*54 lot was made (Lot No. Y26).

Two wells have been added to the HLA-B*54 kit,
wells **15 and 16**.

The primers of the wells detailed below have been added, exchanged or modified.

Well	5'-primer	3'-primer	rationale
15	New	New	New primer pair for the B*5414, B*5415 and B*5416 alleles.
16	New	New	New primer pair for the B*5417 allele.

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PRODUCT DESCRIPTION

HLA-B*54 SSP subtyping

CONTENT

The primer set contains 5'- and 3'-primers for identifying the B*5401 to B*5417 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 PCR plate is marked with 'HLA-B*54' in silver/gray ink.

Well No. 1 is marked with the Lot Number '41F'.

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

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

INTERPRETATION

The interpretation of HLA-B*54 SSP subtypings will be influenced by five B*07, six B*08, most B*13, most B*15, all B*18, eight B*27, most B*35, the B*370104, most B*38, the B*39, most B*40, four B*41, two B*42, ten B*44, eight B*45, the B*46, the B*48, the B*49, the B*50, the B*51, the B*52, the B*53, most B*55, most B*56, many B*57, the B*58, the B*59, the B*67, the B*78, the B*81 and B*82 alleles when present on the other haplotype. In addition, the Cw*0203 allele will be amplified by primer mix 9.

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UNIQUELY IDENTIFIED ALLELES

All the HLA-B*54 alleles, i.e. **B*5401 to B*5417**, recognized by the HLA Nomenclature Committee in October 2008¹ will give rise to unique amplification patterns by the primers in the HLA-B*54 subtyping kit.

¹HLA-B 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 17 HLA-B*54 alleles can be combined in 153 homozygous and heterozygous combinations. Forty-one of these genotypes do not give rise to unique amplification patterns.

+++---+--	---+-----	5403,5411 = 5408N,5411
+++---+--	-----+--	5403,5415 = 5408N,5415 = 5408N,5416
+++---+--	-----+--	5401,5408N = 5403,5404 = 5403,5408N = 5404,5408N = 5408N,5408N
+++---+--	-----+--	5401,5403 = 5403,5403
+++---+--	-----+--	5401,5415 = 5404,5416 = 5415,5416
+++---+--	-----+--	5401,5414 = 5406,5416 = 5414,5416
+++---+--	---+-----	5401,5410 = 5410,5410
+++---+--	---+-----	5401,5412 = 5412,5412
+++---+--	---+-----	5401,5413 = 5413,5413
+++---+--	---+-----	5401,5407 = 5407,5407
+++---+--	---+-----	5401,5416 = 5416,5416
+++---+--	---+-----	5401,5417 = 5417,5417
+---+---+	-----+--	5404,5414 = 5406,5415 = 5414,5415
+---+---+	---+-----	5404,5411 = 5411,5411
+---+---+	-----+--	5404,5415 = 5415,5415
+---+---+	+-----+--	5406,5409 = 5409,5409
+---+---+	-----+--	5406,5414 = 5414,5414

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SPECIFICITY TABLE

HLA-B*54 SSP subtyping

Specificities and sizes of the PCR products of the 16 primer mixes used for HLA-B*54 SSP subtyping

Primer Mix	Size of spec. PCR product ¹	Size of control band ²	Amplified HLA-B*54 alleles	Other amplified HLA Class I alleles ³
1	215 bp	800 bp	5401-5417	150104, 370104
2⁴	105 bp	1070 bp	5401-5403, 5405N, 5407, 5408N, 5410, 5412, 5413, 5416, 5417	130201-1303, 1308Q, 1309, 1314-1316, 1318, 1319, 1542, 3560, 4415, 4418, 4501, 4503-4508, 4611, 4618, 490101-4903, 5001, 5002, 5004, 5115, 550101-5503, 5505, 5507, 5509-5512, 5515, 5516, 5518, 5519, 5521, 5522, 5524-5526, 5529-5531, 5533, 5534, 5601, 5607, 5608, 5613, 5614, 5616, 5617, 5619N, 5620, 5623, 5624, 5901
3	160 bp	1070 bp	5401, 5403, 5404, 5406-5417	4424, 5139
4	165 bp	1070 bp	5402	0713, 3811, 6702
5	180 bp	1070 bp	5403, 5408N	1303, 1573, 4071, 4410, 4415, 4418, 4501, 4504-4507, 4611, 490101-4903, 5001, 5002, 5004, 5115, 5162, 5601, 5602, 5604, 5607, 5608, 5613, 5614, 5616, 5617, 5620, 5624, 8201, 8202
6^{4,5}	105, 235 bp	1070 bp	5404, 5408N, 5411, 5415	0809, 1583, 2714, 40060101-400602, 4044, 4053, 4070, 4075, 4083, 4093, 4101, 4105-4107, 4204, 4420, 4447, 510101-5103, 5105, 5107-5112, 5114, 5116-512402, 5126-5136, 5138-5141N, 5143, 5144N, 5148-5155, 5157, 5158, 5160, 5161, 520101-5213, 5517, 5520, 5527, 5528, 560501-5606, 5615, 5621, 5808, 5902, 7801-7806
7⁴	140 bp	1070 bp	5405N	

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8	275 bp	1070 bp	5406, 5409, 5414	0709, 0711, 0717, 0828, 0835, 0837, 1304, 1310, 15010101- 150104, 150106-1508, 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, 180101- 1815, 1817N-1825, 1827-1832, 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, 3907, 3943, 4003, 4020, 4038, 4052, 4059, 4060, 4209, 4417, 4443, 4509, 460101-4610, 4612-4617, 4802, 4814, 4904, 4905, 5137, 5145, 530101-5303, 5305, 5306, 5308-5316, 5514, 5523, 5532, 5603, 5609, 5618, 570101- 570103, 5706, 5708, 5710, 5711, 5713-5716, 5718, 5719, 580101-5802, 5804-5807, 5809-5819
9	200 bp	1070 bp	5409	0748, 0813, 0825, 1310, 1311, 1505, 1531, 1548, 1552, 1555, 1591, 9507, 9514, 9523, 9524, 9536, 9551, 180101-180103, 1803-1807, 1809-1814, 1817N, 1820, 1823N-1826, 1828, 1829, 1831, 1832, 2707, 2711, 2732-2734, 2743, 3505, 3522, 3531, 3532, 3551, 3566, 356802, 3572, 3589, 380101- 3809, 3811-3817, 39010101- 39010102L, 390103-3905, 3907, 3908, 3910-3917, 391901-3920, 3922, 3923, 3925N-3932, 3937-3941, 3943-3945, 400101-400103,

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				400105-4003, 4007-401403, 4018-4022N, 4024, 4025, 4027, 4029, 4031, 4033, 4035- 4040, 4042, 4043, 4045-4050, 4052, 4054-4058, 4061- 4063, 4065-4067, 4069, 4071- 4074, 4076-4082, 4084, 4085, 4087-4092, 4431, 4454, 4606, 4613, 480101-480102, 480301, 4804, 4806, 4807, 4809-4814, 4816, 4818, 5314, 5504, 5508, 5602, 5604, 5610, 5618, 5816, 5818, 5820, 670101-6702, 8101-8104N, Cw*0203
10	225 bp	1070 bp	5410	1318, 1504, 9537, 3933, 5105, 5129, 5154, 5161, 5509, 5521
11	185 bp	1070 bp	5411	
12	150 bp	1070 bp	5412	
13⁴	135 bp	1070 bp	5413	
14	210 bp	800 bp	5407	
15⁴	95 bp	1070 bp	5414, 5415, 5416	1304, 1504, 1516, 1567, 1595, 3537, 4044, 4420, 4447, 4509, 4904, 4905, 5137, 5212, 5523, 5527
16	340	1070 bp	5417	

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*54 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 is 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*54 subtyping.

In addition, well 14 contains the primer pair giving rise to the shorter, 800 bp, internal positive control in order to allow kit identification.

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

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³Due to the sharing of sequence motifs between HLA-B alleles non-HLA-B*54 alleles will be amplified by primer mixes 1 to 6, 8 to 10 and 15. In addition, the Cw*0203 will be amplified by primer mix 10.

⁴Specific PCR fragments shorter than 150 base pairs have a lower intensity than longer PCR bands.

⁵Primer mix 6: Specific PCR fragment of 105 bp in the B*5404, B*5411 and B*5415 and the B*0809, 1583, 2714, 40060101-400602, 4044, 4053, 4070, 4075, 4083, 4093, 4101, 4105-4107, 4204, 4420, 4447, 510101-5103, 5105, 5107-5112, 5114, 5116-512402, 5126-5136, 5138-5141N, 5143, 5144N, 5148-5155, 5157, 5158, 5160, 5161, 520101-5213, 5517, 5520, 5527, 5528, 560501-5606, 5615, 5621, 5808, 5902 and 7801-7806 alleles. Specific PCR fragment of 235 bp in the B*5408N allele.

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INTERPRETATION TABLE								
HLA-B*54 SSP subtyping								
Amplification patterns of the B*5401 to 5417 alleles								
	Well⁴							
	1	2	3	4	5	6	7	8
Length of spec.	215	105	160	165	180	105	140	275
PCR product						235		
Length of int.	800	1070	1070	1070	1070	1070	1070	1070
pos. control¹								
5'-primer²	1st in.	357	106	103	420	357	106	419
	5'-CAg ^{3'}	5'-Tgg ^{3'}	5'-CCA ^{3'}	5'-CCT ^{3'}	5'-TTA ^{3'}	5'-Tgg ^{3'}	5'-CCA ^{3'}	5'-gTC ^{3'}
3'-primer(s)³	175	420	226	226	553	419	207	3rd I
	5'-CCg ^{3'}	5'-gCT ^{3'}	5'-CAC ^{3'}	5'-CAC ^{3'}	5'-CTA ^{3'}	5'-CgT ^{3'}	5'-TCC ^{3'}	5'-TAT ^{3'}
					559	553		
					5'-CAg ^{3'}	5'-CTA ^{3'}		
Well No.	1	2	3	4	5	6	7	8
HLA-B allele								
*5401	1	2	3					
*5402	1	2		4				
*5403	1	2	3		5			
*5404	1		3			6		
*5405N	1	2					7	
*5406	1		3					8
*5407	1	2	3					
*5408N	1	2	3		5	6		
*5409	1		3					8
*5410	1	2	3					
*5411	1		3			6		
*5412	1	2	3					
*5413	1	2	3					
*5414	1		3					8
*5415	1		3			6		
*5416	1	2	3					
*5417	1	2	3					
Well No.	1	2	3	4	5	6	7	8

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INTERPRETATION TABLE								
HLA-B*54 SSP subtyping								
Amplification patterns of the B*5401 to 5417 alleles								
Well ⁴								
9	10	11	12	13	14	15	16	
200	225	185	150	135	210	95	340	Length of spec. PCR product
1070	1070	1070	1070	1070	800	1070	1070	Length of int. pos. control ¹
369	357	357	206	133	106	357	709	5'-primer ²
5'-TAC ^{3'}	5'-Tgg ^{3'}	5'-Tgg ^{3'}	5'-Agg ^{3'}	5'-CCg ^{3'}	5'-CCA ^{3'}	5'-Tgg ^{3'}	5'-Agg ^{3'}	
527	539	499	317	226	275	412	916	3'-primer(s) ³
5'-CCA ^{3'}	5'-TCC ^{3'}	5'-ggA ^{3'}	5'-ggA ^{3'}	5'-CAC ^{3'}	5'-CCA ^{3'}	5'-gTC ^{3'}	5'-gAT ^{3'}	
9	10	11	12	13	14	15	16	Well No. HLA-B allele
								*5401
								*5402
								*5403
								*5404
								*5405N
								*5406
					14			*5407
								*5408N
9								*5409
	10							*5410
		11						*5411
			12					*5412
				13				*5413
						15		*5414
						15		*5415
						15		*5416
							16	*5417
9	10	11	12	13	14	15	16	Well No.

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Length of spec.	215	105	160	165	180	105	140	275	
PCR product						235			
Well No.	1	2	3	4	5	6	7	8	
*0709, 0711, 0717, 0828, 0835, 0837, 15010101-150103, 150106-1503, 1506-1508, 151101-1515, 1518-1521, 1523-1529, 1532-1536, 1538-1540, 1543, 1544, 1546, 1547, 1549-1551, 1553, 1554, 1556, 1557, 1560-1562, 1564-1566, 1568-1572, 1574-1576, 1578-1582, 1584, 1585, 1587-1589, 1592-1594N, 1596-1598, 9501-9506, 9508-9513, 9515-9522, 9525-9529, 9531, 9532, 9534, 9535, 9538-9549N, 1802, 1808, 1815, 1818, 1819, 1821, 1822, 1827, 1830, 2741, 350101-350107, 3507-350803, 3510, 3511, 351401-3517, 3519-3521, 3523-3530, 3535, 3540N-3543, 3545-3550, 3552-3554, 3557, 3558, 3561-3564, 3567, 356801, 3569, 3571, 3576-3580, 3582, 3586, 3590-3594, 4059, 4060, 4209, 4417, 4443, 460101-4605, 4607N-4610, 4612, 4614-4617, 4802, 5145, 530101-5303, 5305, 5306, 5308-5313, 5315, 5316, 5514, 5532, 5603, 5609, 570101-570103, 5706, 5708, 5710, 5711, 5713-5716, 5718, 5719, 580101-5802, 5804-5807, 5809-5815, 5817N, 5819									8
*0713				4					
*0748, 0813, 0825, 1311, 1548, 1826, 2707, 2711, 2732-2734, 2743, 3522, 3531, 380101-3809, 3812-3817, 39010101-39010102L, 390103-3905, 3908, 3910-3917, 391901-3920, 3922, 3923, 3925N-3932, 3937-3941, 3944, 3945, 400101-400103, 400105-400203, 4007-401403, 4018, 4019, 4021, 4022N, 4024, 4025, 4027, 4029, 4031, 4033, 4035-4037, 4039, 4040, 4042, 4043, 4045-4050, 4054-4058, 4061-4063, 4065-4067, 4069, 407201-4074, 4076-4082, 4084, 4085, 4087-4092, 4431, 4454, 480101-480102, 480301, 4804, 4806, 4807, 4809-4813, 4816, 4818, 5504, 5508, 5610, 5820, 670101-670102, 8101-8104N									
Well No.	1	2	3	4	5	6	7	8	

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200	225	185	150	135	210	95	340	Length of spec. PCR product
9	10	11	12	13	14	15	16	Well No.
								*0709, 0711, 0717, 0828, 0835, 0837, 15010101-150103, 150106-1503, 1506-1508, 151101-1515, 1518-1521, 1523-1529, 1532-1536, 1538-1540, 1543, 1544, 1546, 1547, 1549-1551, 1553, 1554, 1556, 1557, 1560-1562, 1564-1566, 1568-1572, 1574-1576, 1578-1582, 1584, 1585, 1587-1589, 1592-1594N, 1596-1598, 9501-9506, 9508-9513, 9515-9522, 9525-9529, 9531, 9532, 9534, 9535, 9538-9549N, 1802, 1808, 1815, 1818, 1819, 1821, 1822, 1827, 1830, 2741, 350101-350107, 3507-350803, 3510, 3511, 351401-3517, 3519-3521, 3523-3530, 3535, 3540N-3543, 3545-3550, 3552-3554, 3557, 3558, 3561-3564, 3567, 356801, 3569, 3571, 3576-3580, 3582, 3586, 3590-3594, 4059, 4060, 4209, 4417, 4443, 460101-4605, 4607N-4610, 4612, 4614-4617, 4802, 5145, 530101-5303, 5305, 5306, 5308-5313, 5315, 5316, 5514, 5532, 5603, 5609, 570101-570103, 5706, 5708, 5710, 5711, 5713-5716, 5718, 5719, 580101-5802, 5804-5807, 5809-5815, 5817N, 5819
								*0713
9								*0748, 0813, 0825, 1311, 1548, 1826, 2707, 2711, 2732-2734, 2743, 3522, 3531, 380101-3809, 3812-3817, 39010101-39010102L, 390103-3905, 3908, 3910-3917, 391901-3920, 3922, 3923, 3925N-3932, 3937-3941, 3944, 3945, 400101-400103, 400105-400203, 4007-401403, 4018, 4019, 4021, 4022N, 4024, 4025, 4027, 4029, 4031, 4033, 4035-4037, 4039, 4040, 4042, 4043, 4045-4050, 4054-4058, 4061-4063, 4065-4067, 4069, 407201-4074, 4076-4082, 4084, 4085, 4087-4092, 4431, 4454, 480101-480102, 480301, 4804, 4806, 4807, 4809-4813, 4816, 4818, 5504, 5508, 5610, 5820, 670101-670102, 8101-8104N
9	10	11	12	13	14	15	16	Well No.

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Length of spec.	215	105	160	165	180	105	140	275
PCR product						235		
Well No.	1	2	3	4	5	6	7	8
*0809, 1583, 2714, 40060101-400602, 4053, 4070, 4075, 4083, 4093, 4101, 4105-4107, 4204, 510101-5103, 5107-5112, 5114, 5116-512402, 5126-5128, 5130-5136, 5138, 5140, 5141N, 5143, 5144N, 5148-5153, 5155, 5157, 5158, 5160, 520101-5211, 5213, 5517, 5520, 5528, 560501-5606, 5615, 5621, 5808, 5902, 7801-7806						6		
*130201-130204, 1308Q, 1309, 1314-1316, 1319, 1542, 3560, 4503, 4508, 4618, 550101-5503, 5505, 5507, 5510-5512, 5515, 5516, 5518, 5519, 5522, 5524-5526, 5529-5531, 5533, 5534, 5619N, 5623, 5901	2							
*1303, 4415, 4418, 4501, 4504-4507, 4611, 490101-4903, 5001, 5002, 5004, 5115, 5601, 5607, 5608, 5613, 5614, 5616, 5617, 5620, 5624		2			5			
*1304, 1516, 1567, 1595, 3537, 4509, 4904, 4905, 5137, 5523					8			
*1310, 1505, 1531, 1552, 1555, 1591, 9507, 9514, 9523, 9524, 9536, 9551, 180101-180103, 1803-1807, 1809-1814, 1817N, 1820, 1823N-1825, 1828, 1829, 1831, 1832, 3505, 3532, 3551, 3566, 356802, 3572, 3589, 3907, 3943, 4003, 4020, 4038, 4052, 4606, 4613, 4814, 5314, 5618, 5816, 5818								8
*1318, 5509, 5521	2							
*150104	1							8
*1504					8			
*1573, 4410, 5162, 8201, 8202					5			
*9537, 3933								
*370104	1							
*3811, 6702	4							
*4044, 4420, 4447, 5212, 5527						6		
*4071, 5602, 5604					5			
*4424			3					
*5105, 5129, 5154, 5161					6			
*5139			3			6		
HLA-B allele								
Cw*0203								
Well No.	1	2	3	4	5	6	7	8

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200	225	185	150	135	210	95	340	Length of spec. PCR product
9	10	11	12	13	14	15	16	Well No.
								*0809, 1583, 2714, 40060101-400602, 4053, 4070, 4075, 4083, 4093, 4101, 4105-4107, 4204, 510101, 5103, 5107-5112, 5114, 5116-512402, 5126-5128, 5130-5136, 5138, 5140, 5141N, 5143, 5144N, 5148-5153, 5155, 5157, 5158, 5160, 520101-5211, 5213, 5517, 5520, 5528, 560501-5606, 5615, 5621, 5808, 5902, 7801-7806
								*130201-130204, 1308Q, 1309, 1314-1316, 1319, 1542, 3560, 4503, 4508, 4618, 550101-5503, 5505, 5507, 5510-5512, 5515, 5516, 5518, 5519, 5522, 5524-5526, 5529-5531, 5533, 5534, 5619N, 5623, 5901
								*1303, 4415, 4418, 4501, 4504-4507, 4611, 490101-4903, 5001, 5002, 5004, 5115, 5601, 5607, 5608, 5613, 5614, 5616, 5617, 5620, 5624
						15		*1304, 1516, 1567, 1595, 3537, 4509, 4904, 4905, 5137, 5523
9								*1310, 1505, 1531, 1552, 1555, 1591, 9507, 9514, 9523, 9524, 9536, 9551, 180101-180103, 1803-1807, 1809-1814, 1817N, 1820, 1823N-1825, 1828, 1829, 1831, 1832, 3505, 3532, 3551, 3566, 356802, 3572, 3589, 3907, 3943, 4003, 4020, 4038, 4052, 4606, 4613, 4814, 5314, 5618, 5816, 5818
	10							*1318, 5509, 5521
								*150104
	10					15		*1504
								*1573, 4410, 5162, 8201, 8202
	10							*9537, 3933
								*370104
9								*3811, 6702
						15		*4044, 4420, 4447, 5212, 5527
9								*4071, 5602, 5604
								*4424
	10							*5105, 5129, 5154, 5161
								*5139
								HLA-B allele
9								Cw*0203
9	10	11	12	13	14	15	16	Well No.

Lot No.: 41F

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*54 subtyping.

In addition, well 14 contains the primer pair giving rise to the shorter, 800 bp, internal positive control in order to allow kit identification.

²The codon, in the 2nd or 3rd exon or the 1st intron, 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 codon, in the 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.

⁴Primer mix 6: Specific PCR fragment of 105 bp in the B*5404, B*5411 and B*5415 and the B*0809, 1583, 2714, 40060101-400602, 4044, 4053, 4070, 4075, 4083, 4093, 4101, 4105-4107, 4204, 4420, 4447, 510101-5103, 5105, 5107-5112, 5114, 5116-512402, 5126-5136, 5138-5141N, 5143, 5144N, 5148-5155, 5157, 5158, 5160, 5161, 520101-5213, 5517, 5520, 5527, 5528, 560501-5606, 5615, 5621, 5808, 5902 and 7801-7806 alleles. Specific PCR fragment of 235 bp in the B*5408N allele.

Lot No.: **41F**

Lot-specific information

CELL LINE VALIDATION SHEET																					
HLA-B*54 SSP subtyping kit																					
					Prod. No.:	Well															
						1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
	IHWC cell line		B*			200508501	200508502	200508503	200508504	200623405	200623406	200737207	200508508	200737209	200737210	200737211	200737212	200737213	200737214	200854415	200854416
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	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.: **41F**

Lot-specific information

CERTIFICATE OF ANALYSIS

Olerup SSP[®] HLA-B*54 SSP

Product number: 101.569-06u – without *Taq* polymerase
Lot number: 41F
Expiry date: 2010-December-01
Number of tests: 6
Number of wells per test: 16

Well specifications:

Well No.	Production No.	Well No.	Production No.
1	2005-085-01	9	2007-372-09
2	2005-085-02	10	2007-372-10
3	2005-085-03	11	2007-372-11
4	2005-085-04	12	2007-372-12
5	2006-234-05	13	2007-372-13
6	2006-234-06	14	2007-372-14
7	2007-372-07	15	2008-544-15
8	2005-085-08	16	2008-544-16

The specificity of each primer solution of the kit has been tested against 48 well characterized cell line DNAs.

No DNAs carrying the alleles to be amplified by primer solutions 4, 7, 11, 12, 13, 14 and 16 were available. The specificities of the primers in primer solutions 4, 11 and 12 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer. In primer solutions 7 and 14 it was only possible to test the 5'-primer, the 3'-primers were not possible to test. In primer solutions 13 and 16 it was only possible to test the 3'-primer, the 5'-primers were not possible to test. In addition, one 3'-primer in primer solution 15 was tested by separately adding an additional 5'-primer.

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

Date of approval: 2009-May-27

Approved by:

Quality Control, Supervisor

Lot No.: **41F**

Lot-specific information

Declaration of Conformity

Product name: *Olerup* SSP® HLA-B*54
Product number: 101.569-06u
Lot number: 41F

Intended use: HLA-B*54 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, 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.: **41F**

Lot-specific information

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