

Lot No.: **59F**

Lot-specific information

Olerup SSP[®] HLA-B*57

Product number: 101.567-12u – without *Taq* polymerase
Lot number: 59F
Expiry date: 2011-January-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. 59F.

CHANGES COMPARED TO THE PREVIOUS *OLERUP SSP[®]* HLA-B*57 LOT

The HLA-B*57 specificity and interpretation tables have been updated for the HLA-B alleles described since the previous *Olerup SSP[®]* HLA-B*57 lot was made (Lot No. 62E).

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

Well	5'-primer	3'-primer	rationale
13	Exchanged	-	Increased specificity of the 5'-primer, and exchanged control primer pair.
14	Added	Added	New primer pair for the B*5717 allele
16	Added	Added	New primer pair for the B*5718 allele

Changes in revision R02 compared to R01:

1. The interpretation table has been corrected, to make all positive alleles in well 9 visible.

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PRODUCT DESCRIPTION

HLA-B*57 SSP subtyping

CONTENT

The primer set contains 5'- and 3'-primers for identifying the B*5701 to B*5719 alleles.

PLATE LAYOUT

Each 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 cut PCR plate is marked with 'HLA-B*57' in silver/gray ink.

Well No. 1 is marked with the Lot No. '59F'.

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*57 SSP subtypings will be influenced by the B*07, two B*08, many B*13, the B*14, most B*15, five B*18, many B*27, most B*35, most B*37, B*3810, four B*39, several B*40, the B*44, the B*46, five B*48, the B*49, the B*50, the B*51, the B*52, the B*53, the B*5406, most B*55, several B*56, most B*58, most B*78 and the B*8301 allele when present on the other haplotype. In addition, the Cw*0510 allele will be weakly amplified by primer mix 4.

UNIQUELY IDENTIFIED ALLELES

All the HLA-B*57 alleles, i.e. **B*5701 to B*5719**, recognized by the HLA Nomenclature Committee in October 2008¹ will give rise to unique amplification patterns by the primers in the HLA-B*57 subtyping kit.

The HLA-B*57 subtyping kit cannot distinguish the B*570101 to B*570103 alleles or the B*570301 and B*570302 alleles.

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

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RESOLUTION IN HOMO- AND HETEROZYGOTES

The 19 HLA-B*57 alleles can be combined in 190 homozygous and heterozygous combinations. Fifty-one of these genotypes do not give rise to unique amplification patterns. The different sizes of the specific PCR products generated by primer mixes 6, 8, 11, 14 and 16 were not considered in these calculations.

+++++---+ ---++----	5702, 5716 = 5707, 5719
+++++---- ---++++--	5702, 5710 = 5717, 5719
+++++---- ---++++++	5701, 5712 = 5702, 5718 = 5712, 5718
+++++---- ---++++--	5701, 5702 = 5703, 5719
+++++---+ ---++++--	5707, 5710 = 5716, 5717
+++++---+ ---++++--	5701, 5707 = 5703, 5716 = 5707, 5716
+++++---- +++++---	5701, 5709 = 5709, 5714
+++++---- ---++++--	5701, 5717 = 5703, 5710 = 5710, 5717
+++-+--- -----+---	5701, 5704 = 5704, 5706 = 5706, 5719
+++-+--- -----+---	5701, 5706 = 5706, 5706
+++----- -----+---	5701, 5715 = 5715, 5715
+++----- -+---+---	5701, 5708 = 5708, 5708
+++----- -+-+---+	5701, 5714 = 5714, 5714
+++----- -----+---	5701, 5710 = 5710, 5710
+++----- -----+---	5701, 5718 = 5718, 5718
++-++--- +++++---	5709, 5713 = 5709, 5719
+---+---+ ---++----	5703, 5707 = 5705, 5707 = 5707, 5707
+---+--- -----+---	5703, 5717 = 5705, 5717 = 5717, 5717
+---+--- -----+---	5703, 5703 = 5703, 5705
+---+--- -----+---	5702, 5712 = 5705, 5712 = 5712, 5712
+---+--- -----+---	5702, 5702 = 5702, 5705
+---+--- +++++---	5705, 5709 = 5709, 5709

5701 = 570101-570103

5703 = 570301-570302

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SPECIFICITY TABLE

HLA-B*57 SSP subtyping

Specificities and sizes of the PCR products of the 16 primer mixes used for HLA-B*57 SSP subtyping

Primer Mix	Size of spec. PCR product ¹	Size of control band ²	Amplified HLA-B*57 alleles	Other amplified HLA Class I alleles ³
1	150 bp	800 bp	570101-5710, 5712, 5714-5719	1301, 1306, 1307N, 1312, 1313, 1317, 1320, 1322, 1323, 1502, 1513, 1520, 1521, 1525, 1536, 1544, 1562, 1577, 1580, 1585, 1588, 1589, 9506, 9512, 9521, 9539, 9544, 1822, 2719, 2730, 350101-350403, 3506-350803, 3510-3517, 3519-3521, 3523-3530, 3533-3536, 3538-3542, 3545-3550, 3552, 3554-3557, 3559, 3561-3563, 3565Q, 3569-3571, 3574, 3576-3578, 3580-3585, 3590-3594, 370101-370104, 3703N-3706, 3708, 3710, 3711, 3713, 3714, 3942, 4028, 44020101-4414, 4416, 4417, 4419N, 4421-4430, 4432-4440, 4442-4446, 4448-4452N, 4455-446402, 4802, 5104, 5142, 5146, 5156, 530101-5306, 5308-5313, 5315, 5316, 5514, 5609, 5611, 5612, 580101-580102, 5804, 5805, 5809-5815, 5817N, 5819, 8301
2⁴	100 bp	1070 bp	570101-570103, 5706, 5708, 5710, 5713-5716, 5718, 5719	5514, 5814
3	220 bp	1070 bp	570101-570103, 570301-	4030, 4034, 5514, 5814

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			570302, 5706-5708, 5710, 5714- 5718	
4^{4,5}	100 bp	800 bp	5702-570302, 5705, 5707, 5709, 5712, 5717	1313, 1321, 350201-350203, 350401-350403, 3506 ^{weakly} , 350901-350902, 3512, 3518, 3559 ^{weakly} , 3581, 3583, 3588, 370101-370104 ^{weakly} , 3703N- 3706 ^{weakly} , 3708 ^{weakly} , 3710 ^{weakly} , 3711 ^{weakly} , 3712, 3713 ^{weakly} , 3714, 3942 ^{weakly} , 4004, 4028, 4030, 4034, 4064, 4068, 4462, 4817 ^{weakly} , 5104, 5146, 5156, 5612, Cw*0510^{weakly}
5	220 bp	1070 bp	5702, 5704, 5712, 5713, 5719	
6^{4,6}	95, 180 bp	1070 bp	5704, 5706	
7^{4,5}	105 bp	1070 bp	5715	
8^{4,7}	90, 250 bp	1070 bp	5707, 5716	
9	170 bp	1070 bp	5709, 5713	070201-0724, 0726-0747, 0749N, 0750, 0752-0768, 0806, 0820, 1316, 1320, 1401-1409, 15010101- 150104, 150106-1504, 1506- 1519, 1521, 1523-1530, 1532-1540, 1542-1547, 1549, 1550, 1553, 1554, 1556- 1558, 1560-1574, 1576-1582, 1585, 1587, 1589, 1590, 1592-1599, 9501-9504, 9506, 9508-9510, 9512, 9513, 9515-9522, 9525-9529, 9531- 9535, 9537-9544, 9546-9550, 1815, 1819, 1821, 1830, 270401-270402, 2706, 2710, 2715, 2718, 2720, 2721, 2724, 2725, 2740, 3511, 351401-351402, 3521, 3543, 3544, 3558, 3567, 3579, 3586, 3707, 3713, 3810, 3918, 3935, 3936, 4005, 4015, 4016, 4023, 4026,

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				4028, 4032, 4051, 460101-4605, 4607N, 4608, 4610, 4612, 4614-4617, 4805, 4808, 4815, 490101-4905, 5001, 5002, 5004, 510101-5104, 5106, 5107, 5111N-5114, 5116-5118, 5121-512402, 5126-5130, 5132-5139, 5141N, 5143, 5145, 5146, 5148-5152, 5155-5162, 520101-5202, 5204-5209, 5211-5214, 5306, 5308, 5406, 550101-550104, 5503, 5505, 5509, 5511, 5514, 5515, 5517, 5521, 5524, 5525, 5528, 5529, 5531, 5533, 5603, 560501-5606, 5621, 5806, 5808, 5819, 7801-7803, 7805, 7806
10	210 bp	1070 bp	5708	
11⁸	165, 215 bp	800 bp	5709, 5714	5514, 5814
12⁴	90 bp	1070 bp	5702-570302, 5707, 5709, 5712, 5717	4030, 4034
13⁴	90 bp	800 bp	570101-5715, 5717-5719	
14⁹	135, 195 bp	1070 bp	5710, 5717	
15	145 bp	1070 bp	5711	1401-1404, 1407N, 1409, 5802, 5806, 5807
16^{4,10}	85, 160 bp	1070 bp	5712, 5718	

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*57 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.

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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*57 subtyping.

In addition, wells number 4, 11 and 13 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*57 alleles will be amplified by primer mixes 1, 2, 3, 4, 9, 11, 12 and 15. In addition, the Cw*0510 allele will be weakly amplified by primer mix 4.

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

⁵Primer mixes 4 and 7 have a tendency of giving rise to nonspecific amplifications. Most pronounced for primer mix 4.

⁶Primer mix 6: Specific PCR fragment of 95 bp in the B*5704 allele. Specific PCR fragment of 180 bp in the B*5706 allele.

⁷Primer mix 8: Specific PCR fragment of 90 bp in the B*5716 allele. Specific PCR fragment of 250 bp in the B*5707 allele.

⁸Primer mix 11: Specific PCR fragment of 165 bp in the B*5714 and B*5514 and 5814 alleles. Specific PCR fragment of 215 bp in the B*5709 allele.

⁹Primer mix 14: Specific PCR fragment of 135 bp in the B*5717 allele. Specific PCR fragment of 195 bp in the B*5710 allele.

¹⁰Primer mix 16: Specific PCR fragment of 85 bp in the B*5712 allele. Specific PCR fragment of 160 bp in the B*5718 allele.

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INTERPRETATION TABLE								
HLA-B*57 SSP subtyping								
Amplification patterns of the B*5701 to 5719 alleles								
	Well ⁴							
	1	2	3	4	5	6	7	8
Length of spec.	150	100	220	100	220	95	105	90
PCR product						180		250
Length of int.	800	1070	1070	800	1070	1070	1070	1070
pos. control ¹								
5'-primer(s) ²	355	362	362	355	362	362	209	209
	5'-TCA 3' 5'-ggT 3' 5'-ggT 3' 5'-TCA 3' 5'-ggT 3' 5'-ggT 3' 5'-ggC 3' 5'-ggA 3'							
								362
								5'-ggT 3'
3'-primer(s) ³	463	419	539	412	539	418	271	256
	5'-gCT 3' 5'-Cgg 3' 5'-TCA 3' 5'-gTT 3' 5'-TCC 3' 5'-gTC 3' 5'-CAC 3' 5'-CCC 3'							
		419				500		572
		5'-CAg 3'				5'-ggA 3'		5'-gCg 3'
Well No.	1	2	3	4	5	6	7	8
HLA-B allele								
*570101-570103	1	2	3					
*5702	1			4	5			
*570301-570302	1		3	4				
*5704	1				5	6		
*5705	1			4				
*5706	1	2	3			6		
*5707	1		3	4				8
*5708	1	2	3					
*5709	1			4				
*5710	1	2	3					
*5711								
*5712	1			4	5			
*5713		2			5			
*5714	1	2	3					
*5715	1	2	3				7	
*5716	1	2	3					8
*5717	1		3	4				
*5718	1	2	3					
*5719	1	2			5			
Well No.	1	2	3	4	5	6	7	8

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INTERPRETATION TABLE								
HLA-B*57 SSP subtyping								
Amplification patterns of the B*5701 to 5719 alleles								
Well ⁴								
9	10	11	12	13	14	15	16	
170	210	165	90	90	135	145	85	Length of spec. PCR product
		215			195		160	
1070	1070	800	1070	800	1070	1070	1070	Length of int. pos. control ¹
527	320	362	362	209	103	361	256	5'-primer(s) ²
5'-TgA 3' ^{5'} -CCC 3' ^{5'} -ggT 3' ^{5'} -ggT 3'				5'-ggC 3' ^{5'} -CCT 3' ^{5'} -AgT 3' ^{5'} -ACg 3'				
					446		362	
					5'-CgA 3'		5'-ggT 3'	
3 rd	2 nd	486	412	256	256	463	302	3'-primer(s) ³
5'-TAT 3' ^{5'} -TCg 3' ^{5'} -gCg 3' ^{5'} -gTT 3'				5'-CCC 3' ^{5'} -CCC 3' ^{5'} -gCT 3' ^{5'} -ggC 3'				
		538			539		481	
		5'-gTC 3'			5'-TCA 3'		5'-gTA 3'	
9	10	11	12	13	14	15	16	Well No.
				13				HLA-B allele *570101-570103
			12	13				*5702
			12	13				*570301-570302
				13				*5704
				13				*5705
				13				*5706
			12	13				*5707
	10			13				*5708
9		11	12	13				*5709
				13	14			*5710
				13		15		*5711
			12	13			16	*5712
9				13				*5713
		11		13				*5714
				13				*5715
								*5716
			12	13	14			*5717
				13			16	*5718
				13				*5719
9	10	11	12	13	14	15	16	Well No.

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Length of spec.	150	100	220	100	220	95	105	90
PCR product						180		250
Well No.	1	2	3	4	5	6	7	8
*070201-0724, 0726-0747, 0749N, 0750, 0752-0768, 0806, 0820, 1316, 1405-140602, 1408, 15010101-150104, 150106-150108, 1503, 1504, 1506-1512, 1514-1519, 1523, 1524, 1526N-1530, 1532-1535, 1537-1540, 1542, 1543, 1545-1547, 1549, 1550, 1553, 1554, 1556-1558, 1560, 1561, 1563-1574, 1576, 1578, 1579N, 1581, 1582, 1587, 1590, 1592-1599, 9501-9504, 9508-9510, 9513, 9515-9520, 9522, 9525-9529, 9531-9535, 9537, 9538, 9540-9543, 9546-9550, 1815, 1819, 1821, 1830, 270401-270402, 2706, 2710, 2715, 2718, 2720, 2721, 2724, 2725, 2740, 3543, 3544, 3558, 3567, 3579, 3586, 3707, 3810, 3918, 3935, 3936, 4005, 4015, 4016, 4023, 4026, 4032, 4051, 460101-4605, 4607N, 4608, 4610, 4612, 4614-4617, 4805, 4808, 4815, 490101-4905, 5001, 5002, 5004, 510101-5103, 5106, 5107, 5111N-5114, 5116-5118, 5121-512402, 5126-5130, 5132-5139, 5141N, 5143, 5145, 5148-5152, 5155, 5157-5162, 520101-5202, 5204-5209, 5211-5214, 5406, 550101-550104, 5503, 5505, 5509, 5511, 5515, 5517, 5521, 5524, 5525, 5528, 5529, 5531, 5533, 5603, 560501-5606, 5621, 5808, 7801-7803, 7805, 7806								
*1301, 1306, 1307N, 1312, 1317, 1322, 1323, 1520, 1588, 1822, 2719, 2730, 350101-350107, 3503, 3507-350803, 3510, 3513, 3515-3517, 3519-352002, 3523-3530, 3533-3536, 3538-3542, 3545-3550, 3552, 3554-3557, 3561-3563, 3565Q, 3569-3571, 3574, 3576-3578, 3580, 3582, 3584, 3585, 3590-3594, 44020101-4414, 4416, 4417, 4419N, 4421-4430, 4432-4440, 4442-4446, 4448-4452N, 4455-4461N, 4463-446402, 4802, 5142, 530101-5305, 5309-5313, 5315, 5316, 5609, 5611, 580101-580102, 5804, 5805, 5809-5813, 5815, 5817N, 8301	1							
*1313, 350201-350203, 350401-350403, 3512, 3581, 3583, 3714, 4462, 5612	1			4				
Well No.	1	2	3	4	5	6	7	8

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170	210	165	90	90	135	145	85	Length of spec.	
		215			195		160	PCR product	
9	10	11	12	13	14	15	16	Well No.	
9								*070201-0724, 0726-0747, 0749N, 0750, 0752-0768, 0806, 0820, 1316, 1405-140602, 1408, 15010101-150104, 150106-150108, 1503, 1504, 1506-1512, 1514-1519, 1523, 1524, 1526N-1530, 1532-1535, 1537-1540, 1542, 1543, 1545-1547, 1549, 1550, 1553, 1554, 1556-1558, 1560, 1561, 1563-1574, 1576, 1578, 1579N, 1581, 1582, 1587, 1590, 1592-1599, 9501-9504, 9508-9510, 9513, 9515-9520, 9522, 9525-9529, 9531-9535, 9537, 9538, 9540-9543, 9546-9550, 1815, 1819, 1821, 1830, 270401-270402, 2706, 2710, 2715, 2718, 2720, 2721, 2724, 2725, 2740, 3543, 3544, 3558, 3567, 3579, 3586, 3707, 3810, 3918, 3935, 3936, 4005, 4015, 4016, 4023, 4026, 4032, 4051, 460101-4605, 4607N, 4608, 4610, 4612, 4614-4617, 4805, 4808, 4815, 490101-4905, 5001, 5002, 5004, 510101-5103, 5106, 5107, 5111N-5114, 5116-5118, 5121-512402, 5126-5130, 5132-5139, 5141N, 5143, 5145, 5148-5152, 5155, 5157-5162, 520101-5202, 5204-5209, 5211-5214, 5406, 550101-550104, 5503, 5505, 5509, 5511, 5515, 5517, 5521, 5524, 5525, 5528, 5529, 5531, 5533, 5603, 560501-5606, 5621, 5808, 7801-7803, 7805, 7806	
								*1301, 1306, 1307N, 1312, 1317, 1322, 1323, 1520, 1588, 1822, 2719, 2730, 350101-350107, 3503, 3507-350803, 3510, 3513, 3515-3517, 3519-352002, 3523-3530, 3533-3536, 3538-3542, 3545-3550, 3552, 3554-3557, 3561-3563, 3565Q, 3569-3571, 3574, 3576-3578, 3580, 3582, 3584, 3585, 3590-3594, 44020101-4414, 4416, 4417, 4419N, 4421-4430, 4432-4440, 4442-4446, 4448-4452N, 4455-4461N, 4463-446402, 4802, 5142, 530101-5305, 5309-5313, 5315, 5316, 5609, 5611, 580101-580102, 5804, 5805, 5809-5813, 5815, 5817N, 8301	
								*1313, 350201-350203, 350401-350403, 3512, 3581, 3583, 3714, 4462, 5612	
9	10	11	12	13	14	15	16	Well No.	

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Length of spec.	150	100	220	100	220	95	105	90
PCR product						180		250
Well No.	1	2	3	4	5	6	7	8
*1320, 1502, 1513, 1521, 1525, 1536, 1544, 1562, 1577, 1580, 1585, 1589, 9506, 9512, 9521, 9539, 9544, 3511, 351401-351402, 3521, 5306, 5308, 5819	1							
*1321, 350901-350902, 3518, 3588, 3712, 4004, 4064, 4068				4				
*1401-1404, 1407N, 1409, 5806								
*3506, 3559, 370101-370104, 3703N-3706, 3708, 3710, 3711, 3942	1			w				
*3713	1			w				
*4028, 5104, 5146, 5156	1			4				
*4030, 4034			3	4				
*4817				w				
*5514	1	2	3					
*5802, 5807								
*5814	1	2	3					
HLA-B allele								
Well No.	1	2	3	4	5	6	7	8
Cw*0510				w				
Well No.	1	2	3	4	5	6	7	8

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*57 subtyping.

In addition, wells number 4, 11 and 13 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 the 2nd or 3rd exon or the 2nd or 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.

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170	210	165	90	90	135	145	85	Length of spec.
		215			195		160	PCR product
9	10	11	12	13	14	15	16	Well No.
9								*1320, 1502, 1513, 1521, 1525, 1536, 1544, 1562, 1577, 1580, 1585, 1589, 9506, 9512, 9521, 9539, 9544, 3511, 351401-351402, 3521, 5306, 5308, 5819
								*1321, 350901-350902, 3518, 3588, 3712, 4004, 4064, 4068
9						15		*1401-1404, 1407N, 1409, 5806
								*3506, 3559, 370101-370104, 3703N-3706, 3708, 3710, 3711, 3942
9								*3713
9								*4028, 5104, 5146, 5156
			12					*4030, 4034
								*4817
9		11						*5514
						15		*5802, 5807
		11						*5814
								HLA-B allele
9	10	11	12	13	14	15	16	Well No.
								Cw*0510
9	10	11	12	13	14	15	16	Well No.

⁴Primer mix 6: Specific PCR fragment of 95 bp in the B*5704 allele. Specific PCR fragment of 180 bp in the B*5706 allele.

Primer mix 8: Specific PCR fragment of 90 bp in the B*5716 allele. Specific PCR fragment of 250 bp in the B*5707 allele.

Primer mix 11: Specific PCR fragment of 165 bp in the B*5714 and B*5514 and 5814 alleles. Specific PCR fragment of 215 bp in the B*5709 allele.

Primer mix 14: Specific PCR fragment of 135 bp in the B*5717 allele. Specific PCR fragment of 195 bp in the B*5710 allele.

Primer mix 16: Specific PCR fragment of 85 bp in the B*5712 allele. Specific PCR fragment of 160 bp in the B*5718 allele.

w', might be weakly amplified.

Lot No.: **59F**

Lot-specific information

CELL LINE VALIDATION SHEET																				
HLA-B*57 SSP subtyping kit																				
				Well																
				1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	
				Prod. No.:	200843601	200856402	200843603	200843604	200843605	200843606	200846407	200843608	200856409	200843610	200843611	200843612	200856413	200856414	200843615	200856416
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	*440301	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
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	*440301	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
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.: **59F**

Lot-specific information

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-B*57 SSP

Product number: 101.567-12u – without *Taq* polymerase
Lot number: 59F
Expiry date: 2011-January-01
Number of tests: 12
Number of wells per test: 16

Well specifications:

Well No.	Production No.	Well No.	Production No.
1	2008-436-01	9	2008-564-09
2	2008-564-02	10	2008-436-10
3	2008-436-03	11	2008-436-11
4	2008-436-04	12	2008-436-12
5	2008-436-05	13	2008-564-13
6	2008-436-06	14	2008-564-14
7	2008-464-07	15	2008-436-15
8	2008-436-08	16	2008-564-16

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 6, 7, 8, 11, 14 and 16 were available. The specificities of the primers in primer solutions 6, 8, 11, 14 and 16 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer. In primer solution 7 it was only possible to test the 5'-primer, the 3'-primer was not possible to test. In primer solutions 6 and 16 one of the 3'-primers was not possible to test, and in primer solution 8 and 14 one of the 5'-primers was not possible to test.

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

Date of approval: 2009-September-30

Approved by:

Quality Control, Supervisor

Lot No.: **59F**

Lot-specific information

Declaration of Conformity

Product name: *Olerup* SSP[®] HLA-B*57
Product number: 101.567-12u
Lot number: 59F

Intended use: HLA-B*57 high resolution histocompatibility testing

Manufacturer: *Olerup* SSP AB
Hasselstigen 1
SE-133 33 Saltsjöbaden, Sweden
Phone: +46-8-717 88 27
Fax: +46-8-717 88 18

We, *Olerup* SSP AB, hereby declare that this product, to which this Declaration of Conformity relates is in conformity with the following Standard(s) and other normative document(s) ISO 9001:2000 and ISO 13485:2003, following the provisions of the 98/79/EC Directive on *in vitro* diagnostic medical devices, Annex II List B, conformity assessed using Annex IV, as transposed into the national laws of the Member States of the European Union.

The Technical Documentation File is maintained at *Olerup* SSP AB, Hasselstigen 1, SE-133 33 Saltsjöbaden, Sweden.

The Authorized Representative located within the Community is: *Olerup* SSP AB.

Notified Body: Lloyd's Register Quality Assurance Limited, Hiramford, Middlemarch Office Village, Siskin Drive, Coventry CV3 4FJ, United Kingdom. (Notified Body number: 0088.)

Saltsjöbaden, Sweden
2009-September-30

Olle Olerup
Managing Director

Lot No.: **59F**

Lot-specific information

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