

Olerup SSP® HLA-B*38

Product number:	101.565-12 – including <i>Taq</i> polymerase
Lot number:	80F
Expiry date:	2011-April-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. 80F.

CHANGES COMPARED TO THE PREVIOUS *OLERUP SSP*® HLA-B*38 Lot

The HLA-B*38 specificity and interpretation tables have been updated for the HLA-B alleles described since the previous *Olerup SSP*® HLA-B*38 lot was made (Lot No. 45E).

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

Well	5'-primer	3'-primer	rationale
12	Modified	-	Increased yield of specific PCR product.

PRODUCT DESCRIPTION

HLA-B*38 SSP subtyping

CONTENT

The primer set contains 5'- and 3'-primers for identifying the B*3801 to B*3817 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*38' in silver/gray ink.

Well No. 1 is marked with the Lot No. '80F'.

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*38 SSP subtypings will be influenced by most B*07, eight B*08, three B*13, the B*14, most B*15, most B*18, several B*27, fourteen B*35, the B*37, most B*39, several B*40, the B*4406, the B*46, the B*48, the B*49, the B*50, the B*51, the B*52, the B*53, the B*5406, several B*55, five B*56, three B*57, the B*58, the B*67 and the B*78 alleles when present on the other haplotype.

UNIQUELY IDENTIFIED ALLELES

All the HLA-B*38 alleles, i.e. **B*3801 to B*3817**, recognized by the HLA Nomenclature Committee in January 2009¹ will give rise to unique amplification patterns by the primers in the HLA-B*38 subtyping kit.

The HLA-B*38 subtyping kit cannot distinguish the B*380201 and B*380202 alleles.

¹HLA-B alleles listed on the IMGT/HLA web page 2009-January-16, release 2.24.0, www.ebi.ac.uk/imgt/hla.

RESOLUTION IN HOMO- AND HETEROZYGOTES

The 17 HLA-B*38 alleles will generate 18 amplification patterns that can be combined in 171 homozygous and heterozygous combinations. Ninety-nine of these genotypes do not give rise to unique amplification patterns. The different specific PCR products generated by primer mixes 8, 10, 11 and 16 were not considered in these calculations.

++++++- - - - + - + -	380101, 3803 = 380102, 3803 = 3803, 3809
+++++ - + - - + - + -	3804, 3812 = 3804, 3816
+++++ - + - - + - + -	3804, 3809 = 3804, 3814
+++++ - + - - - + - + -	380101, 3804 = 380102, 3804
+++++ - - + - - + - + -	3812, 3815 = 3815, 3816
+++++ - - + - - + - + -	3805, 3808 = 3813, 3815
+++++ - - + - - + - + -	3809, 3815 = 3814, 3815
+++++ - - + - - - + - + -	380101, 3815 = 380102, 3815 =
	3802, 3805 = 3805, 3815
+++++ - - - - + - + - + -	3808, 3812 = 3808, 3816
+++++ - - - - + - + - + -	3802, 3812 = 3802, 3816
+++++ - - - - + - + - + -	3808, 3809 = 3808, 3814
+++++ - - - - + - + - + -	380101, 3808 = 3802, 3813 = 3808, 3813
+++++ - - - - + - + - + -	3802, 3809 = 3802, 3814
+++++ - - - - + - + - + -	380101, 3802 = 380102, 3802
+++++ - - - - + - + - + -	3805, 3812 = 3805, 3816
+++++ - - - - + - + - + -	3805, 3811 = 3805, 3817
+++++ - - - - + - + - + -	380101, 3805 = 380102, 3805
+++++ - - - - + - + - + -	3807, 3809 = 3807, 3814
+++++ - - - - + - + - + -	380101, 3807 = 380102, 3807 =
	3806, 3812 = 3807, 3812
+++++ - - - - + - + - + -	3806, 3809 = 3806, 3814
+++++ - - - - + - + - + -	380101, 3806 = 380102, 3806
+++++ - - - - + - + - + -	3809, 3812 = 3809, 3816 = 3812, 3814
+++++ - - - - + - + - + -	3810, 3812 = 3810, 3816
+++++ - - - - + - + - + -	3811, 3812 = 3811, 3816 =
	3812, 3817 = 3816, 3817
+++++ - - - - + - + - + -	380101, 3812 = 380101, 3816 = 380102, 3812 =
	380102, 3816 = 3812, 3812 = 3812, 3816
+++++ - - - - + - + - + -	3811, 3813 = 3813, 3817
+++++ - - - - + - + - + -	380101, 3813 = 380102, 3813
+++++ - - - - + - + - + -	3809, 3810 = 3810, 3814
+++++ - - - - + - + - + -	3809, 3811 = 3809, 3817 =
	3811, 3814 = 3814, 3817
+++++ - - - - + - + - + -	380101, 3809 = 380101, 3814 = 380102, 3809 =
	380102, 3814 = 3809, 3809 = 3809, 3814
+++++ - - - - + - + - + -	3810, 3811 = 3810, 3817
+++++ - - - - + - + - + -	380101, 3811 = 380101, 3817 = 380102, 3811 =
	380102, 3817 = 3811, 3811 = 3811, 3817
+++++ - - - - + - + - + -	380101, 380101 = 380101, 380102
+++++ - - - - + - + - + -	380102, 3810 = 3810, 3810
+++ - +++ - - - + - + -	3802, 3803 = 3803, 3804
+++ - + - - + - - - + - + -	3802, 3815 = 3815, 3815
++ - + - - - + - + - + -	3806, 3816 = 3807, 3816
++ - - - - - + - + - + -	3806, 3807 = 3807, 3807

SPECIFICITY TABLE

HLA-B*38 SSP subtyping

Specificities and sizes of the PCR products of the 16 primer mixes used for HLA-B*38 SSP subtyping

Primer Mix	Size of spec. PCR product ¹	Size of control band ²	Amplified HLA-B*38 alleles ³	Other amplified HLA-B alleles ⁴
1	185 bp	800 bp	380101-3803, 3807-3817	1401, 1407N, 1408, 39010101-39010102L, 390103-390201, 3903, 3905-390602, 3907 [?] , 3908, 3909, 3911, 3914, 3915, 3918, 391902, 3922, 3924-3930, 3932-3944, 3946, 670101
2	190 bp	800 bp	380101-380202, 3804-3812, 3815, 3817	0716, 0727, 0737, 0738, 0750, 0803, 0823, 1503, 1509, 1510, 1518, 1523, 1529, 1537, 1547, 1549, 1551, 1552, 1554, 1562, 1564, 1568, 1569, 1572, 1574, 1580, 1590, 1591, 1593, 1598, 1599, 9503, 9508, 9514, 9515, 9519, 9523, 9524, 9527, 9531-9534, 9551, 180101, 180103, 1802, 1805-1815, 1817N-1828, 1830-1832, 3525, 370101-3714, 3905, 3907 [?] , 3908, 3911, 391301-391302, 3920, 3937, 4012, 480101-4819, 5812
3	170 bp	800 bp	380101-380202, 3804, 3805, 3808-3815, 3817	1401-1409, 1509, 1510, 1518, 1523, 1537, 1551, 1552, 1572, 1580, 1590, 1593, 1599, 9508, 9514, 9515, 9519, 9524, 9533, 9534, 39010101-39010102L, 390103-390106, 3903-390602, 3907 [?] , 3909, 3911, 3912, 3914, 3915, 3918-391902, 3922, 3924-3938Q, 3940N-3946
4⁵	105 bp	1070 bp	380101, 380102, 3805, 3809-3814, 3816	
5	210 bp	1070 bp	380201-3804, 3808, 3815	0802, 9515, 1809, 3710

Lot No.: **80F**

Lot-specific information

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6⁶	170 bp	800 bp	3803	0727, 0750, 0804, 0817, 1503, 1547, 1554, 1561, 1562, 1564, 1568, 1569, 1591, 1598, 9503, 9523, 9527, 9531, 9532, 9551, 180101-1803, 1805, 1806, 1808-1815, 1817N-1828, 1830-1832, 370101-3714, 390201-390202, 3908, 391301-391302, 3923, 3939, 4012, 480101-4805, 4807-4819
7⁶	160 bp	800 bp	3803, 3804	0817, 0838, 1503, 1547, 1549, 1554, 1561, 1562, 1568, 1569, 1574, 1591, 1598, 9503, 9523, 9527, 9531, 9532, 9551, 1812, 370101-3707, 3709-3714, 390201-390202, 3908, 391301-391302, 3922, 3923, 4012, 480101-4805, 4807-4815, 4817-4819
8⁷	185, 240 bp	800 bp	3805, 3815	140201-1403, 1405-140602, 1409, 3526, 3904, 3907 [?]
9⁵	145 bp	1070 bp	3806, 3807	4406, 4903, 510101-512402, 5126-5146, 5148, 5149, 5151-5153, 5155-5163, 520101-520104, 5203-5214, 530101-5302, 5304-5308, 5310, 5314-5316, 580101-5802, 5804-5816, 5818-5820
10^{5,8}	90, 145 bp	1070 bp	3807, 3812, 3816	391902
11^{5,9}	90, 135 bp	1070 bp	3808, 3813	
12⁵	90 bp	800 bp	3803, 3809, 3814	1401-1409, 39010101-39010102L, 390103, 390105-390106, 390201, 3903, 3904, 390601-390602, 3909, 3912, 3914, 3915, 3918, 391902, 3922, 3924-3936, 3938Q-3946, 670101
13	175 bp	800 bp	380101, 380201-3807, 3809, 3811-3817	39010101-39010102L, 390103-390602, 3908-3914, 3916, 3918-3920, 3922-3924, 3926-3928, 3931, 3935, 3937, 3939, 3941, 3942, 3944-3946, 5820, 670101-6702
14	170 bp	1070 bp	3810	070201-0724, 0726-0747, 0749N, 0750, 0752-0768, 0806, 0820, 1316, 1320, 1401-1409,

Lot No.: **80F**

Lot-specific information

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				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, 3918, 3935, 3936, 4005, 4015, 4016, 4023, 4026, 4028, 4032, 4051, 460101-4605, 4607N, 4608, 4610, 4612, 4614-4617, 4805, 4808, 4815, 4901-4905, 5001, 5002, 5004, 510101-5104, 5106, 5107, 5111N-5114, 5116-5118, 5121-512402, 5126-5130, 5132-5139, 5141N, 5143, 5145, 5146, 5148-5152, 5155-5163, 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, 5709, 5713, 5806, 5808, 5819, 7801-7803, 7805, 7806
15	230 bp	1070 bp	380101-380202, 3804, 3806-3812, 3815-3817	0716, 0727, 0737, 0738, 0750, 1314, 1568, 1571, 180101, 180103, 1802, 1805-1815, 1817N-1824, 1826-1832, 2701, 2718, 2723, 2729, 2744, 3550, 3584, 370101-3714, 3905, 3907 [?] , 3908, 3911, 391301-391302, 3920, 3937, 400201-400602, 4008, 4009, 4011, 4013, 4018-4020, 4024, 4026-4029, 4035, 4037, 4039, 4040, 4044, 4056, 4057, 4064, 4068, 4070, 4071, 4074, 4075, 4078, 4082, 4083, 4085, 4086, 4089-

				4091, 4093, 4094, 480101- 4819, 5157, 5710
16^{5,10}	95, 355 bp	1070 bp	3811, 3817	0713, 0727, 6702

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*38 SSP typings.

When the primers in a primer mix can give rise to specific PCR products of more than one length this is indicated if the size difference is 20 base pairs or more. Size differences shorter than 20 base pairs are not given. For high resolution SSP kits the respective lengths of the specific PCR product(s) of the alleles amplified by these primer mixes are given.

Nonspecific amplifications, i.e. a ladder or a smear of bands, may sometimes be seen. GC-rich primers have a higher tendency of giving rise to nonspecific amplifications than other primers.

PCR fragments longer than the control bands may sometimes be observed. Such bands should be disregarded and do not influence the interpretation of the SSP typings.

PCR fragments migrating faster than the control bands, but slower than a 400 bp fragment may be seen in some gel read-outs. Such bands can be disregarded and do not influence the interpretation of the SSP typings.

Some primers may give rise to primer oligomer artifacts. Sometimes this phenomenon is an inherent feature of the primer pair(s) of a primer mix. More often it is due to other factors such as too low amount of DNA in the PCR reactions, taking too long time in setting up the PCR reactions, working at elevated room temperature or using thermal cyclers that are not pre-heated.

²The internal positive control primer pairs amplify segments of the human growth hormone gene. The two different control primer pairs give rise to either an internal positive control band of 1070 base pairs, for most wells, or a band of 800 base pairs, for some wells. Well number 1 contains the primer pair giving rise to the shorter, 800 bp, internal positive control band in order to help in the correct orientation of the HLA-B*38 subtyping. In addition, wells number 2, 3, 6, 7, 8, 12 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.

³For some HLA-B alleles complete 2nd exon nucleotide sequences are not available. In these instances it is not known whether some of the primers of the SSP sets are completely matched with the target sequences or not. We assume that unknown sequences in the second exon are conserved within allelic groups.

⁴Due to the sharing of sequence motifs between HLA-B alleles and non-HLA-B*38 alleles will be amplified by primer mixes 1 to 3, 5 to 10 and 12 to 16.

⁵Short specific PCR fragments are less intense and not as sharp as longer specific bands.

⁶Primer solutions 6 and 7 may yield less specific PCR product than the other HLA-B*38 primer mixes.

⁷Primer mix 8: Specific PCR fragment of 185 bp in the B*3805 and B*140201 to 1403, 1405 to 140602, 1409, 3526, 3904 and 3907² alleles. Specific PCR fragment of 240 bp in the B*3815 allele.

⁸Primer mix 10: Specific PCR fragment of 90 bp in the B*3807 and 3812 and B*391902 alleles. Specific PCR fragment of 145 bp in the B*3816 allele.

⁹Primer mix 11: Specific PCR fragment of 90 bp in the B*3813 allele. Specific PCR fragment of 135 bp in the B*3808 allele.

¹⁰Primer mix 16: Specific PCR fragment of 95 bp in the B*3817 allele. Specific PCR fragment of 355 bp in the B*3811 and the B*0713 and 6702 alleles. Specific PCR fragment of 430 bp in the B*0727 allele.

‘?’, nucleotide sequence information not available for the primer matching sequence.

INTERPRETATION TABLE								
HLA-B*38 SSP subtyping								
Amplification patterns of the B*3801 to 3817 alleles								
	Well⁴							
	1	2	3	4	5	6	7	8
Length of spec.	185	190	170	105	210	170	160	185
PCR product								240
Length of int.	800	800	800	1070	1070	800	800	800
pos. control¹								
5'-primers²	103	142	142	246	142	142	142	103
	5'-CCT ^{3'}	5'-TCT ^{3'}	5'-TCT ^{3'}	5'-gAA ^{3'}	5'-TCT ^{3'}	5'-TCT ^{3'}	5'-TCT ^{3'}	5'-CCg ^{3'}
								346
								5'-ggC ^{3'}
3'-primer(s)³	246	292	272	309	309	272	259	246
	5'-TAT ^{3'}	5'-gTA ^{3'}	5'-TgC ^{3'}	5'-ATC ^{3'}	5'-gTg ^{3'}	5'-Tgg ^{3'}	5'-CTC ^{3'}	5'-TAT ^{3'}
		292						544
		5'-gTA ^{3'}						5'-ggT ^{3'}
Well No.	1	2	3	4	5	6	7	8
HLA-B allele								
*380101	1	2	3	4				
*380102	1	2	3	4				
*380201- 380202	1	2	3		5			
*3803	1				5	6	7	
*3804		2	3		5		7	
*3805		2	3	4				8
*3806		2						
*3807	1	2						
*3808	1	2	3		5			
*3809	1	2	3	4				
*3810	1	2	3	4				
*3811	1	2	3	4				
*3812	1	2	3	4				
*3813	1		3	4				
*3814	1		3	4				
*3815	1	2	3		5			8
*3816	1			4				
*3817	1	2	3					
Well No.	1	2	3	4	5	6	7	8

INTERPRETATION TABLE								
HLA-B*38 SSP subtyping								
Amplification patterns of the B*3801 to 3817 alleles								
Well ⁴								
9	10	11	12	13	14	15	16	
145	90	90	90	175	170	230	95	Length of spec.
	145	135					355	PCR product
							430	
1070	1070	1070	800	800	1070	1070	1070	Length of int.
								pos. control ¹
206	142	246	246	412	527	103	44	5'-primers) ²
5'-gAC ³	5'-TCA ³	5'-gAA ³	5'-gAA ³	5'-ATA ³	5'-TgA ³	5'-CCT ³	5'-ggC ³	
	193	463	483				246	
	5'-CCA ³	5'-TgA ³	5'-gAg ³				5'-gAA ³	
	206							
	5'-gAC ³							
309	246	296	292	544	3 rd	292	226	3'-primer(s) ³
5'-ATC ³	5'-TAT ³	5'-CTA ³	5'-gTC ³	5'-ggT ³	5'-TAT ³	5'-gTA ³	5'-CAC ³	
		559	544			292	301	
		5'-CAT ³	5'-ggT ³			5'-gTA ³	5'-gTC ³	
9	10	11	12	13	14	15	16	Well No.
								HLA-B allele
				13		15		*380101
						15		*380102
				13		15		*380201- 380202
			12	13				*3803
				13		15		*3804
				13				*3805
9				13		15		*3806
9	10			13		15		*3807
		11				15		*3808
			12	13		15		*3809
					14	15		*3810
				13		15	16	*3811
	10			13		15		*3812
		11		13				*3813
			12	13				*3814
				13		15		*3815
	10			13		15		*3816
				13		15	16	*3817
9	10	11	12	13	14	15	16	Well No.

Length of spec.	185	190	170	105	210	170	160	185
PCR product								240
Well No.	1	2	3	4	5	6	7	8
*070201-0712, 0714, 0715, 0717-0724, 0726, 0728-0736, 0739-0747, 0749N, 0752-0768, 0806, 0820, 1316, 1320, 15010101-1502, 1504, 1506-1508, 151101-151702, 1519, 1521, 1524-1528, 1530, 1532-1536, 1538-1540, 1542-1546, 1550, 1553, 1556-1558, 1560, 1563, 1565-1567, 1570, 1573, 1576-1579N, 1581, 1582, 1585, 1587, 1589, 1592, 1594N-1597, 9501, 9502, 9504, 9506, 9509, 9510, 9512, 9513, 9516-9518, 9520-9522, 9525, 9526, 9528, 9529, 9535, 9537-9544, 9546-9550, 270401-270402, 2706, 2710, 2715, 2720, 2721, 2724, 2725, 2740, 3511, 351401-351402, 3521, 3543, 3544, 3558, 3567, 3579, 3586, 4015, 4016, 4023, 4032, 4051, 460101-4605, 4607N, 4608, 4610, 4612, 4614-4617, 490101-4902, 4904, 4905, 5001, 5002, 5004, 5150, 5202, 5406, *550101-550104, 5503, 5505, 5509, 5511, 5514, 5515, 5517, 5521, 5524, 5525, 5528, 5529, 5531, 5533, 5603, 560501-5606, 5621, 5709, 5713, 7801-7803, 7805, 7806								
*0713								
*0716, 0737, 0738		2						
*0727		2				6		
*0750, 1815, 1819, 1821, 1830		2				6		
*0802					5			
*0803, 0823, 3525		2						
*0804, 180102, 1803						6		
*0817						6	7	
*0838							7	
Well No.	1	2	3	4	5	6	7	8

Lot No.: **80F**

Lot-specific information

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145	90	90	90	175	170	230	95	Length of spec.
	145	135					355	PCR product
							430	
9	10	11	12	13	14	15	16	Well No.
					14			*070201-0712, 0714, 0715, 0717-0724, 0726, 0728-0736, 0739-0747, 0749N, 0752-0768, 0806, 0820, 1316, 1320, 15010101-1502, 1504, 1506-1508, 151101-151702, 1519, 1521, 1524-1528, 1530, 1532-1536, 1538-1540, 1542-1546, 1550, 1553, 1556-1558, 1560, 1563, 1565-1567, 1570, 1573, 1576-1579N, 1581, 1582, 1585, 1587, 1589, 1592, 1594N-1597, 9501, 9502, 9504, 9506, 9509, 9510, 9512, 9513, 9516-9518, 9520-9522, 9525, 9526, 9528, 9529, 9535, 9537-9544, 9546-9550, 270401- 270402, 2706, 2710, 2715, 2720, 2721, 2724, 2725, 2740, 3511, 351401-351402, 3521, 3543, 3544, 3558, 3567, 3579, 3586, 4015, 4016, 4023, 4032, 4051, 460101-4605, 4607N, 4608, 4610, 4612, 4614-4617, 490101-4902, 4904, 4905, 5001, 5002, 5004, 5150, 5202, 5406, *550101-550104, 5503, 5505, 5509, 5511, 5514, 5515, 5517, 5521, 5524, 5525, 5528, 5529, 5531, 5533, 5603, 560501-5606, 5621, 5709, 5713, 7801- 7803, 7805, 7806
					14		16	*0713
					14	15		*0716, 0737, 0738
					14	15	16	*0727
					14	15		*0750, 1815, 1819, 1821, 1830
								*0802
								*0803, 0823, 3525
								*0804, 180102, 1803
								*0817
								*0838
9	10	11	12	13	14	15	16	Well No.

Length of spec.	185	190	170	105	210	170	160	185
PCR product								240
Well No.	1	2	3	4	5	6	7	8
*1314, 1829, 2701, 2723, 2729, 2744, 3550, 3584, 400201-4004, 40060101-400602, 4008, 4009, 4011, 4013, 4018-4020, 4024, 4027, 4029, 4035, 4037, 4039, 4040, 4044, 4056, 4057, 4064, 4068, 4070, 4071, 4074, 4075, 4078, 4082, 4083, 4085, 4086, 4089-4091, 4093, 4094, 5710								
*1401, 1407N, 1408, 3936	1		3					
*140201-1403, 1405-140602, 1409			3					8
*1404			3					
*1503, 1547, 1554, 1562, 1569, 1598, 9503, 9527, 9531, 9532		2				6	7	
*1509, 1510, 1518, 1523, 1537, 1572, 1580, 1590, 1593, 1599, 9508, 9519, 9533, 9534		2	3					
*1529		2						
*1549, 1574		2					7	
*1551, 1552, 9514, 9524		2	3					
*1561						6	7	
*1564		2				6		
*1568, 3707, 3713, 4805, 4808, 4815		2				6	7	
*1571, 2718, 4005, 4026, 4028								
*1591, 9523, 9551 4012		2				6	7	
*9515		2	3		5			
*180101, 180103, 1802, 1805, 1806, 1808, 1810, 1811, 1813, 1814, 1817N, 1818, 1820, 1822-1824, 1826-1828, 1831, 1832, 3708, 4816		2				6		
*1807, 4806		2						
*1809		2			5	6		
*1812, 370101-3706, 3709, 3711, 3712, 3714, 480101-4804, 4807, 4809-4814, 4817-4819		2				6	7	
*1825		2				6		
*3526								8
*3710		2			5	6	7	
Well No.	1	2	3	4	5	6	7	8

Lot No.: **80F**

Lot-specific information

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145	90	90	90	175	170	230	95	Length of spec.
	145	135					355	PCR product
							430	
9	10	11	12	13	14	15	16	Well No.
				15				*1314, 1829, 2701, 2723, 2729, 2744, 3550, 3584, 400201-4004, 40060101-400602, 4008, 4009, 4011, 4013, 4018-4020, 4024, 4027, 4029, 4035, 4037, 4039, 4040, 4044, 4056, 4057, 4064, 4068, 4070, 4071, 4074, 4075, 4078, 4082, 4083, 4085, 4086, 4089-4091, 4093, 4094, 5710
			12		14			*1401, 1407N, 1408, 3936
			12		14			*140201-1403, 1405-140602, 1409
			12		14			*1404
				14				*1503, 1547, 1554, 1562, 1569, 1598, 9503, 9527, 9531, 9532
					14			*1509, 1510, 1518, 1523, 1537, 1572, 1580, 1590, 1593, 1599, 9508, 9519, 9533, 9534
					14			*1529
					14			*1549, 1574
								*1551, 1552, 9514, 9524
					14			*1561
					14			*1564
					14	15		*1568, 3707, 3713, 4805, 4808, 4815
				14 15				*1571, 2718, 4005, 4026, 4028
								*1591, 9523, 9551 4012
				14				*9515
						15		*180101, 180103, 1802, 1805, 1806, 1808, 1810, 1811, 1813, 1814, 1817N, 1818, 1820, 1822-1824, 1826-1828, 1831, 1832, 3708, 4816
				15				*1807, 4806
						15		*1809
				15				*1812, 370101-3706, 3709, 3711, 3712, 3714, 480101-4804, 4807, 4809-4814, 4817-4819
								*1825
								*3526
						15		*3710
9	10	11	12	13	14	15	16	Well No.

Length of spec.	185	190	170	105	210	170	160	185
PCR product								240
Well No.	1	2	3	4	5	6	7	8
*39010101-390103, 390105-390106, 3903, 390601-390602, 3909, 3914, 3924, 3926-3928, 3941, 3942, 3944, 3946	1		3					
*390104	1		3					
*390201	1					6	7	
*390202, 3923						6	7	
*3904			3					8
*3905, 3911, 3937	1	2	3					
*3907	?	?	?					?
*3908	1	2				6	7	
*3910, 3916, 670102								
*3912, 3931, 3945			3					
*391301-391302		2				6	7	
*3915, 3925N, 3929, 3930, 3932-3934, 3938Q, 3940N, 3943	1		3					
*3918, 3935	1		3					
*391901			3					
*391902	1		3					
*3920		2						
*3922	1		3				7	
*3939	1					6		
*4406, *5105, 5108-5110, 5115, 5119, 5120, 5131, 5140, 5142, 5144N, 5153, *5203, 5210, *530101-5302, 5304, 5305, 5307, 5310, 5314-5316, *580101-5802, 5804, 5805, 5807, 5809-5811, 5813- 5816, 5818								
*4903, 510101-5104, 5106, 5107, 5111N- 5114, 5116-5118, 5121-512402, 5126- 5130, 5132-5139, 5141N, 5143, 5145, 5146, 5148, 5149, 5151, 5152, 5155, 5156, 5158-5163, 520101-520104, 5204- 5209, 5211-5214, 5306, 5308, 5806, 5808, 5819								
*5157								
*5812		2						
*5820								
*670101	1							
*6702								
HLA-B allele								
Well No.	1	2	3	4	5	6	7	8

145	90	90	90	175	170	230	95	Length of spec.
	145	135					355	PCR product
							430	
9	10	11	12	13	14	15	16	Well No.
			12	13				*39010101-390103, 390105-390106, 3903, 390601-390602, 3909, 3914, 3924, 3926-3928, 3941, 3942, 3944, 3946
				13				*390104
			12	13				*390201
				13				*390202, 3923
			12	13				*3904
				13		15		*3905, 3911, 3937
						?		*3907
				13		15		*3908
				13				*3910, 3916, 670102
			12	13				*3912, 3931, 3945
				13		15		*391301-391302
			12					*3915, 3925N, 3929, 3930, 3932-3934, 3938Q, 3940N, 3943
			12	13	14			*3918, 3935
				13				*391901
	10		12	13				*391902
				13		15		*3920
			12	13				*3922
			12	13				*3939
9								*4406, *5105, 5108-5110, 5115, 5119, 5120, 5131, 5140, 5142, 5144N, 5153, *5203, 5210, *530101-5302, 5304, 5305, 5307, 5310, 5314-5316, *580101-5802, 5804, 5805, 5807, 5809-5811, 5813- 5816, 5818
9								*4903, 510101-5104, 5106, 5107, 5111N- 5114, 5116-5118, 5121-512402, 5126- 5130, 5132-5139, 5141N, 5143, 5145, 5146, 5148, 5149, 5151, 5152, 5155, 5156, 5158-5163, 520101-520104, 5204- 5209, 5211-5214, 5306, 5308, 5806, 5808, 5819
9					14	15		*5157
9								*5812
9				13				*5820
			12	13				*670101
				13			16	*6702
								HLA-B allele
9	10	11	12	13	14	15	16	Well No.

Lot No.: 80F

Lot-specific information

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¹The internal positive control primer pairs amplify segments of the human growth hormone gene. The two different control primer pairs give rise to either an internal positive control band of 1070 base pairs, for most wells, or a band of 800 base pairs, for some wells.

Well number 1 contains the primer pair giving rise to the shorter, 800 bp, internal positive control band in order to help in the correct orientation of the HLA-B*38 subtyping.

In addition, wells number 2, 3, 6, 7, 8, 12 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 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 8: Specific PCR fragment of 185 bp in the B*3805 and B*140201 to 1403, 1405 to 140602, 1409, 3526, 3904 and 3907[?] alleles. Specific PCR fragment of 240 bp in the B*3815 allele.

Primer mix 10: Specific PCR fragment of 90 bp in the B*3807 and 3812 and B*391902 alleles. Specific PCR fragment of 145 bp in the B*3816 allele.

Primer mix 11: Specific PCR fragment of 90 bp in the B*3813 allele. Specific PCR fragment of 135 bp in the B*3808 allele.

Primer mix 16: Specific PCR fragment of 95 bp in the B*3817 allele. Specific PCR fragment of 355 bp in the B*3811 and the B*0713 and 6702 alleles. Specific PCR fragment of 430 bp in the B*0727 allele.

'?', nucleotide sequence information not available for the primer matching sequence.

CELL LINE VALIDATION SHEET															
HLA-B*38 SSP subtyping kit															
						Well									
						1	2	3	4	5	6	7	8	9	10
					Prod. No.:	200617001	200617002	200617003	200617004	200617005	200617006	200617007	200844908	200617009	200844910
						200730311	200958812	200844913	200958814	200617015	200844916				
IHC cell line						B*									
1	9001	SA	*0702			-	-	-	-	-	-	-	-	-	-
2	9280	LK707	*5201	*7301		-	-	-	-	-	-	-	-	-	-
3	9011	E4181324	*52011			-	-	-	-	-	-	-	-	-	-
4	9275	GU373	*1510	*5301		-	+	+	-	-	-	-	-	-	-
5	9009	KAS011	*3701			-	+	-	-	+	-	-	-	-	-
6	9353	SM	*3901	*5101		+	-	+	-	-	-	-	-	-	-
7	9020	QBL	*1801			-	+	-	-	-	+	-	-	-	-
8	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		-	-	-	-	-	-	-	-	-	-

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-B*38 SSP

Product number: 101.565-12 – including *Taq* polymerase
Lot number: 80F
Expiry date: 2011-April-01
Number of tests: 12
Number of wells per test: 16

Well specifications:

Well No.	Production No.	Well No.	Production No.
1	2006-170-01	9	2006-170-09
2	2006-170-02	10	2008-449-10
3	2006-170-03	11	2007-303-11
4	2006-170-04	12	2009-588-12
5	2006-170-05	13	2008-449-13
6	2006-170-06	14	2009-588-14
7	2006-170-07	15	2006-170-15
8	2008-449-08	16	2008-449-16

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 10, 11 and 16 were available. The specificities of the primers in primer solutions 10 and 16 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer. In primer solution 11 it was only possible to the 5'-primers, the 3'-primer were not possible to test. In primer solution 8, one 3'-primer was tested by separately adding one additional 5'-primer, and one of the 5'-primers 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

Declaration of Conformity

Product name: *Olerup* SSP® HLA-B*38
Product number: 101.565-12
Lot number: 80F

Intended use: HLA-B*38 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-May-27

Olle Olerup
Managing Director

Lot No.: **80F**

Lot-specific information

www.olerup.com

ADDRESSES:

Manufacturer:

Olerup SSP AB, Hasselstigen 1, SE-133 33 Saltsjöbaden, Sweden.

Tel: +46-8-717 88 27

Fax: +46-8-717 88 18

E-mail: info-ssp@olerup.com

Web page: <http://www.olerup.com>

Distributed by:

Olerup GmbH, Löwengasse 47 / 6, AT-1030 Vienna, Austria.

Tel: +43-1-710 15 00

Fax: +43-1-710 15 00 10

E-mail: support-at@olerup.com

Web page: <http://www.olerup.com>

Olerup Inc., 901 S. Bolmar St., Suite R, West Chester, PA 19382

Tel: 1-877-OLERUP1

Fax: 610-344-7989

E-mail: info.us@olerup.com

Web page: <http://www.olerup.com>

For information on *Olerup* SSP distributors worldwide, contact **Olerup GmbH**.