

Olerup SSP® HLA-B*46

Product number:	101.544-06 – including <i>Taq</i> polymerase
Lot number:	60F
Expiry date:	2011-February-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. 60F.

CHANGES COMPARED TO THE PREVIOUS *OLERUP SSP*® HLA-B*46 LOT

The HLA-B*46 specificity and interpretation tables have been updated for the HLA-B alleles described since the previous *Olerup SSP*® HLA-B*46 lot was made (Lot No. Y24).

Two wells have been added to the HLA-B*46 kit,
wells **15 and 16**.

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

Well	5'-primer	3'-primer	rationale
2	-	Added	New primer for the B*4616 allele.
3	Exchanged	Exchanged	New primer pair for the B*4603 and B*4618 alleles .
4	Added	-	New primer for the B*4614 allele.
7	Added	Added	New primer pair for the B*4616 allele.
8	Exchanged	Exchanged	Exchanged primer pair to decrease tendencies of dimer formation.
10	Added	Added	New primer pair for the B*4615N allele.
15	New	New	New primer pair for the B*4613 allele.
16	New	New	New primer pair for the B*4617 allele.

Changes in revision R02 compared to R01:

1. Alleles amplified by primer mixes 13 in the Specificity Table have been corrected.

PRODUCT DESCRIPTION

HLA-B*46 SSP typing

CONTENT

The primer set contains 5'- and 3'-primers for identifying the B*4601 to B*4618 alleles.

PLATE LAYOUT

Each HLA-B*46 test consists of 16 PCR reactions in a 16 well cut PCR plate.

1	2	3	4	5	6	7	8
9	10	11	12	13	14	15	16

The 16 well PCR plate is marked with 'HLA-B*46' in silver/gray ink.

Well No. 1 is marked with the Lot Number '60F'.

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*46 SSP subtypings will be influenced by many other HLA-B alleles, in particular the HLA-B*15 alleles.

UNIQUELY IDENTIFIED ALLELES

All the HLA-B*46, i.e. **B*4601 to B*4618**, recognized by the HLA Nomenclature Committee in January 2009¹ will be amplified by the primers in the HLA-B*46 SSP kit.

The B*46 primer set cannot separate the B*460101 and B*460102 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 18 HLA-B*46 alleles can be combined in 171 homozygous and heterozygous combinations. Ninety-four of these genotypes do not give rise to unique amplification patterns. The different sizes of the specific PCR fragments generated by primer mixes 4, 7 and 10 were not considered in these calculations.

++-++-+-	+-----	4604, 4616 = 4614, 4616
++-++---	+-----	4602, 4604 = 4602, 4614
++-++-+-	++-----	4605, 4616 = 4615N, 4616
++-++-+-	+-----	4601, 4616 = 4602, 4607N = 4602, 4616 = 4607N, 4616 = 4616, 4616
++-++---	++-----	4602, 4605 = 4602, 4615N
++-++---	+-----	4601, 4602 = 4602, 4602
+--++-+-	+---+--	4604, 4618 = 4614, 4618
+--++---	+-----	4603, 4604 = 4603, 4614

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+--+---+ +--+---+	4605, 4618 = 4615N, 4618
+--+---+ ----+--+	4603, 4611 = 4603, 4618 = 4608, 4618 =
	4611, 4618 = 4613, 4618 = 4618, 4618
+--+---+ +-----	4603, 4605 = 4603, 4615N
+-----+ +-----	4604, 4606 = 4606, 4614
+-----+ +-----	4604, 4607N = 4607N, 4614
+-----+ +-----	4604, 4611 = 4611, 4614
+-----+ +-----	4604, 4613 = 4613, 4614
+-----+ +-----	4604, 4608 = 4608, 4614
+-----+ +-----	4604, 4605 = 4604, 4615N = 4605, 4614 =
	4614, 4615N
+-----+ +-----	4604, 4609 = 4609, 4614
+-----+ +-----	4604, 4610 = 4610, 4614
+-----+ +-----	4604, 4612 = 4612, 4614
+-----+ +-----	4604, 4617 = 4614, 4617
+-----+ +-----	4601, 4604 = 4601, 4614 = 4604, 4614 =
	4614, 4614
+-----+ +-----	4605, 4606 = 4606, 4615N
+-----+ +-----	4606, 4606 = 4606, 4608
+-----+ +-----	4605, 4607N = 4607N, 4615N
+-----+ +-----	4601, 4607N = 4607N, 4607N
+-----+ +-----	4605, 4611 = 4611, 4615N
+-----+ +-----	4605, 4613 = 4613, 4615N
+-----+ +-----	4605, 4608 = 4608, 4615N
+-----+ +-----	4608, 4611 = 4611, 4611 = 4611, 4613
+-----+ +-----	4608, 4613 = 4613, 4613
+-----+ +-----	4605, 4609 = 4609, 4615N
+-----+ +-----	4605, 4610 = 4610, 4615N
+-----+ +-----	4605, 4612 = 4612, 4615N
+-----+ +-----	4605, 4617 = 4615N, 4617
+-----+ +-----	4601, 4605 = 4601, 4615N = 4605, 4615N =
	4615N, 4615N
+-----+ +-----	4601, 4609 = 4609, 4609
+-----+ +-----	4601, 4610 = 4610, 4610
+-----+ +-----	4601, 4612 = 4612, 4612
+-----+ +-----	4601, 4617 = 4617, 4617

4601=460101-460102

SPECIFICITY TABLE

HLA-B*46 SSP subtyping

Specificities and sizes of the PCR products of the 16 primer mixes used for HLA-B*46 SSP subtyping

Primer Mix	Size of spec. PCR product ¹	Size of control band ²	Amplified HLA-B*46 alleles	Other amplified HLA Class I alleles ³
1 ⁴	130 bp	800 bp	460101-4603, 4605-4618	1557 ^{weakly}
2 ⁴	115 bp	1070 bp	4602, 4616	
3	385 bp	1070 bp	4603, 4618	1542, 1544, 1550, 1569, 1586, 1593, 9521
4 ^{4,6}	130, 245 bp	1070 bp	4604, 4614	1806, 4073, 7301 ^{weakly}
5	235 bp	1070 bp	460101-4604, 4606-4618	0815, 1557 ^{weakly} , 3574, 4073, 5503
6	230 bp	800 bp	4606	0709, 0711, 0835, 0837, 9538, 3566, 4038, 4052, 4059, 4209, 4814, 5315
7 ^{4,5,7}	105, 140 bp	1070 bp	4607N, 4616	1407N, 3940N, 5619N
8	365 bp	1070 bp	4606, 4608, 4611, 4613, 4618	1502, 1503, 1505, 1506, 1509, 1510, 1513, 1516-1518, 1521, 1523, 1525, 1529, 1531, 1536, 1537, 1539, 1540, 1542, 1544, 1548, 1552, 1555, 1561, 1562, 1564, 1567, 1569, 1572, 1574, 1580, 1586, 1588-1591, 1593, 1595, 1598, 9503, 9506-9508, 9512, 9514, 9515, 9519, 9521, 9523, 9524, 9527, 9531-9534, 9536, 9538, 9539, 9551
9 ⁴	115 bp	1070 bp	460101-4602, 4604, 4605, 4607N, 4609, 4610, 4612, 4614-4617	15010101-150104, 150106-150108, 1504, 1507, 1508, 151101-1512, 1514, 1515, 1519, 1524, 1526N-1528, 1530, 1532, 1534, 1535, 1538, 1543, 1545, 1546, 1550, 1553, 1554, 1556-1558, 1560, 1563, 1566, 1568, 1570, 1571, 1573, 1575-1577, 1579N, 1581, 1582, 1585, 1587, 1592, 1594N, 1596, 1597, 9501, 9502, 9504, 9505, 9509-9511N, 9513, 9517, 9518, 9520, 9522,

				9525, 9526, 9528, 9529, 9535, 9537, 9540, 9542-9549N, 1819, 2725, 351401-351402, 3543, 3544, 3562, 3567, 3579, 3586, 3918, 3936, 5161, 5406, 5521, 5603
10^{4,8}	100, 310 bp	800 bp	4605, 4615N	9525, 3554
11	150 bp	1070 bp	4609	3562
12⁵	170 bp	1070 bp	4610	
13⁴	105 bp	1070 bp	4611, 4618	130201-1303, 1308Q, 1309, 1314-1316, 1318, 1319, 1542, 3560, 4415, 4418, 4501, 4503-4508, 490101-4903, 5001, 5002, 5004, 5115, 5401-5403, 5405N, 5407, 5408N, 5410, 5412, 5413, 5416, 5417, 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, 5904
14	215 bp	1070 bp	4612	0755, 1507, 1545, 1568, 9526, 4819
15	315 bp	1070 bp	4611, 4613, 4618	152703, 1542, 1548, 1586
16	195 bp	1070 bp	4617	1514, 1591, 9531, 3545, 3571, 4417, 4443, 4509, 5807

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*46 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*46 SSP subtyping. In addition, well

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number 6 and 10 contains the primer pair giving rise to the longer, 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 one non-HLA-B*46 alleles will be amplified by all primer mixes except for mixes 2 and 12.

⁴Specific PCR fragments shorter than 150 base pairs are less intense and not as sharp as longer specific bands.

⁵Primer mixes 7 and 12 may have a tendency of giving rise to nonspecific amplifications.

⁶Primer mix 4: Specific PCR fragment of 130 bp in the B*4604 allele. Specific PCR fragment of 245 bp in the B*4614 and in the B*1806, 4073 and 7301^{weakly} alleles.

⁷Primer mix 7: Specific PCR fragment of 105 bp in the B*4616 allele. Specific PCR fragment of 140 bp in the B*4607N and in the B*1407N, 3940N and 5619N alleles.

⁸Primer mix 10: Specific PCR fragment of 100 bp in the B*4605 and in the B*9524 and 3554 alleles. Specific PCR fragment of 310 bp in the B*4615N allele.

INTERPRETATION TABLE								
HLA-B*46 SSP subtyping								
Amplification patterns of the B*4601 to 4618 alleles								
	Well⁴							
	1	2	3	4	5	6	7	8
Length of spec.	130	115	385	130	235	230	105	365
PCR product(s)				245			140	
Length of int.	800	1070	1070	1070	1070	800	1070	1070
pos. control¹								
5'-primer(s)²	209	209	2nd 	97	106	419	209	2nd
	5'-ggC ^{3'}	5'-ggC ^{3'}	5'-CAA ^{3'}	5'-TCC ^{3'}	5'-CCA ^{3'}	5'-gTC ^{3'}	5'-ggC ^{3'}	5'-CAA ^{3'}
				209			463	
				5'-ggg ^{3'}			5'-TgA ^{3'}	
3'-primer(s)³	299	272	559	299	299	610	272	538
	5'TCA ^{3'}	5'-TgA ^{3'}	5'-CgT ^{3'}	5'TCA ^{3'}	5'TCA ^{3'}	5'CTC ^{3'}	5'-TgA ^{3'}	5'-CAg ^{3'}
		293					564	
		5'-ggC ^{3'}					5'ACT ^{3'}	
Wells No.	1	2	3	4	5	6	7	8
HLA-B allele								
*460101-460102	1				5			
*4602	1	2			5			
*4603	1		3		5			
*4604				4	5			
*4605	1							
*4606	1				5	6		8
*4607N	1				5		7	
*4608	1				5			8
*4609	1				5			
*4610	1				5			
*4611	1				5			8
*4612	1				5			
*4613	1				5			8
*4614	1			4	5			
*4615N	1				5			
*4616	1	2			5		7	
*4617	1				5			
*4618	1		3		5			8
*0709, 0711, 0835, 0837, 3566, 4038, 4052, 4059, 4209, 4814, 5315						6		
*0755, 4819								
*0815, 3574					5			
Well No.	1	2	3	4	5	6	7	8

INTERPRETATION TABLE

HLA-B*46 SSP subtyping

Amplification patterns of the B*4601 to 4618 alleles

Well ⁴								
9	10	11	12	13	14	15	16	
115	100	150	170	105	215	315	195	Length of spec.
	310							PCR product(s)
1070	800	1070	1070	1070	1070	1070	1070	Length of int.
								pos. control ¹
463	106	419	142	357	363	2 nd I	419	5'-primer(s) ²
5'-TgA ^{3'}	5'-CCg ^{3'}	5'-gTC ^{3'}	5'-TCA ^{3'}	5'-Tgg ^{3'}	5'-AgC ^{3'}	5'-CAA ^{3'}	5'-gTC ^{3'}	
	736							
	5'-gCT ^{3'}							
538	165	527	269	420	538	486	572	3'-primer(s) ³
5'-CCA ^{3'}	5'-Tgg ^{3'}	5'-CCA ^{3'}	5'-ACT ^{3'}	5'-gCT ^{3'}	5'-CCA ^{3'}	5'-gCg ^{3'}	5'-gCg ^{3'}	
	916							
	5'-gAT ^{3'}							
9	10	11	12	13	14	15	16	Wells No.
								HLA-B allele
9								*460101-460102
9								*4602
								*4603
9								*4604
9	10							*4605
								*4606
9								*4607N
								*4608
9		11						*4609
9			12					*4610
				13		15		*4611
9					14			*4612
						15		*4613
9								*4614
9	10							*4615N
9								*4616
9							16	*4617
				13		15		*4618
								*0709, 0711, 0835, 0837, 3566, 4038, 4052, 4059, 4209, 4814, 5315
					14			*0755, 4819
								*0815, 3574
9	10	11	12	13	14	15	16	Well No.

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Length of spec.	130	115	385	130	235	230	105	365
PCR product				245			140	
Well No.	1	2	3	4	5	6	7	8
*130201-1303, 1308Q, 1309, 1314-1316, 1318, 1319, 3560, 4415, 4418, 4501, 4503-4508, 490101-4903, 5001, 5002, 5004, 5115, 5401-5403, 5405N, 5407, 5408N, 5410, 5412, 5413, 5416, 5417, 550101-550203, 5505, 5507, 5509-5512, 5515, 5516, 5518, 5519, 5522, 5524-5526, 5529-5531, 5533, 5534, 5601, 5607, 5608, 5613, 5614, 5616, 5617, 5620, 5623, 5624, 5901, 5904								
*1407N, 3940N							7	
*15010101-150104, 150106-150108, 1504, 1508, 151101-1512, 1515, 1519, 1524, 1526N-152702, 1528, 1530, 1532, 1534, 1535, 1538, 1543, 1546, 1553, 1554, 1556, 1558, 1560, 1563, 1566, 1570, 1571, 1573, 1575-1577, 1579N, 1581, 1582, 1585, 1587, 1592, 1594N, 1596, 1597, 9501, 9502, 9504, 9505, 9509-9511N, 9513, 9517, 9518, 9520, 9522, 9528, 9529, 9535, 9537, 9540, 9542-9549N, 1819, 2725, 351401-351402, 3543, 3544, 3567, 3579, 3586, 3918, 3936, 5161, 5406, 5603								
*1502, 1503, 1505, 1506, 1509, 1510, 1513, 1516-1518, 1521, 1523, 1525, 1529, 1531, 1536, 1537, 1539, 1540, 1552, 1555, 1561, 1562, 1564, 1567, 1572, 1574, 1580, 1588-1590, 1595, 1598, 9503, 9506-9508, 9512, 9514, 9515, 9519, 9523, 9524, 9527, 9532-9534, 9536, 9539, 9551								8
*1507, 1545, 1568, 9526								
*1514								
*152703								
*1542			3					8
*1544, 1569, 1593, 9521			3					8
*1548								8
*1550			3					
*1557	w				w			
*1586			3					8
Well No.	1	2	3	4	5	6	7	8

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115	100	150	170	105	215	315	195	Length of spec.
	310							PCR product
9	10	11	12	13	14	15	16	Well No.
				13				*130201-1303, 1308Q, 1309, 1314-1316, 1318, 1319, 3560, 4415, 4418, 4501, 4503, 4508, 490101-4903, 5001, 5002, 5004, 5115, 5401-5403, 5405N, 5407, 5408N, 5410, 5412, 5413, 5416, 5417, 550101-550203, 5505, 5507, 5509-5512, 5515, 5516, 5518, 5519, 5522, 5524-5526, 5529-5531, 5533, 5534, 5601, 5607, 5608, 5613, 5614, 5616, 5617, 5620, 5623, 5624, 5901, 5904
								*1407N, 3940N
9								*15010101-150104, 150106-150108, 1504, 1508, 151101-1512, 1515, 1519, 1524, 1526N-152702, 1528, 1530, 1532, 1534, 1535, 1538, 1543, 1546, 1553, 1554, 1556, 1558, 1560, 1563, 1566, 1570, 1571, 1573, 1575-1577, 1579N, 1581, 1582, 1585, 1587, 1592, 1594N, 1596, 1597, 9501, 9502, 9504, 9505, 9509-9511N, 9513, 9517, 9518, 9520, 9522, 9528, 9529, 9535, 9537, 9540, 9542-9549N, 1819, 2725, 351401-351402, 3543, 3544, 3567, 3579, 3586, 3918, 3936, 5161, 5406, 5603
								*1502, 1503, 1505, 1506, 1509, 1510, 1513, 1516-1518, 1521, 1523, 1525, 1529, 1531, 1536, 1537, 1539, 1540, 1552, 1555, 1561, 1562, 1564, 1567, 1572, 1574, 1580, 1588-1590, 1595, 1598, 9503, 9506-9508, 9512, 9514, 9515, 9519, 9523, 9524, 9527, 9532-9534, 9536, 9539, 9551
9					14			*1507, 1545, 1568, 9526
9							16	*1514
9						15		*152703
				13		15		*1542
								*1544, 1569, 1593, 9521
						15		*1548
9								*1550
9								*1557
						15		*1586
9	10	11	12	13	14	15	16	Well No.

Length of spec.	130	115	385	130	235	230	105	365
PCR product				245			140	
Well No.	1	2	3	4	5	6	7	8
*1591, 9531								8
*9525								
*9538						6		8
*1806				4				
*3545, 3571, 4417, 4443, 4509, 5807								
*3554								
*3562								
*4073				4	5			
*5503					5			
*5521								
*5619N							7	
*7301				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*46 SSP subtyping.

In addition, wells number 6 and 10 contain the primer pair giving rise to the shorter, 800 bp, internal positive control in order to allow kit identification.

²The nucleotide position, in the 2nd, 3rd or 4th 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, 3rd or 4th exon, matching the specificity-determining 3'-end of the primer is given in the anti-sense direction. Nucleotide numbering as on the www.ebi.ac.uk/imgt/hla web site. The sequence of the 3 terminal nucleotides of the primer is given.

115	100	150	170	105	215	315	195	Length of spec.
	310							PCR product
9	10	11	12	13	14	15	16	Well No.
							16	*1591, 9531
9	10							*9525
								*9538
								*1806
							16	*3545, 3571, 4417, 4443, 4509, 5807
	10							*3554
9		11						*3562
								*4073
				13				*5503
9				13				*5521
				13				*5619N
								*7301
9	10	11	12	13	14	15	16	Well No.

⁴Primer mix 4: Specific PCR fragment of 130 bp in the B*4604 allele. Specific PCR fragment of 245 bp in the B*4614 and in the B*1806, 4073 and 7301^{weakly} alleles.

⁷Primer mix 7: Specific PCR fragment of 105 bp in the B*4616 allele. Specific PCR fragment of 140 bp in the B*4607N and in the B*1407N, 3940N and 5619N alleles.

⁸Primer mix 10: Specific PCR fragment of 100 bp in the B*4605 and in the B*9524 and 3554 alleles. Specific PCR fragment of 310 bp in the B*4615N allele.

‘w’, might be weakly amplified.

CELL LINE VALIDATION SHEET																				
HLA-B*46 SSP primer set																				
				Well																
				1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	
				Prod. No.:	200623201	200956602	200956603	200956604	200623205	200956606	200956607	200956608	200623209	200956610	200737911	200737912	200737913	200737914	200956615	200956616
IHC cell line		B*																		
1	9001	SA	*0702	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2	9280	LK707	*5201 *7301	-	-	-	w	-	-	-	-	-	-	-	-	-	-	-	-	-
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	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-B*46 SSP

Product number: 101.544-06 – including *Taq* polymerase
Lot number: 60F
Expiry date: 2011-February-01
Number of tests: 6
Number of wells per test: 16

Well specifications:

Well No.	Production No.	Well No.	Production No.
1	2006-232-01	9	2006-232-09
2	2009-566-02	10	2009-566-10
3	2009-566-03	11	2007-379-11
4	2009-566-04	12	2007-379-12
5	2006-232-05	13	2007-379-13
6	2009-566-06	14	2007-379-14
7	2009-566-07	15	2009-566-15
8	2009-566-08	16	2009-566-16

The specificity of each primer solution of the HLA-B*46 primer set has been tested against 48 well characterized IHWC cell line DNAs.

No DNAs carrying the alleles to be amplified by primer solutions 2, 3, 4, 6, 7, 10, 11, 12 and 15 were available. In primer solutions 3, 4, 6, 10, 11, 12 and 15 it was possible to test both the 5'-primer and the 3'-primer. It was only possible to test the 5'-primer in primer solutions 2 and 7, the 3'-primer was not possible to test. In primer solutions 4 and 10, one of the 5'-primers was not possible to test.

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

Date of approval: 2009-December-15

Approved by:

Quality Control, Supervisor

Lot No.: **60F**

Lot-specific information

www.olerup.com

Declaration of Conformity

Product name: *Olerup* SSP® HLA-B*46
Product number: 101.544-06
Lot number: 60F

Intended use: HLA-B*46 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-December-15

Olle Olerup
Managing Director

Lot No.: **60F**

Lot-specific information

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