

Olerup SSP[®] HLA-B*52

Product number:	101.562-06 – including <i>Taq</i> polymerase
Lot number:	90E
Expiry date:	2010-June-01
Number of tests:	6
Number of wells per test:	15
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. 90E.

CHANGES COMPARED TO THE PREVIOUS *OLERUP SSP[®]* HLA-B*52 LOT.

The HLA-B*52 specificity and interpretation tables have been updated for the HLA-B alleles described since the previous *Olerup SSP[®]* HLA-B*52 lot was made (Lot No. y31).

One well has been added to the HLA-B*52 kit,
well **15**.

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

Well	5'-primer	3'-primer	rationale
4	Exchanged	Exchanged	Exchanged primer pair for less primer dimer formation tendency.
15	New	New	New primer pair for the B*5212 allele.

PRODUCT DESCRIPTION

HLA-B*52 SSP typing

CONTENT

The primer set contains 5'- and 3'-primers for identifying the B*5201 to B*5212 alleles.

PLATE LAYOUT

Each HLA-B*52 test consists of 15 PCR reactions in a 16 well cut PCR plate. Well 16 is empty.

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

The 16 well PCR plate is marked with 'HLA-B*52'.

Well No. 1 is marked with the Lot No. '90E'.

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*52 SSP subtypings will be influenced by most other HLA-B alleles.

UNIQUELY IDENTIFIED ALLELES

All the HLA-B*52, i.e. **B*5201 to B*5212**, recognized by the HLA Nomenclature Committee in April 2008¹ will be amplified by the primers in the HLA-B*52 SSP kit. The HLA-B*52 subtyping kit cannot distinguish the B*520101 to B*520104 alleles.

¹HLA-B alleles listed on the IMGT/HLA web page 2008-April-08, release 2.21.0, www.ebi.ac.uk/imgt/hla.

RESOLUTION IN HOMO- AND HETEROZYGOTES

The 12 HLA-B*52 alleles can be combined in 78 homozygous and heterozygous combinations. Fourteen of these genotypes do not give rise to unique amplification patterns.

+++-----	----+---	5201,5209 = 5209,5209
+-------+	----+---	5201,5205 = 5205,5205
+-------+	----+---	5201,5204 = 5204,5204
+-------	-+-+---	5201,5208 = 5208,5208
+-------	----+--+	5201,5212 = 5212,5212
---+---+-	----+---	5203,5203 = 5203,5210 = 5203,5211 = 5210,5211

SPECIFICITY TABLE

HLA-B*52 SSP subtyping

Specificities and sizes of the PCR products of the 15 primer mixes used for HLA-B*52 SSP subtyping

Primer Mix	Size of spec. PCR product ¹	Size of control band ²	Amplified HLA-B*52 alleles	Other amplified HLA Class I alleles ³
1 ⁴	95 bp	800 bp	520101-5202, 5204-5209, 5212	1401-1408, 1537, 1538, 1815, 1819, 3521, 4028, 4051, 510101-510109, 5103, 5104, 5106, 5107, 5111N-5114, 5116-5118, 5121, 5122, 512401-512402, 5126-5130, 5132, 5133, 5135, 5137-5139, 5141N, 5143, 5145, 5146, 5148-5152, 5155, 5306, 560501-5606, 5621, 5808, 7801-7803, 7805
2 ⁵	235 bp	1070 bp	5209	1587, 5305, 5316
3 ⁴	95 bp	1070 bp	520101-520104, 5203-5212	1812, 3510, 3513, 3516, 3528, 3569, 3580, 370101-3705, 3707, 3709-3713, 4903
4 ^{5,6}	140 bp	1070 bp	5202	1513, 1516-151702, 1524, 1567, 1587, 1595, 570101-5711, 5713-5715
5	190 bp	1070 bp	5203, 5211	070503, 150102, 1509, 350402, 400106, 4026, 510201-510203, 5105, 5123, 5134, 5136, 5140, 5154, 7804
6 ⁴	135 bp	1070 bp	5203, 5210	350402, 400106, 5105, 510901-510902, 5119, 5131, 5140, 5154, 7804
7	225 bp	800 bp	5205	
8	320 bp	1070 bp	5204	
9 ⁴	100 bp	800 bp	520601	
10 ⁴	245 bp	1070 bp	5208	130201-130204, 1308Q, 1309, 1314-1316, 1318, 1319, 2714, 40060101-400602, 4044, 4053, 4070, 4075, 4083, 4086, 5110,

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Lot-specific information

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				5116, 5131, 5134, 5509, 5522, 5524, 7301
11⁴	85 bp	1070 bp	520601- 520602	0738, 0802, 0803, 2723, 3806, 3807, 4013, 4406, 510101-5106, 5108-5121, 5123-512402, 5126-5146, 5148-5155, 530101-5308, 5310-5316, 5901, 5902
12⁴	85 bp	1070 bp	520101- 5205, 5207- 5212	1301-1304, 1306, 1308Q, 1310-1318, 1320, 1321, 1524, 1536, 1543, 1587, 2729, 370101-3704, 3706, 3707, 3709, 3710, 3712, 3713, 3803, 4019, 4047, 44020101-4405, 4407, 4408, 4410, 4411, 4413-4445, 4447-4460, 47010101- 47010102, 4703-4705, 4818, 4901-4905
13^{5,7}	165 bp	800 bp	520101- 520602, 5208-5212	1520, 350101-3530, 3532- 3542, 3544, 3545, 3547- 3556, 3558, 3559, 3561- 3572, 3574-3578, 3580- 3586, 3588, 4802, 510101- 512402, 5126-5146, 5148- 5155, 530101-5316, 5621, 580101-5802, 5804-5810N, 5812-5817N, 7801-7805, 8103
14^{5,6,7}	165 bp	1070 bp	5207	070201-0757, 0759-0764, 080101-0836, 1301-1304, 1306-1321, 1401-1408, 15010101-150104, 150106- 1519, 1521, 1523-1540, 1542-1558, 1560-1599, 9501, 9503-9529, 9531- 9546, 180101-1815, 1817N- 1829, 2701-270402, 270502-2721, 2723-2742, 3531, 3543, 3546, 3557, 3560, 3579, 3587, 370101- 3713, 380101-3817, 39010101-39010102L, 390103-3920, 3922-3943, 400101-4016, 4018-4040, 4042-4088, 4101-4108, 4201, 4202, 4204-4209, 44020101-4460, 4501-

				4508, 460101-4614, 47010101-4705, 480101- 480102, 480301-4819, 4901-4905, 5001, 5002, 5004, 5401-5413, 550101- 5505, 5507-5530, 5601- 5620, 5622, 5623, 570101- 5716, 5811, 5901, 5902, 670101-6702, 8101, 8102, 8104N, 8201, 8202, 8301
15⁴	95 bp	1070 bp	5212	1304, 1504, 1516, 1567, 1595, 3537, 4044, 4420, 4447, 4904, 4905, 5137, 5523, 5527

¹ Alleles 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*52 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.

² The 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*52 SSP subtyping.

In addition, wells number 7, 9 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.

³ Due to the sharing of sequence motifs between HLA-B alleles many non-HLA-B*52 alleles will be amplified by primer mixes 1 to 6 and 10 to 15

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

⁵ Primer mixes 2, 4, 13 and 14 may give rise to nonspecific amplifications.

⁶ Primer mixes 13 and 14: For many HLA-B alleles fourth exon nucleotide sequences are not available. We assume that unknown sequences in the fourth exon are conserved within allelic groups.

⁷ Primer mix 14 may give rise to a primer oligomer artefact.

INTERPRETATION TABLE

HLA-B*52 SSP subtyping

Amplification patterns of the B*5201 to B*5212 alleles

	Well							
	1	2	3	4	5	6	7	8
Length of spec.	95	235	95	140	190	135	225	320
PCR product								
Length of int.	800	1070	1070	1070	1070	1070	800	1070
pos. control ¹								
5'-primer ²	527	106	206	209	435	435	134	49
	<small>5'-TgA^{3'}</small>	<small>5'-CCA^{3'}</small>	<small>5'-gAC^{3'}</small>	<small>5'-ggC^{3'}</small>	<small>5'-AAA^{3'}</small>	<small>5'-AAA^{3'}</small>	<small>5'-CCC^{3'}</small>	<small>5'-CAG^{3'}</small>
3'-primer ³	583	302	259	309	583	527	317	200
	<small>5'-gTg^{3'}</small>	<small>5'-ggC^{3'}</small>	<small>5'-CTC^{3'}</small>	<small>5'-ATC^{3'}</small>	<small>5'-gTA^{3'}</small>	<small>5'-CCA^{3'}</small>	<small>5'-ggA^{3'}</small>	<small>5'-TCT^{3'}</small>
Well No.	1	2	3	4	5	6	7	8
HLA-B allele								
*520101-520104	1		3					
*5202	1			4				
*5203			3		5	6		
*5204	1		3					8
*5205	1		3				7	
*520601	1		3					
*520602	1		3					
*5207	1		3					
*5208	1		3					
*5209	1	2	3					
*5210			3			6		
*5211			3		5			
*5212	1		3					
Well No.	1	2	3	4	5	6	7	8

INTERPRETATION TABLE							
HLA-B*52 SSP subtyping							
Amplification patterns of the B*5201 to B*5212 alleles							
Well							
9	10	11	12	13	14	15	
100	245	85	85	165	165	95	Length of spec.
							PCR product
800	1070	1070	1070	800	1070	1070	Length of int.
							pos. control ¹
213	357	272	272	652	652	357	5'-primer ²
5'-CCg ³	5'-Tgg ³	5'-CTT ³	5'-CTC ³	5'-CCg ³	5'-CCA ³	5'-Tgg ³	
272	559	317	317	774	774	412	3'-primer ³
5'-TgA ³	5'-CTC ³	5'-ggA ³	5'-ggA ³	5'-ggT ³	5'-ggT ³	5'-gTC ³	
9	10	11	12	13	14	15	Well No.
							HLA-B allele
			12	13			*520101-520104
			12	13			*5202
			12	13			*5203
			12	13			*5204
			12	13			*5205
9		11		13			*520601
		11		13			*520602
			12	14			*5207
	10		12	13			*5208
			12	13			*5209
			12	13			*5210
			12	13			*5211
			12	13		15	*5212
9	10	11	12	13	14	15	Well No.

Length of spec.	95	235	95	140	190	135	225	320
PCR product								
Well No.	1	2	3	4	5	6	7	8
*070201-070502, 0706-0737, 0739-0757, 0759-0764, 080101-080105, 0804-0836, 1307N, 15010101-15010102N, 150103-150104, 150106-1503, 1505-1508, 1510-1512, 1514, 1515, 1518, 1519, 1521, 1523, 1525-1535, 1539, 1540, 1542, 1544-1558, 1560-1566, 1568-1586, 1588-1594N, 1596-1599, 9501, 9503-9529, 9531-9546, 180101-1811, 1813, 1814, 1817N, 1818, 1820-1829, 2701-270402, 270502-2713, 2715-2721, 2724-2728, 2730-2742, 3531, 3543, 3546, 3557, 3560, 3579, 3587, 3708, 380101-380202, 3804, 3805, 3808-3817, 39010101-39010102L, 390103-3920, 3922-3943, 400101-400105, 400201-4005, 4007-4012, 401401-4016, 4018, 4020-4025, 4027, 4029-4040, 4042, 4043, 4045, 4046, 4048-4050, 4052, 4054-4069, 4071-4074, 4076-4082, 4084, 4085, 4087, 4088, 4101-4108, 4201, 4202, 4204-4209, 4409, 4412, 4446, 4501-4508, 460101-4614, 4702, 480101-480102, 480301-4817, 4819, 5001, 5002, 5004, 5401-5413, 550101-5505, 5507, 5508, 5510-5521, 5525, 5526, 5528-5530, 5601-5604, 5607-5620, 5622, 5623, 5712, 5716, 5811, 670101-6702, 8101, 8102, 8104N, 8201, 8202, 8301								
*070503, 150102, 1509, 4026					5			
*0738, 0802, 0803, 2723, 3806, 3807, 4013, 4406, 5901, 5902								
*1301, 1303, 1306, 1310-1313, 1317, 1320, 1321, 1536, 1543, 2729, 3706, 3803, 4019, 4047, 44020101-4405, 4407, 4408, 4410, 4411, 4413-4419N, 4421-4445, 4448-4460, 47010101-47010102, 4703-4705, 4818, 4901, 4902								
*130201-130204, 1308Q, 1314-1316, 1318								
*1304, 4420, 4447, 4904, 4905								
*1309, 1319, 2714, 40060101-400602, 4053, 4070, 4075, 4083, 4086, 5509, 5522, 5524								
Well No.	1	2	3	4	5	6	7	8

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Lot-specific information

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100	245	85	85	165	165	95	Length of spec. PCR product
9	10	11	12	13	14	15	Well No.
							*070201-070502, 0706-0737, 0739-0757, 0759-0764, 080101-080105, 0804-0836, 1307N, 15010101-15010102N, 150103-150104, 150106-1503, 1505-1508, 1510-1512, 1514, 1515, 1518, 1519, 1521, 1523, 1525-1535, 1539, 1540, 1542, 1544-1558, 1560-1566, 1568-1586, 1588-1594N, 1596-1599, 9501, 9503-9529, 9531-9546, 180101-1811, 1813, 1814, 1817N, 1818, 1820-1829, 2701-270402, 270502-2713, 2715-2721, 2724-2728, 2730-2742, 3531, 3543, 3546, 3557, 3560, 3579, 3587, 3708, 380101-380202, 3804, 3805, 3808-3817, 39010101-39010102L, 390103-3920, 3922-3943, 400101-400105, 400201-4005, 4007-4012, 401401-4016, 4018, 4020-4025, 4027, 4029-4040, 4042, 4043, 4045, 4046, 4048-4050, 4052, 4054-4069, 4071-4074, 4076-4082, 4084, 4085, 4087, 4088, 4101-4108, 4201, 4202, 4204-4209, 4409, 4412, 4446, 4501-4508, 460101-4614, 4702, 480101-480102, 480301-4817, 4819, 5001, 5002, 5004, 5401-5413, 550101-5505, 5507, 5508, 5510-5521, 5525, 5526, 5528-5530, 5601-5604, 5607-5620, 5622, 5623, 5712, 5716, 5811, 670101-6702, 8101, 8102, 8104N, 8201, 8202, 8301
					14		*070503, 150102, 1509, 4026
		11			14		*0738, 0802, 0803, 2723, 3806, 3807, 4013, 4406, 5901, 5902
			12		14		*1301, 1303, 1306, 1310-1313, 1317, 1320, 1321, 1536, 1543, 2729, 3706, 3803, 4019, 4047, 44020101-4405, 4407, 4408, 4410, 4411, 4413-4419N, 4421-4445, 4448-4460, 47010101-47010102, 4703-4705, 4818, 4901, 4902
	10		12		14		*130201-130204, 1308Q, 1314-1316, 1318
			12		14	15	*1304, 4420, 4447, 4904, 4905
	10				14		*1309, 1319, 2714, 40060101-400602, 4053, 4070, 4075, 4083, 4086, 5509, 5522, 5524
9	10	11	12	13	14	15	Well No.

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Lot-specific information

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Length of spec.	95	235	95	140	190	135	225	320
PCR product								
Well No.	1	2	3	4	5	6	7	8
*1401-1408, 1537, 1538, 1815, 1819, 4028, 4051, 560501-5606	1							
*1504, 5523, 5527								
*1513, 15170101-151702, 570101-5711, 5713-5715				4				
*1516, 1567, 1595				4				
*1520, 350101-350401, 3505-350902, 3511, 3512, 351401-3515, 3517-352002, 3522-3527, 3529, 3530, 3532-3536, 3538- 3542, 3544, 3545, 3547-3556, 3558, 3559, 3561-356802, 3570-3572, 3574-3578, 3581-3586, 3588, 4802, 5309, 580101- 5802, 5804-5807, 5809, 5810N, 5812- 5817N, 8103								
*1524				4				
*1587		2		4				
*1812, 3705, 3711			3					
*350402, 7804					5	6		
*3510, 3513, 3516, 3528, 3569, 3580			3					
*3521, 5107, 5122, 5621, 5808, 7801- 7803, 7805	1							
*3537								
*370101-3704, 3707, 3709, 3710, 3712, 3713, 4903			3					
*400106					5	6		
*4044								
*510101-510109, 5103, 5104, 5106, 5111N 5114, 5117, 5118, 5121, 512401-512402, 5126-5130, 5132, 5133, 5135, 5138, 5139, 5141N, 5143, 5145, 5146, 5148-5152, 5155, 5306	1							
*510201-510203, 5123, 5136					5			
*5105, 5140, 5154					5	6		
*5108, 5115, 5120, 5142, 5144N, 5153, 530101-5304, 5307, 5308, 5310-5315								
*510901-510902, 5119						6		
*5110								
*5116	1							
Well No.	1	2	3	4	5	6	7	8

Lot No.: **90E**

Lot-specific information

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100	245	85	85	165	165	95	Length of spec. PCR product Well No.
9	10	11	12	13	14	15	
					14		*1401-1408, 1537, 1538, 1815, 1819, 4028, 4051, 560501-5606
					14	15	*1504, 5523, 5527
					14		*1513, 15170101-151702, 570101-5711, 5713-5715
					14	15	*1516, 1567, 1595
				13			*1520, 350101-350401, 3505-350902, 3511, 3512, 351401-3515, 3517-352002, 3522-3527, 3529, 3530, 3532-3536, 3538- 3542, 3544, 3545, 3547-3556, 3558, 3559, 3561-356802, 3570-3572, 3574-3578, 3581-3586, 3588, 4802, 5309, 580101- 5802, 5804-5807, 5809, 5810N, 5812- 5817N, 8103
			12		14		*1524
			12		14		*1587
					14		*1812, 3705, 3711
				13			*350402, 7804
				13			*3510, 3513, 3516, 3528, 3569, 3580
				13			*3521, 5107, 5122, 5621, 5808, 7801- 7803, 7805
				13		15	*3537
			12		14		*370101-3704, 3707, 3709, 3710, 3712, 3713, 4903
					14		*400106
	10				14	15	*4044
		11		13			*510101-510109, 5103, 5104, 5106, 5111N, 5114, 5117, 5118, 5121, 512401-512402, 5126-5130, 5132, 5133, 5135, 5138, 5139, 5141N, 5143, 5145, 5146, 5148-5152, 5155, 5306
		11		13			*510201-510203, 5123, 5136
		11		13			*5105, 5140, 5154
		11		13			*5108, 5115, 5120, 5142, 5144N, 5153, 530101-5304, 5307, 5308, 5310-5315
		11		13			*510901-510902, 5119
	10	11		13			*5110
	10	11		13			*5116
9	10	11	12	13	14	15	Well No.

Length of spec.	95	235	95	140	190	135	225	320
PCR product								
Well No.	1	2	3	4	5	6	7	8
*5131						6		
*5134					5			
*5137	1							
*5305, 5316	2							
*7301								
HLA-B allele								
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*52 SSP subtyping. In addition, wells number 7, 9 and 13 contain the primer pair giving rise to the shorter, 800 bp, internal positive control band in order to allow kit identification.

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Lot-specific information

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100	245	85	85	165	165	95	Length of spec. PCR product
9	10	11	12	13	14	15	Well No.
	10	11		13			*5131
	10	11		13			*5134
		11		13		15	*5137
		11		13			*5305, 5316
	10						*7301
							HLA-B allele
9	10	11	12	13	14	15	Well No.

²The nucleotide position, in the 1st, 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.

CELL LINE VALIDATION SHEET																				
HLA-B*52 SSP primer set																				
				Prod. No.:	Well															
					1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
					200737101	200737102	200737103	200849304	200737105	200737106	200737107	200737108	200737109	200737110	200737111	200737112	200737113	200737114	200849315	
	IHC cell line		B*																	
1	9001 SA		*0702		-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	-
2	9280 LK707		*5201	*7301	+	-	+	-	-	-	-	-	-	+	-	+	+	+	-	-
3	9011 E4181324		*52011		+	-	+	-	-	-	-	-	-	-	-	+	+	-	-	-
4	927 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		*44031		-	-	-	-	-	-	-	-	-	-	-	-	+	-	+	-
12	9052 DBB		*5701		-	-	-	+	-	-	-	-	-	-	-	-	-	-	+	-
13	9067 BTB		*27052		-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	-
14	9071 OLGA		*1501	*1520	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	-
15	9075 DKB		*4001		-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	-
16	9037 SWEIG007		*4002		-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	-
17	9008 WILJON		*1801		-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	-
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		*44031		-	-	-	-	-	-	-	-	-	-	-	+	-	+	-	-
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 WHONP		*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	*44	-	-	-	-	-	-	-	-	-	-	-	+	+	+	-	-

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-B*52 SSP

Product number: 101.562-06 – including *Taq* polymerase
Lot number: 90E
Expiry date: 2010-June-01
Number of tests: 6
Number of wells per test: 15

Well specifications:

Well No.	Production No.	Well No.	Production No.
1	2007-371-01	9	2007-371-09
2	2007-371-02	10	2007-371-10
3	2007-371-03	11	2007-371-11
4	2008-493-04	12	2007-371-12
5	2007-371-05	13	2007-371-13
6	2007-371-06	14	2007-371-14
7	2007-371-07	15	2008-493-15
8	2007-371-08		

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

No DNAs carrying the alleles to be amplified by primer solutions 2, 6 to 9 were available. The specificities of the primers in primer solutions 2 and 6 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer. In primer mixes 7 and 9 it was only possible to test the 3'-primers, the 5'-primers were not possible to test. In primer mix 8 it was only possible to test the 5'-primer, the 3'-primer 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

Lot No.: **90E**

Lot-specific information

www.olerup.com

Declaration of Conformity

Product name: *Olerup* SSP® HLA-B*52
Product number: 101.562-06
Lot number: 90E

Intended use: HLA-B*52 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.: **90E**

Lot-specific information

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