

## **Olerup SSP<sup>®</sup> HLA-B\*57**

<b>Product number:</b>	<b>101.567-12 – including <i>Taq</i> polymerase 101.567-12u - without <i>Taq</i> polymerase</b>
<b>Lot number:</b>	<b>31E</b>
<b>Expiry date:</b>	<b>2010-February-01</b>
<b>Number of tests:</b>	<b>12</b>
<b>Number of wells per test:</b>	<b>16</b>
<b>Storage - pre-aliquoted primers:</b>	<b>dark at -20°C</b>
<b>- PCR Master Mix:</b>	<b>-20°C</b>

**This Product Description is only valid for Lot No. 31E.**

### **CHANGES COMPARED TO THE PREVIOUS *OLERUP SSP*<sup>®</sup> 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*<sup>®</sup> HLA-B\*57 lot was made (**Lot No. Y36**).

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

<b>Well</b>	<b>5'-primer</b>	<b>3'-primer</b>	<b>rationale</b>
6	Added	Added	Primer pair moved from vial 7 to vial 6.
7	New	New	New primer pair for the B*5715 allele.
8	Added	Added	Primer pair added for the B*5716 allele.
11	-	Removed	Primer removed for increased resolution.

## PRODUCT DESCRIPTION

### HLA-B\*57 SSP subtyping

#### CONTENT

The primer set contains 5'- and 3'-primers for identifying the B\*5701 to B\*5716 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 'B\*57'.

Well No. 1 is marked with the Lot No. '31E'.

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 only be influenced by the B\*07, two B\*08, many B\*13, the B\*14, most B\*15, four 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\*5716**, recognized by the HLA Nomenclature Committee in January 2008<sup>1</sup> 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.

<sup>1</sup>HLA-B alleles listed on the IMGT/HLA web page 2008-January-11, release 2.20.0, [www.ebi.ac.uk/imgt/hla](http://www.ebi.ac.uk/imgt/hla).

### RESOLUTION IN HOMO- AND HETEROZYGOTES

The 16 HLA-B\*57 alleles can be combined in 136 homozygous and heterozygous combinations. Twenty-nine of these genotypes do not give rise to unique amplification patterns.

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

## 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 <sup>1</sup>	Size of control band <sup>2</sup>	Amplified HLA-B*57 alleles	Other amplified HLA Class I alleles <sup>3</sup>
<b>1</b>	150 bp	<b>800 bp</b>	570101-5710, 5712, 5714-5716	1301, 1306, 1307N, 1312, 1313, 1317, 1320, 1502, 1513, 1520, 1521, 1525, 1536, 1544, 1562, 1577, 1580, 1585, 1588, 1589, 9506, 9512, 9521, 9539, 1822, 2719, 2730, 350101-350402, 3506-350803, 3510-3517, 3519-3521, 3523-3530, 3533-3536, 3538-3542, 3545-3550, 3552-3557, 3559, 3561-3563, 3565Q, 3569-3571, 3574, 3576-3578, 3580-3585, 370101-370104, 3703N-3706, 3708, 3710, 3711, 3713, 3942, 4028, 44020101-4414, 4416, 4417, 4419N, 4421-4430, 4432-4440, 4442-4446, 4448-4452N, 4455-4459, 4802, 5104, 5142, 5146, 530101-5306, 5308-5313, 5514, 5609, 5611, 5612, 5801, 5804, 5805, 5809-5815, 8301
<b>2<sup>4</sup></b>	100 bp	1070 bp	570101-570103, 5706, 5708, 5710, 5713-5716	5514, 5814
<b>3</b>	220 bp	1070 bp	570101-570103, 570301-570302, 5706-5708, 5710, 5714-5716	4030, 4034, 5514, 5814
<b>4<sup>4,5</sup></b>	100 bp	<b>800 bp</b>	5702-570302,	1313, 1321, 350201-350202,

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			5705, 5707, 5709, 5712	350401-350402, 3506 <sup>weakly</sup> , 350901-350902, 3512, 3518, 3559 <sup>weakly</sup> , 3581, 3583, 370101-370104 <sup>weakly</sup> , 3703N- 3706 <sup>weakly</sup> , 3708 <sup>weakly</sup> , 3710 <sup>weakly</sup> , 3711 <sup>weakly</sup> , 3712, 3713 <sup>weakly</sup> , 3942 <sup>weakly</sup> , 4004, 4028, 4030, 4034, 4064, 4068, 4817 <sup>weakly</sup> , 5104, 5146, 5612, <b>Cw*0510<sup>weakly</sup></b>
<b>5</b>	220 bp	1070 bp	5702, 5704, 5712, 5713	
<b>6<sup>4,6</sup></b>	95, 180 bp	1070 bp	5704, 5706	
<b>7<sup>4,5</sup></b>	105 bp	1070 bp	5715	
<b>8<sup>4,7</sup></b>	90, 250 bp	1070 bp	5707, 5716	
<b>9</b>	170 bp	1070 bp	5709, 5713	070201-0724, 0726-0741, 0743-0747, 0749N, 0750, 0752-0762, 0806, 0820, 1316, 1320, 1401-1407N, 15010101-1504, 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, 9537-9539, 1815, 1819, 1821, 270401-270402, 2706, 2710, 2715, 2718, 2720, 2721, 2724, 2725, 3511, 351401-351402, 3521, 3543, 3544, 3558, 3567, 3579, 3707, 3713, 3810, 3918, 3935, 3936, 4005, 4015, 4016, 4023, 4026, 4028, 4032, 4051, 460101- 4605, 4607N, 4608, 4610, 4612, 4805, 4808, 4815, 4901-4905, 5001, 5002, 5004, 510101-5104, 5106, 5107, 5111N-5114, 5116- 5118, 5121-5124, 5126-5130, 5132-5139, 5141N, 5143,

				5145, 5146, 5148-5152, 520101-5202, 5204-5209, 5211, 5306, 5308, 5406, 550101-550104, 5503, 5505, 5509, 5511, 5514, 5515, 5517, 5521, 5524, 5525, 5528, 5529, 5603, 560501- 5606, 5621, 5806, 5808, 7801-7803, 7805
<b>10</b>	210 bp	1070 bp	5708	
<b>11<sup>8</sup></b>	165, 215 bp	<b>800 bp</b>	5709, 5714	5514, 5814
<b>12<sup>4</sup></b>	90 bp	1070 bp	5702-570302, 5707, 5709, 5712	4030, 4034
<b>13<sup>4</sup></b>	90 bp	1070 bp	570101-5716	
<b>14</b>	195 bp	1070 bp	5710	
<b>15</b>	145 bp	1070 bp	5711	1401-1404, 1407N, 5802, 5806, 5807
<b>16<sup>4</sup></b>	85 bp	1070 bp	5712	

<sup>1</sup>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\*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.

<sup>2</sup>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\*57 subtyping.

In addition, wells number 4 and 11 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.

<sup>3</sup>Due 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.

<sup>4</sup>Short specific PCR fragments are less intense and not as sharp as longer specific bands.

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

<sup>6</sup>Primer mix 6: Specific PCR fragment of 95 bp in the B\*5704 allele. Specific PCR fragment of 180 bp in the B\*5706 allele.

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<sup>7</sup>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.

<sup>8</sup>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.

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



INTERPRETATION TABLE								
HLA-B*57 SSP subtyping								
Amplification patterns of the B*5701 to 5716 alleles								
Well <sup>4</sup>								
9	10	11	12	13	14	15	16	
170	210	165	90	90	195	145	85	Length of spec.
		215						PCR product
1070	1070	<b>800</b>	1070	1070	1070	1070	1070	Length of int.
								pos. control <sup>1</sup>
527	209	362	362	209	103	361	256	5'-primer(s) <sup>2</sup>
5'-TgA <sup>3'</sup>	5'-ggC <sup>3'</sup>	5'-ggT <sup>3'</sup>	5'-ggT <sup>3'</sup>	5'-ggC <sup>3'</sup>	5'-CCT <sup>3'</sup>	5'-AgT <sup>3'</sup>	Acg	
3 <sup>rd</sup> I	2 <sup>nd</sup> I	486	412	256	256	463	302	3'-primer(s) <sup>3</sup>
5'-TAT <sup>3'</sup>	5'-TCg <sup>3'</sup>	5'-gCg <sup>3'</sup>	5'-gTT <sup>3'</sup>	5'-CCC <sup>3'</sup>	5'-CCC <sup>3'</sup>	5'-gCT <sup>3'</sup>	5'-ggC <sup>3'</sup>	
		538						
		5'-gTC <sup>3'</sup>						
9	10	11	12	13	14	15	16	Well No.
								HLA-B allele
				13				*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
				13				*5716
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, 0726-0741, 0743-0747, 0749N, 0750, 0752-0762, 0806, 0820, 1316, 1405-140602, 15010101-150104, 150106-150107, 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, 1815, 1819, 1821, 270401-270402, 2706, 2710, 2715, 2718, 2720, 2721, 2724, 2725, 3543, 3544, 3558, 3567, 3579, 3707, 3810, 3918, 3935, 3936, 4005, 4015, 4016, 4023, 4026, 4032, 4051, 460101-4605, 4607N, 4608, 4610, 4612, 4805, 4808, 4815, 4901-4905, 5001, 5002, 5004, 510101-5103, 5106, 5107, 5111N-5114, 5116-5118, 5121-5124, 5126-5130, 5132-5139, 5141N, 5143, 5145, 5148-5152, 520101-5202, 5204-5209, 5211, 5406, 550101-550104, 5503, 5505, 5509, 5511, 5515, 5517, 5521, 5524, 5525, 5528, 5529, 5603, 560501-5606, 5621, 5808, 7801-7803, 7805								
*1301, 1306, 1307N, 1312, 1317, 1520, 1588, 1822, 2719, 2730, 350101-350106, 3503, 3507-350803, 3510, 3513, 3515-3517, 3519-352002, 3523-3530, 3533-3536, 3538-3542, 3545-3550, 3552-3557, 3561-3563, 3565Q, 3569-3571, 3574, 3576-3578, 3580, 3582, 3584, 3585, 44020101-4414, 4416, 4417, 4419N, 4421-4430, 4432-4440, 4442-4446, 4448-4452N, 4455-4459, 4802, 5142, 530101-5305, 5309-5313, 5609, 5611, 5801, 5804, 5805, 5809-5813, 5815, 8301	1							
*1313, 350201-350202, 350401-350402, 3512, 3581, 3583, 5612	1			4				
*1320, 1502, 1513, 1521, 1525, 1536, 1544, 1562, 1577, 1580, 1585, 1589, 9506, 9512, 9521, 9539, 3511, 351401-351402, 3521, 5306, 5308	1							
*1321, 350901-350902, 3518, 3712, 4004, 4064, 4068				4				
*1401-1404, 1407N, 5806								
Well No.	1	2	3	4	5	6	7	8

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170	210	165	90	90	195	145	85	Length of spec. PCR product
9	10	11	12	13	14	15	16	Well No.
		215						
9								*070201-0724, 0726-0741, 0743-0747, 0749N, 0750, 0752-0762, 0806, 0820, 1316, 1405-140602, 15010101-150104, 150106-150107, 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, 1815, 1819, 1821, 270401-270402, 2706, 2710, 2715, 2718, 2720, 2721, 2724, 2725, 3543, 3544, 3558, 3567, 3579, 3707, 3810, 3918, 3935, 3936, 4005, 4015, 4016, 4023, 4026, 4032, 4051, 460101-4605, 4607N, 4608, 4610, 4612, 4805, 4808, 4815, 4901-4905, 5001, 5002, 5004, 510101-5103, 5106, 5107, 5111N-5114, 5116-5118, 5121-5124, 5126-5130, 5132-5139, 5141N, 5143, 5145, 5148-5152, 520101-5202, 5204-5209, 5211, 5406, 550101-550104, 5503, 5505, 5509, 5511, 5515, 5517, 5521, 5524, 5525, 5528, 5529, 5603, 560501-5606, 5621, 5808, 7801-7803, 7805
								*1301, 1306, 1307N, 1312, 1317, 1520, 1588, 1822, 2719, 2730, 350101-350106, 3503, 3507-350803, 3510, 3513, 3515-3517, 3519-352002, 3523-3530, 3533-3536, 3538-3542, 3545-3550, 3552-3557, 3561-3563, 3565Q, 3569-3571, 3574, 3576-3578, 3580, 3582, 3584, 3585, 44020101-4414, 4416, 4417, 4419N, 4421-4430, 4432-4440, 4442-4446, 4448-4452N, 4455-4459, 4802, 5142, 530101-5305, 5309-5313, 5609, 5611, 5801, 5804, 5805, 5809-5813, 5815, 8301
								*1313, 350201-350202, 350401-350402, 3512, 3581, 3583, 5612
9								*1320, 1502, 1513, 1521, 1525, 1536, 1544, 1562, 1577, 1580, 1585, 1589, 9506, 9512, 9521, 9539, 3511, 351401-351402, 3521, 5306, 5308
								*1321, 350901-350902, 3518, 3712, 4004, 4064, 4068
9						15		*1401-1404, 1407N, 5806
9	10	11	12	13	14	15	16	Well No.

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
*3506, 3559, 370101-370104, 3703N-3706, 3708, 3710, 3711, 3942	1			w				
*3713	1			w				
*4028, 5104, 5146	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

<sup>1</sup>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\*57 subtyping.

In addition, wells number 4 and 11 contain the primer pair giving rise to the shorter, 800 bp, internal positive control band in order to allow kit identification.

<sup>2</sup>The nucleotide position, in the 2<sup>nd</sup> or 3<sup>rd</sup> exon, matching the specificity-determining 3'-end of the primer is given. Nucleotide numbering as on the [www.ebi.ac.uk/imgt/hla](http://www.ebi.ac.uk/imgt/hla) web site. The sequence of the 3 terminal nucleotides of the primer is given.

<sup>3</sup>The nucleotide position, in the 2<sup>nd</sup> or 3<sup>rd</sup> exon or the 2<sup>nd</sup> or 3<sup>rd</sup> 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](http://www.ebi.ac.uk/imgt/hla) web site. The sequence of the 3 terminal nucleotides of the primer is given.

170	210	165	90	90	195	145	85	Length of spec. PCR product
9	10	11	12	13	14	15	16	Well No.
		215						*3506, 3559, 370101-370104, 3703N-3706, 3708, 3710, 3711, 3942
9								*3713
9								*4028, 5104, 5146
			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.

<sup>4</sup>Primer 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.  
 w', might be weakly amplified.

<b>CELL LINE VALIDATION SHEET</b>																				
<b>HLA-B*57 SSP subtyping kit</b>																				
				Prod. No.:	Well															
					1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
					200843601	200843602	200843603	200843604	200843605	200843606	200843607	200843608	200843609	200843610	200843611	200843612	200843613	200843614	200843615	200843616
	<b>IHWC cell line</b>		<b>B*</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	9067 BTB		*270502		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
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		*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<sup>®</sup> HLA-B\*57 SSP**

**Product number:** 101.567-12 – including *Taq* polymerase  
101.567-12u – without *Taq* polymerase  
**Lot number:** 31E  
**Expiry date:** 2010-February-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	2008-436-09
2	2008-436-02	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	2008-436-13
6	2008-436-06	14	2008-436-14
7	2008-436-07	15	2008-436-15
8	2008-436-08	16	2008-436-16

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.

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

**Date of approval:** 2008-February-29

**Approved by:**

**Quality Control, Supervisor**

## Declaration of Conformity

**Product name:** *Olerup* SSP<sup>®</sup> HLA-B\*57  
**Product number:** 101.567-12, 101.567-12u  
**Lot number:** 31E

**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  
2008-February-29

Olle Olerup  
Managing Director



HLA-B\*57

Product Insert

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101.567-12 – including *Taq* polymerase

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Lot No.: **31E**

Lot-specific information

[www.olerup.com](http://www.olerup.com)

HLA-B\*57  
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Lot No.: **31E**

Lot-specific information

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101.567-12 – including *Taq* polymerase

101.567-12u – without *Taq* polymerase

Lot No.: **31E**

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HLA-B\*57  
101.567-12 – including *Taq* polymerase  
101.567-12u – without *Taq* polymerase

Product Insert

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Lot No.: **31E**

Lot-specific information

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