

Lot No.: **66F**

Lot-specific information

## ***Olerup SSP*<sup>®</sup> HLA-B\*78**

Product number: 101.551-06u – without *Taq* polymerase  
Lot number: 66F  
Expiry date: 2011-March-01  
Number of tests: 6  
Number of wells per test: 13  
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. 66F.**

### **CHANGES COMPARED TO THE PREVIOUS *OLERUP SSP*<sup>®</sup> HLA-B\*78 LOT.**

The HLA-B\*78 specificity and interpretation tables have been updated for the HLA-B alleles described since the previous *Olerup SSP*<sup>®</sup> HLA-B\*78 lot was made (Lot No. Y33).

One well has been added to the HLA-B\*78kit,  
well **13**.

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

Well	5'-primer	3'-primer	rationale
5	-	-	Exchanged positive control primer pair.
10	Modified	-	Modified 5'-primer for increased yield of specific PCR product.
13	New	New	New primer pair for the B*7806 allele.

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## PRODUCT DESCRIPTION

### HLA-B\*78 SSP typing

#### CONTENT

The primer set contains 5'- and 3'-primers for identifying the B\*7801 to B\*7806 alleles.

#### PLATE LAYOUT

Each HLA-B\*78 test consists of 13 PCR reactions in a 16 well cut PCR plate. Wells 14 to 16 are empty.

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

The 16 well PCR plate is marked with 'HLA-B\*78' in silver/gray ink.

Well No. 1 is marked with the Lot No '66F'.

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\*78 SSP subtypings will be influenced by many other HLA-B alleles due to the sharing of sequence motifs.

#### UNIQUELY IDENTIFIED ALLELES

All the HLA-B\*78, i.e. **B\*7801 to B\*7806**, recognized by the HLA Nomenclature Committee in January 2009<sup>1</sup> will be amplified by the primers in the HLA-B\*78 SSP kit.

<sup>1</sup>HLA-B alleles listed on the IMGT/HLA web page 2009-January-16, release 2.24.0, [www.ebi.ac.uk/imgt/hla](http://www.ebi.ac.uk/imgt/hla).

#### RESOLUTION IN HOMO- AND HETEROZYGOTES

The 6 HLA-B\*78 alleles will give rise to 7 different amplification patterns (the B\*780201 and the B\*780201 alleles yield different amplification patterns), that can be combined in 23 homozygous and heterozygous combinations. Thirteen of these genotypes do not give rise to unique amplification patterns.

++++--+- -+--+ 780201,7803 = 780202,7803  
+++----+ -+--+ 7801,780201 = 7801,780202  
++-+---- -+--+ 7801,7803 = 7803,7803  
+-+----+ -+--+ 780201,7806 = 7805,7806 = 7806,7806  
+-+----+ -+--+ 780201,7805 = 7805,7805  
+-+----+ -+--+ 780201,780202 = 780202,780202

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## SPECIFICITY TABLE

### HLA-B\*78 SSP subtyping

Specificities and sizes of the PCR products of the 13 primer mixes used for HLA-B\*78 SSP subtyping

Primer Mix	Approx. spec. PCR product <sup>1</sup>	Size of control band <sup>2</sup>	Amplified HLA-B*78 alleles	Other amplified HLA-B alleles <sup>3</sup>
1	265 bp	800 bp	7801-7803, 7805, 7806	1315, 510101- 510109, 5103, 5107- 510902, 5111N-5114, 5116-5122, 512401- 512402, 5126-5133, 5135, 5137-5139, 5141N, 5143, 5144N, 5148-5153, 5155, 5157, 5158, 5160, 5161,5163, 520101- 5202, 5204-5210, 5212-5214, 560501- 5606, 5621, 5808, 7301
2	190 bp	1070 bp	7801, 7803	0765, 560501, 5606
3	225 bp	1070 bp	780201-780202, 7804-7806	0823, 1309, 15010101-150104, 150106-1512, 1514, 1515, 1518-1521, 1525-1535, 1537- 1540, 1542, 1544- 1556, 1558, 1560, 1562-1566, 1569, 1572-1575, 1577- 1588, 1590-1593, 1596-1599, 9502- 9514, 9516-9529, 9531-9547, 9549N- 9551, 1804, 1825, 350101-3528, 3530- 3549, 3551-356802, 3570-3572, 3574, 3575, 3577-3583, 3585-3594, 400101- 400106, 4007, 4010, 4012, 401401-4016,

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				4021-4023, 4025, 4030-4034, 4036, 4038, 4042, 4045, 4046, 4048, 4049, 4051-4055, 4058- 4063, 4065, 4067, 4069, 407201-4073, 4076, 4077, 4079- 4081, 4084, 4087, 4088, 4092, 4101- 4108, 4409, 4446, 4501-4505, 4507- 4509, 4702, 4703, 5001, 5002, 5004, 5209, 5305, 5316, 5518, 5531, 5623, 5712
<b>4</b>	170 bp	1070 bp	7803	5122
<b>5</b>	210 bp	<b>800 bp</b>	7804	130201-1304, 1308Q, 1309, 1314, 1315, 1318 <sup>weakly</sup> , 1319, 2714, 3537, 3560, 390601-390602, 3933 <sup>weakly</sup> , 3934, 40060101-400602, 4044, 4053, 4070, 4075, 4083, 4086, 4093, 4447, 4611, 4618, 5105 <sup>weakly</sup> , 510901-5110, 5115, 5119, 5131, 5140, 5154 <sup>weakly</sup> , 5203, 5210, 5401-5405N, 5407, 5408N, 5410 <sup>weakly</sup> , 5411-5417, 550201-550203, 5507, 5510, 5512, 5513, 5516, 5518, 5519, 5522, 5523, 5526, 5527, 5530, 5532, 5534, 5601, 5607, 5608, 5614- 5617, 5619N, 5620, 5622-5624, 5901- 5904, 7301
<b>6</b>	95 bp	1070 bp	7805, 7806	1812, 3510, 3513, 3516, 3528, 3569, 3580, 370101-3705,

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				3707, 3709-3714, 4903, 520101- 520104, 5203-5214
<b>7</b>	210 bp	1070 bp	7801, 780202, 7803	0765, 1804, 4058, 560501, 5606
<b>8</b>	210 bp	1070 bp		4406, 4903, 510101, 510103-510108, 510201, 510203- 5104, 5106-510901, 5110-5114, 5116- 512402, 5126-5146, 5148, 5149, 5151- 5153, 5155-5163, 520102, 520104- 5203, 520601- 520602, 5209, 5306, 5808
<b>9</b>	325 bp	1070 bp		070201-070207, 0704-0707, 0709- 0715, 0717-0726, 0728-0731, 0733- 0736, 0739-0746, 0748, 0749N, 0751- 0768, 1576, 9501, 2701-270402, 270502-2711, 2713- 2715, 2717, 2719- 2721, 2724-2728, 2730-2738, 2740- 2745, 3576, 4201, 4202, 4204-4206, 4208, 4209, 4506, 460101-4618, 5401- 5417, 550101-5505, 5507-5517, 5519- 5534, 5601-5616, 5618-5622, 5624, 670101-6702, 7301, 8101-8104N, 8201, 8202, 8301
<b>10</b>	190 bp	1070 bp	7801-7806	0821, 0825, 1303, 1509, 1530, 1548, 1558, 1573, 9550, 350201-350203 <sup>weakly</sup> , 350401-350403, 3506, 350901- 350902, 3512, 3518,

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				3522, 3544, 3559, 3581 <sup>weakly</sup> , 3583 <sup>weakly</sup> , 3932, 3933, 4005, 4026, 4028, 4063, 4071, 4092, 4410, 4414, 4462, 4611, 510101-510202, 510204-510902, 5111N-5115, 5118 <sup>weakly</sup> , 5119, 5120, 5122-512402, 5126- 5130, 5132, 5133, 5135, 5138-5141N, 5143, 5144N, 5146, 5148-5163, 520101- 5207, 5209-5211, 5213, 5214, 5403, 5508, 5601, 5602, 5604-5608, 5613- 5617, 5620-5622, 5624, 5702-570302, 5707, 5709, 5712, 5717, 5808, 5904, 8201, 8202
<b>11</b>	150 bp	1070 bp		1809, 370101-3704, 3707-3710, 3712- 3714, 3806, 3807, 4406, 4903, 510101- 512402, 5126-5146, 5148-5163, 520101- 520104, 5203-5214, 530101-5316, 580101-5802, 5804- 5820
<b>12</b>	145 bp	1070 bp	7801-7806	0765, 0832, 180101- 1808, 1810-1815, 1817N-1832, 350101- 350801, 350803- 3518, 352001-3524, 3527-3545, 3548, 3550-3562, 3564- 3572, 3574-3594, 3705, 3711, 391901- 391902, 5606
<b>13</b>	135 bp	1070 bp	7806	3527, 3556, 3705

<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\*78 SSP typings.

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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 addition, well number 5 contains 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 many non-HLA-B\*78 alleles will be amplified by primer mixes 1 to 13.

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<b>INTERPRETATION TABLE</b>								
<b>HLA-B*78 SSP subtyping</b>								
<b>Amplification patterns of the B*7801 to B*7806 alleles</b>								
	<b>Well</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>265</b>	<b>190</b>	<b>225</b>	<b>170</b>	<b>210</b>	<b>95</b>	<b>210</b>	<b>210</b>
<b>PCR product</b>								
<b>Length of int.</b>	<b>800</b>	<b>1070</b>	<b>1070</b>	<b>1070</b>	<b>800</b>	<b>1070</b>	<b>1070</b>	<b>1070</b>
<b>pos. control<sup>1</sup></b>								
<b>5'-primer<sup>2</sup></b>	<b>357</b>	<b>141</b>	<b>106</b>	<b>141</b>	<b>357</b>	<b>206</b>	<b>141</b>	<b>141</b>
	5'-Tgg <sup>3'</sup>	5'-ATT <sup>3'</sup>	5'-CCA <sup>3'</sup>	5'-ATT <sup>3'</sup>	5'-Tgg <sup>3'</sup>	5'-gAC <sup>3'</sup>	5'-ATT <sup>3'</sup>	5'-ATT <sup>3'</sup>
			<b>106</b>					
			5'-CCg <sup>3'</sup>					
<b>3'-primer<sup>3</sup></b>	<b>583</b>	<b>292</b>	<b>292</b>	<b>272</b>	<b>527</b>	<b>259</b>	<b>311</b>	<b>309</b>
	5'-gTg <sup>3'</sup>	5'-gTC <sup>3'</sup>	5'-gTA <sup>3'</sup>	5'-TgC <sup>3'</sup>	5'-CCA <sup>3'</sup>	5'-CTC <sup>3'</sup>	5'-ggT <sup>3'</sup>	5'-ATC <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>*7801</b>	<b>1</b>	<b>2</b>					<b>7</b>	
<b>*780201</b>	<b>1</b>		<b>3</b>					
<b>*780202</b>	<b>1</b>		<b>3</b>				<b>7</b>	
<b>*7803</b>	<b>1</b>	<b>2</b>		<b>4</b>			<b>7</b>	
<b>*7804</b>			<b>3</b>		<b>5</b>			
<b>*7805</b>	<b>1</b>		<b>3</b>			<b>6</b>		
<b>*7806</b>	<b>1</b>		<b>3</b>			<b>6</b>		
<b>*070201-070207, 0704-0707, 0709-0715, 0717-0726, 0728-0731, 0733-0736, 0739-0746, 0748, 0749N, 0751-0764, 0766-0768, 1576, 9501, 2701-270402, 270502-2711, 2713, 2715, 2717, 2719-2721, 2724-2728, 2730-2738, 2740-2745, 4201, 4202, 4204-4206, 4208, 4209, 4506, 460101-4610, 4612-4617, 5406, 5409, 550101-550104, 5503-5505, 5509, 5511, 5514, 5515, 5517, 5520, 5521, 5524, 5525, 5528, 5529, 5533, 5603, 5609-5612, 5618, 670101-6702, 8101-8104N, 8301</b>								
<b>*0765</b>		<b>2</b>					<b>7</b>	
<b>*0821, 0825, 3932, 4005, 4026, 4028, 4071, 4410, 4414, 4462, 5702-570302, 5707, 5709, 5717</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>



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<b>INTERPRETATION TABLE</b>					
<b>HLA-B*78 SSP subtyping</b>					
<b>Amplification patterns of the B*7801 to B*7806 alleles</b>					
<b>Well</b>					
<b>9</b>	<b>10</b>	<b>11</b>	<b>12</b>	<b>13</b>	
<b>325</b>	<b>190</b>	<b>150</b>	<b>145</b>	<b>135</b>	<b>Length of spec. PCR product</b>
<b>1070</b>	<b>1070</b>	<b>1070</b>	<b>1070</b>	<b>1070</b>	<b>Length of int. pos. control<sup>1</sup></b>
<b>1<sup>st</sup> I</b>	<b>412</b>	<b>206</b>	<b>206</b>	<b>206</b>	<b>5'-primer<sup>2</sup></b>
5'-CAG <sup>3'</sup>	5'-ATA <sup>3'</sup>	5'-gAC <sup>3'</sup>	5'-gAC <sup>3'</sup>	5'-gAC <sup>3'</sup>	
<b>282</b>	<b>559</b>	<b>317</b>	<b>311</b>	<b>302</b>	<b>3'-primer<sup>3</sup></b>
5'-gCC <sup>3'</sup>	5'-CAG <sup>3'</sup>	5'-ggA <sup>3'</sup>	5'-ggT <sup>3'</sup>	5'-ggT <sup>3'</sup>	
<b>9</b>	<b>10</b>	<b>11</b>	<b>12</b>	<b>13</b>	<b>Well No.</b>
					<b>HLA-B allele</b>
	<b>10</b>		<b>12</b>		<b>*7801</b>
	<b>10</b>		<b>12</b>		<b>*780201</b>
	<b>10</b>		<b>12</b>		<b>*780202</b>
	<b>10</b>		<b>12</b>		<b>*7803</b>
	<b>10</b>		<b>12</b>		<b>*7804</b>
	<b>10</b>		<b>12</b>		<b>*7805</b>
	<b>10</b>		<b>12</b>	<b>13</b>	<b>*7806</b>
<b>9</b>					<b>*070201-070207, 0704-0707, 0709-0715, 0717-0726, 0728-0731, 0733-0736, 0739-0746, 0748, 0749N, 0751-0764, 0766-0768, 1576, 9501, 2701-270402, 270502-2711, 2713, 2715, 2717, 2719-2721, 2724-2728, 2730-2738, 2740-2745, 4201, 4202, 4204-4206, 4208, 4209, 4506, 460101-4610, 4612-4617, 5406, 5409, 550101-550104, 5503-5505, 5509, 5511, 5514, 5515, 5517, 5520, 5521, 5524, 5525, 5528, 5529, 5533, 5603, 5609-5612, 5618, 670101-6702, 8101-8104N, 8301</b>
<b>9</b>			<b>12</b>		<b>*0765</b>
	<b>10</b>				<b>*0821, 0825, 3932, 4005, 4026, 4028, 4071, 4410, 4414, 4462, 5702-570302, 5707, 5709, 5717</b>
<b>9</b>	<b>10</b>	<b>11</b>	<b>12</b>	<b>13</b>	<b>Well No.</b>

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Length of spec.	265	190	225	170	210	95	210	210
PCR product								
Well No.	1	2	3	4	5	6	7	8
*0823, 15010101-15010104, 150106-1508, 1510-1512, 1514, 1515, 1518-1521, 1525-1529, 1531-1535, 1537-1540, 1542, 1544-1547, 1549-1556, 1560, 1562-1566, 1569, 1572, 1574, 1575, 1577-1588, 1590-1593, 1596-1599, 9502-9514, 9516-9529, 9531-9547, 9549N, 9551, 350802, 3519, 3525, 3526, 3546, 3547, 3549, 3563, 400101-400106, 4007, 4010, 4012, 401401-4016, 4021-4023, 4025, 4030-4034, 4036, 4038, 4042, 4045, 4046, 4048, 4049, 4051, 4052, 4054, 4055, 4059-4062, 4065, 4067, 4069, 407201-4073, 4076, 4077, 4079-4081, 4084, 4087, 4088, 4101-4108, 4409, 4446, 4501-4505, 4507-4509, 4702, 4703, 5001, 5002, 5004			3					
*0832, 180101-1803, 1805-1808, 1810, 1811, 1813-1815, 1817N-1824, 1826-1832, 3529, 3550, 3584, 391901-391902								
*130201-130204, 1304, 1308Q, 1314, 1319, 390601-390602, 3934, 40060101-400602, 4044, 4070, 4075, 4083, 4086, 4093, 4447, 5901-5903					5			
*1303, 5617, 5904					5			
*1309, 4053, 5518, 5623			3		5			
*1315	1					5		
*1318					w			
*1509, 1530, 1548, 1558, 1573, 9550, 4063, 4092, 5712					3			
*1804			3				7	
*1809, 3708, 3806, 3807, 530101-5304, 5307-5315, 580101-5802, 5804-5807, 5809-5820								
*1812, 3569, 3711						6		
Well No.	1	2	3	4	5	6	7	8

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325	190	150	145	135	Length of spec. PCR product
9	10	11	12	13	Well No.
					*0823, 15010101-15010104, 150106-1508, 1510-1512, 1514, 1515, 1518-1521, 1525-1529, 1531-1535, 1537-1540, 1542, 1544-1547, 1549-1556, 1560, 1562-1566, 1569, 1572, 1574, 1575, 1577-1588, 1590-1593, 1596-1599, 9502-9514, 9516-9529, 9531-9547, 9549N, 9551, 350802, 3519, 3525, 3526, 3546, 3547, 3549, 3563, 400101-400106, 4007, 4010, 4012, 401401-4016, 4021-4023, 4025, 4030-4034, 4036, 4038, 4042, 4045, 4046, 4048, 4049, 4051, 4052, 4054, 4055, 4059-4062, 4065, 4067, 4069, 407201-4073, 4076, 4077, 4079-4081, 4084, 4087, 4088, 4101-4108, 4409, 4446, 4501-4505, 4507-4509, 4702, 4703, 5001, 5002, 5004
			12		*0832, 180101-1803, 1805-1808, 1810, 1811, 1813-1815, 1817N-1824, 1826-1832, 3529, 3550, 3584, 391901-391902
					*130201-130204, 1304, 1308Q, 1314, 1319, 390601-390602, 3934, 40060101-400602, 4044, 4070, 4075, 4083, 4086, 4093, 4447, 5901-5903
	10				*1303, 5617, 5904
					*1309, 4053, 5518, 5623
					*1315
					*1318
	10				*1509, 1530, 1548, 1558, 1573, 9550, 4063, 4092, 5712
			12		*1804
		11			*1809, 3708, 3806, 3807, 530101-5304, 5307-5315, 580101-5802, 5804-5807, 5809-5820
			12		*1812, 3569, 3711
9	10	11	12	13	Well No.

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Length of spec.	265	190	225	170	210	95	210	210
PCR product								
Well No.	1	2	3	4	5	6	7	8
*1825, 350101-350107, 3503, 3505, 3507, 350801, 350803, 3511, 351401-3515, 3517, 352001-3521, 3523, 3524, 3530-3536, 3538-3543, 3545, 3548, 3551-3555, 3557, 3558, 3561, 3562, 3564-356802, 3570-3572, 3574, 3575, 3577-3579, 3582, 3585-3594	3							
*2714, 4618, 5401, 5402, 5404, 5405N, 5407, 5408N, 5411-5417, 550201-550203, 5507, 5510, 5512, 5513, 5516, 5519, 5522, 5523, 5526, 5527, 5530, 5532, 5534, 5619N					5			
*350201-350203, 3581, 3583			3					
*350401-350403, 3506, 350901-350902, 3512, 3518, 3522, 3544, 3559			3					
*3510, 3513, 3516, 3528, 3580			3			6		
*3527, 3556			3					
*3537, 3560			3		5			
*3576								
*370101-3704, 3707, 3709, 3710, 3712-3714						6		
*3705						6		
*3933					w			
*4058			3				7	
*4406, 510203, 5134, 5136, 5142, 5145, 5306								8
*4611, 5403, 5601, 5607, 5608, 5614-5616, 5620, 5622, 5624					5			
*4903						6		8
*510101, 510103-510108, 5103, 5107, 5108, 5111N-5114, 5120, 512401-512402, 5126-5130, 5132, 5133, 5135, 5138, 5139, 5141N, 5143, 5144N, 5148, 5149, 5151-5153, 5155, 5157, 5158, 5160, 5161, 5163, 5808	1							8
*510102, 510109, 5150	1							
*510201, 510204, 5104, 5106, 5123, 5146, 5156, 5159, 5162								8
*510202								
Well No.	1	2	3	4	5	6	7	8

Lot No.: **66F**

Lot-specific information

325	190	150	145	135	Length of spec. PCR product
9	10	11	12	13	Well No.
					*1825, 350101-350107, 3503, 3505, 3507, 350801, 350803, 3511, 351401-3515, 3517, 352001-3521, 3523, 3524, 3530-3536, 3538-3543, 3545, 3548, 3551-3555, 3557, 3558, 3561, 3562, 3564-356802, 3570-3572, 3574, 3575, 3577-3579, 3582, 3585-3594
9			12		*2714, 4618, 5401, 5402, 5404, 5405N, 5407, 5408N, 5411-5417, 550201-550203, 5507, 5510, 5512, 5513, 5516, 5519, 5522, 5523, 5526, 5527, 5530, 5532, 5534, 5619N
	w		12		*350201-350203, 3581, 3583
	10		12		*350401-350403, 3506, 350901-350902, 3512, 3518, 3522, 3544, 3559
			12		*3510, 3513, 3516, 3528, 3580
			12	13	*3527, 3556
			12		*3537, 3560
9			12		*3576
11					*370101-3704, 3707, 3709, 3710, 3712-3714
			12	13	*3705
10					*3933
					*4058
11					*4406, 510203, 5134, 5136, 5142, 5145, 5306
9	10				*4611, 5403, 5601, 5607, 5608, 5614-5616, 5620, 5622, 5624
11					*4903
	10	11			*510101, 510103-510108, 5103, 5107, 5108, 5111N-5114, 5120, 512401-512402, 5126-5130, 5132, 5133, 5135, 5138, 5139, 5141N, 5143, 5144N, 5148, 5149, 5151-5153, 5155, 5157, 5158, 5160, 5161, 5163, 5808
10		11			*510102, 510109, 5150
	10	11			*510201, 510204, 5104, 5106, 5123, 5146, 5156, 5159, 5162
10		11			*510202
9	10	11	12	13	Well No.

Lot No.: **66F**

Lot-specific information

Length of spec.	265	190	225	170	210	95	210	210
PCR product								
Well No.	1	2	3	4	5	6	7	8
*5105, 5154					w			
*510901, 5119	1				5			8
*510902	1				5			
*5110					5			8
*5115					5			
*5116, 5117, 5121, 5137	1							8
*5118	1							8
*5122	1			4				8
*5131	1				5			8
*5140					5			8
*520101, 520103, 5204, 5205, 5207, 5213, 5214	1					6		
*520102, 520104, 520601-520602	1					6		8
*5202	1							8
*5203					5	6		8
*5208, 5212	1					6		
*5209	1		3			6		8
*5210	1				5	6		
*5211						6		
*5305, 5316			3					
*5410					w			
*5508, 5602, 5604, 5613, 8201, 8202								
*5531			3					
*560501	1	2					7	
*560502, 5621	1							
*5606	1	2					7	
*7301	1				5			
HLA-B allele								
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 addition, well number 5 contains the primer pair giving rise to the shorter, 800 bp, internal positive control band in order to allow kit identification.

Lot No.: **66F**

Lot-specific information

325	190	150	145	135	Length of spec. PCR product
9	10	11	12	13	Well No.
	10	11			*5105, 5154
	10	11			*510901, 5119
	10	11			*510902
		11			*5110
	10	11			*5115
		11			*5116, 5117, 5121, 5137
	w	11			*5118
	10	11			*5122
		11			*5131
	10	11			*5140
	10	11			*520101, 520103, 5204, 5205, 5207, 5213, 5214
	10	11			*520102, 520104, 520601-520602
	10				*5202
	10	11			*5203
		11			*5208, 5212
	10	11			*5209
	10	11			*5210
	10	11			*5211
		11			*5305, 5316
9					*5410
9	10				*5508, 5602, 5604, 5613, 8201, 8202
9					*5531
9	10				*560501
9	10				*560502, 5621
9	10		12		*5606
9					*7301
					HLA-B allele
9	10	11	12		Well No.

<sup>2</sup>The nucleotide position, in the 2<sup>nd</sup> or 3<sup>rd</sup> exon or 1<sup>st</sup> intron, 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, 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.

'w', might be weakly amplified.

Lot No.: **66F**

Lot-specific information

CELL LINE VALIDATION SHEET																		
HLA-B*78 SSP primer set																		
					Prod. No.:	Well												
						1	2	3	4	5	6	7	8	9	10	11	12	13
						200957301	200957302	200957303	200957304	200957305	200957306	200957307	200957308	200957309	200957310	200957311	200957312	200957313
	IHWC cell line		B*															
1	9001 SA		*0702			-	-	-	-	-	-	-	-	+	-	-	-	-
2	9280 LK707		*5201	*7301		+	-	-	-	+	+	-	-	+	+	+	-	-
3	9011 E4181324		*52011			+	-	-	-	-	+	-	-	-	+	+	-	-
4	9275 GU373		*1510	*5301		-	-	+	-	-	-	-	-	-	-	+	-	-
5	9009 KAS011		*3701			-	-	-	-	-	+	-	-	-	-	+	-	-
6	9353 SM		*3901	*5101		+	-	-	-	-	-	-	+	-	+	+	-	-
7	9020 QBL		*1801			-	-	-	-	-	-	-	-	-	-	-	+	-
8	9007 DEM		*5701			-	-	-	-	-	-	-	-	-	-	-	-	-
9	9026 YAR		*3801			-	-	-	-	-	-	-	-	-	-	-	-	-
10	9107 LKT3		*5401			-	-	-	-	+	-	-	-	+	-	-	-	-
11	9051 PITOUT		*4403			-	-	-	-	-	-	-	-	-	-	-	-	-
12	9052 DBB		*5701			-	-	-	-	-	-	-	-	-	-	-	-	-
13	904 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 DHF		*3801			-	-	-	-	-	-	-	-	-	-	-	-	-
35	9302 SSTO		*4402			-	-	-	-	-	-	-	-	-	-	-	-	-
36	9024 KT17		*1501	*3501		-	-	+	-	-	-	-	-	-	-	-	+	-
37	9065 HHKB		*0702			-	-	-	-	-	-	-	-	+	-	-	-	-
38	9099 LZL		*1501			-	-	+	-	-	-	-	-	-	-	-	-	-
39	9315 CML		*0801	*2705		-	-	-	-	-	-	-	-	+	-	-	-	-
40	9134 WHONP199		*1302	*4601		-	-	-	-	+	-	-	-	+	-	-	-	-
41	9055 H0301		*1402			-	-	-	-	-	-	-	-	-	-	-	-	-
42	9066 TAB089		*4601			-	-	-	-	-	-	-	-	+	-	-	-	-
43	9076 T7526		*4601			-	-	-	-	-	-	-	-	+	-	-	-	-
44	9057 TEM		*3801			-	-	-	-	-	-	-	-	-	-	-	-	-
45	9239 SHJO		*4201	*5001		-	-	+	-	-	-	-	-	+	-	-	-	-
46	9013 SCHU		*0702			-	-	-	-	-	-	-	-	+	-	-	-	-
47	9045 TUBO		*5101			+	-	-	-	-	-	-	+	-	+	+	-	-
48	9303 TER-ND		*3501	*4403		-	-	+	-	-	-	-	-	-	-	-	+	+



Lot No.: **66F**

Lot-specific information

## CERTIFICATE OF ANALYSIS

### **Olerup SSP<sup>®</sup> HLA-B\*78 SSP**

**Product number:** 101.551-06u – without *Taq* polymerase  
**Lot number:** 66F  
**Expiry date:** 2011-March-01  
**Number of tests:** 6  
**Number of wells per test:** 13

#### **Well specifications:**

Well No.	Production No.	Well No.	Production No.
1	2009-573-01	9	2009-573-09
2	2009-573-02	10	2009-573-10
3	2009-573-03	11	2009-573-11
4	2009-573-04	12	2009-573-12
5	2009-573-05	13	2009-573-13
6	2009-573-06		
7	2009-573-07		
8	2009-573-08		

The specificity of each primer solution of the HLA-B\*78 primer set has been tested against 48 well characterized cell line DNAs.

No DNAs carrying the alleles to be amplified by primer solution 4 and 13 were available. The specificities of the primers in primer solution 4 were tested by separately adding one additional 3'-primer, respectively one additional 5'-primer. In primer solution 13, only the 5'-primer could be tested, 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.: **66F**

Lot-specific information

## Declaration of Conformity

**Product name:** *Olerup* SSP® HLA-B\*78  
**Product number:** 101.551-06u  
**Lot number:** 66F

**Intended use:** HLA-B\*78 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.: **66F**

Lot-specific information

Lot No.: **66F**

Lot-specific information

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