

Lot No.: **55E**

Lot-specific information

## **Olerup SSP<sup>®</sup> HLA-B\*55**

Product number:	101.570-06u – without <i>Taq</i> polymerase
Lot number:	55E
Expiry date:	2010-May-01
Number of tests:	6
Number of wells per test:	24
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. 55E.**

### **CHANGES COMPARED TO THE PREVIOUS *OLERUP SSP<sup>®</sup>* HLA-B\*55 LOT**

The HLA-B\*55 specificity and interpretation tables have been updated for the HLA-B alleles described since the previous *Olerup SSP<sup>®</sup>* HLA-B\*55 lot was made (**Lot No. X67**).

The primers of the wells detailed below has been exchanged or modified.

Well	5'-primer	3'-primer	rationale
2	Modified	-	Increased yield of specific PCR product.
9	Modified	Modified	Increases specificity of specific primer pair.
12	-	Modified	Increases specificity of specific primer pair.
18	-	Added	Primer moved from vial 19.
19	New	New	New primer pair for the B*5530 allele.
23	-	Added	Primer added for the B*5529 allele.
24	-	Added	Primer added for the B*5527 allele.

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## PRODUCT DESCRIPTION

### HLA-B\*55 SSP subtyping

#### CONTENT

The primer set contains 5'- and 3'-primers for identifying the B\*5501 to B\*5530 alleles.

#### PLATE LAYOUT

Each test consists of 24 PCR reactions in a 24 well PCR plate.

1	2	3	4	5	6	7	8
9	10	11	12	13	14	15	16
17	18	19	20	21	22	23	24

The 24 well PCR plate is marked with 'B\*55'.

Well No. 1 is marked with the Lot No. '55E'.

The PCR plates are covered with a PCR-compatible foil.

**Please note:** When removing each 24 well PCR plate, make sure that the remaining plates stay covered. Use a scalpel or a similar instrument to carefully cut the foil between the plates.

#### INTERPRETATION

The interpretation of HLA-B\*55 SSP subtypings will be influenced by most B\*07, most B\*08, the B\*13, the B\*1405, several B\*15, most B\*18, the B\*2714, the B\*35, the B\*37, nine B\*39, several B\*40, the B\*41, the B\*42, six B\*44, the B\*45, the B\*46, the B\*4802, the B\*49, the B\*50, the B\*51, the B\*52, the B\*53, the B\*54, the B\*56, the B\*57, the B\*58, the B\*59, the B\*78, the B\*81, the B\*82 and the B\*8301 alleles when present on the other haplotype. In addition, the Cw\*0808 allele will be amplified by primer mix 5.

#### UNIQUELY IDENTIFIED ALLELES

All the HLA-B\*55 alleles, i.e. **B\*5501 to B\*5530**, recognized by the HLA Nomenclature Committee in April 2008<sup>1</sup> will give rise to unique amplification patterns by the primers in the HLA-B\*55 subtyping kit.

The HLA-B\*55 subtyping kit cannot separate the B\*550101 to B\*550104 alleles or the B\*550201 and B\*550202 alleles.

<sup>1</sup>HLA-B alleles listed on the IMGT/HLA web page 2008-April-08, release 2.21.0, [www.ebi.ac.uk/imgt/hla](http://www.ebi.ac.uk/imgt/hla).

#### RESOLUTION IN HOMO- AND HETEROZYGOTES

The 29 HLA-B\*55 alleles can be combined in 435 homozygous and heterozygous combinations. 214 of these genotypes do not give rise to unique amplification patterns. The different sizes of the specific PCR products in primer mixes 8, 9, 11, 18, 20 and 23 were not considered in these calculations.

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++++-----	+-----+-	-----	5503,5511 = 5503,5514
++++-----	--+----+-	-----	5503,5515 = 5503,5524
++++-----	-----+-	+-----	5503,5518 = 5503,5519
++++-----	-----+-	+-----	5503,5517 = 5503,5528
++++-----	-----+-	-----	5501,5503 = 5503,5503
+++-----	+-----+-	-----	5505,5511 = 5505,5514
+++-----	--+----+-	-----	5505,5515 = 5505,5524
+++-----	-----+-	+-----	5505,5518 = 5505,5519
+++-----	-----+-	+-----	5505,5517 = 5505,5528
+++-----	-----+-	-----	5501,5505 = 5505,5505
+++-----	--+----+-	-----	5512,5515 = 5512,5524
+++-----	--+----+-	-----	5513,5515 = 5513,5524
+++-----	+--+--+--	-----	5511,5522 = 5515,5516 = 5516,5524
+++-----	+--+--+--	-----	5511,5515 = 5511,5524 = 5514,5515
+++-----	+--+--+--	+-----	5511,5518 = 5511,5519 = 5516,5525
+++-----	+--+--+--	-----	5501,5516 = 5502,5511 = 5511,5516
+++-----	+-----+-	+-----	5511,5517 = 5511,5528
+++-----	+-----+-	+-----	5511,5525 = 5514,5525
+++-----	+-----+-	-----	5511,5529 = 5514,5529
+++-----	+-----+-	-----	5501,5511 = 5501,5514 = 5511,5511 = 5511,5514
+++-----	--+----+-	-----	5507,5515 = 5507,5524
+++-----	-----+-	-----	5510,5515 = 5510,5524
+++-----	--+----+-	+-----	5509,5518 = 5509,5519
+++-----	--+----+-	+-----	5515,5518 = 5515,5519 = 5518,5524 = 5519,5524 = 5522,5525
+++-----	--+----+-	-----	5515,5530 = 5524,5530
+++-----	--+----+-	-----	5515,5526 = 5524,5526
+++-----	--+----+-	-----	5501,5522 = 5502,5515 = 5502,5524 = 5515,5522
+++-----	--+----+-	+-----	5515,5520 = 5520,5524
+++-----	--+----+-	+-----	5509,5517 = 5509,5528
+++-----	--+----+-	-----	5515,5527 = 5524,5527
+++-----	--+----+-	+-----	5515,5517 = 5515,5528 = 5517,5524 = 5524,5528
+++-----	--+----+-	+-----	5515,5525 = 5524,5525
+++-----	--+----+-	-----	5509,5521 = 5509,5529 = 5515,5521 = 5521,5524
+++-----	--+----+-	-----	5501,5509 = 5509,5515
+++-----	--+----+-	-----	5515,5529 = 5524,5529
+++-----	--+----+-	-----	5515,5523 = 5523,5524
+++-----	--+----+-	-----	5501,5515 = 5501,5524 = 5515,5515 = 5515,5524
+++-----	--+----+-	-----	5509,5509 = 5509,5524
+++-----	-----+-	+-----	5518,5529 = 5519,5529
+++-----	-----+-	+-----	5501,5518 = 5501,5519 = 5502,5525 = 5518,5525 = 5519,5525
+++-----	-----+-	+-----	5517,5525 = 5525,5528
+++-----	-----+-	+-----	5517,5529 = 5528,5529
+++-----	-----+-	+-----	5501,5517 = 5501,5528
+++-----	-----+-	+-----	5501,5525 = 5525,5525
+++-----	-----+-	-----	5501,5521 = 5521,5529
+++-----	-----+-	-----	5501,5529 = 5529,5529

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++-+----	----+--	+------	5504,5518 = 5504,5519
++-----	----+--	+------	5508,5518 = 5508,5519
++-----	+---+--	-----	5512,5514 = 5512,5516
++-----	----+--	+-----	5512,5517 = 5512,5528
++-----	----+--	+------	5513,5518 = 5513,5519
++-----	----+--	+------	5512,5518 = 5512,5519
++-----	----+--	-----	5502,5513 = 5512,5513 = 5512,5523
++-----	----+--	-----	5502,5512 = 5512,5512
++-----	-----	+-----	5513,5517 = 5513,5527 = 5513,5528
++-----	-----	+-----	5513,5513 = 5513,5523
++-----	++---+--	-----	5507,5514 = 5507,5516
++-----	+---+--	-----	5510,5514 = 5510,5516
++-----	+---+--	+-----	5516,5517 = 5516,5528
++-----	+---+--	+------	5514,5518 = 5514,5519 = 5516,5518 = 5516,5519
++-----	+---+--	--+-----	5514,5530 = 5516,5530
++-----	+---+--	---+-----	5514,5526 = 5516,5526
++-----	+---+--	-----	5502,5514 = 5502,5516 = 5514,5516 = 5516,5516
++-----	+---+--	+-----	5507,5517 = 5507,5528
++-----	+---+--	+------	5507,5518 = 5507,5519
++-----	+---+--	-----	5502,5507 = 5507,5507
++-----	---+---	+-----	5517,5522 = 5522,5528
++-----	---+---	+------	5518,5522 = 5519,5522
++-----	---+---	+-----	5510,5517 = 5510,5528
++-----	---+---	+------	5510,5518 = 5510,5519
++-----	---+---	-----	5502,5510 = 5510,5510
++-----	---+---	++-+-----	5518,5520 = 5519,5520
++-----	---+---	++-----	5518,5527 = 5519,5527
++-----	---+---	++-----	5517,5518 = 5517,5519 = 5518,5528 = 5519,5528
++-----	---+---	+--+-----	5517,5530 = 5528,5530
++-----	---+---	+--+-----	5502,5520 = 5517,5526 = 5520,5526 = 5526,5528
++-----	---+---	+-----	5502,5517 = 5502,5528
++-----	---+---	++-+-----	5518,5530 = 5519,5530
++-----	---+---	++-+-----	5518,5526 = 5519,5526
++-----	---+---	+-+-----	5518,5521 = 5519,5521
++-----	---+---	+-+-----	5518,5523 = 5519,5523
++-----	---+---	+-+-----	5502,5518 = 5502,5519 = 5518,5519 = 5519,5519
++-----	---+---	--+-----	5502,5530 = 5530,5530
++-----	---+---	---+-----	5502,5526 = 5526,5526
++-----	-----	+--+-----	5520,5523 = 5520,5527
++-----	-----	+--+-----	5517,5521 = 5521,5528
++-----	-----	+--+-----	5517,5523 = 5517,5527 = 5523,5527 = 5523,5528 = 5527,5527 = 5527,5528
++-----	-----	+-----	5517,5528 = 5528,5528
+------	-----	+--+-----	5517,5520 = 5520,5520

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## SPECIFICITY TABLE

### HLA-B\*55 SSP subtyping

Specificities and sizes of the PCR products of the 24 primer mixes used for HLA-B\*55 SSP subtyping

Primer Mix	Size of spec. PCR product <sup>1</sup>	Size of control band <sup>2</sup>	Amplified HLA-B*55 alleles	Other amplified HLA Class I alleles <sup>3</sup>
<b>1<sup>5</sup></b>	400 bp	<b>800 bp</b>	550101-5505, 5507-5517, 5519-5530	3576, 5401-5406, 5408N-5413, 5601-5607, 5608 <sup>weakly</sup> , 5609-5613, 5615, 5616, 5618-5622, 8101, 8103 <sup>?</sup> , 8104 <sup>?</sup> , 8201, 8202, 8301
<b>2<sup>4</sup></b>	125 bp	1070 bp	550101-5503, 5505, 5507, 5509-5513, 5515, 5516, 5518, 5519, 5521-5530	1301-1304, 1306-1309, 1311-1320, 1516, 1520, 1534, 1542, 1562, 1567, 1585, 1586, 1595, 9537, 1822, 2714, 350101-350803, 3510, 3511, 3513-3515, 3519-3521, 3523-3530, 3533-3538, 3540N-3542, 3545-3550, 3552, 3954-3558, 3560, 3562, 3563, 3565Q, 3566, 356801-3572, 3574-3578, 3580-3585, 4028, 4410, 4415, 4418, 4448, 4501-4508, 4611, 4802, 4901-4905, 5001, 5002, 5115, 530101-5306, 5308-5316, 5401-5405N, 5407, 5408N, 5410, 5412, 55413, 5601, 5602, 5607-5611, 5613-5617, 5619N, 5622, 5623, 5705, 580101-5802, 5804-5807, 5809-5817N, 5901, 8201, 8202
<b>3</b>	150 bp	1070 bp	550101-550104, 5503, 5505, 5509 <sup>weakly</sup> , 5511, 5515, 5524, 5525, 5529	1316, 1320, 1542
<b>4</b>	235 bp	1070 bp	5503	0815, 3574, 4073, 460101-4604, 4606-4614
<b>5</b>	235 bp	<b>800 bp</b>	5504	0719, 0731, 0734, 0743, 080101-0808N, 0810, 0813-

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				0815, 0817-0820, 0822-0824, 0826-0836, 1405, 1814, 1822 <sup>weakly</sup> , 3587, 3709, 3903, 3914, 3924, 3929, 3937, 4039, 4102, 4104, 4201, 4202, 420501-4209, <b>Cw*0808</b>
<b>6<sup>4,6</sup></b>	100 bp	1070 bp	5505	
<b>7</b>	180 bp	1070 bp	5508	0720, 0724, 0760, 0821, 0825, 1509, 1510, 1530, 1537, 1545, 1548, 1563, 1590, 1599, 350201-350202, 350401-350402, 350901-350902, 3512, 3518, 3522, 3534, 3539, 3544, 3581, 3583, 4005, 4026, 4028, 4063, 510101-510902, 5111N, 5112, 5118-5120, 5122-512402, 5126-5130, 5132, 5133, 5135, 5138-5141N, 5143, 5144N, 5146, 5148-5155, 520101-5207, 5209-5212, 560501-5606, 5615, 5621, 5702-570302, 5705, 5707, 5709, 5712, 5808, 7801-7805
<b>8<sup>4,5,7</sup></b>	105, 425 bp	<b>800 bp</b>	5512, 5513	9537, 390601-390602, 3933, 3934, 4086, 4502, 511301-511302, 5622, 7301
<b>9<sup>8</sup></b>	215, 325 bp	1070 bp	5511, 5514, 5516	4030, 4034, 4202, 4209, 4506, 5402, 5712
<b>10</b>	140 bp	1070 bp	5507	5401, 5403, 5404, 5406-5413
<b>11<sup>4,9</sup></b>	125, 180 bp	1070 bp	5509, 5515, 5522, 5524	1301-130204, 1307N-1309, 1311, 1314-1320, 4048
<b>12</b>	210 bp	1070 bp	5510	070201-070207, 0704-0707, 0709, 0711, 0712, 0714, 0715, 0717-0726, 0728, 0730, 0731, 0733-0736, 0739-0749N, 0751-0764, 4201, 4202, 4204-4206, 4208, 670101-670102, 8101-8104N
<b>13</b>	150 bp	1070 bp	550201-550202, 5507, 5510, 5512, 5516, 5518, 5519, 5522, 5526, 5530	1301-1303, 1306-1309, 1311, 1312, 1314, 1315, 1317, 1318 <sup>weakly</sup> , 1319, 1586, 3560, 4048, 4071, 4410, 4611, 5115, 5401-5403, 5405N, 5407, 5408N, 5410 <sup>weakly</sup> , 5412, 5413, 5601, 5602, 5604, 5607, 5608,

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				5610, 5614, 5616, 5617, 5619N, 5620, 5623, 5901
<b>14</b>	215 bp	<b>800 bp</b>		150104, 370104, 5401-5413
<b>15</b>	245 bp	1070 bp	550101-5503, 5505, 5507, 5510-5513, 5515-5521, 5523, 5525- 5530	0809, 1542, 1583, 3560, 390601-390602, 3934, 4101, 4105-4107, 4204, 4508, 5121, 5136, 5401, 5402, 5404, 5405N, 5407, 5408N, 5410- 5413, 5623, 5901, 5902
<b>16</b>	245 bp	1070 bp		1303, 1304, 1504, 1516, 1567, 1595, 9537, 3537, 3933, 4415, 4418, 4420, 4447, 4501-4507, 4611, 4901-4905, 5001, 5002, 5004, 510101-5103, 5105, 5107-510902, 5111N-5115, 5117-5120, 5122-512402, 5126-5130, 5132, 5133, 5135, 5137-5141N, 5143, 5144N, 5148-5155, 520101-5207, 5209-5212, 5403, 5601, 560501-5608, 5613-5617, 5620-5622, 5808, 7801-7805
<b>17<sup>4</sup></b>	105 bp	1070 bp	5517, 5520, 5527, 5528	0809, 1583, 2714, 40060101- 400602, 4044, 4053, 4070, 4075, 4083, 4101, 4105-4107, 4204, 4420, 4447, 510101- 5103, 5105, 5107-5112, 5114, 5116-5124, 5126-5136, 5138- 5141N, 5143, 5144N,, 5148- 5155, 520101-5212, 5404, 5411, 560501-5606, 5615, 5621, 5808, 5902, 7801-7805
<b>18<sup>10</sup></b>	215, 310, 395 bp	<b>800 bp</b>	5518, 5519, 5525	
<b>19<sup>4</sup></b>	205 bp	<b>800 bp</b>	5530	
<b>20<sup>5,11</sup></b>	95, 220 bp	1070 bp	5520, 5526	0809, 1583, 4101, 4105-4107, 4204, 4415, 4418, 4420, 4501-4508, 5108, 5120, 5136, 5144N, 5613
<b>21</b>	270 bp	<b>800 bp</b>	5510	180101-1803, 1805-1815, 1818-1828, 3525, 370101- 3713, 5616, 5812, 8101, 8103 <sup>?</sup> , 8104 <sup>?</sup> , 8201, 8202, 8301
<b>22</b>	225 bp	1070 bp	5509, 5521	1318, 1504, 9537, 3933, 5105, 5129, 5154, 5410
<b>23<sup>12</sup></b>	165, 220	<b>800 bp</b>	5521, 5529	1504, 9537

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	bp			
<b>24<sup>4</sup></b>	100 bp	1070 bp	5513, 5523, 5527	1304, 1504, 1516, 1567, 1595, 9537, 3537, 390601-390602, 3933, 3934, 4044, 4086, 4420, 4447, 4502, 4904, 4905, 511301-511302, 5137, 5212, 5622, 7301

<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\*55 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 430 base pairs, for most wells, or a band of 515 base pairs, for some wells.

Well number 1 contains the primer pair giving rise to the longer, 515 bp, internal positive control band in order to help in the correct orientation of the HLA-B\*55 subtyping.

In addition, wells number 5, 8, 14, 18, 19, 21 and 23 contain the primer pair giving rise to the longer, 515 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 non-HLA-B\*55 alleles will be amplified by primer mixes 1 to 5, 7 to 17 and 20 to 24. In addition, the Cw\*0808 allele will be amplified by primer mix 5.

<sup>4</sup>Specific PCR fragments shorter than 125 base pairs have a lower intensity than longer PCR bands.

<sup>5</sup>Primer mixes 1 and 8 might have a tendency of giving rise to primer oligomer formation.

<sup>6</sup>Primer mix 6 has a tendency of giving rise to non-specific amplifications.

<sup>7</sup>Primer mix 8: Specific PCR fragment of 105 bp in the B\*5513 and B\*9537, 390601-390602, 3933, 3934, 4086, 4502, 511301-511302, 5622 and 7301 alleles. Specific PCR fragment of 425 bp in the B\*5512 allele.

<sup>8</sup>Primer mix 9: Specific PCR fragment of 215 bp in the B\*5516 and B\*4202, 4209, 4506 and 5402 alleles. Specific PCR fragment of 325 bp in the B\*5511, 5514 and B\*4030, 4034 and 5712 alleles.

<sup>9</sup>Primer mix 11: Specific PCR fragment of 125 bp in the B\*5515 allele. Specific PCR fragment of 180 bp in the B\*5509, 5522, 5524 and B\*1301-130204, 1307N-1309, 1311, 1314-1320 and 4048 alleles.

<sup>10</sup>Primer mix 18: Specific PCR fragment of 215 bp in the B\*5525 allele. Specific PCR fragment of 310 bp in the B\*5519 allele. Specific PCR fragment of 395 bp in the B\*5518 allele.

<sup>11</sup>Primer mix 20: Specific PCR fragment of 220 bp in the B\*5520 and B\*0809, 1583, 4101, 4105-4107, 4204, 4415, 4418, 4420, 4501-4508, 5108, 5120, 5136, 5144N and 5613 alleles. Specific PCR fragment of 95 bp in the B\*5526 allele.



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<sup>12</sup>Primer mix 23: Specific PCR fragment of 165 bp in the B\*5529 allele. Specific PCR fragment of 220 bp in the B\*5521 and B\*1504 and 9537 alleles.

\*?\*, nucleotide sequence of the primer matching region is not known.

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<b>INTERPRETATION TABLE</b>												
<b>HLA-B*55 SSP subtyping</b>												
<b>Amplification patterns of the B*5501 to B*5530 alleles</b>												
	<b>Well<sup>5</sup></b>											
	1	2	3	4	5	6	7	8	9	10	11	12
Length of spec.	400	125	150	235	235	100	180	105	215	140	125	210
PCR products								425	325		180	
Length of int.	800	1070	1070	1070	800	1070	1070	800	1070	1070	1070	1070
pos. control <sup>1</sup>												
5'-primer(s) <sup>2</sup>	41	379	420	106	363	245	419	48	97	106	186	103
	5'-CTg <sup>3'</sup>	5'-ACC <sup>3'</sup>	5'-TTA <sup>3'</sup>	5'-CCA <sup>3'</sup>	5'-AgC <sup>3'</sup>	5'-ggC <sup>3'</sup>	5'-gTA <sup>3'</sup>	5'-gCC <sup>3'</sup>	5'-TCC <sup>3'</sup>	5'-CCA <sup>3'</sup>	5'-AgA <sup>3'</sup>	5'-CCT <sup>3'</sup>
								357	319		420	
								5'-Tgg <sup>3'</sup>	5'-gCg <sup>3'</sup>		5'-TTA <sup>3'</sup>	
3'-primer(s) <sup>3</sup>	272	463	527	299	559	302	559	302	272	206	272	272
	5'-TgT <sup>3'</sup>	5'-gCT <sup>3'</sup>	5'-CCT <sup>3'</sup>	5'-TCA <sup>3'</sup>	5'-CgT <sup>3'</sup>	5'-ggC <sup>3'</sup>	5'-CAg <sup>3'</sup>	5'-ggT <sup>3'</sup>	5'-TgT <sup>3'</sup>	5'-CCC <sup>3'</sup>	5'-TgT <sup>3'</sup>	5'-TgT <sup>3'</sup>
								419	362		559	
								5'-CgA <sup>3'</sup>	5'-TCA <sup>3'</sup>		5'-CTC <sup>3'</sup>	
Well No.	1	2	3	4	5	6	7	8	9	10	11	12
HLA-B allele <sup>4</sup>												
*550101-550104	1	2	3									
*550201-550202	1	2										
*5503	1	2	3	4								
*5504	1				5							
*5505	1	2	3			6						
*5507	1	2								10		
*5508	1						7					
*5509	1	2	w								11	
*5510	1	2										12
*5511	1	2	3						9			
*5512	1	2						8				
*5513	1	2						8				
*5514	1								9			
*5515	1	2	3								11	
*5516	1	2							9			
*5517	1											
*5518		2										
*5519	1	2										
*5520	1											
Well No.	1	2	3	4	5	6	7	8	9	10	11	12

Lot No.: **55E**

Lot-specific information

<b>INTERPRETATION TABLE</b>												
<b>HLA-B*55 SSP subtyping</b>												
<b>Amplification patterns of the B*5501 to B*5530 alleles</b>												
<b>Well<sup>5</sup></b>												
13	14	15	16	17	18	19	20	21	22	23	24	
150	215	245	245	105	215	205	95	270	225	165	100	Length of spec.
					310		220			220		PCR products
					395							
1070	800	1070	1070	1070	800	800	1070	800	1070	800	1070	Length of int.
												pos. control <sup>1</sup>
420	1 <sup>st</sup> I	357	357	357	48	134	106	41	357	357	357	5'-primer(s) <sup>2</sup>
5'-TTA <sup>3'</sup>	5'-CAG <sup>3'</sup>	5'-Tgg <sup>3'</sup>	5'-Tgg <sup>3'</sup>	5'-Tgg <sup>3'</sup>	5'-gCC <sup>3'</sup>	5'-CCA <sup>3'</sup>	5'-CCA <sup>3'</sup>	5'-CTg <sup>3'</sup>	5'-Tgg <sup>3'</sup>	5'-Tgg <sup>3'</sup>	5'-Tgg <sup>3'</sup>	
							357					
							5'-Tgg <sup>3'</sup>					
527	175	559	559	419	94	299	160	142	539	479	412	3'-primer(s) <sup>3</sup>
5'-CCA <sup>3'</sup>	5'-CCg <sup>3'</sup>	5'-CgT <sup>3'</sup>	5'-CAG <sup>3'</sup>	5'-CgT <sup>3'</sup>	5'-gAC <sup>3'</sup>	5'-TCT <sup>3'</sup>	5'-gTT <sup>3'</sup>	5'-TgA <sup>3'</sup>	5'-TCC <sup>3'</sup>	5'-CCA <sup>3'</sup>	5'-gTC <sup>3'</sup>	
					187		538			538	419	
					5'-gTT <sup>3'</sup>		5'-gTC <sup>3'</sup>			5'-CCA <sup>3'</sup>	5'-Cgg <sup>3'</sup>	
					272						419	
					5'-Tgg <sup>3'</sup>						5'-CgA <sup>3'</sup>	
13	14	15	16	17	18	19	20	21	22	23	24	Well No.
												HLA-B allele <sup>4</sup>
		15										*550101-550104
13		15										*550201-550202
		15										*5503
												*5504
		15										*5505
13		15										*5507
												*5508
									22			*5509
13		15						21				*5510
		15										*5511
13		15										*5512
		15									24	*5513
												*5514
		15										*5515
13		15										*5516
		15		17								*5517
13		15			18							*5518
13		15			18							*5519
		15		17			20					*5520
13	14	15	16	17	18	19	20	21	22	23	24	Well No.

Lot No.: **55E**

Lot-specific information

Length of spec.	400	125	150	235	235	100	180	105	215	140	125	210
PCR products								425	325		180	
Well No.	1	2	3	4	5	6	7	8	9	10	11	12
*5521	1	2										
*5522	1	2									11	
*5523	1	2										
*5524	1	2	3								11	
*5525	1	2	3									
*5526	1	2										
*5527	1	2										
*5528	1	2										
*5529	1	2	3									
*5530	1	2										
*070201-070207, 0704-0707, 0709, 0711, 0712, 0714, 0715, 0717-071802, 0721-0723, 0725, 0726, 0728, 0730, 0733, 0735, 0736, 0739-0742, 0744-0749N, 0751-0759, 0761-0764, 670101-670102, 8102												12
*0719, 0731, 0734, 0743, 4201, 420501-4206, 4208					5							12
*0720, 0724, 0760							7					12
*080101-0808N, 0810, 0813, 0814, 0817-0820, 0822-0824, 0826-0836, 1405, 3587, 3903, 3914, 3924, 3929, 3937, 4039, 4102, 4104, 4207					5							
*0809, 1583, 4101, 4105-4107, 5136												
*0815				4	5							
*0821, 0825, 1509, 1510, 1530, 1537, 1545, 1548, 1563, 1590, 1599, 350901-350902, 3512, 3518, 3522, 3539, 3544, 4005, 4026, 4063, 5104, 5106, 5146, 5702-570302, 5707, 5709							7					
Well No.	1	2	3	4	5	6	7	8	9	10	11	12

Lot No.: **55E**

Lot-specific information

150	215	245	245	105	215	205	95	270	225	165	100	Length of spec. PCR products
					310		220			220		
					395							
13	14	15	16	17	18	19	20	21	22	23	24	Well No.
		15							22	23		*5521
13												*5522
		15									24	*5523
												*5524
		15			18							*5525
13		15					20					*5526
		15		17							24	*5527
		15		17								*5528
		15							23			*5529
13		15				19						*5530
												*070201-070207, 0704-0707, 0709, 0711, 0712, 0714, 0715, 0717-071802, 0721-0723, 0725, 0726, 0728, 0730, 0733, 0735, 0736, 0739-0742, 0744-0749N, 0751-0759, 0761-0764, 670101-670102, 8102
												*0719, 0731, 0734, 0743, 4201, 420501-4206, 4208
												*0720, 0724, 0760
												*080101-0808N, 0810, 0813, 0814, 0817-0820, 0822-0824, 0826-0836, 1405, 3587, 3903, 3914, 3924, 3929, 3937, 4039, 4102, 4104, 4207
		15		17			20					*0809, 1583, 4101, 4105-4107, 5136
												*0815
												*0821, 0825, 1509, 1510, 1530, 1537, 1545, 1548, 1563, 1590, 1599, 350901-350902, 3512, 3518, 3522, 3539, 3544, 4005, 4026, 4063, 5104, 5106, 5146, 5702-570302, 5707, 5709
13	14	15	16	17	18	19	20	21	22	23	24	Well No.

Lot No.: **55E**

Lot-specific information

Length of spec.	400	125	150	235	235	100	180	105	215	140	125	210
PCR products								425	325		180	
Well No.	1	2	3	4	5	6	7	8	9	10	11	12
*1301-130204, 1307N-1309, 1311, 1314, 1315, 1317, 1319		2									11	
*1303, 5115, 5614, 5617		2										
*1304, 1516, 1567, 1595, 3537, 4904, 4905		2										
*1306, 1312, 1586, 4410		2										
*1313, 1520, 1534, 1562, 1585, 350101-350107, 3503, 3505-350803, 3510, 3511, 3513-3515, 3519-3521, 3523, 3524, 3526-3530, 3533, 3535, 3536, 3538, 3540N-3542, 3545-3550, 3552, 3554-3558, 3562, 3563, 3565Q, 3566, 356801-3573, 3575, 3577, 3578, 3580, 3582, 3584, 3585, 4448, 4802, 530101-5306, 5308-5316, 580101-5802, 5804-5807, 5809-5811, 5813-5817N		2										
*1316, 1320		2	3								11	
*1318		2									11	
*150104												
*1504												
*1542		2	3									
*9537		2						8				
*180101-1803, 1805-1813, 1815, 1818-1821, 1823N-1828, 370101-370103, 3702-3708, 3710-3713												
*1814, 3709					5							
*1822		2			w							
*2714		2										
*350201-350202, 350401-350402, 3534, 3581, 3583, 4028, 5705		2					7					
Well No.	1	2	3	4	5	6	7	8	9	10	11	12

Lot No.: **55E**

Lot-specific information

150	215	245	245	105	215	205	95	270	225	165	100	Length of spec. PCR products
					310		220			220		
					395							
13	14	15	16	17	18	19	20	21	22	23	24	Well No.
13												*1301-130204, 1307N-1309, 1311, 1314, 1315, 1317, 1319
13			16									*1303, 5115, 5614, 5617
			16								24	*1304, 1516, 1567, 1595, 3537, 4904, 4905
13												*1306, 1312, 1586, 4410
												*1313, 1520, 1534, 1562, 1585, 350101-350107, 3503, 3505-350803, 3510, 3511, 3513-3515, 3519- 3521, 3523, 3524, 3526- 3530, 3533, 3535, 3536, 3538, 3540N-3542, 3545- 3550, 3552, 3554-3558, 3562, 3563, 3565Q, 3566, 356801-3573, 3575, 3577, 3578, 3580, 3582, 3584, 3585, 4448, 4802, 530101- 5306, 5308-5316, 580101- 5802, 5804-5807, 5809- 5811, 5813-5817N
												*1316, 1320
w												*1318
	14											*150104
			16						22	23	24	*1504
		15										*1542
			16						22	23	24	*9537
								21				*180101-1803, 1805-1813, 1815, 1818-1821, 1823N- 1828, 370101-370103, 3702 3708, 3710-3713
								21				*1814, 3709
								21				*1822
				17								*2714
												*350201-350202, 350401- 350402, 3534, 3581, 3583, 4028, 5705
13	14	15	16	17	18	19	20	21	22	23	24	Well No.

Lot No.: **55E**

Lot-specific information

Length of spec.	400	125	150	235	235	100	180	105	215	140	125	210
PCR products								425	325		180	
Well No.	1	2	3	4	5	6	7	8	9	10	11	12
*3525, 5812		2										
*3560, 5623, 5901		2										
*3574		2		4								
*3576, 5609, 5611	1	2										
*370104												
*390601-390602, 3934								8				
*3933								8				
*40060101-400602, 4044, 4053, 4070, 4075, 4083, 5110, 5116, 5131, 5134, 5208												
*4030, 4034									9			
*4048											11	
*4071												
*4073, 460101-4604, 4606- 4610, 4612-4614				4								
*4086, 7301								8				
*4202, 4209					5				9			
*4204												12
*4415, 4418, 4501, 4503- 4505, 4507		2										
*4420												
*4447												
*4502		2						8				
*4506		2							9			
*4508		2										
*4611		2		4								
*4901-4903, 5001, 5002		2										
*5004												
*510101-5103, 5107, 510901-510902, 5111N, 5112, 5118, 5119, 5122- 512402, 5126-5128, 5130, 5132, 5133, 5135, 5138- 5141N, 5143, 5148-5153, 5155, 520101-5207, 5209- 5211, 5808, 7801-7805								7				
*5105, 5129, 5154								7				
Well No.	1	2	3	4	5	6	7	8	9	10	11	12



Lot No.: **55E**

Lot-specific information

150	215	245	245	105	215	205	95	270	225	165	100	Length of spec. PCR products
					310		220			220		
					395							
13	14	15	16	17	18	19	20	21	22	23	24	Well No.
								21				*3525, 5812
13		15										*3560, 5623, 5901
												*3574
												*3576, 5609, 5611
	14							21				*370104
		15									24	*390601-390602, 3934
			16						22		24	*3933
				17								*40060101-400602, 4044, 4053, 4070, 4075, 4083, 5110, 5116, 5131, 5134, 5208
												*4030, 4034
13												*4048
13												*4071
												*4073, 460101-4604, 4606- 4610, 4612-4614
											24	*4086, 7301
												*4202, 4209
		15		17			20					*4204
			16				20					*4415, 4418, 4501, 4503- 4505, 4507
			16	17			20				24	*4420
			16	17							24	*4447
			16				20				24	*4502
			16				20					*4506
		15					20					*4508
13		15										*4611
			16									*4901-4903, 5001, 5002
			16									*5004
			16	17								*510101-5103, 5107, 510901-510902, 5111N, 5112, 5118, 5119, 5122- 512402, 5126-5128, 5130, 5132, 5133, 5135, 5138- 5141N, 5143, 5148-5153, 5155, 520101-5207, 5209- 5211, 5808, 7801-7805
			16	17					22			*5105, 5129, 5154
13	14	15	16	17	18	19	20	21	22	23	24	Well No.

Lot No.: **55E**

Lot-specific information

Length of spec.	400	125	150	235	235	100	180	105	215	140	125	210
PCR products								425	325		180	
Well No.	1	2	3	4	5	6	7	8	9	10	11	12
*5108, 5120, 5144N					7							
*511301-511302								8				
*5114, 5117												
*5121, 5902												
*5137												
*5212							7					
*5401, 5408N, 5412, 5413	1	2							10			
*5402	1	2							9			
*5403	1	2							10			
*5404	1	2								10		
*5405N	1	2										
*5406, 5409	1									10		
*5407		2							10			
*5410	1	2								10		
*5411	1								10			
*5601, 5607	1	2										
*5602, 5610, 5619N	1	2										
*5603, 5612, 5618	1											
*5604	1											
*560501-5606, 5621	1						7					
*5608	w	2										
*5613	1	2										
*5615	1	2							7			
*5616	1	2										
*5620	1											
*5622	1	2						8				
*5712					7				9			
*8101	1											12
*8103, 8104N	?								12			
*8201, 8202	1	2										
*8301	1											
HLA-B allele <sup>4</sup>												
Well No.	1	2	3	4	5	6	7	8	9	10	11	12
Cw*0808					5							
Well No.	1	2	3	4	5	6	7	8	9	10	11	12

Lot No.: **55E**

Lot-specific information

150	215	245	245	105	215	205	95	270	225	165	100	Length of spec. PCR products
					310		220			220		
					395							
13	14	15	16	17	18	19	20	21	22	23	24	Well No.
			16	17			20					*5108, 5120, 5144N
			16								24	*511301-511302
			16	17								*5114, 5117
		15		17								*5121, 5902
			16								24	*5137
			16	17							24	*5212
13	14	15										*5401, 5408N, 5412, 5413
13	14	15										*5402
13	14		16									*5403
	14	15		17								*5404
13	14	15										*5405N
	14											*5406, 5409
13	14	15										*5407
w	14	15							22			*5410
	14	15		17								*5411
13			16									*5601, 5607
13												*5602, 5610, 5619N
												*5603, 5612, 5618
13												*5604
			16	17								*560501-5606, 5621
13			16									*5608
			16				20					*5613
			16	17								*5615
13			16					21				*5616
13			16									*5620
			16								24	*5622
												*5712
								21				*8101
								?				*8103, 8104N
								21				*8201, 8202
								21				*8301
												HLA-B allele <sup>4</sup>
13	14	15	16	17	18	19	20	21	22	23	24	Well No.
												Cw*0808
13	14	15	16	17	18	19	20	21	22	23	24	Well No.

**Lot No.: 55E**

**Lot-specific information**

<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 430 base pairs, for most wells, or a band of 515 base pairs, for some wells.

Well number 1 contains the primer pair giving rise to the longer, 515 bp, internal positive control band in order to help in the correct orientation of the HLA-B\*55 subtyping.

In addition, wells number 5, 8, 14, 18, 19, 21 and 23 contain the primer pair giving rise to the longer, 515 bp, internal positive control band in order to allow kit identification.

<sup>2</sup>The codon, in the 1<sup>st</sup>, 2<sup>nd</sup> or 3<sup>rd</sup> exon or the 1<sup>st</sup> intron, matching the specificity-determining 3'-end of the primer is given. Codon numbering as in *Tissue Antigens* 1998, **51:II**, 467-507. The sequence of the 3 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 codon, 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.

<sup>4</sup>The B\*5506 sequence shown to contain errors and be identical to B\*5504.

<sup>5</sup>Primer mix 8: Specific PCR fragment of 105 bp in the B\*5513 and B\*9537, 390601-390602, 3933, 3934, 4086, 4502, 511301-511302, 5622 and 7301 alleles. Specific PCR fragment of 425 bp in the B\*5512 allele.

Primer mix 9: Specific PCR fragment of 215 bp in the B\*5516 and B\*4202, 4209, 4506 and 5402 alleles. Specific PCR fragment of 325 bp in the B\*5511, 5514 and B\*4030, 4034 and 5712 alleles.

Primer mix 11: Specific PCR fragment of 125 bp in the B\*5515 allele. Specific PCR fragment of 180 bp in the B\*5509, 5522, 5524 and B\*1301-130204, 1307N-1309, 1311, 1314-1320 and 4048 alleles.

Primer mix 18: Specific PCR fragment of 215 bp in the B\*5525 allele. Specific PCR fragment of 310 bp in the B\*5519 allele. Specific PCR fragment of 395 bp in the B\*5518 allele.

Primer mix 20: Specific PCR fragment of 220 bp in the B\*5520 and B\*0809, 1583, 4101, 4105-4107, 4204, 4415, 4418, 4420, 4501-4508, 5108, 5120, 5136, 5144N and 5613 alleles. Specific PCR fragment of 95 bp in the B\*5526 allele.

Primer mix 23: Specific PCR fragment of 165 bp in the B\*5529 allele. Specific PCR fragment of 220 bp in the B\*5521 and B\*1504 and 9537 alleles.

'w', may be weakly amplified.

'?', the nucleotide sequence of the primer matching region is not know.

Lot No.: **55E**

Lot-specific information

CELL LINE VALIDATION SHEET																					
HLA-B*55 SSP subtyping kit																					
				Prod. No.:	Well																
					1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	
					200732701	200845902	200845903	200732704	200732705	200732706	200732707	200732708	200732709	200732710	200732711	200732712	200732713	200732714	200732715	200732716	
	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	9067	BTB	*2705		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
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	*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	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

Lot No.: **55E**

Lot-specific information

CELL LINE VALIDATION SHEET														
HLA-B*55 SSP subtyping kit														
				Prod. No.:	Well									
					17	18	19	20	21	22	23	24		
					200732717	200845918	200845919	200845920	200732721	200732722	200845923	200845924		
	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	9067 BTB		*2705		-	-	-	-	-	-	-	-	-	-
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		*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	-	-	-	-	-	-	-	-	-	-

Lot No.: **55E**

Lot-specific information

## CERTIFICATE OF ANALYSIS

### **Olerup SSP<sup>®</sup> HLA-B\*55 SSP**

**Product number:** 101.570-06u – without *Taq* polymerase  
**Lot number:** 55E  
**Expiry date:** 2010-May-01  
**Number of tests:** 6  
**Number of wells per test:** 24

#### **Well specifications:**

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2007-327-01	9	2007-327-09	17	2007-327-17
2	2008-459-02	10	2007-327-10	18	2008-459-18
3	2008-459-03	11	2007-327-11	19	2008-459-19
4	2007-327-04	12	2007-327-12	20	2008-459-20
5	2007-327-05	13	2007-327-13	21	2007-327-21
6	2007-327-06	14	2007-327-14	22	2007-327-22
7	2007-327-07	15	2007-327-15	23	2008-459-23
8	2007-327-08	16	2007-327-16	24	2008-459-24

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, 9, 18 and 19 were available. The specificities of the primers in primer solutions 9 and 18 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer. In primer solution 6 it was only possible to test the 3'-primer, the 5'-primer was not possible to test. In primer solution 9 it was not possible to test one of the 3'-primers. In primer solution 19 it was only possible to test the 5'-primer, the 3'-primer was not possible to test. Additional 5'-primers in primer solutions 5 and 8, and additional 3'-primers in primer solutions 8 and 11 were tested by separately adding one additional 3'-primer, respectively one additional 5'-primer.

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

**Date of approval:** 2009-May-27

**Approved by:**

**Quality Control, Supervisor**

Lot No.: **55E**

Lot-specific information

## Declaration of Conformity

**Product name:** *Olerup* SSP® HLA-B\*55  
**Product number:** 101.570-06u  
**Lot number:** 55E

**Intended use:** HLA-B\*55 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.: **55E**

Lot-specific information

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