

101.572-12– including *Taq* pol., IFU-01  
 101. 572-12u– without *Taq* pol., IFU-02

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 “Instructions for Use” (IFU)

Lot No.: **14R**

Lot-specific information

## **Olerup SSP<sup>®</sup> HLA-B\*57:01**

<b>Product number:</b>	<b>101.572-12 – including <i>Taq</i> polymerase</b> <b>101.572-12u – without <i>Taq</i> polymerase</b>
<b>Lot number:</b>	<b>14R</b>
<b>Expiry date:</b>	<b>2015-February-01</b>
<b>Number of tests:</b>	<b>12</b>
<b>Number of wells per test:</b>	<b>15+1</b>
<b>Storage - pre-aliquoted primers:</b>	<b>dark at -20°C</b>
- PCR Master Mix:	-20°C
- Adhesive PCR seals	RT
- Product Insert	RT

**This Product Description is only valid for Lot No. 14R.**

### **CHANGES COMPARED TO THE PREVIOUS OLERUP SSP<sup>®</sup> HLA-B\*57:01 LOT (86M).**

Three wells have been added to the HLA-B\*57:01 kit, wells **14 to 16**.

The Lot-specific information for HLA-B\*57:01 including and without *Taq* polymerase is now described in one common Product Insert.

The HLA-B\*57:01 specificity and interpretation tables have been updated for the HLA-B alleles described since the previous *Olerup SSP<sup>®</sup>* HLA-B\*57:01 lot was made (**Lot No. 86M**).

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

Well	5'-primer	3'-primer	rationale
7	-	Added	Primers added for the B*57:50 and 57:53 alleles.
10	-	Modified	Improved specificity of HLA-specific primer pair.
13	New, removed	New, removed	New primer pairs for the B*57:45 and 57:49 alleles, negative control moved to well 13.
14	New	New	New primer pairs for the B*57:47 and 57:54 alleles.
15	New	New	New primer pairs for the B*57:56, 57:57 and 57:48 alleles
16	New	New	Negative control from well 13.

Change in revision R01 compared to R00:

1. Primer mix 11 amplifies weakly the B\*57:40 allele. This has been corrected in the Specificity and Interpretation Tables.

101.572-12– including *Taq* pol., IFU-01  
 101. 572-12u– without *Taq* pol., IFU-02

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Lot No.: **14R**

**Lot-specific information**

Well **16** contains Negative Control primer pairs, that will amplify more than 95% of the *Olerup* SSP<sup>®</sup> HLA Class I, DRB, DQB1 and DPB1 amplicons as well as amplicons generated by control primer pairs.

PCR product sizes range from 75 to 430 base pairs.

The PCR product generated by the control primer pair is 430 base pairs.

Length of PCR product	105	200	105	80	75	80
<b>5'-primer<sup>1</sup></b>	<b>164</b>	<b>340</b>	<b>440</b>	<b>45</b>	<b>45</b>	<b>43</b>
	<sup>5</sup> -CAC <sup>3</sup>	<sup>5</sup> -Agg <sup>3</sup>	<sup>5</sup> -TTA <sup>3</sup>	<sup>5</sup> -Tgg <sup>3</sup>	<sup>5</sup> -Tgg <sup>3</sup>	<sup>5</sup> -Tgg <sup>3</sup>
<b>3'-primer<sup>2</sup></b>	<b>231</b>	<b>2<sup>nd</sup> I</b>	<b>507</b>	<b>59</b>	<b>58</b>	<b>57</b>
	<sup>5</sup> -TgC <sup>3</sup>	<sup>5</sup> -AAA <sup>3</sup>	<sup>5</sup> -TTg <sup>3</sup>	<sup>5</sup> -CTC <sup>3</sup>	<sup>5</sup> -ggC <sup>3</sup>	<sup>5</sup> -CTC <sup>3</sup>
<b>A*</b>	<b>+</b>	<b>+</b>	<b>+</b>			
<b>B*</b>	<b>+</b>	<b>+</b>	<b>+</b>			
<b>C*</b>	<b>+</b>	<b>+</b>	<b>+</b>			
<b>DRB1</b>				<b>+</b>	<b>+</b>	
<b>DRB3</b>				<b>+</b>	<b>+</b>	
<b>DRB5</b>				<b>+</b>		
<b>DQB1</b>					<b>+</b>	
<b>DPB1</b>						<b>+</b>

<sup>1</sup>The nucleotide position for HLA class I genes and the codon for HLA class II genes, in the 2<sup>nd</sup> or 3<sup>rd</sup> exon, matching the specificity-determining 3'-end of the primer is given. Nucleotide and codon 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>2</sup>The nucleotide position for HLA class I genes and the codon for HLA class II genes, in the 2<sup>nd</sup> or 3<sup>rd</sup> exon or the 2<sup>nd</sup> intron, matching the specificity-determining 3'-end of the primer is given in the anti-sense direction. Nucleotide and codon 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.

101.572-12– including *Taq* pol., IFU-01  
101. 572-12u– without *Taq* pol., IFU-02

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Lot No.: **14R**

Lot-specific information

101.572-12– including *Taq pol.*, IFU-01  
 101. 572-12u– without *Taq pol.*, IFU-02

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Lot No.: **14R**

Lot-specific information

## PRODUCT DESCRIPTION

### HLA-B\*57:01 SSP subtyping

#### CONTENT

The primer set contains 5'- and 3'-primers for identifying the B\*57:01:01 to 57:01:13 alleles.

#### PLATE LAYOUT

Each test consists of 16 PCR reactions in a 16 well cut PCR plate.

<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>9</b>	<b>10</b>	<b>11</b>	<b>12</b>	<b>13</b>	<b>14</b>	<b>15</b>	<b>16</b>

Wells 1 to 15 – HLA-B\*57:01 primers.

Well 16 – Negative Control.

The 16 well cut PCR plate is marked with ‘B\*57:01’ in silver/gray ink.

Well No. 1 is marked with the Lot No. ‘14R’.

A faint row of numbers is seen between wells 1 and 2 or wells 7 and 8 of the PCR trays. These stem from the manufacture of the trays, and should be disregarded.

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\*57:01 SSP subtypings will influence by the other B\*57 alleles and also by the B\*07:120, 14:20, 15:33, 15:214, 35:127, 40:30, 40:34, 40:150, 51:126, 55:14, 58:14 and 58:36 alleles. In addition, primer mix 13 will amplify the A\*02:285 allele, primer mix 14 will amplify the C\*03:87, C\*05:27 and C\*05:39 alleles, primer mix 15 will amplify the A\*33:12 allele and primer mixes 5, 7, 10 and 11 will amplify the C\*06:72 allele.

#### UNIQUELY IDENTIFIED ALLELES

HLA-B\*57:01 will give rise to a unique amplification pattern by the primers in the HLA-B\*57:01 kit<sup>1</sup>.

The HLA-B\*57:01 typing kit cannot distinguish the silent mutations in the B\*57:01:01 to B\*57:01:13 alleles.

<sup>1</sup>HLA-B alleles listed on the IMGT/HLA web page 2012-July-12, release 3.9.0, [www.ebi.ac.uk/imgt/hla](http://www.ebi.ac.uk/imgt/hla).

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Lot No.: **14R**

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**SPECIFICITY TABLE**

**HLA-B\*57:01 SSP subtyping**

Specificities and sizes of the PCR products of the 15+1 primer mixes used for HLA-B\*57:01 SSP subtyping

Primer Mix	Size of spec. PCR product <sup>1</sup>	Size of control band <sup>2</sup>	Amplified HLA-B*57:01 alleles	Other amplified HLA-B alleles <sup>3,4</sup>
<b>1<sup>5</sup></b>	90 bp	<b>800 bp</b>	*57:01:01-57:01:13	*57:02:01-57:15, 57:17-57:19, 57:21-57:35, 57:37-57:44, 57:46-57:50, 57:52-57:57, <b>58:36</b>
<b>2</b>	220 bp	<b>800 bp</b>	*57:01:01-57:01:13,	*57:03:01-57:03:02, 57:06-57:08, 57:10, 57:14-57:18, 57:20-57:23, 57:25-57:27, 57:29, 57:31-57:41, 57:43-57:51, 57:53-57:57, <b>40:30, 40:34, 55:14, 58:14</b>
<b>3<sup>5,7</sup></b>	95 bp, 170 bp, 215 bp	<b>800 bp</b>		*57:04, 57:06, 57:18, 57:27, 57:32
<b>4<sup>5</sup></b>	100 bp	1070 bp		*57:15, 57:20, 57:29, <b>07:120, 15:214, 40:150</b>
<b>5<sup>5,8</sup></b>	90 bp, 165 bp, 245 bp	<b>800 bp</b>		*57:07, 57:16, 57:23, 57:26, 57:34, <b>55:14, C*06:72</b>
<b>6<sup>5,9</sup></b>	90 bp, 210 bp, 380 bp	1070 bp		*57:02:01-57:03:02, 57:07-57:09, 57:12, 57:17, 57:39, 57:42, 57:46, 57:57, <b>40:30, 40:34</b>
<b>7<sup>5,6,10</sup></b>	100 bp, 140 bp, 175 bp, 215 bp, 240 bp	1070 bp		*57:09, 57:13-57:14, 57:24-57:25, 57:31, 57:50, 57:53, <b>40:30, 40:34, 55:14, 58:14, C*06:72</b>
<b>8</b>	185 bp	1070 bp		*57:10, 57:44
<b>9<sup>5,11</sup></b>	110 bp, 150 bp	<b>800 bp</b>		*57:21, 57:33, 57:40, <b>14:20, 35:127</b>
<b>10<sup>5,6,12</sup></b>	90 bp, 170 bp, 205 bp, 240 bp	1070 bp		*57:04, 57:13, 57:22, 57:37, 57:41, 57:43, 57:57, <b>55:14, C*06:72</b>
<b>11<sup>5</sup></b>	100 bp	1070 bp	*57:01:01-57:01:13	*57:06, 57:08, 57:10, 57:13-57:16, 57:18-57:27, 57:29-57:31, 57:33-57:38, 57:40 <sup>w</sup> , 57:41, 57:43-57:45,

101.572-12– including *Taq* pol., IFU-01  
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 “Instructions for Use” (IFU)

Lot No.: **14R**

Lot-specific information

			57:47-57:52, 57:54-57:56, <b>55:14, 58:14, C*06:72</b>
<b>12<sup>5,13</sup></b>	75 bp, 100 bp, 135 bp	1070 bp	*57:35-57:36, 57:38
<b>13<sup>5,14</sup></b>	105 bp, 200 bp	1070 bp	*57:45, 57:49, 57:51, <b>A*02:285</b>
<b>14<sup>5</sup></b>	125 bp	1070 bp	*57:47, 57:54, <b>15:33,</b> <b>51:126, C*03:87, C*05:27,</b> <b>C*05:39</b>
<b>15<sup>15</sup></b>	145 bp, 185 bp, 295 bp	1070 bp	*57:48, 57:55-57:56, <b>A*33:12</b>
<b>16<sup>16</sup></b>	-	-	<b>Negative control</b>

<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\*57:01 SSP typings.

When the primers in a primer mix can give rise to specific PCR products of more than one length this is indicated if the size difference is 20 base pairs or more. Size differences shorter than 20 base pairs are not given. For high resolution SSP kits the respective lengths of the specific PCR product(s) of the alleles amplified by these primer mixes are given.

Nonspecific amplifications, i.e. a ladder or a smear of bands, may sometimes be seen. GC-rich primers have a higher tendency of giving rise to nonspecific amplifications than other primers.

PCR fragments longer than the control bands may sometimes be observed. Such bands should be disregarded and do not influence the interpretation of the SSP typings.

PCR fragments migrating faster than the control bands, but slower than a 400 bp fragment may be seen in some gel read-outs. Such bands can be disregarded and do not influence the interpretation of the SSP typings.

Some primers may give rise to primer oligomer artifacts. Sometimes this phenomenon is an inherent feature of the primer pair(s) of a primer mix. More often it is due to other factors such as too low amount of DNA in the PCR reactions, taking too long time in setting up the PCR reactions, working at elevated room temperature or using thermal cyclers that are not pre-heated.

<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\*57:01 subtyping.

In addition, wells number 2, 3, 5 and 9 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, 4 to 7, 9 to 11 and 14. In addition, primer mix 13 will amplify the A\*02:285 allele, primer mix 14 will amplify the C\*03:87, C\*05:27 and C\*05:39 alleles, primer mix 15 will amplify the A\*33:12 allele and primer mixes 5, 7, 10 and 11 will amplify the C\*06:72 allele.

<sup>3</sup>For several HLA-B alleles fourth and fifth exon and intron nucleotide sequences are not available. In these instances it is not known whether some of the primers of the SSP sets are completely matched with the target sequences or not. We assume that unknown sequences in these first regions are conserved within allelic groups.

<sup>5</sup>Short specific PCR fragments are less intense and not as sharp as longer specific bands.

<sup>6</sup>Primer mixes 7 and 10 have a tendency of giving rise to nonspecific amplifications.

<sup>7</sup>Primer mix 3: Specific PCR fragment of 95 bp in the B\*57:04 and 57:32 alleles. Specific PCR fragment of 170 bp in the B\*57:06 and B\*57:18 alleles. Specific PCR fragment of 215 bp in the B\*57:27 allele.

<sup>8</sup>Primer mix 5: Specific PCR fragment of 90 bp in the B\*57:16 and 57:34 alleles. Specific PCR fragment of 165 bp in the B\*57:23 allele. Specific PCR fragment of 245 bp in the B\*57:07 and 57:26 and the B\*55:14 and in the C\*06:72 alleles.

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“Instructions for Use” (IFU)

**Lot No.: 14R****Lot-specific information**

<sup>9</sup>Primer mix 6: Specific PCR fragment of 90 bp in the B\*57:02:01-57:03:02, 57:07, 57:09, 57:12, 57:17, 57:39, 57:42, 57:46 and 57:57 and the B\*40:30 and 40:34 alleles. Specific PCR fragment of 210 bp in the B\*57:08 allele.

<sup>10</sup>Primer mix 7: Specific PCR fragment of 100 bp in the B \*57:53 allele. Specific PCR fragment of 140 bp in the B\*57:31 and in the C\*06:72 alleles. Specific PCR fragment of 175 bp in the B\*57:14 and 57:50 and B\*55:14 and 58:14 alleles. Specific PCR fragment of 215 bp in the B\*57:09 and 57:24 alleles. Specific PCR fragment of 240 bp in the B\*57:25 allele. Specific PCR fragment of 140 and 240bp in the B\*57:13 and in the B\*40:30 and 40:34 alleles.

<sup>11</sup>Primer mix 9: Specific PCR fragment of 110 bp in the B\*57:33 allele. Specific PCR fragment of 150 bp in the B\*57:21 and 57:40 and in the B\*14:20 and 35:127 alleles.

<sup>12</sup>Primer mix 10: Specific PCR fragment of 90 bp in the B\*57:04 and 57:41 and the C\*06:72 alleles. Specific PCR fragment of 170 bp in the B\*57:37 allele. Specific PCR fragment of 205 bp in the B\*57:13, 57:22 and 57:57 and the 55:14 and in the C\*06:72<sup>w</sup> alleles.

Specific PCR fragment of 240 bp in the B\*57:43 allele. <sup>13</sup>Primer mix 12: Specific PCR fragment of 75 bp in the B\*57:35 allele. Specific PCR fragment of 100 bp in the B \*57:36 allele. Specific PCR fragment of 135 bp in the B \*57:38 allele.

<sup>14</sup>Primer mix 13: Specific PCR fragment of 105 bp in the B\*57:45 and 57:51 and in the A\*02:285 alleles. Specific PCR fragment of 200 bp in the B\*57:49 allele.

<sup>15</sup>Primer mix 15: Specific PCR fragment of 145 bp in the B \*57:56 allele. Specific PCR fragment of 185 bp in the B \*57:48 and in the A\*33:12 alleles. Specific PCR fragment of 295 bp in the B\*57:55 allele.

<sup>16</sup>Well 16 contains a negative control, which will amplify more than 95% of HLA amplicons as well as the amplicons generated by control primer pairs. PCR product sizes range from 75 to 200 base pairs. The PCR product generated by the control primer pair is 430 base pairs.

101.572-12- including *Taq* pol., IFU-01  
 101.572-12u- without *Taq* pol., IFU-02

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 "Instructions for Use" (IFU)

Lot No.: 14R

Lot-specific information

INTERPRETATION TABLE																
HLA-B*57:01 SSP typing																
	Well <sup>4,5</sup>															
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
Length of spec.	90	220	95	100	90	90	100	185	110	90	100	75	105	125	145	
PCR product(s)			170		165	210	140		150	170		100	200		185	
			215		245	380	175			205		135			295	
							215			240						
							240									
Length of int.	800	800	800	1070	800	1070	1070	1070	800	1070	1070	1070	1070	1070	1070	
pos. control <sup>1</sup>																
5'-primer(s) <sup>2</sup>	209	362	362	209	130	320	362	103	352	362	362	209	97	467	106	
	5'-ggC 3'	5'-ggT 3'	5'-ggT 3'	5'-ggC 3'	5'-AgT 3'	5'-CCC 3'	5'-ggT 3'	5'-CCT 3'	5'-ACg 3'	5'-ggT 3'	5'-ggT 3'	5'-ggC 3'	5'-TCg 3'	5'-CTg 3'	5'-CCA 3'	
				704	200	362		122	353	878			193	485	395	
				5'-TgT 3'	5'-TCg 3'	5'-ggT 3'		5'-CCT 3'	5'-CAA 3'	5'-gCA 3'			5'-CCA 3'	5'-CAA 3'	5'-gCC 3'	
					209				392						757	
					5'-ggA 3'				5'-CgA 3'						5'-CCA 3'	
					362										5'-CCA 3'	
					5'-ggT 3'											
3'-primer(s) <sup>3</sup>	256	539	418	259	256	2 <sup>nd</sup> I	421	256	463	409	419	244	256	559	212	
	5'-CCC 3'	5'-TCA 3'	5'-gTC 3'	5'-CTT 3'	5'-CCC 3'		5'-gGT 3'	5'-CCC 3'	5'-gCT 3'	5'-ATA 3'	5'-Cgg 3'	5'-CTT 3'	5'-CCC 3'	5'-CAG 3'	5'-ggT 3'	
			481	271	559	412	463			527	419	268			539	
			5'-gTA 3'	5'-CAC 3'	5'-CgT 3'	5'-gTT 3'	5'-gCg 3'			5'-CCT 3'	5'-CAG 3'	5'-gTg 3'			5'-TCA 3'	
			500	774	572		486			559		302			916	
			5'-ggA 3'	5'-ggT 3'	5'-gCg 3'		5'-gCg 3'			5'-Cgg 3'		5'-ggg 3'			5'-GAC 3'	
			537				505			916					5'-GAC 3'	
			5'-Agg 3'				538									
							559									
							5'-CTC 3'									
Well No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16

Negative Control





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Lot No.: 14R

Lot-specific information

Well No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
HLA-B allele																
*57:01:01-57:01:13	1	2									11					
*57:02:01-57:02:02, 57:12, 57:42	1					6										
*57:03:01-57:03:02, 57:17, 57:39, 57:46	1	2				6										
*57:04	1		3							10						
*57:05, 57:11, 57:28N, 58:36	1															
*57:06, 57:18, 57:27	1	2	3								11					
*57:07	1	2			5	6										
*57:08	1	2				6					11					
*57:09	1					6	7									
*57:10, 57:44	1	2						8			11					
*57:13	1						7			10	11					
*57:14, 57:25, 57:31, 57:50	1	2					7				11					
*57:15, 57:29	1	2		4							11					
*57:16		2			5						11					
*57:19, 57:30, 57:52	1										11					
*57:20		2		4							11					
*57:21, 57:33	1	2							9		11					
*57:22, 57:37, 57:41, 57:43	1	2								10	11					
*57:23, 57:26, 57:34	1	2			5						11					
*57:24	1						7				11					
*57:32	1	2	3													
*57:35, 57:38	1	2									11	12				
*57:36		2									11	12				
*57:40	1	2							9		w					
*57:45, 57:51		2									11		13			
*57:47, 57:54	1	2									11			14		
*57:48, 57:55-57:56	1	2									11				15	
*57:49	1	2									11		13			
*57:53	1	2					7									
*57:57	1	2				6				10						
*07:120, 15:214, 40:150				4												
*14:20, 35:127									9							
*15:33, 51:126, C*03:87, C*05:27, C*05:39														14		
*40:30, 40:34		2				6	7									
*55:14		2			5		7			10	11					
*58:14		2					7				11					
A*02:285													13			
A*33:12															15	
C*06:72					5		7			10	11					
HLA-B allele																
Well No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16

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<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\*57:01 subtyping.

In addition, wells number 2, 3, 5 and 9 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>, 3<sup>rd</sup> or 4<sup>th</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>, 3<sup>rd</sup>, 4<sup>th</sup> or 5<sup>th</sup> exon or the 2<sup>nd</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.

<sup>4</sup>Primer mix 3: Specific PCR fragment of 95 bp in the B\*57:04 and 57:32 alleles. Specific PCR fragment of 170 bp in the B\*57:06 and B\*57:18 alleles. Specific PCR fragment of 215 bp in the B\*57:27 allele.

Primer mix 5: Specific PCR fragment of 90 bp in the B\*57:16 and 57:34 alleles. Specific PCR fragment of 165 bp in the B\*57:23 allele. Specific PCR fragment of 245 bp in the B\*57:07 and 57:26 and the B\*55:14 and in the C\*06:72 alleles.

Primer mix 6: Specific PCR fragment of 90 bp in the B\*57:02:01-57:03:02, 57:07, 57:09, 57:12, 57:17, 57:39, 57:42, 57:46 and 57:57 and the B\*40:30 and 40:34 alleles. Specific PCR fragment of 210 bp in the B\*57:08 allele.

Primer mix 7: Specific PCR fragment of 100 bp in the B \*57:53 allele. Specific PCR fragment of 140 bp in the B\*57:31 and in the C\*06:72 alleles. Specific PCR fragment of 175 bp in the B\*57:14 and 57:50 and B\*55:14 and 58:14 alleles. Specific PCR fragment of 215 bp in the B\*57:09 and 57:24 alleles. Specific PCR fragment of 240 bp in the B\*57:25 allele. Specific PCR fragment of 140 and 240bp in the B\*57:13 and in the B\*40:30 and 40:34 alleles.

Primer mix 9: Specific PCR fragment of 110 bp in the B\*57:33 allele. Specific PCR fragment of 150 bp in the B\*57:21 and 57:40 and in the B\*14:20 and 35:127 alleles.

Primer mix 10: Specific PCR fragment of 90 bp in the B\*57:04 and 57:41 and the C\*06:72 alleles. Specific PCR fragment of 170 bp in the B\*57:37 allele. Specific PCR fragment of 205 bp in the B\*57:13, 57:22 and 57:57 and the 55:14 and in the C\*06:72<sup>w</sup> alleles.

Specific PCR fragment of 240 bp in the B\*57:43 allele. Primer mix 12: Specific PCR fragment of 75 bp in the B\*57:35 allele. Specific PCR fragment of 100 bp in the B \*57:36 allele. Specific PCR fragment of 135 bp in the B \*57:38 allele.

Primer mix 13: Specific PCR fragment of 105 bp in the B\*57:45 and 57:51 and in the A\*02:285 alleles. Specific PCR fragment of 200 bp in the B\*57:49 allele.

Primer mix 15: Specific PCR fragment of 145 bp in the B \*57:56 allele. Specific PCR fragment of 185 bp in the B \*57:48 and in the A\*33:12 alleles. Specific PCR fragment of 295 bp in the B\*57:55 allele.

<sup>5</sup>Primer mix 16 contains a negative control, which will amplify more than 95% of HLA amplicons as well as the amplicons generated by control primer pairs. PCR product sizes range from 75 to 200 base pairs. The PCR product generated by the control primer pair is 430 base pairs.

101.572-12– including *Taq* pol., IFU-01  
 101. 572-12u– without *Taq* pol., IFU-02

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Lot No.: **14R**

Lot-specific information

<b>CELL LINE VALIDATION SHEET</b>																			
<b>HLA-B*57:01 SSP typing kit</b>																			
				<b>Well</b>															
				1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
				Prod. No.:	201184501	201184502	201184503	201184504	201184505	201184506	201205607	201192208	201184509	201205610	201184511	201184512	201205613	201205614	201205615
	<b>IHWC cell line</b>		<b>B*</b>																
1	9001 SA		*07:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	
2	9280 LK707		*52:01	*73:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
3	9011 E4181324		*52:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	
4	9275 GU373		*15:10	*53:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
5	9009 KAS011		*37:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	
6	9353 SM		*39:01	*51:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
7	9020 QBL		*18:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	
8	9025 DEU		*35:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	
9	9026 YAR		*38:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	
10	9107 LKT3		*54:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	
11	9051 PITOUT		*44:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	
12	9052 DBB		*57:01		+	+	-	-	-	-	-	-	-	+	-	-	-	-	
13	9025 JESTHOM		*27:05		-	-	-	-	-	-	-	-	-	-	-	-	-	-	
14	9071 OLGA		*15:01	*15:20	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
15	9075 DKB		*40:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	
16	9037 SWEIG007		*40:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	
17	9282 CTM3953540		*08:01	*55:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
18	9257 32367		*14:01	*56:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
19	9038 BM16		*18:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	
20	9059 SLE005		*40:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	
21	9064 AMALA		*15:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	
22	9056 KOSE		*35:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	
23	9124 IHL		*40:02	*56:02	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
24	9035 JBUSH		*38:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	
25	9049 IBW9		*14:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	
26	9285 WT49		*58:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	
27	9191 CH1007		*07:05	*51:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
28	9320 BEL5GB		*44:02	*44:03	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
29	9050 MOU		*44:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	
30	9021 RSH		*42:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	
31	9019 DUCAF		*18:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	
32	9297 HAG		*41:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	
33	9098 MT14B		*40:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	
34	9104 DHIF		*38:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	
35	9302 SSTO		*44:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	
36	9024 KT17		*15:01	*35:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
37	9065 HHKB		*07:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	
38	9099 LZL		*15:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	
39	9315 CML		*08:01	*27:05	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
40	9134 WHONP199		*13:02	*46:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
41	9055 H0301		*14:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	
42	9066 TAB089		*46:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	
43	9076 T7526		*46:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	
44	9057 TEM		*38:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	
45	9239 SHJO		*42:01	*50:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
46	9013 SCHU		*07:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	
47	9045 TUBO		*51:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	
48	9303 TER-ND		*35:01	*44:03	-	-	-	-	-	-	-	-	-	-	-	-	-	-	

101.572-12– including *Taq* pol., IFU-01  
 101. 572-12u– without *Taq* pol., IFU-02

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Lot No.: **14R**

Lot-specific information

## CERTIFICATE OF ANALYSIS

### Olerup SSP® HLA-B\*57:01 SSP

**Product number:** 101.572-12 – including *Taq* polymerase  
 101.572-12u – without *Taq* polymerase  
**Lot number:** 14R  
**Expiry date:** 2015-February-01  
**Number of tests:** 12  
**Number of wells per test:** 15+1

#### Well specifications:

Well No.	Production No.	Well No.	Production No.
1	2011-845-01	9	2011-845-09
2	2011-845-02	10	2012-056-10
3	2011-845-03	11	2011-845-11
4	2011-845-04	12	2011-845-12
5	2011-845-05	13	2012-056-13
6	2011-845-06	14	2012-056-14
7	2012-056-07	15	2012-056-15
8	2011-922-08		

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 3 to 5, 7 to 10 and 12 to 15 were available. The specificities of the primers in primer solutions 3 to 5, 7, 8, 10 and 13 to 15 were tested by separately adding one to four additional 5'-primers, respectively one or two 3'-primers. In primer solution 9 it was only possible to test the 3'-primer, the 5'-primers were not possible to test. In primer solution 12 it was only possible to test the 5'-primer, the 3'-primers were not possible to test.

In primer solutions 3, 4, 7, 10, 11 and 15 one to three 3'-primers were not possible to test, and in primer solutions 4, 5, 8, 10, 14 and 15 one to three 5'-primers were not possible to test.

The negative control primer pairs, **Production No. 2012-002-01**, can detect contamination with PCR products diluted  $10^{-7}$ .

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

**Date of approval:** 2012-August-23

**Approved by:**

#### Production Quality Control

101.572-12– including *Taq pol.*, IFU-01  
101. 572-12u– without *Taq pol.*, IFU-02

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Lot-specific information

## Declaration of Conformity

**Product name:** *Olerup SSP*<sup>®</sup> HLA-B\*57:01  
**Product number:** 101.572-12/12u  
**Lot number:** 14R

**Intended use:** HLA-B\*57:01 histocompatibility testing

**Manufacturer:** *Olerup SSP AB*  
Franzengatan 5  
SE-112 51 Stockholm, 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 9001:2008 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*, Franzengatan 5, SE-112 51 Stockholm, Sweden.

Notified Body: Lloyd's Register Quality Assurance Limited, Hiramford, Middlemarch Office Village, Siskin Drive, Coventry CV3 4FJ, United Kingdom. (Notified Body number: 0088.)

Stockholm, Sweden  
2013-August-23

Ann-Cathrin Jareman  
Head of QA and Regulatory Affairs

101.572-12– including *Taq* pol., IFU-01  
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Lot-specific information

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Lot No.: **14R**

Lot-specific information

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For information on *Olerup SSP* distributors worldwide, contact **Olerup GmbH**.