

101.567-12 – including *Taq* pol., IFU-01  
101.567-12u – without *Taq* pol., IFU-02

Visit [www.olerup-ssp.com](http://www.olerup-ssp.com) for  
“Instructions for Use” (IFU)

Lot No.: **01V**

Lot-specific information  
**Olerup SSP® HLA-B\*57**

Product number:	101.567-12 – including <i>Taq</i> polymerase 101.567-12u – without <i>Taq</i> polymerase
Lot number:	01V
Expiry date:	2016-May-01
Number of tests:	12
Number of wells per test:	23+1
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. 01V.**

Complete product documentation consists of generic Instructions for Use (IFU), lot specific Product Insert, Worksheet and Certificate.

**CHANGES COMPARED TO THE PREVIOUS OLERUP SSP®  
HLA-B\*57 LOT (45R)**

The HLA-B\*57 kit is updated for new alleles to enable separation of:

- Confirmed<sup>1</sup> alleles as listed in the IMGT/HLA database
- Polymorphisms in exons outside of the region encoding the peptide binding domain
- Null and Alternatively expressed alleles

A well containing Negative Control primer pairs has been added.

The format of the Product Insert and Worksheet have been changed.

<sup>1</sup>As described in section Uniquely Identified Alleles.

The HLA-B\*57 specificity and interpretation tables have been updated for the HLA-B alleles described since the previous *Olerup SSP®* HLA-B\*57 lot was made (**Lot No. 45R**).

As of lot series V, the Specificity Table is included in the lot-specific Product Insert, and the Interpretation Table is included in the Worksheet.

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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	Added	Primer pair added from well 24.
15	Modified	-	5'-primer modified to decrease tendency of unspecific amplification.
19	-	Added	3'-primer added from well 20.
20	-	Moved	3'-primer moved to well 19.
21	Modified	-	5'-primer modified to decrease tendency of unspecific amplification.
22	Added	Added	Primer pair added for the B*57:40 allele.
24	Moved, added	Moved, added	Primer pair moved to well 7, negative control.

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Well **24** contains Negative Control primer pairs, that will amplify more than 95% of the *Olerup SSP*® HLA Class I, DRB, DQB1 and DPB1 amplicons as well as amplicons generated by a control primer pair.

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>
	5'-CAC <sup>3'</sup>	5'-Agg <sup>3'</sup>	5'-TTA <sup>3'</sup>	5'-Tgg <sup>3'</sup>	5'-Tgg <sup>3'</sup>	5'-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>
	5'-TgC <sup>3'</sup>	5'-AAA <sup>3'</sup>	5'-TTg <sup>3'</sup>	5'-CTC <sup>3'</sup>	5'-ggC <sup>3'</sup>	5'-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.

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Lot-specific information

## PRODUCT DESCRIPTION

### HLA-B\*57 SSP subtyping

#### CONTENT

The primer set contains 5'- and 3'-primers for identifying the B\*57:01 to B\*57:65 alleles.

#### PLATE LAYOUT

Each test consists of 24 PCR reactions in a 24 well cut 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	NC

The 24 well cut PCR plate is marked with 'HLA-B\*57' in silver/gray ink.

Well No. 1 is marked with the Lot No. '01V'.

Well 24 – Negative Control (NC).

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 24 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

Due to the sharing of sequence motifs between HLA-B alleles, non-HLA-B\*57 alleles will be amplified by primer mixes 1 to 4, 6, 8, 9, 11 to 13 and 15 to 22. In addition, a few HLA-C alleles will be amplified by primer mixes 1, 2, 4, 5, 14, 15, 17, 19 and 20.

For further details see Specificity Table.

#### UNIQUELY IDENTIFIED ALLELES

All the HLA-B\*57 alleles, i.e. **B\*57:01 to B\*57:65**, recognized by the HLA Nomenclature Committee in July 2013 will be amplified by the primers in the HLA-B\*57 subtyping kit.

The HLA-B\*57 kit enables separation of the confirmed HLA-B\*57 alleles as listed in the IMGT/HLA database. An HLA allele is listed as confirmed by IMGT/HLA if it has been sequenced by more than a single laboratory or from multiple sources. Current allele confirmation status for HLA-B\*57 alleles is listed below.

The HLA-B\*57 kit also enables identification of polymorphisms in exons outside of the region encoding the peptide binding domain and of null and alternatively expressed alleles.

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**Lot-specific information**

The following HLA-B57 alleles can be distinguished by the different sizes of the HLA-specific PCR product:

**Alleles** **Primer mix**

B*57:15, 57:37, 57:55	7
B*57:25, 57:41	19

The HLA-B\*57 subtyping kit cannot distinguish the silent mutations in the B\* 57:01:01-57:01:04 and 57:01:06-57:01:15 alleles, the B\*57:02:01-57:02:02 alleles or the B\*57:03:01-57:03:02 alleles.

<sup>1</sup>HLA-B alleles listed on the IMGT/HLA web page 2013-July-25 release 3.13.1, [www.ebi.ac.uk/imgt/hla](http://www.ebi.ac.uk/imgt/hla).

<sup>2</sup>Alleles that have been deleted from or renamed in the official WHO HLA Nomenclature up to and including the last IMGT/HLA database release can be retrieved from web page <http://hla.alleles.org/alleles/deleted.html>.

**ALLELE CONFIRMATION STATUS**

Allele	Status <sup>1</sup>	Allele	Status <sup>1</sup>	Allele	Status <sup>1</sup>
<b>B*57:01:01</b>	<b>Confirmed</b>	<b>B*57:15</b>	<b>Confirmed</b>	B*57:45	Unconfirmed
B*57:01:02	Unconfirmed	B*57:16	Unconfirmed	B*57:46	Unconfirmed
B*57:01:03	Unconfirmed	<b>B*57:17</b>	<b>Confirmed</b>	B*57:47	Unconfirmed
B*57:01:04	Unconfirmed	B*57:18	Unconfirmed	B*57:48	Unconfirmed
<b>B*57:01:05</b>	<b>Confirmed</b>	B*57:19	Unconfirmed	<b>B*57:49</b>	<b>Confirmed</b>
B*57:01:06	Unconfirmed	<b>B*57:20</b>	<b>Confirmed</b>	B*57:50	Unconfirmed
<b>B*57:01:07</b>	<b>Confirmed</b>	<b>B*57:21</b>	<b>Confirmed</b>	B*57:51	Unconfirmed
B*57:01:08	Unconfirmed	<b>B*57:22</b>	<b>Confirmed</b>	B*57:52	Unconfirmed
B*57:01:09	Unconfirmed	<b>B*57:23</b>	<b>Confirmed</b>	B*57:53	Unconfirmed
<b>B*57:01:10</b>	<b>Confirmed</b>	<b>B*57:24</b>	<b>Confirmed</b>	B*57:54	Unconfirmed
B*57:01:11	Unconfirmed	B*57:25	Unconfirmed	B*57:55	Unconfirmed
B*57:01:12	Unconfirmed	<b>B*57:26</b>	<b>Confirmed</b>	B*57:56	Unconfirmed
B*57:01:13	Unconfirmed	B*57:27	Unconfirmed	<b>B*57:57</b>	<b>Confirmed</b>
B*57:01:14	Unconfirmed	B*57:28N	Unconfirmed	B*57:58	Unconfirmed
B*57:01:15	Unconfirmed	<b>B*57:29</b>	<b>Confirmed</b>	B*57:59	Unconfirmed
<b>B*57:02:01</b>	<b>Confirmed</b>	B*57:30	Unconfirmed	B*57:60	Unconfirmed
<b>B*57:02:02</b>	<b>Confirmed</b>	B*57:31	Unconfirmed	B*57:61	Unconfirmed
<b>B*57:03:01</b>	<b>Confirmed</b>	<b>B*57:32</b>	<b>Confirmed</b>	B*57:62	Unconfirmed
B*57:03:02	Unconfirmed	B*57:33	Unconfirmed	B*57:63	Unconfirmed
<b>B*57:04</b>	<b>Confirmed</b>	<b>B*57:34</b>	<b>Confirmed</b>	B*57:64	Unconfirmed
B*57:05	Unconfirmed	<b>B*57:35</b>	<b>Confirmed</b>	B*57:65	Unconfirmed
B*57:06	Unconfirmed	B*57:36	Unconfirmed		
B*57:07	Unconfirmed	B*57:37	Unconfirmed		
B*57:08	Unconfirmed	B*57:38	Unconfirmed		
<b>B*57:09</b>	<b>Confirmed</b>	<b>B*57:39</b>	<b>Confirmed</b>		
B*57:10	Unconfirmed	B*57:40	Unconfirmed		
<b>B*57:11</b>	<b>Confirmed</b>	<b>B*57:41</b>	<b>Confirmed</b>		
B*57:12	Unconfirmed	B*57:42	Unconfirmed		
<b>B*57:13</b>	<b>Confirmed</b>	<b>B*57:43</b>	<b>Confirmed</b>		
<b>B*57:14</b>	<b>Confirmed</b>	B*57:44	Unconfirmed		

<sup>1</sup>Allele status “confirmed” or “unconfirmed” as listed on the IMGT/HLA web page 2013-July-25, release 3.13.1, [www.ebi.ac.uk/imgt/hla](http://www.ebi.ac.uk/imgt/hla).

**RESOLUTION IN HOMO- AND HETEROZYGOTES**

Results file with resolution in HLA-B\*57 homo- and heterozygotes is available upon request.

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**SPECIFICITY TABLE**

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

Specificities and sizes of the PCR products of the 24 primer mixes used for  
HLA-B\*57 SSP subtyping

Primer Mix	Size of spec. PCR product <sup>1</sup>	Size of control band <sup>2</sup>	Amplified HLA-B*57 alleles <sup>3</sup>	Other amplified HLA Class I alleles <sup>4</sup>
1	150 bp	800 bp	*57:01:01-57:01:04, 57:01:06-57:10, 57:12, 57:14-57:30, 57:32- 57:46, 57:48-57:65	*08:49, 13:01:01-13:01:06, 13:06-13:07N, 13:12:01-13:13, 13:17, 13:20, 13:22:01- 13:23, 13:25-13:26, 13:28-13:29, 13:36, 13:39, 13:43, 13:50-13:52, 13:57, 13:60- 13:61, 13:63N, 14:10, 15:02:01-15:02:06, 15:13:01-15:13:02, 15:20-15:21, 15:25:01- 15:25:03, 15:36, 15:44, 15:62, 15:77, 15:80, 15:85, 15:88-15:89, 15:106, 15:112, 15:121, 15:139, 15:144, 15:154, 15:165, 15:170, 15:194, 15:204, 15:213-15:214, 15:223, 15:240, 15:250, 15:265, 15:271, 18:22, 18:69, 27:19, 27:30, 35:01:01:01- 35:04:03, 35:06-35:08:06, 35:10-35:17, 35:19-35:21, 35:23-35:30, 35:33-35:36, 35:38-35:42:02, 35:45-35:50, 35:52, 35:54- 35:57, 35:59, 35:61:01-35:63, 35:65Q, 35:69-35:71, 35:74, 35:76-35:78, 35:80- 35:85, 35:90-35:96, 35:98, 35:100- 35:101:02, 35:103-35:113, 35:115-35:116, 35:120-35:126, 35:128-35:134N, 35:136- 35:150, 35:152-35:173N, 35:175-35:184, 35:186-35:198, 35:200-35:204, 35:206- 35:229, 35:231, 35:233, 37:01:01-37:01:07, 37:01:09, 37:03N-37:06, 37:08, 37:10- 37:11, 37:13-37:37, 38:20, 39:42, 40:28, 44:02:01:01-44:14, 44:16-44:17, 44:19N, 44:21-44:30, 44:32-44:40, 44:42-44:46, 44:48-44:52N, 44:55-44:64:02, 44:66- 44:98, 44:101-44:105, 44:107-44:134, 44:136-44:137, 44:139-44:157, 44:159- 44:165, 44:167-44:181, 46:33, 48:02:01- 48:02:03, 48:25, 50:17, 51:04, 51:42, 51:46, 51:56:01-51:56:02, 51:139, 53:01:01-53:13, 53:15-53:31, 55:14, 56:09, 56:11-56:12, 58:01:01-58:01:02, 58:01:04-58:01:12, 58:04-58:05, 58:09-58:15, 58:17N, 58:19, 58:21-58:24, 58:28-58:29, 58:31N-58:37, 58:39N-58:42, 58:44-58:45, 83:01, <b>C*03:102</b>
2 <sup>5</sup>	100 bp	1070 bp	*57:01:01-57:01:15, 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> ,	*35:208, 55:14, 58:14, <b>C*06:72</b>

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			57:41, 57:43-57:45, 57:47-57:52, 57:54- 57:56, 57:58-57:62, 57:64-57:65
<b>3</b>	220 bp	1070 bp	*57:01:01-57:01:15, 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- 57:60, 57:62, 57:64- 57:65
			*35:208, 40:30, 40:34, 44:153, 55:14, 58:14
<b>4<sup>5</sup></b>	100 bp	<b>800 bp</b>	*57:02:01-57:03:02, 57:05, 57:07, 57:09, 57:12, 57:17, 57:39, 57:42, 57:46, 57:57, 57:63
			*07:137, 08:60, 08:76 <sup>w</sup> , 13:13, 13:21, 35:02:01-35:02:05, 35:04:01-35:04:03, 35:06 <sup>w</sup> , 35:09:01-35:09:03, 35:12:01- 35:12:03, 35:18, 35:59 <sup>w</sup> , 35:81, 35:83, 35:88, 35:95, 35:129N, 35:149, 35:154, 35:157, 35:162, 35:172, 35:182-35:184, 35:201, 35:211, 35:220, 35:233, 37:01:01 <sup>w</sup> - 37:01:09 <sup>w</sup> , 37:03N <sup>w</sup> -37:06 <sup>w</sup> , 37:08 <sup>w</sup> , 37:10 <sup>w</sup> - 37:11 <sup>w</sup> , 37:12, 37:13 <sup>w</sup> -37:18 <sup>w</sup> , 37:19, 37:20 <sup>w</sup> -37:24 <sup>w</sup> , 37:26 <sup>w</sup> -37:34 <sup>w</sup> , 37:36 <sup>w</sup> - 37:37 <sup>w</sup> , 38:20 <sup>w</sup> , 39:42 <sup>w</sup> , 40:04, 40:28, 40:30, 40:34, 40:64, 40:68, 40:99 <sup>w</sup> , 40:129, 40:137, 40:160:01-40:160:02, 42:13, 44:62, 44:77, 44:82 <sup>w</sup> , 48:17 <sup>w</sup> , 51:04, 51:46, 51:56:01-51:56:02, 51:139, 53:19, 56:12, 58:28, <b>C*05:10<sup>w</sup>, C*15:24</b>
<b>5</b>	220 bp	1070 bp	*57:02:01-57:02:02, 57:04, 57:12-57:13, 57:19, 57:28N, 57:30, 57:42, 57:63
			<b>C*06:72</b>
<b>6<sup>5</sup></b>	95 bp 180 bp 205 bp	1070 bp	*57:04, 57:32
			*44:153
			*57:06
			*57:30
<b>7<sup>5</sup></b>	105 bp 170 bp 295 bp	1070 bp	*57:15
			*57:37
			*57:55
<b>8<sup>5</sup></b>	90 bp 200 bp 250 bp	1070 bp	*57:16
			*57:49
			*57:07
			*44:153
<b>9<sup>6</sup></b>	170 bp	1070 bp	*57:09, 57:13, 57:22, 57:57, 57:63
			*07:02:01-07:24, 07:26-07:47, 07:49N- 07:50, 07:52-07:154, 07:156-07:163, 07:165-07:198, 08:20, 08:53:01-08:53:02, 08:79, 13:16, 13:20, 13:31, 13:48, 13:62, 14:01:01-14:37, 15:01:01:01-15:01:04, 15:01:06-15:04, 15:06-15:19, 15:21, 15:23- 15:30, 15:32-15:40, 15:42-15:47:02, 15:49- 15:50, 15:53-15:54, 15:56-15:58, 15:60- 15:74, 15:76-15:82, 15:85, 15:87, 15:89- 15:90, 15:92-15:99, 15:101-15:104, 15:106, 15:108-15:110, 15:112-15:113, 15:115- 15:122, 15:125-15:129, 15:131-15:135,

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			15:137-15:144, 15:146-15:150, 15:152-15:154, 15:156-15:161, 15:163-15:175, 15:177-15:178, 15:180-15:184, 15:187, 15:189-15:199, 15:201-15:217, 15:219-15:221, 15:223, 15:225-15:234, 15:236, 15:238-15:249, 15:251-15:274, 15:276-15:282, 18:15, 18:19, 18:21, 18:30, 18:57, 27:04:01-27:04:03, 27:06, 27:10, 27:15, 27:18, 27:20-27:21, 27:24-27:25, 27:40, 27:54, 27:63, 27:66N, 27:68-27:69, 27:79, 27:86, 27:91-27:92, 27:100, 27:103, 27:105-27:106, 35:11:01-35:11:03, 35:14:01-35:14:02, 35:21, 35:43:01-35:44, 35:58, 35:67, 35:79, 35:86, 35:96, 35:99, 35:102, 35:117-35:118, 35:135, 35:167, 35:185, 35:188, 35:213, 35:232, 37:07, 37:13, 38:10, 38:32, 39:18, 39:35-39:36, 40:05, 40:15-40:16, 40:23, 40:26, 40:28, 40:32, 40:51, 40:95, 40:98, 40:148, 40:158, 40:161, 40:174, 40:183, 40:198, 42:19, 44:76, 44:79, 44:146, 44:150, 46:01:01-46:05, 46:07N-46:08, 46:10, 46:12, 46:14-46:17, 46:20, 46:22-46:24, 46:26-46:32, 46:34-46:40, 46:42, 48:05, 48:08, 48:15, 48:25, 49:01:01-49:10, 49:12-49:26, 50:01:01-50:02, 50:04-50:20, 50:31-50:33, 51:01:01-51:04, 51:06:01-51:07:02, 51:11N-51:14, 51:16-51:18, 51:21-51:24:04, 51:26-51:30, 51:32-51:39, 51:41N, 51:43, 51:45-51:46, 51:48-51:52, 51:55-51:72, 51:74-51:80, 51:82-51:92, 51:94-51:96, 51:98N-51:107, 51:109-51:114, 51:116-51:119, 51:121, 51:123-51:138, 51:140, 51:142-51:147, 51:149N-51:152, 51:154, 52:01:01:01-52:02, 52:04-52:09, 52:11-52:18, 52:20-52:27, 52:30-52:31, 53:06, 53:08:01-53:08:02, 53:28, 54:06, 54:20, 55:01:01-55:01:11, 55:03, 55:05, 55:09, 55:11, 55:14-55:15, 55:17, 55:21, 55:24-55:25, 55:28-55:29, 55:31, 55:33, 55:36, 55:38, 55:40, 55:44-55:45, 55:52-55:53, 55:55N-55:56, 55:58-55:59, 56:03, 56:05:01-56:06, 56:21, 56:25, 56:32, 56:37, 58:06, 58:08:01-58:08:02, 58:19, 58:46, 78:01:01-78:03, 78:05-78:07	
<b>10</b>	210 bp	1070 bp	*57:08	
<b>11</b>	165 bp 215 bp 240 bp	<b>800 bp</b>	*57:14 *57:09, 57:24 *57:43	
<b>12<sup>5</sup></b>	90 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, 57:63	
<b>13<sup>5</sup></b>	90 bp	<b>800 bp</b>	*57:01:01-57:15, 57:17-57:19, 57:21-	
				*35:208, 44:153, 55:14, 58:14
				*40:30, 40:34
				*58:36



101.567-12 – including *Taq* pol., IFU-01  
101.567-12u – without *Taq* pol., IFU-02

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“Instructions for Use” (IFU)

Lot No.: **01V**

Lot-specific information

Lot No.: <b>01V</b>		Lot-specific information		
			57:35, 57:37-57:44, 57:46-57:50, 57:52- 57:61, 57:63-57:65	
<b>14</b>	135 bp 195 bp	1070 bp	*57:17 *57:10	<b>*C*07:239</b>
<b>15<sup>5</sup></b>	110 bp 145 bp	1070 bp	*57:29, 57:33 *57:11	*07:120, 15:214, 18:81, 40:150 *14:01:01-14:02:08, 14:03-14:04, 14:07N, 14:09, 14:11-14:12, 14:14-14:36, 18:44:01- 18:44:02, 39:79, 58:02, 58:06-58:07, 58:25, 58:38, 58:43, <b>C*01:32, C*06:20</b>
<b>16<sup>5</sup></b>	85 bp 160 bp	1070 bp	*57:12 *57:18	*14:24, 35:226
<b>17</b>	140 bp 210 bp	1070 bp	*57:13, 57:31 *57:13, 57:22, 57:27 57:57, 57:63,	*40:30, 40:34, <b>C*06:72</b> *55:14, <b>C*06:72<sup>w</sup></b>
<b>18</b>	165 bp 200 bp	1070 bp	*57:23 *57:39, 57:51	*58:41
<b>19<sup>5</sup></b>	90 bp 240 bp	1070 bp	*57:04, 57:41 *57:13, 57:25, 57:43	*44:153, <b>C*06:72</b> *40:30, 40:34
<b>20<sup>5</sup></b>	90 bp 240 bp	1070 bp	*57:20 *57:26	*55:14, <b>C*06:72</b>
<b>21<sup>5</sup></b>	110 bp 150 bp	1070 bp	*57:33 *57:21	*35:127
<b>22<sup>5</sup></b>	95 bp 150 bp	<b>800 bp</b>	*57:34 *57:40	*14:20
<b>23<sup>5</sup></b>	75 bp 100 bp	1070 bp	*57:35 *57:36	
<b>24<sup>7</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 SSP typings.

When the primers in a primer mix can give rise to HLA-specific PCR products of more than one length this is indicated if the size difference is more than 20 base pairs. Size differences of 20 base pairs or less are not given. For high resolution SSP kits, the alleles listed are specified according to amplicon length.

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 internal positive control bands are 1070 or 800 base pairs respectively, well distribution as outlined in the table. Well number 1 contains the shorter, 800 bp, internal positive control band. The well distribution of the internal controls can help in orientation of the kit on gel photo, as well as allow for kit identification. In the presence of a specific amplification the intensity of the control band often decreases.

In the presence of a specific amplification the intensity of the control band often decreases.

101.567-12 – including *Taq* pol., IFU-01  
101.567-12u – without *Taq* pol., IFU-02

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**Lot No.: 01V**

**Lot-specific information**

<sup>3</sup>For several HLA Class I alleles 1<sup>st</sup> and/or 4<sup>th</sup> exon(s) and beyond, as well as 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. Assumptions is made that unknown sequences in these regions are conserved within allelic groups.

<sup>4</sup>Due to the sharing of sequence motifs between HLA-B alleles, non-HLA-B\*57 alleles will be amplified by primer mixes 1 to 4, 6, 8, 9, 11 to 13 and 15 to 22. In addition, a few HLA-C alleles will be amplified by primer mixes 1, 2, 4, 5, 14, 15, 17, 19 and 20.

<sup>5</sup>HLA-specific PCR products shorter than 125 base pairs have a lower intensity and are less sharp than longer PCR products.

<sup>6</sup>Primer mix 9 may have tendencies of unspecific amplifications.

<sup>7</sup>Primer mix 24 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.

‘w’, might be weakly amplified.

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Lot No.: **01V**

Lot-specific information  
**PRIMER SPECIFICATION**

Well No.	1	2	3	4	5	6	7	8	9	10	11	12
Length of spec. PCR product	150	100	220	100	220	95	105	90	170	210	165	90
						180	170	200			215	
						205	295	250			240	
Length of int. pos. control <sup>1</sup>	800	1070	1070	800	1070	1070	1070	1070	1070	1070	800	1070
5'-primer(s) <sup>2</sup>	355 5'-TCA 3'	362 5'-ggT 3'	362 5'-ggT 3'	355 5'-TCA 3'	362 5'-ggT 3'	362 5'-ggT 3'	209 5'-ggC 3'	97 5'-TCg 3'	527 5'-TgA 3'	320 5'-CCC 3'	362 5'-ggT 3'	362 5'-ggT 3'
							757 5'-CCA 3'	209 5'-ggA 3'				
							878 5'-gCA 3'	362 5'-ggT 3'				
3'-primer(s) <sup>3</sup>	463 5'-gCT 3'	419 5'-Cgg 3'	539 5'-TCA 3'	412 5'-gTT 3'	539 5'-TCC 3'	418 5'-gTC 3'	271 5'-CAC 3'	256 5'-CCC 3'	3 <sup>rd</sup>   5'-TAT 3'	2 <sup>nd</sup>   5'-TCg 3'	486 5'-gCg 3'	412 5'-gTT 3'
		419 5'-CAg 3'				500 5'-ggA 3'	916 5'-gAC 3'	572 5'-gCg 3'			538 5'-gTC 3'	
						527 5'-CCg 3'					559 5'-Cgg 3'	
Well No.	1	2	3	4	5	6	7	8	9	10	11	12

Well No.	13	14	15	16	17	18	19	20	21	22	23
Length of spec. PCR product	90	135	110	85	140	165	90	90	110	95	75
		195	145	160	210	200	240	240	150	150	100
Length of int. pos. control <sup>1</sup>	800	1070	1070	1070	1070	1070	1070	1070	1070	800	1070
5'-primer(s) <sup>2</sup>	209 5'-ggC 3'	103 5'-CCT 3'	361 5'-AgT 3'	256 5'-ACg 3'	362 5'-ggT 3'	97 5'-TCC 3'	362 5'-ggT 3'	209 5'-ggC 3'	352 5'-ACg 3'	200 5'-TCg 3'	209 5'-ggC 3'
		446 5'-CgA 3'	392 5'-CgA 3'	362 5'-ggT 3'		130 5'-AgT 3'		362 5'-ggT 3'	392 5'-CgA 3'	353 5'-CAA 3'	
			704 5'-TgT 3'								
3'-primer(s) <sup>3</sup>	256 5'-CCC 3'	256 5'-CCC 3'	463 5'-gCT 3'	302 5'-ggC 3'	463 5'-gCg 3'	256 5'-CCC 3'	409 5'-ATA 3'	259 5'-CTT 3'	463 5'-gCT 3'	256 5'-CCC 3'	244 5'-CTT 3'
		539 5'-TCA 3'	774 5'-ggT 3'	481 5'-gTA 3'	527 5'-CCT 3'		559 5'-CTC 3'	559 5'-CgT 3'		463 5'-gCT 3'	268 5'-gTg 3'
					537 5'-Agg 3'		559 5'-Cgg 3'				
Well No.	13	14	15	16	17	18	19	20	21	22	23

<sup>1</sup>The internal positive control primer pairs amplify segments of the human growth hormone gene. The internal positive control bands are 1070 or 800 base pairs respectively, well distribution as outlined in the table. Well number 1 contains the shorter, 800 bp, internal positive control band. The well distribution of the internal controls can help in orientation of the kit on gel photo, as well as allow for kit identification. In the presence of a specific amplification the intensity of the control band often decreases.

<sup>2</sup>The nucleotide position 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 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.

101.567-12 – including *Taq* pol., IFU-01  
101.567-12u – without *Taq* pol., IFU-02

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Lot No.: **01V**

Lot-specific information

<b>CELL LINE VALIDATION SHEET</b>																			
<b>HLA-B*57 SSP subtyping kit</b>																			
			Prod. No.:	Well															
				1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
				201326401	201326402	201326403	201326404	201326405	201326406	201326407	201326408	201326409	201326410	201326411	201326412	201326413	201326414	201326415	201326416
	<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	9004 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	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

101.567-12 – including *Taq* pol., IFU-01  
101.567-12u – without *Taq* pol., IFU-02

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Lot No.: **01V**

Lot-specific information

CELL LINE VALIDATION SHEET											
HLA-B*57 SSP subtyping kit											
				Well							
				17	18	19	20	21	22	23	
				Prod. No.:	201326417	201326418	201326419	201326420	201326421	201326422	201326423
	IHWC cell line		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	9004 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	-	-	-	-	-	-	-

<sup>1</sup>The provided cell line HLA specificities are retrieved from the <http://www.ihwg.org/hla> web site. The specificity of an individual cell line may thus be subject to change.

101.567-12 – including *Taq* pol., IFU-01  
101.567-12u – without *Taq* pol., IFU-02

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**Lot No.: 01V**

**Lot-specific information**

<sup>2</sup>The specificity of each primer solution in the kit has been tested against 48 well characterized cell line DNAs and where applicable, additional cell line DNAs.

No DNAs carrying the alleles to be amplified by primer solutions 6 to 8, 11, 14 and 16 to 23 were available. The specificities of the primers in primer solutions 6, 7, 8, 11, 14 and 16 to 20 were tested by separately adding additional 5'-primers, respectively additional 3'-primers. In primer solution 23 it was only possible to test the 5'-primer, the 3'-primer was not possible to test. In primer solution 21 and 22 it was only possible to test the 3'-primer, the 5'-primer was not possible to test.

In primer solutions 2, 6, 11, 16, 17, 19 and 20 one of the 3'-primers was not possible to test, and in primer solutions 7, 8, 14, 15 and 18 one or two of the 5'-primers were not possible to test. One additional 3'-primer in primer solution 15 was tested by separately adding one 5'-primer.

101.567-12 – including *Taq* pol., IFU-01  
101.567-12u – without *Taq* pol., IFU-02

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Lot No.: **01V**

Lot-specific information

101.567-12 – including *Taq* pol., IFU-01  
101.567-12u – without *Taq* pol., IFU-02

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“Instructions for Use” (IFU)

Lot No.: **01V**

Lot-specific information

**ADDRESSES:**

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**Olerup SSP AB**, Franzengatan 5, SE-112 51 Stockholm, Sweden.

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