

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

Visit www.olerup-ssp.com for
“Instructions for Use” (IFU)

Lot No.: **02S**

Lot-specific information

Olerup SSP® HLA-B*57:01

Product number:	101.572-12 – including <i>Taq</i> polymerase 101.572-12u – without <i>Taq</i> polymerase
Lot number:	02S
Expiry date:	2015-August-01
Number of tests:	12
Number of wells per test:	15+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. 02S.

CHANGES COMPARED TO THE PREVIOUS OLERUP SSP® HLA-B*57:01 LOT (14R).

The HLA-B*57:01 specificity and interpretation tables have been updated for the HLA-B alleles described since the previous *Olerup SSP®* HLA-B*57:01 lot was made (**Lot No. 14R**).

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

Well	5'-primer	3'-primer	rationale
12	-	Added	3'-primers added for the B*57:60 allele and for improved allelic resolution.
13	Added	-	5'-primer added for the B*57:58 allele.
14	Added	-	5'-primer added for the B*57:59 allele.

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-01101. 572-12u– without *Taq* pol., IFU-02Visit www.olerup-ssp.com for

“Instructions for Use” (IFU)

Lot No.: **02S**

Lot-specific information

Well **16** 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 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
5'-primer¹	164	340	440	45	45	43
	5'-CAC ^{3'}	5'-Agg ^{3'}	5'-TTA ^{3'}	5'-Tgg ^{3'}	5'-Tgg ^{3'}	5'-Tgg ^{3'}
3'-primer²	231	2nd I	507	59	58	57
	5'-TgC ^{3'}	5'-AAA ^{3'}	5'-TTg ^{3'}	5'-CTC ^{3'}	5'-ggC ^{3'}	5'-CTC ^{3'}
A*	+	+	+			
B*	+	+	+			
C*	+	+	+			
DRB1				+	+	
DRB3				+	+	
DRB5				+		
DQB1					+	
DPB1						+

¹The nucleotide position for HLA class I genes and the codon for HLA class II genes, in the 2nd or 3rd 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 web site. The sequence of the 3 terminal nucleotides of the primer is given.

²The nucleotide position for HLA class I genes and the codon for HLA class II genes, in the 2nd or 3rd exon or the 2nd 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 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

Visit www.olerup-ssp.com for
“Instructions for Use” (IFU)

Lot No.: **02S**

Lot-specific information

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

Visit www.olerup-ssp.com for
“Instructions for Use” (IFU)

Lot No.: **02S**

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 57:01:14 alleles.

PLATE LAYOUT

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

1	2	3	4	5	6	7	8
9	10	11	12	13	14	15	16

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. '02S'.

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, B*14:20, five B*15, B*18:81, B*35:127, B*35:208, five B*40, B*44:153, B*49:22, B*51:126, B*55:14, B*58:12, B*58:14 and B*58:36 alleles.

In addition, primer mix 13 will amplify the A*02:42, A*02:285 and A*02:310 alleles, primer mix 15 will amplify the A*33:12 allele, primer mix 14 will amplify the C*03:87, C*03:129, C*05:27, C*05:39 and C*17:07 alleles, 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 kit¹.

The HLA-B*57:01 typing kit cannot distinguish the silent mutations in the B*57:01:01 to B*57:01:14 alleles.

¹HLA-B alleles listed on the IMGT/HLA web page 2012-October-17, release 3.10.0, www.ebi.ac.uk/imgt/hla.

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

Visit www.olerup-ssp.com for
 “Instructions for Use” (IFU)

Lot No.: **02S**

Lot-specific information

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 ¹	Size of control band ²	Amplified HLA-B*57:01 alleles	Other amplified HLA-B alleles ^{3,4}
1⁵	90 bp	800 bp	*57:01:01-57:01:14	*57:02:01-57:15, 57:17-57:19, 57:21-57:35, 57:37-57:44, 57:46-57:50, 57:52-57:60, 58:36
2	220 bp	800 bp	*57:01:01-57:01:14	*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, 35:208, 40:30, 40:34, 44:153, 55:14, 58:14
3^{5,7}	95 bp, 170 bp, 215 bp	800 bp		*57:04, 57:06, 57:18, 57:27, 57:32, 44:153
4⁵	100 bp	1070 bp		*57:15, 57:20, 57:29, 07:120, 15:214, 18:81, 40:150
5^{5,8}	90 bp, 165 bp, 245 bp	800 bp		*57:07, 57:16, 57:23, 57:26, 57:34, 44:153, 55:14, C*06:72
6^{5,9}	90 bp, 210 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, 40:30, 40:34
7^{5,6,10}	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, 35:208, 40:30, 40:34, 44:153, 55:14, 58:14, C*06:72
8	185 bp	1070 bp		*57:10, 57:44
9^{5,11}	110 bp, 150 bp	800 bp		*57:21, 57:33, 57:40, 14:20, 35:127
10^{5,6,12}	90 bp, 170 bp, 205 bp, 240 bp	1070 bp		*57:04, 57:13, 57:22, 57:37, 57:41, 57:43, 57:57, 44:153, 55:14, C*06:72

101.572-12– including *Taq* pol., IFU-01101. 572-12u– without *Taq* pol., IFU-02Visit www.olerup-ssp.com for

“Instructions for Use” (IFU)

Lot No.: **02S**

Lot-specific information

11⁵	100 bp	1070 bp	*57:01:01- 57:01:14	*57:06, 57:08, 57:10, 57:13- 57:16, 57:18-57:27, 57:29- 57:31, 57:33-57:38, 57:40 ^w , 57:41, 57:43-57:45, 57:47- 57:52, 57:54-57:56, 57:58- 57:60, 35:208, 55:14, 58:14, C*06:72
12^{5,6,13}	75 bp, 100 bp, 140 bp	1070 bp		*57:08, 57:35-57:36, 57:38, 57:60, 15:87
13^{5,14}	105 bp, 155 bp, 200 bp	1070 bp		*57:45, 57:49, 57:51, 57:58, 58:12, A*02:42, A*02:285, A*02:310
14⁵	125 bp	1070 bp		*57:47, 57:54, 57:59, 15:33, 15:116, 15:248, 40:63, 40:92, 49:22, 51:126, C*03:87, C*03:129, C*05:27, C*05:39, C*17:07
15¹⁵	145 bp, 185 bp, 295 bp	1070 bp		*57:48, 57:55-57:56, A*33:12
16¹⁶	-	-		Negative control

¹Alleles 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 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 respective lengths of the HLA-specific PCR product(s) are given for the alleles amplified by these primer mixes.

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.

²The 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.

³Due to the sharing of sequence motifs between HLA-B alleles some non-HLA-B*57 alleles will be amplified by primer mixes 1 to 7 and 9 to 14. In addition, primer mix 13 will amplify the A*02:42, A*02:285 and A*02:310 alleles, primer mix 15 will amplify the A*33:12 allele, primer mix 14 will

101.572-12– including *Taq* pol., IFU-01101. 572-12u– without *Taq* pol., IFU-02Visit www.olerup-ssp.com for
“Instructions for Use” (IFU)**Lot No.: 02S****Lot-specific information**

amplify the C*03:87, C*03:129, C*05:27, C*05:39 and C*17:07 alleles, and primer mixes 5, 7, 10 and 11 will amplify the C*06:72 allele.

⁴For several HLA Class I alleles 1st and/or 4th 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. We assume that unknown sequences in these regions are conserved within allelic groups.

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

⁶Primer mixes 7, 10 and 12 may have tendencies of unspecific amplifications.

⁷Primer mix 3: Specific PCR fragment of 95 bp in the B*57:04 and 57:32 and the B*44:153 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.

⁸Primer 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 in the B*44:153, 55:14 and the C*06:72 alleles.

⁹Primer 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.

¹⁰Primer 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 the B*35:208, 44:153, 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.

¹¹Primer 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 the B*14:20 and 35:127 alleles.

¹²Primer mix 10: Specific PCR fragment of 90 bp in the B *57:04, 57:41 and the B*44:153 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, 57:57 and the B*55:14 alleles. Specific PCR fragment of 240 bp in the B*57:43 allele. Specific PCR fragment of 90 and 205 bp in the C*06:72 allele.

¹³Primer 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 140 bp in the B*57:08, 57:38 and 57:60 and the B*15:87 alleles.

¹⁴Primer 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 155 bp in the B*57:58 and in the B*58:12 and the A*02:42 and A*02:310 alleles. Specific PCR fragment of 200 bp in the B*57:49 allele.

¹⁵Primer 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.

¹⁶Well 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

Visit www.olerup-ssp.com for
“Instructions for Use” (IFU)

Lot No.: 02S

Lot-specific information

INTERPRETATION TABLE																
HLA-B*57:01 SSP typing																
	Well ^{4,5}															
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
Length of spec. PCR product(s)	90	220	95	100	90	90	100	185	110	90	100	75	105	125	145	Negative Control
			170		165	210	140		150	170		100	155		185	
			215		245		175			205		140	200		295	
							215			240						
							240									
Length of int. pos. control ¹	800	800	800	1070	800	1070	1070	1070	800	1070	1070	1070	1070	1070	1070	
5'-primer(s) ²	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			142	485	395	
				5' -TgT ^{3'}	5' -TCg ^{3'}	5' -ggT ^{3'}		5' -CCT ^{3'}	5' -CAA ^{3'}	5' -gCA ^{3'}			5' -TCT ^{3'}	5' -CAA ^{3'}	5' -gCC ^{3'}	
					209				392				193	499	757	
					5' -ggA ^{3'}				5' -CgA ^{3'}				5' -CCA ^{3'}	5' -TCT ^{3'}	5' -CCA ^{3'}	
					362											
					5' -ggT ^{3'}											
3'-primer(s) ³	256	539	418	259	256	2 nd 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' -TCg ^{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		302				
			5' -Agg ^{3'}				5' -gCC ^{3'}			5' -gAC ^{3'}		5' -ggC ^{3'}				
							538					320				
							5' -gTC ^{3'}					5' -Agg ^{3'}				
							559									
							5' -CTC ^{3'}									
Well No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16

Negative Control

101.572-12– including *Taq* pol., IFU-01101. 572-12u– without *Taq* pol., IFU-02Visit www.olerup-ssp.com for

“Instructions for Use” (IFU)

Lot No.: **02S**

Lot-specific information

Well No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
HLA-B allele																
*57:01:01-57:01:14	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	12				
*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, 57:60	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, 57:59	1	2									11			14		
*57:48, 57:55-57:56	1	2									11				15	
*57:49, 57:58	1	2									11		13			
*57:53	1	2					7									
*57:57	1	2				6				10						
*07:120, 15:214, 18:81, 40:150				4												
*14:20, 35:127									9							
*15:33, 15:116, 15:248, 40:63, 40:92, 49:22, 51:126, C*03:87, C*03:129, C*05:27, C*05:39, C*17:07														14		
*15:87												12				
*35:208, 58:14		2					7				11					
*40:30, 40:34		2				6	7									
*44:153		2	3		5		7			10						
*55:14		2			5		7			10	11					
*58:12, A*02:42, A*02:285, A*02:310													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

Negative Control

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

Visit www.olerup-ssp.com for
“Instructions for Use” (IFU)

Lot No.: **02S**

Lot-specific information

¹The 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.

²The nucleotide position, in the 2nd, 3rd or 4th exon, matching the specificity-determining 3'-end of the primer is given. Nucleotide numbering as on the www.ebi.ac.uk/imgt/hla web site. The sequence of the 3 terminal nucleotides of the primer is given.

³The nucleotide position, in the 2nd, 3rd, 4th or 5th exon or the 2nd 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 web site. The sequence of the 3 terminal nucleotides of the primer is given.

⁴Primer mix 3: Specific PCR fragment of 95 bp in the B*57:04 and 57:32 and the B*44:153 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 in the B*44:153, 55:14 and 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 the B*35:208, 44:153, 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 the B*14:20 and 35:127 alleles.

Primer mix 10: Specific PCR fragment of 90 bp in the B *57:04, 57:41 and the B*44:153 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, 57:57 and the B*55:14 alleles. Specific PCR fragment of 240 bp in the B*57:43 allele. Specific PCR fragment of 90 and 205 bp in the C*06:72 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 140 bp in the B*57:08, 57:38 and 57:60 and the B*15:87 alleles.

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 155 bp in the B*57:58 and in the B*58:12 and the A*02:42 and A*02:310 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.

⁵Primer 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

Visit www.olerup-ssp.com for
 “Instructions for Use” (IFU)

Lot No.: **02S**

Lot-specific information

CELL LINE VALIDATION SHEET																			
HLA-B*57:01 SSP typing kit																			
					Well														
					1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
				Prod. No.:	201315201	201315202	201315203	201315204	201315205	201315206	201315207	201315208	201315209	201315210	201315211	201315212	201315213	201315214	201315215
	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	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

Visit www.olerup-ssp.com for
“Instructions for Use” (IFU)

Lot No.: **02S**

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: 02S
Expiry date: 2015-August-01
Number of tests: 12
Number of wells per test: 15+1

Well specifications:

Well No.	Production No.	Well No.	Production No.
1	2013-152-01	9	2013-152-09
2	2013-152-02	10	2013-152-10
3	2013-152-03	11	2013-152-11
4	2013-152-04	12	2013-152-12
5	2013-152-05	13	2013-152-13
6	2013-152-06	14	2013-152-14
7	2013-152-07	15	2013-152-15
8	2013-152-08		

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 12 to 15 were tested by separately adding additional 5'-primers, respectively 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 solutions 3, 4, 7, 10, 11, 12 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. 2012-085-01**, can detect contamination with PCR products diluted 10^{-7} .

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

Date of approval: 2013-February-26

Approved by:

Production Quality Control

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

Visit www.olerup-ssp.com for
“Instructions for Use” (IFU)

Lot No.: **02S**

Lot-specific information

Declaration of Conformity

Product name: *Olerup* SSP® HLA-B*57:01
Product number: 101.572-12/12u
Lot number: 02S

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 13485:2012, 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-February-26

Ann-Cathrin Jareman
Head of QA and Regulatory Affairs

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

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

Visit www.olerup-ssp.com for
“Instructions for Use” (IFU)

Lot No.: **02S**

Lot-specific information

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

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

Visit www.olerup-ssp.com for
“Instructions for Use” (IFU)

Lot No.: **02S**

Lot-specific information

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

Visit www.olerup-ssp.com for
“Instructions for Use” (IFU)

Lot No.: **02S**

Lot-specific information

ADDRESSES:

Manufacturer:

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

Tel: +46-8-717 88 27

Fax: +46-8-717 88 18

E-mail: info-ssp@olerup.com

Web page: <http://www.olerup-ssp.com>

Distributed by:

Olerup GmbH, Löwengasse 47 / 6, AT-1030 Vienna, Austria.

Tel: +43-1-710 15 00

Fax: +43-1-710 15 00 10

E-mail: support-at@olerup.com

Web page: <http://www.olerup.com>

Olerup Inc., 901 S. Bolmar St., Suite R, West Chester, PA 19382

Tel: 1-877-OLERUP1

Fax: 610-344-7989

E-mail: info.us@olerup.com

Web page: <http://www.olerup.com>

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