Olerup SSP® HLA-B*57:01

Product number:	**101.572-12 – including *Taq* polymerase**
Lot number:	**08M**
Expiry date:	**2013-October-01**
Number of tests:	**12**
Number of wells per test:	**12+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. 08M.

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

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. 12K)**.

Two wells have been added to the HLA-B*57:01 kit,
wells **12 and 13.**

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

Well	5'-primer	3'-primer	rationale
5	Modified, added	-	Improved specificity, primer added for the B*57:34 allele.
9	Added	-	Primers added for the B*57:33 and 57:40 alleles.
10	Added	Added	Primer pairs added for the B*57:37, 57:41 and 57:43 alleles.
11	New, removed	New, removed	New primer pair for improved allelic resolution, negative control moved to well 13.
12	New	New	New primer pair for the B*57:35, 57:36 and 57:38 alleles.
13	Moved	Moved	Negative control moved from well 11.

Well **13** 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 the 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'-primer[1]	**164**	**340**	**440**	**45**	**45**	**43**
	5'-CAC3'	**5'-Agg3'**	**5'-TTA3'**	**5'-Tg g3'**	**5'-Tg g3'**	**5'-Tg g3'**
3'-primer[2]	**231**	**2nd I**	**507**	**59**	**58**	**57**
	5'-TgC3'	**5'-AAA3'**	**5'-TTg3'**	**5'-CTC3'**	**5'-ggC3'**	**5'-CTC3'**
A*	**+**	**+**	**+**			
B*	**+**	**+**	**+**			
C*	**+**	**+**	**+**			
DRB1				**+**	**+**	
DRB3				**+**	**+**	
DRB5				**+**		
DQB1					**+**	
DPB1						**+**

[1]The 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.

[2]The 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.

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 57:01:10 alleles.

PLATE LAYOUT
Each test consists of 13 PCR reactions in a 16 well cut PCR plate. Wells 14 to 16 are empty.

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

The 16 well cut PCR plate is marked with 'B*57:01' in silver/gray ink.
Well No. 1 is marked with the Lot No. '08M'.
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, 15:214, 35:127, 40:30, 40:34, 40:150, 55:14 and 58:14 alleles.

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[1].
The HLA-B*57:01 typing kit cannot distinguish the B*57:01:01 to B*57:01:10 alleles.

[1]HLA-B alleles listed on the IMGT/HLA web page 2011-January-14, release 3.3.0, www.ebi.ac.uk/imgt/hla.

SPECIFICITY TABLE

HLA-B*57:01 SSP subtyping

Specificities and sizes of the PCR products of the 13 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]
1[4]	90 bp	**800 bp**	*57:01:01-57:01:10	*57:02:01-57:15, 57:17-57:19, 57:21-57:35, 57:37-57:43
2	220 bp	**800 bp**	*57:01:01-57:01:10	*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, **40:30, 40:34, 55:14, 58:14**
3[4,6]	95 bp, 170 bp, 215 bp	**800 bp**		*57:04, 57:06, 57:18, 57:27, 57:32
4[4]	100 bp	1070 bp		*57:15, 57:20, 57:29, **07:120, 15:214, 40:150**
5[4,7]	90 bp, 165 bp, 245 bp	**800 bp**		*57:07, 57:16, 57:23, 57:26, 57:34, **55:14**
6[4,8]	90 bp, 210 bp	1070 bp		*57:02:01-57:03:02, 57:07-57:09, 57:12, 57:17, 57:39, 57:42, **40:30, 40:34**
7[5,9]	140 bp, 165 bp, 215 bp, 240 bp	1070 bp		*57:09, 57:13-57:14, 57:24-57:25, 57:31, **40:30, 40:34, 55:14, 58:14**
8	195 bp	1070 bp		*57:10
9[4,10]	110 bp, 150 bp	**800 bp**		*57:21, 57:33, 57:40, **14:20, 35:127**
10[4,5,11]	90 bp, 170 bp, 205 bp, 240 bp	1070 bp		*57:04, 57:13, 57:22, 57:37, 57:41, 57:43, **55:14**
11[4]	100 bp	1070 bp	*57:01:01-57:01:10	*57:06, 57:08, 57:10, 57:13-57:16, 57:18-57:27, 57:29-57:31, 57:33-57:38, 57:40-57:41, 57:43, **55:14, 58:14**
12[4,12]	75 bp, 100 bp, 135 bp	1070 bp		*57:35-57:36, 57:38
13[13]				**Negative control**

[1]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 inherit 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.
[2]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.
[3]Due to the sharing of sequence motifs between HLA-B alleles some non-HLA-B*57 alleles will be amplified by primer mixes 2, 4 to 7 and 9 to 11.
[4]Short specific PCR fragments are less intense and not as sharp as longer specific bands.
[5]Primer mixes 7 and 10 have a tendency of giving rise to nonspecific amplifications, most pronounced in primer mix 10.
[6]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.
[7]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*55:14, alleles.
[8]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 and 57:42 and in the B*40:30 and 40:34 alleles. Specific PCR fragment of 210 bp in the B*57:08 allele.
[9]Primer mix 7: Specific PCR fragment of 140 bp in the B*57:31 allele. Specific PCR fragment of 165 bp in the B*57:14 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.
[10]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.
[11]Primer mix 10: Specific PCR fragment of 90 bp in the B*57:04 and 57:41 alleles. Specific PCR fragment of 170 bp in the B*57:04, 57:37, 57:41 and 57:43 alleles. Specific PCR fragment of 240 bp in the B*57:43 allele. Specific PCR fragment of 90 and 205 bp in the B*57:13 and 57:22 and the B*55:14 alleles.
[12]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.
[13]Well13 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.

INTERPRETATION TABLE

HLA-B*57:01 SSP typing

	Well[4,5]												
	1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**
Length of spec.	**90**	**220**	**95**	**100**	**90**	**90**	**140**	**195**	**110**	**90**	**100**	**75**	
PCR product(s)			**170**		**165**	**210**	**165**		**150**	**170**		**100**	
			215		**245**		**215**			**205**		**135**	
							240			**240**			
Length of int.	**800**	**800**	**800**	**1070**	**800**	**1070**	**1070**	**1070**	**800**	**1070**	**1070**	**1070**	
pos. control[1]													
5'-primer(s)[2]	**209**	**362**	**362**	**209**	**130**	**320**	**362**	**103**	**352**	**362**	**362**	**209**	
	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'	
				704	**200**	**362**			**353**	**878**			
				5' -TgT 3'	5' -TCg 3'	5' -ggT 3'			5' -CAA 3'	5' -gCA 3'			
					209				**392**				
					5' -ggA 3'				5' -CgA 3'				
					362								
					5' -ggT 3'								
3'-primer(s)[3]	**256**	**539**	**418**	**259**	**256**	**2nd I**	**463**	**256**	**463**	**409**	**419**	**244**	
	5' -CCC 3'	5' -TCA 3'	5' -gTC 3'	5' -CTT 3'	5' -CCC 3'	5' -TCg 3'	5' -gCg 3'	5' -CCC 3'	5' -gCT 3'	5' -ATA 3'	5' -Cgg 3'	5' -CTT 3'	
			481	**271**	**559**	**412**	**486**			**527**	**419**	**268**	
			5' -gTA 3'	5' -CAC 3'	5' -CgT 3'	5' -gTT 3'	5' -gCg 3'			5' -CCT 3'	5' -CAg 3'	5' -gTg 3'	
			500	**774**	**572**		**538**			**559**		**302**	
			5' -ggA 3'	5' -ggT 3'	5' -gCg 3'		5' -gTC 3'			5' -Cgg 3'		5' -ggg 3'	
			537				**559**			**916**			
			5' -Agg 3'				5' -CTC 3'			5' -gAC 3'			
Well No.	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**
HLA-B allele													
***57:01:01-57:01:10**	**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**	**1**	**2**				**6**							
***57:04**	**1**		**3**							**10**			
***57:05, 57:11, 57:28N**	**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**	**1**	**2**						**8**			**11**		
***57:13**	**1**						**7**			**10**	**11**		
***57:14, 57:25, 57:31**	**1**	**2**					**7**				**11**		
***57:15, 57:29**	**1**	**2**		**4**							**11**		
***57:16**		**2**			**5**						**11**		
***57:19, 57:30**	**1**										**11**		
***57:20**		**2**		**4**							**11**		
***57:21, 57:33, 57:40**	**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**										
Well No.	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**

Negative Control

Negative Control

Length of spec.	**90**	**220**	**95**	**100**	**90**	**90**	**140**	**195**	**110**	**90**	**100**	**75**	
PCR product(s)			**170**		**165**	**210**	**165**		**150**	**170**		**100**	
			215		**245**		**215**			**205**		**135**	
							240			**240**			
Well No.	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**
***57:35, 57:38**	**1**	**2**									**11**	**12**	**Negative Control**
***57:36**		**2**									**11**	**12**	
***07:120, 15:214, 40:150**				**4**									
***14:20, 35:127**									**9**				
***40:30, 40:34**		**2**				**6**	**7**						
***55:14**		**2**			**5**		**7**			**10**	**11**		
***58:14**		**2**					**7**				**11**		
HLA-B allele													
Well No.	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**

[1]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.
[2]The 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.
[3]The 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.
[4]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 in the B*55:14, 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 and 57:42 and in 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 140 bp in the B*57:31 allele. Specific PCR fragment of 165 bp in the B*57:14 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 alleles. Specific PCR fragment of 170 bp in the B*57:04, 57:37, 57:41 and 57:43 alleles. Specific PCR fragment of 240 bp in the B*57:43 allele. Specific PCR fragment of 90 and 205 bp in the B*57:13 and 57:22 and the B*55:14 alleles.
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.
[5]Primer mix 13 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.

CELL LINE VALIDATION SHEET

HLA-B*57:01 SSP typing kit

					Well											
					1	2	3	4	5	6	7	8	9	10	11	12
				Prod. No.:	201184501	201184502	201184503	201184504	201184505	201184506	201184507	201184508	201184509	201184510	201184511	201184512
	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	-	-	-	-	-	-	-	-	-	-	-	-

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-B*57:01 SSP

Product number: **101.572-12 – including *Taq* polymerase**
Lot number: **08M**
Expiry date: **2013-October-01**
Number of tests: **12**
Number of wells per test: **12+1**

Well specifications:

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

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 were available. The specificities of the primers in primer solutions 3 to 5, 7, 8 and 10 were tested by separately adding one to four additional 5'-primers, respectively one 3'-primer. 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, 10 and 11 one to three 3'-primers were not possible to test, and in primer solutions 4, 5 and 10 one to three 5'-primers were not possible to test.
The negative control primer pairs, **Production No. 2010-760-01**, can detect contamination with PCR products diluted 10^{-7}.

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

Date of approval: 2011-April-20

Approved by:

Quality Control, Supervisor

Declaration of Conformity

Product name: *Olerup* SSP® HLA-B*57:01
Product number: 101.572-12
Lot number: 08M

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.

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.)

Stockholm, Sweden
2011-April-20

Olle Olerup
Managing Director

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