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Lot No.: 76R Lot-specific information

Olerup SSP® HLA-B*67

Product number: 101.550-06 – including *Taq* polymerase

101.550-06u – without *Taq* polymerase

Lot number: 76R

Expiry date: 2015-May-01

Number of tests: 6 Number of wells per test: 6

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. 76R.

Changes compared to the previous *OLERUP* SSP® HLA-B*67 Lot (49M).

The HLA-A*67 kit is updated for new alleles to enable separation of:

- Confirmed¹ 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

The Lot-specific information for HLA-A*67 including and without *Taq* polymerase is now described in one common Product Insert.

The HLA-B*67 specificity and interpretation tables have been updated for the HLA-B alleles described since the previous *Olerup* SSP® HLA-B*67 lot was made (Lot No. 49M).

The HLA-B*67 primer set is unchanged compared to the previous lot.

¹As described in section Uniquely Identified Alleles.

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PRODUCT DESCRIPTION

HLA-B*67 SSP typing

CONTENT

The primer set contains 5'- and 3'-primers for identifying the B*67:01 to B*67:03 alleles.

PLATE LAYOUT

Each HLA-B*67 test consists of 6 PCR reactions in an 8 well cut PCR plate. Wells 7 and 8 are empty.

1 2 3 4 5 6 empty	npty
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The 8 well PCR plate is marked with 'B67' in silver/gray ink.

Well No. 1 is marked with the Lot No. '76R'.

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 8 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*67 SSP subtypings will be influenced by most B*07, the B*08:94, ten B*14, five B*15, most B*18, eight B*27, six B*35, two B*37, the B*38, most B*39, several B*40, most B*42, the B*44:131, the B*46, the B*48, two B*54, two B*55, three B*56, the B*58:20, the B*73, the B*81 and the B*83:01 alleles when present on the other haplotype.

In addition, the C*01:73, C*07:02:30 and C*08:16:02 alleles will be amplified by primer mix 4, the C*03:137, C*07:102 $^{\rm w}$ and C*12:82 alleles will be amplified by primer mix 5, the C*05:70, C*06:40 and C*07:137:01-07:137:02 alleles will be amplified by primer mix 6 and the C*15:51 allele will be amplified by primer mixes 3 and 6.

UNIQUELY IDENTIFIED ALLELES

All the HLA-B*67, i.e. **B*67:01 to B*67:03**, recognized by the HLA Nomenclature Committee in October 2012¹ will be amplified by the primers in the HLA-B*67 SSP kit.

The HLA- B*67 kit enables separation of the confirmed HLA-B*67 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*67 alleles is listed below.

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The HLA- B*67 kit also enables identification of polymorphisms in exons outside of the region encoding the peptide binding domain and of null and alternatively expressed alleles.

The HLA-B*67 subtyping kit cannot distinguish the silent mutations in the B*67:01:01 and B*67:01:02 alleles.

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

ALLELE CONFIRMATION STATUS

Allele	Status ¹
B*67:01:01	Confirmed
B*67:01:02	Confirmed
B*67:02	Confirmed
B*67:03	Unconfirmed

¹Allele status "confirmed" or "unconfirmed" as listed on the IMGT/HLA web page 2012-October-17, release 3.10.0, <u>www.ebi.ac.uk/imgt/hla</u>.

RESOLUTION IN HOMO- AND HETEROZYGOTES

A total of 4 alleles generate 3 amplification patterns that can be combined in 6 homozygous and heterozygous combinations. 2 of these genotypes do not give rise to unique amplification patterns.

*67:01:01, *67:03 = *67:03, *67:03

*67:01:01 = *67:01:01-67:01:02

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Lot No.: 76R Lot-specific information

SPECIFICITY TABLE

HLA-B*67 SSP subtyping

Specificities and sizes of the PCR products of the 6 primer mixes used for HLA-B*67 SSP subtyping

Primer Mix	Size of spec. PCR product ¹	Size of control band ²	Amplified HLA-B*67 alleles ³	Other amplified HLA-B alleles ⁴
1	210 bp	800 bp	*67:01:01- 67:01:02, 67:03	*07:02:01-07:02:27, 07:02:29- 07:02:37, 07:04-07:07, 07:09, 07:11- 07:12, 07:14-07:15, 07:17-07:26, 07:28, 07:30-07:31, 07:33-07:36, 07:39-07:49N, 07:51-07:64, 07:66- 07:68:03, 07:73-07:82, 07:84, 07:87- 07:124, 07:126-07:176, 38:26, 42:01:01-42:02, 42:04-42:06, 42:08- 42:10, 42:12-42:17, 54:02, 55:10, 56:35, 81:01-81:04N, 81:06
2	325 bp	1070 bp	*67:02	
3 ⁶	165 bp	800 bp	*67:01:01- 67:03	*38:01:01, 38:01:03-38:07, 38:09, 38:11-38:21, 38:23-38:29, 38:31-38:35, 38:38-38:42, 39:01:01:01-39:01:01:03, 39:01:03-39:06:02, 39:08-39:13:02, 39:15-39:16, 39:18-39:20, 39:22-39:24:02, 39:26-39:28, 39:31, 39:35, 39:37-39:42, 39:44-39:46, 39:48-39:49, 39:51-39:69, 39:71-39:73, 39:75-39:79, 40:184, 58:20, C*15:51
4	160 bp	1070 bp		*07:02:01-07:02:02, 07:02:04-07:02:37, 07:04-07:05:03, 07:05:05-07:07, 07:09-07:15, 07:17-07:26, 07:28-07:31, 07:33-07:36, 07:39-07:46, 07:48-07:49N, 07:51-07:55, 07:56:02-07:68:03, 07:70-07:72, 07:74-07:84, 07:86-07:108, 07:110-07:176, 15:76, 15:101, 27:75, 35:76, 35:186, 42:01:01-42:02, 42:04-42:06, 42:08-42:10, 42:12-42:17, 46:01:01-46:36, 46:38, 54:01:02, 55:35, 56:03, 56:06, 73:01*-73:02*, 81:01-81:06, 83:01, C*01:73, C*07:02:30, C*08:16:02

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67:03 07:30-07:35, 07:37, 07:39-07:56:02, 07:58-064, 07:64, 07:66-07:69, 07:73-07:74, 07:76-07:80, 07:82-07:85, 07:87-07:148, 07:150-07:176, 08:94, 14:01:01-14:01:02, 14:07N-14:08, 14:10, 14:12, 14:14, 14:19, 14:26, 14:32, 15:68, 15:71, 15:175, 18:01:01-01-18:01:12, 18:01:14-18:03, 18:05-18:08, 18:10-18:15, 18:17N-18:24, 18:26-18:48, 18:50-18:53, 18:55-18:66, 18:69, 18:71-18:78, 18:80-18:83, 27:08, 27:12, 27:18, 27:26, 27:33, 27:40, 27:44, 35:50, 35:84, 35:162, 35:197, 37:11, 37:37, 39:01:01:03-39:01:01:03, 39:03:03-39:03, 39:05:01-39:11, 39:13:01-39:19:02, 39:22-39:24:01, 39:25N-39:62, 39:64-39:71, 39:73-39:75, 39:77-39:79, 40:02:01-40:06:06, 40:08-40:09, 40:11:01-40:11:02, 40:18, 40:20, 40:24, 40:26, 40:29, 40:35, 40:39-40:40, 40:44, 40:50, 40:56, 40:64, 40:68, 40:70-40:71, 40:74-40:75, 40:78, 40:82-40:83, 40:89-40:91, 40:93-40:91, 40:93-40:90, 40:11-01-40:11:02, 40:1120, 40:1120, 40:1120, 40:115, 40:119-40:120, 40:1140, 40:145, 40:189-40:190, 40:1140, 40:145, 40:149, 40:149, 40:141, 40:115, 40:119-40:120, 40:1142, 40:147, 40:115, 40:119-40:120, 40:1142, 40:147, 40:114, 40:145, 40:149, 40:159, 40:61-40:177, 40:114, 40:115, 40:114, 40:1149, 40:159, 40:161, 40:162, 40:165, 40:167, 40:169, 40:173-40:174, 40:176-40:177, 40:181, 40:189-40:190, 40:200, 40:204-40:203, 40:205-40:206, 40:209-40:211, 40:205-40:206, 40:209-40:211, 40:205-40:206, 40:209-40:211, 40:205-40:206, 40:209-40:211, 40:212, 40:226, 42:01:01-42:02, 42:04-42:14, 42:16-42:17, 44:131, 48:01-148:17, 48:15, 48:21, 48:23-48:28, 54:02, 55:10-56:35, 73:01-73:02, 81:01-81:06, C*03:137, C*07:102*, C*12:82	Lot No.:	701	Lui-spi	ecific informat	tion
C*03:137, C*07:102 ^w , C*12:82		-	•	*67:01:01-	*07:02:01-07:10, 07:12-07:26, 07:28, 07:30-07:35, 07:37, 07:39-07:56:02, 07:58-07:64, 07:66-07:69, 07:73-07:74, 07:76-07:80, 07:82-07:85, 07:87-07:148, 07:150-07:176, 08:94, 14:01:01-14:01:02, 14:07N-14:08, 14:10, 14:12, 14:14, 14:19, 14:26, 14:32, 15:68, 15:71, 15:175, 18:01:01:01-18:01:12, 18:01:14-18:03, 18:05-18:08, 18:10-18:15, 18:17N-18:24, 18:26-18:48, 18:50-18:53, 18:55-18:66, 18:69, 18:71-18:78, 18:80-18:83, 27:08, 27:12, 27:18, 27:26, 27:33, 27:40, 27:44, 35:50, 35:84, 35:162, 35:197, 37:11, 37:37, 39:01:01:01-39:01:01:03, 39:01:03-39:03, 39:05:01-39:11, 39:13:01-39:19:02, 39:22-39:24:01, 39:25N-39:62, 39:64-39:71, 39:73-39:75, 39:77-39:79, 40:02:01-40:06:06, 40:08-40:09, 40:11:01-40:11:02, 40:18, 40:20, 40:24, 40:26-40:29, 40:35, 40:39-40:40, 40:44, 40:50, 40:56, 40:64, 40:68, 40:70-40:71, 40:74-40:75, 40:78, 40:82-40:83, 40:85-40:86, 40:89-40:91, 40:93-40:95, 40:107, 40:111, 40:115, 40:119-40:120, 40:112, 40:127, 40:131, 40:133Q, 40:142N-40:145, 40:148-40:149, 40:159, 40:161-40:162, 40:165, 40:167, 40:169, 40:173-40:174, 40:176-40:177, 40:180-40:181, 40:184, 40:189-40:190, 40:200, 40:204-40:203, 40:205-40:206, 40:209-40:211, 40:214, 40:220, 40:224-40:226, 42:01:01-42:02, 42:04-42:14, 42:16-42:17, 44:131, 48:01:01-48:17, 48:1948:21, 48:23-48:28, 54:02, 55:10,
6° 110 pp 1070 pp 167:03 C105:70, C106:40, C107:137:01- 07:137:02, C*15:51	6 ⁵	110 bp	1070 bp	*67:03	48:21, 48:23-48:28, 54:02, 55:10, 56:35, 73:01-73:02, 81:01-81:06, C*03:137, C*07:102 ^w , C*12:82 C*05:70, C*06:40, C*07:137:01-

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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*67 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 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.

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.

Wells number 1 and 3 contain the primer pair giving rise to the shorter, 800 bp, internal positive control band.

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

³For 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.

⁴Due to the sharing of sequence motifs between HLA-B alleles non-HLA-B*67 alleles will be amplified by primer mixes 1 and 3 to 5. In addition, the C*01:73, C*07:02:30 and C*08:16:02 alleles will be amplified by primer mix 4, the C*03:137, C*07:102^w and C*12:82 alleles will be amplified by primer mix 5, the C*05:70, C*06:40 and C*07:137:01-07:137:02 alleles will be amplified by primer mix 6 and the C*15:51 allele will be amplified by primer mixes 3 and 6.

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

⁶Primer mix 3 may give rise to a lower yield of HLA-specific PCR product than the other HLA-B*67 primer mixes.

"w", may be weakly amplified.

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INTERPRETATION TABLE						
HLA-B*67 S	SP su	btypin	g			
Amplification patter	ns of t	he B*6	7 allele	s		
			We	ell		
	1	2	3	4	5	6
Length of spec.	210	325	165	160	240	110
PCR product						
Length of int.	800	1070	800	1070	1070	1070
pos. control ¹						
5'-primer ²	103	44	419	165	103	477
	5' -CCT 3'	^{5'} -ggC ^{3'}	^{5'} -gTT ^{3'}	^{5'} -ACC ^{3'}	5' -CCT 3'	^{5'} -gCC ^{3'}
	103				103	
	5' -CCT 3'				5' -CCT 3'	
3'-primer ³	272	201	544	282	302	544
	^{5'} -TgT ^{3'}	5' -CTT 3'	^{5'} -ggT ^{3'}	^{5'} -gCC ^{3'}	^{5'} -ggC ^{3'}	^{5'} -ggT ^{3'}
Well No.	1	2	3	4	5	6
HLA-B allele ⁴			_			
*67:01:01-67:01:02	1		3		5	
*67:02		2	3		5	
*67:03	1		3		5	6
*07:02:01-07:02:02, 07:02:04-07:02:27,						
07:02:29-07:02:37, 07:04-07:05:03, 07:05:05-						
07:07, 07:09, 07:12, 07:14-07:15, 07:17-07:26, 07:28, 07:30-07:31, 07:33-07:35, 07:39-07:46,						
07:48-07:49N, 07:51-07:55, 07:56:02, 07:58-						
07:64, 07:66-07:68:03, 07:74, 07:76-07:80,	1			4	5	
07:82, 07:84, 07:87-07:108, 07:110-07:124,						
07:126-07:148, 07:150-07:176, 42:01:01-42:02,						
42:04-42:06, 42:08-42:10, 42:12-42:14, 42:16-						
42:17, 81:01-81:04N, 81:06						
*07:02:03, 07:05:04, 07:47, 07:56:01, 07:73,	_				_	
07:109, 54:02, 55:10, 56:35	1				5	
*07:02:28, 07:10, 07:13, 07:83, 07:125, 81:05				4	5	
Well No.	1	2	3	4	5	6

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Length of spec.	210	325	165	160	240	110
PCR product						
Well No.	1	2	3	4	5	6
*07:03, 07:08, 07:16, 07:32, 07:37, 07:50, 07:69, 07:85, 08:94, 14:01:01-14:01:02, 14:07N-14:08, 14:10, 14:12, 14:14, 14:19, 14:26, 14:32, 15:68, 15:71, 15:175, 18:01:01:01-18:01:12, 18:01:14-18:03, 18:05-18:08, 18:10-18:15, 18:17N-18:24, 18:26-18:48, 18:50-18:53, 18:55-18:66, 18:69, 18:71-18:78, 18:80-18:83, 27:08, 27:12, 27:18, 27:26, 27:33, 27:40, 27:44, 35:50, 35:84, 35:162, 35:197, 37:11, 37:37, 39:07, 39:14, 39:17, 39:25N, 39:29-39:30, 39:32-39:34, 39:36, 39:43, 39:47, 39:50, 39:70, 39:74, 40:02:01-40:06:06, 40:08-40:09, 40:11:01-40:11:02, 40:18, 40:20, 40:24, 40:26-40:29, 40:35, 40:39-40:40, 40:44, 40:50, 40:56, 40:64, 40:68, 40:70-40:71, 40:74-40:75, 40:78, 40:82-40:83, 40:85-40:86, 40:89-40:91, 40:93-40:95, 40:97-40:99, 40:103-40:105, 40:107, 40:111, 40:115, 40:119-40:120, 40:122, 40:127, 40:131, 40:133Q, 40:142N-40:145, 40:148-40:149, 40:159, 40:161-40:162, 40:165, 40:167, 40:169, 40:173-40:174, 40:176-40:177, 40:180-40:181, 40:189-40:190, 40:200, 40:202-40:203, 40:205-40:206, 40:209-40:211, 40:214, 40:220, 40:224-40:226, 42:07, 42:11, 44:131, 48:01:01-48:17, 48:19-48:21, 48:23-48:28, <i>C*03:137, C*12:82</i>					5	
*07:11, 07:36, 07:57, 07:75, 07:81, 07:149, 42:15	1			4		
*07:29, 07:65, 07:70-07:72, 07:86, 15:76, 15:101, 27:75, 35:76, 35:186, 46:01:01-46:36, 46:38, 54:01:02, 55:35, 56:03, 56:06, 83:01, <i>C*01:73, C*07:02:30, C*08:16:02</i>				4		
*38:01:01, 38:01:03-38:07, 38:09, 38:11-38:21, 38:23-38:25, 38:27-38:29, 38:31-38:35, 38:38-38:42, 39:04, 39:12, 39:20, 39:24:02, 39:63, 39:72, 39:76, 58:20			3			
*38:26	1		3			
Well No.	1	2	3	4	5	6

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Length of spec.	210	325	165	160	240	110
PCR product						
Well No.	1	2	3	4	5	6
*39:01:01:01-39:01:01:03, 39:01:03-39:03,						
39:05:01-39:06:02, 39:08-39:11, 39:13:01-						
39:13:02, 39:15-39:16, 39:18-39:19:02, 39:22-						
39:24:01, 39:26-39:28, 39:31, 39:35, 39:37-			3		5	
39:42, 39:44-39:46, 39:48-39:49, 39:51-39:62,						
39:64-39:69, 39:71, 39:73, 39:75, 39:77-39:79,						
40:184						
*73:01-73:02				w	5	
C*05:70, C*06:40, C*07:137:01-07:137:02						6
C*07:102					w	
C*15:51			3			6
HLA-B allele						
Well No.	1	2	3	4	5	6

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.

Wells number 1 and 3 contain the primer pair giving rise to the shorter, 800 bp, internal positive control band.

²The nucleotide position, in the 1st, 2nd or 3rd 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 or 3rd exon, matching the specificity-determining 3'-end of the

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

⁴HLA-B*67 alleles in bold lettering are listed as confirmed alleles on the IMGT/HLA web page www.ebi.ac.uk/imgt/hla, release 3.10.0, October 2012.

[&]quot;w", may be weakly amplified.

Visit <u>www.olerup-ssp.com</u> for "Instructions for Use" (IFU)

Lot No.: / OK Lot-specific information										
	CELL LINE VALIDATION SHEET									
	HLA-B*67 SSP primer set									
							W	ell		
					1	2	3	4	5	6
					_	2	3	4	5	6
				Prod. No.:	201189201	200854802	201189203	200854804	201189205	201189206
				9	186	857	189	857	98	186
				J 20	201	200	201	500	201	201
	IHV	VC cell line		 B*		<u>``</u>				•
1	9001		*07:02		+	-	-	+	+	-
2		LK707	*52:01	*73:01	-	-	-	w	+	-
3	9011	E4181324	*52:01		-	-	-	-	-	-
4	9275	GU373	*15:10	*53:01	-	-	-	-	-	-
5	9009	KAS011	*37:01		-	-	-	-	-	-
6	9353		*39:01	*51:01	-	-	+	-	+	-
7	9020		*18:01		-	-	-	-	+	-
8	9025		*35:01		-	-	-	-	-	-
9	9026		*38:01		-	-	+	-	-	-
10		LKT3	*54:01		-	<u>-</u>	-	-	-	-
11		PITOUT	*44:03		-	-	-	-	-	-
12	9052		*57:01		-	-	-	-	-	-
13		JESTHOM	*27:05	*45.00	-	-	-	-	-	-
14		OLGA	*15:01	*15:20	-	-	-	-	-	-
15	9075		*40:01		-	-	-	-	i.	-
16		SWEIG007	*40:02	*5F.04	-	-	-	-	+	-
17		CTM3953540 32367	*08:01 *14:01	*55:01 *56:01	-	-	-	-	-	-
18 19		32367 BM16	*18:01	50.01	<u> </u>			Ė	+	
20		SLE005	*40:01		l -			Ė	-	
21		AMALA	*15:01		Ε-	-	-	÷	÷	-
22		KOSE	*35:03		-	-	-			-
23	9124		*40:02	*56:02	-	-	-	-	+	-
24		JBUSH	*38:01	33.02	-	-	+	-	Ė	-
25		IBW9	*14:02		-	-	-	-	-	-
26		WT49	*58:01		-	-	-	-	-	-
27		CH1007	*07:05	*51:01	+	-	-	+	+	-
28	9320	BEL5GB	*44:02	*44:03	-	-	-	-	-	-
29	9050	MOU	*44:03		-	-	-	-	-	-
30	9021		*42:01		+			+	+	
31	9019	DUCAF	*18:01		-	-	-	-	+	-
32	9297	HAG	*41:02		-	-	-	-	-	-
33		MT14B	*40:01		-	-	-	-	-	-
34	9104		*38:01		-	-	+	-	-	-
35		SSTO	*44:02		-	-	-	-	-	-
36		KT17	*15:01	*35:01	-	-	-	-	-	-
37		HHKB	*07:02		+	-	-	+	+	-
38	9099		*15:01	*07.05	-	-	-	-	-	-
39	9315		*08:01	*27:05	-	-	-	-	-	-
40		WHONP199	*13:02	*46:01	<u> </u>	-	-	+	-	-
41		H0301	*14:02		-	-	-	-	-	-
42		TAB089	*46:01		-	-	-	+	-	-
43		T7526	*46:01		ļ <u>-</u>	-		+	-	-
44	9057		*38:01	*50.01	-	-	+	-	-	-
45 46		SHJO SCHU	*42:01 *07:02	*50:01	+	-	-	+	+	-
46		TUBO	*51:01		-			-	-	-
48		TER-ND	*35:01	*44:03	<u> </u>			Ť	Ė	
40	9303	ILITIND	33.01	44.03	ت	_	_	Ē	_	

Visit <u>www.olerup-ssp.com</u> for "Instructions for Use" (IFU)

Lot No.: **76R** Lot-specific information

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-B*67 SSP

Product number: 101.550-06 – including *Taq* polymerase

101.550-06u – without *Taq* polymerase

Lot number: 76R

Expiry date: 2015-May-01

Number of tests: 6 Number of wells per test: 6

Well specifications:

Well No.	Production No.
1	2011-892-01
2	2008-548-02
3	2011-892-03
4	2008-548-04
5	2011-892-05
6	2011-892-06

The specificity of each primer solution of the HLA-B*67 primer set has been tested against 48 well characterized IHWC cell line DNAs.

No DNAs carrying the alleles to be amplified by primer solutions 2 and 6 were available. The specificities of the primers in primer solutions 2 and 6 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer.

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

Date of approval: 2012-December-19

Approved by:

Production Quality Control

HLA-B*67 Product Insert Page 12 of 16

101.550-06 – including *Taq* **pol.**, IFU-01 **101.550-06u – without** *Taq* **pol.**, IFU-02

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Lot No.: 76R Lot-specific information

Declaration of Conformity

Product name: Olerup SSP® HLA-B*67

Product number: 101.550-06/06u

Lot number: 76R

Intended use: HLA-B*67 high resolution 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 2012-December-19

Ann-Cathrin Jareman
Head of QA and Regulatory Affairs

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Lot No.: **76R** Lot-specific information

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