

Olerup SSP[®] HLA-B*42

Product number:	101.543-06 – including <i>Taq</i> polymerase
Lot number:	57M
Expiry date:	2014-February-01
Number of tests:	6
Number of wells per test:	15
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. 57M.

CHANGES COMPARED TO THE PREVIOUS *OLERUP SSP[®]* HLA-B*42 LOT.

The HLA-B*42 specificity and interpretation tables have been updated for the HLA-B alleles described since the previous *Olerup SSP[®]* HLA-B*42 lot was made (**Lot No. 62K**).

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	-	5'- primer added for the HLA-B*42:16 allele
8	-	Added	Increased yield of HLA-specific PCR product.
10	-	-	Exchanged positive control primer pair.
14	Added	Added	Primer pair added for the HLA-B*42:15 allele.

PRODUCT DESCRIPTION

HLA-B*42 SSP typing

CONTENT

The primer set contains 5'- and 3'-primers for identifying the B*42:01 to B*42:16 alleles.

PLATE LAYOUT

Each HLA-B*42 test consists of 15 PCR reactions in a 16 well cut PCR plate. Well 16 is empty.

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

The 16 well PCR plate is marked with 'HLA-B*42' in silver/gray ink.

Well No. 1 is marked with the Lot No. '57M'.

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 covered 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*42 SSP subtypings will be influenced by most B*07, most B*08, two B*13, nine B*14, several B*15, the B*18, six B*27, seven B*35, the B*37, the B*38, the B*39, several B*40, the B*41, many B*44, the B*45, the B*48, seven B*51, two B*52, three B*53, most B*54, many B*55, most B*56, two B*57, three B*67, the B*81, the B*82 and the B*83:01 alleles when present on the other haplotype. In addition, the C*07:04:01-07:04:05, C*07:11-07:12, C*07:45, C*07:63, C*07:101, C*07:139, C*07:142, C*07:181 and C*15:25 alleles will be amplified by primer mixes 7 and 10, the C*07:68 allele will be amplified by primer mix 10 and the C*07:49 allele will be amplified by primer mix 14.

UNIQUELY IDENTIFIED ALLELES

All the HLA-B*42, i.e. **B*42:01 to B*42:16**, recognized by the HLA Nomenclature Committee in April 2011¹ will be amplified by the primers in the HLA-B*42 SSP kit. The HLA-B*42 subtyping kit cannot distinguish the B*42:01:01 and 42:01:02 or the 42:05:01 and 42:05:02 alleles.

¹HLA-B alleles listed on the IMGT/HLA web page 2011-April-08, release 3.4.0, www.ebi.ac.uk/imgt/hla.

RESOLUTION IN HOMO- AND HETEROZYGOTES

A total of 17 alleles generate 15 amplification patterns that can be combined in 120 homozygous and heterozygous combinations. 62 of these genotypes do not give rise to unique amplification patterns. The different lengths of the specific PCR products were not considered in these calculations.

+++-----+ +-----+-	*42:09, *42:13 = *42:09, *42:15
+++-----+ +-----	*42:01:01, *42:09 = *42:02, *42:06 = *42:02, *42:16 = *42:06, *42:09
+++-----+ +-----+-	*42:02, *42:13 = *42:02, *42:15
++-+-----+ +-----	*42:04, *42:06 = *42:04, *42:16
++-----++- +-----	*42:05:01, *42:06 = *42:05:01, *42:16
++-----++- +-----+-	*42:05:01, *42:13 = *42:05:01, *42:15
++-----++- +-----	*42:01:01, *42:05:01 = *42:05:01, *42:05:01
++-----++- +-----+-	*42:06, *42:11 = *42:11, *42:16
++-----++- +-----	*42:06, *42:07 = *42:07, *42:16
++-----++- ++-----	*42:06, *42:08 = *42:08, *42:16
++-----++- ++-----	*42:06, *42:10 = *42:10, *42:16
++-----++- +-----+-	*42:06, *42:12 = *42:12, *42:16
++-----++- +-----+-	*42:06, *42:13 = *42:06, *42:15 = *42:13, *42:16 = *42:15, *42:16
++-----++- +-----+-	*42:06, *42:14 = *42:14, *42:16
++-----++- +-----	*42:01:01, *42:06 = *42:01:01, *42:16 = *42:06, *42:06 = *42:06, *42:16
++-----++- +-----+-	*42:11, *42:13 = *42:11, *42:15
++-----++- +-----+-	*42:07, *42:13 = *42:07, *42:15
++-----++- ++-----	*42:08, *42:13 = *42:08, *42:15
++-----++- ++-----	*42:01:01, *42:08 = *42:08, *42:08
++-----++- ++-----	*42:10, *42:13 = *42:10, *42:15
++-----++- ++-----	*42:01:01, *42:10 = *42:10, *42:10
++-----++- +-----+-	*42:12, *42:13 = *42:12, *42:15
++-----++- +-----+-	*42:01:01, *42:12 = *42:12, *42:12
++-----++- +-----+-	*42:13, *42:14 = *42:14, *42:15
++-----++- +-----+-	*42:01:01, *42:13 = *42:01:01, *42:15 = *42:13, *42:15 = *42:15, *42:15
++-----++- +-----+-	*42:01:01, *42:14 = *42:14, *42:14
-+-----++- +-----	*42:07, *42:11 = *42:11, *42:11

42:01:01 = 42:01:01 and 42:01:02

42:05:01 = 42:05:01 and 42:05:02

SPECIFICITY TABLE

HLA-B*42 SSP subtyping

Specificities and sizes of the PCR products of the 15 primer mixes used for HLA-B*42 SSP subtyping

Primer Mix	Size of spec. PCR product ¹	Size of control band ²	Amplified HLA-B*42 alleles	Other amplified HLA-B alleles ³
1	215 bp	800 bp	*42:01:01-42:01:02, 42:04-42:06, 42:08, 42:10, 42:12-42:16	*07:02:01-07:02:20, 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, 07:51-07:68:02, 07:70, 07:72-07:82, 07:84, 07:86-07:124, 07:126-07:130, 14:21, 15:76, 15:101, 35:76, 38:26, 44:90, 54:01:01-54:01:02, 54:03-54:06, 54:08N-54:23, 55:01:01-55:05, 55:07-55:15, 55:17, 55:19-55:24, 55:26-55:33, 55:35-55:46, 55:48-55:51, 56:01:01-56:07, 56:09-56:13, 56:15-56:16, 56:18-56:22, 56:24-56:32, 67:01:01-67:01:02, 67:03, 81:01-81:04N, 82:01-82:03, 83:01
2	215 bp	1070 bp	*42:01:01-42:02, 42:05:01-42:12, 42:14-42:16	*07:04, 07:19, 07:25, 08:01:01-08:05, 08:07-08:08N, 08:10-08:11, 08:14-08:15, 08:17-08:19N, 08:21-08:24, 08:26-08:39, 08:41-08:48, 08:50-08:54, 08:56-08:59, 08:61-08:69, 35:87, 37:09, 41:02:01-41:02:03, 41:04, 41:10-41:11, 41:13, 41:15, 41:18, 44:106
3	215 bp	1070 bp	*42:02, 42:09	*45:06, 54:02, 55:16
4	220 bp	1070 bp	*42:04	*08:09, 13:46, 15:83, 41:01, 41:05-41:07, 41:09, 41:12, 41:14, 41:16-41:17, 44:15, 44:18, 44:20, 44:100, 45:01-45:13, 51:08, 51:20, 51:36, 51:44N, 51:97, 52:19, 55:20, 56:13
5⁴	105 bp	800 bp	*42:05:01-42:05:02	*07:04, 07:25, 40:136, 41:08
6	165 bp	1070 bp	*42:01:01-42:02, 42:04-	*08:01:01-08:05, 08:08N-08:12:03, 08:15-08:19N, 08:21-

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			42:08, 42:10-42:15	08:24, 08:26-08:27, 08:29-08:36, 08:38-08:39, 08:41-08:48, 08:50-08:54, 08:56-08:69, 15:83, 35:87, 37:12, 38:30, 40:136, 41:01-41:03:02, 41:05-41:09, 41:11-41:17, 44:14, 44:62, 51:08, 51:20, 51:36, 51:44N, 51:97, 52:19, 55:20, 56:13, 57:09, 82:01-82:03
7	165 bp	1070 bp	*42:06, 42:09, 42:16	*07:04, 07:19, 07:25, 08:07, 08:37, 08:49, 08:69, 13:46, 15:51, 15:179, 15:199, 15:218Q, 18:56, 35:38, 35:115, 37:01:01-37:01:07, 37:03N-37:06, 37:08-37:11, 37:13-37:24, 37:26-37:29, 38:30, 41:04, 41:18, 44:15, 44:17-44:18, 44:51, 44:117 ^w , 44:123, 45:01-45:02, 45:04-45:13, 53:22, 56:13, 57:24, 82:01-82:03, C*07:04:01^w-07:04:05^w, C*07:11^w-07:12^w, 07:45^w, C*07:63^w, C*07:101^w, C*07:139^w, C*07:142^w, C*07:181^w, C*15:25
8	215 bp	1070 bp	*42:07, 42:11	*07:03, 07:08, 07:16, 07:27, 07:32, 07:38, 07:50, 07:69, 07:85, 13:14, 14:01:01-14:01:02, 14:07N-14:08, 14:10, 14:12, 14:14, 14:19, 15:68, 15:71, 15:175, 18:01:01-18:01:12, 18:02-18:03, 18:05-18:15, 18:17N-18:24, 18:26-18:63, 27:12, 27:16, 27:18, 27:23, 27:29, 35:50, 35:84, 35:162, 37:01:01-37:29, 38:01:01-38:04, 38:06-38:25, 38:27-38:30, 39:01:01:01-39:01:01:02L, 39:01:03-39:03, 39:05:01-39:11, 39:13:01-39:20, 39:22-39:51, 39:53-39:62, 40:02:01-40:06:03, 40:08-40:09, 40:11:01-40:11:02, 40:13, 40:18-40:20, 40:24, 40:26-40:27:01, 40:28-40:29, 40:35, 40:37, 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, 40:93-40:99, 40:104-40:105, 40:107, 40:109, 40:111, 40:115, 40:119-40:120,

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				40:122, 40:127, 40:131, 40:133Q, 40:142N-40:145, 40:148-40:149, 40:157, 40:159, 40:161-40:162, 44:103, 44:130, 48:01:01-48:21, 48:23-48:25, 51:57, 51:103, 53:21
9	170 bp	1070 bp	*42:01:01- 42:02, 42:04- 42:06, 42:08- 42:10, 42:12- 42:16	*07:02:01-07:02:20, 07:04-07:07, 07:09, 07:11-07:12, 07:14-07:15, 07:17-07:26, 07:28-07:31, 07:33- 07:36, 07:39-07:49N, 07:51- 07:55, 07:57-07:64, 07:66- 07:68:02, 07:70-07:71, 07:73- 07:82, 07:84, 07:86-07:124, 07:126-07:130, 14:21, 38:26, 54:21, 55:10, 56:16, 67:01:01- 67:01:02, 67:03, 81:01-81:04N, 82:01-82:03, 83:01
10^{4,5}	105 bp	800 bp	*42:08	*07:19, 13:46, 15:51, 15:83, 15:179, 15:199, 15:218Q, 18:56, 27:47, 35:38, 35:115, 37:01:01- 37:01:07, 37:03N-37:04:01, 37:05-37:06, 37:08-37:29, 38:30, 41:09, 44:02:01:01-44:02:16, 44:02:18, 44:05:01-44:06, 44:08- 44:09, 44:11-44:12, 44:14-44:25, 44:27:01-44:27:02, 44:33-44:34, 44:41:01-44:42, 44:44, 44:48- 44:49, 44:51-44:53, 44:55, 44:58N-44:59, 44:62-44:63, 44:66-44:68, 44:70, 44:72-44:75, 44:78, 44:80, 44:83-44:84, 44:86- 44:91, 44:93, 44:95, 44:97, 44:99-44:102, 44:104, 44:106, 44:112-44:113, 44:116-44:119, 44:121, 44:123, 44:126-44:127, 45:01-45:04, 45:06-45:13, 51:08, 51:20, 51:36, 51:44N, 51:97, 52:19, 53:22, 56:13, 57:09, 57:24, 82:01-82:03, 83:01, C*07:04:01- 07:04:05, 07:11-07:12, 07:45, 07:63, 07:68, 07:101, 07:139, 07:142, 07:181, C*15:25
11	180 bp	1070 bp	*42:10	*08:49, 53:15
12⁴	105 bp	1070 bp	*42:11	*07:27, 07:50, 08:04, 08:17, 08:54, 15:03:01-15:03:03, 15:47, 15:54, 15:61-15:62, 15:64, 15:68-

				15:69, 15:91, 15:98, 15:103, 15:123, 15:127, 15:131-15:132, 15:151, 15:156, 15:158, 15:173, 15:210, 18:37, 27:18, 27:29, 37:28, 38:03, 39:02:01-39:02:02, 39:08, 39:13:01-39:13:02, 39:23, 39:39, 39:49, 40:12, 40:46, 40:93, 44:40, 44:44, 44:130, 48:01:01- 48:05, 48:07-48:25, 52:16, 55:18
13⁴	65 bp	1070 bp	*42:12	
14⁶	200 bp, 290 bp	1070 bp	*42:13, 42:15	*07:11, 07:57, 07:75, 08:17, 08:47, 08:49, 08:60, 18:49, 37:05, 39:20, 53:15, C*07:49
15	230 bp	1070 bp	*42:14	*41:06, 41:15

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*42 SSP typings.

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

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

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

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

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

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*42 subtyping.

In addition, wells number 5 and 10 contain the primer pair giving rise to the shorter, 800 bp, internal positive control band in order to allow kit identification.

³Due to the sharing of sequence motifs between HLA-B alleles non-HLA-B*42 alleles will be amplified by primer mixes 1 to 12, 14 and 15. In addition, the C*07:04:01-07:04:05, C*07:11-07:12, C*07:45, C*07:63, C*07:101, C*07:139, C*07:142, C*07:181 and C*15:25 alleles will be amplified by primer mixes 7 and 10, the C*07:68 allele will be amplified by primer mix 10 and the C*07:49 allele will be amplified by primer mix 14.

⁴Specific PCR fragments shorter than 125 base pairs are less intense and not as sharp as longer specific bands.

⁵Primer mix 10 may give rise to nonspecific amplifications.

⁶Primer mix 14: Specific PCR fragment of 200 bp in the B*42:15 and the B*07:11, 07:57, 07:75, 08:17, 08:47, 18:49, 37:05 and 39:20 and in the C*07:49 alleles. Specific PCR fragment of 290 bp in the B*42:13 and the B*08:49, 08:60 and 53:15 alleles.

'w', might be weakly amplified.

INTERPRETATION TABLE

HLA-B*42 SSP subtyping

Amplification patterns of the B*42:01 to 42:16 alleles

	Well ⁵							
	1	2	3	4	5	6	7	8
Length of spec. PCR product(s)	215	215	215	220	105	165	165	215
Length of int. pos. control ¹	800	1070	1070	1070	800	1070	1070	1070
5'-primer ²	97	363	97	357	540	412	412	103
	5' -TCT 3'	5' -AgC 3'	5' -TCC 3'	5' -Tgg 3'	5' -gAC 3'	5' -ATA 3'	5' -ATg 3'	5' -CCT 3'
							419	103
							5' -gTT 3'	5' -CCT 3'
							419	
							5' -gTT 3'	
3'-primer ³	272	538	272	538	605	538	538	277
	5' -TgT 3'	5' -gTC 3'	5' -TgT 3'	5' -gTC 3'	5' -gCT 3'	5' -gTC 3'	5' -gTC 3'	5' -ggT 3'
Well No.	1	2	3	4	5	6	7	8
HLA-B allele ⁴								
*42:01:01-42:01:02	1	2				6		
*42:02		2	3			6		
*42:04	1			4		6		
*42:05:01-42:05:02	1	2			5	6		
*42:06	1	2				6	7	
*42:07		2				6		8
*42:08	1	2				6		
*42:09		2	3				7	
*42:10	1	2				6		
*42:11		2				6		8
*42:12	1	2				6		
*42:13	1					6		
*42:14	1	2				6		
*42:15	1	2				6		
*42:16	1	2					7	
Well No.	1	2	3	4	5	6	7	8

INTERPRETATION TABLE							
HLA-B*42 SSP subtyping							
Amplification patterns of the B*42:01 to 42:16 alleles							
Well⁵							
9	10	11	12	13	14	15	
170	105	180	105	65	200	230	Length of spec. PCR product(s)
					290		
1070	800	1070	1070	1070	1070	1070	Length of int. pos. control ¹
142	540	463	206	540	142	412	5'-primer ²
5' -TCT 3'	5' -gAC 3'	5' -TgA 3'	5' -AgA 3'	5' -gAC 3'	5' -TCT 3'	5' -ATA 3'	
					355		
					5' -TCA 3'		
272	603	603	272	566	302	603	3'-primer ³
5' -TgT 3'	5' -gTC 3'	5' -gTg 3'	5' -Tgg 3'	5' -CCC 3'	5' -ggT 3'	5' -gTg 3'	
					603		
					5' -gTg 3'		
9	10	11	12	13	14	15	Well No.
							HLA-B allele ⁴
9							*42:01:01-42:01:02
9							*42:02
9							*42:04
9							*42:05:01-42:05:02
9							*42:06
							*42:07
9	10						*42:08
9							*42:09
9		11					*42:10
			12				*42:11
9				13			*42:12
9					14		*42:13
9						15	*42:14
9					14		*42:15
9							*42:16
9	10	11	12	13	14	15	Well No.

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Length of spec.	215	215	215	220	105	165	165	215
PCR product(s)								
Well No.	1	2	3	4	5	6	7	8
*07:02:01-07:02:20, 07:05:01-07:07, 07:09, 07:12, 07:14-07:15, 07:17-07:18:02, 07:20-07:24, 07:26, 07:28, 07:30-07:31, 07:33-07:36, 07:39-07:49N, 07:51-07:55, 07:58-07:64, 07:66-07:68:02, 07:70, 07:73-07:74, 07:76-07:82, 07:84, 07:86-07:124, 07:126-07:130, 14:21, 38:26, 54:21, 55:10, 56:16, 67:01:01-67:01:02, 67:03, 81:01-81:04N	1							
*07:03, 07:08, 07:16, 07:32, 07:38, 07:69, 07:85, 13:14, 14:01:01-14:01:02, 14:07N-14:08, 14:10, 14:12, 14:14, 14:19, 15:71, 15:175, 18:01:01-18:01:12, 18:02-18:03, 18:05-18:15, 18:17N-18:24, 18:26-18:36, 18:38-18:48, 18:50-18:55, 18:57-18:63, 27:12, 27:16, 27:23, 35:50, 35:84, 35:162, 37:02, 37:07, 38:01:01-38:02:03, 38:04, 38:06-38:25, 38:27-38:29, 39:01:01:01-39:01:01:02L, 39:01:03-39:01:12, 39:03, 39:05:01-39:07, 39:09-39:11, 39:14-39:19:02, 39:22, 39:24:01-39:38Q, 39:40N-39:48, 39:50-39:51, 39:53-39:62, 40:02:01-40:06:03, 40:08-40:09, 40:11:01-40:11:02, 40:13, 40:18-40:20, 40:24, 40:26-40:27:01, 40:28-40:29, 40:35, 40:37, 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, 40:94-40:99, 40:104-40:105, 40:107, 40:109, 40:111, 40:115, 40:119-40:120, 40:122, 40:127, 40:131, 40:133Q, 40:142N-40:145, 40:148-40:149, 40:157, 40:159, 40:161-40:162, 44:103, 48:06, 51:57, 51:103, 53:21								8
Well No.	1	2	3	4	5	6	7	8

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170	105	180	105	65	200	230	Length of spec. PCR product(s)
9	10	11	12	13	14	15	Well No.
					290		
9							*07:02:01-07:02:20, 07:05:01-07:07:07:09, 07:12, 07:14-07:15, 07:17-07:18:02, 07:20-07:24, 07:26, 07:28, 07:30-07:31, 07:33-07:36, 07:39-07:49N, 07:51-07:55, 07:58-07:64, 07:66-07:68:02, 07:70, 07:73-07:74, 07:76-07:82, 07:84, 07:86-07:124, 07:126-07:130, 14:21, 38:26, 54:21, 55:10, 56:16, 67:01:01-67:01:02, 67:03, 81:01-81:04N
							*07:03, 07:08, 07:16, 07:32, 07:38, 07:69, 07:85, 13:14, 14:01:01-14:01:02, 14:07N-14:08, 14:10, 14:12, 14:14, 14:19, 15:71, 15:175, 18:01:01-18:01:12, 18:02-18:03, 18:05-18:15, 18:17N-18:24, 18:26-18:36, 18:38-18:48, 18:50-18:55, 18:57-18:63, 27:12, 27:16, 27:23, 35:50, 35:84, 35:162, 37:02, 37:07, 38:01:01-38:02:03, 38:04, 38:06-38:25, 38:27-38:29, 39:01:01:01-39:01:01:02L, 39:01:03-39:01:12, 39:03, 39:05:01-39:07, 39:09-39:11, 39:14-39:19:02, 39:22, 39:24:01-39:38Q, 39:40N-39:48, 39:50-39:51, 39:53-39:62, 40:02:01-40:06:03, 40:08-40:09, 40:11:01-40:11:02, 40:13, 40:18-40:20, 40:24, 40:26-40:27:01, 40:28-40:29, 40:35, 40:37, 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, 40:94-40:99, 40:104-40:105, 40:107, 40:109, 40:111, 40:115, 40:119-40:120, 40:122, 40:127, 40:131, 40:133Q, 40:142N-40:145, 40:148-40:149, 40:157, 40:159, 40:161-40:162, 44:103, 48:06, 51:57, 51:103, 53:21
9	10	11	12	13	14	15	Well No.

Lot No.: **57M**

Lot-specific information

www.olerup-ssp.com

Length of spec.	215	215	215	220	105	165	165	215
PCR product(s)								
Well No.	1	2	3	4	5	6	7	8
*07:04, 07:25	1	2			5		7	
*07:11, 07:57, 07:75	1							
*07:19	1	2					7	
*07:27, 07:50, 15:68, 18:37, 27:18, 27:29, 38:03, 39:02:01-39:02:02, 39:08, 39:13:01-39:13:02, 39:23, 39:39, 39:49, 40:93, 44:130, 48:01:01-48:05, 48:07- 48:21, 48:23-48:25								8
*07:29, 07:71								
*07:56, 07:65, 07:72, 15:76, 15:101, 35:76, 54:01:01-54:01:02, 54:03-54:06, 54:08N-54:20, 54:22-54:23, 55:01:01- 55:05, 55:07-55:09, 55:11-55:15, 55:17, 55:19, 55:21-55:24, 55:26-55:33, 55:35- 55:46, 55:48-55:51, 56:01:01-56:07, 56:09-56:12, 56:15, 56:18-56:22, 56:24- 56:32	1							
*08:01:01-08:03, 08:05, 08:08N, 08:10- 08:11, 08:15, 08:18-08:19N, 08:21- 08:24, 08:26-08:27, 08:29-08:36, 08:38- 08:39, 08:41-08:46, 08:48, 08:50-08:53, 08:56-08:59, 08:61-08:68, 35:87, 41:02:01-41:02:03, 41:11, 41:13		2				6		
*08:04, 08:54		2				6		
*08:07, 08:37, 41:04, 41:18		2					7	
*08:09, 41:01, 41:05, 41:07, 41:12, 41:14, 41:16-41:17				4		6		
*08:12:01-08:12:03, 08:16, 41:03:01- 41:03:02						6		
*08:14, 08:28, 41:10		2						
*08:17		2				6		
*08:47		2				6		
*08:49							7	
*08:60						6		
*08:69		2				6	7	
*13:46, 44:15, 44:18, 45:01-45:02, 45:04, 45:07-45:13				4			7	
Well No.	1	2	3	4	5	6	7	8

Lot No.: **57M**

Lot-specific information

www.olerup-ssp.com

170	105	180	105	65	200	230	Length of spec. PCR product(s)
9	10	11	12	13	14	15	Well No.
9							*07:04, 07:25
9					14		*07:11, 07:57, 07:75
9	10						*07:19
			12				*07:27, 07:50, 15:68, 18:37, 27:18, 27:29, 38:03, 39:02:01-39:02:02, 39:08, 39:13:01-39:13:02, 39:23, 39:39, 39:49, 40:93, 44:130, 48:01:01-48:05, 48:07- 48:21, 48:23-48:25
9							*07:29, 07:71
							*07:56, 07:65, 07:72, 15:76, 15:101, 35:76, 54:01:01-54:01:02, 54:03-54:06, 54:08N-54:20, 54:22-54:23, 55:01:01- 55:05, 55:07-55:09, 55:11-55:15, 55:17, 55:19, 55:21-55:24, 55:26-55:33, 55:35- 55:46, 55:48-55:51, 56:01:01-56:07, 56:09-56:12, 56:15, 56:18-56:22, 56:24- 56:32
							*08:01:01-08:03, 08:05, 08:08N, 08:10- 08:11, 08:15, 08:18-08:19N, 08:21- 08:24, 08:26-08:27, 08:29-08:36, 08:38- 08:39, 08:41-08:46, 08:48, 08:50-08:53, 08:56-08:59, 08:61-08:68, 35:87, 41:02:01-41:02:03, 41:11, 41:13
			12				*08:04, 08:54
							*08:07, 08:37, 41:04, 41:18
							*08:09, 41:01, 41:05, 41:07, 41:12, 41:14, 41:16-41:17
							*08:12:01-08:12:03, 08:16, 41:03:01- 41:03:02
							*08:14, 08:28, 41:10
			12		14		*08:17
					14		*08:47
		11			14		*08:49
					14		*08:60
							*08:69
	10						*13:46, 44:15, 44:18, 45:01-45:02, 45:04, 45:07-45:13
9	10	11	12	13	14	15	Well No.

Lot No.: **57M**

Lot-specific information

www.olerup-ssp.com

Length of spec. PCR product(s)	215	215	215	220	105	165	165	215
Well No.	1	2	3	4	5	6	7	8
*15:03:01-15:03:03, 15:47, 15:54, 15:61-15:62, 15:64, 15:69, 15:91, 15:98, 15:103, 15:123, 15:127, 15:131- 15:132, 15:151, 15:156, 15:158, 15:173, 15:210, 40:12, 40:46, 44:40, 48:22, 52:16, 55:18								
*15:51, 15:179, 15:199, 15:218Q, 35:38, 35:115, 44:17, 44:51, 44:123, 53:22, 57:24, C*15:25							7	
*15:83, 41:09, 51:08, 51:20, 51:36, 51:44N, 51:97, 52:19				4		6		
*18:49, 39:20								8
*18:56, 37:01:01-37:01:07, 37:03N- 37:04:01, 37:06, 37:08, 37:10-37:11, 37:13-37:24, 37:26-37:27, 37:29							7	8
*27:47, 44:02:01:01-44:02:16, 44:02:18, 44:05:01-44:06, 44:08-44:09, 44:11-44:12, 44:16, 44:19N, 44:21- 44:25, 44:27:01-44:27:02, 44:33-44:34, 44:41:01-44:42, 44:48-44:49, 44:52N- 44:53, 44:55, 44:58N-44:59, 44:63, 44:66-44:68, 44:70, 44:72-44:75, 44:78, 44:80, 44:83-44:84, 44:86-44:89, 44:91, 44:93, 44:95, 44:97, 44:99, 44:101- 44:102, 44:104, 44:112-44:113, 44:116, 44:118-44:119, 44:121, 44:126-44:127, C*07:68								
*37:04:02							7	8
*37:05							7	8
*37:09		2					7	8
*37:12						6		8
*37:25								8
*37:28							7	8
*38:30						6	7	8
*40:136, 41:08					5	6		
*41:06				4		6		
*41:15		2				6		
*44:14, 44:62, 57:09						6		
*44:20, 44:100, 45:03				4				
*44:44								
*44:90	1							
Well No.	1	2	3	4	5	6	7	8

Lot No.: **57M**

Lot-specific information

www.olerup-ssp.com

170	105	180	105	65	200	230	Length of spec. PCR product(s)
9	10	11	12	13	14	15	Well No.
			12				*15:03:01-15:03:03, 15:47, 15:54, 15:61-15:62, 15:64, 15:69, 15:91, 15:98, 15:103, 15:123, 15:127, 15:131- 15:132, 15:151, 15:156, 15:158, 15:173, 15:210, 40:12, 40:46, 44:40, 48:22, 52:16, 55:18
	10						*15:51, 15:179, 15:199, 15:218Q, 35:38, 35:115, 44:17, 44:51, 44:123, 53:22, 57:24, C*15:25
	10						*15:83, 41:09, 51:08, 51:20, 51:36, 51:44N, 51:97, 52:19
					14		*18:49, 39:20
	10						*18:56, 37:01:01-37:01:07, 37:03N- 37:04:01, 37:06, 37:08, 37:10-37:11, 37:13-37:24, 37:26-37:27, 37:29
	10						*27:47, 44:02:01:01-44:02:16, 44:02:18, 44:05:01-44:06, 44:08-44:09, 44:11-44:12, 44:16, 44:19N, 44:21- 44:25, 44:27:01-44:27:02, 44:33-44:34, 44:41:01-44:42, 44:48-44:49, 44:52N- 44:53, 44:55, 44:58N-44:59, 44:63, 44:66-44:68, 44:70, 44:72-44:75, 44:78, 44:80, 44:83-44:84, 44:86-44:89, 44:91, 44:93, 44:95, 44:97, 44:99, 44:101- 44:102, 44:104, 44:112-44:113, 44:116, 44:118-44:119, 44:121, 44:126-44:127, C*07:68
							*37:04:02
	10				14		*37:05
	10						*37:09
	10						*37:12
	10						*37:25
	10		12				*37:28
	10						*38:30
							*40:136, 41:08
						15	*41:06
						15	*41:15
	10						*44:14, 44:62, 57:09
	10						*44:20, 44:100, 45:03
	10		12				*44:44
	10						*44:90
9	10	11	12	13	14	15	Well No.

Lot No.: **57M**

Lot-specific information

www.olerup-ssp.com

Length of spec.	215	215	215	220	105	165	165	215
PCR product(s)								
Well No.	1	2	3	4	5	6	7	8
*44:106		2						
*44:117, C*07:04:01-07:04:05, C*07:11-07:12, C*07:45, C*07:63, C*07:101, C*07:139, C*07:142, C*07:181							w	
*45:05				4			7	
*45:06			3	4			7	
*53:15								
*54:02, 55:16			3					
*55:20	1			4		6		
*56:13	1			4		6	7	
*82:01-82:03	1					6	7	
*83:01	1							
C*07:49								
HLA-B allele ⁴								
Well No.	1	2	3	4	5	6	7	8

Lot No.: **57M**

Lot-specific information

www.olerup-ssp.com

170	105	180	105	65	200	230	Length of spec. PCR product(s)
9	10	11	12	13	14	15	Well No.
	10						*44:106
	10						*44:117, C*07:04:01-07:04:05, C*07:11-07:12, C*07:45, C*07:63, C*07:101, C*07:139, C*07:142, C*07:181
	10						*45:05
	10						*45:06
		11			14		*53:15
							*54:02, 55:16
	10						*55:20
	10						*56:13
9	10						*82:01-82:03
9	10						*83:01
					14		C*07:49
							HLA-B allele ⁴
9	10	11	12	13	14	15	Well No.

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*42 SSP subtyping.

In addition, wells number 5 and 10 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 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 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.

⁴The B*4203 allele was never assigned.

⁵Primer mix 14: Specific PCR fragment of 200 bp in the B*42:15 and the B*07:11, 07:57, 07:75, 08:17, 08:47, 18:49, 37:05 and 39:20 and in the C*07:49 alleles. Specific PCR fragment of 290 bp in the B*42:13 and the B*08:49, 08:60 and 53:15 alleles.

'w', might be weakly amplified.

CELL LINE VALIDATION SHEET																			
HLA-B*42 SSP primer set																			
				Well															
				1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
				Prod. No.:	200960601	200960602	200960603	200960604	200960605	200960606	201189007	201189008	200960609	201189010	200960611	201078312	201078313	201189014	201078315
IHC 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 ¹	*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 ¹	*51:01			-	-	-	-	-	-	-	-	-	+	-	-	-	-	-
48	9303 TER-ND	*35:01	*44:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

¹The C*07:04 allele is amplified by primer mix 10 in the CH1007 and TUBO cell lines.

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-B*42 SSP

Product number: 101.543-06 – including *Taq* polymerase
Lot number: 57M
Expiry date: 2014-February-01
Number of tests: 6
Number of wells per test: 15

Well specifications:

Well No.	Production No.	Well No.	Production No.
1	2009-606-01	9	2009-606-09
2	2009-606-02	10	2011-890-10
3	2009-606-03	11	2009-606-11
4	2009-606-04	12	2010-783-12
5	2009-606-05	13	2010-783-13
6	2009-606-06	14	2011-890-14
7	2011-890-07	15	2010-783-15
8	2011-890-08		

The specificity of each primer solution of the HLA-B*42 primer set has been tested against 48 well characterized IHWC cell line DNAs.

No DNAs carrying the alleles to be amplified by primer solution 5, 11 and 13 to 15 were available. The specificities of the primers in primer solution 5, 11 and 14 were tested by separately adding one additional 3'-primer, respectively one additional 5'-primer. In primer solutions 13 and 15 it was only possible to test the 5'-primers, the 3'-primers were not possible to test. In primer solution 14 one 3'-primer was not possible to test. One additional 5'-primer in primer solution 7 was tested by separately adding one additional 3'-primer.

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

Date of approval: 2011-September-01

Approved by:

Quality Control, Supervisor

Lot No.: **57M**

Lot-specific information

www.olerup-ssp.com

Declaration of Conformity

Product name: *Olerup* SSP® HLA-B*42
Product number: 101.543-06
Lot number: 57M

Intended use: HLA-B*42 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.

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
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