

Olerup SSP[®] HLA-B*14

Product number:	101.524-12 – including <i>Taq</i> polymerase
Lot number:	90K
Expiry date:	2013-July-01
Number of tests:	12
Number of wells per test:	16
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. 90K.

CHANGES COMPARED TO THE PREVIOUS *OLERUP SSP*[®] HLA-B*14 LOT

The HLA-B*14 specificity and interpretation tables have been updated for the HLA-B alleles described since the previous *Olerup SSP*[®] HLA-B*14 lot was made (Lot No. 61G).

Five wells have been added to the HLA-B*14 kit,
wells **12 to 16**.

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

Well	5'-primer	3'-primer	rationale
3	-	Exchanged	New primer pair for the B*14:02:01-B*14:02:06 alleles.
6	Added	Added	Primer pair added for the B*14:17 allele.
10	Added	Added	Primer pair added for the B*14:11 allele.
11	Modified	-	Improved specificity of primer pair.
12	New	New	New primer pair for the B*14:12 and B*14:19 alleles.
13	New	New	New primer pair for the B*14:13 allele.
14	New	New	New primer pair for the B*14:14 and B*14:18 alleles.
15	New	New	New primer pair for the B*14:15 allele.
16	New	New	New primer pair for the B*14:16 allele.

PRODUCT DESCRIPTION

HLA-B*14 SSP subtyping

CONTENT

The primer set contains 5'- and 3'-primers for identifying the HLA-B*14:01 to B*14:19 alleles.

PLATE LAYOUT

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

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

The 16 well cut PCR plate is marked with 'HLA-B*14' in silver/gray ink.

Well No. 1 is marked with the Lot No. '90K'.

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 covered. Use a scalpel or a similar instrument to carefully cut the foil between the plates.

INTERPRETATION

The interpretation of HLA-B*14 SSP subtypings will be influenced by most B*07, most B*08, two B*13, several B*15, the B*18, twelve B*27, several B*35, the B*37, the B*38, the B*39, many B*40, the B*41, the B*42, two B*44, the B*45:08, four B*46, the B*48, most B*51, most B*52, two B*53, most B*54, most B*55, eight B*56, three B*57, nine B*58, most B*59, the B*67, the B*73, B*78 and B*81 alleles when present on the other haplotype. In addition, the C*01:30 allele will be amplified by primer mixes 1 and 4, the C*01:35, C*03:17, C*03:71 and C*14:20 alleles will be amplified by primer mix 12, the C*07:102 allele will be weakly amplified by primer mix 8, the C*08:08 allele will be amplified by primer mix 6 and the C*15:39 allele will be amplified by primer mix 10.

UNIQUELY IDENTIFIED ALLELES

All the HLA-B*14 alleles, i.e. **B*14:01 to B*14:19**, recognized by the HLA Nomenclature Committee in October 2010¹ will give rise to unique amplification patterns by the primers in the HLA-B*14 subtyping kit².

The HLA-B*14 primer set cannot distinguish the B*14:01:01-14:01:02 alleles, the B*14:02:01-14:02:06 or the B*14:06:01-14:06:02 alleles.

¹HLA-B alleles listed on the IMGT/HLA web page 2010-October-15, release 3.2.0, www.ebi.ac.uk/imgt/hla.

²The B*14:08 and B*39:43 alleles will give rise to identical amplification patterns with the HLA-B*14 subtyping kit. These alleles can be distinguished by the HLA-B low resolution kit and/or the HLA-B*39 subtyping kit.

RESOLUTION IN HOMO- AND HETEROZYGOTES

A total of 26 alleles generate 19 amplification patterns that can be combined in 190 homozygous and heterozygous combinations. 99 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.

++++---+ +-----	*14:03, *14:12 = *14:03, *14:19
++++---+ +-----	*14:05, *14:07N = *14:07N, *14:17
+++-+--+ +-----	*14:04, *14:08 = *14:06:01, *14:07N
+++-+--+ -+-----	*14:04, *14:10 = *14:07N, *14:11
+++-+--+ -+-----	*14:04, *14:12 = *14:04, *14:19
+++-+--+ -+-----	*14:04, *14:14 = *14:07N, *14:18
+++-+--+ -+-----	*14:01:01, *14:04 = *14:02:01, *14:07N = *14:04, *14:07N
+++-+--+ -+-----	*14:05, *14:12 = *14:05, *14:19 = *14:12, *14:17 = *14:17, *14:19
+++-+--+ -+-----	*14:05, *14:14 = *14:14, *14:17
+++-+--+ -+-----	*14:01:01, *14:05 = *14:01:01, *14:17
+++-+--+ -+-----	*14:06:01, *14:12 = *14:06:01, *14:19
+++-+--+ -+-----	*14:06:01, *14:14 = *14:08, *14:18
+++-+--+ -+-----	*14:01:01, *14:06:01 = *14:02:01, *14:08
+++-+--+ +-----	*14:09, *14:12 = *14:09, *14:19
+++-+--+ -+-----	*14:11, *14:12 = *14:11, *14:19
+++-+--+ -+-----	*14:10, *14:18 = *14:11, *14:14
+++-+--+ -+-----	*14:01:01, *14:11 = *14:02:01, *14:10 = *14:10, *14:11
+++-+--+ -+-----	*14:12, *14:13 = *14:13, *14:19
+++-+--+ -+-----	*14:12, *14:18 = *14:18, *14:19
+++-+--+ -+-----	*14:12, *14:15 = *14:15, *14:19
+++-+--+ -+-----	*14:12, *14:16 = *14:16, *14:19
+++-+--+ -+-----	*14:02:01, *14:12 = *14:02:01, *14:19
+++-+--+ -+-----	*14:01:01, *14:18 = *14:02:01, *14:14 = *14:14, *14:18
+++-+--+ -+-----	*14:07N, *14:12 = *14:07N, *14:19
+++-+--+ -+-----	*14:01:01, *14:07N = *14:07N, *14:07N
+++-+--+ -+-----	*14:08, *14:12 = *14:08, *14:19
+++-+--+ -+-----	*14:10, *14:12 = *14:10, *14:19
+++-+--+ -+-----	*14:12, *14:14 = *14:14, *14:19
+++-+--+ -+-----	*14:01:01, *14:12 = *14:01:01, *14:19 = *14:12, *14:12 = *14:12, *14:19
+++-+--+ -+-----	*14:01:01, *14:14 = *14:14, *14:14
+++-+--+ -+-----	*14:03, *14:05 = *14:03, *14:17
+++-+--+ -+-----	*14:02:01, *14:03 = *14:03, *14:03
+++-+--+ -+-----	*14:04, *14:05 = *14:04, *14:17
+++-+--+ -+-----	*14:02:01, *14:04 = *14:04, *14:04
+++-+--+ +-----	*14:05, *14:09 = *14:09, *14:17
+++-+--+ -+-----	*14:05, *14:11 = *14:11, *14:17
+++-+--+ -+-----	*14:05, *14:18 = *14:17, *14:18
+++-+--+ -+-----	*14:05, *14:15 = *14:15, *14:17
+++-+--+ -+-----	*14:05, *14:16 = *14:16, *14:17
+++-+--+ -+-----	*14:02:01, *14:05 = *14:02:01, *14:17 = *14:05, *14:17 = *14:17, *14:17
+++-+--+ +-----	*14:02:01, *14:09 = *14:09, *14:09
+++-+--+ -+-----	*14:02:01, *14:11 = *14:11, *14:11
+++-+--+ -+-----	*14:02:01, *14:18 = *14:18, *14:18
+++-+--+ -+-----	*14:02:01, *14:15 = *14:15, *14:15
+++-+--+ -+-----	*14:02:01, *14:16 = *14:16, *14:16

*14:01:01 = B*14:01:01-14:01:02
*14:02:01 = B*14:02:01-14:02:06
*14:06:01 = B*14:06:01-14:06:02
*14:08 = B*14:08 and B*39:43

SPECIFICITY TABLE

HLA-B*14 SSP subtyping

Specificities and sizes of the PCR products of the 16 primer mixes used for HLA-B*14 SSP subtyping

Primer Mix	Size of spec. PCR product ¹	Size of control band ²	Amplified HLA-B*14 alleles	Other amplified HLA Class I alleles ³
1	265 bp	800 bp	*14:01:01-14:04, 14:07N, 14:09, 14:11-14:12, 14:14-14:19	*18:44, C*01:30
2⁵	185 bp	1070 bp	*14:01:01-14:01:02, 14:07N-14:08, 14:10, 14:12, 14:14, 14:19	*38:01:01-38:02:02, 38:03, 38:07-38:24, 38:26, 39:01:01:01-39:01:01:02L, 39:01:03-39:01:08, 39:01:10-39:02:01, 39:03, 39:05:01-39:09, 39:11, 39:14-39:15, 39:18, 39:19:02, 39:22, 39:24-39:44, 39:46-39:48, 39:50-39:62, 67:01:01, 67:03
3	210 bp	800 bp	*14:02:01-14:03, 14:04 ^W , 14:05-14:06:02, 14:09, 14:11, 14:13, 14:15-14:18	*15:09-15:10:02, 15:18:01-15:18:04, 15:21, 15:23, 15:37, 15:44, 15:51-15:52, 15:66, 15:72, 15:80, 15:90, 15:93, 15:99, 15:108, 15:114-15:115, 15:119, 15:124, 15:133-15:134, 15:153, 15:161, 15:176, 15:186, 15:189, 15:197-15:198, 15:200, 35:26, 35:82, 35:85, 35:135, 38:05, 39:04, 51:22, 78:03
4⁴	85 bp	1070 bp	*14:03	*18:13, 18:30, 51:29, 51:82, C*01:30
5⁷	135 bp, 220 bp	1070 bp	*14:04, 14:07N	*39:40N
6^{4,8}	95 bp, 175 bp	1070 bp	*14:05, 14:17	*07:115, 38:19, 39:03, 39:24, 39:37, 42:06, 48:07, C*08:08
7	260 bp	1070 bp	*14:06:01-14:06:02, 14:08	*15:37-15:38:02, 15:185, 18:01:01-18:01:09, 18:03-18:09, 18:12-18:13, 18:15, 18:17N-18:20, 18:23N-18:26, 18:28-18:34, 18:36-18:38, 18:40-18:43, 18:45-18:52, 39:32, 39:43, 39:48, 40:51, 40:113, 51:06, 51:45, 51:62

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8	250 bp	1070 bp	*14:01:01- 14:01:02, 14:07N-14:08, 14:10, 14:12, 14:14, 14:19	*07:02:01-07:02:15, 07:02:17- 07:05:04, 07:05:06-07:26, 07:28, 07:30-07:35, 07:37, 07:39-07:64, 07:66-07:69, 07:73-07:78, 07:80, 07:82- 07:85, 07:87-07:110, 07:112- 07:117, 15:68, 15:71, 15:175, 18:01:01-18:03, 18:05-18:08, 18:10-18:15, 18:17N-18:24, 18:26-18:52, 27:08, 27:12, 27:18, 27:26, 27:33, 27:40, 27:42, 27:44, 35:50, 35:84, 37:05, 37:11, 39:01:01:01- 39:01:01:02L, 39:01:03-39:03, 39:05:01-39:11, 39:13:01-39:20, 39:22-39:62, 40:02:01-40:06:03, 40:08-40:09, 40:11:01-40:11:02, 40:18, 40:20, 40:24, 40:26- 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, 40:93-40:95, 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, 42:01:01-42:02, 42:04-42:14, 48:01:01-48:17, 48:19-48:21, 48:23-48:24, 54:02, 55:10, 67:01:01-67:03, 73:01-73:02, 81:01-81:05, C*07:102^W
9	160 bp	1070 bp	*14:09	
10^{5,9}	180 bp, 270 bp	1070 bp	*14:10-14:11	*15:189, 18:22, 35:21, 35:24:01- 35:24:02, 35:26, 35:81, 35:96, 35:109, 37:04:01-37:04:02, 39:04, 40:28, 51:04, 51:46, 51:56, 53:02, 53:06, 57:14, 58:09, C*15:39
11	135 bp	1070 bp	*14:01:01-14:18	*07:19, 07:31, 07:34, 07:43, 08:01:01-08:05, 08:07-08:10, 08:12:01-08:20, 08:22-08:24, 08:26-08:39, 08:41-08:66, 13:06, 15:42, 15:44, 15:50,

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				15:69, 15:83, 15:86, 15:93, 15:121, 15:186, 15:188, 15:199, 18:01:01-18:09, 18:11-18:15, 18:17N-18:20, 18:22-18:34, 18:37-18:49, 18:51-18:52, 27:15, 27:28, 27:62, 27:71, 35:35, 35:60, 35:87, 35:93, 35:96, 37:01:01- 37:01:04, 37:01:06-37:01:07, 37:03N-37:06, 37:08-37:25, 38:01:01-38:07, 38:09-38:21, 38:23-38:26, 39:01:01:01- 39:01:01:02L, 39:01:03-39:20, 39:22-39:31, 39:34-39:46, 39:48-39:49, 39:51-39:62, 40:39, 40:51, 41:01-41:16, 42:01:01-42:02, 42:04-42:14, 44:04, 44:56N, 45:08, 46:03, 46:18, 46:21:01-46:21:02, 51:21, 51:36, 51:101, 54:01- 54:02, 54:04-54:05N, 54:07- 54:23, 55:01:01-55:05, 55:07, 55:10-55:21, 55:23, 55:25- 55:48, 56:10, 56:12, 56:18, 56:23, 57:26, 58:05, 58:20, 59:01-59:03, 59:05, 67:01:01- 67:03, 78:07
12	230 bp	1070 bp	*14:12, 14:19	*57:11, 58:02, 58:06-58:07, 58:25, C*01:35, C*03:17, C*03:71, C*14:20
13⁶	210 bp	1070 bp	*14:13	*13:15, 18:26, 39:32, 39:48, 40:28, 40:51, 40:113, 51:01:01- 51:01:18, 51:01:20, 51:03- 51:04, 51:06-51:09:02, 51:11N- 51:14, 51:16, 51:19-51:22, 51:24:01-51:24:04, 51:26-51:33, 51:35, 51:38-51:39, 51:41N, 51:43-51:44N, 51:46, 51:48- 51:53, 51:55-51:58, 51:60- 51:80, 51:82-51:84, 51:86- 51:89, 51:91, 51:95-51:106, 52:01:01-52:02, 52:04-52:10, 52:13-52:22, 56:05:01-56:06, 56:21, 58:08, 78:01-78:03, 78:05-78:07
14	190 bp	1070 bp	*14:14, 14:18	*07:16, 07:27, 07:37-07:38, 07:50, 07:75, 07:91, 08:03, 08:23, 08:54,

				15:03:01-15:03:03, 15:09-15:10:02, 15:18:01-15:18:04, 15:23, 15:29, 15:37, 15:47, 15:49, 15:51-15:52, 15:54, 15:62, 15:64, 15:68-15:69, 15:72, 15:74, 15:80, 15:90-15:91, 15:93, 15:98-15:99, 15:103, 15:108, 15:114-15:115, 15:119, 15:123-15:124, 15:127, 15:131-15:134, 15:151, 15:153, 15:156, 15:158, 15:161, 15:173, 15:176, 15:186, 15:197-15:198, 15:200, 18:01:01, 18:01:03-18:02, 18:05-18:15, 18:17N-18:28, 18:30-18:52, 35:25, 35:124-35:125, 35:142, 37:01:01-37:21, 37:23-37:25, 38:01:01-38:02:03, 38:04-38:12, 38:15, 38:17-38:25, 39:05:01-39:05:02, 39:07-39:08, 39:11, 39:13:01-39:13:02, 39:20, 39:37, 39:49, 39:55-39:56, 40:12, 40:149, 42:11, 48:01:01-48:02:01, 48:03:01-48:24, 52:16, 58:12
15⁴	100 bp	800 bp	*14:15	
16	175 bp	1070 bp	*14:16	

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*14 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*14 subtyping.

In addition, wells number 3 and 15 contain the primer pair giving rise to the shorter, 800 bp, internal positive control band in order to allow kit identification.

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Lot-specific information

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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*14 alleles will be amplified by primer mixes 1 to 8 and 10 to 14. In addition, the C*01:30 allele will be amplified by primer mixes 1 and 4, the C*01:35, C*03:17, C*03:71 and C*14:20 alleles will be amplified by primer mix 12, the C*07:102 allele will be weakly amplified by primer mix 8, the C*08:08 allele will be amplified by primer mix 6 and the C*15:39 allele will be amplified by primer mix 10.

The B*14:08 and B*39:43 alleles will give rise to identical amplification patterns with the HLA-B*14 subtyping kit. These alleles can be distinguished by the HLA-B low resolution kit and/or the HLA-B*39 subtyping kit.

⁴Short specific PCR fragments are less intense and not as sharp as longer specific bands.

⁵Primer mixes 2 and 10 may give a lower yield of specific PCR product than the other B*14 primer mixes.

⁶Primer mix 13 may give rise to nonspecific amplifications.

⁷Primer mix 5: Specific PCR fragment of 135 bp in the B*14:07N and B*39:40N alleles. Specific PCR fragment of 220 bp in the B*14:04 allele.

⁸Primer mix 6: Specific PCR fragment of 95 bp in the B*14:05 and the B*07:115, 38:19, 39:03, 39:24, 39:37, 42:06 and 48:07 and the C*08:08 alleles. Specific PCR fragment of 175 bp in the B*14:17 allele.

⁹Primer mix 10: Specific PCR fragment of 180 bp in the B*14:11 and the B*15:189, 35:26 and 39:04 alleles. Specific PCR fragment of 270 bp in the B*14:10 and in the B*18:22, 35:21, 35:24:01-35:24:02, 35:81, 35:96, 35:109, 37:04:01-37:04:02, 40:28, 51:04, 51:46, 51:56, 53:02, 53:06, 57:14 and 58:09 and the C*15:39 allele.

‘w’, might be weakly amplified.

‘?’, nucleotide sequence of the primer matching sequence is not known.

INTERPRETATION TABLE

HLA-B*14 SSP subtyping

Amplification patterns of the B*14:01 to B*14:19 alleles

	Well ⁵							
	1	2	3	4	5	6	7	8
Length of spec.	265	185	210	85	135	95	260	250
PCR product(s)					220	175		
Length of int.	800	1070	800	1070	1070	1070	1070	1070
pos. control ¹								
5'-primer(s) ²	361	103	103	539	91	113	363	103
	5' -AgT 3' 5' -CCT 3' 5' -CCg 3' 5' -gCg 3' 5' -ggC 3' 5' -CCA 3' 5' -Agg 3' 5' -CCT 3'							
		103			564	363		103
		5' -CCT 3'			5' -TgA 3' 5' -AgC 3'			5' -CCT 3'
3'-primer(s) ³	583	246	272	583	269	246	583	310
	5' -gTg 3' 5' -TAT 3' 5' -TgC 3' 5' -gTg 3' 5' -AgT 3' 5' -TAT 3' 5' -gTg 3' 5' -gTT 3'							
		246			3 rd I	419		
		5' -TAT 3'			5' -TAT 3' 5' -CgA 3'			
Well No.	1	2	3	4	5	6	7	8
HLA-B allele								
*14:01:01-14:01:02	1	2						8
*14:02:01-14:02:06	1		3					
*14:03	1		3	4				
*14:04	1		w		5			
*14:05			3			6		
*14:06:01-14:06:02			3				7	
*14:07N	1	2			5			8
*14:08, 39:43 ⁴		2					7	8
*14:09	1		3					
*14:10		2						8
*14:11	1		3					
*14:12	1	2						8
*14:13			3					
*14:14	1	2						8
*14:15	1		3					
*14:16	1		3					
*14:17	1		3			6		
*14:18	1		3					
*14:19	1	2						8
Well No.	1	2	3	4	5	6	7	8

INTERPRETATION TABLE

HLA-B*14 SSP subtyping

Amplification patterns of the B*14:01 to B*14:19 alleles

Well ⁵								
9	10	11	12	13	14	15	16	
160	180	135	230	210	190	100	175	Length of spec.
	270							PCR product(s)
1070	1070	1070	1070	1070	1070	800	1070	Length of int.
								pos. control ¹
361	106	560	361	412	142	103	361	5'-primer(s) ²
5' -AgT 3' 5'	-CCA 3' 5'	-CAC 3' 5'	-AgT 3' 5'	-ATA 3' 5'	-TCT 3' 5'	-CCg 3' 5'	-AgT 3'	
	355							
	5' -TCA 3'							
479	246	3 rd I	541	583	292	164	494	3'-primer(s) ³
5' -CCC 3' 5'	-TAT 3' 5'	-TAT 3' 5'	-TCC 3' 5'	-gTg 3' 5'	-gTA 3' 5'	-gCA 3' 5'	-TCC 3'	
	583		559		292			
	5' -gTg 3'		5' -CAg 3'		5' -gTA 3'			
					292			
					5' -gTA 3'			
9	10	11	12	13	14	15	16	Well No.
								HLA-B allele
		11						*14:01:01-14:01:02
		11						*14:02:01-14:02:06
		11						*14:03
		11						*14:04
		11						*14:05
		11						*14:06:01-14:06:02
		11						*14:07N
		11						*14:08, 39:43 ⁴
9		11						*14:09
	10	11						*14:10
	10	11						*14:11
		11	12					*14:12
		11		13				*14:13
		11			14			*14:14
		11				15		*14:15
		11					16	*14:16
		11						*14:17
		11			14			*14:18
			12					*14:19
9	10	11	12	13	14	15	16	Well No.

Length of spec.	265	185	210	85	135	95	260	250
PCR product(s)					220	175		
Well No.	1	2	3	4	5	6	7	8
*07:02:01-07:02:15, 07:02:17-07:05:04, 07:05:06-07:15, 07:17-07:18:02, 07:20-07:26, 07:28, 07:30, 07:32-07:33, 07:35, 07:39-07:42, 07:44-07:49N, 07:51-07:64, 07:66-07:69, 07:73-07:74, 07:76-07:78, 07:80, 07:82-07:85, 07:87-07:90, 07:92-07:110, 07:112-07:114, 07:116-07:117, 15:71, 15:175, 27:08, 27:12, 27:18, 27:26, 27:33, 27:40, 27:42, 27:44, 35:50, 35:84, 40:02:01-40:06:03, 40:08-40:09, 40:11:01-40:11:02, 40:18, 40:20, 40:24, 40:26-40:27, 40:29, 40:35, 40:37, 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, 48:02:02, 73:01-73:02, 81:01-81:05								8
*07:16, 07:37, 07:50, 07:75, 07:91, 15:68, 18:10, 18:21, 18:35, 40:149, 48:01:01-48:02:01, 48:03:01-48:06, 48:08-48:17, 48:19-48:21, 48:23-48:24								8
*07:19, 07:31, 07:34, 07:43, 39:01:09, 39:02:02, 39:10, 39:16-39:17, 39:19:01, 39:23, 39:45, 40:39, 42:01:01-42:02, 42:04-42:05:02, 42:07-42:10, 42:12-42:14, 54:02, 55:10, 67:01:02-67:02								8
*07:27, 07:38, 15:03:01-15:03:03, 15:29, 15:47, 15:49, 15:54, 15:62, 15:64, 15:74, 15:91, 15:98, 15:103, 15:123, 15:127, 15:131-15:132, 15:151, 15:156, 15:158, 15:173, 35:25, 35:124-35:125, 35:142, 37:01:05, 37:02, 37:07, 40:12, 48:18, 48:22, 58:12								
*07:115						6		8
Well No.	1	2	3	4	5	6	7	8

Lot No.: **90K**

Lot-specific information

www.olerup-ssp.com

160	180	135	230	210	190	100	175	Length of spec. PCR product(s)
9	10	11	12	13	14	15	16	Well No.
	270							
								*07:02:01-07:02:15, 07:02:17-07:05:04, 07:05:06-07:15, 07:17-07:18:02, 07:20- 07:26, 07:28, 07:30, 07:32-07:33, 07:35, 07:39-07:42, 07:44-07:49N, 07:51-07:64, 07:66-07:69, 07:73-07:74, 07:76-07:78, 07:80, 07:82-07:85, 07:87-07:90, 07:92- 07:110, 07:112-07:114, 07:116-07:117, 15:71, 15:175, 27:08, 27:12, 27:18, 27:26, 27:33, 27:40, 27:42, 27:44, 35:50, 35:84, 40:02:01-40:06:03, 40:08-40:09, 40:11:01- 40:11:02, 40:18, 40:20, 40:24, 40:26- 40:27, 40:29, 40:35, 40:37, 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, 48:02:02, 73:01-73:02, 81:01- 81:05
					14			*07:16, 07:37, 07:50, 07:75, 07:91, 15:68, 18:10, 18:21, 18:35, 40:149, 48:01:01- 48:02:01, 48:03:01-48:06, 48:08-48:17, 48:19-48:21, 48:23-48:24
		11						*07:19, 07:31, 07:34, 07:43, 39:01:09, 39:02:02, 39:10, 39:16-39:17, 39:19:01, 39:23, 39:45, 40:39, 42:01:01-42:02, 42:04-42:05:02, 42:07-42:10, 42:12- 42:14, 54:02, 55:10, 67:01:02-67:02
					14			*07:27, 07:38, 15:03:01-15:03:03, 15:29, 15:47, 15:49, 15:54, 15:62, 15:64, 15:74, 15:91, 15:98, 15:103, 15:123, 15:127, 15:131-15:132, 15:151, 15:156, 15:158, 15:173, 35:25, 35:124-35:125, 35:142, 37:01:05, 37:02, 37:07, 40:12, 48:18, 48:22, 58:12
								*07:115
9	10	11	12	13	14	15	16	Well No.

Lot No.: **90K**

Lot-specific information

www.olerup-ssp.com

Length of spec.	265	185	210	85	135	95	260	250
PCR product(s)					220	175		
Well No.	1	2	3	4	5	6	7	8
*08:01:01-08:02, 08:04-08:05, 08:07-08:10, 08:12:01-08:20, 08:22, 08:24, 08:26-08:39, 08:41-08:53, 08:55-08:66, 13:06, 15:42, 15:50, 15:83, 15:86, 15:121, 15:188, 15:199, 27:15, 27:28, 27:62, 27:71, 35:35, 35:60, 35:87, 35:93, 37:22, 39:12, 41:01-41:16, 44:04, 44:56N, 45:08, 46:03, 46:18, 46:21:01-46:21:02, 51:36, 54:01, 54:04-54:05N, 54:07-54:23, 55:01:01-55:05, 55:07, 55:11-55:21, 55:23, 55:25-55:48, 56:10, 56:12, 56:18, 56:23, 57:26, 58:05, 58:20, 59:01-59:03, 59:05								
*08:03, 08:23, 08:54, 15:69, 37:01:01-37:01:04, 37:01:06-37:01:07, 37:03N, 37:06, 37:08-37:10, 37:12-37:21, 37:23-37:25, 38:02:03, 38:04, 38:06, 38:25								
*13:15, 51:01:01-51:01:18, 51:01:20, 51:03, 51:07:01-51:09:02, 51:11N-51:14, 51:16, 51:19-51:20, 51:24:01-51:24:04, 51:26-51:28, 51:30-51:33, 51:35, 51:38-51:39, 51:41N, 51:43-51:44N, 51:48-51:53, 51:55, 51:57-51:58, 51:60-51:61, 51:63-51:80, 51:83-51:84, 51:86-51:89, 51:91, 51:95-51:100, 51:102-51:106, 52:01:01-52:02, 52:04-52:10, 52:13-52:15, 52:17-52:22, 56:05:01-56:06, 56:21, 58:08, 78:01-78:02:02, 78:05-78:06								
*15:09-15:10:02, 15:18:01-15:18:04, 15:23, 15:51-15:52, 15:72, 15:80, 15:90, 15:99, 15:108, 15:114-15:115, 15:119, 15:124, 15:133-15:134, 15:153, 15:161, 15:176, 15:197-15:198, 15:200			3					
*15:21, 15:66, 35:82, 35:85, 35:135			3					
*15:37			3				7	
*15:38:01-15:38:02, 15:185, 51:45							7	
*15:44			3					
*15:93, 15:186, 38:05			3					
*15:189, 35:26			3					
Well No.	1	2	3	4	5	6	7	8

Lot No.: **90K**

Lot-specific information

www.olerup-ssp.com

160	180	135	230	210	190	100	175	Length of spec. PCR product(s)
9	10	11	12	13	14	15	16	Well No.
		11						*08:01:01-08:02, 08:04-08:05, 08:07-08:10, 08:12:01-08:20, 08:22, 08:24, 08:26-08:39, 08:41-08:53, 08:55-08:66, 13:06, 15:42, 15:50, 15:83, 15:86, 15:121, 15:188, 15:199, 27:15, 27:28, 27:62, 27:71, 35:35, 35:60, 35:87, 35:93, 37:22, 39:12, 41:01-41:16, 44:04, 44:56N, 45:08, 46:03, 46:18, 46:21:01-46:21:02, 51:36, 54:01, 54:04-54:05N, 54:07-54:23, 55:01:01-55:05, 55:07, 55:11-55:21, 55:23, 55:25-55:48, 56:10, 56:12, 56:18, 56:23, 57:26, 58:05, 58:20, 59:01-59:03, 59:05
		11			14			*08:03, 08:23, 08:54, 15:69, 37:01:01-37:01:04, 37:01:06-37:01:07, 37:03N, 37:06, 37:08-37:10, 37:12-37:21, 37:23-37:25, 38:02:03, 38:04, 38:06, 38:25
				13				*13:15, 51:01:01-51:01:18, 51:01:20, 51:03, 51:07:01-51:09:02, 51:11N-51:14, 51:16, 51:19-51:20, 51:24:01-51:24:04, 51:26-51:28, 51:30-51:33, 51:35, 51:38-51:39, 51:41N, 51:43-51:44N, 51:48-51:53, 51:55, 51:57-51:58, 51:60-51:61, 51:63-51:80, 51:83-51:84, 51:86-51:89, 51:91, 51:95-51:100, 51:102-51:106, 52:01:01-52:02, 52:04-52:10, 52:13-52:15, 52:17-52:22, 56:05:01-56:06, 56:21, 58:08, 78:01-78:02:02, 78:05-78:06
					14			*15:09-15:10:02, 15:18:01-15:18:04, 15:23, 15:51-15:52, 15:72, 15:80, 15:90, 15:99, 15:108, 15:114-15:115, 15:119, 15:124, 15:133-15:134, 15:153, 15:161, 15:176, 15:197-15:198, 15:200
					14			*15:21, 15:66, 35:82, 35:85, 35:135
								*15:37
		11						*15:38:01-15:38:02, 15:185, 51:45
								*15:44
		11			14			*15:93, 15:186, 38:05
	10							*15:189, 35:26
9	10	11	12	13	14	15	16	Well No.

Lot No.: **90K**

Lot-specific information

www.olerup-ssp.com

Length of spec.	265	185	210	85	135	95	260	250
PCR product(s)					220	175		
Well No.	1	2	3	4	5	6	7	8
*18:01:01, 18:01:03-18:01:09, 18:05-18:08, 18:12, 18:15, 18:17N-18:20, 18:23N-18:24, 18:28, 18:31-18:34, 18:37-18:38, 18:40-18:43, 18:45-18:49, 18:51-18:52							7	8
*18:01:02, 18:03, 18:29							7	8
*18:02, 18:11, 18:14, 18:27, 18:39, 37:05, 37:11, 39:13:01-39:13:02, 39:20, 39:49, 42:11								8
*18:04							7	
*18:09, 18:25							7	
*18:13, 18:30				4			7	8
*18:22								8
*18:26							7	8
*18:36, 18:50							7	8
*18:44	1							8
*35:21, 35:24:01-35:24:02, 35:81, 35:109, 53:02, 53:06, 57:14, 58:09, C*15:39								
*35:96								
*37:04:01-37:04:02								
*38:01:01-38:02:02, 38:07, 38:09-38:12, 38:15, 38:17-38:18, 38:20-38:21, 38:23-38:24		2						
*38:03, 38:13-38:14, 38:16, 38:26		2						
*38:08, 38:22		2						
*38:19		2				6		
*39:01:01:01-39:01:01:02L, 39:01:03-39:01:08, 39:01:10-39:02:01, 39:06:01-39:06:02, 39:09, 39:14-39:15, 39:18, 39:19:02, 39:22, 39:25N-39:31, 39:34-39:36, 39:38Q-39:39, 39:41-39:42, 39:44, 39:46, 39:51-39:54, 39:57-39:62, 67:01:01, 67:03		2						8
*39:03, 39:24		2				6		8
*39:04			3					
*39:05:01-39:05:02, 39:07-39:08, 39:11, 39:55-39:56		2						8
*39:32		2					7	8
*39:33, 39:47, 39:50		2						8
*39:37		2				6		8
Well No.	1	2	3	4	5	6	7	8

Lot No.: **90K**

Lot-specific information

www.olerup-ssp.com

160	180	135	230	210	190	100	175	Length of spec. PCR product(s)
9	10	11	12	13	14	15	16	Well No.
		11			14			*18:01:01, 18:01:03-18:01:09, 18:05-18:08, 18:12, 18:15, 18:17N-18:20, 18:23N-18:24, 18:28, 18:31-18:34, 18:37-18:38, 18:40-18:43, 18:45-18:49, 18:51-18:52
		11						*18:01:02, 18:03, 18:29
		11			14			*18:02, 18:11, 18:14, 18:27, 18:39, 37:05, 37:11, 39:13:01-39:13:02, 39:20, 39:49, 42:11
		11						*18:04
		11			14			*18:09, 18:25
		11			14			*18:13, 18:30
	10	11			14			*18:22
		11		13	14			*18:26
					14			*18:36, 18:50
		11			14			*18:44
	10							*35:21, 35:24:01-35:24:02, 35:81, 35:109, 53:02, 53:06, 57:14, 58:09, C*15:39
	10	11						*35:96
	10	11			14			*37:04:01-37:04:02
		11			14			*38:01:01-38:02:02, 38:07, 38:09-38:12, 38:15, 38:17-38:18, 38:20-38:21, 38:23-38:24
		11						*38:03, 38:13-38:14, 38:16, 38:26
					14			*38:08, 38:22
		11			14			*38:19
		11						*39:01:01:01-39:01:01:02L, 39:01:03-39:01:08, 39:01:10-39:02:01, 39:06:01-39:06:02, 39:09, 39:14-39:15, 39:18, 39:19:02, 39:22, 39:25N-39:31, 39:34-39:36, 39:38Q-39:39, 39:41-39:42, 39:44, 39:46, 39:51-39:54, 39:57-39:62, 67:01:01, 67:03
		11						*39:03, 39:24
	10	11						*39:04
		11			14			*39:05:01-39:05:02, 39:07-39:08, 39:11, 39:55-39:56
				13				*39:32
								*39:33, 39:47, 39:50
		11			14			*39:37
9	10	11	12	13	14	15	16	Well No.

Length of spec.	265	185	210	85	135	95	260	250
PCR product(s)					220	175		
Well No.	1	2	3	4	5	6	7	8
*39:40N		2			5			8
*39:48		2					7	8
*40:28								8
*40:51							7	
*40:113, 51:06, 51:62							7	
*42:06						6		8
*48:07						6		8
*51:04, 51:46, 51:56								
*51:21, 51:101, 78:07								
*51:22, 78:03			3					
*51:29, 51:82				4				
*52:16								
*57:11, 58:02, 58:06-58:07, 58:25, C*01:35, C*03:17, C*03:71, C*14:20								
C*01:30	1			4				
C*07:102								w
C*08:08						6		
HLA-B allele								
Well No.	1	2	3	4	5	6	7	8

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*14 subtyping. .

In addition, wells number 3 and 15 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 or 3rd 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.

160	180	135	230	210	190	100	175	Length of spec. PCR product(s)
9	10	11	12	13	14	15	16	Well No.
	270							
		11						*39:40N
		11		13				*39:48
	10			13				*40:28
		11		13				*40:51
				13				*40:113, 51:06, 51:62
		11						*42:06
					14			*48:07
	10			13				*51:04, 51:46, 51:56
		11		13				*51:21, 51:101, 78:07
				13				*51:22, 78:03
				13				*51:29, 51:82
				13	14			*52:16
			12					*57:11, 58:02, 58:06-58:07, 58:25, C*01:35, C*03:17, C*03:71, C*14:20
								C*01:30
								C*07:102
								C*08:08
								HLA-B allele
9	10	11	12	13	14	15	16	Well No.

⁴The B*14:08 and B*39:43 alleles will give rise to identical amplification patterns with the HLA-B*14 subtyping kit. These alleles can be distinguished by the HLA-B low resolution kit and/or the HLA-B*39 subtyping kit.

⁵Primer mix 5: Specific PCR fragment of 135 bp in the B*14:07N and B*39:40N alleles. Specific PCR fragment of 220 bp in the B*14:04 allele.

Primer mix 6: Specific PCR fragment of 95 bp in the B*14:05 and the B*07:115, 38:19, 39:03, 39:24, 39:37, 42:06 and 48:07 and the C*08:08 alleles. Specific PCR fragment of 175 bp in the B*14:17 allele.

Primer mix 10: Specific PCR fragment of 180 bp in the B*14:11 and the B*15:189, 35:26 and 39:04 alleles. Specific PCR fragment of 270 bp in the B*14:10 and in the B*18:22, 35:21, 35:24:01-35:24:02, 35:81, 35:96, 35:109, 37:04:01-37:04:02, 40:28, 51:04, 51:46, 51:56, 53:02, 53:06, 57:14 and 58:09 and the C*15:39 allele.

'w', might be weakly amplified.

'?', nucleotide sequence of the primer matching sequence is not known.

CELL LINE VALIDATION SHEET																				
HLA-B*14 SSP subtyping kit																				
				Well																
				1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	
				Prod. No.:	201081301	201081302	201081303	201081304	200732305	201081306	200732307	200964502	200964509	201081310	201081311	201081312	201081313	201081314	201081315	201081316
	IHWC cell line		B*																	
1	9001 SA		*07:02	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-
2	9280 LK707		*52:01	*73:01	-	-	-	-	-	-	-	+	-	-	-	-	+	-	-	-
3	9011 E4181324		*52:01		-	-	-	-	-	-	-	-	-	-	-	+	-	-	-	-
4	9275 GU373		*15:10	*53:01	-	-	-	-	-	-	-	-	-	-	-	-	+	-	-	-
5	9009 KAS011		*37:01		-	-	-	-	-	-	-	-	-	-	+	-	-	+	-	-
6	9353 SM		*39:01	*51:01	-	+	-	-	-	-	-	+	-	-	+	-	+	-	-	-
7	9020 QBL		*18:01		-	-	-	-	-	-	+	+	-	-	+	-	-	+	-	-
8	9025 DEU		*35:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
9	9026 YAR		*38:01		-	+	-	-	-	-	-	-	-	-	+	-	-	+	-	-
10	9107 LKT3		*54:01		-	-	-	-	-	-	-	-	-	-	+	-	-	-	-	-
11	9051 PITOUT		*44:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
12	9052 DBB		*57:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
13	9004 JESTHOM		*27:05		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
14	9071 OLGA		*15:01	*15:20	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
15	9075 DKB		*40:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
16	9037 SWEIG007		*40:02		-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-
17	9282 CTM3953540		*08:01	*55:01	-	-	-	-	-	-	-	-	-	-	+	-	-	-	-	-
18	9257 32367		*14:01	*56:01	+	+	-	-	-	-	-	+	-	-	+	-	-	-	-	-
19	9038 BM16		*18:01		-	-	-	-	-	-	-	+	+	-	+	-	-	+	-	-
20	9059 SLE005		*40:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
21	9064 AMALA		*15:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
22	9056 KOSE		*35:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
23	9124 IHL		*40:02	*56:02	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-
24	9035 JBUSH		*38:01		-	+	-	-	-	-	-	-	-	-	+	-	-	+	-	-
25	9049 IBW9		*14:02		+	-	+	-	-	-	-	-	-	-	+	-	-	-	-	-
26	9285 WT49		*58:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
27	9191 CH1007		*07:05	*51:01	-	-	-	-	-	-	-	-	+	-	-	-	+	-	-	-
28	9320 BEL5GB		*44:02	*44:03	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
29	9050 MOU		*44:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
30	9021 RSH		*42:01		-	-	-	-	-	-	-	-	+	-	-	+	-	-	-	-
31	9019 DUCAF		*18:01		-	-	-	-	-	-	-	+	+	-	-	+	-	-	+	-
32	9297 HAG		*41:02		-	-	-	-	-	-	-	-	-	-	+	-	-	-	-	-
33	9098 MT14B		*40:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
34	9104 DHIF		*38:01		-	+	-	-	-	-	-	-	-	-	+	-	-	+	-	-
35	9302 SSTO		*44:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
36	9024 KT17		*15:01	*35:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
37	9065 HHKB		*07:02		-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-
38	9099 LZL		*15:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
39	9315 CML		*08:01	*27:05	-	-	-	-	-	-	-	-	-	-	+	-	-	-	-	-
40	9134 WHONP199		*13:02	*46:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
41	9055 H0301		*14:02		+	-	+	-	-	-	-	-	-	-	+	-	-	-	-	-
42	9066 TAB089		*46:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
43	9076 T7526		*46:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
44	9057 TEM		*38:01		-	+	-	-	-	-	-	-	-	-	+	-	-	+	-	-
45	9239 SHJO		*42:01	*50:01	-	-	-	-	-	-	-	+	-	-	+	-	-	-	-	-
46	9013 SCHU		*07:02		-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-
47	9045 TUBO		*51:01		-	-	-	-	-	-	-	-	-	-	-	-	+	-	-	-
48	9303 TER-ND		*35:01	*44:03	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-B*14 SSP

Product number: 101.524-12 – including *Taq* polymerase
Lot number: 90K
Expiry date: 2013-July-01
Number of tests: 12
Number of wells per test: 16

Well specifications:

Well No.	Production No.	Well No.	Production No.
1	2010-813-01	9	2009-645-09
2	2010-813-02	10	2010-813-10
3	2010-813-03	11	2010-813-11
4	2010-813-04	12	2010-813-12
5	2007-323-05	13	2010-813-13
6	2010-813-06	14	2010-813-14
7	2007-323-07	15	2010-813-15
8	2009-645-08	16	2010-813-16

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 solution 4 to 6, 9, 15 and 16 were available. The specificities of the primers in primer solution 4 to 6 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer. In primer solution 9, 15 and 16 it was only possible to test the 5'-primer, the 3'-primer was not possible to test. In primer solutions 5 and 6, one 5'-primer was not possible to test, and in primer solutions 5 and 12 one 3'-primer was not possible to test.

Additional primers in primer solution 10 were tested by separately adding one additional 5'-primer, respective one additional 3'-primer.

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

Date of approval: 2011-February -04

Approved by:

Quality Control, Supervisor

Lot No.: **90K**

Lot-specific information

www.olerup-ssp.com

Declaration of Conformity

Product name: *Olerup* SSP® HLA-B*14
Product number: 101.524-12
Lot number: 90K

Intended use: HLA-B*14 high resolution histocompatibility testing

Manufacturer: *Olerup* SSP AB
Hasselstigen 1
SE-133 33 Saltsjöbaden, 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, Hasselstigen 1, SE-133 33 Saltsjöbaden, 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.)

Saltsjöbaden, Sweden
2011-February-04

Olle Olerup
Managing Director

Lot No.: **90K**

Lot-specific information

www.olerup-ssp.com

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