

Olerup SSP® HLA-B*37

Product number:	101.541-06u – without <i>Taq</i> polymerase
Lot number:	72K
Expiry date:	2013-May-01
Number of tests:	6
Number of wells per test:	23
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. 72K.

CHANGES COMPARED TO THE PREVIOUS *OLERUP SSP*® HLA-B*37 LOT.

The HLA-B*37 specificity and interpretation tables have been updated for the HLA-B alleles described since the previous *Olerup SSP*® HLA-B*37 lot was made (**Lot No. 98F**).

Seven wells have been added to the HLA-B*37 kit,
wells **17 to 23**.

The primers of the wells detailed below has been exchanged, added or modified.

Well	5'-primer	3'-primer	rationale
9	Added	-	Primer added for the B*37:22 allele.
11	Added	-	Primer added for the B*37:18 allele.
13	-	Added	Primer added for the B*37:15 allele.
17	New	New	New primer pair for the B*37:25 allele.
18	New	New	New primer pair for the B*37:20 allele.
19	New	New	New primer pair for the B*37:21 allele.
20	New	New	New primer pair for the B*37:16Q allele.
21	New	New	New primer pair for the B*37:24 allele.
22	New	New	New primer pair for the B*37:17 allele.
23	New	New	New primer pair for the B*37:19 and 37:23 alleles.

PRODUCT DESCRIPTION

HLA-B*37 SSP typing

CONTENT

The primer set contains 5'- and 3'-primers for identifying the B*37:01 to B*37:25 alleles.

PLATE LAYOUT

Each HLA-B*37 test consists of 23 PCR reactions in a 24 well cut PCR plate. Well 24 is empty.

1	2	3	4	5	6	7	8
9	10	11	12	13	14	15	16
17	18	19	20	21	22	23	empty

The 24 well PCR plate is marked with ‘HLA-B*37’ in silver/gray ink.

Well No. 1 is marked with the Lot No. ‘72K’.

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 24 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*37 SSP subtypings will be influenced by most B*07, the B*08, the B*13:23, the B*14:10, thirteen B*15, the B*18, the B*27, the B*35, two B*38, four B*39, the B*40, the B*41, the B*42, thirteen B*44, the B*45, the B*46:14, B*47, three B*48, the B*49, the B*50, seven B*51, the B*52:19, two B*53, the B*54:02, two B*55, two B*56, two B*57, the B*73, the B*78 and B*82 alleles when present on the other haplotype. In addition, the C*07:68 allele will be amplified by primer mix 1, and the C*02:23 and C*04:77 alleles will be amplified by primer mix 8.

UNIQUELY IDENTIFIED ALLELES

All the HLA-B*37, i.e. **B*37:01 to B*37:25**, recognized by the HLA Nomenclature Committee in October 2010¹ will be amplified by the primers in the HLA-B*37 SSP kit.

The HLA-B*37 subtyping kit cannot distinguish the B*37:01:01 to B*37:01:07 or the B*37:04:01 and 37:04:02 alleles.

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

RESOLUTION IN HOMO- AND HETEROZYGOTES

A total of 32 alleles generate 25 amplification patterns that can be combined in 325 homozygous and heterozygous combinations. 144 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.

++-+--	+---+---	-----	*37:02, *37:08 = *37:02, *37:22
++-+--	---++---	-----	*37:02, *37:10 = *37:02, *37:15
+--+--	+---+---	-----	*37:08, *37:13 = *37:13, *37:22
+--+--	---++---	-----	*37:10, *37:13 = *37:13, *37:15
+--+--	---+---	-----+	*37:13, *37:19 = *37:13, *37:23
+--+--	---+---	-----	*37:01:01, *37:13 = *37:03N, *37:04:01 = *37:03N, *37:13 = *37:04:01, *37:13 = *37:13, *37:13
+--+--	+---+---	-----	*37:03N, *37:08 = *37:03N, *37:22
+--+--	---++---	-----	*37:03N, *37:10 = *37:03N, *37:15
+--+--	---+---	-----+	*37:03N, *37:19 = *37:03N, *37:23
+--+--	---+---	-----	*37:01:01, *37:03N = *37:03N, *37:03N
+--+--	+---+---	-----	*37:04:01, *37:08 = *37:04:01, *37:22
+--+--	---++---	-----	*37:04:01, *37:10 = *37:04:01, *37:15
+--+--	---+---	-----+	*37:04:01, *37:19 = *37:04:01, *37:23
+--+--	---+---	-----	*37:01:01, *37:04:01 = *37:04:01, *37:04:01
+--+--	-++-+---	-----+	*37:14, *37:19 = *37:14, *37:23
+--+--	---++---	-----+	*37:11, *37:19 = *37:11, *37:23
+--+--	---+---	-----+	*37:05, *37:19 = *37:05, *37:23
+--+--	+---+---	-----	*37:06, *37:08 = *37:06, *37:22
+--+--	---++---	-----	*37:06, *37:10 = *37:06, *37:15
+--+--	---+---	-----+	*37:06, *37:19 = *37:06, *37:23
+--+--	---+---	-----	*37:01:01, *37:06 = *37:06, *37:06
+--+--	+---+---	-----	*37:07, *37:08 = *37:07, *37:22
+--+--	---++---	-----	*37:07, *37:10 = *37:07, *37:15
+--+--	+---+---	-----	*37:08, *37:09 = *37:09, *37:22
+--+--	+---+---	-----	*37:08, *37:18 = *37:18, *37:22
+--+--	+---+---	-----	*37:08, *37:10 = *37:08, *37:15 = *37:15, *37:22
+--+--	+---+---	-----	*37:08, *37:12 = *37:12, *37:22
+--+--	+---+---	+-----	*37:08, *37:25 = *37:22, *37:25
+--+--	+---+---	-+-----	*37:08, *37:20 = *37:20, *37:22
+--+--	+---+---	---+-----	*37:08, *37:21 = *37:21, *37:22
+--+--	+---+---	---+-----	*37:08, *37:16Q = *37:16Q, *37:22
+--+--	+---+---	---+---	*37:08, *37:24 = *37:22, *37:24
+--+--	+---+---	-----+	*37:08, *37:17 = *37:17, *37:22
+--+--	+---+---	-----+	*37:08, *37:19 = *37:08, *37:23 = *37:19, *37:22 = *37:22, *37:23
+--+--	+---+---	-----	*37:01:01, *37:08 = *37:01:01, *37:22 = *37:08, *37:22
+--+--	---++---	-----	*37:09, *37:10 = *37:09, *37:15
+--+--	---++---	-----	*37:10, *37:18 = *37:15, *37:18
+--+--	---++---	-----	*37:01:01, *37:09 = *37:09, *37:18 = *37:12, *37:18
+--+--	---++---	-----+	*37:18, *37:19 = *37:18, *37:23
+--+--	---++---	-----	*37:01:01, *37:18 = *37:18, *37:18
+--+--	---++---	-----	*37:10, *37:12 = *37:12, *37:15
+--+--	---++---	+-----	*37:10, *37:25 = *37:15, *37:25
+--+--	---++---	-+-----	*37:10, *37:20 = *37:15, *37:20
+--+--	---++---	---+-----	*37:10, *37:21 = *37:15, *37:21
+--+--	---++---	---+-----	*37:10, *37:16Q = *37:15, *37:16Q

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Lot-specific information

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+----+--- --++--- ----+--	*37:10, *37:24 = *37:15, *37:24
+----+--- --++--- ----+--	*37:10, *37:17 = *37:15, *37:17
+----+--- --++--- ----+--	*37:10, *37:19 = *37:10, *37:23 = *37:15, *37:19 = *37:15, *37:23
+----+--- --++--- ----+--	*37:01:01, *37:10 = *37:01:01, *37:15 = *37:10, *37:15 = *37:15, *37:15
+----+--- --++--- +-----	*37:19, *37:25 = *37:23, *37:25
+----+--- --++--- +-----	*37:01:01, *37:25 = *37:25, *37:25
+----+--- --++--- -+-----	*37:19, *37:20 = *37:20, *37:23
+----+--- --++--- -+-----	*37:01:01, *37:20 = *37:20, *37:20
+----+--- --++--- -+-----	*37:19, *37:21 = *37:21, *37:23
+----+--- --++--- -+-----	*37:01:01, *37:21 = *37:21, *37:21
+----+--- --++--- -+-----	*37:16Q, *37:19 = *37:16Q, *37:23
+----+--- --++--- -+-----	*37:01:01, *37:16Q = *37:16Q, *37:16Q
+----+--- --++--- -+-----	*37:19, *37:24 = *37:23, *37:24
+----+--- --++--- -+-----	*37:01:01, *37:24 = *37:24, *37:24
+----+--- --++--- -+-----	*37:17, *37:19 = *37:17, *37:23
+----+--- --++--- -+-----	*37:01:01, *37:17 = *37:17, *37:17
+----+--- --++--- -+-----	*37:01:01, *37:19 = *37:01:01, *37:23 = *37:19, *37:23 = *37:23, *37:23
+----+--- --++--- -+-----	*37:05, *37:14 = *37:14, *37:14
+----+--- --++--- -+-----	*37:05, *37:11 = *37:11, *37:11
+----+--- --++--- -+-----	*37:09, *37:09 = *37:09, *37:12

*37:01:01 = *37:01:01-37:01:07

*37:04:01 = *37:04:01-37:04:02

SPECIFICITY TABLE

HLA-B*37 SSP subtyping

Specificities and sizes of the PCR products of the 23 primer mixes used for HLA-B*37 SSP subtyping

Primer Mix	Size of spec. PCR product ¹	Size of control band ²	Amplified HLA-B*37 alleles	Other amplified HLA-B alleles ³
1	210 bp	800 bp	*37:01:01-37:01:07, 37:03N-37:06, 37:08, 37:10-37:11, 37:13-37:18, 37:20-37:25	*08:49, C*07:68
2⁴	95 bp	1070 bp	*37:02	*27:01-27:05:15, 27:08, 27:10, 27:12-27:13, 27:15-27:18, 27:23, 27:25-27:26, 27:28-27:29, 27:31, 27:36-27:40, 27:42, 27:44-27:45, 27:47-27:69, 27:71-27:73, 47:04-47:05
3⁸	200 bp, 235 bp	1070 bp	*37:03N, 37:13	
4⁹	200 bp, 255 bp	1070 bp	*37:04:01-37:04:02, 37:13	*18:18
5	210 bp	1070 bp	*37:01:01-37:04:02, 37:06-37:09, 37:12-37:13, 37:15-37:21, 37:23-37:25	*07:27, 38:17
6⁴	145 bp	1070 bp	*37:05, 37:11, 37:14 ^w	*07:65, 08:32, 15:46, 15:53, 15:106, 15:143, 15:202, 18:01:01-18:08, 18:10-18:15, 18:17N-18:36, 18:38-18:52, 35:01:01:01-35:08:01, 35:08:03-35:24:02, 35:27-35:45, 35:47-35:48, 35:50-35:72, 35:74-35:151, 39:19:01-39:19:02, 40:01:01-40:11:02, 40:14:01-40:16, 40:18, 40:20, 40:22N-40:40, 40:42-40:45, 40:48-40:75, 40:77-40:92, 40:94-40:95,

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				40:97-40:108, 40:111-40:116, 40:118N-40:136, 40:138-40:156, 40:158, 41:01-41:04, 41:05 ^w , 41:06-41:16, 44:09, 44:46, 44:75, 44:90, 45:01-45:13, 47:02, 47:03 ^w , 50:01-01-50:02, 50:04-50:05, 50:07-50:12, 56:06, 78:01-78:07
7⁴	135 bp	1070 bp	*37:06	*47:01:01:01-47:01:01:02, 47:05-47:07
8^{4,5}	120 bp	1070 bp	*37:07	*07:02:01-07:18:02, 07:20-07:24, 07:26-07:32, 07:34-07:39, 07:41-07:47, 07:49N-07:50, 07:52, 07:54-07:59, 07:61-07:99, 07:101-07:117, 15:138, 40:15-40:16, 40:23, 40:32, 40:98, 40:158, 48:05, 48:08, 48:15, C*02:23 , C*04:77
9^{4,10}	80 bp, 215 bp	1070 bp	*37:08, 37:22	*07:27, 38:17, 53:03
10^{4,6}	145 bp	1070 bp	*37:14	
11^{4,11}	95 bp, 215 bp	1070 bp	*37:09, 37:18	*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, 08:61-08:66, 35:87, 41:02:01-41:02:03, 41:04, 41:10-41:11, 41:13, 41:15, 42:01:01-42:02, 42:05:01-42:12, 42:14, 44:106
12	205 bp	1070 bp	*37:01:01-37:07, 37:09-37:25	*13:23, 15:71, 15:175, 15:204, 18:12, 27:01-27:21, 27:24-27:36, 27:38-27:73, 35:63, 40:01:01-40:07, 40:09, 40:11:01-40:11:02, 40:13-40:16, 40:18-40:20, 40:22N-40:24, 40:26-40:39, 40:42-40:48, 40:50-40:57, 40:59-40:67,

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				40:70-40:105, 40:107-40:109, 40:111-40:128, 40:130-40:136, 40:138-40:158, 41:01-41:16, 44:15, 44:18, 44:55, 44:103, 45:01-45:13, 48:22, 49:01:01-49:09, 49:11-49:15, 50:01:01-50:02, 50:04-50:12
13^{5,12}	170 bp, 255 bp	800 bp	*37:10, 37:15	*13:23, 18:09, 27:01, 40:47, 40:96, 40:157, 44:15, 44:55, 44:103, 49:02
14⁷	245 bp	1070 bp	*37:11	*08:62, 15:71, 15:175, 15:204, 18:01:01-18:03, 18:05-18:08, 18:10-18:15, 18:17N-18:24, 18:26-18:42, 18:44-18:48, 18:50-18:52, 27:08, 27:12, 27:18, 27:26, 27:33, 27:40, 27:44, 35:50, 35:63, 35:84, 39:31, 40:01:01-40:01:04, 40:01:06-40:09, 40:11:01-40:11:02, 40:14:01-40:16, 40:18, 40:20, 40:22N-40:36, 40:38-40:39, 40:42-40:46, 40:48, 40:50-40:57, 40:59-40:75, 40:77-40:95, 40:97-40:108, 40:111-40:116, 40:118N-40:128, 40:130-40:134, 40:136, 40:138-40:156, 40:158, 41:01-41:04, 41:06-41:16, 42:02, 42:09, 45:01-45:13, 46:14, 48:22, 50:01:01-50:02, 50:04-50:12, 54:02, 55:16, 73:01-73:02
15⁴	135 bp	1070 bp	*37:11	*07:65, 08:32, 15:202, 18:01:01-18:08, 18:10-18:15, 18:17N-18:36, 18:38-18:47, 18:50-18:52, 35:01:01:01-35:02:02, 35:02:04-35:03:02, 35:03:04-35:08:01, 35:08:03-35:18, 35:20:01-35:24:02, 35:28-35:45, 35:48, 35:50-35:55, 35:57-35:62, 35:64-35:72,

				35:74-35:151, 39:19:01-39:19:02, 56:06, 78:01-78:05, 78:07
16	170 bp	1070 bp	*37:09, 37:12	*07:04, 07:19, 07:25, 08:01:01-08:05, 08:07-08:12:03, 08:15-08:19N, 08:21-08:24, 08:26-08:27, 08:29-08:39, 08:41-08:48, 08:50-08:54, 08:56-08:66, 15:51, 15:83, 15:179, 15:199, 35:38, 35:87, 35:115, 40:136, 41:01-41:09, 41:11-41:16, 42:01:01-42:02, 42:04-42:14, 44:14, 44:17, 44:51, 44:62, 45:09, 51:08, 51:20, 51:36, 51:44N, 51:97, 52:19, 53:22, 55:20, 56:13, 57:09, 57:24, 82:01-82:03
17	165 bp	1070 bp	*37:25	*45:03
18	195 bp	1070 bp	*37:20	
19	215 bp	1070 bp	*37:21	*08:62, 18:07:01-18:07:02, 18:29, 27:23, 35:50, 35:84, 40:07-40:08, 40:13, 40:68, 40:106, 51:103
20	235 bp	800 bp	*37:16Q	
21	270 bp	1070 bp	*37:24	*40:152
22⁶	175 bp	1070 bp	*37:17	*40:153
23^{4,13}	90 bp, 345 bp	1070 bp	*37:19, 37:23	*14:10, 27:69, 35:59, 38:20, 39:42, 51:32

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*37 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.

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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*37 SSP subtyping.

In addition, wells number 13 and 20 contain the primer pair giving rise to the shorter, 800 bp, internal positive control band in order to allow kit identification.

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

³Due to the sharing of sequence motifs between HLA-B alleles non-HLA-B*37 alleles will be amplified by primer mixes 1,2, 4 to 9, 11 to 17, 19 and 21 to 23. In addition, the C*07:68 allele will be amplified by primer mix 1, and the C*02:23 and C*04:77 alleles will be amplified by primer mix 8.

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

⁵Primer mixes 8 and 13 have a tendency of giving rise to primer oligomer formation.

⁶Primer mixes 10 and 22 may give rise to nonspecific amplifications.

⁷Primer mix 14 may give a lower yield of specific PCR product than the other HLA-B*37 primer mixes.

⁸Primer mix 3: Specific PCR fragment of 200 bp in the B*37:13 allele. Specific PCR fragment of 235 bp in the B*37:03N allele.

⁹Primer mix 4: Specific PCR fragment of 200 bp in the B*37:13 allele. Specific PCR fragment of 255 bp in the B*37:04:01-37:04:02 and B*18:18 alleles.

¹⁰Primer mix 9: Specific PCR fragment of 80 bp in the B*37:08 and B*07:27, 38:17 and 53:03 alleles. Specific PCR fragment of 215 bp in the B*37:22 allele.

¹¹Primer mix 11: Specific PCR fragment of 95 bp in the B*37:18 allele. Specific PCR fragment of 215 bp in the B*37:09 and B*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, 08:61-08:66, 35:87, 41:02:01-41:02:03, 41:04, 41:10-41:11, 41:13, 41:15, 42:01:01-42:02, 42:05:01-42:12, 42:14 and 44:106 alleles.

¹²Primer mix 13: Specific PCR fragment of 170 bp in the B*37:15 allele. Specific PCR fragment of 255 bp in the B*37:10 and B*13:23, 18:09, 27:01, 40:47, 40:96, 40:157, 44:15, 44:55, 44:103 and 49:02 alleles.

¹³Primer mix 23: Specific PCR fragment of 90 bp in the B*37:19 and B*14:10, 35:59, 38:20 and 39:42 alleles. Specific PCR fragment of 345 bp in the B*37:23 and in the B*27:69 and 51:32 alleles. ‘w’, might be weakly amplified.

INTERPRETATION TABLE

HLA-B*37 SSP subtyping

Amplification patterns of the HLA-B*37:01 to *37:25 alleles

	Well ⁴											
	1	2	3	4	5	6	7	8	9	10	11	12
Length of spec.	210	95	200	200	210	145	135	120	80	145	95	205
PCR product(s)			235	255					215		215	
Length of int.	800	1070	1070	1070	1070	1070	1070	1070	1070	1070	1070	1070
pos. control ¹												
5'-primer(s) ²	368	363	142	368	142	206	206	527	126	206	363	97
	5' -gTC 3'	5' -AAT 3'	5' -TCT 3'	5' -gTC 3'	5' -TCT 3'	5' -gAA 3'	5' -gAA 3'	5' -TgA 3'	5' -ggA 3'	5' -gAC 3'	5' -AgC 3'	5' -TCC 3'
			368			206			261		483	
			5' -gTC 3'			5' -gAC 3'			5' -AAC 3'		5' -gAA 3'	
3'-primer(s) ³	538	418	337	527	311	311	301	605	301	311	538	259
	5' -gTC 3'	5' -gTC 3'	5' -CTA 3'	5' -CCT 3'	5' -ggg 3'	5' -ggT 3'	5' -gTC 3'	5' -gCT 3'	5' -gTC 3'	5' -ggT 3'	5' -gTC 3'	5' -CTC 3'
			527	583	311							259
			5' -CCT 3'	5' -gTg 3'	5' -ggg 3'							5' -CTC 3'
Well No.	1	2	3	4	5	6	7	8	9	10	11	12
HLA-B allele												
*37:01:01-37:01:07	1				5							12
*37:02		2			5							12
*37:03N	1		3		5							12
*37:04:01-37:04:02	1			4	5							12
*37:05	1					6						12
*37:06	1				5		7					12
*37:07					5			8				12
*37:08	1				5				9			
*37:09					5						11	12
*37:10	1											12
*37:11	1					6						12
*37:12					5							12
*37:13	1		3	4	5							12
*37:14	1					w				10		12
*37:15	1				5							12
*37:16Q	1				5							12
Well No.	1	2	3	4	5	6	7	8	9	10	11	12

INTERPRETATION TABLE											
HLA-B*37 SSP subtyping											
Amplification patterns of the HLA-B*37:01 to *37:25 alleles											
Well ⁴											
13	14	15	16	17	18	19	20	21	22	23	
170	245	135	170	165	195	215	235	270	175	90	Length of spec.
255										345	PCR product(s)
800	1070	1070	1070	1070	1070	1070	800	1070	1070	1070	Length of int.
											pos. control ¹
97	97	206	409	416	385	97	368	97	520	369	5'-primer(s) ²
5' -TCC 3'	5' -TCC 3'	5' -gAC 3'	5' -ggC 3'	5' -CCg 3'	5' -ggg 3'	5' -TCC 3'	5' -gTC 3'	5' -TCC 3'	5' -CgA 3'	5' -TAC 3'	
										3 rd I	
										5' -Agg 3'	
227	302	302	538	538	538	272	563	326	3 rd I	419	3'-primer(s) ³
5' -CTg 3'	5' -ggC 3'	5' -ggC 3'	5' -gTC 3'	5' -gTC 3'	5' -gTC 3'	5' -TgA 3'	5' -CgT 3'	5' -TgC 3'	5' -TAT 3'	5' -CgA 3'	
309										872	
5' -gTg 3'										5' -TCA 3'	
13	14	15	16	17	18	19	20	21	22	23	Well No.
											HLA-B allele
											*37:01:01-37:01:07
											*37:02
											*37:03N
											*37:04:01-37:04:02
											*37:05
											*37:06
											*37:07
											*37:08
			16								*37:09
13											*37:10
	14	15									*37:11
			16								*37:12
											*37:13
											*37:14
13											*37:15
							20				*37:16Q
13	14	15	16	17	18	19	20	21	22	23	Well No.

Lot No.: **72K**

Lot-specific information

www.olerup-ssp.com

Length of spec.	210	95	200	200	210	145	135	120	80	145	95	205
PCR product(s)			235	255					215		215	
Well No.	1	2	3	4	5	6	7	8	9	10	11	12
*37:17	1				5							12
*37:18	1				5						11	12
*37:19					5							12
*37:20	1				5							12
*37:21	1				5							12
*37:22	1								9			12
*37:23	1				5							12
*37:24	1				5							12
*37:25	1				5							12
*07:02:01-07:03, 07:05:01-07:18:02, 07:20-07:24, 07:26, 07:28-07:32, 07:34-07:39, 07:41-07:47, 07:49N- 07:50, 07:52, 07:54-07:59, 07:61- 07:64, 07:66-07:99, 07:101-07:117, 15:138, 48:05, 48:08, 48:15, C*02:23, C*04:77								8				
*07:04								8			11	
*07:19, 07:25, 08:01:01-08:05, 08:07- 08:08N, 08:10-08:11, 08:15, 08:17- 08:19N, 08:21-08:24, 08:26-08:27, 08:29-08:31, 08:33-08:39, 08:41- 08:48, 08:50-08:54, 08:56-08:59, 08:61, 08:63-08:66, 42:01:01- 42:01:02, 42:05:01-42:08, 42:10- 42:12, 42:14											11	
*07:27					5			8	9			
*07:65						6		8				
*08:09, 08:12:01-08:12:03, 08:16, 08:60, 15:51, 15:83, 15:179, 15:199, 42:04, 42:13, 44:14, 44:17, 44:51, 44:62, 51:08, 51:20, 51:36, 51:44N, 51:97, 52:19, 53:22, 55:20, 56:13, 57:09, 57:24, 82:01-82:03												
*08:14, 08:28, 44:106											11	
*08:32, 35:87						6					11	
*08:49, C*07:68	1											
*08:62											11	
*13:23, 40:47, 40:96, 40:157, 44:15, 44:55, 44:103, 49:02												12
*14:10, 38:20, 39:42, 51:32												
Well No.	1	2	3	4	5	6	7	8	9	10	11	12

Lot No.: **72K**

Lot-specific information

www.olerup-ssp.com

170	245	135	170	165	195	215	235	270	175	90	Length of spec. PCR product(s)
255										345	
13	14	15	16	17	18	19	20	21	22	23	Well No.
									22		*37:17
											*37:18
										23	*37:19
					18						*37:20
						19					*37:21
											*37:22
										23	*37:23
								21			*37:24
				17							*37:25
											*07:02:01-07:03, 07:05:01-07:18:02, 07:20-07:24, 07:26, 07:28-07:32, 07:34-07:39, 07:41-07:47, 07:49N- 07:50, 07:52, 07:54-07:59, 07:61- 07:64, 07:66-07:99, 07:101-07:117, 15:138, 48:05, 48:08, 48:15, C*02:23, C*04:77
			16								*07:04
			16								*07:19, 07:25, 08:01:01-08:05, 08:07- 08:08N, 08:10-08:11, 08:15, 08:17- 08:19N, 08:21-08:24, 08:26-08:27, 08:29-08:31, 08:33-08:39, 08:41- 08:48, 08:50-08:54, 08:56-08:59, 08:61, 08:63-08:66, 42:01:01- 42:01:02, 42:05:01-42:08, 42:10- 42:12, 42:14
											*07:27
		15									*07:65
			16								*08:09, 08:12:01-08:12:03, 08:16, 08:60, 15:51, 15:83, 15:179, 15:199, 42:04, 42:13, 44:14, 44:17, 44:51, 44:62, 51:08, 51:20, 51:36, 51:44N, 51:97, 52:19, 53:22, 55:20, 56:13, 57:09, 57:24, 82:01-82:03
											*08:14, 08:28, 44:106
		15	16								*08:32, 35:87
											*08:49, C*07:68
	14		16			19					*08:62
13											*13:23, 40:47, 40:96, 40:157, 44:15, 44:55, 44:103, 49:02
										23	*14:10, 38:20, 39:42, 51:32
13	14	15	16	17	18	19	20	21	22	23	Well No.

Length of spec.	210	95	200	200	210	145	135	120	80	145	95	205
PCR product(s)			235	255					215		215	
Well No.	1	2	3	4	5	6	7	8	9	10	11	12
*15:46, 15:53, 15:106, 15:143, 18:49, 35:02:03, 35:03:03, 35:19, 35:27, 35:47, 35:56, 40:10:01-40:10:02, 40:40, 40:49, 40:58, 40:129, 44:09, 44:46, 44:75, 44:90, 47:02, 78:06						6						
*15:71, 15:175, 15:204, 27:33, 40:46, 40:93, 48:22, 50:06												12
*15:202, 18:04, 18:25, 18:43, 35:01:01:01-35:02:02, 35:02:04-35:03:02, 35:03:04-35:08:01, 35:08:03-35:18, 35:20:01-35:24:02, 35:28-35:37, 35:39-35:45, 35:48, 35:51-35:55, 35:57-35:58, 35:60-35:62, 35:64-35:72, 35:74-35:83, 35:85-35:86, 35:88-35:114, 35:116-35:151, 39:19:01-39:19:02, 56:06, 78:01-78:05, 78:07						6						
*18:01:01-18:03, 18:05-18:06, 18:08, 18:10-18:11, 18:13-18:15, 18:17N, 18:19-18:24, 18:26-18:28, 18:30-18:36, 18:38-18:42, 18:44-18:47, 18:50-18:52						6						
*18:07:01-18:07:02, 18:29, 35:50, 35:84						6						
*18:09												
*18:12						6						12
*18:18				4		6						
*18:37, 39:31, 46:14, 54:02, 55:16, 73:01-73:02												
*18:48, 40:25, 40:69						6						
*27:01		2										12
*27:02-27:05:15, 27:10, 27:13, 27:15-27:17, 27:25, 27:28-27:29, 27:31, 27:36, 27:38-27:39, 27:42, 27:45, 27:47-27:68, 27:71-27:73		2										12
Well No.	1	2	3	4	5	6	7	8	9	10	11	12

170	245	135	170	165	195	215	235	270	175	90	Length of spec.
255										345	PCR product(s)
13	14	15	16	17	18	19	20	21	22	23	Well No.
											*15:46, 15:53, 15:106, 15:143, 18:49, 35:02:03, 35:03:03, 35:19, 35:27, 35:47, 35:56, 40:10:01-40:10:02, 40:40, 40:49, 40:58, 40:129, 44:09, 44:46, 44:75, 44:90, 47:02, 78:06
	14										*15:71, 15:175, 15:204, 27:33, 40:46, 40:93, 48:22, 50:06
		15									*15:202, 18:04, 18:25, 18:43, 35:01:01:01-35:02:02, 35:02:04- 35:03:02, 35:03:04-35:08:01, 35:08:03-35:18, 35:20:01-35:24:02, 35:28-35:37, 35:39-35:45, 35:48, 35:51-35:55, 35:57-35:58, 35:60- 35:62, 35:64-35:72, 35:74-35:83, 35:85-35:86, 35:88-35:114, 35:116- 35:151, 39:19:01-39:19:02, 56:06, 78:01-78:05, 78:07
	14	15									*18:01:01-18:03, 18:05-18:06, 18:08, 18:10-18:11, 18:13-18:15, 18:17N, 18:19-18:24, 18:26-18:28, 18:30- 18:36, 18:38-18:42, 18:44-18:47, 18:50-18:52
	14	15				19					*18:07:01-18:07:02, 18:29, 35:50, 35:84
13											*18:09
	14	15									*18:12
	14	15									*18:18
	14										*18:37, 39:31, 46:14, 54:02, 55:16, 73:01-73:02
	14										*18:48, 40:25, 40:69
13											*27:01
											*27:02-27:05:15, 27:10, 27:13, 27:15- 27:17, 27:25, 27:28-27:29, 27:31, 27:36, 27:38-27:39, 27:42, 27:45, 27:47-27:68, 27:71-27:73
13	14	15	16	17	18	19	20	21	22	23	Well No.

Length of spec.	210	95	200	200	210	145	135	120	80	145	95	205
PCR product(s)			235	255					215		215	
Well No.	1	2	3	4	5	6	7	8	9	10	11	12
*27:06-27:07, 27:09, 27:11, 27:14, 27:19-27:21, 27:24, 27:27, 27:30, 27:32, 27:34-27:35, 27:41, 27:43, 27:46, 27:70, 40:19, 40:76, 40:109, 40:117, 44:18, 49:01:01-49:01:02, 49:03-49:09, 49:11-49:15												12
*27:08, 27:12, 27:18, 27:26, 27:40, 27:44		2										12
*27:23		2										
*27:37, 47:04		2										
*27:69		2										12
*35:38, 35:115						6						
*35:59						6						
*35:63, 40:01:01-40:01:04, 40:01:06-40:06:03, 40:09, 40:11:01-40:11:02, 40:14:01-40:14:03, 40:18, 40:20, 40:22N, 40:24, 40:26-40:31, 40:33-40:36, 40:38-40:39, 40:42-40:45, 40:48, 40:50-40:57, 40:59-40:67, 40:70-40:75, 40:77-40:92, 40:94-40:95, 40:97, 40:99-40:105, 40:107-40:108, 40:111-40:116, 40:118N-40:128, 40:130-40:134, 40:138-40:151, 40:154-40:156, 45:01-45:02, 45:04-45:08, 45:10-45:13, 50:01:01-50:02, 50:04-50:05, 50:07-50:12						6						12
*38:17					5				9			
*40:01:05, 40:37, 40:135						6						12
*40:07						6						12
*40:08, 40:68, 40:106						6						
*40:13												12
*40:15-40:16, 40:23, 40:32, 40:98, 40:158						6		8				12
*40:136, 41:01, 41:03:01-41:03:02, 41:06-41:09, 41:12, 41:14, 41:16, 45:09						6						12
*40:152						6						12
*40:153						6						12
*41:02:01-41:02:03, 41:04, 41:11, 41:13, 41:15						6					11	12
Well No.	1	2	3	4	5	6	7	8	9	10	11	12

170	245	135	170	165	195	215	235	270	175	90	Length of spec.
255										345	PCR product(s)
13	14	15	16	17	18	19	20	21	22	23	Well No.
											*27:06-27:07, 27:09, 27:11, 27:14, 27:19-27:21, 27:24, 27:27, 27:30, 27:32, 27:34-27:35, 27:41, 27:43, 27:46, 27:70, 40:19, 40:76, 40:109, 40:117, 44:18, 49:01:01-49:01:02, 49:03-49:09, 49:11-49:15
	14										*27:08, 27:12, 27:18, 27:26, 27:40, 27:44
						19					*27:23
											*27:37, 47:04
										23	*27:69
		15	16								*35:38, 35:115
		15								23	*35:59
	14										*35:63, 40:01:01-40:01:04, 40:01:06-40:06:03, 40:09, 40:11:01-40:11:02, 40:14:01-40:14:03, 40:18, 40:20, 40:22N, 40:24, 40:26-40:31, 40:33-40:36, 40:38-40:39, 40:42-40:45, 40:48, 40:50-40:57, 40:59-40:67, 40:70-40:75, 40:77-40:92, 40:94-40:95, 40:97, 40:99-40:105, 40:107-40:108, 40:111-40:116, 40:118N-40:128, 40:130-40:134, 40:138-40:151, 40:154-40:156, 45:01-45:02, 45:04-45:08, 45:10-45:13, 50:01:01-50:02, 50:04-50:05, 50:07-50:12
											*38:17
											*40:01:05, 40:37, 40:135
	14					19					*40:07
	14					19					*40:08, 40:68, 40:106
						19					*40:13
	14										*40:15-40:16, 40:23, 40:32, 40:98, 40:158
	14		16								*40:136, 41:01, 41:03:01-41:03:02, 41:06-41:09, 41:12, 41:14, 41:16, 45:09
	14							21			*40:152
	14								22		*40:153
	14		16								*41:02:01-41:02:03, 41:04, 41:11, 41:13, 41:15
13	14	15	16	17	18	19	20	21	22	23	Well No.

Length of spec.	210	95	200	200	210	145	135	120	80	145	95	205
PCR product(s)			235	255					215		215	
Well No.	1	2	3	4	5	6	7	8	9	10	11	12
*41:05						w						12
*41:10						6					11	12
*42:02, 42:09											11	
*45:03						6						12
*47:01:01:01-47:01:01:02, 47:06-47:07							7					
*47:03						w						
*47:05		2					7					
*51:103												
*53:03									9			
HLA-B allele												
Well No.	1	2	3	4	5	6	7	8	9	10	11	12

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*37 SSP subtyping.

In addition, wells number 13 and 20 contains 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 or the 3rd intron, matching the specificity-determining 3'-end of the primer is given. Nucleotide numbering as on the www.ebi.ac.uk/imgt/hla web site. The sequence of the 3 terminal nucleotides of the primer is given.

³The nucleotide position, in the 2nd, 3rd or 4th exon or the 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.

170	245	135	170	165	195	215	235	270	175	90	Length of spec. PCR product(s)
255										345	
13	14	15	16	17	18	19	20	21	22	23	Well No.
			16								*41:05
	14										*41:10
	14		16								*42:02, 42:09
	14			17							*45:03
											*47:01:01:01-47:01:01:02, 47:06- 47:07
											*47:03
											*47:05
						19					*51:103
											*53:03
13	14	15	16	17	18	19	20	21	22	23	HLA-B allele Well No.

⁴Primer mix 3: Specific PCR fragment of 200 bp in the B*37:13 allele. Specific PCR fragment of 235 bp in the B*37:03N allele.

Primer mix 4: Specific PCR fragment of 200 bp in the B*37:13 allele. Specific PCR fragment of 255 bp in the B*37:04:01-37:04:02 and B*18:18 alleles.

Primer mix 9: Specific PCR fragment of 80 bp in the B*37:08 and B*07:27, 38:17 and 53:03 alleles. Specific PCR fragment of 215 bp in the B*37:22 allele.

Primer mix 11: Specific PCR fragment of 95 bp in the B*37:18 allele. Specific PCR fragment of 215 bp in the B*37:09 and B*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, 08:61-08:66, 35:87, 41:02:01-41:02:03, 41:04, 41:10-41:11, 41:13, 41:15, 42:01:01-42:02, 42:05:01-42:12, 42:14 and 44:106 alleles.

Primer mix 13: Specific PCR fragment of 170 bp in the B*37:15 allele. Specific PCR fragment of 255 bp in the B*37:10 and B*13:23, 18:09, 27:01, 40:47, 40:96, 40:157, 44:15, 44:55, 44:103 and 49:02 alleles.

Primer mix 23: Specific PCR fragment of 90 bp in the B*37:19 and B*14:10, 35:59, 38:20 and 39:42 alleles. Specific PCR fragment of 345 bp in the B*37:23 and in the B*27:69 and 51:32 alleles.

‘w’, might be weakly amplified.

[illegible]

CELL LINE VALIDATION SHEET												
HLA-B*37 SSP primer set												
					Well							
					17	18	19	20	21	22	23	
				Prod. No.:	201079717	201079718	201079719	201079720	201079721	201079722	201079723	
	IHCW 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*37 SSP

Product number: 101.541-06u – without *Taq* polymerase
Lot number: 72K
Expiry date: 2013-May-01
Number of tests: 6
Number of wells per test: 23

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2008-457-01	9	2010-797-09	17	2010-797-17
2	2008-457-02	10	2009-608-10	18	2010-797-18
3	2008-457-03	11	2010-797-11	19	2010-797-19
4	2008-457-04	12	2009-608-12	20	2010-797-20
5	2008-457-05	13	2010-797-13	21	2010-797-21
6	2008-457-06	14	2009-608-14	22	2010-797-22
7	2008-457-07	15	2008-457-15	23	2010-797-23
8	2009-608-08	16	2008-457-16		

The specificity of each primer solution of the HLA-B*37 primer set has been tested against 48 well characterized IHWC cell line DNAs.

No DNAs carrying the allele to be amplified by primer solutions 3, 4, 9, 10, 17, 18 and 20 to 23 were available. The specificities of the primers in primer solutions 4, 9, 10 and 23 were tested by separately adding one additional 3'-primer, respectively one additional 5'-primer.

In primer solutions 3, 20 and 21 the 5'-primers were tested by separately adding one additional 3'-primer, the 3'-primers were not possible to test. In primer solutions 17, 18 and 22 the 3'-primers were tested by separately adding one additional 3'-primer, the 5'-primers were not possible to test. In primer solutions 4, 13 and 23 one 3'-primer was not possible to test, and in primer solutions 9 and 11 one 5'-primer was not possible to test.

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

Date of approval: 2010-November-24

Approved by:

Quality Control, Supervisor

Lot No.: **72K**

Lot-specific information

www.olerup-ssp.com

Declaration of Conformity

Product name: Olerup SSP® HLA-B*37
Product number: 101.541-06u
Lot number: 72K

Intended use: HLA-B*37 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
2010-November-24

Olle Olerup
Managing Director

Lot No.: **72K**

Lot-specific information

www.olerup-ssp.com

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