Olerup SSP® HLA-B*46

Product number:	**101.544-06 – including *Taq* polymerase**
Lot number:	**93M**
Expiry date:	**2014-May-01**
Number of tests:	**6**
Number of wells per test:	**24**
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. 93M.

CHANGES COMPARED TO THE PREVIOUS *OLERUP* SSP® HLA-B*46 LOT

The HLA-B*46 specificity and interpretation tables have been updated for the HLA-B alleles described since the previous *Olerup* SSP® HLA-B*46 lot was made **(Lot No. 29M)**.

Two wells have been added to the HLA-B*46 kit,
wells **23 and 24.**

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

Well	5'-primer	3'-primer	rationale
23	New	New	New primer pair for the B*46:28 allele.
24	New	New	New primer pair for the B*46:30 allele.

PRODUCT DESCRIPTION

HLA-B*46 SSP typing

CONTENT
The primer set contains 5'- and 3'-primers for identifying the B*46:01 to B*46:30 alleles.

PLATE LAYOUT
Each HLA-B*46 test consists of 24 PCR reactions in a 24 well cut PCR plate.

1	**2**	**3**	**4**	**5**	**6**	**7**	**8**
9	**10**	**11**	**12**	**13**	**14**	**15**	**16**
17	**18**	**19**	**20**	**21**	**22**	**23**	**24**

The 24 well PCR plate is marked with 'HLA-B*46' in silver/gray ink.
Well No. 1 is marked with the Lot Number '93M'.
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*46 SSP subtypings will be influenced by many other HLA-B alleles, in particular the HLA-B*15 alleles. In addition, the C*07:38 allele will be amplified by primer mix 6, the A*26:68, A*68:56, C*06:20 and C*12:50 alleles will be amplified by primer mix 9, the C*02:28 allele will be amplified by primer mix 11 and the C*03:125 allele will be amplified by primer mix 22.

UNIQUELY IDENTIFIED ALLELES
All the HLA-B*46, i.e. **B*46:01 to B*46:30**, recognized by the HLA Nomenclature Committee in October 2011[1] will be amplified by the primers in the HLA-B*46 SSP kit.
The B*46 primer set cannot separate the B*46:01:01-46:01:02 and 46:01:04-46:01:07 alleles or the B*46:13:01-46:13:02 alleles.

[1]HLA-B alleles listed on the IMGT/HLA web page 2011-October-10, release 3.6.0, www.ebi.ac.uk/imgt/hla.

RESOLUTION IN HOMO- AND HETEROZYGOTES
A total of 39 alleles generate 33 amplification patterns that can be combined in 561 homozygous and heterozygous combinations. 266 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.

+++-+-+-	+-------	--------	*46:03, *46:16 = *46:16, *46:29
+++-+---	+-------	--------	*46:02, *46:03 = *46:02, *46:29
++-++-+-	+-------	--------	*46:04, *46:16 = *46:14, *46:16
++-++---	+-------	--------	*46:02, *46:04 = *46:02, *46:14
++--+-+-	++------	--------	*46:05, *46:16 = *46:15N, *46:16
++--+-+-	+-------	--------	*46:01:01, *46:16 = *46:02, *46:07N = *46:02, *46:16 = *46:07N, *46:16 = *46:16, *46:16
++--+---	++------	--------	*46:02, *46:05 = *46:02, *46:15N
++--+---	+-------	--------	*46:01:01, *46:02 = *46:02, *46:02
+-++++-+	+--+-+-+	+-------	*46:04, *46:18 = *46:14, *46:18
+-++++-+	+----+-+	+-------	*46:04, *46:21:02 = *46:14, *46:21:02
+-++++-+	+-------	+-------	*46:04, *46:21:01 = *46:14, *46:21:01
+-++++--	+-------	--------	*46:03, *46:04 = *46:03, *46:14 = *46:04, *46:29 = *46:14, *46:29
+-+-++-+	-------	+------+	*46:03, *46:06 = *46:06, *46:21:01
+-+-++--	+-------	--------	*46:03, *46:20 = *46:20, *46:29
+-+-+-+-	+-------	--------	*46:03, *46:07N = *46:07N, *46:29
+-+-+--+	++--+-+-	+-------	*46:05, *46:18 = *46:15N, *46:18
+-+-+--+	++----+-	+-------	*46:05, *46:21:02 = *46:15N, *46:21:02
+-+-+--+	++------	+-------	*46:05, *46:21:01 = *46:15N, *46:21:01
+-+-+--+	+--+-++	+-------	*46:17, *46:18 = *46:18, *46:22 = *46:21:02, *46:22
+-+-+--+	+--+-+-	+-------	*46:01:01, *46:18 = *46:01:03, *46:18 = *46:11, *46:29 = *46:18, *46:29
+-+-+--+	+----+-	+-------	*46:01:01, *46:21:02 = *46:01:03, *46:21:01 = *46:01:03, *46:21:02 = *46:13:01, *46:29 = *46:21:02, *46:29
+-+-+--+	+-------	+-------	*46:01:01, *46:21:01 = *46:13:03, *46:29 = *46:21:01, *46:29
+-+-+--+	---+-+-	+-------	*46:03, *46:11 = *46:03, *46:18 = *46:08, *46:18 = *46:11, *46:18 = *46:11, *46:21:01 = *46:11, *46:21:02 = *46:13:01, *46:18 = *46:13:03, *46:18 = *46:18, *46:18 = *46:18, *46:21:01 = *46:18, *46:21:02
+-+-+--+	-----+-	+-------	*46:03, *46:13:01 = *46:03, *46:21:02 = *46:08, *46:21:02 = *46:13:01, *46:21:01 = *46:13:01, *46:21:02 = *46:13:03, *46:21:02 = *46:21:01, *46:21:02 = *46:21:02, *46:21:02
+-+-+--+	-------	+---+---	*46:03, *46:26 = *46:21:01, *46:26
+-+-+--+	-------	+-------	*46:03, *46:13:03 = *46:03, *46:21:01 = *46:08, *46:21:01 = *46:13:03, *46:21:01 = *46:21:01, *46:21:01
+-+-+---	++------	--------	*46:03, *46:05 = *46:03, *46:15N = *46:05, *46:29 = *46:15N, *46:29
+-+-+---	+-+-----	--------	*46:03, *46:09 = *46:09, *46:29
+-+-+---	+--+----	--------	*46:03, *46:10 = *46:10, *46:29
+-+-+---	+---+--+	--------	*46:03, *46:22 = *46:22, *46:29
+-+-+---	+----+--	--------	*46:03, *46:12 = *46:12, *46:29
+-+-+---	+-----+-	--------	*46:01:03, *46:03 = *46:01:03, *46:29
+-+-+---	+------+	--------	*46:03, *46:17 = *46:17, *46:29

+-+-+--- +------- -+------	*46:03, *46:23 = *46:23, *46:29
+-+-+--- +------- --+-----	*46:03, *46:24 = *46:24, *46:29
+-+-+--- +------- -----+--	*46:03, *46:27 = *46:27, *46:29
+-+-+--- +------- ------+-	*46:03, *46:28 = *46:28, *46:29
+-+-+--- +------- -------+	*46:03, *46:30 = *46:29, *46:30
+-+-+--- +------- --------	*46:01:01, *46:03 = *46:01:01, *46:29 = *46:03, *46:29 = *46:29, *46:29
+--++-+ +------- +------+	*46:04, *46:06 = *46:06, *46:14
+--++-- +------- --------	*46:04, *46:20 = *46:14, *46:20
+--++-+- +------- --------	*46:04, *46:07N = *46:07N, *46:14
+--++--+ +--+---- --------	*46:04, *46:19 = *46:14, *46:19
+--++--+ +---+-+- +-------	*46:04, *46:11 = *46:11, *46:14
+--++--+ +-----+- +-------	*46:04, *46:13:01 = *46:13:01, *46:14
+--++--+ +------- +---+---	*46:04, *46:26 = *46:14, *46:26
+--++--+ +------- +-------	*46:04, *46:13:03 = *46:13:03, *46:14
+--++--+ +------- --------	*46:04, *46:08 = *46:08, *46:14
+--++--- ++------ --------	*46:04, *46:05 = *46:04, *46:15N = *46:05, *46:14 = *46:14, *46:15N
+--++--- +-+----- --------	*46:04, *46:09 = *46:09, *46:14
+--++--- +--+---- --------	*46:04, *46:10 = *46:10, *46:14
+--++--- +---+--+ --------	*46:04, *46:22 = *46:14, *46:22
+--++--- +----+-- --------	*46:04, *46:12 = *46:12, *46:14
+--++--- +-----+- --------	*46:01:03, *46:04 = *46:01:03, *46:14
+--++--- +------+ --------	*46:04, *46:17 = *46:14, *46:17
+--++--- +------- -+------	*46:04, *46:23 = *46:14, *46:23
+--++--- +------- --+-----	*46:04, *46:24 = *46:14, *46:24
+--++--- +------- ---+----	*46:04, *46:25 = *46:14, *46:25
+--++--- +------- -----+--	*46:04, *46:27 = *46:14, *46:27
+--++--- +------- ------+-	*46:04, *46:28 = *46:14, *46:28
+--++--- +------- -------+	*46:04, *46:30 = *46:14, *46:30
+--++--- +------- --------	*46:01:01, *46:04 = *46:01:01, *46:14 = *46:04, *46:14 = *46:14, *46:14
+---++-+ ++------ +------+	*46:05, *46:06 = *46:06, *46:15N
+---++-+ +------- +------+	*46:01:01, *46:06 = *46:06, *46:20 = *46:06, *46:30
+---++-+ -------- +------+	*46:06, *46:06 = *46:06, *46:08 = *46:06, *46:13:03
+---++-- ++------ --------	*46:05, *46:20 = *46:15N, *46:20
+---++-- +------- --------	*46:01:01, *46:20 = *46:20, *46:20
+----+-+- ++------ --------	*46:05, *46:07N = *46:07N, *46:15N
+----+-+- +------- --------	*46:01:01, *46:07N = *46:07N, *46:07N
+---+--+ ++-+---- --------	*46:05, *46:19 = *46:15N, *46:19
+---+--+ ++--+-+- +-------	*46:05, *46:11 = *46:11, *46:15N
+---+--+ ++-----+- +-------	*46:05, *46:13:01 = *46:13:01, *46:15N
+---+--+ ++------ +---+---	*46:05, *46:26 = *46:15N, *46:26
+---+--+ ++------ +-------	*46:05, *46:13:03 = *46:13:03, *46:15N
+---+--+ ++------ --------	*46:05, *46:08 = *46:08, *46:15N

+---+--+ +--+---- --------	*46:01:01, *46:19 = *46:08, *46:10 = *46:10, *46:19
+---+--+ +---+-++ +-------	*46:11, *46:17 = *46:11, *46:22 = *46:13:01, *46:22
+---+--+ +---+-+- +-------	*46:01:01, *46:11 = *46:01:03, *46:11
+---+--+ +-----+- +-------	*46:01:01, *46:13:01 = *46:01:03, *46:13:01 = *46:01:03, *46:13:03
+---+--+ ---+---- --------	*46:08, *46:19 = *46:19, *46:19
+---+--+ ----+-+- +-------	*46:08, *46:11 = *46:11, *46:11 = *46:11, *46:13:01 = *46:11, *46:13:03
+---+--+ ------+- +-------	*46:08, *46:13:01 = *46:13:01, *46:13:01 = *46:13:01, *46:13:03
+---+--+ -------- +---+---	*46:08, *46:26 = *46:13:03, *46:26 = *46:26, *46:26
+---+--+ -------- +-------	*46:08, *46:13:03 = *46:13:03, *46:13:03
+---+--- ++------ --------	*46:05, *46:09 = *46:09, *46:15N
+---+--- ++-+---- --------	*46:05, *46:10 = *46:10, *46:15N

*46:01:01 = *46:01:01-46:01:02 and 46:01:04-46:01:07
*46:13:01 = *46:13:01-46:13:02

SPECIFICITY TABLE

HLA-B*46 SSP subtyping

Specificities and sizes of the PCR products of the 24 primer mixes used for HLA-B*46 SSP subtyping

Primer Mix	Size of spec. PCR product[1]	Size of control band[2]	Amplified HLA-B*46 alleles[3]	Other amplified HLA Class I alleles[4]
1	130 bp	**800 bp**	*46:01:01-46:03, 46:05-46:30	*15:57[W]
2[5]	115 bp	1070 bp	*46:02, 46:16	
3	395 bp	1070 bp	*46:03, 46:18, 46:21:01-46:21:02, 46:29	*15:42, 15:44, 15:50, 15:69, 15:86, 15:93, 15:121, 15:186, 15:188, 15:199, 15:224
4[7]	130 bp, 245 bp	1070 bp	*46:04, 46:14	*18:06, 40:73, 73:01[W]-73:02[W]
5	235 bp	1070 bp	*46:01:01-46:04, 46:06-46:30	*08:15, 15:57[W], 35:74, 35:186, 40:73, 55:03, 55:49
6[5,8]	120 bp, 225 bp	**800 bp**	*46:06, 46:20	*07:09, 07:11, 07:17, 15:138, 18:35, 35:66, 40:38, 40:52, 40:59-40:60, 40:158, 48:14, 48:23, 55:19, **C*07:38**
7[5,6,9]	105 bp, 140 bp	1070 bp	*46:07N, 46:16	*14:07N, 39:40N, 56:19N
8	375 bp	**800 bp**	*46:06, 46:08, 46:11, 46:13:01-46:13:03, 46:18-46:19, 46:21:01-46:21:02, 46:26	*15:02:01-15:03:03, 15:05:01-15:06, 15:09-15:10:02, 15:13:01-15:13:02, 15:16:01-15:18:04, 15:21, 15:23, 15:25:01-15:25:03, 15:29, 15:31, 15:36-15:37, 15:39:01-15:40, 15:42, 15:44, 15:48, 15:52, 15:55, 15:61-15:62, 15:64, 15:67, 15:69, 15:72, 15:74, 15:80, 15:86, 15:88-15:91, 15:93, 15:95, 15:98, 15:103, 15:106-15:108, 15:112, 15:114-15:115, 15:119, 15:121, 15:123-15:124, 15:127, 15:131-15:134, 15:136, 15:138-15:139, 15:151, 15:153, 15:155-15:156, 15:158, 15:161-15:162, 15:168, 15:170, 15:173, 15:176-15:177, 15:185-15:186, 15:188, 15:194-15:198, 15:200, 15:204, 15:208, 15:210, 15:213-15:214, 15:216, 15:219-15:220, 15:222-15:224, 15:226N, 15:229-15:230, 15:235

9[5]	115 bp	1070 bp	*46:01:01-46:02, 46:04-46:05, 46:07N, 46:09-46:10, 46:12, 46:14-46:17, 46:20, 46:22-46:24, 46:27-46:30	*07:100, 13:31, 13:41, 15:01:01:01-15:01:04, 15:01:06-15:01:16, 15:01:18-15:01:24, 15:04, 15:07:01-15:08, 15:11:01-15:12, 15:14-15:15, 15:19, 15:24, 15:26N-15:28, 15:30, 15:32, 15:34-15:35, 15:38:01-15:38:02, 15:43, 15:45-15:46, 15:50, 15:53-15:54, 15:56-15:58, 15:60, 15:63, 15:66, 15:68, 15:70-15:71, 15:73, 15:75-15:77, 15:79N, 15:81-15:82, 15:85, 15:87, 15:92, 15:94N, 15:96-15:97, 15:101-15:102, 15:104-15:105, 15:109-15:111N, 15:113, 15:117-15:118, 15:120, 15:122, 15:125-15:126, 15:128-15:129, 15:135, 15:137, 15:140, 15:142-15:149N, 15:152, 15:154, 15:157, 15:159-15:160, 15:163-15:167, 15:169, 15:171-15:172, 15:174-15:175, 15:178, 15:180-15:184, 15:187, 15:189-15:193, 15:201-15:203, 15:205-15:207, 15:209N, 15:211-15:212, 15:215, 15:217, 15:225, 15:227-15:228, 15:231-15:234, 15:236, 18:19, 27:25, 35:14:01-35:14:02, 35:43:01-35:44, 35:62, 35:67, 35:79, 35:86, 35:102, 35:117, 35:135, 35:163, 35:185, 39:36, 51:61, 52:21, 54:06, 55:21, 56:03, **A*26:68, A*68:56, C*06:20, C*12:50**
10[5,6,10]	100 bp, 315 bp	**800 bp**	*46:05, 46:15N	*15:125, 35:54
11	150 bp	1070 bp	*46:09	*35:62, **C*02:28**
12[11]	170 bp, 380 bp	1070 bp	*46:10, 46:19	*15:48, 15:108, 15:136, 15:235
13[5,6,12]	105 bp, 215 bp	1070 bp	*46:11, 46:18, 46:22	*07:78, 13:02:01-13:03, 13:08Q-13:09, 13:14-13:16, 13:18-13:19, 13:27, 13:30-13:34, 13:37-13:38, 13:40-13:42, 13:44-13:45, 15:42, 35:60, 44:15, 44:18, 45:01, 45:03-45:08, 45:10-45:13, 49:01:01-49:03, 49:06-49:17, 49:19N-49:20, 50:01:01-50:02, 50:04-50:08, 50:10-50:13, 50:15, 51:15, 52:25, 54:01:01-54:03, 54:05N, 54:07-54:08N, 54:10, 54:12-54:13, 54:16-54:24, 55:01:01-55:01:03, 55:01:05-55:03, 55:05, 55:07, 55:09-55:12, 55:15-55:16, 55:18-55:19, 55:21-55:22, 55:24-55:26, 55:29-55:31, 55:33-55:38,

				55:40-55:41, 55:43, 55:45-55:48, 55:50, 55:52, 55:54, 56:01:01-56:01:04, 56:07-56:08, 56:13-56:14, 56:16-56:17, 56:19N-56:20:02, 56:23-56:30, 59:01:01:01-59:01:01:02, 59:04-59:05
14[6]	215 bp	1070 bp	*46:12	*07:55, 07:100, 08:70, 15:07:01-15:07:02, 15:45, 15:68, 15:126, 15:207, 48:19
15	330 bp	1070 bp	*46:01:03, 46:11, 46:13:01-46:13:02, 46:18, 46:21:02	*15:03:02, 15:05:02, 15:13:02, 15:27:03, 15:38:02, 15:39:02, 15:42, 15:48, 15:86, 15:179, 15:188, 15:224
16[6,13]	195 bp, 215 bp	1070 bp	*46:17, 46:22	*15:14, 15:91, 15:131, 15:161, 18:56, 35:45, 35:71, 44:17, 44:43:01-44:43:02, 45:09, 53:22, 58:07
17	365 bp	**800 bp**	*46:06, 46:11, 46:13:01-46:13:03, 46:18, 46:21:01-46:21:02, 46:26	*15:05:01-15:05:02, 15:31, 15:52, 15:55, 15:84[W], 15:86, 15:91, 15:107, 15:114, 15:123-15:124, 15:151, 15:155, 15:185, 15:188, 15:222, 15:224
18[5]	95 bp	1070 bp	*46:23	
19	230 bp	1070 bp	*46:24	*15:19
20	375 bp	1070 bp	*46:25	
21	270 bp	1070 bp	*46:26	
22	215 bp	1070 bp	*46:27	*35:113, 44:98, **C*03:125**
23[5]	45 bp	1070 bp	*46:28	
24	395 bp	1070 bp	*46:06, 46:30	*15:40, 15:47, 15:49, 15:52, 15:114, 15:117, 15:124, 15:138

[1]Alleles are assigned by the presence of specific PCR product(s). However, the sizes of the specific PCR products may be helpful in the interpretation of HLA-B*46 SSP typings.
When the primers in a primer mix can give rise to specific PCR products of more than one length this is indicated if the size difference is 20 base pairs or more. Size differences shorter than 20 base pairs are not given. For high resolution SSP kits the respective lengths of the specific PCR product(s) of the alleles amplified by these primer mixes are given.
Nonspecific amplifications, i.e. a ladder or a smear of bands, may sometimes be seen. GC-rich primers have a higher tendency of giving rise to nonspecific amplifications than other primers.
PCR fragments longer than the control bands may sometimes be observed. Such bands should be disregarded and do not influence the interpretation of the SSP typings.
PCR fragments migrating faster than the control bands, but slower than a 400 bp fragment may be seen in some gel read-outs. Such bands can be disregarded and do not influence the interpretation of the SSP typings.
Some primers may give rise to primer oligomer artifacts. Sometimes this phenomenon is an inherit feature of the primer pair(s) of a primer mix. More often it is due to other factors such as too low amount of DNA in the PCR reactions, taking too long time in setting up the PCR reactions, working at elevated room temperature or using thermal cyclers that are not pre-heated.
[2]The internal positive control primer pairs amplify segments of the human growth hormone gene. The two different control primer pairs give rise to either an internal positive control band of 1070 base pairs, for most wells, or a band of 800 base pairs, for some wells.

Well number 1 contains the primer pair giving rise to the shorter, 800 bp, internal positive control band in order to help in the correct orientation of the HLA-B*46 SSP subtyping. In addition, well number 6, 8, 10 and 17 contains the primer pair giving rise to the longer, 800 bp, internal positive control band in order to allow kit identification.
In the presence of a specific amplification the intensity of the control band often decreases.
[3]For several HLA-B alleles first exon nucleotide sequences are not available. In these instances it is not known whether some of the primers of the SSP sets are completely matched with the target sequences or not. We assume that unknown sequences in the first exon are conserved within allelic groups.
[4]Due to the sharing of sequence motifs between HLA-B alleles one non-HLA-B*46 alleles will be amplified by primer mixes 1, 3 to 17, 19, 22 and 24. In addition, the C*07:38 allele will be amplified by primer mix 6, the A*26:68, A*68:56, C*06:20 and C*12:50 alleles will be amplified by primer mix 9, the C*02:28 allele will be amplified by primer mix 11 and the C*03:125 allele will be amplified by primer mix 22.
[5]Specific PCR fragments shorter than 150 base pairs are less intense and not as sharp as longer specific bands.
[6]Primer mixes 7, 10, 13, 14 and 16 may give rise to nonspecific amplifications.
[7]Primer mix 4: Specific PCR fragment of 130 bp in the B*46:04 allele. Specific PCR fragment of 245 bp in the B*46:14 and the B*18:06, 40:73, 73:01^{w}-73:02^{w} alleles.
[8]Primer mix 6: Specific PCR fragment of 120 bp in the B*46:20 and the B*55:19 alleles. Specific PCR fragment of 225 bp in the B*46:06 and the B*07:09, 07:11, 07:17, 15:138, 18:35, 35:66, 40:38, 40:52, 40:59-40:60, 40:158, 48:14 and 48:23 and in the C*07:38 alleles.
[9]Primer mix 7: Specific PCR fragment of 105 bp in the B*46:16 allele. Specific PCR fragment of 140 bp in the B*46:07N and the B*14:07N, 39:40N and 56:19N alleles.
[10]Primer mix 10: Specific PCR fragment of 100 bp in the B*46:05 and the B*15:125 and 35:54 alleles. Specific PCR fragment of 315 bp in the B*46:15N allele.
[11]Primer mix 12: Specific PCR fragment of 170 bp in the B*46:10 allele. Specific PCR fragment of 380 bp in the B*46:19 and the B*15:48, 15:108, 15:136 and 15:235alleles.
[12]Primer mix 13: Specific PCR fragment of 105 bp in the B*46:11 and 46:18 and the B*07:78, 13:02:01-13:03, 13:08Q-13:09, 13:14-13:16, 13:18-13:19, 13:27, 13:30-13:34, 13:37-13:38, 13:40-13:42, 13:44-13:45, 15:42, 35:60, 44:15, 44:18, 45:01, 45:03-45:08, 45:10-45:13, 49:01:01-49:03, 49:06-49:17, 49:19N-49:20, 50:01:01-50:02, 50:04-50:08, 50:10-50:13, 50:15, 51:15, 52:25, 54:01:01-54:03, 54:05N, 54:07-54:08N, 54:10, 54:12-54:13, 54:16-54:24, 55:01:01-55:01:03, 55:01:05-55:03, 55:05, 55:07, 55:09-55:12, 55:15-55:16, 55:18-55:19, 55:21-55:22, 55:24-55:26, 55:29-55:31, 55:33-55:38, 55:40-55:41, 55:43, 55:45-55:48, 55:50, 55:52, 55:54, 56:01:01-56:01:04, 56:07-56:08, 56:13-56:14, 56:16-56:17, 56:19N-56:20:02, 56:23-56:30, 59:01:01:01-59:01:01:02 and 59:04-59:05 alleles. Specific PCR fragment of 215 bp in the B*46:22 allele.
[13]Primer mix 16: Specific PCR fragment of 195 bp in the B*46:17 and the B*15:14, 15:91, 15:131, 15:161, 18:56, 35:45, 35:71, 44:17, 44:43:01-44:43:02, 45:09, 53:22 and 58:07 alleles. Specific PCR fragment of 215 bp in the B*46:22 allele.
'w', might be weakly amplified.

INTERPRETATION TABLE

HLA-B*46 SSP subtyping

Amplification patterns of the B*46:01 to 46:30 alleles

	Well[4]											
	1	2	3	4	5	6	7	8	9	10	11	12
Length of spec.	130	115	395	130	235	120	105	375	115	100	150	170
PCR product(s)				245		225	140			315		380
Length of int.	800	1070	1070	1070	1070	800	1070	800	1070	800	1070	1070
pos. control[1]												
5'-primer(s)[2]	209	209	2nd I	97	106	106	209	2nd I	463	106	419	142
	5'-ggC 3'	5'-ggC 3'	5'-CAA 3'	5'-TCC 3'	5'-CCA 3'	5'-CCA 3'	5'-ggC 3'	5'-CAA 3'	5'-TgA 3'	5'-CCg 3'	5'-gTC 3'	5'-TCA 3'
				209		419	463			736		2nd I
				5'-ggg 3'		5'-gTC 3'	5'-TgA 3'			5'-gCT 3'		5'-CAA 3'
3'-primer(s)[3]	299	272	559	299	299	187	272	538	538	165	527	269
	5'-TCA 3'	5'-TgA 3'	5'-CgT 3'	5'-TCA 3'	5'-TCA 3'	5'-gTT 3'	5'-TgA 3'	5'-CAg 3'	5'-CCA 3'	5'-Tgg 3'	5'-CCA 3'	5'-ACT 3'
		293				605	564	544		916		544
		5'-ggC 3'				5'-gCT 3'	5'-ACT 3'	5'-ggT 3'		5'-gAT 3'		5'-ggT 3'
Well No.	1	2	3	4	5	6	7	8	9	10	11	12
HLA-B allele												
***46:01:01-46:01:02, 46:01:04-46:01:07**	1				5				9			
***46:01:03**	1				5				9			
***46:02**	1	2			5				9			
***46:03**	1		3		5							
***46:04**				4	5				9			
***46:05**	1								9	10		
***46:06**	1				5	6		8				
***46:07N**	1				5		7		9			
***46:08**	1				5			8				
***46:09**	1				5				9		11	
***46:10**	1				5				9			12
***46:11**	1				5			8				
***46:12**	1				5				9			
***46:13:01-46:13:02**	1				5			8				
***46:13:03**	1				5			8				
***46:14**	1			4	5				9			
***46:15N**	1				5				9	10		
Well No.	1	2	3	4	5	6	7	8	9	10	11	12

INTERPRETATION TABLE

HLA-B*46 SSP subtyping

Amplification patterns of the B*46:01 to 46:30 alleles

Well[4]												
13	14	15	16	17	18	19	20	21	22	23	24	
105	215	330	195	365	95	230	375	270	215	45	395	Length of spec.
215			215									PCR product(s)
1070	1070	1070	1070	800	1070	1070	1070	1070	1070	1070	1070	Length of int.
												pos. control[1]
106	363	2nd I	106	2nd I	419	821	2nd I	369	385	209	2nd I	5'-primer(s)[2]
5'-CCA 3'	5'-AgC 3'	5'-CAA 3'	5'-CCA 3'	5'-CAA 3'	5'-gTC 3'	5'-gCT 3'	5'-CAA 3'	5'-TAC 3'	5'-ggT 3'	5'-ggC 3'	5'-CAA 3'	
357			419									
5'-Tgg 3'			5'-gTC 3'									
281	538	486	281	527	472	916	539	599	559	214	559	3'-primer(s)[3]
5'-CCC 3'	5'-CCA 3'	5'-gCg 3'	5'-CCC 3'	5'-CCA 3'	5'-ggA 3'	5'-gAT 3'	5'-TCT 3'	5'-CCC 3'	5'-CAg 3'	5'-CCA 3'	5'-CTC 3'	
420		498	572									
5'-gCT 3'		5'-gTA 3'	5'-gCg 3'									
13	14	15	16	17	18	19	20	21	22	23	24	Well No.
												HLA-B allele
												*46:01:01-46:01:02, 46:01:04-46:01:07
		15										*46:01:03
												*46:02
												*46:03
												*46:04
												*46:05
				17							24	*46:06
												*46:07N
												*46:08
												*46:09
												*46:10
13		15		17								*46:11
	14											*46:12
		15		17								*46:13:01-46:13:02
				17								*46:13:03
												*46:14
												*46:15N
13	14	15	16	17	18	19	20	21	22	23	24	Well No.

Length of spec.	**130**	**115**	**395**	**130**	**235**	**120**	**105**	**375**	**115**	**100**	**150**	**170**
PCR product(s)				**245**		**225**	**140**			**315**		**380**
Well No.	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**
***46:16**	**1**	**2**			**5**		**7**		**9**			
***46:17**	**1**				**5**				**9**			
***46:18**	**1**		**3**		**5**			**8**				
***46:19**	**1**				**5**			**8**				**12**
***46:20**	**1**				**5**	**6**			**9**			
***46:21:01**	**1**		**3**		**5**			**8**				
***46:21:02**	**1**		**3**		**5**			**8**				
***46:22**	**1**				**5**				**9**			
***46:23**	**1**				**5**				**9**			
***46:24**	**1**				**5**				**9**			
***46:25**	**1**				**5**							
***46:26**	**1**				**5**			**8**				
***46:27**	**1**				**5**				**9**			
***46:28**	**1**				**5**				**9**			
***46:29**	**1**		**3**		**5**				**9**			
***46:30**	**1**				**5**				**9**			
07:09, 07:11, 07:17, 18:35, 35:66, 40:38, 40:52, 40:59-40:60, 40:158, 48:14, 48:23, *C*07:38						**6**						
***07:55, 08:70, 48:19**												
Well No.	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**

105	215	330	195	365	95	230	375	270	215	45	395	Length of spec.
215			215									PCR product(s)
13	14	15	16	17	18	19	20	21	22	23	24	Well No.
												*46:16
			16									*46:17
13		15		17								*46:18
												*46:19
												*46:20
				17								*46:21:01
		15		17								*46:21:02
13			16									*46:22
					18							*46:23
						19						*46:24
							20					*46:25
				17				21				*46:26
									22			*46:27
										23		*46:28
												*46:29
											24	*46:30
												*07:09, 07:11, 07:17, 18:35, 35:66, 40:38, 40:52, 40:59-40:60, 40:158, 48:14, 48:23, *C*07:38*
	14											*07:55, 08:70, 48:19
13	14	15	16	17	18	19	20	21	22	23	24	Well No.

Length of spec.	**130**	**115**	**395**	**130**	**235**	**120**	**105**	**375**	**115**	**100**	**150**	**170**
PCR product(s)				**245**		**225**	**140**			**315**		**380**
Well No.	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**
***07:78, 13:02:01-13:03, 13:08Q-13:09, 13:14-13:16, 13:18-13:19, 13:27, 13:30, 13:32-13:34, 13:37-13:38, 13:40, 13:42, 13:44-13:45, 35:60, 44:15, 44:18, 45:01, 45:03-45:08, 45:10-45:13, 49:01:01-49:03, 49:06-49:17, 49:19N-49:20, 50:01:01-50:02, 50:04-50:08, 50:10-50:13, 50:15, 51:15, 52:25, 54:01:01-54:03, 54:05N, 54:07-54:08N, 54:10, 54:12-54:13, 54:16-54:24, 55:01:01-55:01:03, 55:01:05-55:02:06, 55:05, 55:07, 55:09-55:12, 55:15-55:16, 55:18, 55:22, 55:24-55:26, 55:29-55:31, 55:33-55:38, 55:40-55:41, 55:43, 55:45-55:48, 55:50, 55:52, 55:54, 56:01:01-56:01:04, 56:07-56:08, 56:13-56:14, 56:16-56:17, 56:20:01-56:20:02, 56:23-56:30, 59:01:01:01-59:01:01:02, 59:04-59:05**												
***07:100, 15:07:01-15:07:02, 15:45, 15:68, 15:126, 15:207**									**9**			
***08:15, 35:74, 35:186, 55:49**					**5**							
***13:31, 13:41, 55:21**									**9**			
***14:07N, 39:40N**							**7**					
Well No.	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**

105	215	330	195	365	95	230	375	270	215	45	395	Length of spec.
215			215									PCR product(s)
13	14	15	16	17	18	19	20	21	22	23	24	Well No.
13												*07:78, 13:02:01-13:03, 13:08Q-13:09, 13:14-13:16, 13:18-13:19, 13:27, 13:30, 13:32-13:34, 13:37-13:38, 13:40, 13:42, 13:44-13:45, 35:60, 44:15, 44:18, 45:01, 45:03-45:08, 45:10-45:13, 49:01:01-49:03, 49:06-49:17, 49:19N-49:20, 50:01:01-50:02, 50:04-50:08, 50:10-50:13, 50:15, 51:15, 52:25, 54:01:01-54:03, 54:05N, 54:07-54:08N, 54:10, 54:12-54:13, 54:16-54:24, 55:01:01-55:01:03, 55:01:05-55:02:06, 55:05, 55:07, 55:09-55:12, 55:15-55:16, 55:18, 55:22, 55:24-55:26, 55:29-55:31, 55:33-55:38, 55:40-55:41, 55:43, 55:45-55:48, 55:50, 55:52, 55:54, 56:01:01-56:01:04, 56:07-56:08, 56:13-56:14, 56:16-56:17, 56:20:01-56:20:02, 56:23-56:30, 59:01:01:01-59:01:01:02, 59:04-59:05
	14											*07:100, 15:07:01-15:07:02, 15:45, 15:68, 15:126, 15:207
												*08:15, 35:74, 35:186, 55:49
13												*13:31, 13:41, 55:21
												*14:07N, 39:40N
13	14	15	16	17	18	19	20	21	22	23	24	Well No.

Length of spec.	**130**	**115**	**395**	**130**	**235**	**120**	**105**	**375**	**115**	**100**	**150**	**170**
PCR product(s)				**245**		**225**	**140**			**315**		**380**
Well No.	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**
15:01:01:01-15:01:04, 15:01:06-15:01:16, 15:01:18-15:01:24, 15:04, 15:08, 15:11:01-15:12, 15:15, 15:24, 15:26N-15:27:02, 15:28, 15:30, 15:32, 15:34-15:35, 15:38:01, 15:43, 15:46, 15:53-15:54, 15:56, 15:58, 15:60, 15:63, 15:66, 15:70-15:71, 15:73, 15:75-15:77, 15:79N, 15:81-15:82, 15:85, 15:87, 15:92, 15:94N, 15:96-15:97, 15:101-15:102, 15:104-15:105, 15:109-15:111N, 15:113, 15:118, 15:120, 15:122, 15:128-15:129, 15:135, 15:137, 15:140, 15:142-15:149N, 15:152, 15:154, 15:157, 15:159-15:160, 15:163-15:167, 15:169, 15:171-15:172, 15:174-15:175, 15:178, 15:180-15:184, 15:187, 15:189-15:193, 15:201-15:203, 15:205-15:206, 15:209N, 15:211-15:212, 15:215, 15:217, 15:225, 15:227-15:228, 15:231-15:234, 15:236, 18:19, 27:25, 35:14:01-35:14:02, 35:43:01-35:44, 35:67, 35:79, 35:86, 35:102, 35:117, 35:135, 35:163, 35:185, 39:36, 51:61, 52:21, 54:06, 56:03, *A*26:68, A*68:56, C*06:20, C*12:50									**9**			
***15:02:01-15:03:01, 15:03:03, 15:06, 15:09-15:10:02, 15:13:01, 15:16:01-15:18:04, 15:21, 15:23, 15:25:01-15:25:03, 15:29, 15:36-15:37, 15:39:01, 15:61-15:62, 15:64, 15:67, 15:72, 15:74, 15:80, 15:88-15:90, 15:95, 15:98, 15:103, 15:106, 15:112, 15:115, 15:119, 15:127, 15:132-15:134, 15:139, 15:153, 15:156, 15:158, 15:162, 15:168, 15:170, 15:173, 15:176-15:177, 15:194-15:198, 15:200, 15:204, 15:208, 15:210, 15:213-15:214, 15:216, 15:219-15:220, 15:223, 15:226N, 15:229-15:230**								**8**				
***15:03:02, 15:13:02, 15:39:02**								**8**				
Well No.	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**

105	215	330	195	365	95	230	375	270	215	45	395	Length of spec.
215			215									PCR product(s)
13	14	15	16	17	18	19	20	21	22	23	24	Well No.
												*15:01:01:01-15:01:04, 15:01:06-15:01:16, 15:01:18-15:01:24, 15:04, 15:08, 15:11:01-15:12, 15:15, 15:24, 15:26N-15:27:02, 15:28, 15:30, 15:32, 15:34-15:35, 15:38:01, 15:43, 15:46, 15:53-15:54, 15:56, 15:58, 15:60, 15:63, 15:66, 15:70-15:71, 15:73, 15:75-15:77, 15:79N, 15:81-15:82, 15:85, 15:87, 15:92, 15:94N, 15:96-15:97, 15:101-15:102, 15:104-15:105, 15:109-15:111N, 15:113, 15:118, 15:120, 15:122, 15:128-15:129, 15:135, 15:137, 15:140, 15:142-15:149N, 15:152, 15:154, 15:157, 15:159-15:160, 15:163-15:167, 15:169, 15:171-15:172, 15:174-15:175, 15:178, 15:180-15:184, 15:187, 15:189-15:193, 15:201-15:203, 15:205-15:206, 15:209N, 15:211-15:212, 15:215, 15:217, 15:225, 15:227-15:228, 15:231-15:234, 15:236, 18:19, 27:25, 35:14:01-35:14:02, 35:43:01-35:44, 35:67, 35:79, 35:86, 35:102, 35:117, 35:135, 35:163, 35:185, 39:36, 51:61, 52:21, 54:06, 56:03, *A*26:68, A*68:56, C*06:20, C*12:50*
												*15:02:01-15:03:01, 15:03:03, 15:06, 15:09-15:10:02, 15:13:01, 15:16:01-15:18:04, 15:21, 15:23, 15:25:01-15:25:03, 15:29, 15:36-15:37, 15:39:01, 15:61-15:62, 15:64, 15:67, 15:72, 15:74, 15:80, 15:88-15:90, 15:95, 15:98, 15:103, 15:106, 15:112, 15:115, 15:119, 15:127, 15:132-15:134, 15:139, 15:153, 15:156, 15:158, 15:162, 15:168, 15:170, 15:173, 15:176-15:177, 15:194-15:198, 15:200, 15:204, 15:208, 15:210, 15:213-15:214, 15:216, 15:219-15:220, 15:223, 15:226N, 15:229-15:230
		15										*15:03:02, 15:13:02, 15:39:02
13	14	15	16	17	18	19	20	21	22	23	24	Well No.

Length of spec.	130	115	395	130	235	120	105	375	115	100	150	170
PCR product(s)				245		225	140			315		380
Well No.	1	2	3	4	5	6	7	8	9	10	11	12
*15:05:01, 15:31, 15:55, 15:107, 15:123, 15:151, 15:155, 15:185, 15:222								8				
*15:05:02								8				
*15:14									9			
*15:19									9			
*15:27:03, 15:38:02									9			
*15:40								8				
*15:42			3					8				
*15:44, 15:69, 15:93, 15:121, 15:186			3					8				
*15:47, 15:49												
*15:48								8				12
*15:50			3						9			
*15:52, 15:114, 15:124								8				
*15:57	w				w				9			
*15:84												
*15:86, 15:188, 15:224			3					8				
*15:91								8				
*15:108, 15:136, 15:235								8				12
*15:117									9			
*15:125									9	10		
*15:131, 15:161								8				
*15:138						6		8				
*15:179												
*15:199			3									
*18:06				4								
*18:56, 35:45, 35:71, 44:17, 44:43:01-44:43:02, 45:09, 53:22, 58:07												
*35:54										10		
*35:62									9		11	
*35:113, 44:98, *C*03:125*												
*40:73				4	5							
*55:03					5							
*55:19						6						
*56:19N							7					
*73:01-73:02				w								
*C*02:28*											11	
Well No.	1	2	3	4	5	6	7	8	9	10	11	12

105	215	330	195	365	95	230	375	270	215	45	395	Length of spec.
215			215									PCR product(s)
13	14	15	16	17	18	19	20	21	22	23	24	Well No.
				17								*15:05:01, 15:31, 15:55, 15:107, 15:123, 15:151, 15:155, 15:185, 15:222
		15		17								*15:05:02
			16									*15:14
						19						*15:19
		15										*15:27:03, 15:38:02
											24	*15:40
13		15										*15:42
												*15:44, 15:69, 15:93, 15:121, 15:186
											24	*15:47, 15:49
		15										*15:48
												*15:50
				17							24	*15:52, 15:114, 15:124
												*15:57
				w								*15:84
		15		17								*15:86, 15:188, 15:224
			16	17								*15:91
												*15:108, 15:136, 15:235
											24	*15:117
												*15:125
			16									*15:131, 15:161
											24	*15:138
		15										*15:179
												*15:199
												*18:06
			16									*18:56, 35:45, 35:71, 44:17, 44:43:01-44:43:02, 45:09, 53:22, 58:07
												*35:54
												*35:62
									22			*35:113, 44:98, *C*03:125*
												*40:73
13												*55:03
13												*55:19
13												*56:19N
												*73:01-73:02
												*C*02:28*
13	14	15	16	17	18	19	20	21	22	23	24	Well No.

[1]The internal positive control primer pairs amplify segments of the human growth hormone gene. The two different control primer pairs give rise to either an internal positive control band of 1070 base pairs, for most wells, or a band of 800 base pairs, for some wells.
Well number 1 contains the primer pair giving rise to the shorter, 800 bp, internal positive control band in order to help in the correct orientation of the HLA-B*46 SSP subtyping.
In addition, wells number 6, 8, 10 and 17 contain the primer pair giving rise to the shorter, 800 bp, internal positive control in order to allow kit identification.
[2]The nucleotide position, in the 2nd, 3rd or 4th exon or in the 2nd 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.
[3]The nucleotide position, in the 2nd, 3rd, 4th or 5th 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.
[4]Primer mix 4: Specific PCR fragment of 130 bp in the B*46:04 allele. Specific PCR fragment of 245 bp in the B*46:14 and the B*18:06, 40:73, 73:01[w]-73:02[w] alleles.
Primer mix 6: Specific PCR fragment of 120 bp in the B*46:20 and the B*55:19 alleles. Specific PCR fragment of 225 bp in the B*46:06 and the B*07:09, 07:11, 07:17, 15:138, 18:35, 35:66, 40:38, 40:52, 40:59-40:60, 40:158, 48:14 and 48:23 and in the C*07:38 alleles.
Primer mix 7: Specific PCR fragment of 105 bp in the B*46:16 allele. Specific PCR fragment of 140 bp in the B*46:07N and the B*14:07N, 39:40N and 56:19N alleles.
Primer mix 10: Specific PCR fragment of 100 bp in the B*46:05 and the B*15:125 and 35:54 alleles. Specific PCR fragment of 315 bp in the B*46:15N allele.
Primer mix 12: Specific PCR fragment of 170 bp in the B*46:10 allele. Specific PCR fragment of 380 bp in the B*46:19 and the B*15:48, 15:108, 15:136 and 15:235alleles.
Primer mix 13: Specific PCR fragment of 105 bp in the B*46:11 and 46:18 and the B*07:78, 13:02:01-13:03, 13:08Q-13:09, 13:14-13:16, 13:18-13:19, 13:27, 13:30-13:34, 13:37-13:38, 13:40-13:42, 13:44-13:45, 15:42, 35:60, 44:15, 44:18, 45:01, 45:03-45:08, 45:10-45:13, 49:01:01-49:03, 49:06-49:17, 49:19N-49:20, 50:01:01-50:02, 50:04-50:08, 50:10-50:13, 50:15, 51:15, 52:25, 54:01:01-54:03, 54:05N, 54:07-54:08N, 54:10, 54:12-54:13, 54:16-54:24, 55:01:01-55:01:03, 55:01:05-55:03, 55:05, 55:07, 55:09-55:12, 55:15-55:16, 55:18-55:19, 55:21-55:22, 55:24-55:26, 55:29-55:31, 55:33-55:38, 55:40-55:41, 55:43, 55:45-55:48, 55:50, 55:52, 55:54, 56:01:01-56:01:04, 56:07-56:08, 56:13-56:14, 56:16-56:17, 56:19N-56:20:02, 56:23-56:30, 59:01:01:01-59:01:01:02 and 59:04-59:05 alleles. Specific PCR fragment of 215 bp in the B*46:22 allele.
Primer mix 16: Specific PCR fragment of 195 bp in the B*46:17 and the B*15:14, 15:91, 15:131, 15:161, 18:56, 35:45, 35:71, 44:17, 44:43:01-44:43:02, 45:09, 53:22 and 58:07 alleles. Specific PCR fragment of 215 bp in the B*46:22 allele.
'w', might be weakly amplified.

CELL LINE VALIDATION SHEET

HLA-B*46 SSP primer set

					Well															
					1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
				Prod. No.:	201193601	201193602	201193603	201193604	201193605	201193606	201193607	201193608	201193609	201193610	201193611	201193612	201193613	201193614	201193615	201193616
	IHWC cell line		B*																	
1	9001	SA	*07:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2	9280	LK707	*52:01	*73:01	-	-	-	w	-	-	-	-	-	-	-	-	-	-	-	-
3	9011	E4181324	*52:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
4	9275	GU373	*15:10	*53:01	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-
5	9009	KAS011	*37:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
6	9353	SM	*39:01	*51:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
7	9020	QBL	*18:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
8	9025	DEU	*35:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
9	9026	YAR	*38:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
10	9107	LKT3	*54:01		-	-	-	-	-	-	-	-	-	-	-	-	+	-	-	-
11	9051	PITOUT	*44:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
12	9052	DBB	*57:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
13	9025	JESTHOM	*27:05		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
14	9071	OLGA	*15:01	*15:20	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-
15	9075	DKB	*40:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
16	9037	SWEIG007	*40:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
17	9282	CTM3953540	*08:01	*55:01	-	-	-	-	-	-	-	-	-	-	-	-	+	-	-	-
18	9257	32367	*14:01	*56:01	-	-	-	-	-	-	-	-	-	-	-	-	+	-	-	-
19	9038	BM16	*18:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
20	9059	SLE005	*40:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
21	9064	AMALA	*15:01		-	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-
22	9056	KOSE	*35:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
23	9124	IHL	*40:02	*56:02	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
24	9035	JBUSH	*38:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
25	9049	IBW9	*14:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
26	9285	WT49	*58:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
27	9191	CH1007	*07:05	*51:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
28	9320	BEL5GB	*44:02	*44:03	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
29	9050	MOU	*44:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
30	9021	RSH	*42:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
31	9019	DUCAF	*18:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
32	9297	HAG	*41:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
33	9098	MT14B	*40:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
34	9104	DHIF	*38:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
35	9302	SSTO	*44:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
36	9024	KT17	*15:01	*35:01	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-
37	9065	HHKB	*07:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
38	9099	LZL	*15:01		-	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-
39	9315	CML	*08:01	*27:05	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
40	9134	WHONP199	*13:02	*46:01	+	-	-	-	+	-	-	-	+	-	-	-	+	-	-	-
41	9055	H0301	*14:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
42	9066	TAB089	*46:01		+	-	-	-	+	-	-	-	+	-	-	-	-	-	-	-
43	9076	T7526	*46:01		+	-	-	-	+	-	-	-	+	-	-	-	-	-	-	-
44	9057	TEM	*38:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
45	9239	SHJO	*42:01	*50:01	-	-	-	-	-	-	-	-	-	-	-	-	+	-	-	-
46	9013	SCHU	*07:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
47	9045	TUBO	*51:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
48	9303	TER-ND	*35:01	*44:03	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

CELL LINE VALIDATION SHEET

HLA-B*46 SSP primer set

					Well							
					17	18	19	20	21	22	23	24
				Prod. No.:	201193617	201193618	201193619	201193620	201193621	201193622	201193623	201193624
	IHWC cell line		B*									
1	9001	SA	*07:02		-	-	-	-	-	-	-	-
2	9280	LK707	*52:01	*73:01	-	-	-	-	-	-	-	-
3	9011	E4181324	*52:01		-	-	-	-	-	-	-	-
4	9275	GU373	*15:10	*53:01	-	-	-	-	-	-	-	-
5	9009	KAS011	*37:01		-	-	-	-	-	-	-	-
6	9353	SM	*39:01	*51:01	-	-	-	-	-	-	-	-
7	9020	QBL	*18:01		-	-	-	-	-	-	-	-
8	9025	DEU	*35:01		-	-	-	-	-	-	-	-
9	9026	YAR	*38:01		-	-	-	-	-	-	-	-
10	9107	LKT3	*54:01		-	-	-	-	-	-	-	-
11	9051	PITOUT	*44:03		-	-	-	-	-	-	-	-
12	9052	DBB	*57:01		-	-	-	-	-	-	-	-
13	9025	JESTHOM	*27:05		-	-	-	-	-	-	-	-
14	9071	OLGA	*15:01	*15:20	-	-	-	-	-	-	-	-
15	9075	DKB	*40:01		-	-	-	-	-	-	-	-
16	9037	SWEIG007	*40:02		-	-	-	-	-	-	-	-
17	9282	CTM3953540	*08:01	*55:01	-	-	-	-	-	-	-	-
18	9257	32367	*14:01	*56:01	-	-	-	-	-	-	-	-
19	9038	BM16	*18:01		-	-	-	-	-	-	-	-
20	9059	SLE005	*40:01		-	-	-	-	-	-	-	-
21	9064	AMALA	*15:01		-	-	-	-	-	-	-	-
22	9056	KOSE	*35:03		-	-	-	-	-	-	-	-
23	9124	IHL	*40:02	*56:02	-	-	-	-	-	-	-	-
24	9035	JBUSH	*38:01		-	-	-	-	-	-	-	-
25	9049	IBW9	*14:02		-	-	-	-	-	-	-	-
26	9285	WT49	*58:01		-	-	-	-	-	-	-	-
27	9191	CH1007	*07:05	*51:01	-	-	-	-	-	-	-	-
28	9320	BEL5GB	*44:02	*44:03	-	-	-	-	-	-	-	-
29	9050	MOU	*44:03		-	-	-	-	-	-	-	-
30	9021	RSH	*42:01		-	-	-	-	-	-	-	-
31	9019	DUCAF	*18:01		-	-	-	-	-	-	-	-
32	9297	HAG	*41:02		-	-	-	-	-	-	-	-
33	9098	MT14B	*40:01		-	-	-	-	-	-	-	-
34	9104	DHIF	*38:01		-	-	-	-	-	-	-	-
35	9302	SSTO	*44:02		-	-	-	-	-	-	-	-
36	9024	KT17	*15:01	*35:01	-	-	-	-	-	-	-	-
37	9065	HHKB	*07:02		-	-	-	-	-	-	-	-
38	9099	LZL	*15:01		-	-	-	-	-	-	-	-
39	9315	CML	*08:01	*27:05	-	-	-	-	-	-	-	-
40	9134	WHONP199	*13:02	*46:01	-	-	-	-	-	-	-	-
41	9055	H0301	*14:02		-	-	-	-	-	-	-	-
42	9066	TAB089	*46:01		-	-	-	-	-	-	-	-
43	9076	T7526	*46:01		-	-	-	-	-	-	-	-
44	9057	TEM	*38:01		-	-	-	-	-	-	-	-
45	9239	SHJO	*42:01	*50:01	-	-	-	-	-	-	-	-
46	9013	SCHU	*07:02		-	-	-	-	-	-	-	-
47	9045	TUBO	*51:01		-	-	-	-	-	-	-	-
48	9303	TER-ND	*35:01	*44:03	-	-	-	-	-	-	-	-

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-B*46 SSP

Product number: **101.544-06 – including *Taq* polymerase**
Lot number: **93M**
Expiry date: **2014-May-01**
Number of tests: **6**
Number of wells per test: **24**

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2011-936-01	9	2011-936-09	17	2011-936-17
2	2011-936-02	10	2011-936-10	18	2011-936-18
3	2011-936-03	11	2011-936-11	19	2011-936-19
4	2011-936-04	12	2011-936-12	20	2011-936-20
5	2011-936-05	13	2011-936-13	21	2011-936-21
6	2011-936-06	14	2011-936-14	22	2011-936-22
7	2011-936-07	15	2011-936-15	23	2011-936-23
8	2011-936-08	16	2011-936-16	24	2011-936-24

The specificity of each primer solution of the HLA-B*46 primer set has been tested against 48 well characterized IHWC cell line DNAs.

No DNAs carrying the alleles to be amplified by primer solutions 2 to 4, 6, 7, 10 to 12, 15, 17, 18 and 20 to 23 were available. The specificities of the primers in primer solutions 3, 4, 6, 10 to 12, 15, 17 and 20 were tested by separately adding one or two additional 5'-primers, respectively one or two additional 3'-primers. In primer solutions 2, 7, 18, 21 and 23 it was only possible to test the 5'-primer, the 3'-primer was not possible to test. In primer solution 22 it was only possible to test the 3'-primer, the 5'-primer was not possible to test.
In primer solutions 4 and 10 one of the 5'-primers was not possible to test, and in primer solutions 6, 8, 12, 13, 15 and 16 one of the 3'-primers was not possible to test. Additional 5'-primers in primer solutions 13 and 16 were tested by separately adding one 3'-primer.

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

Date of approval: 2011-December-02

Approved by:

Production Quality Control

Declaration of Conformity

Product name: *Olerup* SSP® HLA-B*46
Product number: 101.544-06
Lot number: 93M

Intended use: HLA-B*46 high resolution histocompatibility testing

Manufacturer: *Olerup* SSP AB
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SE-112 51 Stockholm, Sweden
Phone: +46-8-717 88 27
Fax: +46-8-717 88 18

We, *Olerup* SSP AB, hereby declare that this product, to which this Declaration of Conformity relates is in conformity with the following Standard(s) and other normative document(s) ISO 9001:2008 and ISO 13485:2003, following the provisions of the 98/79/EC Directive on *in vitro* diagnostic medical devices, Annex II List B, conformity assessed using Annex IV, as transposed into the national laws of the Member States of the European Union.

The Technical Documentation File is maintained at *Olerup* SSP AB, Franzengatan 5, SE-112 51 Stockholm, Sweden.

Notified Body: Lloyd's Register Quality Assurance Limited, Hiramford, Middlemarch Office Village, Siskin Drive, Coventry CV3 4FJ, United Kingdom. (Notified Body number: 0088.)

Stockholm, Sweden
2011-December-02

Ann-Cathrin Jareman
Head of QA and Regulatory Affairs

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