

101.544-06 – including *Taq* pol., IFU-01
101.544-06u – without *Taq* pol., IFU-02

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“Instructions for Use” (IFU)

Lot No.: **08R**

Lot-specific information
***Olerup SSP*[®] HLA-B*46**

Product number:	101.544-06– including <i>Taq</i> polymerase 101.544-06u – without <i>Taq</i> polymerase
Lot number:	08R
Expiry date:	2015-March-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. 08R.

**CHANGES COMPARED TO THE PREVIOUS *OLERUP SSP*[®]
HLA-B*46 LOT (93M)**

The HLA-B*46 kit is updated for new alleles to enable separation of:

- Confirmed¹ alleles as listed in the IMGT/HLA database
- Polymorphisms in exons outside of the region encoding the peptide binding domain
- Null and Alternatively expressed alleles

The Lot-specific information for HLA-B*46 including and without *Taq* polymerase is now described in one common Product Insert.

¹As described in section Uniquely Identified Alleles.

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. 93M).

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

Well	5'-primer	3'-primer	rationale
8	-	Modified	Improved specificity of amplification.
12	-	Modified	Improved specificity of amplification.

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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 '08R'.

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*07:38:01-07:38:02 alleles will be amplified by primer mix 6, the A*26:68, A*68:56, C*02:56, C*06:20 and C*12:50 alleles will be amplified by primer mix 9, the C*07:02:30 and C*08:16:02 alleles will be amplified by primer mix 10, 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 April 2012¹ will be amplified by the primers in the HLA-B*46 SSP kit.

The HLA-B*46 kit enables separation of the confirmed HLA-B*46 alleles as listed in the IMGT/HLA database. An HLA allele is listed as confirmed by IMGT/HLA if it has been sequenced by more than a single laboratory or from multiple sources. Current allele confirmation status for HLA-B*46 alleles is listed below.

The HLA-B*46 kit also enables identification of polymorphisms in exons outside of the region encoding the peptide binding domain and of null and alternatively expressed alleles

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The HLA-B*46 subtyping kit cannot distinguish the silent mutations in 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.

¹HLA-B alleles listed on the IMGT/HLA web page 2012-April-12, release 3.8.0, www.ebi.ac.uk/imgt/hla.

ALLELE CONFIRMATION STATUS

Allele	Status ¹	Allele	Status ¹
B*46:01:01	Confirmed	B*46:13:03	Unconfirmed
B*46:01:02	Unconfirmed	B*46:14	Unconfirmed
B*46:01:03	Unconfirmed	B*46:15N	Unconfirmed
B*46:01:04	Unconfirmed	B*46:16	Unconfirmed
B*46:01:05	Unconfirmed	B*46:17	Unconfirmed
B*46:01:06	Unconfirmed	B*46:18	Unconfirmed
B*46:01:07	Unconfirmed	B*46:19	Unconfirmed
B*46:02	Unconfirmed	B*46:20	Unconfirmed
B*46:03	Unconfirmed	B*46:21:01	Unconfirmed
B*46:04	Unconfirmed	B*46:21:02	Unconfirmed
B*46:05	Unconfirmed	B*46:22	Confirmed
B*46:06	Unconfirmed	B*46:23	Unconfirmed
B*46:07N	Unconfirmed	B*46:24	Unconfirmed
B*46:08	Unconfirmed	B*46:25	Unconfirmed
B*46:09	Unconfirmed	B*46:26	Unconfirmed
B*46:10	Unconfirmed	B*46:27	Confirmed
B*46:11	Confirmed	B*46:28	Unconfirmed
B*46:12	Unconfirmed	B*46:29	Unconfirmed
B*46:13:01	Unconfirmed	B*46:30	Confirmed
B*46:13:02	Unconfirmed		

¹Allele status “confirmed” or “unconfirmed” as listed on the IMGT/HLA web page 2012-April-12, release 3.8.0, www.ebi.ac.uk/imgt/hla.

RESOLUTION IN HOMO- AND HETEROZYGOTES

A total of 43 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.

```

+----+---- +-----+ -----+ *46:01:01, *46:30 = *46:30, *46:30
+----+---- +-----+ -----+ *46:01:01, *46:28 = *46:28, *46:28
+----+---- +-----+ -----+ *46:01:01, *46:27 = *46:27, *46:27
+----+---- +-----+ --+----- *46:01:01, *46:24 = *46:24, *46:24
+----+---- +-----+ -+----- *46:01:01, *46:23 = *46:23, *46:23
+----+---- +-----+ -----+ *46:01:01, *46:17 = *46:17, *46:17
+----+---- +-----+ -----+ *46:01:01, *46:01:03 = *46:01:03, *46:01:03
+----+---- +-----+ -----+ *46:01:01, *46:12 = *46:12, *46:12

```

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+---+---	+---+---	-----	*46:01:01, *46:10 = *46:10, *46:10
+---+---	+---+---	-----	*46:01:01, *46:09 = *46:09, *46:09
+---+---	+---+---	-----	*46:01:01, *46:05 = *46:01:01, *46:15N = *46:05, *46:15N = *46:15N, *46:15N
+---+---	+---+---	-----	*46:08, *46:13:03 = *46:13:03, *46:13:03
+---+---	+---+---	-----	*46:08, *46:19 = *46:19, *46:19
+---+---	+---+---	-----	*46:01:01, *46:07N = *46:07N, *46:07N
+---+---	+---+---	-----	*46:01:01, *46:20 = *46:20, *46:20
+---+---	+---+---	-----	*46:01:01, *46:04 = *46:01:01, *46:14 = *46:04, *46:14 = *46:14, *46:14
+---+---	+---+---	-----	*46:01:01, *46:03 = *46:01:01, *46:29 = *46:03, *46:29 = *46:29, *46:29
+---+---	+---+---	-----	*46:01:01, *46:02 = *46:02, *46:02
+---+---	+---+---	-----	*46:01:01, *46:22 = *46:17, *46:22 = *46:22, *46:22
+---+---	+---+---	-----	*46:05, *46:30 = *46:15N, *46:30
+---+---	+---+---	-----	*46:05, *46:28 = *46:15N, *46:28
+---+---	+---+---	-----	*46:05, *46:27 = *46:15N, *46:27
+---+---	+---+---	-----	*46:05, *46:25 = *46:15N, *46:25
+---+---	+---+---	-----	*46:05, *46:24 = *46:15N, *46:24
+---+---	+---+---	-----	*46:05, *46:23 = *46:15N, *46:23
+---+---	+---+---	-----	*46:05, *46:17 = *46:15N, *46:17
+---+---	+---+---	-----	*46:01:03, *46:05 = *46:01:03, *46:15N
+---+---	+---+---	-----	*46:05, *46:12 = *46:12, *46:15N
+---+---	+---+---	-----	*46:05, *46:10 = *46:10, *46:15N
+---+---	+---+---	-----	*46:05, *46:09 = *46:09, *46:15N
+---+---	+---+---	-----	*46:08, *46:26 = *46:13:03, *46:26 = *46:26, *46:26
+---+---	+---+---	-----	*46:08, *46:13:01 = *46:13:01, *46:13:01 = *46:13:01, *46:13:03
+---+---	+---+---	-----	*46:01:01, *46:19 = *46:08, *46:10 = *46:10, *46:19
+---+---	+---+---	-----	*46:05, *46:08 = *46:08, *46:15N
+---+---	+---+---	-----	*46:05, *46:07N = *46:07N, *46:15N
+---+---	+---+---	-----	*46:05, *46:20 = *46:15N, *46:20
+---+---	+---+---	-----	*46:04, *46:30 = *46:14, *46:30
+---+---	+---+---	-----	*46:04, *46:28 = *46:14, *46:28
+---+---	+---+---	-----	*46:04, *46:27 = *46:14, *46:27
+---+---	+---+---	-----	*46:04, *46:25 = *46:14, *46:25
+---+---	+---+---	-----	*46:04, *46:24 = *46:14, *46:24
+---+---	+---+---	-----	*46:04, *46:23 = *46:14, *46:23
+---+---	+---+---	-----	*46:04, *46:17 = *46:14, *46:17
+---+---	+---+---	-----	*46:01:03, *46:04 = *46:01:03, *46:14
+---+---	+---+---	-----	*46:04, *46:12 = *46:12, *46:14
+---+---	+---+---	-----	*46:04, *46:10 = *46:10, *46:14
+---+---	+---+---	-----	*46:04, *46:09 = *46:09, *46:14
+---+---	+---+---	-----	*46:04, *46:05 = *46:04, *46:15N = *46:05, *46:14 = *46:14, *46:15N
+---+---	+---+---	-----	*46:04, *46:08 = *46:08, *46:14
+---+---	+---+---	-----	*46:04, *46:07N = *46:07N, *46:14
+---+---	+---+---	-----	*46:04, *46:20 = *46:14, *46:20
+---+---	+---+---	-----	*46:03, *46:30 = *46:29, *46:30
+---+---	+---+---	-----	*46:03, *46:28 = *46:28, *46:29
+---+---	+---+---	-----	*46:03, *46:27 = *46:27, *46:29
+---+---	+---+---	-----	*46:03, *46:24 = *46:24, *46:29
+---+---	+---+---	-----	*46:03, *46:23 = *46:23, *46:29
+---+---	+---+---	-----	*46:03, *46:17 = *46:17, *46:29
+---+---	+---+---	-----	*46:01:03, *46:03 = *46:01:03, *46:29
+---+---	+---+---	-----	*46:03, *46:12 = *46:12, *46:29
+---+---	+---+---	-----	*46:03, *46:10 = *46:10, *46:29
+---+---	+---+---	-----	*46:03, *46:09 = *46:09, *46:29
+---+---	+---+---	-----	*46:03, *46:05 = *46:03, *46:15N = *46:05, *46:29 = *46:15N, *46:29
+---+---	+---+---	-----	*46:03, *46:13:03 = *46:03, *46:21:01 = *46:08, *46:21:01 = *46:13:03,

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+-+-+--	+	-----	-----	*46:21:01 = *46:21:01, *46:21:01
+-+-+--	+	-----	-----	*46:03, *46:07N = *46:07N, *46:29
+-+-+--	+	-----	-----	*46:03, *46:20 = *46:20, *46:29
+++++--	+	-----	-----	*46:03, *46:04 = *46:03, *46:14 = *46:04, *46:29 = *46:14, *46:29
++-+--	++	-----	-----	*46:02, *46:05 = *46:02, *46:15N
++-+--	+	-----	-----	*46:01:01, *46:16 = *46:02, *46:07N = *46:02, *46:16 = *46:07N, *46:16 = *46:16, *46:16
++-+--	+	-----	-----	*46:02, *46:04 = *46:02, *46:14
+++--	+	-----	-----	*46:02, *46:03 = *46:02, *46:29
+-+--	++	-----	-----	*46:05, *46:22 = *46:15N, *46:22
+-+--	+	-----	-----	*46:08, *46:11 = *46:11, *46:11 = *46:11, *46:13:01 = *46:11, *46:13:03
+-+--	+	-----	-----	*46:01:01, *46:13:01 = *46:01:03, *46:13:01 = *46:01:03, *46:13:03
+-+--	++	-----	-----	*46:05, *46:13:03 = *46:13:03, *46:15N
+-+--	++	-----	-----	*46:05, *46:19 = *46:15N, *46:19
+-+--	+	-----	-----	*46:06, *46:06 = *46:06, *46:08 = *46:06, *46:13:03
+-+--	+	-----	-----	*46:04, *46:22 = *46:14, *46:22
+-+--	+	-----	-----	*46:04, *46:13:03 = *46:13:03, *46:14
+-+--	+	-----	-----	*46:04, *46:19 = *46:14, *46:19
+-+--	+	-----	-----	*46:03, *46:22 = *46:22, *46:29
+-+--	+	-----	-----	*46:03, *46:26 = *46:21:01, *46:26
+-+--	+	-----	-----	*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
+-+--	+	-----	-----	*46:01:01, *46:21:01 = *46:13:03, *46:29 = *46:21:01, *46:29
+-+--	++	-----	-----	*46:05, *46:16 = *46:15N, *46:16
+-+--	+	-----	-----	*46:04, *46:16 = *46:14, *46:16
+++++	+	-----	-----	*46:03, *46:16 = *46:16, *46:29
+-+--	+	-----	-----	*46:01:01, *46:11 = *46:01:03, *46:11
+-+--	++	-----	-----	*46:05, *46:26 = *46:15N, *46:26
+-+--	++	-----	-----	*46:05, *46:13:01 = *46:13:01, *46:15N
+-+--	+	-----	-----	*46:01:01, *46:06 = *46:06, *46:20 = *46:06, *46:30
+-+--	+	-----	-----	*46:04, *46:26 = *46:14, *46:26
+-+--	+	-----	-----	*46:04, *46:13:01 = *46:13:01, *46:14
+-+--	+	-----	-----	*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
+-+--	+	-----	-----	*46:01:01, *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
+-+--	++	-----	-----	*46:05, *46:21:01 = *46:15N, *46:21:01
+-+--	+	-----	-----	*46:03, *46:06 = *46:06, *46:21:01
+-+--	+	-----	-----	*46:04, *46:21:01 = *46:14, *46:21:01
+-+--	+	-----	-----	*46:11, *46:17 = *46:11, *46:22 = *46:13:01, *46:22
+-+--	++	-----	-----	*46:05, *46:11 = *46:11, *46:15N
+-+--	++	-----	-----	*46:05, *46:06 = *46:06, *46:15N
+-+--	+	-----	-----	*46:04, *46:11 = *46:11, *46:14
+-+--	+	-----	-----	*46:04, *46:06 = *46:06, *46:14
+-+--	+	-----	-----	*46:01:01, *46:18 = *46:01:03, *46:18 = *46:11, *46:29 = *46:18, *46:29
+-+--	++	-----	-----	*46:05, *46:21:02 = *46:15N, *46:21:02
+++++	+	-----	-----	*46:04, *46:21:02 = *46:14, *46:21:02
+-+--	+	-----	-----	*46:17, *46:18 = *46:18, *46:22 = *46:21:02, *46:22
+-+--	++	-----	-----	*46:05, *46:18 = *46:15N, *46:18
+++++	+	-----	-----	*46:04, *46:18 = *46:14, *46:18

*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

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Lot-specific information
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
2⁵	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
4⁷	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, 15:241, 18:35, 35:66, 40:38, 40:52, 40:59-40:60, 40:158, 48:14, 48:23, 55:19, C*07:38:01-07:38:02
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, 15:238, 15:240, 15:242-15:243

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9⁵	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- 15:01:28, 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, 15:239, 15:241, 15:244, 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, 44:146, 51:61, 52:21, 54:06, 55:21, 56:03, A*26:68, A*68:56, C*02:56, C*06:20, C*12:50
10^{5,6,10}	100 bp, 315 bp	800 bp	*46:05, 46:15N	*15:125, 35:54, C*07:02:30, C*08:16:02
11	150 bp	1070 bp	*46:09	*35:62, C*02:28
12¹¹	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, 13:53-13:54, 15:42, 35:60, 44:15, 44:18, 45:01, 45:03-45:08, 45:10-45:14, 49:01:01-49:03, 49:06-49:17, 49:19N- 49:20, 50:01:01-50:02, 50:04-50:08, 50:10-50:11, 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, 54:16-54:26, 55:01:01-55:01:03, 55:01:05-55:01:06,

101.544-06 – including *Taq* pol., IFU-01
 101.544-06u – without *Taq* pol., IFU-02

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Lot-specific information

				55:01:08-55:03, 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, 55:54-55:56, 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, 56:33-56:35, 59:01:01:01-59:01:01:02, 59:04-59:05
14⁶	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, 44:144, 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, 15:237 ^w
18⁵	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
23⁵	45 bp	1070 bp	*46:28	
24	395 bp	1070 bp	*46:06, 46:30	*15:40, 15:47:01-15:47:02, 15:49, 15:52, 15:114, 15:117, 15:124, 15:138, 15:238, 15:241

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*46 SSP typings.

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

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

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

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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*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.

³For several HLA-B alleles 1st and/or 4th exon(s) and beyond, as well as intron nucleotide sequences, are not available. In these instances it is not known whether some of the primers of the SSP sets are completely matched with the target sequences or not. We assume that unknown sequences in these regions are conserved within allelic groups.

⁴Due to the sharing of sequence motifs between HLA-B alleles one non-HLA-B*46 alleles will be amplified by primer mixes 1, 3 to 17, 19, 22 and 24. In addition, the C*07:38:01-07:38:02 alleles will be amplified by primer mix 6, the A*26:68, A*68:56, C*02:56, C*06:20 and C*12:50 alleles will be amplified by primer mix 9, the C*07:02:30 and C*08:16:02 alleles will be amplified by primer mix 10, 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.

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

⁶Primer mixes 7, 10, 13, 14 and 16 may have tendencies of unspecific amplifications.

⁷Primer 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.

⁸Primer 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, 15:241, 18:35, 35:66, 40:38, 40:52, 40:59-40:60, 40:158, 48:14 and 48:23 and the C*07:38:01-07:38:02 alleles.

⁹Primer 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.

¹⁰Primer mix 10: Specific PCR fragment of 100 bp in the B*46:05 and the B*15:125 and 35:54 and in the C*07:02:30 and C*08:16:02 alleles. Specific PCR fragment of 315 bp in the B*46:15N allele.

¹¹Primer 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 15:235 alleles.

¹²Primer 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, 13:53-13:54, 15:42, 35:60, 44:15, 44:18, 45:01, 45:03-45:08, 45:10-45:14, 49:01:01-49:03, 49:06-49:17, 49:19N-49:20, 50:01:01-50:02, 50:04-50:08, 50:10-50:11, 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, 54:16-54:26, 55:01:01-55:01:03, 55:01:05-55:01:06, 55:01:08-55:03, 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, 55:54-55:56, 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, 56:33-56:35, 59:01:01-59:01:01:02 and 59:04-59:05 alleles. Specific PCR fragment of 215 bp in the B*46:22 allele.

¹³Primer 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, 44:144, 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.

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Lot-specific information

INTERPRETATION TABLE												
HLA-B*46 SSP subtyping												
Amplification patterns of the B*46:01 to 46:30 alleles												
	Well⁵											
	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. control¹												
5'-primer(s)²	209	209	2 nd I	97	106	106	209	2 nd 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		2 nd 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 allele⁴												
*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				
Well No.	1	2	3	4	5	6	7	8	9	10	11	12

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Lot-specific information

For *In Vitro* Diagnostic Use.

101.544-06 – including *Taq* pol., IFU-01
 101.544-06u – without *Taq* pol., IFU-02

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Length of spec. PCR product(s)	130	115	395	130	235	120	105	375	115	100	150	170
				245		225	140			315		380
Well No.	1	2	3	4	5	6	7	8	9	10	11	12
*46:14	1			4	5				9			
*46:15N	1				5				9	10		
*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*07:38:01-07:38:02						6						
*07:55, 08:70, 48:19												
Well No.	1	2	3	4	5	6	7	8	9	10	11	12

101.544-06 – including *Taq* pol., IFU-01
 101.544-06u – without *Taq* pol., IFU-02

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Lot No.: **08R**

Lot-specific information

105	215	330	195	365	95	230	375	270	215	45	395	Length of spec. PCR product(s)
215			215									
13	14	15	16	17	18	19	20	21	22	23	24	Well No.
												*46:14
												*46:15N
												*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*07:38:01-07:38:02
	14											*07:55, 08:70, 48:19
13	14	15	16	17	18	19	20	21	22	23	24	Well No.

101.544-06 – including *Taq* pol., IFU-01
 101.544-06u – without *Taq* pol., IFU-02

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Lot No.: **08R**

Lot-specific information

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, 13:53-13:54, 35:60, 44:15, 44:18, 45:01, 45:03-45:08, 45:10-45:14, 49:01:01-49:03, 49:06-49:17, 49:19N-49:20, 50:01:01-50:02, 50:04-50:08, 50:10-50:11, 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, 54:16-54:26, 55:01:01-55:01:03, 55:01:05-55:01:06, 55:01:08-55:02:06, 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, 55:54-55:56, 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, 56:33-56:35, 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

101.544-06 – including *Taq* pol., IFU-01
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Lot No.: **08R**

Lot-specific information

105	215	330	195	365	95	230	375	270	215	45	395	Length of spec. PCR product(s)
215			215									
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, 13:53-13:54, 35:60, 44:15, 44:18, 45:01, 45:03-45:08, 45:10-45:14, 49:01:01-49:03, 49:06-49:17, 49:19N- 49:20, 50:01:01-50:02, 50:04-50:08, 50:10-50:11, 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, 54:16-54:26, 55:01:01-55:01:03, 55:01:05-55:01:06, 55:01:08-55:02:06, 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, 55:54-55:56, 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, 56:33- 56:35, 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.

101.544-06 – including *Taq* pol., IFU-01
 101.544-06u – without *Taq* pol., IFU-02

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Lot No.: **08R**

Lot-specific information

Length of spec. PCR product(s)	130	115	395	130	235	120	105	375	115	100	150	170
				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, 15:01:18-15:01:28, 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, 15:239, 15:244, 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, 44:146, 51:61, 52:21, 54:06, 56:03, A*26:68, A*68:56, C*02:56, 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, 15:240, 15:242-15:243								8				
Well No.	1	2	3	4	5	6	7	8	9	10	11	12

101.544-06 – including *Taq* pol., IFU-01
 101.544-06u – without *Taq* pol., IFU-02

Visit www.olerup-ssp.com for
 “Instructions for Use” (IFU)

Lot No.: **08R**

Lot-specific information

105	215	330	195	365	95	230	375	270	215	45	395	Length of spec. 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, 15:01:18-15:01:28, 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, 15:239, 15:244, 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, 44:146, 51:61, 52:21, 54:06, 56:03, A*26:68, A*68:56, C*02:56, 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, 15:240, 15:242-15:243
13	14	15	16	17	18	19	20	21	22	23	24	Well No.

101.544-06 – including *Taq* pol., IFU-01101.544-06u – without *Taq* pol., IFU-02Visit www.olerup-ssp.com for
“Instructions for Use” (IFU)Lot No.: **08R**

Lot-specific information

Length of spec. PCR product(s)	130	115	395	130	235	120	105	375	115	100	150	170
Well No.	1	2	3	4	5	6	7	8	9	10	11	12
*15:03:02, 15:13:02, 15:39:02								8				
*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, 15:238								8				
*15:42			3					8				
*15:44, 15:69, 15:93, 15:121, 15:186			3					8				
*15:47:01-15:47:02, 15:49												
*15:48								8				12
*15:50			3						9			
*15:52, 15:114, 15:124								8				
*15:57	w				w				9			
*15:84, 15:237												
*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									
*15:241						6			9			
*18:06				4								
*18:56, 35:45, 35:71, 44:17, 44:43:01- 44:43:02, 44:144, 45:09, 53:22, 58:07												
*35:54, C*07:02:30, C*08:16:02										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

101.544-06 – including *Taq* pol., IFU-01
 101.544-06u – without *Taq* pol., IFU-02

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 “Instructions for Use” (IFU)

Lot No.: **08R**

Lot-specific information

105	215	330	195	365	95	230	375	270	215	45	395	Length of spec. PCR product(s)
215			215									
13	14	15	16	17	18	19	20	21	22	23	24	Well No.
		15										*15:03:02, 15:13:02, 15:39:02
				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, 15:238
13		15										*15:42
												*15:44, 15:69, 15:93, 15:121, 15:186
											24	*15:47:01-15:47:02, 15:49
		15										*15:48
												*15:50
				17							24	*15:52, 15:114, 15:124
												*15:57
				w								*15:84, 15:237
		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
											24	*15:241
												*18:06
			16									*18:56, 35:45, 35:71, 44:17, 44:43:01- 44:43:02, 44:144, 45:09, 53:22, 58:07
												*35:54, C*07:02:30, C*08:16:02
												*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.

101.544-06 – including *Taq* pol., IFU-01
101.544-06u – without *Taq* pol., IFU-02

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“Instructions for Use” (IFU)

Lot No.: 08R**Lot-specific information**

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*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.

²The 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.

³The nucleotide position, in the 2nd, 3rd 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.

⁴HLA-B*46 alleles in bold lettering are listed as confirmed alleles on the on the IMGT/HLA web page www.ebi.ac.uk/imgt/hla, release 3.8.0, April 2012.

⁵Primer 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, 15:241, 18:35, 35:66, 40:38, 40:52, 40:59-40:60, 40:158, 48:14 and 48:23 and the C*07:38:01-07:38:02 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 and in the C*07:02:30 and C*08:16:02 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 15:235 alleles.

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, 13:53-13:54, 15:42, 35:60, 44:15, 44:18, 45:01, 45:03-45:08, 45:10-45:14, 49:01:01-49:03, 49:06-49:17, 49:19N-49:20, 50:01:01-50:02, 50:04-50:08, 50:10-50:11, 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, 54:16-54:26, 55:01:01-55:01:03, 55:01:05-55:01:06, 55:01:08-55:03, 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, 55:54-55:56, 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, 56:33-56:35, 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, 44:144, 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.

101.544-06 – including *Taq* pol., IFU-01
 101.544-06u – without *Taq* pol., IFU-02

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 “Instructions for Use” (IFU)

Lot No.: **08R**

Lot-specific information

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
					201193601	201193602	201193603	201193604	201193605	201193606	201193607	201204908	201193609	201193610	201193611	201204912	201193613	201193614	201193615	201193616
	IHWC cell line	B*	Prod. No.:																	
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		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

101.544-06 – including *Taq* pol., IFU-01
 101.544-06u – without *Taq* pol., IFU-02

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Lot No.: **08R**

Lot-specific information

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	-	-	-	-	-	-	-	-

101.544-06 – including *Taq* pol., IFU-01
101.544-06u – without *Taq* pol., IFU-02

Visit www.olerup-ssp.com for
“Instructions for Use” (IFU)

Lot No.: **08R**

Lot-specific information

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-B*46 SSP

Product number: 101.544-06– including *Taq* polymerase
101.544-06u – without *Taq* polymerase
Lot number: 08R
Expiry date: 2015-March-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	2012-049-12	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	2012-049-08	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: 2012-October-12

Approved by:

Production Quality Control

101.544-06 – including *Taq* pol., IFU-01
101.544-06u – without *Taq* pol., IFU-02

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Lot No.: **08R**

Lot-specific information

Declaration of Conformity

Product name: *Olerup* SSP® HLA-B*46
Product number: 101.544-06/06u
Lot number: 08R

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

Manufacturer: *Olerup* SSP AB
Franzengatan 5
SE-112 51 Stockholm, Sweden
Phone: +46-8-717 88 27
Fax: +46-8-717 88 18

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

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

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

Stockholm, Sweden
2012-October-12

Ann-Cathrin Jareman
Head of QA and Regulatory Affairs

101.544-06 – including *Taq* pol., IFU-01
101.544-06u – without *Taq* pol., IFU-02

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Lot-specific information

101.544-06 – including *Taq* pol., IFU-01
101.544-06u – without *Taq* pol., IFU-02

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Lot No.: **08R**

Lot-specific information

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