

101.562-06 – including *Taq* polymerase, IFU-01 Rev. No. 03
101.562-06u – without *Taq* polymerase, IFU-02 Rev. No. 03

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

Lot No.: **39N**

Lot-specific information

Olerup SSP[®] HLA-B*52

| | |
|----------------------------------|---|
| Product number: | 101.562-06 – including <i>Taq</i> polymerase 101.562-06u – without <i>Taq</i> polymerase |
| Lot number: | 39N |
| Expiry date: | 2014-August- 01 |
| Number of tests: | 6 |
| Number of wells per test: | 16 |
| Storage - pre-aliquoted primers: | dark at -20°C |
| - PCR Master Mix: | -20°C |
| - Adhesive PCR seals | RT |
| - Product Insert | RT |

This Product Description is only valid for Lot No. 39N.

CHANGES COMPARED TO THE PREVIOUS *OLERUP SSP[®]* HLA-B*52 LOT.

The HLA-B*52 specificity and interpretation tables have been updated for the HLA-B alleles described since the previous *Olerup SSP[®]* HLA-B*52 lot was made (Lot No. 59K).

The HLA-B*52 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*52 including and without *Taq* polymerase is now described in one common Product Insert.

¹As described in section Uniquely Identified Alleles.

The HLA-B*52 primer set is unchanged compared to the previous lot.

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Lot-specific information

PRODUCT DESCRIPTION

HLA-B*52 SSP typing

CONTENT

The primer set contains 5'- and 3'-primers for identifying the B*52:01 to B*52:27 alleles.

PLATE LAYOUT

Each HLA-B*52 test consists of 16 PCR reactions in a 16 well cut PCR plate.

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

The 16 well PCR plate is marked with ‘HLA-B*52’ in silver/gray ink.

Well No. 1 is marked with the Lot No. ‘39N’.

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 16 well PCR plate, make sure that the remaining plates stay sealed. Use a scalpel or a similar instrument to carefully cut the foil between the plates.

INTERPRETATION

The interpretation of HLA-B*52 SSP subtypings will be influenced by most other HLA-B alleles. In addition, the C*01:30, C*08:51 and C*15:39 alleles will be amplified by primer mix 1.

UNIQUELY IDENTIFIED ALLELES

All the HLA-B*52, i.e. **B*52:01 to B*52:27**, recognized by the HLA Nomenclature Committee in January 2012¹ will be amplified by the primers in the HLA-B*14 subtyping kit.

The HLA-B*52 kit enables separation of the confirmed HLA-B*52 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*52 alleles is listed below.

The HLA-B*52 kit also enables identification of polymorphisms in exons outside of the region encoding the peptide binding domain and of null and alternatively expressed alleles

The HLA-B*52 primer set cannot distinguish the following silent mutations: the B*52:01:01:01-52:01:10 or the B*52:10:01-52:10:02 alleles.

¹HLA-B alleles listed on the IMGT/HLA web page 2012-January-12, release 3.7.0, www.ebi.ac.uk/imgt/hla.

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ALLELE CONFIRMATION STATUS

| Allele | Status ¹ | Allele | Status ¹ |
|----------------------|---------------------|----------------|---------------------|
| B*52:01:01:01 | Confirmed | B*52:10:01 | Unconfirmed |
| B*52:01:01:02 | Unconfirmed | B*52:10:02 | Unconfirmed |
| B*52:01:02 | Confirmed | B*52:11 | Confirmed |
| B*52:01:03 | Confirmed | B*52:12 | Confirmed |
| B*52:01:04 | Unconfirmed | B*52:13 | Unconfirmed |
| B*52:01:05 | Confirmed | B*52:14 | Unconfirmed |
| B*52:01:06 | Confirmed | B*52:15 | Unconfirmed |
| B*52:01:07 | Confirmed | B*52:16 | Unconfirmed |
| B*52:01:08 | Unconfirmed | B*52:17 | Unconfirmed |
| B*52:01:09 | Unconfirmed | B*52:18 | Unconfirmed |
| B*52:01:10 | Unconfirmed | B*52:19 | Unconfirmed |
| B*52:02 | Unconfirmed | B*52:20 | Unconfirmed |
| B*52:03 | Unconfirmed | B*52:21 | Confirmed |
| B*52:04 | Unconfirmed | B*52:22 | Unconfirmed |
| B*52:05 | Confirmed | B*52:23 | Unconfirmed |
| B*52:06:01 | Unconfirmed | B*52:24 | Unconfirmed |
| B*52:06:02 | Confirmed | B*52:25 | Unconfirmed |
| B*52:07 | Unconfirmed | B*52:26 | Unconfirmed |
| B*52:08 | Confirmed | B*52:27 | Unconfirmed |
| B*52:09 | Unconfirmed | | |

¹Allele status “confirmed” or “unconfirmed” as listed on the IMGT/HLA web page 2012-January-10, release 3.7.0, www.ebi.ac.uk/imgt/hla.

RESOLUTION IN HOMO- AND HETEROZYGOTES

A total of 39 alleles generate 21 amplification patterns that can be combined in 231 homozygous and heterozygous combinations. 181 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.

```

+++---- -++----- *52:04, *52:11 = *52:04, *52:21
+++---- -++----- *52:04, *52:10:01 = *52:04, *52:15
+++---- -++----- *52:04, *52:08 = *52:04, *52:18
+++---- -++----- *52:04, *52:06:02 = *52:04, *52:17
+++---- -++----- *52:04, *52:12 = *52:04, *52:16
+++---- -++----- *52:04, *52:13 = *52:04, *52:19
+++---- -++----- *52:01:01:01, *52:04 = *52:04, *52:04
++++---- -++----- *52:02, *52:11 = *52:02, *52:21
+-+---- -++----- *52:02, *52:10:01 = *52:02, *52:15
+-+---- -++----- *52:02, *52:06:02 = *52:02, *52:17
+-+---- -++----- *52:02, *52:13 = *52:02, *52:19
+-+---- -++----- *52:03, *52:08 = *52:03, *52:18
+-+---- -++----- *52:03, *52:06:02 = *52:03, *52:17
+-+---- -++----- *52:03, *52:12 = *52:03, *52:16
+-+---- -++----- *52:01:01:01, *52:03 = *52:03, *52:15 = *52:03, *52:21 = *52:10:01, *52:21 =
*52:11, *52:15 = *52:15, *52:21
+-+---- -++----- *52:05, *52:11 = *52:05, *52:21
+-+---- -++----- *52:11, *52:20 = *52:20, *52:21
+-+---- -++----- *52:06:01, *52:11 = *52:06:01, *52:21
+-+---- -++----- *52:11, *52:14 = *52:14, *52:21
+-+---- -++----- *52:08, *52:11 = *52:08, *52:21 = *52:11, *52:18 = *52:18, *52:21
+-+---- -++----- *52:06:02, *52:11 = *52:06:02, *52:21 = *52:11, *52:17 = *52:17, *52:21

```

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+--+---- -+++++-- *52:07, *52:11 = *52:07, *52:21
 +--+---- -+++++-- *52:11, *52:12 = *52:11, *52:16 = *52:12, *52:21 = *52:16, *52:21
 +--+---- -+++++-- *52:11, *52:13 = *52:13, *52:21 = *52:19, *52:21
 +--+---- -+++++-- *52:01:01:01, *52:11 = *52:01:01:01, *52:21 = *52:11, *52:21 = *52:21, *52:21
 +--+---- -+++++-- *52:05, *52:10:01 = *52:05, *52:15
 +--+---- -+++++-- *52:10:01, *52:20 = *52:15, *52:20
 +--+---- ++++++-- *52:06:01, *52:10:01 = *52:06:01, *52:15
 +--+---- ++++++-- *52:10:01, *52:14 = *52:14, *52:15
 +--+---- -+++++-- *52:08, *52:10:01 = *52:08, *52:15 = *52:10:01, *52:18 = *52:15, *52:18
 +--+---- -+++++-- *52:06:02, *52:10:01 = *52:06:02, *52:15 = *52:10:01, *52:17 = *52:15, *52:17
 +--+---- -+++++-- *52:07, *52:10:01 = *52:07, *52:15
 +--+---- -+++++-- *52:10:01, *52:12 = *52:10:01, *52:16 = *52:12, *52:15 = *52:15, *52:16
 +--+---- -+++++-- *52:10:01, *52:13 = *52:13, *52:15 = *52:15, *52:19
 +--+---- -+++++-- *52:01:01:01, *52:10:01 = *52:01:01:01, *52:15 = *52:10:01, *52:15 = *52:15,
 *52:15
 +--+---- -+++++-- *52:05, *52:08 = *52:05, *52:18
 +--+---- -+++++-- *52:05, *52:06:02 = *52:05, *52:17
 +--+---- -+++++-- *52:05, *52:12 = *52:05, *52:16
 +--+---- -+++++-- *52:05, *52:13 = *52:05, *52:19
 +--+---- -+++++-- *52:01:01:01, *52:05 = *52:05, *52:05
 +--+---- -+++++-- *52:08, *52:20 = *52:18, *52:20
 +--+---- -+++++-- *52:06:02, *52:20 = *52:17, *52:20
 +--+---- -+++++-- *52:12, *52:20 = *52:16, *52:20
 +--+---- -+++++-- *52:13, *52:20 = *52:19, *52:20
 +--+---- -+++++-- *52:01:01:01, *52:20 = *52:20, *52:20
 +--+---- ++++++-- *52:08, *52:14 = *52:14, *52:18
 +--+---- ++++++-- *52:06:01, *52:12 = *52:06:01, *52:16
 +--+---- ++++++-- *52:06:01, *52:13 = *52:06:01, *52:19
 +--+---- ++++++-- *52:01:01:01, *52:06:01 = *52:06:01, *52:14 = *52:06:01, *52:17 = *52:06:02,
 *52:14 = *52:14, *52:17
 +--+---- ++++++-- *52:06:01, *52:06:01 = *52:06:01, *52:06:02
 +--+---- ++++++-- *52:12, *52:14 = *52:14, *52:16
 +--+---- ++++++-- *52:13, *52:14 = *52:14, *52:19
 +--+---- ++++++-- *52:01:01:01, *52:14 = *52:14, *52:14
 +--+---- -+++++-- *52:06:02, *52:08 = *52:08, *52:17 = *52:17, *52:18
 +--+---- -+++++-- *52:07, *52:08 = *52:07, *52:18
 +--+---- -+++++-- *52:08, *52:12 = *52:08, *52:16 = *52:12, *52:18
 +--+---- -+++++-- *52:08, *52:13 = *52:08, *52:19 = *52:13, *52:18 = *52:18, *52:19
 +--+---- -+++++-- *52:01:01:01, *52:08 = *52:01:01:01, *52:18 = *52:08, *52:08 = *52:08, *52:18
 +--+---- -+++++-- *52:06:02, *52:07 = *52:07, *52:17
 +--+---- -+++++-- *52:06:02, *52:12 = *52:06:02, *52:16 = *52:12, *52:17 = *52:16, *52:17
 +--+---- -+++++-- *52:06:02, *52:13 = *52:06:02, *52:19 = *52:13, *52:17 = *52:17, *52:19
 +--+---- -+++++-- *52:01:01:01, *52:06:02 = *52:01:01:01, *52:17 = *52:06:02, *52:17 = *52:17,
 *52:17
 +--+---- -+++++-- *52:07, *52:12 = *52:07, *52:16
 +--+---- -+++++-- *52:07, *52:13 = *52:07, *52:19
 +--+---- -+++++-- *52:12, *52:13 = *52:12, *52:19 = *52:13, *52:16 = *52:16, *52:19
 +--+---- -+++++-- *52:01:01:01, *52:12 = *52:01:01:01, *52:16 = *52:12, *52:12 = *52:12, *52:16
 +--+---- -+++++-- *52:01:01:01, *52:13 = *52:01:01:01, *52:19 = *52:13, *52:13 = *52:13, *52:19
 +--+---- -+++++-- *52:03, *52:03 = *52:03, *52:10:01 = *52:03, *52:11 = *52:10:01, *52:11

*52:01:01 = *52:01:01:01-52:01:10 and 52:22-52:25

*52:04 = *52:04 and 52:09

*52:10:01 = *52:10:01-52:10:02

*52:12 = *52:12, 52:26-52:27

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Lot-specific information
SPECIFICITY TABLE

HLA-B*52 SSP subtyping

Specificities and sizes of the PCR products of the 16 primer mixes used for
 HLA-B*52 SSP subtyping

| Primer Mix | Size of spec. PCR product ¹ | Size of control band ² | Amplified HLA-B*52 alleles | Other amplified HLA Class I alleles ^{3,4} |
|------------------------|--|-----------------------------------|---|--|
| 1⁵ | 95 bp | 800 bp | *52:01:01:01-52:02, 52:04-52:09, 52:12-52:18, 52:20-52:27 | *14:01:01-14:28, 15:37-15:38:02, 18:15, 18:19, 18:30, 18:57, 35:21, 35:96, 40:28, 40:51, 40:174, 49:09, 51:01:01-51:01:30, 51:03-51:04, 51:06:01-51:07:02, 51:11N-51:14, 51:16-51:18, 51:21-51:22, 51:24:01-51:24:04, 51:26-51:30, 51:32-51:33, 51:35, 51:37-51:39, 51:41N, 51:43, 51:45-51:46, 51:48-51:52, 51:55-51:58, 51:60-51:72, 51:74-51:80, 51:82-51:92, 51:94-51:96, 51:98N-51:107, 51:109-51:114, 51:116-51:119, 51:121, 51:123-51:126, 53:06, 56:05:01-56:06, 56:21, 58:08:01-58:08:02, 78:01:01-78:03, 78:05-78:07, C*01:30, C*08:51, C*15:39 |
| 2⁹ | 135 bp, 235 bp | 1070 bp | *52:04, 52:09 | *08:52, 15:87, 53:05, 53:16 |
| 3^{5,6} | 95 bp | 1070 bp | *52:01:01:01-52:01:10, 52:03-52:15, 52:17, 52:19-52:27 | *15:202, 18:12, 35:10, 35:13, 35:16, 35:28, 35:69, 35:80, 37:01:01-37:01:05, 37:01:07-37:05, 37:07, 37:09-37:27, 37:29-37:31, 44:83, 44:134, 49:03, 53:17:01-53:17:02, 78:05-78:06 |
| 4 | 140 bp | 1070 bp | *52:02 | *15:13:01-15:13:02, 15:16:01-15:17:02, 15:24, 15:67, 15:87, 15:95, 15:157, 15:162, 15:168, 15:177, 15:196, 15:208, 15:216, 15:222, 15:230, 51:104, 57:01:01-57:11, 57:13-57:15, 57:17-57:44, 57:46-57:50, 57:52, 58:36 |
| 5¹⁰ | 145 bp, 190 bp | 1070 bp | *52:03, 52:11, 52:21 | *07:02:11, 07:05:03, 15:01:02, 15:09, 27:04:03, 35:01:10, 35:04:02, 40:01:06, 40:26, 40:95, 44:62, 49:18, 50:14, 51:02:01-51:02:03, |

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| | | | | |
|----------------------------|-------------------|---------------|--|---|
| | | | | 51:02:05, 51:05, 51:23, 51:34, 51:36, 51:40, 51:54, 51:59, 51:61, 51:93, 51:108, 55:01:04, 78:04 |
| 6¹¹ | 135 bp, 180 bp | 1070 bp | *52:03, 52:10:01- 52:10:02, 52:15 | *35:01:10, 35:04:02, 40:01:06, 44:62 ^w , 51:05 ^w , 51:09:01-51:09:02, 51:19, 51:23 ^w , 51:31, 51:40, 51:54 ^w , 51:73, 51:93, 51:108, 51:122, 78:04 |
| 7 | 225 bp | 800 bp | *52:05 | |
| 8 | 145 bp | 1070 bp | *52:20 | *18:09, 37:10, 44:83, 44:134, 51:54, 51:78, 53:09, 53:11-53:13 |
| 9⁵ | 100 bp | 800 bp | *52:06:01, 52:14 | *13:46, 15:137, 35:01:08, 35:01:15, 39:06:01-39:06:02, 39:33-39:34, 39:50, 39:57, 39:62, 39:64, 40:86, 45:02, 50:09, 51:13:01-51:13:02, 51:92, 55:13, 56:22, 59:03, 73:01- 73:02 |
| 10^{5,12} | 95 bp, 245 bp | 1070 bp | *52:08, 52:18 | *07:78, 07:84, 13:02:01-13:02:12, 13:08Q-13:09, 13:14-13:16, 13:18- 13:19, 13:27, 13:30-13:35, 13:37- 13:38, 13:40-13:42, 13:44-13:45, 13:47, 13:49N, 27:81, 39:50, 40:06:01:01-40:06:04, 40:44, 40:53, 40:70, 40:75, 40:83, 40:86, 40:93, 40:95-40:96, 40:103, 40:109- 40:110, 40:127, 40:131, 40:148, 40:159, 40:161-40:162, 40:165, 40:167, 40:177, 45:10, 49:07, 51:10, 51:16, 51:31, 51:34, 51:82, 51:93, 55:09, 55:22, 55:24, 73:01-73:02 |
| 11^{5,7,13} | 85 bp, 225 bp | 1070 bp | *52:06:01- 52:06:02, 52:17 | *07:38, 08:02-08:03, 08:52, 08:78, 27:23, 37:21, 38:06-38:07, 40:13, 44:06, 51:01:01-51:01:16, 51:01:18- 51:06:02, 51:08-51:21, 51:23- 51:24:04, 51:26-51:46, 51:48- 51:117, 51:119-51:126, 53:01:01- 53:08:02, 53:10-53:16, 53:18-53:27, 59:01:01:01-59:05 |
| 12⁵ | 85 bp | 1070 bp | *52:01:01:01- 52:05, 52:07- 52:17, 52:19- 52:27 | *13:01:01-13:04, 13:06, 13:08Q, 13:10-13:18, 13:20-13:23, 13:25- 13:35, 13:37-13:38, 13:40-13:52, 15:24, 15:36, 15:43, 15:87, 15:157, 27:29, 37:01:01-37:04:02, 37:06- 37:07, 37:09-37:10, 37:12-37:20, 37:22-37:31, 38:03, 40:19, 40:47, 40:96, 40:109-40:110, 40:117, |

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| | | | | |
|-----------------------|--------|---------------|---|--|
| | | | | 40:157, 44:02:01:01-44:05:03, 44:07-44:08, 44:10-44:11, 44:14-44:45, 44:47-44:66, 44:68, 44:70-44:74, 44:76-44:89, 44:91- 44:96, 44:98-44:112, 44:114- 44:126, 44:128, 44:130, 44:132- 44:139, 47:01:01:01-47:01:02, 47:03-47:08, 48:18, 49:01:01-49:20, 53:17:01-53:17:02 |
| 13 | 165 bp | 800 bp | *52:01:01:01- 52:06:02, 52:08-52:27 | *15:20, 15:228, 35:01:01:01- 35:01:27, 35:01:29-35:30, 35:32:01- 35:42:02, 35:44-35:56, 35:58-35:59, 35:61-35:72, 35:74-35:78, 35:80- 35:86, 35:88-35:184, 35:186, 48:02:01-48:02:02, 51:01:01- 51:24:04, 51:26-51:41N, 51:43- 51:46, 51:48-51:126, 53:01:01- 53:27, 56:05:01-56:05:02, 56:21, 58:01:01-58:02, 58:04-58:10N, 58:12-58:19, 58:21-58:36, 78:01:01- 78:07, 81:03, 83:01 [?] |
| 14⁷ | 165 bp | 1070 bp | *52:07 | *07:02:01-07:57, 07:59-07:144, 08:01:01-08:05, 08:07-08:80, 13:01:01-13:04, 13:06-13:23, 13:25- 13:52, 14:01:01-14:28, 15:01:01:01- 15:01:04, 15:01:06-15:19, 15:21, 15:23-15:40, 15:42-15:58, 15:60- 15:99, 15:101, 15:103-15:129, 15:131-15:227, 15:229-15:238, 18:01:01-18:15, 18:17N-18:68, 27:01-27:21, 27:23-27:86, 35:31, 35:35, 35:43:01, 35:46, 35:57, 35:60, 35:79, 35:87, 35:96, 35:98, 35:43:02, 37:01:01-37:31, 38:01:01- 38:37, 39:01:01:01-39:01:01:02L, 39:01:03-39:20, 39:22-39:45, 39:47- 39:68, 40:01:01-40:16, 40:18-40:40, 40:42-40:180, 41:01-41:19, 42:01:01-42:02, 42:04-42:16, 44:02:01:01-44:65, 44:67-44:117, 44:119-44:139, 45:01-45:13, 46:01:01-46:30, 47:01:01:01-47:08, 48:01:01-48:01:03, 48:02:02-48:27, 49:01:01-49:20, 50:01:01-50:02, 50:04-50:15, 51:42, 54:01:01-54:24, 55:01:01-55:05, 55:07-55:54, 56:01:01-56:04, 56:06-56:20:02, |

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| | | | | |
|-------------------------------|-------------------|---------------|-----------------------------------|---|
| | | | | 56:22-56:32, 57:01:01-57:01:10, 57:01:12-57:52, 58:11, 58:20, 59:01:01:01-59:05, 67:01:01-67:03, 81:01-81:02, 81:04N-81:05, 82:01-82:03, 83:01 [?] |
| 15 ^{5,6,8,14} | 95 bp, 170 bp | 800 bp | *52:12, 52:16, 52:26- 52:27 | *07:27, 07:50, 07:84, 08:04, 08:17, 08:54, 13:04, 13:35, 15:03:01-15:04, 15:16:01-15:16:03, 15:47, 15:54, 15:61-15:62, 15:64, 15:67-15:69, 15:91, 15:95, 15:98, 15:103, 15:123, 15:127, 15:131-15:132, 15:151, 15:155-15:156, 15:158, 15:173, 15:210, 15:220, 15:222, 15:226N, 15:235, 15:238, 18:01:01-18:03, 18:05-18:06, 18:08-18:15, 18:17N- 18:28, 18:30-18:32, 18:34-18:68, 35:37, 37:01:01-37:20, 37:23-37:25, 37:27-37:31, 38:03, 39:02:01- 39:02:02, 39:08, 39:13:01-39:13:02, 39:23, 39:29, 39:39, 39:49, 40:12, 40:44, 40:149, 40:159, 42:11, 44:20, 44:47, 44:100, 44:130, 45:09, 48:01:01-48:02:01, 48:03:01-48:05, 48:07-48:27, 49:04-49:05, 51:37, 51:90, 51:92, 54:14-54:15, 55:23, 55:27 |
| 16 ¹⁵ | 160 bp, 215 bp | 1070 bp | *52:13, 52:19 | *08:09, 13:46, 15:83, 42:04, 44:20, 51:08, 51:20, 51:36, 51:44N, 51:97, 55:20, 56:13 |

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*52 SSP typings.

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

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

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

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

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

²The internal positive control primer pairs amplify segments of the human growth hormone gene. The two different control primer pairs give rise to either an internal positive control band of 1070 base pairs, for most wells, or a band of 800 base pairs, for some wells.

Well number 1 contains the primer pair giving rise to the shorter, 800 bp, internal positive control

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band in order to help in the correct orientation of the HLA-B*52 SSP subtyping.

In addition, wells number 7, 9, 13 and 15 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.

³For several HLA-B alleles fourth 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 fourth exon are conserved within allelic groups.

⁴Due to the sharing of sequence motifs between HLA-B alleles many non-HLA-B*52 alleles will be amplified by primer mixes 1 to 6 and 8 to 16. In addition, the C*01:30, C*08:51 and C*15:39 alleles will be amplified by primer mix 1.

⁵Short specific PCR fragments are less intense and not as sharp as longer specific bands.

⁶Primer mixes 3 and 15 may give a lower yield of specific PCR product than the other HLA-B*52 primer mixes.

⁷Primer mixes 11 and 14 may give rise to nonspecific amplifications.

⁸Primer mix 15 may give rise to a weak band of about 550 bp. This band should be disregarded when interpreting HLA-B*52 SSP subtypings.

⁹Primer mix 2: Specific PCR fragment of 135 bp in the B*52:04 allele. Specific PCR fragment of 235 bp in the B*52:09 and in the B*08:52, 15:87, 53:05 and 53:16 alleles.

¹⁰Primer mix 5: Specific PCR fragment of 145 bp in the B*52:21 and in the B*15:01:02 and 51:61 alleles. Specific PCR fragment of 190 bp in the B*52:03 and 52:11 and the B*07:02:11, 07:05:03, 15:01:02, 15:09, 27:04:03, 35:01:10, 35:04:02, 40:01:06, 40:26, 40:95, 44:62, 49:18, 50:14, 51:02:01-51:02:03, 51:02:05, 51:05, 51:23, 51:34, 51:36, 51:40, 51:54, 51:59, 51:93, 51:108, 55:01:04 and 78:04 alleles.

¹¹Primer mix 6: Specific PCR fragment of 135 bp in the B*52:03 and 52:10:01-52:10:02 and the B*35:01:10, 35:04:02, 40:01:06, 51:05^w, 51:09:01-51:09:02, 51:19, 51:31, 51:40, 51:54^w, 51:73, 51:93, 51:122 and 78:04 alleles. Specific PCR fragment of 180 bp in the B*52:15 and the B*44:62^w and 51:23^w alleles. Specific PCR fragment of 135 and 180 in the B*51:108 allele.

¹²Primer mix 10: Specific PCR fragment of 95 bp in the B*52:18 allele. Specific PCR fragment of 245 bp in the B*52:08 and the B*07:78, 07:84, 13:02:01-13:02:12, 13:08Q-13:09, 13:14-13:16, 13:18-13:19, 13:27, 13:30-13:35, 13:37-13:38, 13:40-13:42, 13:44-13:45, 13:47, 13:49N, 27:81, 39:50, 40:06:01:01-40:06:04, 40:44, 40:53, 40:70, 40:75, 40:83, 40:86, 40:93, 40:95-40:96, 40:103, 40:109-40:110, 40:127, 40:131, 40:148, 40:159, 40:161-40:162, 40:165, 40:167, 40:177, 45:10, 49:07, 51:10, 51:16, 51:31, 51:34, 51:82, 51:93, 55:09, 55:22, 55:24 and 73:01-73:02 alleles.

¹³Primer mix 11: Specific PCR fragment of 85 bp in the B*52:06:01-52:06:02 and the B*07:38, 08:02-08:03, 08:52, 08:78, 27:23, 37:21, 38:06-38:07, 40:13, 44:06, 51:01:01-51:01:16, 51:01:18-51:06:02, 51:08-51:21, 51:23-51:24:04, 51:26-51:46, 51:48-51:117, 51:119-51:126, 53:01:01-53:08:02, 53:10-53:16, 53:18-53:27 and 59:01:01:01-59:05 alleles. Specific PCR fragment of 225 bp in the B*52:17 allele.

¹⁴Primer mix 15: Specific PCR fragment of 95 bp in the B*52:12 and 52:26 and the B*07:84, 13:04, 13:35, 15:04, 15:16:01-15:16:03, 15:67, 15:95, 15:155, 15:222, 35:37, 40:44, 40:159, 44:20, 44:47, 44:100, 45:09, 49:04-49:05, 51:37, 51:90, 51:92, 54:14-54:15, 55:23 and 55:27 alleles. Specific PCR fragment of 170 bp in the B*52:16 and 52:27, 07:27, 07:50, 08:04, 08:17, 08:54, 15:03:01-15:03:03, 15:47, 15:54, 15:61-15:62, 15:64, 15:68-15:69, 15:91, 15:98, 15:103, 15:123, 15:127, 15:131-15:132, 15:151, 15:156, 15:158, 15:173, 15:210, 15:220, 15:235, 18:01:01-18:03, 18:05-18:06, 18:08-18:15, 18:17N-18:28, 18:30-18:32, 18:34-18:68, 37:01:01-37:20, 37:23-37:25, 37:27-37:31, 38:03, 39:02:01-39:02:02, 39:08, 39:13:01-39:13:02, 39:23, 39:39, 39:49, 40:12, 40:149, 42:11, 44:130, 48:01:01-48:02:01, 48:03:01-48:05 and 48:07-48:27 alleles.

¹⁵Primer mix 16: Specific PCR fragment of 160 bp in the B*52:13 allele. Specific PCR fragment of 215 bp in the B*52:19 and in the B*08:09, 13:46, 15:83, 42:04, 44:20, 51:08, 51:20, 51:36, 51:44N, 51:97, 55:20 and 56:13 alleles.

‘?’, nucleotide sequence information not available for the primer matching sequence.

‘w’, might be weakly amplified.

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Lot-specific information

| INTERPRETATION TABLE | | | | | | | | |
|--|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|
| HLA-B*52 SSP subtyping | | | | | | | | |
| Amplification patterns of the B*52:01 to B*52:27 alleles | | | | | | | | |
| | Well ⁶ | | | | | | | |
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
| Length of spec. | 95 | 135 | 95 | 140 | 145 | 135 | 225 | 145 |
| PCR product(s) | | 235 | | | 190 | 180 | | |
| Length of int. pos. control ¹ | 800 | 1070 | 1070 | 1070 | 1070 | 1070 | 800 | 1070 |
| 5'-primer ² | 527 | 106 | 206 | 209 | 435 | 435 | 134 | 206 |
| | 5'-TgA ^{3'} | 5'-CCA ^{3'} | 5'-gAC ^{3'} | 5'-ggC ^{3'} | 5'-AAA ^{3'} | 5'-AAA ^{3'} | 5'-CCC ^{3'} | 5'-gAC ^{3'} |
| 3'-primer ³ | 583 | 200 | 259 | 309 | 538 | 527 | 317 | 309 |
| | 5'-gTg ^{3'} | 5'-TCT ^{3'} | 5'-CTC ^{3'} | 5'-ATC ^{3'} | 5'-CCA ^{3'} | 5'-CCA ^{3'} | 5'-gga ^{3'} | 5'-gTg ^{3'} |
| | | 302 | | | 583 | 527 | | |
| | | 5'-ggC ^{3'} | | | 5'-gTA ^{3'} | 5'-CCA ^{3'} | | |
| | | | | | | 572 | | |
| | | | | | | 5'-gCg ^{3'} | | |
| Well No. | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
| HLA-B allele ⁴ | | | | | | | | |
| *52:01:01:01-52:01:10, 52:22-52:25 | 1 | | 3 | | | | | |
| *52:02 | 1 | | | 4 | | | | |
| *52:03 | | | 3 | | 5 | 6 | | |
| *52:04, 52:09 ⁵ | 1 | 2 | 3 | | | | | |
| Well No. | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |

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Lot-specific information

| INTERPRETATION TABLE | | | | | | | | |
|--|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|--|
| HLA-B*52 SSP subtyping | | | | | | | | |
| Amplification patterns of the B*52:01 to B*52:27 alleles | | | | | | | | |
| Well ⁶ | | | | | | | | |
| 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | |
| 100 | 95 | 85 | 85 | 165 | 165 | 95 | 160 | Length of spec. PCR product(s) |
| | 245 | 225 | | | | 170 | 215 | |
| 800 | 1070 | 1070 | 1070 | 800 | 1070 | 800 | 1070 | Length of int. pos. control ¹ |
| 213 | 206 | 133 | 272 | 652 | 652 | 142 | 86 | 5'-primer ² |
| 5'-CCg ^{3'} | 5'-gAC ^{3'} | 5'-CCA ^{3'} | 5'-CTC ^{3'} | 5'-CCg ^{3'} | 5'-CCA ^{3'} | 5'-TCT ^{3'} | 5'-CAA ^{3'} | |
| 357 | 357 | 272 | | | | 357 | 362 | |
| 5'-Tgg ^{3'} | 5'-Tgg ^{3'} | 5'-CTT ^{3'} | | | | 5'-Tgg ^{3'} | 5'-gAC ^{3'} | |
| 272 | 262 | 317 | 317 | 774 | 774 | 272 | 206 | 3'-primer ³ |
| 5'-TgA ^{3'} | 5'-TgC ^{3'} | 5'-gGA ^{3'} | 5'-gGA ^{3'} | 5'-ggT ^{3'} | 5'-ggT ^{3'} | 5'-Tgg ^{3'} | 5'-CCg ^{3'} | |
| 419 | 559 | | | | | 412 | 538 | |
| 5'-CgA ^{3'} | 5'-CTC ^{3'} | | | | | 5'-gTC ^{3'} | 5'-gTC ^{3'} | |
| 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | Well No. |
| | | | | | | | | HLA-B allele ⁴ |
| | | | 12 | 13 | | | | *52:01:01:01-52:01:10, 52:22-52:25 |
| | | | 12 | 13 | | | | *52:02 |
| | | | 12 | 13 | | | | *52:03 |
| | | | 12 | 13 | | | | *52:04, 52:09 ⁵ |
| 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | Well No. |

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Lot-specific information

| Length of spec. | 95 | 135 | 95 | 140 | 145 | 135 | 225 | 145 |
|---------------------|----|-----|----|-----|-----|-----|-----|-----|
| PCR product(s) | | 235 | | | 190 | 180 | | |
| Well No. | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
| *52:05 | 1 | | 3 | | | | 7 | |
| *52:06:01 | 1 | | 3 | | | | | |
| *52:06:02 | 1 | | 3 | | | | | |
| *52:07 | 1 | | 3 | | | | | |
| *52:08 | 1 | | 3 | | | | | |
| *52:10:01-52:10:02 | | | 3 | | | 6 | | |
| *52:11 | | | 3 | | 5 | | | |
| *52:12, 52:26-52:27 | 1 | | 3 | | | | | |
| *52:14 | 1 | | 3 | | | | | |
| *52:15 | 1 | | 3 | | | 6 | | |
| *52:16 | 1 | | | | | | | |
| *52:17 | 1 | | 3 | | | | | |
| *52:18 | 1 | | | | | | | |
| *52:19 | | | 3 | | | | | |
| *52:20 | 1 | | 3 | | | | | 8 |
| *52:21 | 1 | | 3 | | 5 | | | |
| Well No. | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |

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Lot No.: **39N**

Lot-specific information

| 100 | 95 | 85 | 85 | 165 | 165 | 95 | 160 | Length of spec. PCR product(s) |
|-----|-----|-----|----|-----|-----|-----|-----|-----------------------------------|
| 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | Well No. |
| | 245 | 225 | | | | 170 | 215 | |
| | | | 12 | 13 | | | | *52:05 |
| 9 | | 11 | | 13 | | | | *52:06:01 |
| | | 11 | | 13 | | | | *52:06:02 |
| | | | 12 | | 14 | | | *52:07 |
| | 10 | | 12 | 13 | | | | *52:08 |
| | | | 12 | 13 | | | | *52:10:01-52:10:02 |
| | | | 12 | 13 | | | | *52:11 |
| | | | 12 | 13 | | 15 | | *52:12, 52:26-52:27 |
| 9 | | | 12 | 13 | | | | *52:14 |
| | | | 12 | 13 | | | | *52:15 |
| | | | 12 | 13 | | 15 | | *52:16 |
| | | 11 | 12 | 13 | | | | *52:17 |
| | 10 | | | 13 | | | | *52:18 |
| | | | 12 | 13 | | | 16 | *52:19 |
| | | | 12 | 13 | | | | *52:20 |
| | | | 12 | 13 | | | | *52:21 |
| 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | Well No. |

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Lot No.: **39N**

Lot-specific information

| Length of spec. | 95 | 135 | 95 | 140 | 145 | 135 | 225 | 145 |
|---|----|-----|----|-----|-----|-----|-----|-----|
| PCR product(s) | | 235 | | | 190 | 180 | | |
| Well No. | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
| *07:02:01-07:02:10, 07:02:12-07:05:02, 07:05:04-07:26, 07:28-07:37, 07:39-07:49N, 07:51-07:57, 07:59-07:77, 07:79-07:83, 07:85-07:144, 08:01:01-08:01:16, 08:05, 08:07-08:08N, 08:10-08:16, 08:18-08:51, 08:53, 08:55-08:77, 08:79-08:80, 13:07N, 13:36, 13:39, 15:01:01:01-15:01:01:02N, 15:01:03-15:01:04, 15:01:06-15:02:05, 15:05:01-15:08, 15:10:01-15:12, 15:14-15:15, 15:18:01-15:19, 15:21, 15:23, 15:25:01-15:35, 15:39:01-15:40, 15:42, 15:44-15:46, 15:48-15:53, 15:55-15:58, 15:60, 15:63, 15:65-15:66, 15:70-15:82, 15:84-15:86, 15:88-15:90, 15:92-15:94N, 15:96-15:97, 15:99, 15:101, 15:104-15:122, 15:124-15:126, 15:128-15:129, 15:133-15:136, 15:138-15:150, 15:152-15:154, 15:159-15:161, 15:163-15:167, 15:169-15:172, 15:174-15:176, 15:178-15:195, 15:197-15:201, 15:203-15:207, 15:209N, 15:211-15:215, 15:217-15:219, 15:221, 15:223-15:225, 15:227, 15:229, 15:231-15:234, 15:236-15:237, 18:04, 18:07:01-18:07:02, 18:29, 18:33, 27:01-27:04:02, 27:05:02-27:21, 27:24-27:28, 27:30-27:80, 27:82-27:86, 35:31, 35:43:01, 35:57, 35:60, 35:79, 35:87, 35:43:02, 38:01:01-38:02:03, 38:04-38:05, 38:08-38:37, 39:01:01:01-39:01:01:02L, 39:01:03-39:01:12, 39:03-39:05:02, 39:07, 39:09-39:12, 39:14-39:20, 39:22, 39:24:01-39:28, 39:30-39:32, 39:35-39:38Q, 39:40N-39:45, 39:47-39:48, 39:51-39:56, 39:58-39:61, 39:63, 39:65-39:68, 40:01:01-40:01:05, 40:01:07-40:05, 40:07-40:11:02, 40:14:01-40:16, 40:18, 40:20-40:25, 40:27:01-40:27:02, 40:29-40:40, 40:42-40:43, 40:45-40:46, 40:48-40:50, 40:52, 40:54-40:69, 40:71-40:74, 40:76-40:82, 40:84-40:85, 40:87:01-40:92, 40:94, 40:97-40:102, 40:104-40:108, 40:111-40:116, 40:118N-40:126, 40:128-40:130, 40:132-40:147, 40:150-40:156, 40:158, 40:160, 40:163-40:164, 40:166, 40:168-40:173, 40:175-40:176, 40:178-40:180, 41:01-41:19, 42:01:01-42:02, 42:05:01-42:10, 42:12-42:16, 44:09, 44:12-44:13, 44:46, 44:67, 44:69, 44:75, 44:90, 44:97, 44:113, 44:127, 44:129, 44:131, 45:01, 45:03-45:08, 45:11-45:13, 46:01:01-46:30, 47:02, 48:06, 50:01:01-50:02, 50:04-50:08, 50:10-50:13, 50:15, 54:01:01-54:13, 54:16-54:24, 55:01:01-55:01:03, 55:01:05-55:05, 55:07-55:08, 55:10-55:12, 55:14-55:19, 55:21, 55:25-55:26, 55:28-55:54, 56:01:01-56:04, 56:07-56:12, 56:14-56:20:02, 56:23-56:32, 57:12, 57:16, 57:45, 57:51, 58:11, 58:20, 67:01:01-67:03, 81:01-81:02, 81:04N-81:05, 82:01-82:03 | | | | | | | | |
| Well No. | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |

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Lot-specific information

| 100 | 95 | 85 | 85 | 165 | 165 | 95 | 160 | Length of spec. PCR product(s) | | | | | | | | |
|-----|-----|-----|----|-----|-----|-----|-----|---|--|--|--|--|--|--|--|--|
| 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | Well No. | | | | | | | | |
| | 245 | 225 | | | | 170 | 215 | | | | | | | | | |
| | | | | | 14 | | | *07:02:01-07:02:10, 07:02:12-07:05:02, 07:05:04-07:26, 07:28-07:37, 07:39-07:49N, 07:51-07:57, 07:59-07:77, 07:79-07:83, 07:85-07:144, 08:01:01-08:01:16, 08:05, 08:07-08:08N, 08:10-08:16, 08:18-08:51, 08:53, 08:55-08:77, 08:79-08:80, 13:07N, 13:36, 13:39, 15:01:01:01-15:01:01:02N, 15:01:03-15:01:04, 15:01:06-15:02:05, 15:05:01-15:08, 15:10:01-15:12, 15:14-15:15, 15:18:01-15:19, 15:21, 15:23, 15:25:01-15:35, 15:39:01-15:40, 15:42, 15:44-15:46, 15:48-15:53, 15:55-15:58, 15:60, 15:63, 15:65-15:66, 15:70-15:82, 15:84-15:86, 15:88-15:90, 15:92-15:94N, 15:96-15:97, 15:99, 15:101, 15:104-15:122, 15:124-15:126, 15:128-15:129, 15:133-15:136, 15:138-15:150, 15:152-15:154, 15:159-15:161, 15:163-15:167, 15:169-15:172, 15:174-15:176, 15:178-15:195, 15:197-15:201, 15:203-15:207, 15:209N, 15:211-15:215, 15:217-15:219, 15:221, 15:223-15:225, 15:227, 15:229, 15:231-15:234, 15:236-15:237, 18:04, 18:07:01-18:07:02, 18:29, 18:33, 27:01-27:04:02, 27:05:02-27:21, 27:24-27:28, 27:30-27:80, 27:82-27:86, 35:31, 35:43:01, 35:57, 35:60, 35:79, 35:87, 35:43:02, 38:01:01-38:02:03, 38:04-38:05, 38:08-38:37, 39:01:01:01-39:01:01:02L, 39:01:03-39:01:12, 39:03-39:05:02, 39:07, 39:09-39:12, 39:14-39:20, 39:22, 39:24:01-39:28, 39:30-39:32, 39:35-39:38Q, 39:40N-39:45, 39:47-39:48, 39:51-39:56, 39:58-39:61, 39:63, 39:65-39:68, 40:01:01-40:01:05, 40:01:07-40:05, 40:07-40:11:02, 40:14:01-40:16, 40:18, 40:20-40:25, 40:27:01-40:27:02, 40:29-40:40, 40:42-40:43, 40:45-40:46, 40:48-40:50, 40:52, 40:54-40:69, 40:71-40:74, 40:76-40:82, 40:84-40:85, 40:87:01-40:92, 40:94, 40:97-40:102, 40:104-40:108, 40:111-40:116, 40:118N-40:126, 40:128-40:130, 40:132-40:147, 40:150-40:156, 40:158, 40:160, 40:163-40:164, 40:166, 40:168-40:173, 40:175-40:176, 40:178-40:180, 41:01-41:19, 42:01:01-42:02, 42:05:01-42:10, 42:12-42:16, 44:09, 44:12-44:13, 44:46, 44:67, 44:69, 44:75, 44:90, 44:97, 44:113, 44:127, 44:129, 44:131, 45:01, 45:03-45:08, 45:11-45:13, 46:01:01-46:30, 47:02, 48:06, 50:01:01-50:02, 50:04-50:08, 50:10-50:13, 50:15, 54:01:01-54:13, 54:16-54:24, 55:01:01-55:01:03, 55:01:05-55:05, 55:07-55:08, 55:10-55:12, 55:14-55:19, 55:21, 55:25-55:26, 55:28-55:54, 56:01:01-56:04, 56:07-56:12, 56:14-56:20:02, 56:23-56:32, 57:12, 57:16, 57:45, 57:51, 58:11, 58:20, 67:01:01-67:03, 81:01-81:02, 81:04N-81:05, 82:01-82:03 | | | | | | | | |
| 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | Well No. | | | | | | | | |

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 101.562-06u – without *Taq* polymerase, IFU-02 Rev. No. 03

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Lot No.: **39N**

Lot-specific information

| Length of spec. | 95 | 135 | 95 | 140 | 145 | 135 | 225 | 145 |
|---|----|-----|----|-----|-----|-----|-----|-----|
| PCR product(s) | | 235 | | | 190 | 180 | | |
| Well No. | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
| *07:02:11, 07:05:03, 15:01:02, 15:09, 27:04:03, 40:26, 50:14, 55:01:04 | | | | | 5 | | | |
| *07:27, 07:50, 08:04, 08:17, 08:54, 15:03:01-15:04, 15:47, 15:54, 15:61-15:62, 15:64, 15:68-15:69, 15:91, 15:98, 15:103, 15:123, 15:127, 15:131-15:132, 15:151, 15:155-15:156, 15:158, 15:173, 15:210, 15:220, 15:226N, 15:235, 15:238, 18:01:01-18:03, 18:05-18:06, 18:08, 18:10-18:11, 18:13-18:14, 18:17N-18:18, 18:20-18:28, 18:31-18:32, 18:34-18:56, 18:58-18:68, 37:08, 39:02:01-39:02:02, 39:08, 39:13:01-39:13:02, 39:23, 39:29, 39:39, 39:49, 40:12, 40:149, 42:11, 45:09, 48:01:01-48:01:03, 48:03:01-48:05, 48:07-48:17, 48:19-48:27, 54:14-54:15, 55:23, 55:27 | | | | | | | | |
| *07:38, 08:02-08:03, 08:78, 27:23, 38:06-38:07, 40:13, 44:06, 51:42, 59:01:01:01-59:02, 59:04-59:05 | | | | | | | | |
| *07:78, 13:09, 13:19, 27:81, 40:06:01:01-40:06:04, 40:53, 40:70, 40:75, 40:83, 40:93, 40:103, 40:127, 40:131, 40:148, 40:161-40:162, 40:165, 40:167, 40:177, 45:10, 55:09, 55:22, 55:24 | | | | | | | | |
| *07:84, 40:44, 40:159 | | | | | | | | |
| *08:09, 15:83, 42:04, 55:20, 56:13 | | | | | | | | |
| *08:52 | | 2 | | | | | | |
| *13:01:01-13:01:06, 13:03, 13:06, 13:10-13:13, 13:17, 13:20-13:23, 13:25-13:26, 13:28-13:29, 13:43, 13:48, 13:50-13:52, 15:36, 15:43, 27:29, 40:19, 40:47, 40:117, 40:157, 44:02:01:01-44:05:03, 44:07-44:08, 44:10-44:11, 44:14-44:19N, 44:21-44:45, 44:48-44:61N, 44:63-44:65, 44:68, 44:70-44:74, 44:76-44:82, 44:84-44:89, 44:91-44:96, 44:98-44:99, 44:101-44:112, 44:114-44:117, 44:119-44:126, 44:128, 44:132-44:133, 44:135-44:139, 47:01:01:01-47:01:02, 47:03-47:08, 49:01:01-49:02, 49:06, 49:08, 49:10-49:17, 49:19N-49:20 | | | | | | | | |
| *13:02:01-13:02:12, 13:08Q, 13:14-13:16, 13:18, 13:27, 13:30-13:34, 13:37-13:38, 13:40-13:42, 13:44-13:45, 13:47, 13:49N, 40:96, 40:109-40:110, 49:07 | | | | | | | | |
| *13:04, 37:01:06, 37:06, 37:28, 38:03, 44:47, 44:100, 44:130, 48:18, 49:04-49:05 | | | | | | | | |
| *13:35 | | | | | | | | |
| *13:46 | | | | | | | | |
| *14:01:01-14:28, 15:37-15:38:02, 40:28, 40:51, 40:174, 56:06 | 1 | | | | | | | |
| *13:46 | | | | | | | | |
| *14:01:01-14:28, 15:37-15:38:02, 40:28, 40:51, 40:174, 56:06 | 1 | | | | | | | |
| Well No. | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |

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 101.562-06u – without *Taq* polymerase, IFU-02 Rev. No. 03

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Lot No.: **39N**

Lot-specific information

| 100 | 95 | 85 | 85 | 165 | 165 | 95 | 160 | Length of spec. PCR product(s) |
|-----|-----|-----|----|-----|-----|-----|-----|---|
| 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | Well No. |
| | 245 | 225 | | | | 170 | 215 | |
| | | | | | 14 | | | *07:02:11, 07:05:03, 15:01:02, 15:09, 27:04:03, 40:26, 50:14, 55:01:04 |
| | | | | | 14 | 15 | | *07:27, 07:50, 08:04, 08:17, 08:54, 15:03:01-15:04, 15:47, 15:54, 15:61-15:62, 15:64, 15:68-15:69, 15:91, 15:98, 15:103, 15:123, 15:127, 15:131-15:132, 15:151, 15:155-15:156, 15:158, 15:173, 15:210, 15:220, 15:226N, 15:235, 15:238, 18:01:01-18:03, 18:05-18:06, 18:08, 18:10-18:11, 18:13-18:14, 18:17N-18:18, 18:20-18:28, 18:31-18:32, 18:34-18:56, 18:58-18:68, 37:08, 39:02:01-39:02:02, 39:08, 39:13:01-39:13:02, 39:23, 39:29, 39:39, 39:49, 40:12, 40:149, 42:11, 45:09, 48:01:01-48:01:03, 48:03:01-48:05, 48:07-48:17, 48:19-48:27, 54:14-54:15, 55:23, 55:27 |
| | | 11 | | | 14 | | | *07:38, 08:02-08:03, 08:78, 27:23, 38:06-38:07, 40:13, 44:06, 51:42, 59:01:01:01-59:02, 59:04-59:05 |
| | 10 | | | | 14 | | | *07:78, 13:09, 13:19, 27:81, 40:06:01:01-40:06:04, 40:53, 40:70, 40:75, 40:83, 40:93, 40:103, 40:127, 40:131, 40:148, 40:161-40:162, 40:165, 40:167, 40:177, 45:10, 55:09, 55:22, 55:24 |
| | 10 | | | | 14 | 15 | | *07:84, 40:44, 40:159 |
| | | | | | 14 | | 16 | *08:09, 15:83, 42:04, 55:20, 56:13 |
| | | 11 | | | 14 | | | *08:52 |
| | | | 12 | | 14 | | | *13:01:01-13:01:06, 13:03, 13:06, 13:10-13:13, 13:17, 13:20-13:23, 13:25-13:26, 13:28-13:29, 13:43, 13:48, 13:50-13:52, 15:36, 15:43, 27:29, 40:19, 40:47, 40:117, 40:157, 44:02:01:01-44:05:03, 44:07-44:08, 44:10-44:11, 44:14-44:19N, 44:21-44:45, 44:48-44:61N, 44:63-44:65, 44:68, 44:70-44:74, 44:76-44:82, 44:84-44:89, 44:91-44:96, 44:98-44:99, 44:101-44:112, 44:114-44:117, 44:119-44:126, 44:128, 44:132-44:133, 44:135-44:139, 47:01:01:01-47:01:02, 47:03-47:08, 49:01:01-49:02, 49:06, 49:08, 49:10-49:17, 49:19N-49:20 |
| | 10 | | 12 | | 14 | | | *13:02:01-13:02:12, 13:08Q, 13:14-13:16, 13:18, 13:27, 13:30-13:34, 13:37-13:38, 13:40-13:42, 13:44-13:45, 13:47, 13:49N, 40:96, 40:109-40:110, 49:07 |
| | | | 12 | | 14 | 15 | | *13:04, 37:01:06, 37:06, 37:28, 38:03, 44:47, 44:100, 44:130, 48:18, 49:04-49:05 |
| | 10 | | 12 | | 14 | 15 | | *13:35 |
| 9 | | | 12 | | 14 | | 16 | *13:46 |
| | | | | | 14 | | | *14:01:01-14:28, 15:37-15:38:02, 40:28, 40:51, 40:174, 56:06 |
| 9 | | | 12 | | 14 | | 16 | *13:46 |
| | | | | | 14 | | | *14:01:01-14:28, 15:37-15:38:02, 40:28, 40:51, 40:174, 56:06 |
| 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | Well No. |

101.562-06 – including *Taq* polymerase, IFU-01 Rev. No. 03
 101.562-06u – without *Taq* polymerase, IFU-02 Rev. No. 03

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Lot No.: **39N**

Lot-specific information

| Length of spec. | 95 | 135 | 95 | 140 | 145 | 135 | 225 | 145 |
|--|----|-----|----|-----|-----|-----|-----|-----|
| PCR product(s) | | 235 | | | 190 | 180 | | |
| Well No. | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
| *15:13:01-15:13:02, 15:17:01:01-15:17:02, 15:162, 15:168, 15:177, 15:196, 15:208, 15:216, 15:230, 57:01:01-57:01:10, 57:01:12-57:11, 57:13-57:15, 57:17-57:44, 57:46-57:50, 57:52 | | | | 4 | | | | |
| *15:16:01-15:16:03, 15:67, 15:95, 15:222 | | | | 4 | | | | |
| *15:20, 15:228, 35:01:01:01-35:01:07, 35:01:09, 35:01:11-35:01:14, 35:01:16-35:01:27, 35:01:29-35:04:01, 35:04:03-35:09:03, 35:11:01-35:12:03, 35:14:01-35:15, 35:17-35:20:02, 35:22-35:27, 35:29-35:30, 35:32:01-35:34, 35:36, 35:38-35:42:02, 35:44-35:45, 35:47-35:56, 35:58-35:59, 35:61-35:68:02, 35:70-35:72, 35:74-35:78, 35:81-35:86, 35:88-35:95, 35:97, 35:99-35:184, 35:186, 58:01:01-58:02, 58:04-58:07, 58:09-58:10N, 58:12-58:19, 58:21-58:35, 81:03 | | | | | | | | |
| *15:24, 15:157 | | | | 4 | | | | |
| *15:87 | | 2 | | 4 | | | | |
| *15:137, 39:06:01-39:06:02, 39:33-39:34, 39:57, 39:62, 39:64, 45:02, 50:09, 55:13, 56:22 | | | | | | | | |
| *15:202 | | | 3 | | | | | |
| *18:09 | | | | | | | | 8 |
| *18:12, 37:05, 37:11 | | | 3 | | | | | |
| *18:15, 18:19, 18:30, 18:57 | 1 | | | | | | | |
| *35:01:08, 35:01:15 | | | | | | | | |
| *35:01:10, 35:04:02, 78:04 | | | | | 5 | 6 | | |
| *35:10, 35:13, 35:16, 35:28, 35:69, 35:80 | | | 3 | | | | | |
| *35:21, 51:01:17, 51:07:01-51:07:02, 51:22, 51:118N, 56:05:01-56:05:02, 56:21, 58:08:01-58:08:02, 78:01:01-78:03, 78:07 | 1 | | | | | | | |
| *35:35, 35:46, 35:98, 48:02:02 | | | | | | | | |
| *35:37, 48:02:01 | | | | | | | | |
| *35:96 | 1 | | | | | | | |
| *37:01:01-37:01:05, 37:01:07-37:04:02, 37:07, 37:09, 37:12-37:20, 37:23-37:25, 37:27, 37:29-37:31 | | | 3 | | | | | |
| *37:10 | | | 3 | | | | | 8 |
| *37:21 | | | 3 | | | | | |
| *37:22, 37:26, 49:03 | | | 3 | | | | | |
| *39:50, 40:86 | | | | | | | | |
| *40:01:06 | | | | | 5 | 6 | | |
| *40:95 | | | | | 5 | | | |
| *44:20 | | | | | | | | |
| *44:62 | | | | | 5 | w | | |
| *44:66, 44:118 | | | | | | | | |
| *44:83, 44:134 | | | 3 | | | | | 8 |
| *49:09 | 1 | | | | | | | |
| Well No. | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |

101.562-06 – including *Taq* polymerase, IFU-01 Rev. No. 03
 101.562-06u – without *Taq* polymerase, IFU-02 Rev. No. 03

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Lot No.: **39N**

Lot-specific information

| 100 | 95 | 85 | 85 | 165 | 165 | 95 | 160 | Length of spec. PCR product(s) |
|-----|-----|-----|----|-----|-----|-----|-----|---|
| 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | Well No. |
| | 245 | 225 | | | | 170 | 215 | |
| | | | | | 14 | | | *15:13:01-15:13:02, 15:17:01:01-15:17:02, 15:162, 15:168, 15:177, 15:196, 15:208, 15:216, 15:230, 57:01:01-57:01:10, 57:01:12-57:11, 57:13-57:15, 57:17-57:44, 57:46-57:50, 57:52 |
| | | | | | 14 | 15 | | *15:16:01-15:16:03, 15:67, 15:95, 15:222 |
| | | | | 13 | | | | *15:20, 15:228, 35:01:01:01-35:01:07, 35:01:09, 35:01:11- 35:01:14, 35:01:16-35:01:27, 35:01:29-35:04:01, 35:04:03- 35:09:03, 35:11:01-35:12:03, 35:14:01-35:15, 35:17-35:20:02, 35:22-35:27, 35:29-35:30, 35:32:01-35:34, 35:36, 35:38- 35:42:02, 35:44-35:45, 35:47-35:56, 35:58-35:59, 35:61- 35:68:02, 35:70-35:72, 35:74-35:78, 35:81-35:86, 35:88-35:95, 35:97, 35:99-35:184, 35:186, 58:01:01-58:02, 58:04-58:07, 58:09-58:10N, 58:12-58:19, 58:21-58:35, 81:03 |
| | | | 12 | | 14 | | | *15:24, 15:157 |
| | | | 12 | | 14 | | | *15:87 |
| 9 | | | | | 14 | | | *15:137, 39:06:01-39:06:02, 39:33-39:34, 39:57, 39:62, 39:64, 45:02, 50:09, 55:13, 56:22 |
| | | | | | 14 | | | *15:202 |
| | | | | | 14 | 15 | | *18:09 |
| | | | | | 14 | 15 | | *18:12, 37:05, 37:11 |
| | | | | | 14 | 15 | | *18:15, 18:19, 18:30, 18:57 |
| 9 | | | | 13 | | | | *35:01:08, 35:01:15 |
| | | | | 13 | | | | *35:01:10, 35:04:02, 78:04 |
| | | | | 13 | | | | *35:10, 35:13, 35:16, 35:28, 35:69, 35:80 |
| | | | | 13 | | | | *35:21, 51:01:17, 51:07:01-51:07:02, 51:22, 51:118N, 56:05:01- 56:05:02, 56:21, 58:08:01-58:08:02, 78:01:01-78:03, 78:07 |
| | | | | 13 | 14 | | | *35:35, 35:46, 35:98, 48:02:02 |
| | | | | 13 | | 15 | | *35:37, 48:02:01 |
| | | | | 13 | 14 | | | *35:96 |
| | | | 12 | | 14 | 15 | | *37:01:01-37:01:05, 37:01:07-37:04:02, 37:07, 37:09, 37:12- 37:20, 37:23-37:25, 37:27, 37:29-37:31 |
| | | | 12 | | 14 | 15 | | *37:10 |
| | | 11 | | | 14 | | | *37:21 |
| | | | 12 | | 14 | | | *37:22, 37:26, 49:03 |
| 9 | 10 | | | | 14 | | | *39:50, 40:86 |
| | | | | | 14 | | | *40:01:06 |
| | 10 | | | | 14 | | | *40:95 |
| | | | 12 | | 14 | 15 | 16 | *44:20 |
| | | | 12 | | 14 | | | *44:62 |
| | | | 12 | | | | | *44:66, 44:118 |
| | | | 12 | | 14 | | | *44:83, 44:134 |
| | | | 12 | | 14 | | | *49:09 |
| 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | Well No. |

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“Instructions for Use” (IFU)Lot No.: **39N**

Lot-specific information

| Length of spec. | 95 | 135 | 95 | 140 | 145 | 135 | 225 | 145 |
|--|----|-----|----|-----|-----|-----|-----|-----|
| PCR product(s) | | 235 | | | 190 | 180 | | |
| Well No. | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
| *49:18 | | | | | 5 | | | |
| *51:01:01-51:01:16, 51:01:18-51:01:30, 51:03-51:04, 51:06:01-51:06:02, 51:11N-51:12, 51:14, 51:17-51:18, 51:21, 51:24:01-51:24:04, 51:26-51:30, 51:32-51:33, 51:35, 51:38-51:39, 51:41N, 51:43, 51:45-51:46, 51:48-51:52, 51:55-51:58, 51:60, 51:62-51:72, 51:74-51:77, 51:79-51:80, 51:83-51:89, 51:91, 51:94-51:96, 51:98N-51:103, 51:105-51:107, 51:109-51:114, 51:116-51:117, 51:119, 51:121, 51:123-51:126, 53:06 | 1 | | | | | | | |
| *51:02:01-51:02:03, 51:02:05, 51:59 | | | | | 5 | | | |
| *51:02:04, 51:15, 51:53, 51:81, 51:115, 51:120, 53:01:01-53:04, 53:07-53:08:02, 53:10, 53:14-53:15, 53:18-53:27 | | | | | | | | |
| *51:05, 51:23 | | | | | 5 | w | | |
| *51:08, 51:20, 51:44N, 51:97 | | | | | | | | |
| *51:09:01-51:09:02, 51:19, 51:73, 51:122 | | | | | | 6 | | |
| *51:10 | | | | | | | | |
| *51:13:01-51:13:02 | 1 | | | | | | | |
| *51:16, 51:82 | 1 | | | | | | | |
| *51:31 | | | | | | 6 | | |
| *51:34 | | | | | 5 | | | |
| *51:36 | | | | | 5 | | | |
| *51:37, 51:90 | 1 | | | | | | | |
| *51:40, 51:108 | | | | | 5 | 6 | | |
| *51:54 | | | | | 5 | w | | 8 |
| *51:61 | 1 | | | | 5 | | | |
| *51:78 | 1 | | | | | | | 8 |
| *51:92 | 1 | | | | | | | |
| *51:93 | | | | | 5 | 6 | | |
| *51:104 | 1 | | | 4 | | | | |
| *53:05, 53:16 | | 2 | | | | | | |
| *53:09 | | | | | | | | 8 |
| *53:11-53:13 | | | | | | | | 8 |
| *53:17:01-53:17:02 | | | 3 | | | | | |
| *57:01:11 | | | | 4 | | | | |
| *58:36 | | | | 4 | | | | |
| *59:03 | | | | | | | | |
| *73:01-73:02 | | | | | | | | |
| *78:05-78:06 | 1 | | 3 | | | | | |
| *83:01 | | | | | | | | |
| C*01:30, C*08:51, C*15:39 | 1 | | | | | | | |
| HLA-B allele | | | | | | | | |
| Well No. | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |

101.562-06 – including *Taq* polymerase, IFU-01 Rev. No. 03
 101.562-06u – without *Taq* polymerase, IFU-02 Rev. No. 03

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 “Instructions for Use” (IFU)

Lot No.: **39N**

Lot-specific information

| 100 | 95 | 85 | 85 | 165 | 165 | 95 | 160 | Length of spec. PCR product(s) |
|-----|-----|-----|----|-----|-----|-----|-----|--|
| 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | Well No. |
| | 245 | 225 | | | | 170 | 215 | |
| | | | 12 | | 14 | | | *49:18 |
| | | 11 | | 13 | | | | *51:01:01-51:01:16, 51:01:18-51:01:30, 51:03-51:04, 51:06:01-51:06:02, 51:11N-51:12, 51:14, 51:17-51:18, 51:21, 51:24:01-51:24:04, 51:26-51:30, 51:32-51:33, 51:35, 51:38-51:39, 51:41N, 51:43, 51:45-51:46, 51:48-51:52, 51:55-51:58, 51:60, 51:62-51:72, 51:74-51:77, 51:79-51:80, 51:83-51:89, 51:91, 51:94-51:96, 51:98N-51:103, 51:105-51:107, 51:109-51:114, 51:116-51:117, 51:119, 51:121, 51:123-51:126, 53:06 |
| | | 11 | | 13 | | | | *51:02:01-51:02:03, 51:02:05, 51:59 |
| | | 11 | | 13 | | | | *51:02:04, 51:15, 51:53, 51:81, 51:115, 51:120, 53:01:01-53:04, 53:07-53:08:02, 53:10, 53:14-53:15, 53:18-53:27 |
| | | 11 | | 13 | | | | *51:05, 51:23 |
| | | 11 | | 13 | | | 16 | *51:08, 51:20, 51:44N, 51:97 |
| | | 11 | | 13 | | | | *51:09:01-51:09:02, 51:19, 51:73, 51:122 |
| | 10 | 11 | | 13 | | | | *51:10 |
| 9 | | 11 | | 13 | | | | *51:13:01-51:13:02 |
| | 10 | 11 | | 13 | | | | *51:16, 51:82 |
| | 10 | 11 | | 13 | | | | *51:31 |
| | 10 | 11 | | 13 | | | | *51:34 |
| | | 11 | | 13 | | | 16 | *51:36 |
| | | 11 | | 13 | | 15 | | *51:37, 51:90 |
| | | 11 | | 13 | | | | *51:40, 51:108 |
| | | 11 | | 13 | | | | *51:54 |
| | | 11 | | 13 | | | | *51:61 |
| | | 11 | | 13 | | | | *51:78 |
| 9 | | 11 | | 13 | | 15 | | *51:92 |
| | 10 | 11 | | 13 | | | | *51:93 |
| | | 11 | | 13 | | | | *51:104 |
| | | 11 | | 13 | | | | *53:05, 53:16 |
| | | | | 13 | | | | *53:09 |
| | | 11 | | 13 | | | | *53:11-53:13 |
| | | | 12 | 13 | | | | *53:17:01-53:17:02 |
| | | | | 13 | | | | *57:01:11 |
| | | | | 13 | | | | *58:36 |
| 9 | | 11 | | | 14 | | | *59:03 |
| 9 | 10 | | | | | | | *73:01-73:02 |
| | | | | 13 | | | | *78:05-78:06 |
| | | | | ? | ? | | | *83:01 |
| | | | | | | | | C*01:30, C*08:51, C*15:39 |
| | | | | | | | | HLA-B allele |
| 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | Well No. |

101.562-06 – including **Taq** polymerase, IFU-01 Rev. No. 03
 101.562-06u – without **Taq** polymerase, IFU-02 Rev. No. 03

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Lot No.: 39N

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*52 SSP subtyping.

In addition, wells number 7, 9, 13 and 15 contain the primer pair giving rise to the shorter, 800 bp, internal positive control band in order to allow kit identification.

²The nucleotide position, in the 2nd, 3rd or 4th, exon, matching the specificity-determining 3'-end of the primer is given. Nucleotide numbering as on the www.ebi.ac.uk/imgt/hla web site. The sequence of the 3 terminal nucleotides of the primer is given.

³The nucleotide position, in the 2nd, 3rd or 4th 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*52 alleles in bold lettering are listed as confirmed alleles on the IMGT/HLA web page www.ebi.ac.uk/imgt/hla, release 3.7.0, January 2012.

⁵The B*52:04 and B*52:09 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 2.

⁶Primer mix 2: Specific PCR fragment of 135 bp in the B*52:04 allele. Specific PCR fragment of 235 bp in the B*52:09 and in the B*08:52, 15:87, 53:05 and 53:16 alleles.

Primer mix 5: Specific PCR fragment of 145 bp in the B*52:21 and in the B*15:01:02 and 51:61 alleles. Specific PCR fragment of 190 bp in the B*52:03 and 52:11 and the B*07:02:11, 07:05:03, 15:01:02, 15:09, 27:04:03, 35:01:10, 35:04:02, 40:01:06, 40:26, 40:95, 44:62, 49:18, 50:14, 51:02:01-51:02:03, 51:02:05, 51:05, 51:23, 51:34, 51:36, 51:40, 51:54, 51:59, 51:93, 51:108, 55:01:04 and 78:04 alleles.

Primer mix 6: Specific PCR fragment of 135 bp in the B*52:03 and 52:10:01-52:10:02 and the B*35:01:10, 35:04:02, 40:01:06, 51:05^w, 51:09:01-51:09:02, 51:19, 51:31, 51:40, 51:54^w, 51:73, 51:93, 51:122 and 78:04 alleles. Specific PCR fragment of 180 bp in the B*52:15 and the B*44:62^w and 51:23^w alleles. Specific PCR fragment of 135 and 180 in the B*51:108 allele.

Primer mix 10: Specific PCR fragment of 95 bp in the B*52:18 allele. Specific PCR fragment of 245 bp in the B*52:08 and the B*07:78, 07:84, 13:02:01-13:02:12, 13:08Q-13:09, 13:14-13:16, 13:18-13:19, 13:27, 13:30-13:35, 13:37-13:38, 13:40-13:42, 13:44-13:45, 13:47, 13:49N, 27:81, 39:50, 40:06:01:01-40:06:04, 40:44, 40:53, 40:70, 40:75, 40:83, 40:86, 40:93, 40:95-40:96, 40:103, 40:109-40:110, 40:127, 40:131, 40:148, 40:159, 40:161-40:162, 40:165, 40:167, 40:177, 45:10, 49:07, 51:10, 51:16, 51:31, 51:34, 51:82, 51:93, 55:09, 55:22, 55:24 and 73:01-73:02 alleles.

Primer mix 11: Specific PCR fragment of 85 bp in the B*52:06:01-52:06:02 and the B*07:38, 08:02-08:03, 08:52, 08:78, 27:23, 37:21, 38:06-38:07, 40:13, 44:06, 51:01:01-51:01:16, 51:01:18-51:06:02, 51:08-51:21, 51:23-51:24:04, 51:26-51:46, 51:48-51:117, 51:119-51:126, 53:01:01-53:08:02, 53:10-53:16, 53:18-53:27 and 59:01:01:01-59:05 alleles. Specific PCR fragment of 225 bp in the B*52:17 allele.

Primer mix 15: Specific PCR fragment of 95 bp in the B*52:12 and 52:26 and the B*07:84, 13:04, 13:35, 15:04, 15:16:01-15:16:03, 15:67, 15:95, 15:155, 15:222, 35:37, 40:44, 40:159, 44:20, 44:47, 44:100, 45:09, 49:04-49:05, 51:37, 51:90, 51:92, 54:14-54:15, 55:23 and 55:27 alleles. Specific PCR fragment of 170 bp in the B*52:16 and 52:27, 07:27, 07:50, 08:04, 08:17, 08:54, 15:03:01-15:03:03, 15:47, 15:54, 15:61-15:62, 15:64, 15:68-15:69, 15:91, 15:98, 15:103, 15:123, 15:127, 15:131-15:132, 15:151, 15:156, 15:158, 15:173, 15:210, 15:220, 15:235, 18:01:01-18:03, 18:05-18:06, 18:08-18:15, 18:17N-18:28, 18:30-18:32, 18:34-18:68, 37:01:01-37:20, 37:23-37:25, 37:27-37:31, 38:03, 39:02:01-39:02:02, 39:08, 39:13:01-39:13:02, 39:23, 39:39, 39:49, 40:12, 40:149, 42:11, 44:130, 48:01:01-48:02:01, 48:03:01-48:05 and 48:07-48:27 alleles.

Primer mix 16: Specific PCR fragment of 160 bp in the B*52:13 allele. Specific PCR fragment of 215 bp in the B*52:19 and in the B*08:09, 13:46, 15:83, 42:04, 44:20, 51:08, 51:20, 51:36, 51:44N, 51:97, 55:20 and 56:13 alleles.

'?', nucleotide sequence information not available for the primer matching sequence.

'w', might be weakly amplified.

101.562-06 – including *Taq* polymerase, IFU-01 Rev. No. 03
 101.562-06u – without *Taq* polymerase, IFU-02 Rev. No. 03

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Lot No.: **39N**

Lot-specific information

| CELL LINE VALIDATION SHEET | | | | | | | | | | | | | | | | | | | | | |
|----------------------------|--------------------------|--------|--------|------------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|---|
| HLA-B*52 SSP primer set | | | | | | | | | | | | | | | | | | | | | |
| | | | | Well | | | | | | | | | | | | | | | | | |
| | | | | Prod. No.: | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | |
| | | | | | 201078001 | 201078002 | 201078003 | 201078004 | 201078005 | 201078006 | 201078007 | 201078008 | 201078009 | 201078010 | 201078011 | 201078012 | 201078013 | 201078014 | 201078015 | 201078016 | |
| IHC cell line | | B* | | | | | | | | | | | | | | | | | | | |
| 1 | 9001 SA | *07:02 | | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | + | - | - |
| 2 | 9280 LK707 | *52:01 | *73:01 | | + | - | + | - | - | - | - | - | + | + | - | + | + | - | - | - | - |
| 3 | 9011 E4181324 | *52:01 | | | + | - | + | - | - | - | - | - | - | - | - | + | + | - | - | - | - |
| 4 | 9275 GU373 | *15:10 | *53:01 | | - | - | - | - | - | - | - | - | - | - | + | - | + | + | - | - | - |
| 5 | 9009 KAS011 | *37:01 | | | - | - | + | - | - | - | - | - | - | - | - | + | - | + | + | - | - |
| 6 | 9353 SM | *39:01 | *51:01 | | + | - | - | - | - | - | - | - | - | - | + | - | + | + | - | - | - |
| 7 | 9020 QBL | *18:01 | | | - | - | - | - | - | - | - | - | - | + | - | - | - | - | + | + | - |
| 8 | 9025 DEU | *35:01 | | | - | - | - | - | - | - | - | - | - | - | - | - | - | + | - | - | - |
| 9 | 9026 YAR | *38:01 | | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | + | - | - |
| 10 | 9107 LKT3 | *54:01 | | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | + | - | - |
| 11 | 9051 PITOUT | *44:03 | | | - | - | - | - | - | - | - | - | - | - | - | - | + | - | + | - | - |
| 12 | 9052 DBB | *57:01 | | | - | - | - | + | - | - | - | - | - | - | - | - | - | - | + | - | - |
| 13 | 9025 JESTHOM | *27:05 | | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | + | - |
| 14 | 9071 OLGA | *15:01 | *15:20 | | - | - | - | - | - | - | - | - | - | - | - | - | - | + | - | - | - |
| 15 | 9075 DKB | *40:01 | | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | + | - | - |
| 16 | 9037 SWEIG007 | *40:02 | | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | + | - |
| 17 | 9282 CTM3953540 | *08:01 | *55:01 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | + | - |
| 18 | 9257 32367 | *14:01 | *56:01 | | + | - | - | - | - | - | - | - | - | - | - | - | - | - | - | + | - |
| 19 | 9038 BM16 | *18:01 | | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | + | + |
| 20 | 9059 SLE005 | *40:01 | | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | + | - |
| 21 | 9064 AMALA | *15:01 | | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | + | - |
| 22 | 9056 KOSE | *35:03 | | | - | - | - | - | - | - | - | - | - | - | - | - | - | + | - | - | - |
| 23 | 9124 IHL | *40:02 | *56:02 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | + | - |
| 24 | 9035 JBUSH | *38:01 | | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | + | - |
| 25 | 9049 IBW9 | *14:02 | | | + | - | - | - | - | - | - | - | - | - | - | - | - | - | - | + | - |
| 26 | 9285 WT49 | *58:01 | | | - | - | - | - | - | - | - | - | - | - | - | - | - | + | - | - | - |
| 27 | 9191 CH1007 ¹ | *07:05 | *51:01 | | + | - | - | - | - | - | - | - | - | - | + | - | + | + | - | - | - |
| 28 | 9320 BEL5GB | *44:02 | *44:03 | | - | - | - | - | - | - | - | - | - | - | - | - | + | - | + | - | - |
| 29 | 9050 MOU | *44:03 | | | - | - | - | - | - | - | - | - | - | - | - | + | - | + | - | - | - |
| 30 | 9021 RSH | *42:01 | | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | + | - |
| 31 | 9019 DUCAF | *18:01 | | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | + | + |
| 32 | 9297 HAG | *41:02 | | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | + | - |
| 33 | 9098 MT14B | *40:01 | | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | + | - |
| 34 | 9104 DHIF | *38:01 | | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | + | - |
| 35 | 9302 SSTO | *44:02 | | | - | - | - | - | - | - | - | - | - | - | - | + | - | + | - | - | - |
| 36 | 9024 KT17 | *15:01 | *35:01 | | - | - | - | - | - | - | - | - | - | - | - | - | + | + | - | - | - |
| 37 | 9065 HHKB | *07:02 | | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | + | - |
| 38 | 9099 LZL | *15:01 | | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | + | - |
| 39 | 9315 CML | *08:01 | *27:05 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 40 | 9134 WHONP199 | *13:02 | *46:01 | | - | - | - | - | - | - | - | - | - | + | - | + | - | + | - | - | - |
| 41 | 9055 H0301 | *14:02 | | | + | - | - | - | - | - | - | - | - | - | - | - | - | - | - | + | - |
| 42 | 9066 TAB089 | *46:01 | | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | + | - |
| 43 | 9076 T7526 | *46:01 | | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | + | - |
| 44 | 9057 TEM | *38:01 | | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | + | - |
| 45 | 9239 SHJO | *42:01 | *50:01 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | + | - |
| 46 | 9013 SCHU | *07:02 | | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | + | - |
| 47 | 9045 TUBO ¹ | *51:01 | | | + | - | - | - | - | - | - | - | - | - | + | - | + | - | - | - | - |
| 48 | 9303 TER-ND | *35:01 | *44:03 | | - | - | - | - | - | - | - | - | - | - | - | - | + | + | + | - | - |

101.562-06 – including *Taq* polymerase, IFU-01 Rev. No. 03101.562-06u – without *Taq* polymerase, IFU-02 Rev. No. 03Visit www.olerup-ssp.com for

“Instructions for Use” (IFU)

Lot No.: **39N**

Lot-specific information

CERTIFICATE OF ANALYSIS**Olerup SSP® HLA-B*52 SSP**

Product number: 101.562-06 – including *Taq* polymerase
 101.562-06u – without *Taq* polymerase

Lot number: 39N

Expiry date: 2014-August 01

Number of tests: 6

Number of wells per test: 16

Well specifications:

| Well No. | Production No. | Well No. | Production No. |
|----------|----------------|----------|----------------|
| 1 | 2010-780-01 | 9 | 2010-780-09 |
| 2 | 2010-780-02 | 10 | 2010-780-10 |
| 3 | 2010-780-03 | 11 | 2010-780-11 |
| 4 | 2010-780-04 | 12 | 2010-780-12 |
| 5 | 2010-780-05 | 13 | 2010-780-13 |
| 6 | 2010-780-06 | 14 | 2010-780-14 |
| 7 | 2010-780-07 | 15 | 2010-780-15 |
| 8 | 2010-780-08 | 16 | 2010-780-16 |

The specificity of each primer solution of has been tested against 48 well characterized IHWC cell line DNAs.

No DNAs carrying the alleles to be amplified by primer solutions 2, 6 to 8 and 16 were available. The specificities of the primers in primer solutions 2, 6, 8 and 16 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer. In primer mix 7 it was only possible to test the 3'-primer, the 5'-primer was not possible to test. In primer solutions 9, 11 and 16 one or two 5'-primers were not possible to test, and in primer solutions 2 and 10 one 3'-primer was not possible to test. Additional primers in primer solutions 5, 9, 10 and 15 were tested by separately adding one additional 5'-primer or 3'-primer.

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

Date of approval: 2012-March-22

Approved by:

Quality Control, Supervisor

101.562-06 – including *Taq* polymerase, IFU-01 Rev. No. 03
101.562-06u – without *Taq* polymerase, IFU-02 Rev. No. 03

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“Instructions for Use” (IFU)

Lot No.: **39N**

Lot-specific information

Declaration of Conformity

Product name: *Olerup* SSP® HLA-B*52
Product number: 101.562-06/06u
Lot number: 39N

Intended use: HLA-B*52 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-March-22

Ann-Cathrin Jareman
Head of QA and Regulatory Affairs

101.562-06 – including *Taq* polymerase, IFU-01 Rev. No. 03
101.562-06u – without *Taq* polymerase, IFU-02 Rev. No. 03

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Lot No.: **39N**

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“Instructions for Use” (IFU)

Lot No.: **39N**

Lot-specific information

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Tel: +46-8-717 88 27

Fax: +46-8-717 88 18

E-mail: info-ssp@olerup.com

Web page: <http://www.olerup-ssp.com>

Distributed by:

Olerup GmbH, Löwengasse 47 / 6, AT-1030 Vienna, Austria.

Tel: +43-1-710 15 00

Fax: +43-1-710 15 00 10

E-mail: support-at@olerup.com

Web page: <http://www.olerup.com>

Olerup Inc., 901 S. Bolmar St., Suite R, West Chester, PA 19382

Tel: 1-877-OLERUP1

Fax: 610-344-7989

E-mail: info.us@olerup.com

Web page: <http://www.olerup.com>

For information on *Olerup* SSP distributors worldwide, contact **Olerup GmbH**.