

101.548-06 – including *Taq* pol., IFU-01
101.548-06u – without *Taq* pol., IFU-02

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“Instructions for Use” (IFU)

Lot No.: **89R**

Lot-specific information

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Olerup SSP[®] HLA-B*50

Product number:	101.548-06 – including <i>Taq</i> polymerase 101.548-06u – without <i>Taq</i> polymerase
Lot number:	89R
Expiry date:	2015-July-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. 89R.

CHANGES COMPARED TO THE PREVIOUS *OLERUP SSP*[®] HLA-B*50 LOT (67M).

The HLA-B*50 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*50 including and without *Taq* polymerase is now described in one common Product Insert.

¹As described in section Uniquely Identified Alleles.

The HLA-B*50 specificity and interpretation tables have been updated for the HLA-B alleles described since the previous *Olerup SSP*[®] HLA-B*50 lot was made (Lot No. 67M).

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

Well	5'-primer	3'-primer	rationale
8	Added	Added	Primer pair added for the B*50:17 allele.
9	Added	Added	Primer pair from well 13.
11	-	Added	3'-primer added for the B*50:16 allele.
12	Added	-	5'-primers added for the B*50:18 and B*50:19 alleles.
13	Moved	Moved	Primer pair moved to well 9, for decreased tendencies of primer oligomer formation.
15	Added	Added	Primer pair added for the B*50:19 allele, exchanged positive control primer pair.
16	Added	Added	Primer pair added for the B*50:15 allele.

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PRODUCT DESCRIPTION

HLA-B*50 SSP typing

CONTENT

The primer set contains 5'- and 3'-primers for identifying the B*50:01 to B*50:19 alleles.

PLATE LAYOUT

Each HLA-B*50 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*50' in silver/gray ink.

Well No. 1 is marked with the Lot No. '89R'.

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*50 SSP subtypings will be influenced by three B*07, three B*08, most B*13, two B*14, several B*15, two B*18, five B*27, several B*35, the B*38:16, ten B*39, most B*40, the B*41, the B*42:04, most B*44, the B*45, three B*46, the B*47, five B*48, the B*49, most B*51, the B*52, three B*53, most B*54, most B*55, most B*56, the B*57:45, two B*58, the B*59, the B*73 and the B*78 alleles when present on the other haplotype. In addition, the A*02:339, C*03:12, C*03:19, C*03:102 and C*15:26 alleles will be amplified by primer mix 3, the C*02:02:23 will be amplified primer mix 16, and the C*03:110, C*04:08, C*04:34, C*05:27, C*05:39, C*08:41 and C*17:07 alleles will be amplified by primer mix 12.

UNIQUELY IDENTIFIED ALLELES

All the HLA-B*50, i.e. **B*50:01 to B*50:19**, recognized by the HLA Nomenclature Committee in October 2012¹ will be amplified by the primers in the HLA-B*50 SSP kit².

The HLA-B*50 kit enables separation of the confirmed HLA-B*50 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*50 alleles is listed below.

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The HLA-B*50 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*50 subtyping kit cannot distinguish the silent mutations in the B*50:01:01-50:01:02 alleles.

¹HLA-B alleles listed on the IMGT/HLA web page 2012-October-17, release 3.10.0, www.ebi.ac.uk/imgt/hla.

²The B*50:14 and 40:95 alleles will give rise to identical amplification patterns with the HLA-B*50 subtyping kit. These alleles can be distinguished by the HLA-B low resolution kit and/or the HLA-B*40 subtyping kit.

ALLELE CONFIRMATION STATUS

Allele	Status ¹	Allele	Status ¹
B*50:01:01	Confirmed	B*50:10	Confirmed
B*50:01:02	Unconfirmed	B*50:11	Confirmed
B*50:01:03	Unconfirmed	B*50:12	Confirmed
B*50:02	Confirmed	B*50:13	Unconfirmed
B*50:04	Unconfirmed	B*50:14	Unconfirmed
B*50:05	Unconfirmed	B*50:15	Unconfirmed
B*50:06	Unconfirmed	B*50:16	Unconfirmed
B*50:07	Confirmed	B*50:17	Unconfirmed
B*50:08	Confirmed	B*50:18	Unconfirmed
B*50:09	Confirmed	B*50:19	Unconfirmed

¹Allele status “confirmed” or “unconfirmed” as listed on the IMGT/HLA web page 2012-October 17, release 3.10.0, www.ebi.ac.uk/imgt/hla.

RESOLUTION IN HOMO- AND HETEROZYGOTES

A total of 20 alleles generate 18 amplification patterns that can be combined in 171 homozygous and heterozygous combinations. 128 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.

```

+-----+ *50:01:01, *50:14 = *50:01:01, *50:15 = *50:14, *50:15 = *50:15, *50:15
+-----+ *50:01:01, *50:13 = *50:13, *50:13
+-----+ *50:01:01, *50:11 = *50:11, *50:11
+-----+ *50:01:01, *50:10 = *50:10, *50:10
+-----+ *50:01:01, *50:09 = *50:01:01, *50:18 = *50:09, *50:18 = *50:18, *50:18
+-----+ *50:01:01, *50:08 = *50:01:01, *50:16 = *50:08, *50:08 = *50:08, *50:16
+-----+ *50:01:01, *50:07 = *50:07, *50:07
+-----+ *50:01:01, *50:06 = *50:01:01, *50:12 = *50:06, *50:12
+-----+ *50:01:01, *50:05 = *50:01:01, *50:17 = *50:05, *50:05 = *50:05, *50:17
+-----+ *50:01:01, *50:04 = *50:04, *50:04
+-----+ *50:13, *50:14 = *50:13, *50:15
+-----+ *50:11, *50:14 = *50:11, *50:15
+-----+ *50:10, *50:14 = *50:10, *50:15
+-----+ *50:09, *50:15 = *50:14, *50:18 = *50:15, *50:18
+-----+ *50:01:01, *50:19 = *50:09, *50:13 = *50:09, *50:19 = *50:13, *50:18 =
*50:13, *50:19 = *50:18, *50:19 = *50:19, *50:19

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+---++++- -++-+---	*50:09, *50:11 = *50:11, *50:18
+---++++- -++-+---	*50:09, *50:10 = *50:10, *50:18
+---++++- -++-+---	*50:08, *50:14 = *50:08, *50:15 = *50:15, *50:16
+---++++- -++-+---	*50:08, *50:13 = *50:13, *50:16
+---++++- -++-+---	*50:08, *50:11 = *50:11, *50:16
+---++++- -++-+---	*50:08, *50:10 = *50:10, *50:16
+---++++- -++-+---	*50:08, *50:09 = *50:08, *50:18 = *50:16, *50:18
+---++++- -++-+---	*50:07, *50:14 = *50:07, *50:15
+---++++- -++-+---	*50:07, *50:09 = *50:07, *50:18
+---++++- -++-+---	*50:07, *50:08 = *50:07, *50:16
+---++++- +-----+	*50:06, *50:14 = *50:06, *50:15 = *50:12, *50:15
+---++++- +-----+	*50:06, *50:13 = *50:12, *50:13
+---++++- +-----+	*50:06, *50:11 = *50:11, *50:12
+---++++- +-----+	*50:06, *50:10 = *50:10, *50:12
+---++++- +-----+	*50:06, *50:09 = *50:06, *50:18 = *50:12, *50:18
+---++++- +-----+	*50:06, *50:08 = *50:06, *50:16 = *50:08, *50:12
+---++++- +-----+	*50:06, *50:07 = *50:07, *50:12
+---++++- -++-+---	*50:05, *50:14 = *50:05, *50:15 = *50:15, *50:17
+---++++- -++-+---	*50:05, *50:13 = *50:13, *50:17
+---++++- -++-+---	*50:05, *50:11 = *50:11, *50:17
+---++++- -++-+---	*50:05, *50:10 = *50:10, *50:17
+---++++- -++-+---	*50:05, *50:09 = *50:05, *50:18 = *50:17, *50:18
+---++++- -++-+---	*50:05, *50:08 = *50:05, *50:16 = *50:08, *50:17
+---++++- -++-+---	*50:05, *50:07 = *50:07, *50:17
+---++++- +-----+	*50:05, *50:06 = *50:05, *50:12 = *50:06, *50:17
+---++++- -++-+---	*50:04, *50:14 = *50:04, *50:15
+---++++- -++-+---	*50:04, *50:09 = *50:04, *50:18
+---++++- -++-+---	*50:04, *50:08 = *50:04, *50:16
+---++++- +-----+	*50:04, *50:06 = *50:04, *50:12
+---++++- -++-+---	*50:04, *50:05 = *50:04, *50:17
++-++++- -++-+---	*50:02, *50:14 = *50:02, *50:15
++-++++- -++-+---	*50:02, *50:09 = *50:02, *50:18
++-++++- -++-+---	*50:02, *50:08 = *50:02, *50:16
+---++++- -++-+---	*50:14, *50:19 = *50:15, *50:19
+---++++- -++-+---	*50:08, *50:19 = *50:16, *50:19
+---++++- +-----+	*50:06, *50:19 = *50:12, *50:19
+---++++- -++-+---	*50:05, *50:19 = *50:17, *50:19

*50:01:01 = *50:01:01 - 50:01:02

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www.olerup-ssp.com**SPECIFICITY TABLE****HLA-B*50 SSP subtyping**

Specificities and sizes of the PCR products of the 16 primer mixes used for
 HLA-B*50 SSP subtyping

Primer Mix	Size of spec. PCR product ¹	Size of control band ²	Amplified HLA-B*50 alleles	Other amplified HLA Class I alleles ³
1	255 bp	800 bp	*50:01:01-50:01:03, 50:04-50:11, 50:13-50:16, 50:18-50:19	*07:78, 07:84, 08:09, 08:84, 13:02:01-13:04, 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, 13:44-13:49N, 13:53-13:56N, 13:58-13:59, 13:62, 15:04, 15:16:01-15:16:03, 15:42, 15:67, 15:83, 15:95, 15:137, 15:155, 15:222, 15:254, 27:14, 27:81, 35:37, 35:60, 39:06:01-39:06:02, 39:33-39:34, 39:50, 39:57, 39:62, 39:64, 40:06:01:01-40:06:06, 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, 40:190, 41:01, 41:05-41:07, 41:09, 41:12, 41:14, 41:16-41:17, 41:20-41:22, 41:25, 42:04, 45:04, 45:08, 45:10, 46:11, 46:18, 46:32, 49:01:01-49:19N, 49:21-49:25, 51:01:01-51:03, 51:05, 51:07:01-51:22, 51:24:01-51:24:04, 51:26-51:41N, 51:43-51:44N, 51:48-51:55, 51:57-51:58, 51:60-51:61:02, 51:63, 51:65-51:69, 51:71-51:80, 51:82-51:107, 51:109-51:134, 51:136-51:138, 51:140-51:147, 52:01:01:01-52:14, 52:16-52:31, 54:01:01-54:05N, 54:07-54:08N, 54:10-54:28, 55:01:01-55:01:06, 55:01:08-55:03, 55:05, 55:07, 55:09-55:13, 55:15-55:48, 55:50, 55:52-55:57, 56:01:01-56:01:04, 56:05:01-56:08, 56:13-56:17, 56:19N-56:30, 56:33-56:38N, 58:08:01-58:08:02, 59:01:01:01-59:05, 73:01-73:02, 78:01:01-78:07
2	255 bp	1070 bp	*50:02	*44:15, 44:18, 44:20, 44:47, 44:100, 45:01-45:03, 45:05-45:07, 45:09, 45:11-45:14, 49:20, 51:23, 51:108, 52:15
3^{4,5}	80 bp	800 bp	*50:04	*15:18:03, 15:73, 15:224, 39:17, 40:48, 40:71, 44:140, 51:62, 56:04, A*02:339, C*03:12, C*03:19, C*03:102, C*15:26

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4⁴	105 bp	1070 bp	*50:01:01-50:02, 50:04-50:08, 50:10-50:11, 50:13, 50:15, 50:18-50:19	*07:78, 13:02:01-13:02:14, 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, 13:48-13:49N, 13:53-13:56N, 13:58, 15:42, 35:60, 44:15, 44:18, 45:01, 45:03-45:08, 45:10-45:14, 46:11, 46:18, 49:01:01-49:03, 49:06-49:17, 49:19N-49:25, 51:15, 52:25, 54:01:01-54:03, 54:05N, 54:07-54:08N, 54:10, 54:12-54:13, 54:16-54:28, 55:01:01-55:01:06, 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, 55:54-55:57, 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, 56:33-56:38N, 59:01:01:01-59:01:01:02, 59:04-59:05
5	145 bp	1070 bp	*50:01:01-50:02, 50:04-50:05, 50:07-50:19	*07:133, 15:46, 15:53, 15:106, 15:143, 15:212, 18:48, 35:19, 35:47, 35:63, 35:154, 35:217, 39:69, 40:01:01-40:11:02, 40:14:01-40:16, 40:18, 40:20, 40:22N-40:40, 40:42-40:45, 40:48-40:75, 40:77-40:92, 40:94-40:95, 40:97-40:108, 40:111-40:116, 40:118N-40:136, 40:138-40:156, 40:158-40:184, 40:186-40:187, 40:189-40:200, 40:202-40:207, 40:210-40:226, 41:01-41:04, 41:06-41:25, 44:09, 44:46, 44:75, 44:90, 44:129, 44:131, 45:01-45:14, 47:02, 47:03 ^w
6⁶	160 bp	1070 bp	*50:01:01-50:02, 50:04-50:08, 50:10-50:13, 50:15-50:19	*13:01:01-13:03, 13:06-13:09, 13:11-13:12, 13:14-13:17, 13:19-13:20, 13:22:01-13:23, 13:25, 13:27-13:30, 13:32-13:34, 13:36-13:40, 13:42-13:45, 13:47-13:50, 13:52-13:58, 13:60-13:61, 13:63N, 15:42, 15:86, 15:224, 35:60, 39:17, 40:48, 40:71, 44:10, 46:11, 46:18, 49:01:01-49:03, 49:06-49:17, 49:19N-49:25, 51:15, 51:62, 51:106, 52:25, 54:01:01-54:03, 54:05N, 54:07-54:08N, 54:12-54:13, 54:17-54:19, 54:21-54:28, 55:01:01-55:03, 55:05, 55:07, 55:10-55:12, 55:15-55:16, 55:18-55:19, 55:22, 55:24-55:26, 55:29-55:31, 55:33-55:36, 55:38-55:45, 55:47-55:48, 55:50, 55:53-55:55N, 55:57, 56:01:01-56:02, 56:04, 56:07-56:08, 56:10, 56:14, 56:16-56:17, 56:19N-56:20:02, 56:23-56:30, 56:33-56:38N, 59:01:01:01-59:01:01:02, 59:04-59:05

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7	150 bp	1070 bp	*50:01:01- 50:01:02, 50:01:03 ^W , 50:02, 50:04- 50:08, 50:10- 50:13, 50:15- 50:19	*07:78 ^W , 13:16 ^W , 13:20 ^W , 13:48 ^W , 15:42 ^W , 49:01:01, 49:01:03-49:03, 49:06-49:10, 49:12-49:17, 49:19N-49:25, 51:62 ^W , 51:106 ^W , 52:25 ^W , 54:20 ^W , 55:01:01 ^W -55:01:10 ^W , 55:03 ^W , 55:05 ^W , 55:09 ^W , 55:11 ^W , 55:15 ^W , 55:24 ^W - 55:25 ^W , 55:29 ^W , 55:31 ^W , 55:33 ^W , 55:36 ^W , 55:38 ^W , 55:40 ^W , 55:44 ^W -55:45 ^W , 55:52 ^W - 55:55N ^W , 56:25 ^W , 56:37 ^W
8⁷	135 bp, 365 bp, 540 bp	1070 bp	*50:05, 50:17	*13:01:01-13:01:06, 13:06, 13:12-13:13, 13:17, 13:20, 13:22:01-13:23, 13:25-13:26, 13:28-13:29, 13:39, 13:43, 13:50-13:52, 13:57, 13:60-13:61, 13:63N, 15:20, 15:25:01, 15:25:03, 15:36, 15:62, 15:85, 15:106, 15:204, 15:240, 15:250, 35:28, 35:50, 35:63, 35:84, 35:162, 35:217, 40:04, 40:28, 40:59, 40:64, 40:68, 40:120, 40:129, 40:137, 40:160:02, 44:02:07, 44:03:02, 44:03:13, 44:03:19, 44:07, 44:28:01, 44:37:02, 44:43:02, 44:48, 44:64:01, 44:124, 44:128, 44:143, 48:02:01-48:02:03, 48:17, 48:25, 53:17:02, 53:28
9^{4,8}	105 bp, 150 bp	800 bp	*50:06, 50:12	*40:208
10⁴	90 bp	800 bp	*50:07	*40:83, 40:170, 44:07
11^{4,9}	105 bp, 280 bp	1070 bp	*50:08, 50:16	*54:28
12¹⁰	145 bp, 180 bp	1070 bp	*50:09, 50:18-50:19	*14:19, 14:27, 15:137, 45:02, 51:107, 53:07, C*03:110, C*04:08, C*04:34, C*05:27, C*05:39, C*08:41, C*17:07
13	270 bp	800 bp	*50:10	
14	300 bp	1070 bp	*50:11	
15	135 bp	800 bp	*50:13, 50:19	*15:46, 15:53, 15:106, 35:47, 35:154, 40:10:01-40:10:02, 40:40, 40:49, 40:58, 40:110, 40:129, 40:164, 40:210, 40:219, 44:02:01:01-44:03:15, 44:03:17-44:05:04, 44:09-44:14, 44:16-44:17, 44:19N-44:39, 44:41:01-44:43:02, 44:45-44:48, 44:50-44:54, 44:56N, 44:58N-44:59:02, 44:61N-44:80, 44:82, 44:84-44:102, 44:104-44:110, 44:112- 44:129, 44:132-44:133, 44:135-44:144, 44:146-44:155, 44:157-44:165, 47:01:01:01- 47:08, 49:10, 49:24, 57:45
16^{4,11}	95 bp, 160 bp, 580 bp	1070 bp	*50:14-50:15	*08:102, 13:36, 13:62, 18:80, 27:04:03, 27:23, 27:92, 35:01:10, 35:04:02, 35:84, 35:90, 35:150, 35:184, 35:201, 35:217,

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38:16, 40:01:06, 40:08, 40:25-40:26, 40:28,
 40:68, 40:95, 40:106, 40:166^W, 44:12, 44:62,
 49:18, 51:56:01-51:56:02, 51:103, 51:119,
 53:28, 55:01:04, 56:36^W, 73:01^W-73:02^W,
C*02:02:23

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*50 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.

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*50 SSP subtyping. In addition, wells number 3, 9, 10, 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.

³Due to the sharing of sequence motifs between HLA-B alleles non-HLA-B*50 alleles will be amplified by primer mixes 1 to 12, 15 and 16. In addition, the A*02:339, C*03:12, C*03:19, C*03:102 and C*15:26 alleles will be amplified by primer mix 3, the C*02:02:23 will be amplified primer mix 16, and the C*03:110, C*04:08, C*04:34, C*05:27, C*05:39, C*08:41 and C*17:07 alleles will be amplified by primer mix 12.

⁴HLA-specific PCR products shorter than 125 base pairs have a lower intensity and are less sharp than longer PCR products.

⁵Primer mix 3 has a tendency of giving rise to primer oligomer formation.

⁶Primer mix 6 may give rise to a lower yield of HLA-specific PCR product than the other B*50 primer mixes.

⁷Primer mix 8: Specific PCR fragment of 135 bp in the B*50:05 allele. Specific PCR fragment of 365 bp in the B*13:01:01-13:01:06, 13:06, 13:12-13:13, 13:17, 13:20, 13:22:01-13:22:02, 13:25-13:26, 13:28-13:29, 13:39, 13:43, 13:50-13:52, 13:57, 13:60-13:61, 13:63N, 15:20, 15:25:01, 15:25:03, 15:36, 15:62, 15:85, 15:106, 15:240, 15:250, 35:28, 40:129, 40:137, 40:160:02, 44:02:07, 44:03:02, 44:03:13, 44:03:19, 44:07, 44:28:01, 44:37:02, 44:43:02, 44:48, 44:64:01, 44:124, 44:128, 44:143, 48:02:01-48:02:03, 48:17, 48:25, 53:17:02 and 53:28 alleles. Specific PCR fragment of 540 bp in the B*35:50, 35:84, 35:162, 35:217, 40:68 and 40:160:02 alleles. Specific PCR fragments of 365 and 540 bp in the B*50:17 and the B*13:23, 15:204, 35:63, 40:04, 40:28, 40:59, 40:64 and 40:120 alleles.

⁸Primer mix 9: Specific PCR fragment of 105 bp in the B*50:12 allele. Specific PCR fragment of 150 bp in the B*50:06 and the B*40:208 alleles.

⁹Primer mix 11: Specific PCR fragment of 105 bp in the B*50:16 allele. Specific PCR fragment of 280 bp in the B*50:08 and the B*54:28 alleles.

101.548-06 – including *Taq* pol., IFU-01
101.548-06u – without *Taq* pol., IFU-02

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¹⁰Primer mix 12: Specific PCR fragment of 145 bp in the B*50:18 and 50:19 and in the B*51:107 and the C*03:110 alleles. Specific PCR fragment of 180 bp in the B*50:09 and in the B*14:19, 14:27, 15:137, 45:02 and 53:07 and the C*04:08, C*04:34, C*05:27, C*05:39, C*08:41 and C*17:07 alleles.

¹¹Primer mix 16: Specific PCR fragment of 95 bp in the B*35:01:10, 35:04:02, 51:56:01-51:56:02, 53:28 and 55:01:04 and the C*02:02:23 alleles. Specific PCR fragment of 160 bp in the B*50:15 and the B*08:102, 13:36, 18:80, 27:23, 27:92, 35:84, 35:90, 35:150, 35:184, 35:201, 35:217, 38:16, 40:08, 40:25, 40:68, 40:106, 40:166w, 44:12, 56:36^w and 73:01^w-73:02^w alleles. Specific PCR fragment of 580 bp in the B*13:62, 27:04:03, 40:01:06, 40:26, 40:95 and 44:62, alleles. Specific PCR fragment of 95 and 580 bp in the B*50:14 and the B*40:28, 49:18, 51:103 and 51:119 alleles.

'w', may be weakly amplified.

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Lot-specific information

www.olerup-ssp.com**INTERPRETATION TABLE****HLA-B*50 SSP subtyping**

Amplification patterns of the B*50:01 to B*50:19 alleles

	Well ⁷							
	1	2	3	4	5	6	7	8
Length of spec. PCR product(s)	255	255	80	105	145	160	150	135
								365
								540
Length of int. pos. control ¹	800	1070	800	1070	1070	1070	1070	1070
5'-primer ²	357	357	379	357	206	420	420	97
	5'-Tgg 3'	5'-Tgg 3'	5'-ACg 3'	5'-Tgg 3'	5'-gAA 3'	5'-TTA 3'	5'-TTA 3'	5'-TCC 3'
								272
								5'-CTC 3'
3'-primer ³	572	572	420	420	311	538	527	191
	5'-gCC 3'	5'-gCg 3'	5'-gCT 3'	5'-gCT 3'	5'-ggT 3'	5'-CAg 3'	5'-CCT 3'	5'-TgA 3'
								353
								5'-TgA 3'
HLA-B allele ^{4,5}								
Well No.	1	2	3	4	5	6	7	8
*50:01:01-50:01:02	1			4	5	6	7	
*50:01:03	1			4	5	6	w	
*50:02		2		4	5	6	7	
*50:04	1		3	4	5	6	7	
*50:05	1			4	5	6	7	8
*50:06	1			4		6	7	
*50:07	1			4	5	6	7	
*50:08	1			4	5	6	7	
*50:09	1				5			
*50:10	1			4	5	6	7	
*50:11	1			4	5	6	7	
*50:12					5	6	7	
*50:13	1			4	5	6	7	
*50:14, 40:95 ⁶	1				5			
*50:15	1			4	5	6	7	
*50:16	1				5	6	7	
*50:17					5	6	7	8
*50:18	1			4	5	6	7	
*50:19	1			4	5	6	7	
Well No.	1	2	3	4	5	6	7	8

101.548-06 – including *Taq* pol., IFU-01
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Lot-specific information

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INTERPRETATION TABLE								
HLA-B*50 SSP subtyping								
Amplification patterns of the B*50:01 to B*50:19 alleles								
Well ⁷								
9	10	11	12	13	14	15	16	
105	90	105	145	270	300	135	95	Length of spec. PCR product(s)
150		280	180				160	
							580	
800	800	1070	1070	800	1070	800	1070	Length of int. pos. control ¹
97	142	357	420	81	357	97	142	5'-primer ²
5' -TCC 3'	5' -TCA 3'	5' -Tgg 3'	5' -TTC 3'	5' -CAg 3'	5' -Tgg 3'	5' -TCT 3'	5' -TCA 3'	
355			454			460	379	
5' -CTg 3'			5' -ACC 3'			5' -ACA 3'	5' -ACC 3'	
			460					
			5' -ACA 3'					
206	193	422	559	311	616	193	259	3'-primer ³
5' -CCC 3'	5' -CgC 3'	5' -AgC 3'	5' -CAg 3'	5' -ggT 3'	5' -CgT 3'	5' -CgT 3'	5' -gTT 3'	
420		594				559	435	
5' -gCT 3'		5' -CCT 3'				5' -CAg 3'	5' -TCT 3'	
								HLA-B allele ^{4,5}
9	10	11	12	13	14	15	16	Well No.
								*50:01:01-50:01:02
								*50:01:03
								*50:02
								*50:04
								*50:05
9								*50:06
	10							*50:07
		11						*50:08
			12					*50:09
				13				*50:10
					14			*50:11
9								*50:12
						15		*50:13
							16	*50:14, 40:95 ⁶
							16	*50:15
		11						*50:16
								*50:17
			12					*50:18
			12			15		*50:19
9	10	11	12	13	14	15	16	Well No.

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Lot-specific information

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Length of spec.	255	255	80	105	145	160	150	135
PCR product(s)								365
								540
Well No.	1	2	3	4	5	6	7	8
*07:78, 54:20, 55:09, 55:52	1			4			w	
*07:84, 08:09, 08:84, 13:04, 13:35, 13:46, 13:59, 15:04, 15:16:01-15:16:03, 15:67, 15:83, 15:95, 15:155, 15:222, 15:254, 27:14, 27:81, 35:37, 39:06:01-39:06:02, 39:33-39:34, 39:50, 39:57, 39:62, 39:64, 40:93, 40:96, 40:109, 41:05, 42:04, 46:32, 49:04-49:05, 51:01:01-51:03, 51:05, 51:07:01-51:14, 51:16-51:22, 51:24:01-51:24:04, 51:26-51:41N, 51:43-51:44N, 51:48-51:55, 51:57-51:58, 51:60-51:61:02, 51:63, 51:65-51:69, 51:71-51:80, 51:82-51:102, 51:104-51:105, 51:109-51:118N, 51:120-51:134, 51:136-51:138, 51:140-51:147, 52:01:01:01-52:14, 52:16-52:24, 52:26-52:31, 54:04, 54:11, 54:14-54:15, 55:13, 55:17, 55:20, 55:23, 55:27-55:28, 55:32, 56:05:01-56:06, 56:15, 56:21-56:22, 58:08:01-58:08:02, 59:02-59:03, 78:01:01-78:07	1							
*07:133, 15:143, 15:212, 18:48, 35:19, 39:69, 40:01:01-40:01:05, 40:01:07-40:03, 40:05, 40:07, 40:09, 40:11:01-40:11:02, 40:14:01-40:16, 40:18, 40:20, 40:22N-40:24, 40:27:01-40:27:02, 40:29-40:39, 40:42-40:43, 40:45, 40:50-40:52, 40:54-40:57, 40:60-40:63, 40:65-40:67, 40:69, 40:72:01-40:74, 40:77-40:82, 40:84-40:85, 40:87:01-40:92, 40:94, 40:97-40:102, 40:104-40:105, 40:107-40:108, 40:111-40:116, 40:118N-40:119, 40:121-40:126, 40:128, 40:130, 40:132-40:136, 40:138-40:147, 40:149-40:156, 40:158, 40:160:01, 40:163, 40:168-40:169, 40:171-40:176, 40:178-40:184, 40:186-40:187, 40:189, 40:191-40:200, 40:202-40:207, 40:211-40:218, 40:220-40:226, 41:02:01-41:04, 41:08, 41:10-41:11, 41:13, 41:15, 41:18-41:19, 41:23-41:24, 44:131					5			
Well No.	1	2	3	4	5	6	7	8

101.548-06 – including *Taq* pol., IFU-01
 101.548-06u – without *Taq* pol., IFU-02

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105	90	105	145	270	300	135	95	Length of spec. PCR product(s)
150		280	180				160	
							580	
9	10	11	12	13	14	15	16	Well No.
								*07:78, 54:20, 55:09, 55:52
								*07:84, 08:09, 08:84, 13:04, 13:35, 13:46, 13:59, 15:04, 15:16:01-15:16:03, 15:67, 15:83, 15:95, 15:155, 15:222, 15:254, 27:14, 27:81, 35:37, 39:06:01-39:06:02, 39:33-39:34, 39:50, 39:57, 39:62, 39:64, 40:93, 40:96, 40:109, 41:05, 42:04, 46:32, 49:04-49:05, 51:01:01-51:03, 51:05, 51:07:01-51:14, 51:16-51:22, 51:24:01-51:24:04, 51:26-51:41N, 51:43-51:44N, 51:48-51:55, 51:57-51:58, 51:60-51:61:02, 51:63, 51:65-51:69, 51:71-51:80, 51:82-51:102, 51:104-51:105, 51:109-51:118N, 51:120-51:134, 51:136-51:138, 51:140-51:147, 52:01:01:01-52:14, 52:16-52:24, 52:26-52:31, 54:04, 54:11, 54:14-54:15, 55:13, 55:17, 55:20, 55:23, 55:27-55:28, 55:32, 56:05:01-56:06, 56:15, 56:21-56:22, 58:08:01-58:08:02, 59:02-59:03, 78:01:01-78:07
								*07:133, 15:143, 15:212, 18:48, 35:19, 39:69, 40:01:01-40:01:05, 40:01:07-40:03, 40:05, 40:07, 40:09, 40:11:01-40:11:02, 40:14:01-40:16, 40:18, 40:20, 40:22N-40:24, 40:27:01-40:27:02, 40:29-40:39, 40:42-40:43, 40:45, 40:50-40:52, 40:54-40:57, 40:60-40:63, 40:65-40:67, 40:69, 40:72:01-40:74, 40:77-40:82, 40:84-40:85, 40:87:01-40:92, 40:94, 40:97-40:102, 40:104-40:105, 40:107-40:108, 40:111-40:116, 40:118N-40:119, 40:121-40:126, 40:128, 40:130, 40:132-40:136, 40:138-40:147, 40:149-40:156, 40:158, 40:160:01, 40:163, 40:168-40:169, 40:171-40:176, 40:178-40:184, 40:186-40:187, 40:189, 40:191-40:200, 40:202-40:207, 40:211-40:218, 40:220-40:226, 41:02:01-41:04, 41:08, 41:10-41:11, 41:13, 41:15, 41:18-41:19, 41:23-41:24, 44:131
9	10	11	12	13	14	15	16	Well No.

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Lot-specific information

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Length of spec. PCR product(s)	255	255	80	105	145	160	150	135
								365
								540
Well No.	1	2	3	4	5	6	7	8
*08:102, 18:80, 27:04:03, 27:23, 27:92, 35:01:10, 35:04:02, 35:90, 35:150, 35:184, 35:201, 38:16, 51:56:01- 51:56:02, C*02:02:23								
*13:01:01-13:01:06, 13:06, 13:12, 13:17, 13:22:01-13:23, 13:25, 13:28-13:29, 13:39, 13:43, 13:50, 13:52, 13:57, 13:60- 13:61, 13:63N						6		8
*13:02:01-13:02:14, 13:03, 13:08Q-13:09, 13:14-13:15, 13:19, 13:27, 13:30, 13:32- 13:34, 13:37-13:38, 13:40, 13:42, 13:44- 13:45, 13:49N, 13:53-13:56N, 13:58, 35:60, 46:11, 46:18, 49:01:02, 49:11, 51:15, 54:01:01-54:03, 54:05N, 54:07- 54:08N, 54:12-54:13, 54:17-54:19, 54:21- 54:27, 55:02:01-55:02:06, 55:07, 55:10, 55:12, 55:16, 55:18-55:19, 55:22, 55:26, 55:30, 55:34-55:35, 55:41, 55:43, 55:47- 55:48, 55:50, 55:57, 56:01:01-56:01:04, 56:07-56:08, 56:14, 56:16-56:17, 56:19N- 56:20:02, 56:23-56:24, 56:26-56:30, 56:33-56:35, 56:38N, 59:01:01:01- 59:01:01:02, 59:04-59:05	1			4		6		
*13:02:15, 13:47, 55:39, 55:42	1					6		
*13:07N, 13:11, 15:86, 56:02, 56:10						6		
*13:13, 13:26, 13:51, 15:20, 15:25:01, 15:25:03, 15:36, 15:62, 15:85, 15:204, 15:240, 15:250, 35:28, 35:50, 35:162, 40:137, 48:02:01-48:02:03, 48:17, 48:25, 53:17:02								8
*13:16, 13:48, 15:42, 52:25, 55:01:01- 55:01:03, 55:01:05-55:01:06, 55:01:08- 55:01:10, 55:03, 55:05, 55:11, 55:15, 55:24-55:25, 55:29, 55:31, 55:33, 55:36, 55:38, 55:40, 55:45, 55:54-55:55N, 56:25, 56:37	1			4		6	w	
*13:18, 13:31, 13:41, 54:10, 54:16, 55:21, 55:37, 55:46, 55:56, 56:13	1			4				
*13:20						6	w	8
*13:36						6		
Well No.	1	2	3	4	5	6	7	8

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 101.548-06u – without *Taq* pol., IFU-02

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Lot-specific information

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105	90	105	145	270	300	135	95	Length of spec. PCR product(s)
150		280	180				160	
							580	
9	10	11	12	13	14	15	16	Well No.
							16	*08:102, 18:80, 27:04:03, 27:23, 27:92, 35:01:10, 35:04:02, 35:90, 35:150, 35:184, 35:201, 38:16, 51:56:01- 51:56:02, C*02:02:23
								*13:01:01-13:01:06, 13:06, 13:12, 13:17, 13:22:01-13:23, 13:25, 13:28-13:29, 13:39, 13:43, 13:50, 13:52, 13:57, 13:60- 13:61, 13:63N
								*13:02:01-13:02:14, 13:03, 13:08Q-13:09, 13:14-13:15, 13:19, 13:27, 13:30, 13:32- 13:34, 13:37-13:38, 13:40, 13:42, 13:44- 13:45, 13:49N, 13:53-13:56N, 13:58, 35:60, 46:11, 46:18, 49:01:02, 49:11, 51:15, 54:01:01-54:03, 54:05N, 54:07- 54:08N, 54:12-54:13, 54:17-54:19, 54:21- 54:27, 55:02:01-55:02:06, 55:07, 55:10, 55:12, 55:16, 55:18-55:19, 55:22, 55:26, 55:30, 55:34-55:35, 55:41, 55:43, 55:47- 55:48, 55:50, 55:57, 56:01:01-56:01:04, 56:07-56:08, 56:14, 56:16-56:17, 56:19N- 56:20:02, 56:23-56:24, 56:26-56:30, 56:33-56:35, 56:38N, 59:01:01:01- 59:01:01:02, 59:04-59:05
								*13:02:15, 13:47, 55:39, 55:42
								*13:07N, 13:11, 15:86, 56:02, 56:10
								*13:13, 13:26, 13:51, 15:20, 15:25:01, 15:25:03, 15:36, 15:62, 15:85, 15:204, 15:240, 15:250, 35:28, 35:50, 35:162, 40:137, 48:02:01-48:02:03, 48:17, 48:25, 53:17:02
								*13:16, 13:48, 15:42, 52:25, 55:01:01- 55:01:03, 55:01:05-55:01:06, 55:01:08- 55:01:10, 55:03, 55:05, 55:11, 55:15, 55:24-55:25, 55:29, 55:31, 55:33, 55:36, 55:38, 55:40, 55:45, 55:54-55:55N, 56:25, 56:37
								*13:18, 13:31, 13:41, 54:10, 54:16, 55:21, 55:37, 55:46, 55:56, 56:13
								*13:20
							16	*13:36
9	10	11	12	13	14	15	16	Well No.

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Lot-specific information

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Length of spec.	255	255	80	105	145	160	150	135
PCR product(s)								365
								540
Well No.	1	2	3	4	5	6	7	8
*13:62, 49:18, 51:103, 51:119	1							
*14:19, 14:27, 53:07, C*03:110, C*04:08, C*04:34, C*05:27, C*05:39, C*08:41, C*17:07								
*15:18:03, 15:73, A*02:339, C*03:12, C*03:19, C*03:102, C*15:26			3					
*15:46, 15:53, 35:47, 35:154, 40:10:01- 40:10:02, 40:40, 40:49, 40:58, 40:164, 40:210, 40:219, 44:09, 44:46, 44:75, 44:90, 44:129, 47:02					5			
*15:106, 40:129					5			8
*15:137, 51:107	1							
*15:224, 39:17, 56:04			3			6		
*35:63, 40:04, 40:59, 40:64, 40:120, 40:160:02					5			8
*35:84, 53:28								8
*35:217, 40:28, 40:68					5			8
*40:01:06, 40:08, 40:25-40:26, 40:106					5			
*40:06:01:01-40:06:06, 40:44, 40:53, 40:70, 40:75, 40:86, 40:103, 40:127, 40:131, 40:148, 40:159, 40:161-40:162, 40:165, 40:167, 40:177, 40:190, 41:01, 41:06-41:07, 41:09, 41:12, 41:14, 41:16- 41:17, 41:20-41:22, 41:25	1				5			
*40:48, 40:71			3		5	6		
*40:83	1				5			
*40:110	1							
*40:166					5			
*40:170					5			
*40:208								
Well No.	1	2	3	4	5	6	7	8

101.548-06 – including *Taq* pol., IFU-01
 101.548-06u – without *Taq* pol., IFU-02

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 “Instructions for Use” (IFU)

Lot No.: **89R**

Lot-specific information

www.olerup-ssp.com

105	90	105	145	270	300	135	95	Length of spec.
150		280	180				160	PCR product(s)
							580	
9	10	11	12	13	14	15	16	Well No.
							16	*13:62, 49:18, 51:103, 51:119
			12					*14:19, 14:27, 53:07, C*03:110, C*04:08, C*04:34, C*05:27, C*05:39, C*08:41, C*17:07
								*15:18:03, 15:73, A*02:339, C*03:12, C*03:19, C*03:102, C*15:26
						15		*15:46, 15:53, 35:47, 35:154, 40:10:01- 40:10:02, 40:40, 40:49, 40:58, 40:164, 40:210, 40:219, 44:09, 44:46, 44:75, 44:90, 44:129, 47:02
						15		*15:106, 40:129
			12					*15:137, 51:107
								*15:224, 39:17, 56:04
								*35:63, 40:04, 40:59, 40:64, 40:120, 40:160:02
							16	*35:84, 53:28
							16	*35:217, 40:28, 40:68
							16	*40:01:06, 40:08, 40:25-40:26, 40:106
								*40:06:01:01-40:06:06, 40:44, 40:53, 40:70, 40:75, 40:86, 40:103, 40:127, 40:131, 40:148, 40:159, 40:161-40:162, 40:165, 40:167, 40:177, 40:190, 41:01, 41:06-41:07, 41:09, 41:12, 41:14, 41:16- 41:17, 41:20-41:22, 41:25
								*40:48, 40:71
	10							*40:83
						15		*40:110
							w	*40:166
	10							*40:170
9								*40:208
9	10	11	12	13	14	15	16	Well No.

101.548-06 – including *Taq* pol., IFU-01101.548-06u – without *Taq* pol., IFU-02Visit www.olerup-ssp.com for

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Lot No.: **89R**

Lot-specific information

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Length of spec. PCR product(s)	255	255	80	105	145	160	150	135
								365
								540
Well No.	1	2	3	4	5	6	7	8
*44:02:01:01-44:02:06, 44:02:08-44:03:01, 44:03:03-44:03:12, 44:03:14-44:03:15, 44:03:17-44:03:18, 44:04-44:05:04, 44:11, 44:13-44:14, 44:16-44:17, 44:19N, 44:21-44:27:02, 44:28:02-44:37:01, 44:38-44:39, 44:41:01-44:43:01, 44:45, 44:50-44:54, 44:56N, 44:58N-44:59:02, 44:61N, 44:63, 44:64:02-44:74, 44:76-44:80, 44:82, 44:84-44:89, 44:91-44:99, 44:101-44:102, 44:104-44:110, 44:112-44:123, 44:125-44:127, 44:132-44:133, 44:135-44:139, 44:141-44:142Q, 44:144, 44:146-44:155, 44:157-44:165, 47:01:01:01-47:01:02, 47:04-47:08, 57:45								
*44:02:07, 44:03:02, 44:03:13, 44:03:19, 44:28:01, 44:37:02, 44:43:02, 44:48, 44:64:01, 44:124, 44:128, 44:143								8
*44:07								8
*44:10						6		
*44:12, 44:62								
*44:15, 44:18		2		4				
*44:20, 44:47, 44:100		2						
*44:140			3					
*45:01, 45:03, 45:05-45:07, 45:11-45:14		2		4	5			
*45:02		2			5			
*45:04, 45:08, 45:10	1			4	5			
*45:09		2			5			
*47:03					w			
*49:01:01, 49:01:03-49:03, 49:06-49:09, 49:12-49:17, 49:19N, 49:21-49:23, 49:25	1			4		6	7	
*49:10, 49:24	1			4		6	7	
*49:20		2		4		6	7	
*51:23, 51:108, 52:15		2						
*51:62			3			6	w	
*51:106, 55:44, 55:53	1					6	w	
*54:28	1			4		6		
*55:01:04	1			4		6	w	
*55:01:07						6	w	
*56:36	1			4		6		
*73:01-73:02	1							
Well No.	1	2	3	4	5	6	7	8

101.548-06 – including *Taq* pol., IFU-01
 101.548-06u – without *Taq* pol., IFU-02

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Lot No.: **89R**

Lot-specific information

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105	90	105	145	270	300	135	95	Length of spec. PCR product(s)
150		280	180				160	
							580	
9	10	11	12	13	14	15	16	Well No.
						15		*44:02:01:01-44:02:06, 44:02:08-44:03:01, 44:03:03-44:03:12, 44:03:14-44:03:15, 44:03:17-44:03:18, 44:04-44:05:04, 44:11, 44:13-44:14, 44:16-44:17, 44:19N, 44:21-44:27:02, 44:28:02-44:37:01, 44:38-44:39, 44:41:01-44:43:01, 44:45, 44:50-44:54, 44:56N, 44:58N-44:59:02, 44:61N, 44:63, 44:64:02-44:74, 44:76-44:80, 44:82, 44:84-44:89, 44:91-44:99, 44:101-44:102, 44:104-44:110, 44:112-44:123, 44:125-44:127, 44:132-44:133, 44:135-44:139, 44:141-44:142Q, 44:144, 44:146-44:155, 44:157-44:165, 47:01:01:01-47:01:02, 47:04-47:08, 57:45
						15		*44:02:07, 44:03:02, 44:03:13, 44:03:19, 44:28:01, 44:37:02, 44:43:02, 44:48, 44:64:01, 44:124, 44:128, 44:143
	10							*44:07
						15		*44:10
						15	16	*44:12, 44:62
								*44:15, 44:18
						15		*44:20, 44:47, 44:100
						15		*44:140
			12					*45:01, 45:03, 45:05-45:07, 45:11-45:14
								*45:02
								*45:04, 45:08, 45:10
								*45:09
						15		*47:03
								*49:01:01, 49:01:03-49:03, 49:06-49:09, 49:12-49:17, 49:19N, 49:21-49:23, 49:25
						15		*49:10, 49:24
								*49:20
								*51:23, 51:108, 52:15
								*51:62
								*51:106, 55:44, 55:53
		11						*54:28
							16	*55:01:04
								*55:01:07
							w	*56:36
							w	*73:01-73:02
9	10	11	12	13	14	15	16	Well No.

101.548-06 – including **Taq pol.**, IFU-01
101.548-06u – without **Taq pol.**, IFU-02

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

Lot No.: 89R**Lot-specific information**www.olerup-ssp.com

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*50 SSP subtyping. In addition, wells number 3, 9, 10, 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 or 3rd exon, matching the specificity-determining 3'-end of the primer is given. Nucleotide numbering as on the www.ebi.ac.uk/imgt/hla web site. The sequence of the 3 terminal nucleotides of the primer is given.

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

⁴The B*5003 allele has been shown to be identical to B*50:02.

⁵HLA-B*50 alleles in bold lettering are listed as confirmed alleles on the IMGT/HLA web page www.ebi.ac.uk/imgt/hla, release 3.10.0, October 2012.

⁶The B*50:14 and 40:95 alleles will give rise to identical amplification patterns with the HLA-B*50 subtyping kit. These alleles can be distinguished by the HLA-B low resolution kit and/or the HLA-B*40 subtyping kit.

⁷Primer mix 8: Specific PCR fragment of 135 bp in the B*50:05 allele. Specific PCR fragment of 365 bp in the B*13:01:01-13:01:06, 13:06, 13:12-13:13, 13:17, 13:20, 13:22:01-13:22:02, 13:25-13:26, 13:28-13:29, 13:39, 13:43, 13:50-13:52, 13:57, 13:60-13:61, 13:63N, 15:20, 15:25:01, 15:25:03, 15:36, 15:62, 15:85, 15:106, 15:240, 15:250, 35:28, 40:129, 40:137, 40:160:02, 44:02:07, 44:03:02, 44:03:13, 44:03:19, 44:07, 44:28:01, 44:37:02, 44:43:02, 44:48, 44:64:01, 44:124, 44:128, 44:143, 48:02:01-48:02:03, 48:17, 48:25, 53:17:02 and 53:28 alleles. Specific PCR fragment of 540 bp in the B*35:50, 35:84, 35:162, 35:217, 40:68 and 40:160:02 alleles. Specific PCR fragments of 365 and 540 bp in the B*50:17 and the B*13:23, 15:204, 35:63, 40:04, 40:28, 40:59, 40:64 and 40:120 alleles.

150 bp in the B*50:06 and the B*40:208 alleles.

Primer mix 11: Specific PCR fragment of 105 bp in the B*50:16 allele. Specific PCR fragment of 280 bp in the B*50:08 and the B*54:28 alleles.

Primer mix 12: Specific PCR fragment of 145 bp in the B*50:18 and 50:19 and in the B*51:107 and the C*03:110 alleles. Specific PCR fragment of 180 bp in the B*50:09 and in the B*14:19, 14:27, 15:137, 45:02 and 53:07 and the C*04:08, C*04:34, C*05:27, C*05:39, C*08:41 and C*17:07 alleles.

Primer mix 16: Specific PCR fragment of 95 bp in the B*35:01:10, 35:04:02, 51:56:01-51:56:02, 53:28 and 55:01:04 and the C*02:02:23 alleles. Specific PCR fragment of 160 bp in the B*50:15 and the B*08:102, 13:36, 18:80, 27:23, 27:92, 35:84, 35:90, 35:150, 35:184, 35:201, 35:217, 38:16, 40:08, 40:25, 40:68, 40:106, 40:166w, 44:12, 56:36^w and 73:01^w-73:02^w alleles. Specific PCR fragment of 580 bp in the B*13:62, 27:04:03, 40:01:06, 40:26, 40:95 and 44:62, alleles. Specific PCR fragment of 95 and 580 bp in the B*50:14 and the B*40:28, 49:18, 51:103 and 51:119 alleles.

'w', may be weakly amplified.

101.548-06 – including *Taq* pol., IFU-01
 101.548-06u – without *Taq* pol., IFU-02

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 “Instructions for Use” (IFU)

Lot No.: **89R**

Lot-specific information

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CELL LINE VALIDATION SHEET																				
HLA-B*50 SSP primer set																				
				Well																
				1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	
				Prod. No.:	201190401	201190402	201190403	201190404	201190405	201190406	201190407	201313808	201313809	201190410	201313811	201313812	201313813	201190414	201313815	201313816
IHCW cell line		B*																		
1	9001	SA	*07:02	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2	9280	LK707	*52:01	*73:01	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	W
3	9011	E4181324	*52:01		+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
4	9275	GU373	*15:10	*53:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
5	9009	KAS011	*37:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
6	9353	SM	*39:01	*51:01	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
7	9020	QBL	*18:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
8	9025	DEU	*35:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
9	9026	YAR	*38:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
10	9107	LKT3	*54:01		+	-	-	+	-	+	-	-	-	-	-	-	-	-	-	-
11	9051	PITOUT	*44:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	-
12	9052	DBB	*57:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
13	9004	JESTHOM	*27:05		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
14	9071	OLGA	*15:01	*15:20	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-
15	9075	DKB	*40:01		-	-	-	-	+	-	-	-	-	-	-	-	-	-	-	-
16	9037	SWEIG007	*40:02		-	-	-	-	+	-	-	-	-	-	-	-	-	-	-	-
17	9282	CTM3953540	*08:01	*55:01	+	-	-	+	-	+	W	-	-	-	-	-	-	-	-	-
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	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	-

101.548-06 – including *Taq* pol., IFU-01
 101.548-06u – without *Taq* pol., IFU-02

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Lot No.: **89R**

Lot-specific information

www.olerup-ssp.com

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-B*50 SSP

Product number: 101.548-06 – including *Taq* polymerase
 101.548-06u – without *Taq* polymerase
 Lot number: 89R
 Expiry date: 2015-July-01
 Number of tests: 6
 Number of wells per test: 16

Well specifications:

Well No.	Production No.	Well No.	Production No.
1	2011-904-01	9	2013-138-09
2	2011-904-02	10	2011-904-10
3	2011-904-03	11	2013-138-11
4	2011-904-04	12	2013-138-12
5	2011-904-05	13	2013-138-13
6	2011-904-06	14	2011-904-14
7	2011-904-07	15	2013-138-15
8	2013-138-08	16	2013-138-16

The specificity of each primer solution of the HLA-B*50 primer set has been tested against 48 well characterized IHWC cell line DNAs.

No DNAs carrying the alleles to be amplified by primer solutions 9 to 14 were available. The specificities of the primers in primer solutions 9 and 12 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer. In primer solutions 10, 11 and 14, it was only possible to test the 5'-primer, the 3'-primer was not possible to test. In primer solution 13, it was only possible to test the 3'-primers, the 5'-primers were not possible to test. In primer solutions 9, 12 and 15, one or two 5'-primers were not possible to test, and in primer solutions 8 and 9, one 3'-primer was not possible to test. Additional primers in primer solutions 8, 15 and 16 were tested by separately adding one 5'-primer or one 3'-primer.

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

Date of approval: 2013-February-07

Approved by:

Production Quality Control

101.548-06 – including *Taq pol.*, IFU-01
101.548-06u – without *Taq pol.*, IFU-02

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

Lot No.: **89R**

Lot-specific information

www.olerup-ssp.com

Declaration of Conformity

Product name: *Olerup SSP*[®] HLA-B*50
Product number: 101.548-06/06u
Lot number: 89R

Intended use: HLA-B*50 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
2013-February-07

Ann-Cathrin Jareman
Head of QA and Regulatory Affairs

101.548-06 – including *Taq* pol., IFU-01
101.548-06u – without *Taq* pol., IFU-02

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Lot No.: **89R**

Lot-specific information

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101.548-06 – including *Taq* pol., IFU-01
101.548-06u – without *Taq* pol., IFU-02

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Lot No.: **89R**

Lot-specific information

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101.548-06 – including *Taq* pol., IFU-01
101.548-06u – without *Taq* pol., IFU-02

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Lot No.: **89R**

Lot-specific information

www.olerup-ssp.com

ADDRESSES:

Manufacturer:

Olerup SSP AB, Franzengatan 5, SE-112 51 Stockholm, Sweden.

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**.