

101.542-06 – including *Taq* polymerase, IFU-01
 101.542-06u – without *Taq* polymerase, IFU-02

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 “Instructions for Use” (IFU)

Lot No.: **20S**

Lot-specific information

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Olerup SSP[®] HLA-B*41

Product number: 101.542-06 – including *Taq* polymerase
 101.542-06u – without *Taq* polymerase
Lot number: 20S
Expiry date: 2015-November-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. 20S.

CHANGES COMPARED TO THE PREVIOUS OLERUP SSP[®] HLA-B*41 LOT (68N).

The HLA-B*41 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*41 including and without *Taq* polymerase is described in one common Product Insert.

¹As described in section Uniquely Identified Alleles.

The HLA-B*41 specificity and interpretation tables have been updated for the HLA-B alleles described since the previous *Olerup SSP[®]* HLA-B*41 lot was made (**Lot No. 68N**).

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

Well	5'-primer	3'-primer	rationale
3	Modified	Added	Improved specificity of primer pair, 3'-primer added for the B*41:22 allele.
5	-	Added	3'-primer added for the B*41:23 allele.

Change in revision R01 compared to R00:

1. The following alleles are amplified by primer mix 14: HLA-B*08:09, 08:84, 13:46, 15:83, 42:04, 44:20, 51:08, 51:20, 51:36, 51:44N, 51:97, 52:19, 55:20, 55:56 and 56:13. This has been corrected in the Specificity and Interpretation Tables.

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PRODUCT DESCRIPTION

HLA-B*41 SSP typing

CONTENT

The primer set contains 5'- and 3'-primers for identifying the B*41:01 to B*41:26 alleles.

PLATE LAYOUT

Each HLA-B*41 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*41' in silver/gray ink.

Well No. 1 with the Lot No. '20S'.

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*41 SSP subtypings will be influenced by ten B*07, most B*08, most B*13, two B*14, several B*15, most B*18, several B*27, several B*35, the B*37, two B*38, several B*39, most B*40, the B*42, several B*44, the B*45, four B*46, five B*48, the B*49, the B*50, most B*51, the B*52, two B*53, most B*54, most B*55, most B*56, the B*57:45, four B*58, the B*59, the B*73 and the B*78 alleles when present on the other haplotype. In addition, the C*06:77 allele will be amplified by primer mix 3, the C*07:04:03 and C*07:199:02 alleles will be amplified by primer mix 12 and the C*02:60, C*03:05, C*03:25, C*03:27, C*03:167 and C*08:08 alleles will be amplified by primer mix 16.

UNIQUELY IDENTIFIED ALLELES

All the HLA-B*41¹, i.e. **B*41:01 to B*41:26** recognized by the HLA Nomenclature Committee in January 2013² will be amplified by the primers in the HLA-B*41 SSP kit.

The HLA-B*41 kit enables separation of the confirmed HLA-B*41 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*41 alleles is listed below.

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The HLA-B*41 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 B*41:07 and 41:12 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 4.

The HLA-B*41 subtyping kit cannot distinguish the silent mutations in the B*41:02:01-41:02:04 alleles.

¹The 41:08, 40:136 and 40:231 alleles give rise to identical amplification patterns with the HLA-B*41 high resolution kit. These two alleles can be distinguished by the HLA-B low resolution and/or HLA-B*40 kits.

The B*41:09 and 45:08 alleles give rise to identical amplification patterns with the HLA-B*41 high resolution kit. These two alleles can be distinguished by the HLA-B low resolution and/or HLA-B*45 kits.

²HLA-B alleles listed on the IMGT/HLA web page 2013-January-11, release 3.11.0, www.ebi.ac.uk/imgt/hla.

ALLELE CONFIRMATION STATUS

Allele	Status ¹	Allele	Status ¹	Allele	Status ¹
B*41:01	Confirmed	B*41:07	Unconfirmed	B*41:17	Unconfirmed
B*41:02:01	Confirmed	B*41:08	Unconfirmed	B*41:18	Unconfirmed
B*41:02:02	Confirmed	B*41:09	Confirmed	B*41:19	Unconfirmed
B*41:02:03	Unconfirmed	B*41:10	Confirmed	B*41:20	Unconfirmed
B*41:02:04	Unconfirmed	B*41:11	Confirmed	B*41:21	Unconfirmed
B*41:03:01	Confirmed	B*41:12	Unconfirmed	B*41:22	Confirmed
B*41:03:02	Unconfirmed	B*41:13	Unconfirmed	B*41:23	Unconfirmed
B*41:04	Unconfirmed	B*41:14	Confirmed	B*41:24	Unconfirmed
B*41:05	Unconfirmed	B*41:15	Unconfirmed	B*41:25	Unconfirmed
B*41:06	Confirmed	B*41:16	Confirmed	B*41:26	Unconfirmed

¹Allele status “confirmed” or “unconfirmed” as listed on the IMGT/HLA web page 2013-January-11, release 3.11.0, www.ebi.ac.uk/imgt/hla.

RESOLUTION IN HOMO- AND HETEROZYGOTES

A total of 32 alleles generate 19 amplification patterns that can be combined in 190 homozygous and heterozygous combinations. 93 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.

```

---+-----+  +-+-----+  *41:03:01, *41:03:01 = *41:03:01, *41:03:02
-+-----+  +-+-----+  *41:02:01, *41:02:01 = *41:02:01, *41:03:02
-----++  +-+-----+  *41:06, *41:09 = *41:09, *41:09
-+-----+  +-+-----+  *41:02:01, *41:15 = *41:03:02, *41:15
-+-----+  +-+-----+  *41:02:01, *41:11 = *41:03:02, *41:11 = *41:11, *41:11
-+-----+  +-+-----+  *41:02:01, *41:13 = *41:03:02, *41:13 = *41:13, *41:13
-+-----+  +-+-----+  *41:02:01, *41:23 = *41:03:02, *41:23
-+-----+  +-+-----+  *41:02:01, *41:04 = *41:03:02, *41:04 = *41:04, *41:04
-+-----+  +-+-----+  *41:02:01, *41:03:01 = *41:02:01, *41:10 = *41:03:01, *41:10 =

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		*41:03:02, *41:10 = *41:10, *41:10
+-----+--+	--+-+-----	*41:01, *41:01 = *41:01, *41:17
-+-+-----+	-+-+-----+	*41:03:01, *41:15 = *41:10, *41:15
-+-+-----+	-+-+-----+	*41:03:01, *41:11 = *41:10, *41:11
-+-+-----+	-+-+-----+	*41:03:01, *41:13 = *41:10, *41:13
-+-+-----+	-+-+-----+	*41:03:01, *41:23 = *41:10, *41:23
-++++-----+	-+-+-----	*41:03:01, *41:04 = *41:04, *41:10
+-----+--+	++-----+	*41:01, *41:14 = *41:14, *41:14 = *41:14, *41:17
+-----+--+	++-----+	*41:01, *41:16 = *41:16, *41:16 = *41:16, *41:17
+-----+++	++-----	*41:01, *41:06 = *41:06, *41:17
+---++--+	++-----	*41:01, *41:05 = *41:05, *41:05 = *41:05, *41:17
+--+--+--+	++-----	*41:01, *41:07 = *41:07, *41:07 = *41:07, *41:17
+--+--+--+	++-----	*41:01, *41:22 = *41:17, *41:22 = *41:22, *41:22
+-----+++	++--+-----	*41:01, *41:09 = *41:09, *41:17
+--+--+--+	++++-----	*41:01, *41:03:01 = *41:03:01, *41:22 = *41:03:02, *41:22
++-----+--+	++++--+---	*41:01, *41:11 = *41:02:01, *41:14 = *41:11, *41:14
++-----+--+	++++--+---	*41:01, *41:13 = *41:02:01, *41:16 = *41:13, *41:16
++-----+--+	++++-----	*41:01, *41:23 = *41:02:01, *41:05 = *41:05, *41:23
++--+--+--+	++++-----	*41:01, *41:04 = *41:02:01, *41:07 = *41:04, *41:07
++++--+--+	++++-----	*41:01, *41:10 = *41:02:01, *41:22 = *41:10, *41:22
++-----+++	++++--+---	*41:11, *41:16 = *41:13, *41:14
++-----+++	++++--+---	*41:05, *41:11 = *41:14, *41:23
++-----+++	++++--+---	*41:05, *41:13 = *41:16, *41:23
++--+--+--+	++++--+---	*41:04, *41:14 = *41:07, *41:11
++--+--+--+	++++--+---	*41:04, *41:16 = *41:07, *41:13
++++++--+	++++-----	*41:04, *41:05 = *41:07, *41:23
++++--+--+	++++--+---	*41:10, *41:14 = *41:11, *41:22
++++--+--+	++++--+---	*41:10, *41:16 = *41:13, *41:22
++++--+--+	++++-----	*41:05, *41:10 = *41:22, *41:23
++++--+--+	++++-----	*41:04, *41:22 = *41:07, *41:10

*41:01 = *41:01, 41:20-41:21, 41:25-41:26
 *41:02:01 = *41:02:01-41:02:04, 41:18-41:19 and 41:24
 *41:07 = *41:07 and 41:12
 *41:08 = *41:08 and 40:136 and 40:231
 *41:09 = *41:09 and 45:08

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SPECIFICITY TABLE

HLA-B*41 SSP subtyping

Specificities and sizes of the PCR products of the 16 primer mixes used for HLA-B*41 SSP subtyping

Primer Mix	Size of spec. PCR product ¹	Size of control band ²	Amplified HLA-B*41 alleles	Other amplified HLA Class I alleles ³
1	285 bp	800 bp	*41:01, 41:05, 41:07, 41:12, 41:14, 41:16-41:17, 41:20-41:22, 41:25-41:26	*08:09, 08:84, 42:04, 55:20
2	215 bp	1070 bp	*41:02:01-41:02:04, 41:04, 41:10-41:11, 41:13, 41:15, 41:18-41:19, 41:23-41:24	*07:04, 07:19, 07:25, 07:146, 08:01:01-08:05, 08:07-08:08N, 08:10-08:11, 08:14-08:15, 08:17-08:19N, 08:21-08:24, 08:26-08:39, 08:41-08:48, 08:50-08:54, 08:56:01-08:59:02, 08:61-08:69, 08:71-08:78, 08:80-08:83, 08:85-08:88, 08:90-08:106, 35:87, 37:09, 42:01:01-42:02, 42:05:01-42:12, 42:14-42:18, 44:106, 44:158, 44:166
3⁴	80 bp	1070 bp	*41:03:01, 41:10, 41:22	*07:143, 08:62, 15:210, 18:01:01:01-18:01:12, 18:01:14-18:03, 18:05-18:15, 18:17N-18:24, 18:26-18:28, 18:30-18:42, 18:44:01-18:79, 18:81-18:86, 27:75, 35:162, 37:01:01-37:21, 37:23-37:37, 39:31, 40:149, 42:02, 42:09, 42:17-42:18, 48:22, 48:30, 51:116, C*06:77
4^{4,7}	90 bp, 265 bp	800 bp	*41:04, 41:07, 41:12	*08:96, 15:46, 15:106, 35:47, 35:154, 40:10:01-40:10:02, 44:34:02, 53:15, 55:20, 57:45
5	255 bp	1070 bp	*41:05, 41:23	
6	220 bp	1070 bp	*41:01, 41:05-41:07, 41:09, 41:12, 41:14, 41:16-41:17, 41:20-41:22, 41:25-41:26	*08:09, 08:84, 13:46, 15:83, 42:04, 44:15, 44:18, 44:20, 44:100, 45:01-45:14, 51:08, 51:20, 51:36, 51:44N, 51:97, 51:141, 52:19, 55:20, 55:56, 56:13
7	295 bp	1070 bp	*41:06, 41:09	*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,

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				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, 40:230, 44:15, 44:18, 44:20, 44:47, 44:100, 45:01-45:04, 45:06-45:14, 46:11, 46:18, 46:32, 49:01:01-49:25, 50:01:01-50:02, 50:04-50:10, 50:13-50:16, 50:18-50:20, 50:31, 51:01:01-51:03, 51:05, 51:07:01-51:24:04, 51:26-51:41N, 51:43-51:44N, 51:48-51:55, 51:57-51:58, 51:60-51:61:02, 51:63, 51:65-51:80, 51:82-51:95, 51:97-51:134, 51:136-51:138, 51:140-51:147, 51:150, 52:01:01:01-52:31, 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, 55:15-55:19, 55:21-55:48, 55:50, 55:52-55:58, 56:01:01-56:01:05, 56:05:01-56:08, 56:13-56:17, 56:19N-56:30, 56:33-56:39, 58:08:01-58:08:02, 59:01:01:01-59:05, 73:01-73:02, 78:01:01-78:07
8⁶	215 bp	1070 bp	*41:01-41:22, 41:24-41:26	*13:23, 13:55, 15:71, 15:175, 15:204, 15:210, 15:212, 15:225, 18:01:01:01-18:01:12, 18:01:14-18:03, 18:05-18:06, 18:08-18:15, 18:17N-18:24, 18:26-18:28, 18:30-18:32, 18:34-18:42, 18:44:01-18:78, 18:80-18:86, 27:18, 27:29, 35:63, 37:01:01-37:20, 37:22-37:25, 37:27-37:37, 40:01:01-40:02:02, 40:02:04-40:06:06, 40:09, 40:11:01-40:11:02, 40:14:01-40:16, 40:18-40:20, 40:22N-40:27:01, 40:28-40:39, 40:42-40:48, 40:50-40:57, 40:59-40:60, 40:62-40:67, 40:69-40:74, 40:76-40:102, 40:104-40:105, 40:107-40:109, 40:111-40:128, 40:130-40:136, 40:138-40:161, 40:163, 40:165, 40:167-40:190, 40:192-40:199, 40:201-40:209, 40:211-40:218, 40:221-40:225, 40:227-40:228, 40:230-40:231, 40:233, 44:15, 44:18, 44:55, 44:103, 44:131, 45:01-45:05,

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				45:07-45:14, 48:22, 48:30, 49:01:01-49:09, 49:11-49:23, 50:01:01-50:02, 50:04-50:12, 50:14-50:20, 50:31
9^{4,5}	105 bp	1070 bp	*41:08	*07:04, 07:25, 07:146, 40:136, 40:231, 42:05:01-42:05:02
10⁴	105 bp	800 bp	*41:01-41:05, 41:07, 41:10-41:14, 41:16-41:26	*08:01:01-08:05, 08:07-08:12:03, 08:14-08:19N, 08:21-08:24, 08:26-08:30N, 08:32-08:39, 08:41-08:42, 08:44-08:54, 08:56:01-08:69, 08:71-08:78, 08:80-08:102, 08:104-08:106, 35:87, 42:01:01-42:02, 42:04, 42:06-42:07, 42:09-42:13, 42:15-42:18, 44:166, 55:20
11	245 bp	800 bp	*41:01, 41:05-41:07, 41:09, 41:12, 41:14, 41:16, 41:20-41:22, 41:25-41:26	*08:09, 08:84, 13:46, 13:53, 15:42, 15:83, 35:60, 39:06:01-39:06:02, 39:34, 39:57, 39:62, 39:64, 42:04, 45:08, 46:18, 51:21, 51:36, 51:101, 51:143, 54:01:01-54:02, 54:04-54:05N, 54:07-54:08N, 54:10-54:25, 54:27-54:28, 55:01:01-55:01:06, 55:01:08-55:03, 55:05, 55:07, 55:10-55:13, 55:15-55:21, 55:23, 55:25-55:48, 55:50, 55:52-55:58, 56:23, 59:01:01:01-59:03, 59:05, 78:07
12	210 bp	1070 bp	*41:02:01-41:04, 41:08, 41:10-41:11, 41:13, 41:15, 41:18-41:19, 41:23-41:24	*07:04, 07:19, 07:25, 07:146, 08:01:01-08:05, 08:07-08:08N, 08:10-08:12:02, 08:14-08:19N, 08:21-08:24, 08:26, 08:28-08:32, 08:34-08:39, 08:41-08:48, 08:50-08:54, 08:56:01-08:59:02, 08:61-08:69, 08:71-08:75, 08:77-08:78, 08:80-08:83, 08:85-08:103, 08:105-08:106, 15:51, 15:179, 15:199, 15:218Q, 18:56, 35:87, 37:09, 37:12, 38:30, 40:136, 40:231, 42:01:01-42:02, 42:05:01-42:12, 42:14-42:18, 44:41:01, 44:106, 44:158, 44:166, C*07:04:03, C*07:199:02
13	285 bp	1070 bp	*41:09	*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,

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14^{4,8}	115 bp, 215 bp	1070 bp	*41:13, 41:16	*08:09, 08:84, 13:46, 15:83, 42:04, 44:20, 51:08, 51:20, 51:36, 51:44N, 51:97, 52:19, 55:20, 55:56, 56:13
15⁹	155 bp, 375 bp	800 bp	*41:11, 41:14	*13:30, 40:79, 40:190
16	290 bp	1070 bp	*41:15	*07:33, 07:53, 07:60, 07:100, 07:139, 14:05, 14:13, 15:07:01-15:07:02, 15:45, 15:55, 15:68, 15:126, 15:207, 18:14, 27:07:01-27:07:03, 27:11, 27:24, 27:32-27:34, 27:43, 35:05:01-35:05:03, 35:22, 35:31, 35:51, 35:58, 35:72, 35:89, 35:97, 35:114, 35:199, 37:09, 38:19, 39:03, 39:14, 39:24:01-39:24:02, 39:29, 39:37, 39:76, 40:02:01-40:03, 40:05, 40:08-40:09, 40:13, 40:18-40:19, 40:24, 40:27:01-40:27:02, 40:29, 40:35, 40:37, 40:39-40:40, 40:50, 40:56-40:58, 40:71, 40:78, 40:82, 40:85, 40:89-40:91, 40:94, 40:97, 40:104-40:105, 40:107, 40:111, 40:115, 40:119, 40:122, 40:133Q, 40:142N-40:145, 40:157, 40:164, 40:169, 40:173-40:174, 40:176, 40:180-40:181, 40:189, 40:200-40:203, 40:205-40:206, 40:209, 40:211, 40:214,

101.542-06 – including *Taq* polymerase, IFU-01
 101.542-06u – without *Taq* polymerase, IFU-02

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Lot No.: **20S**

Lot-specific information

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40:219-40:220, 40:224, 40:226, 40:229,
 40:232, 42:08, 42:14, 44:54, 44:106,
 44:135, 44:158, 46:12, 48:04, 48:13,
 48:24, 51:64, 51:81, 51:148, 53:14,
 55:04, 55:49, 55:51, 58:18, 58:27,
**C*02:60, C*03:05, C*03:25, C*03:27,
 C*03:167, C*08:08**

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*41 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*41 subtyping.

In addition, wells number 4, 10, 11 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*41 alleles will be amplified by primer mixes 1 to 4, 6 to 13, 15 and 16. In addition, the C*06:77 allele will be amplified by primer mix 3, the C*07:04:03 and C*07:199:02 alleles will be amplified by primer mix 12 and the C*02:60, C*03:05, C*03:25, C*03:27, C*03:167 and C*08:08 alleles will be amplified by primer mix 16.

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

⁵Primer mixes 9 may have tendencies of unspecific amplifications.

⁶In primer mix 8, the positive control band may be weaker than the other B*41 primer mixes

⁷Primer mix 4: Specific PCR fragment of 90 bp in the B*41:12 and the B*15:46, 15:106, 35:47, 35:154, 40:10:01-40:10:02, 44:34:02 and 57:45 alleles. Specific PCR fragment of 265 bp in the B*41:04 and 41:07 and in the B*08:96, 53:15 and 55:20 alleles.

⁸Primer mix 14: Specific PCR fragment of 115 bp in the B*41:13 allele. Specific PCR fragment of 215 bp in the B*41:16 and the B*08:09, 08:84, 13:46, 15:83, 42:04, 44:20, 51:08, 51:20, 51:36, 51:44N, 51:97, 52:19, 55:20, 55:56 and 56:13 alleles.

⁹Primer mix 15: Specific PCR fragment of 155 bp in the B*41:11 and the B*13:30 alleles. Specific PCR fragment of 375 bp in the B*41:14 and the B*40:79 and 40:190 alleles.

101.542-06 – including *Taq* polymerase, IFU-01
 101.542-06u – without *Taq* polymerase, IFU-02

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Lot-specific information

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INTERPRETATION TABLE								
HLA-B*41 SSP subtyping								
Amplification patterns of the HLA-B*41:01 to B*41:26 alleles								
	Well ⁸							
	1	2	3	4	5	6	7	8
Length of spec. PCR product(s)	285	215	80	90	255	220	295	215
Length of int. pos. control ¹	800	1070	1070	800	1070	1070	1070	1070
5'-primer ²	357	363	97	144	97	357	357	97
	5'-Tgg 3'	5'-AgC 3'	5'-TCC 3'	5'-gCA 3'	5'-TCC 3'	5'-Tgg 3'	5'-Tgg 3'	5'-TCC 3'
			363	379				
			5'-AgC 3'	5'-ACC 3'				
3'-primer ³	603	538	126	193	278	538	610	272
	5'-gTg 3'	5'-gTC 3'	5'-TCT 3'	5'-CgT 3'	5'-TgT 3'	5'-gTC 3'	5'-CTg 3'	5'-Tgg 3'
			142	603	312			
			5'-TgA 3'	5'-gTg 3'	5'-AgC 3'			
			407					
			5'-gCT 3'					
Well No.	1	2	3	4	5	6	7	8
HLA-B allele ⁴								
*41:01, 41:20-41:21, 41:25-41:26	1					6		8
*41:02:01-41:02:04, 41:18-41:19, 41:24		2						8
*41:03:01			3					8
*41:03:02								8
*41:04		2		4				8
*41:05	1				5	6		8
*41:06						6	7	8
*41:07, 41:12 ⁷	1			4		6		8
*41:08, 40:136, 40:231 ⁵								8
*41:09, 45:08 ⁶						6	7	8
*41:10		2	3					8
*41:11		2						8
*41:13		2						8
*41:14	1					6		8
*41:15		2						8
*41:16	1					6		8
Well No.	1	2	3	4	5	6	7	8

101.542-06 – including *Taq* polymerase, IFU-01
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Lot No.: **20S**

Lot-specific information

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INTERPRETATION TABLE							
HLA-B*41 subtyping							
Amplification patterns of the HLA-B*41:01 to B*41:26 alleles							
Well ⁸							
9	10	11	12	13	14	15	16
105	105	245	210	285	115	155	290
					215	375	
1070	800	800	1070	1070	1070	800	1070
540	540	357	369	357	366	160	363
5'-gAC ^{3'}	5'-gAC ^{3'}	5'-Tgg ^{3'}	5'-TAC ^{3'}	5'-Tgg ^{3'}	5'-ATT ^{3'}	5'-ACT ^{3'}	5'-AgC ^{3'}
					463	322	
					5'-TgT ^{3'}	5'-gCC ^{3'}	
605	603	559	538	603	538	272	610
5'-gCT ^{3'}	5'-gTg ^{3'}	5'-CgT ^{3'}	5'-gTC ^{3'}	5'-gTC ^{3'}	5'-gTC ^{3'}	5'-Tgg ^{3'}	5'-CTg ^{3'}
						412	
						5'-gTT ^{3'}	
9	10	11	12	13	14	15	16
	10	11					
	10		12				
	10		12				
	10		12				
	10		12				
	10		12				
	10	11					
		11					
	10	11					
9			12				
		11		13			
	10		12				
	10		12			15	
	10		12		14		
	10	11				15	
			12				16
	10	11			14		
9	10	11	12	13	14	15	16

101.542-06 – including *Taq* polymerase, IFU-01
 101.542-06u – without *Taq* polymerase, IFU-02

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Lot-specific information

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Length of spec.	285	215	80	90	255	220	295	215
PCR product(s)				265				
Well No.	1	2	3	4	5	6	7	8
*41:17	1					6		8
*41:22	1		3			6		8
*41:23		2			5			
*07:04, 07:25, 07:146, 42:05:01-42:05:02		2						
*07:19, 08:31, 08:43, 08:103		2						
*07:33, 07:53, 07:60, 07:100, 07:139, 14:05, 14:13, 15:07:01-15:07:02, 15:45, 15:55, 15:68, 15:126, 15:207, 27:07:01-27:07:03, 27:11, 27:24, 27:32-27:34, 27:43, 35:05:01-35:05:03, 35:22, 35:31, 35:51, 35:58, 35:72, 35:89, 35:97, 35:114, 35:199, 38:19, 39:03, 39:14, 39:24:01- 39:24:02, 39:29, 39:37, 39:76, 40:02:03, 40:08, 40:13, 40:27:02, 40:40, 40:58, 40:164, 40:200, 40:219-40:220, 40:226, 40:229, 40:232, 44:54, 44:135, 46:12, 48:04, 48:13, 48:24, 51:64, 51:81, 51:148, 53:14, 55:04, 55:49, 55:51, 58:18, 58:27, C*02:60, C*03:05, C*03:25, C*03:27, C*03:167, C*08:08								
*07:143, 18:07:01-18:07:02, 18:33, 18:79, 27:75, 35:162, 37:21, 37:26, 39:31, C*06:77			3					
*08:01:01-08:05, 08:07-08:08N, 08:10-08:11, 08:14-08:15, 08:17-08:19N, 08:21-08:24, 08:26, 08:28-08:30N, 08:32, 08:34-08:39, 08:41-08:42, 08:44-08:48, 08:50-08:54, 08:56:01-08:59:02, 08:61, 08:63-08:69, 08:71-08:75, 08:77- 08:78, 08:80-08:83, 08:85-08:88, 08:90-08:95, 08:97- 08:102, 08:105-08:106, 35:87, 42:01:01-42:01:03, 42:06- 42:07, 42:10-42:12, 42:15-42:16, 44:166		2						
*08:09, 08:84, 42:04	1					6		
*08:12:01-08:12:02, 08:16, 08:89								
*08:12:03, 08:49, 08:60, 42:13								
*08:27, 08:33, 08:76, 08:104		2						
*08:62, 42:02, 42:09, 42:17-42:18		2	3					
*08:96		2		4				
*13:02:01-13:04, 13:08Q-13:09, 13:14-13:16, 13:18-13:19, 13:27, 13:31-13:35, 13:37-13:38, 13:40-13:42, 13:44-13:45, 13:47-13:49N, 13:54, 13:56N, 13:58-13:59, 13:62, 15:04, 15:16:01-15:16:03, 15:67, 15:95, 15:137, 15:155, 15:222, 15:254, 27:14, 27:81, 35:37, 39:33, 39:50, 40:75, 40:103, 40:110, 40:162, 44:47, 46:11, 46:32, 49:10, 49:24-49:25, 50:13, 51:01:01-51:03, 51:05, 51:07:01-51:07:02, 51:09:01- 51:19, 51:22-51:24:04, 51:26-51:35, 51:37-51:41N, 51:43, 51:48-51:55, 51:57-51:58, 51:60-51:61:02, 51:63, 51:65- 51:80, 51:82-51:95, 51:98N-51:100, 51:102-51:115, 51:117- 51:134, 51:136-51:138, 51:140, 51:142, 51:144-51:147, 51:150, 52:01:01-52:18, 52:20-52:31, 54:03, 54:26, 55:09, 55:22, 55:24, 56:01:01-56:01:05, 56:05:01-56:08, 56:14-56:17, 56:19N-56:22, 56:24-56:30, 56:33-56:39, 58:08:01-58:08:02, 59:04, 73:01-73:02, 78:01:01-78:06							7	
Well No.	1	2	3	4	5	6	7	8

101.542-06 – including *Taq* polymerase, IFU-01
 101.542-06u – without *Taq* polymerase, IFU-02

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105	105	245	210	285	115	155	290	Length of spec. PCR product(s)
					215	375		
9	10	11	12	13	14	15	16	Well No.
	10							*41:17
	10	11						*41:22
	10		12					*41:23
9			12					*07:04, 07:25, 07:146, 42:05:01-42:05:02
			12					*07:19, 08:31, 08:43, 08:103
							16	*07:33, 07:53, 07:60, 07:100, 07:139, 14:05, 14:13, 15:07:01-15:07:02, 15:45, 15:55, 15:68, 15:126, 15:207, 27:07:01-27:07:03, 27:11, 27:24, 27:32-27:34, 27:43, 35:05:01-35:05:03, 35:22, 35:31, 35:51, 35:58, 35:72, 35:89, 35:97, 35:114, 35:199, 38:19, 39:03, 39:14, 39:24:01-39:24:02, 39:29, 39:37, 39:76, 40:02:03, 40:08, 40:13, 40:27:02, 40:40, 40:58, 40:164, 40:200, 40:219-40:220, 40:226, 40:229, 40:232, 44:54, 44:135, 46:12, 48:04, 48:13, 48:24, 51:64, 51:81, 51:148, 53:14, 55:04, 55:49, 55:51, 58:18, 58:27, C*02:60, C*03:05, C*03:25, C*03:27, C*03:167, C*08:08
								*07:143, 18:07:01-18:07:02, 18:33, 18:79, 27:75, 35:162, 37:21, 37:26, 39:31, C*06:77
	10		12					*08:01:01-08:05, 08:07-08:08N, 08:10-08:11, 08:14-08:15, 08:17-08:19N, 08:21-08:24, 08:26, 08:28-08:30N, 08:32, 08:34-08:39, 08:41-08:42, 08:44-08:48, 08:50-08:54, 08:56:01-08:59:02, 08:61, 08:63-08:69, 08:71-08:75, 08:77-08:78, 08:80-08:83, 08:85-08:88, 08:90-08:95, 08:97-08:102, 08:105-08:106, 35:87, 42:01:01-42:01:03, 42:06-42:07, 42:10-42:12, 42:15-42:16, 44:166
	10	11			14			*08:09, 08:84, 42:04
	10		12					*08:12:01-08:12:02, 08:16, 08:89
	10							*08:12:03, 08:49, 08:60, 42:13
	10							*08:27, 08:33, 08:76, 08:104
	10		12					*08:62, 42:02, 42:09, 42:17-42:18
	10		12					*08:96
				13				*13:02:01-13:04, 13:08Q-13:09, 13:14-13:16, 13:18-13:19, 13:27, 13:31-13:35, 13:37-13:38, 13:40-13:42, 13:44-13:45, 13:47-13:49N, 13:54, 13:56N, 13:58-13:59, 13:62, 15:04, 15:16:01-15:16:03, 15:67, 15:95, 15:137, 15:155, 15:222, 15:254, 27:14, 27:81, 35:37, 39:33, 39:50, 40:75, 40:103, 40:110, 40:162, 44:47, 46:11, 46:32, 49:10, 49:24-49:25, 50:13, 51:01:01-51:03, 51:05, 51:07:01-51:07:02, 51:09:01-51:19, 51:22-51:24:04, 51:26-51:35, 51:37-51:41N, 51:43, 51:48-51:55, 51:57-51:58, 51:60-51:61:02, 51:63, 51:65-51:80, 51:82-51:95, 51:98N-51:100, 51:102-51:115, 51:117-51:134, 51:136-51:138, 51:140, 51:142, 51:144-51:147, 51:150, 52:01:01:01-52:18, 52:20-52:31, 54:03, 54:26, 55:09, 55:22, 55:24, 56:01:01-56:01:05, 56:05:01-56:08, 56:14-56:17, 56:19N-56:22, 56:24-56:30, 56:33-56:39, 58:08:01-58:08:02, 59:04, 73:01-73:02, 78:01:01-78:06
9	10	11	12	13	14	15	16	Well No.

101.542-06 – including *Taq* polymerase, IFU-01
 101.542-06u – without *Taq* polymerase, IFU-02

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Length of spec.	285	215	80	90	255	220	295	215
PCR product(s)				265				
Well No.	1	2	3	4	5	6	7	8
*13:23, 15:71, 15:175, 15:204, 15:212, 15:225, 18:80, 27:18, 27:29, 35:63, 37:22, 40:01:01-40:01:29, 40:04, 40:11:01-40:11:02, 40:14:01-40:16, 40:20, 40:22N-40:23, 40:25-40:26, 40:28, 40:30-40:34, 40:36, 40:38, 40:42-40:43, 40:45-40:48, 40:51-40:52, 40:54-40:55, 40:59-40:60, 40:62-40:67, 40:69, 40:72:01-40:74, 40:76-40:77, 40:80-40:81, 40:84, 40:87:01-40:88, 40:92, 40:98-40:102, 40:108, 40:112-40:114, 40:116-40:118N, 40:120-40:121, 40:123-40:126, 40:128, 40:130, 40:132, 40:134-40:135, 40:138-40:141, 40:146-40:147, 40:150-40:156, 40:158, 40:160:01-40:160:02, 40:163, 40:168, 40:170-40:172, 40:175, 40:178-40:179, 40:182-40:188, 40:192-40:199, 40:204, 40:207-40:208, 40:212-40:213, 40:215-40:218, 40:221-40:223, 40:225, 40:227-40:228, 40:233, 44:55, 44:103, 44:131, 50:12, 50:17								8
*13:30							7	
*13:46, 15:83, 51:36, 55:56						6	7	
*13:53, 15:42, 35:60, 39:06:01-39:06:02, 39:34, 39:57, 39:62, 39:64, 46:18, 51:21, 51:101, 51:143, 54:01:01-54:02, 54:04-54:05N, 54:07-54:08N, 54:10-54:25, 54:27-54:28, 55:01:01-55:01:06, 55:01:08-55:03, 55:05, 55:07, 55:10-55:13, 55:15-55:19, 55:21, 55:23, 55:25-55:48, 55:50, 55:52-55:55N, 55:57-55:58, 56:23, 59:01:01:01-59:03, 59:05, 78:07							7	
*13:55, 40:06:01:01-40:06:06, 40:44, 40:53, 40:70, 40:83, 40:86, 40:93, 40:95-40:96, 40:109, 40:127, 40:131, 40:148, 40:159, 40:161, 40:165, 40:167, 40:177, 40:230, 49:01:01-49:09, 49:11-49:13, 49:15-49:23, 50:01:01-50:02, 50:04-50:10, 50:14-50:16, 50:18-50:20, 50:31							7	8
*15:46, 15:106, 35:47, 35:154, 40:10:01-40:10:02, 44:34:02, 53:15, 57:45				4				
*15:51, 15:179, 15:199, 15:218Q, 38:30, 44:41:01, C*07:04:03, 07:199:02								
*15:210, 18:01:01:01-18:01:12, 18:01:14-18:03, 18:05-18:06, 18:08-18:13, 18:15, 18:17N-18:24, 18:26-18:28, 18:30-18:32, 18:34-18:42, 18:44:01-18:55, 18:57-18:78, 18:81-18:86, 37:01:01-37:08, 37:10-37:11, 37:13-37:20, 37:23-37:25, 37:27-37:37, 40:149, 48:22, 48:30			3					8
*18:14			3					8
*18:56, 37:12			3					8
*37:09		2	3					8
Well No.	1	2	3	4	5	6	7	8

101.542-06 – including *Taq* polymerase, IFU-01
 101.542-06u – without *Taq* polymerase, IFU-02

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Lot No.: **20S**

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105	105	245	210	285	115	155	290	Length of spec. PCR product(s)
					215	375		
9	10	11	12	13	14	15	16	Well No.
								*13:23, 15:71, 15:175, 15:204, 15:212, 15:225, 18:80, 27:18, 27:29, 35:63, 37:22, 40:01:01-40:01:29, 40:04, 40:11:01-40:11:02, 40:14:01-40:16, 40:20, 40:22N-40:23, 40:25-40:26, 40:28, 40:30-40:34, 40:36, 40:38, 40:42-40:43, 40:45-40:48, 40:51-40:52, 40:54-40:55, 40:59-40:60, 40:62-40:67, 40:69, 40:72:01-40:74, 40:76-40:77, 40:80-40:81, 40:84, 40:87:01-40:88, 40:92, 40:98-40:102, 40:108, 40:112-40:114, 40:116-40:118N, 40:120-40:121, 40:123-40:126, 40:128, 40:130, 40:132, 40:134-40:135, 40:138-40:141, 40:146-40:147, 40:150-40:156, 40:158, 40:160:01-40:160:02, 40:163, 40:168, 40:170-40:172, 40:175, 40:178-40:179, 40:182-40:188, 40:192-40:199, 40:204, 40:207-40:208, 40:212-40:213, 40:215-40:218, 40:221-40:223, 40:225, 40:227-40:228, 40:233, 44:55, 44:103, 44:131, 50:12, 50:17
				13		15		*13:30
		11		13	14			*13:46, 15:83, 51:36, 55:56
		11		13				*13:53, 15:42, 35:60, 39:06:01-39:06:02, 39:34, 39:57, 39:62, 39:64, 46:18, 51:21, 51:101, 51:143, 54:01:01-54:02, 54:04-54:05N, 54:07-54:08N, 54:10-54:25, 54:27-54:28, 55:01:01-55:01:06, 55:01:08-55:03, 55:05, 55:07, 55:10-55:13, 55:15-55:19, 55:21, 55:23, 55:25-55:48, 55:50, 55:52-55:55N, 55:57-55:58, 56:23, 59:01:01:01-59:03, 59:05, 78:07
				13				*13:55, 40:06:01:01-40:06:06, 40:44, 40:53, 40:70, 40:83, 40:86, 40:93, 40:95-40:96, 40:109, 40:127, 40:131, 40:148, 40:159, 40:161, 40:165, 40:167, 40:177, 40:230, 49:01:01-49:09, 49:11-49:13, 49:15-49:23, 50:01:01-50:02, 50:04-50:10, 50:14-50:16, 50:18-50:20, 50:31
								*15:46, 15:106, 35:47, 35:154, 40:10:01-40:10:02, 44:34:02, 53:15, 57:45
			12					*15:51, 15:179, 15:199, 15:218Q, 38:30, 44:41:01, C*07:04:03, 07:199:02
								*15:210, 18:01:01:01-18:01:12, 18:01:14-18:03, 18:05-18:06, 18:08-18:13, 18:15, 18:17N-18:24, 18:26-18:28, 18:30-18:32, 18:34-18:42, 18:44:01-18:55, 18:57-18:78, 18:81-18:86, 37:01:01-37:08, 37:10-37:11, 37:13-37:20, 37:23-37:25, 37:27-37:37, 40:149, 48:22, 48:30
							16	*18:14
			12					*18:56, 37:12
			12				16	*37:09
9	10	11	12	13	14	15	16	Well No.

101.542-06 – including *Taq* polymerase, IFU-01
 101.542-06u – without *Taq* polymerase, IFU-02

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Lot No.: **20S**

Lot-specific information

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Length of spec.	285	215	80	90	255	220	295	215
PCR product(s)				265				
Well No.	1	2	3	4	5	6	7	8
*40:02:01-40:02:02, 40:02:04-40:03, 40:05, 40:09, 40:18-40:19, 40:24, 40:27:01, 40:29, 40:35, 40:37, 40:39, 40:50, 40:56-40:57, 40:71, 40:78, 40:82, 40:85, 40:89-40:91, 40:94, 40:97, 40:104-40:105, 40:107, 40:111, 40:115, 40:119, 40:122, 40:133Q, 40:142N-40:145, 40:157, 40:169, 40:173-40:174, 40:176, 40:180-40:181, 40:189, 40:201-40:203, 40:205-40:206, 40:209, 40:211, 40:214, 40:224								8
*40:79								8
*40:190							7	8
*42:08, 42:14, 44:106, 44:158		2						
*44:15, 44:18, 45:01-45:04, 45:07, 45:09-45:14						6	7	8
*44:20, 51:08, 51:20, 51:44N, 51:97, 52:19, 56:13						6	7	
*44:100, 45:06, 51:141						6	7	
*45:05						6		8
*49:14							7	8
*50:11								8
*51:116			3				7	
*55:20	1			4		6		
Well No.	1	2	3	4	5	6	7	8

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*41 SSP subtyping.

In addition, wells number 4, 10, 11 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 exons, 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 exons, 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.

⁴HLA-B*53 alleles in bold lettering are listed as confirmed alleles on the on the IMGT/HLA web page www.ebi.ac.uk/imgt/hla, release 3.11.0, January 2013.

101.542-06 – including *Taq* polymerase, IFU-01
 101.542-06u – without *Taq* polymerase, IFU-02

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Lot No.: 20S				Lot-specific information				www.olerup-ssp.com
105	105	245	210	285	115	155	290	Length of spec.
					215	375		PCR product(s)
9	10	11	12	13	14	15	16	Well No.
							16	*40:02:01-40:02:02, 40:02:04-40:03, 40:05, 40:09, 40:18-40:19, 40:24, 40:27:01, 40:29, 40:35, 40:37, 40:39, 40:50, 40:56-40:57, 40:71, 40:78, 40:82, 40:85, 40:89-40:91, 40:94, 40:97, 40:104-40:105, 40:107, 40:111, 40:115, 40:119, 40:122, 40:133Q, 40:142N-40:145, 40:157, 40:169, 40:173-40:174, 40:176, 40:180-40:181, 40:189, 40:201-40:203, 40:205-40:206, 40:209, 40:211, 40:214, 40:224
						15		*40:79
				13		15		*40:190
			12				16	*42:08, 42:14, 44:106, 44:158
				13				*44:15, 44:18, 45:01-45:04, 45:07, 45:09-45:14
				13	14			*44:20, 51:08, 51:20, 51:44N, 51:97, 52:19, 56:13
				13				*44:100, 45:06, 51:141
				13				*45:05
								*49:14
				13				*50:11
				13				*51:116
	10	11			14			*55:20
9	10	11	12	13	14	15	16	Well No.

⁵The 41:08, 40:136 and 40:231 alleles give rise to identical amplification patterns with the HLA-B*41 high resolution kit. These two alleles can be distinguished by the HLA-B low resolution and/or HLA-B*40 kits.

⁶The B*41:09 and 45:08 alleles give rise to identical amplification patterns with the HLA-B*41 high resolution kit. These two alleles can be distinguished by the HLA-B low resolution and/or HLA-B*45 kits.

⁷The B*41:07 and 41:12 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 4.

⁸Primer mix 4: Specific PCR fragment of 90 bp in the B*41:12 and the B*15:46, 15:106, 35:47, 35:154, 40:10:01-40:10:02, 44:34:02 and 57:45 alleles. Specific PCR fragment of 265 bp in the B*41:04 and 41:07 and in the B*08:96, 53:15 and 55:20 alleles.

Primer mix 14: Specific PCR fragment of 115 bp in the B*41:13 allele. Specific PCR fragment of 215 bp in the B*41:16 and the B*08:09, 08:84, 13:46, 15:83, 42:04, 44:20, 51:08, 51:20, 51:36, 51:44N, 51:97, 52:19, 55:20, 55:56 and 56:13 alleles.

Primer mix 15: Specific PCR fragment of 155 bp in the B*41:11 and the B*13:30 alleles. Specific PCR fragment of 375 bp in the B*41:14 and the B*40:79 and 40:190 alleles.

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CELL LINE VALIDATION SHEET					
HLA-B*41 SSP primer set					
					Well
					1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16
				Prod. No.:	201317101 201317102 201317103 201317104 201317105 201317106 201317107 201317108 201317109 201317110 201317111 201317112 201317113 201317114 201317115 201317116
	IHWC cell line	B*			
1	9001 SA	*07:02		- - - - - - - -	- - - - - - - -
2	9280 LK707	*52:01 *73:01	- - - - - + -	- - - - - + -	- - - - - + -
3	9011 E4181324	*52:01	- - - - - + -	- - - - - + -	- - - - - + -
4	9275 GU373	*15:10 *53:01	- - - - - - -	- - - - - - -	- - - - - - -
5	9009 KAS011	*37:01	- - + - - - - +	- - - - - - -	- - - - - - -
6	9353 SM	*39:01 *51:01	- - - - - + -	- - - - - + -	- - - - - + -
7	9020 QBL	*18:01	- - + - - - - +	- - - - - - -	- - - - - - -
8	9025 DEJ	*35:01	- - - - - - -	- - - - - - -	- - - - - - -
9	9026 YAR	*38:01	- - - - - - -	- - - - - - -	- - - - - - -
10	9107 LKT3	*54:01	- - - - - + -	- - - + - - -	- - - + - - -
11	9051 PITOUT	*44:03	- - - - - - -	- - - - - - -	- - - - - - -
12	9052 DBB	*57:01	- - - - - - -	- - - - - - -	- - - - - - -
13	9004 JESTHOM	*27:05	- - - - - - -	- - - - - - -	- - - - - - -
14	9071 OLGA	*15:01 *15:20	- - - - - - -	- - - - - - -	- - - - - - -
15	9075 DKB	*40:01	- - - - - - +	- - - - - - +	- - - - - - +
16	9037 SWEIG007	*40:02	- - - - - - +	- - - - - - +	- - - - - - +
17	9282 CTM3953540	*08:01 *55:01	- + - - - - + -	- + + + + - -	- + + + + - -
18	9257 32367	*14:01 *56:01	- - - - - + -	- - - - - + -	- - - - - + -
19	9038 BM16	*18:01	- - + - - - +	- - - - - +	- - - - - +
20	9059 SLE005	*40:01	- - - - - - +	- - - - - - +	- - - - - - +
21	9064 AMALA	*15:01	- - - - - - -	- - - - - - -	- - - - - - -
22	9056 KOSE	*35:03	- - - - - - -	- - - - - - -	- - - - - - -
23	9124 IHL	*40:02 *56:02	- - - - - - +	- - - - - - +	- - - - - - +
24	9035 JBUSH	*38:01	- - - - - - -	- - - - - - -	- - - - - - -
25	9049 IBW9	*14:02	- - - - - - -	- - - - - - -	- - - - - - -
26	9285 WT49	*58:01	- - - - - - -	- - - - - - -	- - - - - - -
27	9191 CH1007	*07:05 *51:01	- - - - - + -	- - - - - + -	- - - - - + -
28	9320 BEL5GB	*44:02 *44:03	- - - - - - -	- - - - - - -	- - - - - - -
29	9050 MOU	*44:03	- - - - - - -	- - - - - - -	- - - - - - -
30	9021 RSH	*42:01	- + - - - - -	- + - - - - -	- + - - - - -
31	9019 DUCAF	*18:01	- - + - - - - +	- - - - - - +	- - - - - - +
32	9297 HAG	*41:02	- + - - - - - +	- + - - - - +	- + - - - - +
33	9098 MT14B	*40:01	- - - - - - +	- - - - - - +	- - - - - - +
34	9104 DHIF	*38:01	- - - - - - -	- - - - - - -	- - - - - - -
35	9302 SSTO	*44:02	- - - - - - -	- - - - - - -	- - - - - - -
36	9024 KT17	*15:01 *35:01	- - - - - - -	- - - - - - -	- - - - - - -
37	9065 HHKB	*07:02	- - - - - - -	- - - - - - -	- - - - - - -
38	9099 LZL	*15:01	- - - - - - -	- - - - - - -	- - - - - - -
39	9315 CML	*08:01 *27:05	- + - - - - -	- + - - - - -	- + - - - - -
40	9134 WHONP199	*13:02 *46:01	- - - - - + -	- - - - - + -	- - - - - + -
41	9055 H0301	*14:02	- - - - - - -	- - - - - - -	- - - - - - -
42	9066 TAB089	*46:01	- - - - - - -	- - - - - - -	- - - - - - -
43	9076 T7526	*46:01	- - - - - - -	- - - - - - -	- - - - - - -
44	9057 TEM	*38:01	- - - - - - -	- - - - - - -	- - - - - - -
45	9239 SHJO	*42:01 *50:01	- + - - - - + +	- + - - - + +	- + - - - + +
46	9013 SCHU	*07:02	- - - - - - -	- - - - - - -	- - - - - - -
47	9045 TUBO	*51:01	- - - - - + -	- - - - - + -	- - - - - + -
48	9303 TER-ND	*35:01 *44:03	- - - - - - -	- - - - - - -	- - - - - - -

101.542-06 – including *Taq* polymerase, IFU-01
101.542-06u – without *Taq* polymerase, IFU-02

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Lot No.: **20S**

Lot-specific information

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CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-B*41 SSP

Product number: 101.542-06 – including *Taq* polymerase
101.542-06u – without *Taq* polymerase
Lot number: 20S
Expiry date: 2015-November-01
Number of tests: 6
Number of wells per test: 16

Well specifications:

Well No.	Production No.	Well No.	Production No.
1	2013-171-01	9	2013-171-09
2	2013-171-02	10	2013-171-10
3	2013-171-03	11	2013-171-11
4	2013-171-04	12	2013-171-12
5	2013-171-05	13	2013-171-13
6	2013-171-06	14	2013-171-14
7	2013-171-07	15	2013-171-15
8	2013-171-08	16	2013-171-16

The specificity of each primer solution of the HLA-B*41 primer set has been tested against 48 well characterized IHWC cell line DNAs.

No DNAs carrying the alleles to be amplified by primer solutions 5, 9, 14 and 15 were available. The specificities of the primers in primer solution 9 were tested by separately adding one 3'-primer, respectively one 5'-primer. In primer solution 5 it was only possible to test the 5'-primer, the 3'-primer was not possible to test, and in primer solutions 14 and 15 it was only possible to test the 3'-primers, the 5'-primers were not possible to test. In primer solution 3, two 3'-primers were not possible to test. Additional 5' and 3'-primers in primer solution 3 and 4 were tested by separately adding additional 3'-primers, respectively additional 5'-primers.

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

Date of approval: 2013-July-01

Approved by:

Production Quality Control

101.542-06 – including *Taq* polymerase, IFU-01
101.542-06u – without *Taq* polymerase, IFU-02

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

Lot No.: **20S**

Lot-specific information

www.olerup-ssp.com

Declaration of Conformity

Product name: *Olerup* SSP® HLA-B*41
Product number: 101.542-06/06u
Lot number: 20S

Intended use: HLA-B*41 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 13485:2012, 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.

The Authorized Representative located within the Community is: *Olerup* SSP AB.

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

Stockholm, Sweden
2013-July-01

Ann-Cathrin Jareman
Head of QA and Regulatory Affairs

101.542-06 – including *Taq* polymerase, IFU-01
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Lot No.: **20S**

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101.542-06 – including *Taq* polymerase, IFU-01
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Lot No.: **20S**

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**.