

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.: **68N**

Lot-specific information

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Olerup SSP[®] HLA-B*41

Product number:	101.542-06 – including <i>Taq</i> polymerase 101.542-06u – without <i>Taq</i> polymerase
Lot number:	68N
Expiry date:	2014-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. 68N.

CHANGES COMPARED TO THE PREVIOUS OLERUP SSP[®] HLA-B*41 LOT (43M).

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 now 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. 43M).

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

Well	5'-primer	3'-primer	rationale
7	-	Modified	Decreased primer oligomer formation.
8	Modified	-	Decreased primer oligomer formation.

Change in revision R01 compared to R00:

1. The following alleles are amplified by primer mix 14: HLA-B*08:09, 13:46, 15:83, 42:04, 44:20, 51:08, 51:20, 51:36, 51:44N, 51:97, 52:19, 55:20 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*41:19 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. '68N'.

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 eight B*07, most B*08, most B*13, two B*14, several B*15, most B*18, twelve B*27, several B*35, the B*37, two B*38, several B*39, most B*40, the B*42, twelve B*44, the B*45, three B*46, four B*48, the B*49, the B*50, most B*51, the B*52, two B*53, the 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*07:04:03 allele will be amplified by primer mix 12 and the C*03:05, C*03:25, C*03:27 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*41:19** recognized by the HLA Nomenclature Committee in January 2012² 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.

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

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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 and 40:136 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.

The 41:15 and 37:09 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*37 kits.

²HLA-B alleles listed on the IMGT/HLA web page 2012-January-12, release 3.7.0, 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*41:02:04	Unconfirmed	B*41:11	Confirmed		
B*41:03:01	Confirmed	B*41:12	Unconfirmed		
B*41:03:02	Unconfirmed	B*41:13	Unconfirmed		
B*41:04	Unconfirmed	B*41:14	Confirmed		
B*41:05	Unconfirmed	B*41:15	Unconfirmed		
B*41:06	Confirmed	B*41:16	Unconfirmed		

¹Allele status “confirmed” or “unconfirmed” as listed on the IMGT/HLA web page 2012-January-12, release 3.7.0, www.ebi.ac.uk/imgt/hla.

RESOLUTION IN HOMO- AND HETEROZYGOTES

A total of 23 alleles generate 17 amplification patterns that can be combined in 153 homozygous and heterozygous combinations. 63 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, *41:04 = *41:03:02, *41:04 = *41:04, *41:04
  
```

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-+++++ -++-----	*41:02:01, *41:03:01 = *41:02:01, *41:10 = *41:03:01, *41:10 = *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, *41:04 = *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, *41:09 = *41:09, *41:17
+-----+ -++-----	*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, *41:04 = *41:02:01, *41:07 = *41:04, *41:07
+-----+ -++-----	*41:11, *41:16 = *41:13, *41:14
+-----+ -++-----	*41:04, *41:14 = *41:07, *41:11
+-----+ -++-----	*41:04, *41:16 = *41:07, *41:13

*41:02:01 = *41:02:01-41:02:04 and 41:18-41:19

*41:07 = *41:07 and 41:12

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www.olerup-ssp.com**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	*08:09, 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	*07:04, 07:19, 07:25, 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, 08:56-08:59, 08:61-08:69, 08:71-08:78, 08:80, 35:87, 37:09, 42:01:01-42:02, 42:05:01-42:12, 42:14-42:16, 44:106
3^{4,5}	80 bp	1070 bp	*41:03:01, 41:10	
4^{4,6}	90 bp, 265 bp	800 bp	*41:04, 41:07, 41:12	*15:46, 15:106, 35:47, 35:154, 40:10:01-40:10:02, 53:15, 55:20, 57:45
5	255 bp	1070 bp	*41:05	
6	220 bp	1070 bp	*41:01, 41:05-41:07, 41:09, 41:12, 41:14, 41:16-41:17	*08:09, 13:46, 15:83, 42:04, 44:15, 44:18, 44:20, 44:100, 45:01-45:13, 51:08, 51:20, 51:36, 51:44N, 51:97, 52:19, 55:20, 56:13
7	295 bp	800 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, 15:04, 15:16:01-15:16:03, 15:42, 15:67, 15:83, 15:95, 15:137, 15:155, 15:222, 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, 40:06:01:01-40:06:04, 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, 44:15, 44:18, 44:20, 44:47, 44:100, 45:01-45:04, 45:06-45:13,

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				46:11, 46:18, 49:01:01-49:20, 50:01:01-50:02, 50:04-50:10, 50:13- 50:15, 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, 51:63, 51:65- 51:80, 51:82-51:95, 51:97-51:126, 52:01:01:01-52:27, 54:01:01-54:05N, 54:07-54:08N, 54:10-54:24, 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- 55:54, 56:01:01-56:01:04, 56:05:01- 56:08, 56:13-56:17, 56:19N-56:30, 58:08:01-58:08:02, 59:01:01:01- 59:05, 73:01-73:02, 78:01:01-78:07
8	215 bp	1070 bp	*41:01-41:19	*13:23, 15:71, 15:175, 15:204, 15:210, 15:212, 15:225, 18:01:01- 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, 18:44-18:68, 27:18, 27:29, 35:63, 37:01:01-37:20, 37:22-37:25, 37:27-37:31, 40:01:01-40:02:02, 40:02:04-40:06:04, 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, 40:167-40:180, 44:15, 44:18, 44:55, 44:103, 44:131, 45:01-45:05, 45:07-45:13, 48:22, 49:01:01-49:09, 49:11-49:20, 50:01:01-50:02, 50:04-50:12, 50:14- 50:15
9^{4,5}	105 bp	1070 bp	*41:08	*07:04, 07:25, 40:136, 42:05:01- 42:05:02
10⁴	105 bp	800 bp	*41:01-41:05, 41:07, 41:10-41:14, 41:16-41:19	*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, 08:56-08:69, 08:71- 08:78, 08:80, 35:87, 42:01:01-42:02,

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				42:04, 42:06-42:07, 42:09-42:13, 42:15-42:16, 55:20
11	245 bp	800 bp	*41:01, 41:05- 41:07, 41:09, 41:12, 41:14, 41:16	*08:09, 13:46, 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, 54:01:01- 54:02, 54:04-54:05N, 54:07-54:08N, 54:10-54:24, 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, 55:52-55:54, 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	*07:04, 07:19, 07:25, 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, 08:56-08:59, 08:61-08:69, 08:71-08:75, 08:77- 08:78, 08:80, 15:51, 15:179, 15:199, 15:218Q, 18:56, 35:87, 37:09, 37:12, 38:30, 40:136, 42:01:01-42:02, 42:05:01-42:12, 42:14-42:16, 44:41:01, 44:106, C*07:04:03
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, 15:04, 15:16:01-15:16:03, 15:42, 15:67, 15:83, 15:95, 15:137, 15:155, 15:222, 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, 40:06:01:01-40:06:04, 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, 44:15, 44:18, 44:20, 44:47, 44:100, 45:01-45:13, 46:11, 46:18, 49:01:01-49:13, 49:15-49:20, 50:01:01-50:02, 50:04-50:11, 50:13- 50:15, 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, 51:63, 51:65- 51:80, 51:82-51:95, 51:97-51:126,

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				52:01:01:01-52:27, 54:01:01-54:05N, 54:07-54:08N, 54:10-54:24, 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, 55:52-55:54, 56:01:01-56:01:04, 56:05:01-56:08, 56:13-56:17, 56:19N-56:30, 58:08:01-58:08:02, 59:01:01:01-59:05, 73:01-73:02, 78:01:01-78:07
14^{4,7}	115 bp, 215 bp	1070 bp	*41:13, 41:16	*08:09, 13:46, 15:83, 42:04, 44:20, 51:08, 51:20, 51:36, 51:44N, 51:97, 52:19, 55:20, 56:13
15⁸	155 bp, 375 bp	800 bp	*41:11, 41:14	*13:30, 40:79
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, 27:07:01-27:07:02, 27:11, 27:24, 27:32-27:34, 27:43, 35:05:01-35:05:02, 35:22, 35:31, 35:51, 35:58, 35:72, 35:89, 35:97, 35:114, 37:09, 38:19, 39:03, 39:14, 39:24:01-39:24:02, 39:29, 39:37, 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, 42:08, 42:14, 44:54, 44:106, 44:135, 46:12, 48:04, 48:13, 48:24, 51:64, 51:81, 53:14, 55:04, 55:49, 55:51, 58:18, 58:27, C*03:05, C*03:25, C*03:27, 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 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.

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

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

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

Well number 1 contains the primer pair giving rise to the shorter, 800 bp, internal positive control band in order to help in the correct orientation of the HLA-B*41 subtyping.

In addition, wells number 4, 7, 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, 2, 4, 6 to 13, 15 and 16. In addition, the C*07:04:03 allele will be amplified by primer mix 12 and the C*03:05, C*03:25, C*03:27 and C*08:08 alleles will be amplified by primer mix 16.

⁴Short specific PCR fragments are less intense and not as sharp as longer specific bands.

⁵Primer mixes 3 and 9 may give rise to nonspecific amplifications.

⁶Primer 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 and 57:45 alleles. Specific PCR fragment of 265 bp in the B*41:04 and 41:07 and in the B*53:15 and 55:20 alleles.

⁷Primer 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, 13:46, 15:83, 42:04, 44:20, 51:08, 51:20, 51:36, 51:44N, 51:97, 52:19, 55:20 and 56:13 alleles.

⁸Primer 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 alleles.

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INTERPRETATION TABLE								
HLA-B*41 SSP subtyping								
Amplification patterns of the HLA-B*41:01 to B*41:19 alleles								
	Well ⁸							
	1	2	3	4	5	6	7	8
Length of spec.	285	215	80	90	255	220	295	215
PCR product(s)				265				
Length of int.	800	1070	1070	800	1070	1070	800	1070
pos. control ¹								
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	312	538	610	272
	5'-gTg ^{3'}	5'-gTC ^{3'}	5'-TCT ^{3'}	5'-CgT ^{3'}	5'-AgC ^{3'}	5'-gTC ^{3'}	5'-CTg ^{3'}	5'-Tgg ^{3'}
			407	603				
			5'-gCT ^{3'}	5'-gTg ^{3'}				
Well No.	1	2	3	4	5	6	7	8
HLA-B allele ⁴								
*41:01	1					6		8
*41:02:01-41:02:04, 41:18-41:19		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 ⁵	1			4		6		8
*41:08, 40:136 ⁶								8
*41:09, 45:08 ⁷						6	7	8
*41:10		2	3					8
*41:11		2						8
*41:13		2						8
*41:14	1					6		8
*41:15, 37:09 ⁸		2						8
*41:16	1					6		8
*41:17	1					6		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.: **68N**

Lot-specific information

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Well ⁸								
9	10	11	12	13	14	15	16	
105	105	245	210	285	115	155	290	Length of spec. PCR product(s)
					215	375		Length of int. pos. control ¹
1070	800	800	1070	1070	1070	800	1070	5'-primer ²
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	3'-primer ³
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	Well No. HLA-B allele ⁴
	10	11						*41:01
	10		12					*41:02:01-41:02:04, 41:18-41:19
	10		12					*41:03:01
	10		12					*41:03:02
	10		12					*41:04
	10	11						*41:05
		11						*41:06
	10	11						*41:07, 41:12 ⁵
9			12					*41:08, 40:136 ⁶
		11		13				*41:09, 45:08 ⁷
	10		12					*41:10
	10		12			15		*41:11
	10		12		14			*41:13
	10	11				15		*41:14
			12				16	*41:15, 37:09 ⁸
	10	11			14			*41:16
	10							*41:17
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.: **68N**

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
*07:04, 07:25, 42:05:01-42:05:02		2						
*07:19, 08:31, 08:43		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, 27:07:01-27:07:02, 27:11, 27:24, 27:32-27:34, 27:43, 35:05:01-35:05:02, 35:22, 35:31, 35:51, 35:58, 35:72, 35:89, 35:97, 35:114, 38:19, 39:03, 39:14, 39:24:01-39:24:02, 39:29, 39:37, 40:02:03, 40:08, 40:13, 40:27:02, 40:40, 40:58, 40:164, 44:54, 44:135, 46:12, 48:04, 48:13, 48:24, 51:64, 51:81, 53:14, 55:04, 55:49, 55:51, 58:18, 58:27, C*03:05, C*03:25, C*03:27, C*08:08								
*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, 08:56-08:59, 08:61-08:69, 08:71-08:75, 08:77-08:78, 08:80, 35:87, 42:01:01-42:02, 42:06-42:07, 42:09-42:12, 42:15-42:16		2						
*08:09, 42:04	1					6		
*08:12:01-08:12:02, 08:16								
*08:12:03, 08:49, 08:60, 42:13								
*08:27, 08:33, 08:76		2						
*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, 15:04, 15:16:01-15:16:03, 15:67, 15:95, 15:137, 15:155, 15:222, 27:14, 27:81, 35:37, 39:33, 39:50, 40:75, 40:103, 40:110, 40:162, 44:47, 46:11, 49:10, 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, 51:63, 51:65-51:80, 51:82-51:95, 51:98N-51:100, 51:102-51:126, 52:01:01:01-52:18, 52:20-52:27, 54:03, 55:09, 55:22, 55:24, 56:01:01-56:01:04, 56:05:01-56:08, 56:14-56:17, 56:19N-56:22, 56:24-56:30, 58:08:01-58:08:02, 59:04, 73:01-73:02, 78:01:01-78:06							7	
*13:23, 15:71, 15:175, 15:204, 15:210, 15:212, 15:225, 18:01:01-18:01:12, 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, 18:44-18:55, 18:57-18:68, 27:18, 27:29, 35:63, 37:01:01-37:08, 37:10-37:11, 37:13-37:20, 37:22-37:25, 37:27-37:31, 40:01:01-40:01:23, 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, 40:149-40:156, 40:158, 40:160, 40:163, 40:168, 40:170-40:172, 40:175, 40:178-40:179, 44:55, 44:103, 44:131, 48:22, 50:12								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.: **68N**

Lot-specific information

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105	105	245	210	285	115	155	290	Length of spec. PCR product(s)
9	10	11	12	13	14	15	16	Well No.
9			12					*07:04, 07:25, 42:05:01-42:05:02
			12					*07:19, 08:31, 08:43
						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, 27:07:01-27:07:02, 27:11, 27:24, 27:32-27:34, 27:43, 35:05:01-35:05:02, 35:22, 35:31, 35:51, 35:58, 35:72, 35:89, 35:97, 35:114, 38:19, 39:03, 39:14, 39:24:01-39:24:02, 39:29, 39:37, 40:02:03, 40:08, 40:13, 40:27:02, 40:40, 40:58, 40:164, 44:54, 44:135, 46:12, 48:04, 48:13, 48:24, 51:64, 51:81, 53:14, 55:04, 55:49, 55:51, 58:18, 58:27, C*03:05, C*03:25, C*03:27, C*08:08
	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, 08:56-08:59, 08:61-08:69, 08:71-08:75, 08:77-08:78, 08:80, 35:87, 42:01:01-42:02, 42:06-42:07, 42:09-42:12, 42:15-42:16
	10	11			14			*08:09, 42:04
	10		12					*08:12:01-08:12:02, 08:16
	10							*08:12:03, 08:49, 08:60, 42:13
	10							*08:27, 08:33, 08:76
				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, 15:04, 15:16:01-15:16:03, 15:67, 15:95, 15:137, 15:155, 15:222, 27:14, 27:81, 35:37, 39:33, 39:50, 40:75, 40:103, 40:110, 40:162, 44:47, 46:11, 49:10, 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, 51:63, 51:65-51:80, 51:82-51:95, 51:98N-51:100, 51:102-51:126, 52:01:01:01-52:18, 52:20-52:27, 54:03, 55:09, 55:22, 55:24, 56:01:01-56:01:04, 56:05:01-56:08, 56:14-56:17, 56:19N-56:22, 56:24-56:30, 58:08:01-58:08:02, 59:04, 73:01-73:02, 78:01:01-78:06
								*13:23, 15:71, 15:175, 15:204, 15:210, 15:212, 15:225, 18:01:01-18:01:12, 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, 18:44-18:55, 18:57-18:68, 27:18, 27:29, 35:63, 37:01:01-37:08, 37:10-37:11, 37:13-37:20, 37:22-37:25, 37:27-37:31, 40:01:01-40:01:23, 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, 40:149-40:156, 40:158, 40:160, 40:163, 40:168, 40:170-40:172, 40:175, 40:178-40:179, 44:55, 44:103, 44:131, 48:22, 50:12
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.: **68N**

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
*13:30							7	
*13:46, 15:83, 51:36						6	7	
*15:42, 35:60, 39:06:01-39:06:02, 39:34, 39:57, 39:62, 39:64, 46:18, 51:21, 51:101, 54:01:01-54:02, 54:04-54:05N, 54:07-54:08N, 54:10-54:24, 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, 55:52-55:54, 56:23, 59:01:01:01-59:03, 59:05, 78:07							7	
*15:46, 15:106, 35:47, 35:154, 40:10:01-40:10:02, 53:15, 57:45				4				
*15:51, 15:179, 15:199, 15:218Q, 38:30, 44:41:01, C*07:04:03								
*18:14, 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								8
*18:56, 37:12								8
*40:06:01:01-40:06:04, 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, 49:01:01-49:09, 49:11-49:13, 49:15-49:20, 50:01:01-50:02, 50:04-50:10, 50:14-50:15							7	8
*40:79								8
*42:08, 42:14, 44:106		2						
*44:15, 44:18, 45:01-45:04, 45:07, 45:09-45:13						6	7	8
*44:20, 51:08, 51:20, 51:44N, 51:97, 52:19, 56:13						6	7	
*44:100, 45:06						6	7	
*45:05						6		8
*49:14							7	8
*50:11								8
*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, 7, 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 3.7.0, January 2012.

⁵The B*41:07 and 41:12 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 4.

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

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Lot No.: 68N				Lot-specific information				www.olerup-ssp.com
105	105	245	210	285	115	155	290	Length of spec. PCR product(s)
9	10	11	12	13	14	15	16	Well No.
				13		15		*13:30
		11		13	14			*13:46, 15:83, 51:36
		11		13				*15:42, 35:60, 39:06:01-39:06:02, 39:34, 39:57, 39:62, 39:64, 46:18, 51:21, 51:101, 54:01:01-54:02, 54:04-54:05N, 54:07-54:08N, 54:10-54:24, 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, 55:52-55:54, 56:23, 59:01:01:01-59:03, 59:05, 78:07
								*15:46, 15:106, 35:47, 35:154, 40:10:01-40:10:02, 53:15, 57:45
			12					*15:51, 15:179, 15:199, 15:218Q, 38:30, 44:41:01, C*07:04:03
							16	*18:14, 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
			12					*18:56, 37:12
				13				*40:06:01:01-40:06:04, 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, 49:01:01-49:09, 49:11-49:13, 49:15-49:20, 50:01:01-50:02, 50:04-50:10, 50:14-50:15
						15		*40:79
			12				16	*42:08, 42:14, 44:106
				13				*44:15, 44:18, 45:01-45:04, 45:07, 45:09-45:13
				13	14			*44:20, 51:08, 51:20, 51:44N, 51:97, 52:19, 56:13
				13				*44:100, 45:06
				13				*45:05
								*49:14
				13				*50:11
	10	11			14			*55:20
9	10	11	12	13	14	15	16	Well No.

⁶The 41:08 and 40:136 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.

⁷The 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.

⁸The 41:15 and 37:09 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*37 kits.

⁹Primer 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 and 57:45 alleles. Specific PCR fragment of 265 bp in the B*41:04 and 41:07 and in the B*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, 13:46, 15:83, 42:04, 44:20, 51:08, 51:20, 51:36, 51:44N, 51:97, 52:19, 55:20 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 alleles.

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.: **68N**

Lot-specific information

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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.:	200962001	200845402	201079303	201079304	200845405	200845406	201200707	201200708	200962009	200962010	200845411	200845412	201079313	201188414	201200715	201079316
IHCW 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	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

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

Lot No.: **68N**

Lot-specific information

www.olerup-ssp.com

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: 68N
Expiry date: 2014-November-01
Number of tests: 6
Number of wells per test: 16

Well specifications:

Well No.	Production No.	Well No.	Production No.
1	2009-620-01	9	2009-620-09
2	2008-454-02	10	2009-620-10
3	2010-793-03	11	2008-454-11
4	2010-793-04	12	2008-454-12
5	2008-454-05	13	2010-793-13
6	2008-454-06	14	2011-884-14
7	2012-007-07	15	2012-007-15
8	2012-007-08	16	2010-793-16

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 3, 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 solutions 3 and 5 it was only possible to test the 5'-primers, the 3'-primers were 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. Additional 5' and 3'-primers in primer solution 4 were tested by separately adding two additional 3'-primers, respectively one additional 5'-primer.

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

Date of approval: 2012-May-25

Approved by:

Production Quality Control

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

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Lot No.: **68N**

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: 68N

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 13485:2003, 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.

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
2012-May-25

Ann-Cathrin Jareman
Head of QA and Regulatory Affairs

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.: **68N**

Lot-specific information

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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.: **68N**

Lot-specific information

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