

101.543-06 – including *Taq* pol., IFU-01
 101.543-06u – without *Taq* pol., IFU-02

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 “Instructions for Use” (IFU)

Lot No.: **35R**

Lot-specific information
Olerup SSP[®] HLA-B*42

Product number:	101.543-06 – including <i>Taq</i> pol. 101.543-06u – without <i>Taq</i> pol.
Lot number:	35R
Expiry date:	2015-March-01
Number of tests:	6
Number of wells per test:	15
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. 35R.

**CHANGES COMPARED TO THE PREVIOUS OLERUP SSP[®]
 HLA-B*42 LOT (57M).**

The HLA-B*42 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*42 including and without *Taq* polymerase is now described in one common Product Insert.

¹As described in section Uniquely Identified Alleles.

The HLA-B*42 specificity and interpretation tables have been updated for the HLA-B alleles described since the previous *Olerup SSP[®]* HLA-B*42 lot was made (**Lot No. 57M**).

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

Well	5'-primer	3'-primer	rationale
10	Exchanged	-	Improved specificity of amplification.

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PRODUCT DESCRIPTION

HLA-B*42 SSP typing

CONTENT

The primer set contains 5'- and 3'-primers for identifying the B*42:01 to B*42:17 alleles.

PLATE LAYOUT

Each HLA-B*42 test consists of 15 PCR reactions in a 16 well cut PCR plate. Well 16 is empty.

1	2	3	4	5	6	7	8
9	10	11	12	13	14	15	empty

The 16 well PCR plate is marked with 'HLA-B*42' in silver/gray ink.

Well No. 1 is marked with the Lot No. '35R'.

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 covered 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*42 SSP subtypings will be influenced by most B*07, most B*08, two B*13, thirteen B*14, several B*15, the B*18, several B*27, several B*35, the B*37, the B*38, the B*39, several B*40, the B*41, several B*44, the B*45, the B*46:12, the B*48, ten B*51, two B*52, four B*53, most B*54, several B*55, most B*56, two B*57, two B*58, three B*67, the B*81, the B*82 and the B*83:01 alleles when present on the other haplotype. In addition, the C*05:62, C*07:04:01^w-07:04:08^w, C*07:11^w-07:12^w, C*07:45^w, C*07:63^w, C*07:101^w, C*07:139^w, C*07:142^w, C*07:181^w, C*07:199:01^w-07:199:02^w and C*15:25 alleles will be amplified by primer mix 7, the C*02:60, C*03:05, C*03:25, C*03:27 and C*08:08 alleles will be amplified by primer mix 10 and the C*01:59, C*06:82, C*07:49, C*07:210, C*07:238 and C*07:247 alleles will be amplified by primer mix 14.

UNIQUELY IDENTIFIED ALLELES

All the HLA-B*42, i.e. **B*42:01 to B*42:17**, recognized by the HLA Nomenclature Committee in July 2012¹ will be amplified by the primers in the HLA-B*42 SSP kit².

The HLA-B*42 kit enables separation of the confirmed HLA-B*42 alleles as listed in the IMGT/HLA database. An HLA allele is listed as confirmed by IMGT/HLA if

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it has been sequenced by more than a single laboratory or from multiple sources. Current allele confirmation status for HLA-B*42 alleles is listed below.

The HLA-B*42 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*42 subtyping kit cannot distinguish the silent mutations in the B*42:01:01-42:01:02 and the 42:05:01- 42:05:02 alleles.

¹HLA-B alleles listed on the IMGT/HLA web page 2012-July-12, release 3.9.0, www.ebi.ac.uk/imgt/hla.

²The HLA-B*42 primer set cannot separate the B*42:07 and the B*08:94 alleles. These alleles can be distinguished by the HLA-B low resolution kit and/or the HLA-B*08 high resolution kit.

ALLELE CONFIRMATION STATUS

Allele	Status ¹	Allele	Status ¹
B*42:01:01	Confirmed	B*42:10	Confirmed
B*42:01:02	Unconfirmed	B*42:11	Unconfirmed
B*42:02	Confirmed	B*42:12	Unconfirmed
B*42:04	Unconfirmed	B*42:13	Unconfirmed
B*42:05:01	Confirmed	B*42:14	Unconfirmed
B*42:05:02	Unconfirmed	B*42:15	Unconfirmed
B*42:06	Unconfirmed	B*42:16	Unconfirmed
B*42:07	Unconfirmed	B*42:17	Unconfirmed
B*42:08	Unconfirmed		
B*42:09	Confirmed		

¹Allele status “confirmed” or “unconfirmed” as listed on the IMGT/HLA web page 2012-July-12, release 3.9.0, www.ebi.ac.uk/imgt/hla.

RESOLUTION IN HOMO- AND HETEROZYGOTES

A total of 18 alleles generate 16 amplification patterns that can be combined in 136 homozygous and heterozygous combinations. 72 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.

```
--+++++  -----  *42:07, *42:11 = *42:11, *42:11
-+++++  -+++++  *42:02, *42:17 = *42:17, *42:17
+++++  +-----+  *42:01:01, *42:14 = *42:14, *42:14
+++++  +-----+  *42:01:01, *42:13 = *42:01:01, *42:15 = *42:13, *42:15 = *42:15, *42:15
+++++  +-----+  *42:01:01, *42:12 = *42:12, *42:12
+++++  -+++++  *42:01:01, *42:10 = *42:10, *42:10
+++++  +-----+  *42:01:01, *42:08 = *42:08, *42:08
+++++  +-----+  *42:01:01, *42:06 = *42:01:01, *42:16 = *42:06, *42:06 = *42:06, *42:16
```

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+++++--- +----- *42:01:01, *42:05:01 = *42:05:01, *42:05:01
 +-----+ +-----+ *42:13, *42:14 = *42:14, *42:15
 +-----+ +-----+ *42:12, *42:13 = *42:12, *42:15
 +-----+ +-----+ *42:10, *42:13 = *42:10, *42:15
 +-----+ +-----+ *42:08, *42:13 = *42:08, *42:15
 +-----+ +-----+ *42:07, *42:13 = *42:07, *42:15
 +-----+ +-----+ *42:06, *42:14 = *42:14, *42:16
 +-----+ +-----+ *42:06, *42:13 = *42:06, *42:15 = *42:13, *42:16 = *42:15, *42:16
 +-----+ +-----+ *42:06, *42:12 = *42:12, *42:16
 +-----+ +-----+ *42:06, *42:10 = *42:10, *42:16
 +-----+ +-----+ *42:06, *42:08 = *42:08, *42:16
 +-----+ +-----+ *42:06, *42:07 = *42:07, *42:16
 +-----+ +-----+ *42:05:01, *42:13 = *42:05:01, *42:15
 +-----+ +-----+ *42:05:01, *42:06 = *42:05:01, *42:16
 +-----+ +-----+ *42:04, *42:06 = *42:04, *42:16
 +-----+ +-----+ *42:02, *42:13 = *42:02, *42:15
 +-----+ +-----+ *42:01:01, *42:17 = *42:02, *42:10 = *42:10, *42:17
 +-----+ +-----+ *42:01:01, *42:09 = *42:02, *42:06 = *42:02, *42:16 = *42:06, *42:09
 +-----+ +-----+ *42:11, *42:13 = *42:11, *42:15
 +-----+ +-----+ *42:06, *42:11 = *42:11, *42:16
 +-----+ +-----+ *42:13, *42:17 = *42:15, *42:17
 +-----+ +-----+ *42:09, *42:13 = *42:09, *42:15
 +-----+ +-----+ *42:06, *42:17 = *42:09, *42:10 = *42:16, *42:17

*42:01:01 = *42:01:01- 42:01:02

*42:05:01 = *42:05:01- 42:05:02

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Lot-specific information
SPECIFICITY TABLE

HLA-B*42 SSP subtyping

Specificities and sizes of the PCR products of the 15 primer mixes used for HLA-B*42 SSP subtyping

Primer Mix	Size of spec. PCR product ¹	Size of control band ²	Amplified HLA-B*42 alleles	Other amplified HLA-B alleles ³
1	215 bp	800 bp	*42:01:01-42:01:02, 42:04-42:06, 42:08, 42:10, 42:12-42:16	*07:02:01-07:02:27, 07:02:29-07:02:33, 07:04-07:07, 07:09, 07:11-07:12, 07:14-07:15, 07:17-07:26, 07:28, 07:30-07:31, 07:33-07:36, 07:39-07:49N, 07:51-07:68:03, 07:70, 07:72-07:82, 07:84, 07:86-07:124, 07:126-07:142, 07:144-07:162, 14:21, 15:76, 15:101, 35:76, 38:26, 44:90, 54:01:01-54:01:03, 54:03-54:06, 54:08N-54:23, 54:25-54:27, 55:01:01-55:05, 55:07-55:15, 55:17, 55:19-55:24, 55:26-55:33, 55:35-55:46, 55:48-55:56, 56:01:01-56:07, 56:09-56:13, 56:15-56:16, 56:18-56:22, 56:24-56:32, 56:34, 56:36, 67:01:01-67:01:02, 67:03, 81:01-81:04N, 82:01-82:03, 83:01
2	215 bp	1070 bp	*42:01:01-42:02, 42:05:01-42:12, 42:14-42:17	*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, 08:56-08:59, 08:61-08:69, 08:71-08:78, 08:80-08:83, 08:85-08:88, 08:90-08:94, 35:87, 37:09, 41:02:01-41:02:04, 41:04, 41:10-41:11, 41:13, 41:15, 41:18-41:19, 44:106
3	215 bp	1070 bp	*42:02, 42:09, 42:17	*07:143, 40:166, 45:06, 54:02, 55:16, 56:35
4	220 bp	1070 bp	*42:04	*08:09, 08:84, 13:46, 15:83, 41:01, 41:05-41:07, 41:09, 41:12, 41:14, 41:16-41:17, 41:20-41:21, 44:15, 44:18, 44:20, 44:100,

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				45:01-45:14, 51:08, 51:20, 51:36, 51:44N, 51:97, 52:19, 55:20, 55:56, 56:13
5⁴	105 bp	800 bp	*42:05:01-42:05:02	*07:04, 07:25, 07:146, 40:136, 41:08
6	165 bp	1070 bp	*42:01:01-42:02, 42:04-42:08, 42:10-42:15, 42:17	*08:01:01-08:05, 08:08N-08:12:03, 08:15-08:19N, 08:21-08:24, 08:26-08:27, 08:29-08:36, 08:38-08:39, 08:41-08:48, 08:50-08:54, 08:56-08:69, 08:71-08:73, 08:75-08:76, 08:78, 08:80-08:86N, 08:88, 08:90-08:94, 15:83, 35:87, 37:12, 38:30, 40:136, 41:01-41:03:02, 41:05-41:09, 41:11-41:17, 41:19-41:20, 44:14, 44:62, 45:14, 51:08, 51:20, 51:36, 51:44N, 51:97, 52:19, 55:20, 55:56, 56:13, 57:09, 82:01-82:03
7	165 bp	1070 bp	*42:06, 42:09, 42:16	*07:04, 07:19, 07:25, 07:146, 08:07, 08:37, 08:49, 08:69, 08:89, 13:46, 15:51, 15:179, 15:199, 15:218Q, 18:56, 35:38, 35:115, 35:169, 37:01:01-37:01:08, 37:03N-37:06, 37:08-37:11, 37:13-37:24, 37:26-37:34, 38:30, 41:04, 41:18, 41:21, 44:15, 44:17-44:18, 44:51, 44:117 ^W , 44:123, 44:140, 45:01-45:02, 45:04-45:14, 53:22, 55:56, 56:13, 57:24, 82:01-82:03, C*05:62, C*07:04:01^W-07:04:08^W, C*07:11^W-07:12^W, C*07:45^W, C*07:63^W, C*07:101^W, C*07:139^W, C*07:142^W, C*07:181^W, C*07:199:01^W-07:199:02^W, C*15:25
8	215 bp	1070 bp	*42:07, 42:11	*07:03, 07:08, 07:16, 07:27, 07:32, 07:38, 07:50, 07:69, 07:85, 08:94, 13:14, 14:01:01-14:01:02, 14:07N-14:08, 14:10, 14:12, 14:14, 14:19, 14:26, 14:32, 15:68, 15:71, 15:175, 18:01:01:01-18:01:12, 18:01:14-18:03, 18:05-18:15, 18:17N-18:24, 18:26-18:67, 18:69, 18:71-18:76, 27:12,

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				27:16, 27:18, 27:23, 27:29, 27:92, 35:50, 35:84, 35:162, 35:197, 37:01:01-37:34, 38:01:01-38:04, 38:06-38:25, 38:27-38:32, 38:35-38:40, 39:01:01:01-39:01:01:03, 39:01:03-39:03, 39:05:01-39:11, 39:13:01-39:20, 39:22-39:51, 39:53-39:62, 39:64-39:71, 39:73-39:75, 40:02:01-40:06:05, 40:08-40:09, 40:11:01-40:11:02, 40:13, 40:18-40:20, 40:24, 40:26-40:27:01, 40:28-40:29, 40:35, 40:37, 40:39-40:40, 40:44, 40:50, 40:56, 40:64, 40:68, 40:70-40:71, 40:74-40:75, 40:78, 40:82-40:83, 40:85-40:86, 40:89-40:91, 40:93-40:99, 40:104-40:105, 40:107, 40:109, 40:111, 40:115, 40:119-40:120, 40:122, 40:127, 40:131, 40:133Q, 40:142N-40:145, 40:148-40:149, 40:157, 40:159, 40:161-40:162, 40:165, 40:167, 40:169, 40:173-40:174, 40:176-40:177, 40:180-40:181, 40:184, 40:189-40:190, 40:201-40:203, 40:205-40:206, 40:209-40:211, 40:214, 44:103, 44:130-44:131, 48:01:01-48:21, 48:23-48:28, 51:57, 51:103, 51:116, 53:21
9	170 bp	1070 bp	*42:01:01-42:02, 42:04-42:06, 42:08-42:10, 42:12-42:17	*07:02:01-07:02:27, 07:02:29-07:02:33, 07:04-07:07, 07:09, 07:11-07:12, 07:14-07:15, 07:17-07:26, 07:28-07:31, 07:33-07:36, 07:39-07:49N, 07:51-07:55, 07:57-07:64, 07:66-07:68:03, 07:70-07:71, 07:73-07:82, 07:84, 07:86-07:124, 07:126-07:162, 14:21, 38:26, 54:21, 55:10, 56:16, 67:01:01-67:01:02, 67:03, 81:01-81:04N, 82:01-82:03, 83:01
10	280 bp	800 bp	*42:08	*07:19, 07:33, 07:53, 07:60, 07:100, 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,

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				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, 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, 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*02:60, C*03:05, C*03:25, C*03:27, C*08:08
11	180 bp	1070 bp	*42:10, 42:17	*08:49, 08:71, 27:83, 53:15
12⁴	105 bp	1070 bp	*42:11	*07:27, 07:50, 08:04, 08:17, 08:54, 15:03:01-15:03:03, 15:47:01-15:47:02, 15:54, 15:61-15:62, 15:64, 15:68-15:69, 15:91, 15:98, 15:103, 15:123, 15:127, 15:131-15:132, 15:151, 15:156, 15:158, 15:173, 15:210, 15:220, 15:235, 15:242, 15:253, 18:37, 27:18, 27:29, 37:28, 38:03, 39:02:01-39:02:02, 39:08, 39:13:01-39:13:02, 39:23, 39:39:01-39:39:02, 39:49, 40:12, 40:46, 40:93, 44:40, 44:44, 44:130, 48:01:01-48:05, 48:07-48:28, 52:16, 55:18
13⁴	65 bp	1070 bp	*42:12	
14⁵	200 bp, 290 bp	1070 bp	*42:13, 42:15	*07:11, 07:57, 07:75, 08:17, 08:47, 08:49, 08:60, 08:76, 18:49, 37:05, 39:20, 53:15, C*01:59, C*06:82, C*07:49, C* 07:210, C*07:238, C*07:247
15	230 bp	1070 bp	*42:14	*41:06, 41:15

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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*42 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*42 subtyping.

In addition, wells number 5 and 10 contain the primer pair giving rise to the shorter, 800 bp, internal positive control band in order to allow kit identification.

³Due to the sharing of sequence motifs between HLA-B alleles non-HLA-B*42 alleles will be amplified by primer mixes 1 to 12, 14 and 15. In addition, the C*05:62, C*07:04:01^w-07:04:08^w, C*07:11^w-07:12^w, C*07:45^w, C*07:63^w, C*07:101^w, C*07:139^w, C*07:142^w, C*07:181^w, C*07:199:01^w-07:199:02^w and C*15:25 alleles will be amplified by primer mix 7, the C*02:60, C*03:05, C*03:25, C*03:27 and C*08:08 alleles will be amplified by primer mix 10 and the C*01:59, C*06:82, C*07:49, C*07:210, C*07:238 and C*07:247 alleles will be amplified by primer mix 14.

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

⁵Primer mix 14: Specific PCR fragment of 200 bp in the B*42:15 and the B*07:11, 07:57, 07:75, 08:17, 08:47, 18:49, 37:05 and 39:20 and in the C*01:59, C*06:82, C*07:49, C*07:210, C*07:238 and C*07:247 alleles. Specific PCR fragment of 290 bp in the B*42:13 and the B*08:49, 08:60, 08:76 and 53:15 alleles.

‘w’, might be weakly amplified.

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INTERPRETATION TABLE								
HLA-B*42 SSP subtyping								
Amplification patterns of the B*42:01 to 42:17 alleles								
	Well ⁷							
	1	2	3	4	5	6	7	8
Length of spec.	215	215	215	220	105	165	165	215
PCR product(s)								
Length of int.	800	1070	1070	1070	800	1070	1070	1070
pos. control ¹								
5'-primer ²	97	363	97	357	540	412	412	103
	5' -TCT 3'	5' -AgC 3'	5' -TCC 3'	5' -Tgg 3'	5' -gAC 3'	5' -ATA 3'	5' -ATg 3'	5' -CCT 3'
							419	103
							5' -gTT 3'	5' -CCT 3'
							419	
							5' -gTT 3'	
3'-primer ³	272	538	272	538	605	538	538	277
	5' -TgT 3'	5' -gTC 3'	5' -TgT 3'	5' -gTC 3'	5' -gCT 3'	5' -gTC 3'	5' -gTC 3'	5' -ggT 3'
Well No.	1	2	3	4	5	6	7	8
HLA-B allele ^{4,5}								
*42:01:01-42:01:02	1	2				6		
*42:02		2	3			6		
*42:04	1			4		6		
*42:05:01-42:05:02	1	2			5	6		
*42:06	1	2				6	7	
*42:07, 08:94 ⁶		2				6		8
*42:08	1	2				6		
*42:09		2	3				7	
*42:10	1	2				6		
*42:11		2				6		8
*42:12	1	2				6		
*42:13	1					6		
*42:14	1	2				6		
*42:15	1	2				6		
*42:16	1	2					7	
*42:17		2	3			6		
Well No.	1	2	3	4	5	6	7	8

101.543-06 – including *Taq* pol., IFU-01101.543-06u – without *Taq* pol., IFU-02Visit www.olerup-ssp.com for

“Instructions for Use” (IFU)

Lot No.: **35R**

Lot-specific information

INTERPRETATION TABLE							
HLA-B*42 SSP subtyping							
Amplification patterns of the B*42:01 to 42:17 alleles							
Well ⁷							
9	10	11	12	13	14	15	
170	280	180	105	65	200	230	Length of spec. PCR product(s)
					290		
1070	800	1070	1070	1070	1070	1070	Length of int. pos. control ¹
142	363	463	206	540	142	412	5'-primer ²
5' -TCT 3'	5' -AgC 3'	5' -TgA 3'	5' -AgA 3'	5' -gAC 3'	5' -TCT 3'	5' -ATA 3'	
					355		
					5' -TCA 3'		
272	603	603	272	566	302	603	3'-primer ³
5' -TgT 3'	5' -gTC 3'	5' -gTg 3'	5' -Tgg 3'	5' -CCC 3'	5' -ggT 3'	5' -gTg 3'	
					603		
					5' -gTg 3'		
9	10	11	12	13	14	15	Well No.
							HLA-B allele ^{4,5}
9							*42:01:01-42:01:02
9							*42:02
9							*42:04
9							*42:05:01-42:05:02
9							*42:06
							*42:07, 08:94 ⁶
9	10						*42:08
9							*42:09
9		11					*42:10
			12				*42:11
9				13			*42:12
9					14		*42:13
9						15	*42:14
9					14		*42:15
9							*42:16
9		11					*42:17
9	10	11	12	13	14	15	Well No.

101.543-06 – including *Taq* pol., IFU-01101.543-06u – without *Taq* pol., IFU-02Visit www.olerup-ssp.com for
“Instructions for Use” (IFU)Lot No.: **35R**

Lot-specific information

Length of spec. PCR product(s)	215	215	215	220	105	165	165	215
	1	2	3	4	5	6	7	8
Well No.	1	2	3	4	5	6	7	8
*07:02:01-07:02:27, 07:02:29-07:02:33, 07:05:01-07:07, 07:09, 07:12, 07:14- 07:15, 07:17-07:18:02, 07:20-07:24, 07:26, 07:28, 07:30-07:31, 07:34-07:36, 07:39-07:49N, 07:51-07:52, 07:54-07:55, 07:58-07:59, 07:61-07:64, 07:66- 07:68:03, 07:70, 07:73-07:74, 07:76- 07:82, 07:84, 07:86-07:99, 07:101- 07:124, 07:126-07:142, 07:144-07:145, 07:147-07:162, 14:21, 38:26, 54:21, 55:10, 56:16, 67:01:01-67:01:02, 67:03, 81:01-81:04N, 83:01	1							
*07:03, 07:08, 07:16, 07:32, 07:38, 07:69, 07:85, 13:14, 14:01:01-14:01:02, 14:07N- 14:08, 14:10, 14:12, 14:14, 14:19, 14:26, 14:32, 15:71, 15:175, 18:01:01:01- 18:01:12, 18:01:14-18:03, 18:05-18:13, 18:15, 18:17N-18:24, 18:26-18:36, 18:38- 18:48, 18:50-18:55, 18:57-18:67, 18:69, 18:71-18:76, 27:12, 27:16, 27:23, 27:92, 35:50, 35:84, 35:162, 35:197, 37:02, 37:07, 37:25, 38:01:01-38:02:03, 38:04, 38:06-38:18, 38:20-38:25, 38:27-38:29, 38:31-38:32, 38:35-38:40, 39:01:01:01- 39:01:01:03, 39:01:03-39:01:14, 39:05:01- 39:07, 39:09-39:11, 39:15-39:19:02, 39:22, 39:25N-39:28, 39:30-39:36, 39:38Q, 39:40N-39:48, 39:50-39:51, 39:53-39:62, 39:64-39:71, 39:73-39:75, 40:04, 40:06:01:01-40:06:05, 40:11:01- 40:11:02, 40:20, 40:26, 40:28, 40:44, 40:64, 40:68, 40:70, 40:74-40:75, 40:83, 40:86, 40:95-40:96, 40:98-40:99, 40:109, 40:120, 40:127, 40:131, 40:148-40:149, 40:159, 40:161-40:162, 40:165, 40:167, 40:177, 40:184, 40:190, 40:210, 44:103, 44:131, 48:06, 51:57, 51:103, 51:116, 53:21								8
Well No.	1	2	3	4	5	6	7	8

101.543-06 – including *Taq* pol., IFU-01
 101.543-06u – without *Taq* pol., IFU-02

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

Lot No.: **35R**

Lot-specific information

170	280	180	105	65	200	230	Length of spec. PCR product(s)
					290		
9	10	11	12	13	14	15	Well No.
9							*07:02:01-07:02:27, 07:02:29-07:02:33, 07:05:01-07:07, 07:09, 07:12, 07:14- 07:15, 07:17-07:18:02, 07:20-07:24, 07:26, 07:28, 07:30-07:31, 07:34-07:36, 07:39-07:49N, 07:51-07:52, 07:54-07:55, 07:58-07:59, 07:61-07:64, 07:66- 07:68:03, 07:70, 07:73-07:74, 07:76- 07:82, 07:84, 07:86-07:99, 07:101- 07:124, 07:126-07:142, 07:144-07:145, 07:147-07:162, 14:21, 38:26, 54:21, 55:10, 56:16, 67:01:01-67:01:02, 67:03, 81:01-81:04N, 83:01
							*07:03, 07:08, 07:16, 07:32, 07:38, 07:69, 07:85, 13:14, 14:01:01-14:01:02, 14:07N- 14:08, 14:10, 14:12, 14:14, 14:19, 14:26, 14:32, 15:71, 15:175, 18:01:01:01- 18:01:12, 18:01:14-18:03, 18:05-18:13, 18:15, 18:17N-18:24, 18:26-18:36, 18:38- 18:48, 18:50-18:55, 18:57-18:67, 18:69, 18:71-18:76, 27:12, 27:16, 27:23, 27:92, 35:50, 35:84, 35:162, 35:197, 37:02, 37:07, 37:25, 38:01:01-38:02:03, 38:04, 38:06-38:18, 38:20-38:25, 38:27-38:29, 38:31-38:32, 38:35-38:40, 39:01:01:01- 39:01:01:03, 39:01:03-39:01:14, 39:05:01- 39:07, 39:09-39:11, 39:15-39:19:02, 39:22, 39:25N-39:28, 39:30-39:36, 39:38Q, 39:40N-39:48, 39:50-39:51, 39:53-39:62, 39:64-39:71, 39:73-39:75, 40:04, 40:06:01:01-40:06:05, 40:11:01- 40:11:02, 40:20, 40:26, 40:28, 40:44, 40:64, 40:68, 40:70, 40:74-40:75, 40:83, 40:86, 40:95-40:96, 40:98-40:99, 40:109, 40:120, 40:127, 40:131, 40:148-40:149, 40:159, 40:161-40:162, 40:165, 40:167, 40:177, 40:184, 40:190, 40:210, 44:103, 44:131, 48:06, 51:57, 51:103, 51:116, 53:21
9	10	11	12	13	14	15	Well No.

101.543-06 – including *Taq* pol., IFU-01101.543-06u – without *Taq* pol., IFU-02Visit www.olerup-ssp.com for

“Instructions for Use” (IFU)

Lot No.: **35R**

Lot-specific information

Length of spec. PCR product(s)	215	215	215	220	105	165	165	215
Well No.	1	2	3	4	5	6	7	8
*07:04, 07:25, 07:146	1	2			5		7	
*07:11, 07:57, 07:75	1							
*07:19	1	2					7	
*07:27, 07:50, 18:37, 27:18, 27:29, 38:03, 39:02:01-39:02:02, 39:08, 39:13:01- 39:13:02, 39:23, 39:39:01-39:39:02, 39:49, 40:93, 44:130, 48:01:01-48:03:02, 48:05, 48:07-48:12, 48:14-48:21, 48:23, 48:25-48:28								8
*07:29, 07:71								
*07:33, 07:53, 07:60, 07:100	1							
*07:56:01-07:56:02, 07:65, 07:72, 15:76, 15:101, 35:76, 44:90, 54:01:01-54:01:03, 54:03-54:06, 54:08N-54:20, 54:22-54:23, 54:25-54:27, 55:01:01-55:03, 55:05, 55:07-55:09, 55:11-55:15, 55:17, 55:19, 55:21-55:24, 55:26-55:33, 55:35-55:46, 55:48, 55:50, 55:52-55:55N, 56:01:01- 56:07, 56:09-56:12, 56:15, 56:18-56:22, 56:24-56:32, 56:34, 56:36	1							
*07:143			3					
*08:01:01-08:03, 08:05, 08:08N, 08:10- 08:11, 08:15, 08:18-08:19N, 08:21-08:24, 08:26-08:27, 08:29-08:36, 08:38-08:39, 08:41-08:46, 08:48, 08:50-08:53, 08:56- 08:59, 08:61-08:68, 08:72N-08:73, 08:75, 08:78, 08:80-08:83, 08:85-08:86N, 08:88, 08:90-08:93, 35:87, 41:02:01-41:02:04, 41:11, 41:13, 41:19		2				6		
*08:04, 08:54		2				6		
*08:07, 08:37, 41:04, 41:18		2					7	
*08:09, 08:84, 15:83, 41:01, 41:05, 41:07, 41:09, 41:12, 41:14, 41:16-41:17, 41:20, 51:08, 51:20, 51:36, 51:44N, 51:97, 52:19				4		6		
*08:12:01-08:12:03, 08:16, 41:03:01- 41:03:02, 44:14, 44:62, 57:09						6		
*08:14, 08:28, 08:74, 08:77, 08:87, 41:10		2						
*08:17		2				6		
Well No.	1	2	3	4	5	6	7	8

101.543-06 – including *Taq* pol., IFU-01
 101.543-06u – without *Taq* pol., IFU-02

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

Lot No.: **35R**

Lot-specific information

170	280	180	105	65	200	230	Length of spec. PCR product(s)
					290		
9	10	11	12	13	14	15	Well No.
9							*07:04, 07:25, 07:146
9					14		*07:11, 07:57, 07:75
9	10						*07:19
			12				*07:27, 07:50, 18:37, 27:18, 27:29, 38:03, 39:02:01-39:02:02, 39:08, 39:13:01- 39:13:02, 39:23, 39:39:01-39:39:02, 39:49, 40:93, 44:130, 48:01:01-48:03:02, 48:05, 48:07-48:12, 48:14-48:21, 48:23, 48:25-48:28
9							*07:29, 07:71
9	10						*07:33, 07:53, 07:60, 07:100
							*07:56:01-07:56:02, 07:65, 07:72, 15:76, 15:101, 35:76, 44:90, 54:01:01-54:01:03, 54:03-54:06, 54:08N-54:20, 54:22-54:23, 54:25-54:27, 55:01:01-55:03, 55:05, 55:07-55:09, 55:11-55:15, 55:17, 55:19, 55:21-55:24, 55:26-55:33, 55:35-55:46, 55:48, 55:50, 55:52-55:55N, 56:01:01- 56:07, 56:09-56:12, 56:15, 56:18-56:22, 56:24-56:32, 56:34, 56:36
9							*07:143
							*08:01:01-08:03, 08:05, 08:08N, 08:10- 08:11, 08:15, 08:18-08:19N, 08:21-08:24, 08:26-08:27, 08:29-08:36, 08:38-08:39, 08:41-08:46, 08:48, 08:50-08:53, 08:56- 08:59, 08:61-08:68, 08:72N-08:73, 08:75, 08:78, 08:80-08:83, 08:85-08:86N, 08:88, 08:90-08:93, 35:87, 41:02:01-41:02:04, 41:11, 41:13, 41:19
			12				*08:04, 08:54
							*08:07, 08:37, 41:04, 41:18
							*08:09, 08:84, 15:83, 41:01, 41:05, 41:07, 41:09, 41:12, 41:14, 41:16-41:17, 41:20, 51:08, 51:20, 51:36, 51:44N, 51:97, 52:19
							*08:12:01-08:12:03, 08:16, 41:03:01- 41:03:02, 44:14, 44:62, 57:09
							*08:14, 08:28, 08:74, 08:77, 08:87, 41:10
			12		14		*08:17
9	10	11	12	13	14	15	Well No.

101.543-06 – including *Taq* pol., IFU-01101.543-06u – without *Taq* pol., IFU-02Visit www.olerup-ssp.com for

“Instructions for Use” (IFU)

Lot No.: **35R**

Lot-specific information

Length of spec. PCR product(s)	215	215	215	220	105	165	165	215
	1	2	3	4	5	6	7	8
Well No.	1	2	3	4	5	6	7	8
*08:47, 08:76		2				6		
*08:49							7	
*08:60						6		
*08:69		2				6	7	
*08:71		2				6		
*08:89, 15:51, 15:179, 15:199, 15:218Q, 35:38, 35:115, 35:169, 44:17, 44:51, 44:123, 44:140, 53:22, 57:24, C*05:62, C*15:25							7	
*13:46, 41:21, 44:15, 44:18, 45:01-45:02, 45:04-45:05, 45:07-45:13				4			7	
*14:05, 14:13, 15:07:01-15:07:02, 15:45, 15:55, 15:126, 15:207, 27:07:01- 27:07:02, 27:11, 27:24, 27:32-27:34, 27:43, 35:05:01-35:05:03, 35:22, 35:31, 35:51, 35:58, 35:72, 35:89, 35:97, 35:114, 35:199, 40:27:02, 40:57-40:58, 40:164, 40:200, 44:54, 44:135, 46:12, 51:64, 51:81, 53:14, 58:18, 58:27, C*02:60, C*03:05, C*03:25, C*03:27, C*08:08								
*15:03:01-15:03:03, 15:47:01-15:47:02, 15:54, 15:61-15:62, 15:64, 15:69, 15:91, 15:98, 15:103, 15:123, 15:127, 15:131- 15:132, 15:151, 15:156, 15:158, 15:173, 15:210, 15:220, 15:235, 15:242, 15:253, 40:12, 40:46, 44:40, 44:44, 48:22, 52:16, 55:18								
*15:68, 48:04, 48:13, 48:24								8
*18:14, 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, 40:29, 40:35, 40:37, 40:39-40:40, 40:50, 40:56, 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								8
Well No.	1	2	3	4	5	6	7	8

101.543-06 – including *Taq* pol., IFU-01101.543-06u – without *Taq* pol., IFU-02Visit www.olerup-ssp.com for
“Instructions for Use” (IFU)Lot No.: **35R**

Lot-specific information

170	280	180	105	65	200	230	Length of spec. PCR product(s)
9	10	11	12	13	14	15	
					290		
		11			14		*08:47, 08:76
					14		*08:49
					14		*08:60
							*08:69
		11					*08:71
							*08:89, 15:51, 15:179, 15:199, 15:218Q, 35:38, 35:115, 35:169, 44:17, 44:51, 44:123, 44:140, 53:22, 57:24, C*05:62, C*15:25
							*13:46, 41:21, 44:15, 44:18, 45:01-45:02, 45:04-45:05, 45:07-45:13
	10						*14:05, 14:13, 15:07:01-15:07:02, 15:45, 15:55, 15:126, 15:207, 27:07:01- 27:07:02, 27:11, 27:24, 27:32-27:34, 27:43, 35:05:01-35:05:03, 35:22, 35:31, 35:51, 35:58, 35:72, 35:89, 35:97, 35:114, 35:199, 40:27:02, 40:57-40:58, 40:164, 40:200, 44:54, 44:135, 46:12, 51:64, 51:81, 53:14, 58:18, 58:27, C*02:60, C*03:05, C*03:25, C*03:27, C*08:08
			12				*15:03:01-15:03:03, 15:47:01-15:47:02, 15:54, 15:61-15:62, 15:64, 15:69, 15:91, 15:98, 15:103, 15:123, 15:127, 15:131- 15:132, 15:151, 15:156, 15:158, 15:173, 15:210, 15:220, 15:235, 15:242, 15:253, 40:12, 40:46, 44:40, 44:44, 48:22, 52:16, 55:18
	10		12				*15:68, 48:04, 48:13, 48:24
	10						*18:14, 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, 40:29, 40:35, 40:37, 40:39-40:40, 40:50, 40:56, 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
9	10	11	12	13	14	15	Well No.

101.543-06 – including *Taq* pol., IFU-01101.543-06u – without *Taq* pol., IFU-02Visit www.olerup-ssp.com for

“Instructions for Use” (IFU)

Lot No.: **35R**

Lot-specific information

Length of spec. PCR product(s)	215	215	215	220	105	165	165	215
	1	2	3	4	5	6	7	8
Well No.	1	2	3	4	5	6	7	8
*18:49, 39:20								8
*18:56, 37:01:01-37:01:08, 37:03N-37:04:02, 37:06, 37:08, 37:10-37:11, 37:13-37:24, 37:26-37:27, 37:29-37:34							7	8
*27:83								
*37:05							7	8
*37:09		2					7	8
*37:12						6		8
*37:28							7	8
*38:30						6	7	8
*40:136, 41:08					5	6		
*40:166, 54:02, 55:16, 56:35			3					
*41:06				4		6		
*41:15		2				6		
*44:20, 44:100, 45:03				4				
*44:106		2						
*44:117, C*07:04:01-07:04:08, C*07:11-07:12, C*07:45, C*07:63, C*07:101, C*07:139, C*07:142, C*07:181, C*07:199:01-07:199:02							w	
*45:06			3	4			7	
*45:14				4		6	7	
*53:15								
*55:04, 55:49, 55:51	1							
*55:20	1			4		6		
*55:56, 56:13	1			4		6	7	
*82:01-82:03	1					6	7	
C*01:59, C*06:82, C*07:49, C*07:210, C*07:238, C*07:247								
HLA-B allele ⁴								
Well No.	1	2	3	4	5	6	7	8

101.543-06 – including *Taq* pol., IFU-01
 101.543-06u – without *Taq* pol., IFU-02

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

Lot No.: **35R**

Lot-specific information

170	280	180	105	65	200	230	Length of spec. PCR product(s)
					290		
9	10	11	12	13	14	15	Well No.
					14		*18:49, 39:20
							*18:56, 37:01:01-37:01:08, 37:03N- 37:04:02, 37:06, 37:08, 37:10-37:11, 37:13-37:24, 37:26-37:27, 37:29-37:34
		11					*27:83
					14		*37:05
	10						*37:09
							*37:12
			12				*37:28
							*38:30
							*40:136, 41:08
							*40:166, 54:02, 55:16, 56:35
						15	*41:06
						15	*41:15
							*44:20, 44:100, 45:03
	10						*44:106
							*44:117, C*07:04:01-07:04:08, C*07:11- 07:12, C*07:45, C*07:63, C*07:101, C*07:139, C*07:142, C*07:181, C*07:199:01-07:199:02
							*45:06
							*45:14
		11			14		*53:15
	10						*55:04, 55:49, 55:51
							*55:20
							*55:56, 56:13
9							*82:01-82:03
					14		C*01:59, C*06:82, C*07:49, C*07:210, C*07:238, C*07:247
							HLA-B allele ⁴
9	10	11	12	13	14	15	Well No.

101.543-06 – including *Taq* pol., IFU-01
101.543-06u – without *Taq* pol., IFU-02

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“Instructions for Use” (IFU)

Lot No.: 35R**Lot-specific information**

¹The internal positive control primer pairs amplify segments of the human growth hormone gene. The two different control primer pairs give rise to either an internal positive control band of 1070 base pairs, for most wells, or a band of 800 base pairs, for some wells.

Well number 1 contains the primer pair giving rise to the shorter, 800 bp, internal positive control band in order to help in the correct orientation of the HLA-B*42 SSP subtyping.

In addition, wells number 5 and 10 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.

⁴HLA-B*42 alleles in bold lettering are listed as confirmed alleles on the on the IMGT/HLA web page www.ebi.ac.uk/imgt/hla, release 3.9.0, July 2012.

⁵The B*4203 allele was never assigned.

⁶The HLA-B*42 primer set cannot separate the B*42:07 and the B*08:94 alleles. These alleles can be distinguished by the HLA-B low resolution kit and/or the HLA-B*08 high resolution kit.

⁷Primer mix 14: Specific PCR fragment of 200 bp in the B*42:15 and the B*07:11, 07:57, 07:75, 08:17, 08:47, 18:49, 37:05 and 39:20 and in the C*01:59, C*06:82, C*07:49, C*07:210, C*07:238 and C*07:247 alleles. Specific PCR fragment of 290 bp in the B*42:13 and the B*08:49, 08:60, 08:76 and 53:15 alleles.

'w', might be weakly amplified.

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Lot No.: **35R**

Lot-specific information

CELL LINE VALIDATION SHEET																			
HLA-B*42 SSP primer set																			
				Well															
				1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
				Prod. No.:	200960601	200960602	200960603	200960604	200960605	200960606	201189007	201189008	200960609	201207810	200960611	201078312	201078313	201189014	201078315
IHWC cell line		B*																	
1	9001	SA	*07:02	+	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-
2	9280	LK707	*52:01	*73:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
3	9011	E4181324	*52:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
4	9275	GU373	*15:10	*53:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
5	9009	KAS011	*37:01		-	-	-	-	-	-	+	+	-	-	-	-	-	-	-
6	9353	SM	*39:01	*51:01	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-
7	9020	QBL	*18:01		-	-	-	-	-	-	-	+	-	-	-	-	-	-	-
8	9025	DEU	*35:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
9	9026	YAR	*38:01		-	-	-	-	-	-	-	+	-	-	-	-	-	-	-
10	9107	LKT3	*54:01		+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
11	9051	PITOUT	*44:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
12	9052	DBB	*57:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
13	9025	JESTHOM	*27:05		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
14	9071	OLGA	*15:01	*15:20	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
15	9075	DKB	*40:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
16	9037	SWEIG007	*40:02		-	-	-	-	-	-	-	+	-	+	-	-	-	-	-
17	9282	CTM3953540	*08:01	*55:01	+	+	-	-	-	+	-	-	-	-	-	-	-	-	-
18	9257	32367	*14:01	*56:01	+	-	-	-	-	-	-	+	-	-	-	-	-	-	-
19	9038	BM16	*18:01		-	-	-	-	-	-	-	+	-	-	-	-	-	-	-
20	9059	SLE005	*40:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
21	9064	AMALA	*15:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
22	9056	KOSE	*35:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
23	9124	IHL	*40:02	*56:02	+	-	-	-	-	-	-	+	-	+	-	-	-	-	-
24	9035	JBUSH	*38:01		-	-	-	-	-	-	-	+	-	-	-	-	-	-	-
25	9049	IBW9	*14:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
26	9285	WT49	*58:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
27	9191	CH1007 ¹	*07:05	*51:01	+	-	-	-	-	-	-	-	+	-	-	-	-	-	-
28	9320	BEL5GB	*44:02	*44:03	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
29	9050	MOU	*44:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
30	9021	RSH	*42:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
31	9019	DUCAF	*18:01		-	-	-	-	-	-	-	+	-	-	-	-	-	-	-
32	9297	HAG	*41:02		-	+	-	-	-	+	-	-	-	-	-	-	-	-	-
33	9098	MT14B	*40:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
34	9104	DHIF	*38:01		-	-	-	-	-	-	-	+	-	-	-	-	-	-	-
35	9302	SSTO	*44:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
36	9024	KT17	*15:01	*35:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
37	9065	HHKB	*07:02		+	-	-	-	-	-	-	-	+	-	-	-	-	-	-
38	9099	LZL	*15:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
39	9315	CML	*08:01	*27:05	-	+	-	-	-	+	-	-	-	-	-	-	-	-	-
40	9134	WHONP199	*13:02	*46:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
41	9055	H0301	*14:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
42	9066	TAB089	*46:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
43	9076	T7526	*46:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
44	9057	TEM	*38:01		-	-	-	-	-	-	-	+	-	-	-	-	-	-	-
45	9239	SHJO	*42:01	*50:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
46	9013	SCHU	*07:02		-	+	-	-	-	-	-	-	+	-	-	-	-	-	-
47	9045	TUBO ¹	*51:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
48	9303	TER-ND	*35:01	*44:03	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

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Lot No.: **35R**

Lot-specific information

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-B*42 SSP

Product number: 101.543-06 – including *Taq* pol.
 101.543-06u – without *Taq* pol.
Lot number: 35R
Expiry date: 2015-March-01
Number of tests: 6
Number of wells per test: 15

Well specifications:

Well No.	Production No.	Well No.	Production No.
1	2009-606-01	9	2009-606-09
2	2009-606-02	10	2012-078-10
3	2009-606-03	11	2009-606-11
4	2009-606-04	12	2010-783-12
5	2009-606-05	13	2010-783-13
6	2009-606-06	14	2011-890-14
7	2011-890-07	15	2010-783-15
8	2011-890-08		

The specificity of each primer solution of the HLA-B*42 primer set has been tested against 48 well characterized IHWC cell line DNAs.

No DNAs carrying the alleles to be amplified by primer solution 5, 11 and 13 to 15 were available. The specificities of the primers in primer solution 5, 11 and 14 were tested by separately adding one additional 3'-primer, respectively one additional 5'-primer. In primer solutions 13 and 15 it was only possible to test the 5'-primers, the 3'-primers were not possible to test. In primer solution 14 one 3'-primer was not possible to test. One additional 5'-primer in primer solution 7 was tested by separately adding one additional 3'-primer.

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

Date of approval: 2012-October-11

Approved by:

Production Quality Control

101.543-06 – including *Taq pol.*, IFU-01
101.543-06u – without *Taq pol.*, IFU-02

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Lot No.: **35R**

Lot-specific information

Declaration of Conformity

Product name: *Olerup SSP*[®] HLA-B*42
Product number: 101.543-06/06u
Lot number: 35R

Intended use: HLA-B*42 high resolution histocompatibility testing

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

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

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

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

Stockholm, Sweden
2012-October-11

Ann-Cathrin Jareman
Head of QA and Regulatory Affairs

101.543-06 – including *Taq pol.*, IFU-01
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Lot-specific information

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