

101.524-12 – including *Taq* polymerase, IFU-01 Rev. No. 03
101.524-12u – without *Taq* polymerase, IFU-02 Rev. No. 03

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“Instructions for Use” (IFU)

Lot No.: **06S**

Lot-specific information

Olerup SSP® HLA-B*14

Product number:	101.524-12 – including <i>Taq</i> polymerase 101.524-12u – without <i>Taq</i> polymerase
Lot number:	06S
Expiry date:	2015-August-01
Number of tests:	12
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. 06S.

CHANGES COMPARED TO THE PREVIOUS *OLERUP SSP*® HLA-B*14 LOT

The HLA-B*14 specificity and interpretation tables have been updated for the HLA-B alleles described since the previous *Olerup SSP*® HLA-B*14 lot was made (Lot No. 56N).

The HLA-B*14 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*14 including and without *Taq* polymerase is now described in one common Product Insert.

¹As described in section Uniquely Identified Alleles.

The HLA-B*14 primer set is unchanged compared to the previous lot.

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PRODUCT DESCRIPTION

HLA-B*14 SSP subtyping

CONTENT

The primer set contains 5'- and 3'-primers for identifying the HLA-B*14:01 to B*14:33 alleles.

PLATE LAYOUT

Each test consists of 16 PCR reactions in a 16 well PCR plate.

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

The 16 well cut PCR plate is marked with ‘HLA-B*14’ in silver/gray ink.

Well No. 1 is marked with the Lot No. ‘06S’.

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 covered. Use a scalpel or a similar instrument to carefully cut the foil between the plates.

INTERPRETATION

The interpretation of HLA-B*14 SSP subtypings will be influenced by most B*07, most B*08, five B*13, several B*15, the B*18, the B*27, several B*35, the B*37, the B*38, the B*39, many B*40, the B*41, the B*42, seven B*44, the B*45:08, five B*46, the B*47:08, the B*48, most B*51, most B*52, three B*53, most B*54, most B*55, the B*56, four B*57, twelve B*58, the B*59, four B*67, the B*73, eight B*78 and the B*81 alleles when present on the other haplotype. In addition, the C*01:30 allele will be amplified by primer mixes 1 and 4, the C*01:35, C*03:17, C*03:71 and C*14:20 alleles will be amplified by primer mix 12, the C*03:137 and C*12:82 alleles will be amplified by primer mix 8, the C*07:102 allele will be weakly amplified by primer mix 8, the C*08:08 allele will be amplified by primer mix 6, the C*08:51 allele will be amplified by primer mixes 4 and 7, the C*12:87 allele will be amplified by primer mix 1, the C*15:39 allele will be amplified by primer mix 15 and the C*15:55 allele will be amplified by primer mix 16.

UNIQUELY IDENTIFIED ALLELES

All the HLA-B*14 alleles, i.e. **B*14:01 to B*14:33**, recognized by the HLA Nomenclature Committee in October 2012¹ will be amplified by the primers in the HLA-B*14 subtyping kit.

The HLA-B*14 kit enables separation of the confirmed HLA-B*14 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*14 alleles is listed below.

The HLA-B*14 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*14 primer set cannot distinguish the following silent mutations: the B*14:01:01-14:01:02, the B*14:02:01-14:02:07 or the B*14:06:01-14:06:02 alleles.

The B*14:16 and B*14:23 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 16.

¹HLA-B alleles listed on the IMGT/HLA web page 2012-October-14, release 3.10.0, www.ebi.ac.uk/imgt/hla.

²The B*14:08 and B*39:43 alleles will give rise to identical amplification patterns with the HLA-B*14 subtyping kit. These alleles can be distinguished by the HLA-B low resolution kit and/or the HLA-B*39 subtyping kit.

ALLELE CONFIRMATION STATUS

Allele	Status ¹	Allele	Status ¹	Allele	Status ¹
B*14:01:01	Confirmed	B*14:12	Confirmed	B*14:32	Unconfirmed
B*14:01:02	Unconfirmed	B*14:13	Unconfirmed	B*14:33	Unconfirmed
B*14:02:01	Confirmed	B*14:14	Unconfirmed		
B*14:02:02	Confirmed	B*14:15	Unconfirmed		
B*14:02:03	Unconfirmed	B*14:16	Unconfirmed		
B*14:02:04	Unconfirmed	B*14:17	Unconfirmed		
B*14:02:05	Unconfirmed	B*14:18	Confirmed		
B*14:02:06	Unconfirmed	B*14:19	Confirmed		
B*14:02:07	Unconfirmed	B*14:20	Confirmed		
B*14:02:08	Unconfirmed	B*14:21	Unconfirmed		
B*14:03	Confirmed	B*14:22	Unconfirmed		
B*14:04	Unconfirmed	B*14:23	Confirmed		
B*14:05	Confirmed	B*14:24	Unconfirmed		
B*14:06:01	Confirmed	B*14:25	Unconfirmed		
B*14:06:02	Confirmed	B*14:26	Unconfirmed		
B*14:07N	Confirmed	B*14:27	Unconfirmed		
B*14:08	Confirmed	B*14:28	Unconfirmed		
B*14:09	Confirmed	B*14:29	Unconfirmed		
B*14:10	Confirmed	B*14:30	Unconfirmed		
B*14:11	Unconfirmed	B*14:31	Unconfirmed		

¹Allele status “confirmed” or “unconfirmed” as listed on the IMGT/HLA web page 2012-October-14, release 3.10.0, www.ebi.ac.uk/imgt/hla.

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RESOLUTION IN HOMO- AND HETEROZYGOTES

A total of 42 alleles generate 23 amplification patterns that can be combined in 276 homozygous and heterozygous combinations. 186 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.

+-----	-+-----	*14:21, *14:28 = *14:28, *14:28
+-----	---+-----	*14:02:01, *14:02:01 = *14:02:01, *14:21
+-----	---+-----+	*14:02:01, *14:16 = *14:16, *14:16 = *14:16, *14:21
+-----	---+-----+	*14:02:01, *14:15 = *14:15, *14:15 = *14:15, *14:21
+-----	---+-----+	*14:02:01, *14:18 = *14:18, *14:18 = *14:18, *14:21
+-----	---+-----+	*14:02:01, *14:13 = *14:13, *14:21
+-----	---+-----	*14:02:01, *14:27 = *14:21, *14:27
+-----	---+-----	*14:02:01, *14:11 = *14:02:01, *14:28 = *14:11, *14:11 = *14:11, *14:21 = *14:11, *14:28
+-----	+-----	*14:02:01, *14:09 = *14:09, *14:09 = *14:09, *14:21
+-----	---+-----	*14:02:01, *14:06:01 = *14:06:01, *14:21
+-----	---+-----	*14:02:01, *14:05 = *14:02:01, *14:17 = *14:05, *14:17 = *14:05, *14:21 = *14:17, *14:17 = *14:17, *14:21
+-----	---+-----	*14:02:01, *14:04 = *14:04, *14:04 = *14:04, *14:21
+-----	---+-----	*14:02:01, *14:03 = *14:02:01, *14:20 = *14:03, *14:03 = *14:03, *14:20 = *14:03, *14:21 = *14:20, *14:21
+-----	---+-----	*14:01:01, *14:01:01 = *14:01:01, *14:21
+-----	---+-----+	*14:11, *14:16 = *14:16, *14:28
+-----	---+-----+	*14:11, *14:15 = *14:15, *14:28
+-----	---+-----+	*14:11, *14:18 = *14:18, *14:28
+-----	---+-----+	*14:11, *14:13 = *14:13, *14:28
+-----	---+-----	*14:11, *14:27 = *14:27, *14:28
+-----	---+-----	*14:09, *14:11 = *14:09, *14:28
+-----	---+-----	*14:06:01, *14:11 = *14:06:01, *14:28
+-----	---+-----+	*14:05, *14:16 = *14:16, *14:17
+-----	---+-----+	*14:05, *14:15 = *14:15, *14:17
+-----	---+-----+	*14:05, *14:18 = *14:17, *14:18
+-----	---+-----	*14:05, *14:27 = *14:17, *14:27
+-----	---+-----	*14:05, *14:11 = *14:05, *14:28 = *14:11, *14:17 = *14:17, *14:28
+-----	---+-----	*14:05, *14:09 = *14:09, *14:17
+-----	---+-----	*14:04, *14:11 = *14:04, *14:28
+-----	---+-----	*14:04, *14:05 = *14:04, *14:17
+-----	---+-----+	*14:03, *14:16 = *14:16, *14:20
+-----	---+-----+	*14:03, *14:15 = *14:15, *14:20
+-----	---+-----+	*14:03, *14:18 = *14:18, *14:20
+-----	---+-----	*14:03, *14:27 = *14:20, *14:27
+-----	---+-----	*14:03, *14:11 = *14:03, *14:28 = *14:11, *14:20 = *14:20, *14:28
+-----	---+-----	*14:03, *14:09 = *14:09, *14:20
+-----	---+-----	*14:03, *14:05 = *14:03, *14:17 = *14:17, *14:20
+-----	---+-----	*14:03, *14:04 = *14:04, *14:20
+-----	---+-----+	*14:01:01, *14:10 = *14:10, *14:21
+-----	---+-----	*14:01:01, *14:14 = *14:14, *14:14 = *14:14, *14:21
+-----	---+-----	*14:01:01, *14:12 = *14:01:01, *14:19 = *14:12, *14:12 = *14:12, *14:19 = *14:12, *14:21 = *14:19, *14:21
+-----	---+-----	*14:01:01, *14:08 = *14:08, *14:21
+-----	---+-----	*14:01:01, *14:07N = *14:07N, *14:07N = *14:07N, *14:21
+-----	---+-----+	*14:10, *14:12 = *14:10, *14:19
+-----	---+-----+	*14:12, *14:14 = *14:14, *14:19
+-----	---+-----	*14:12, *14:28 = *14:19, *14:28
+-----	---+-----	*14:08, *14:12 = *14:08, *14:19
+-----	---+-----	*14:07N, *14:12 = *14:07N, *14:19
+-----	---+-----+	*14:01:01, *14:15 = *14:02:01, *14:10 = *14:10, *14:15
+-----	---+-----	*14:01:01, *14:18 = *14:02:01, *14:14 = *14:14, *14:18
+-----	---+-----	*14:01:01, *14:27 = *14:02:01, *14:12 = *14:02:01, *14:19 = *14:12, *14:27

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+++-----	---+-----	*14:01:01, *14:06:01 = *14:02:01, *14:08
+++-----	---+-----	*14:01:01, *14:05 = *14:01:01, *14:17
+++-----	---+-----	*14:01:01, *14:04 = *14:02:01, *14:07N = *14:04, *14:07N
+++-----	---+-----	*14:01:01, *14:03 = *14:01:01, *14:20
+++-----	---+-----	*14:10, *14:18 = *14:14, *14:15
+++-----	---+-----	*14:12, *14:16 = *14:16, *14:19
+++-----	---+-----	*14:10, *14:27 = *14:12, *14:15 = *14:15, *14:19
+++-----	---+-----	*14:12, *14:18 = *14:14, *14:27 = *14:18, *14:19
+++-----	---+-----	*14:12, *14:13 = *14:13, *14:19
+++-----	---+-----	*14:11, *14:12 = *14:11, *14:19
+++-----	---+-----	*14:09, *14:12 = *14:09, *14:19
+++-----	---+-----	*14:06:01, *14:14 = *14:08, *14:18
+++-----	---+-----	*14:06:01, *14:12 = *14:06:01, *14:19 = *14:08, *14:27
+++-----	---+-----	*14:05, *14:14 = *14:14, *14:17
+++-----	---+-----	*14:05, *14:12 = *14:05, *14:19 = *14:12, *14:17 = *14:17, *14:19
+++-----	---+-----	*14:04, *14:10 = *14:07N, *14:15
+++-----	---+-----	*14:04, *14:14 = *14:07N, *14:18
+++-----	---+-----	*14:04, *14:12 = *14:04, *14:19 = *14:07N, *14:27
+++-----	---+-----	*14:04, *14:08 = *14:06:01, *14:07N
+++-----	---+-----	*14:05, *14:07N = *14:07N, *14:17
+++-----	---+-----	*14:03, *14:14 = *14:14, *14:20
+++-----	---+-----	*14:03, *14:12 = *14:03, *14:19 = *14:12, *14:20 = *14:19, *14:20
+++-----	---+-----	*14:03, *14:07N = *14:07N, *14:20

*14:01:01 = *14:01:01-14:01:02 and 14:26, 14:32

*14:02:01 = *14:02:01-14:02:07 and 14:22, 14:24-14:25, 14:29-14:31, 14:33

*14:06:01 = *14:06:01-14:06:02

*14:16 = *14:16 and 14:23

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SPECIFICITY TABLE**HLA-B*14 SSP subtyping**

Specificities and sizes of the PCR products of the 16 primer mixes used for HLA-B*14 SSP subtyping

Primer Mix	Size of spec. PCR product ¹	Size of control band ²	Amplified HLA-B*14 alleles	Other amplified HLA Class I alleles ^{3,4}
1	265 bp	800 bp	*14:01:01-14:04, 14:07N, 14:09, 14:11-14:12, 14:14-14:19, 14:21-14:33	*18:44:01-18:44:02, C*01:30 , C*12:87
2⁶	185 bp	1070 bp	*14:01:01-14:01:02, 14:07N-14:08, 14:10, 14:12, 14:14, 14:19, 14:26, 14:32	*07:02:32, 38:01:01-38:02:02, 38:02:04-38:03, 38:07-38:24, 38:26-38:32, 38:34N-38:42, 39:01:01:01-39:01:01:03, 39:01:03-39:01:08, 39:01:10-39:02:01, 39:03, 39:05:01-39:09, 39:11, 39:14-39:15, 39:18, 39:19:02, 39:22, 39:24:01-39:39:01, 39:40:01N-39:44, 39:46-39:48, 39:50-39:62, 39:64-39:71, 39:73-39:75, 39:77, 39:79, 67:01:01, 67:03
3	210 bp	800 bp	*14:02:01-14:03, 14:04 ^w , 14:05-14:06:02, 14:09, 14:11, 14:13, 14:15-14:18, 14:20, 14:22-14:25, 14:27, 14:29-14:31, 14:33	*15:09-15:10:02, 15:18:01-15:18:05, 15:21, 15:23, 15:37, 15:44, 15:51-15:52, 15:66, 15:72, 15:80, 15:90, 15:93, 15:99, 15:108, 15:114-15:115, 15:119, 15:124, 15:133-15:134, 15:153, 15:161, 15:176, 15:186, 15:189, 15:197-15:198, 15:200, 15:221, 15:226N, 15:229, 15:238, 15:243, 15:252, 15:263, 35:26, 35:82, 35:85, 35:135, 38:05, 38:33, 39:04, 51:22, 56:33, 78:03
4^{5,7,8}	85 bp, 270 bp	1070 bp	*14:03, 14:20	*18:13, 18:30, 51:29, 51:82, 52:24, C*01:30 , C*08:51
5⁹	135 bp, 220 bp	1070 bp	*14:04, 14:07N	*39:40:01N-39:40:02N
6^{5,10}	95 bp, 175 bp	1070 bp	*14:05, 14:17	*07:115, 08:69, 38:19, 39:03, 39:24:01-39:24:02, 39:37, 39:76, 41:18, 42:06, 48:07, C*08:08
7	260 bp	1070 bp	*14:06:01-	*15:37-15:38:02, 15:185,

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			14:06:02, 14:08	18:01:01:01-18:01:15, 18:01:17-18:01:18, 18:03-18:09, 18:12-18:13, 18:15, 18:17N-18:20, 18:23N-18:26, 18:28-18:34, 18:36-18:38, 18:40-18:43, 18:45-18:55, 18:57, 18:59-18:68, 18:70-18:83, 39:32, 39:43, 39:48, 40:51, 40:113, 40:163, 51:06:01-51:06:02, 51:45, 51:62, 51:135, 56:31, C*08:51
8	250 bp	1070 bp	*14:01:01-14:01:02, 14:07N-14:08, 14:10, 14:12, 14:14, 14:19, 14:26, 14:32	*07:02:01-07:02:15, 07:02:17-07:05:04, 07:05:06-07:26, 07:28, 07:30-07:35, 07:37, 07:39-07:64, 07:66-07:69, 07:73-07:78, 07:80, 07:82-07:85, 07:87-07:110, 07:112-07:148, 07:150-07:176, 08:94, 15:68, 15:71, 15:175, 18:01:01:01-18:01:12, 18:01:14-18:03, 18:05-18:08, 18:10-18:15, 18:17N-18:24, 18:26-18:53, 18:55-18:66, 18:69, 18:71-18:83, 27:08, 27:12, 27:18, 27:26, 27:33, 27:40, 27:42, 27:44, 27:89, 35:50, 35:84, 35:162, 35:197, 37:05, 37:11, 37:37, 39:01:01:01-39:01:01:03, 39:01:03-39:01:14, 39:02:01-39:03, 39:05:01-39:11, 39:13:01-39:20, 39:22-39:62, 39:64-39:71, 39:73-39:75, 39:77-39:79, 40:02:01-40:02:14, 40:02:16-40:06:06, 40:08-40:09, 40:11:01-40:11:02, 40:18, 40:20, 40:24, 40:26-40:29, 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, 40:93-40:95, 40:97-40:99, 40:103-40:105, 40:107, 40:111, 40:115, 40:119-40:120, 40:122, 40:127, 40:131, 40:133Q, 40:142N-40:145, 40:148-40:149, 40:159, 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, 40:200, 40:202-40:203, 40:205-40:206, 40:209-40:211, 40:214, 40:220, 40:224-40:226, 42:01:01-42:02,

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				42:04-42:17, 44:131, 48:01:01-48:17, 48:19-48:21, 48:23-48:28, 54:02, 55:10, 56:35, 67:01:01-67:03, 73:01-73:02, 81:01-81:06, C*03:137, C*07:102^w, C*12:82
9	160 bp	1070 bp	*14:09	
10⁶	180 bp	1070 bp	*14:11, 14:28	*15:189, 35:26, 38:33, 39:04
11	135 bp	1070 bp	*14:01:01-14:18, 14:20-14:26, 14:28-14:33	*07:19, 07:31, 07:34, 07:43, 08:01:01-08:05, 08:07-08:10, 08:12:01-08:20, 08:22-08:24, 08:26-08:39, 08:41-08:78, 08:80-08:105, 13:06, 13:46, 13:53, 15:42, 15:44, 15:50, 15:69, 15:83, 15:86, 15:93, 15:121, 15:186, 15:188, 15:199, 15:218Q, 15:224, 15:252, 18:01:01:01-18:09, 18:11-18:15, 18:17N-18:20, 18:22-18:34, 18:37-18:49, 18:51-18:55, 18:59-18:83, 27:15, 27:28, 27:62, 27:71, 35:35, 35:60, 35:87, 35:93, 35:96, 35:157, 35:188, 35:190, 35:213, 37:01:01-37:01:04, 37:01:06-37:01:09, 37:03N-37:06, 37:08-37:25, 37:27-37:37, 38:01:01-38:07, 38:09-38:21, 38:23-38:29, 38:31-38:42, 39:01:01:01-39:01:01:03, 39:01:03-39:20, 39:22-39:31, 39:34-39:46, 39:48-39:49, 39:51-39:73, 39:75-39:79, 40:39, 40:51, 40:163, 40:184, 40:199, 41:01-41:16, 41:18, 41:20-41:25, 42:01:01-42:02, 42:04-42:17, 44:04, 44:56N, 44:132, 44:163, 45:08, 46:03, 46:18, 46:21:01-46:21:02, 46:29, 47:08, 51:21, 51:36, 51:101, 51:143, 54:01:01-54:02, 54:04-54:05N, 54:07-54:25, 54:27-54:28, 55:01:01-55:05, 55:07, 55:10-55:21, 55:23, 55:25-55:50, 55:52-55:57, 56:10, 56:12, 56:18, 56:23, 56:31-56:32, 57:26, 58:05, 58:20, 58:35, 59:01:01:01-59:03, 59:05, 67:01:01-67:03, 78:07
12	230 bp	1070 bp	*14:12, 14:19, 14:27	*57:11, 58:02, 58:06-58:07, 58:25, 58:38, C*01:35, C*03:17, C*03:71, C*14:20

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13⁷	210 bp	1070 bp	*14:13	*13:15, 13:62, 18:26, 18:61, 39:32, 39:48, 40:28, 40:51, 40:113, 40:163, 40:174, 51:01:01-51:01:18, 51:01:20-51:01:30, 51:01:32-51:01:38, 51:03-51:04, 51:06:01-51:09:02, 51:11N-51:14, 51:16, 51:19-51:22, 51:24:01-51:24:04, 51:26-51:33, 51:35, 51:38-51:39, 51:41N, 51:43-51:44N, 51:46, 51:48-51:53, 51:55-51:58, 51:60-51:80, 51:82-51:84, 51:86-51:89, 51:91, 51:95-51:107, 51:109-51:134, 51:136-51:142, 51:145, 51:147, 52:01:01-52:01:10, 52:01:12-52:02, 52:04-52:10:02, 52:13-52:25, 52:27-52:31, 56:05:01-56:06, 56:21, 56:34, 58:08:01-58:08:02, 78:01:01-78:03, 78:05-78:07
14⁷	190 bp	1070 bp	*14:14, 14:18	*07:16, 07:27, 07:37-07:38, 07:50, 07:75, 07:91, 08:03, 08:23, 08:54, 15:03:01-15:03:03, 15:09-15:10:02, 15:18:01-15:18:05, 15:23, 15:29, 15:37, 15:47:01-15:47:02, 15:49, 15:51-15:52, 15:54, 15:62, 15:64:01-15:64:02, 15:68-15:69, 15:72, 15:74, 15:80, 15:90-15:91, 15:93, 15:98-15:99, 15:103, 15:108, 15:114-15:115, 15:119, 15:123-15:124, 15:127, 15:131-15:134, 15:151, 15:153, 15:156, 15:158, 15:161, 15:173, 15:176, 15:186, 15:197-15:198, 15:200, 15:210, 15:220-15:221, 15:226N, 15:229, 15:235, 15:238, 15:242-15:243, 15:251-15:253, 15:263, 18:01:01:01-18:01:01:02, 18:01:03-18:02, 18:05-18:15, 18:17N-18:28, 18:30-18:79, 18:81-18:83, 35:25, 35:124-35:125, 35:142, 35:162, 37:01:01-37:21, 37:23-37:36, 38:01:01-38:02:04, 38:04-38:12, 38:15, 38:17-38:25, 38:27, 38:29-38:40, 38:42, 39:05:01-39:05:02, 39:07-39:08, 39:11, 39:13:01-39:13:02, 39:20, 39:37, 39:49, 39:55-39:56, 40:12, 40:149, 41:22,

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 101.524-12u – without *Taq* polymerase, IFU-02 Rev. No. 03

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Lot-specific information

				42:11, 44:130, 44:156, 48:01:01-48:02:01, 48:02:03-48:28, 49:25, 51:116, 52:16, 52:27, 57:58, 58:12
15^{5,11}	100 bp, 270 bp	800 bp	*14:10, 14:15	*18:22, 18:69, 35:21, 35:24:01-35:24:02, 35:81, 35:96, 35:109, 35:157, 35:188, 35:190, 37:04:01-37:04:02, 40:28, 51:04, 51:46, 51:56:01-51:56:02, 51:139, 53:02, 53:06, 53:28, 57:14, 58:09, C*15:39
16^{5,12}	90 bp, 175 bp	1070 bp	*14:16, 14:23	C*15:55

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*14 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*14 subtyping.

In addition, wells number 3 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 some non-HLA-B*14 alleles will be amplified by primer mixes 1 to 8 and 10 to 15. In addition, the C*01:30 allele will be amplified by primer mixes 1 and 4, the C*01:35, C*03:17, C*03:71 and C*14:20 alleles will be amplified by primer mix 12, the C*03:137 and C*12:82 alleles will be amplified by primer mix 8, the C*07:102 allele will be weakly amplified by primer mix 8, the C*08:08 allele will be amplified by primer mix 6, the C*08:51 allele will be amplified by primer mixes 4 and 7, the C*12:87 allele will be amplified by primer mix 1, the C*15:39 allele will be amplified by primer mix 15 and the C*15:55 allele will be amplified by primer mix 16.

⁴For several HLA Class I alleles 1st and/or 4th exon(s) and beyond, as well as intron nucleotide sequences, are not available. In these instances it is not known whether some of the primers of the SSP sets are completely matched with the target sequences or not. We assume that unknown sequences in these regions are conserved within allelic groups.

⁵HLA-specific PCR products shorter than 125 base pairs have a lower intensity and are less sharp than longer PCR products.

⁶Primer mixes 2 and 10 may give rise to a lower yield of HLA-specific PCR product than the other B*14 primer mixes.

⁷Primer mix 4, 13 and 14 may have tendencies of unspecific amplifications.

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⁸Primer mix 4: Specific PCR fragment of 85 bp in the B*14:03 and the B*18:13, 18:30, 51:29, 51:82 and 52:24 and in the C*01:30 and C*08:51 alleles. Specific PCR fragment of 270 bp in the B*14:20 allele.

⁹Primer mix 5: Specific PCR fragment of 135 bp in the B*14:07N and 39:40:01N-39:40:02N alleles. Specific PCR fragment of 220 bp in the B*14:04 allele.

¹⁰Primer mix 6: Specific PCR fragment of 95 bp in the B*14:05 and the B*07:115, 08:69, 38:19, 39:03, 39:24:01-39:24:02, 39:37, 39:76, 41:18, 42:06 and 48:07 and in the C*08:08 alleles. Specific PCR fragment of 175 bp in the B*14:17 allele.

¹¹Primer mix 15: Specific PCR fragment of 100 bp in the B*14:15 allele. Specific PCR fragment of 270 bp in the B*14:10 and in the B*18:22, 18:69, 35:21, 35:24:01-35:24:02, 35:81, 35:96, 35:109, 35:157, 35:188, 35:190, 37:04:01-37:04:02, 40:28, 51:04, 51:46, 51:56:01-51:56:02, 51:139, 53:02, 53:06, 53:28, 57:14 and 58:09 and the C*15:39 alleles.

¹²Primer mix 16: Specific PCR fragment of 90 bp in the B*14:23 and the C*15:55 alleles. Specific PCR fragment of 175 bp in the B*14:16 allele.
'w', might be weakly amplified.

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Lot-specific information

INTERPRETATION TABLE								
HLA-B*14 SSP subtyping								
Amplification patterns of the B*14:01 to B*14:33 alleles								
	Well⁷							
	1	2	3	4	5	6	7	8
Length of spec.	265	185	210	85	135	95	260	250
PCR product(s)				270	220	175		
Length of int.	800	1070	800	1070	1070	1070	1070	1070
pos. control¹								
5'-primer(s)²	361	103	103	353	91	113	363	103
	5' -AgT 3' 5' -CCT 3' 5' -CCg 3' 5' -CAA 3' 5' -ggC 3' 5' -CCA 3' 5' -Agg 3' 5' -CCT 3'							
		103		539	564	363		103
		5' -CCT 3'		5' -gCg 3'	5' -TgA 3' 5' -AgC 3'			5' -CCT 3'
3'-primer(s)³	583	246	272	583	269	246	583	310
	5' -gTg 3' 5' -TAT 3' 5' -TgC 3' 5' -gTg 3' 5' -AgT 3' 5' -TAT 3' 5' -gTg 3' 5' -gTT 3'							
		246			3rd I	419		
		5' -TAT 3'			5' -TAT 3' 5' -CgA 3'			
Well No.	1	2	3	4	5	6	7	8
HLA-B allele⁴								
*14:01:01-14:01:02, 14:26, 14:32	1	2						8
*14:02:01-14:02:07, 14:22, 14:24-14:25, 14:29-14:31, 14:33	1		3					
*14:03	1		3	4				
*14:04	1		w		5			
*14:05			3			6		
*14:06:01-14:06:02			3				7	
*14:07N	1	2			5			8
*14:08, 39:43⁵		2					7	8
*14:09	1		3					
*14:10		2						8
*14:11	1		3					
*14:12	1	2						8
*14:13			3					
*14:14	1	2						8
*14:15	1		3					
*14:16, 14:23⁶	1		3					
*14:17	1		3			6		
*14:18	1		3					
Well No.	1	2	3	4	5	6	7	8

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Lot-specific information

INTERPRETATION TABLE							
HLA-B*14 SSP subtyping							
Amplification patterns of the B*14:01 to B*14:33 alleles							
Well ⁷							
9	10	11	12	13	14	15	16
160	180	135	230	210	190	100	90
						270	175
1070	1070	1070	1070	1070	1070	800	1070
361	106	560	361	412	142	103	361
5' -AgT 3'	5' -CCA 3'	5' -CAC 3'	5' -AgT 3'	5' -ATA 3'	5' -TCT 3'	5' -CCg 3'	5' -AgT 3'
						355	
						5' -TCA 3'	
479	246	3rd I	541	583	292	164	409
5' -CCC 3'	5' -TAT 3'	5' -TAT 3'	5' -TCC 3'	5' -gTg 3'	5' -gTA 3'	5' -gCA 3'	5' -ATg 3'
			559		292	583	494
			5' -CAg 3'		5' -gTA 3'	5' -gTg 3'	5' -TCC 3'
					292		
					5' -gTA 3'		
9	10	11	12	13	14	15	16
Well No.							
HLA-B allele ⁴							
		11					
		11					
		11					
		11					
		11					
		11					
		11					
		11					
		11					
		11					
		11					
9		11					
		11				15	
	10	11					
		11	12				
		11		13			
		11			14		
		11				15	
		11					16
		11					
		11			14		
9	10	11	12	13	14	15	16
Well No.							

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Lot No.: **06S**

Lot-specific information

Length of spec.	265	185	210	85	135	95	260	250
PCR product(s)				270	220	175		
Well No.	1	2	3	4	5	6	7	8
*14:19	1	2						8
*14:20			3	4				
*14:21	1							
*14:27	1		3					
*14:28	1							
*07:02:01-07:02:15, 07:02:17-07:02:31, 07:02:33-07:05:04, 07:05:06-07:15, 07:17- 07:18:02, 07:20-07:26, 07:28, 07:30, 07:32- 07:33, 07:35, 07:39-07:42, 07:44-07:49N, 07:51-07:64, 07:66-07:69, 07:73-07:74, 07:76-07:78, 07:80, 07:82-07:85, 07:87- 07:90, 07:92-07:110, 07:112-07:114, 07:116- 07:148, 07:150-07:176, 15:71, 15:175, 27:08, 27:12, 27:18, 27:26, 27:33, 27:40, 27:42, 27:44, 27:89, 35:50, 35:84, 35:197, 40:02:01-40:02:14, 40:02:16-40:06:06, 40:08-40:09, 40:11:01-40:11:02, 40:18, 40:20, 40:24, 40:26-40:27:02, 40:29, 40:35, 40:37, 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, 40:93-40:95, 40:97-40:99, 40:103-40:105, 40:107, 40:111, 40:115, 40:119-40:120, 40:122, 40:127, 40:131, 40:133Q, 40:142N- 40:145, 40:148, 40:159, 40:161-40:162, 40:165, 40:167, 40:169, 40:173, 40:176- 40:177, 40:180-40:181, 40:189, 40:200, 40:202-40:203, 40:205-40:206, 40:209- 40:211, 40:214, 40:220, 40:224-40:226, 44:131, 48:02:02, 56:35, 73:01-73:02, 81:01- 81:06, C*03:137, C*12:82								8
*07:02:32, 39:33, 39:47, 39:50, 39:74		2						8
*07:16, 07:37, 07:50, 07:75, 07:91, 15:68, 18:10, 18:21, 18:35, 18:56, 18:58, 35:162, 40:149, 48:01:01-48:02:01, 48:02:03-48:06, 48:08-48:17, 48:19-48:21, 48:23-48:28								8
Well No.	1	2	3	4	5	6	7	8

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 101.524-12u – without *Taq* polymerase, IFU-02 Rev. No. 03

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Lot No.: **06S**

Lot-specific information

160	180	135	230	210	190	100	90	Length of spec. PCR product(s)
						270	175	
9	10	11	12	13	14	15	16	Well No.
			12					*14:19
		11						*14:20
		11						*14:21
			12					*14:27
	10	11						*14:28
								*07:02:01-07:02:15, 07:02:17-07:02:31, 07:02:33-07:05:04, 07:05:06-07:15, 07:17- 07:18:02, 07:20-07:26, 07:28, 07:30, 07:32- 07:33, 07:35, 07:39-07:42, 07:44-07:49N, 07:51-07:64, 07:66-07:69, 07:73-07:74, 07:76-07:78, 07:80, 07:82-07:85, 07:87- 07:90, 07:92-07:110, 07:112-07:114, 07:116- 07:148, 07:150-07:176, 15:71, 15:175, 27:08, 27:12, 27:18, 27:26, 27:33, 27:40, 27:42, 27:44, 27:89, 35:50, 35:84, 35:197, 40:02:01-40:02:14, 40:02:16-40:06:06, 40:08-40:09, 40:11:01-40:11:02, 40:18, 40:20, 40:24, 40:26-40:27:02, 40:29, 40:35, 40:37, 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, 40:93-40:95, 40:97-40:99, 40:103-40:105, 40:107, 40:111, 40:115, 40:119-40:120, 40:122, 40:127, 40:131, 40:133Q, 40:142N- 40:145, 40:148, 40:159, 40:161-40:162, 40:165, 40:167, 40:169, 40:173, 40:176- 40:177, 40:180-40:181, 40:189, 40:200, 40:202-40:203, 40:205-40:206, 40:209- 40:211, 40:214, 40:220, 40:224-40:226, 44:131, 48:02:02, 56:35, 73:01-73:02, 81:01- 81:06, C*03:137, C*12:82
								*07:02:32, 39:33, 39:47, 39:50, 39:74
					14			*07:16, 07:37, 07:50, 07:75, 07:91, 15:68, 18:10, 18:21, 18:35, 18:56, 18:58, 35:162, 40:149, 48:01:01-48:02:01, 48:02:03-48:06, 48:08-48:17, 48:19-48:21, 48:23-48:28
9	10	11	12	13	14	15	16	Well No.

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Lot No.: **06S**

Lot-specific information

Length of spec.	265	185	210	85	135	95	260	250
PCR product(s)				270	220	175		
Well No.	1	2	3	4	5	6	7	8
*07:19, 07:31, 07:34, 07:43, 08:94, 37:37, 39:01:09, 39:02:02, 39:10:01-39:10:02, 39:16-39:17, 39:19:01, 39:23, 39:39:02, 39:45, 39:78, 40:39, 40:184, 42:01:01-42:02, 42:04-42:05:02, 42:07-42:10, 42:12-42:17, 54:02, 55:10, 67:01:02-67:02								8
*07:27, 07:38, 15:03:01-15:03:03, 15:29, 15:47:01-15:47:02, 15:49, 15:54, 15:62, 15:64:01-15:64:02, 15:74, 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, 15:251, 15:253, 35:25, 35:124-35:125, 35:142, 37:01:05, 37:02, 37:07, 37:26, 40:12, 44:130, 44:156, 48:18, 48:22, 49:25, 57:58, 58:12								
*07:115						6		8
*08:01:01-08:02, 08:04-08:05, 08:07-08:10, 08:12:01-08:20, 08:22, 08:24, 08:26-08:39, 08:41-08:53:02, 08:55-08:68, 08:70-08:78, 08:80-08:93, 08:95-08:105, 13:06, 13:46, 13:53, 15:42, 15:50, 15:83, 15:86, 15:121, 15:188, 15:199, 15:218Q, 15:224, 27:15, 27:28, 27:62, 27:71, 35:35, 35:60, 35:87, 35:93, 35:213, 37:22, 39:12, 39:63, 39:72, 40:199, 41:01-41:16, 41:20-41:21, 41:23-41:25, 44:04, 44:56N, 44:132, 44:163, 45:08, 46:03, 46:18, 46:21:01-46:21:02, 46:29, 47:08, 51:36, 51:143, 54:01:01-54:01:03, 54:04-54:05N, 54:07-54:25, 54:27-54:28, 55:01:01-55:05, 55:07, 55:11-55:21, 55:23, 55:25-55:50, 55:52-55:57, 56:10, 56:12, 56:18, 56:23, 56:32, 57:26, 58:05, 58:20, 58:35, 59:01:01:01-59:03, 59:05								
*08:03, 08:23, 08:54, 15:69, 37:01:01-37:01:04, 37:01:06-37:01:09, 37:03N, 37:06, 37:08-37:10, 37:12-37:21, 37:23-37:25, 37:27-37:36, 38:02:03, 38:04, 38:06, 38:25, 41:22								
*08:69, 39:76, 41:18						6		
Well No.	1	2	3	4	5	6	7	8

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Lot No.: **06S**

Lot-specific information

160	180	135	230	210	190	100	90	Length of spec. PCR product(s)
						270	175	
9	10	11	12	13	14	15	16	Well No.
		11						*07:19, 07:31, 07:34, 07:43, 08:94, 37:37, 39:01:09, 39:02:02, 39:10:01-39:10:02, 39:16-39:17, 39:19:01, 39:23, 39:39:02, 39:45, 39:78, 40:39, 40:184, 42:01:01- 42:02, 42:04-42:05:02, 42:07-42:10, 42:12- 42:17, 54:02, 55:10, 67:01:02-67:02
					14			*07:27, 07:38, 15:03:01-15:03:03, 15:29, 15:47:01-15:47:02, 15:49, 15:54, 15:62, 15:64:01-15:64:02, 15:74, 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, 15:251, 15:253, 35:25, 35:124-35:125, 35:142, 37:01:05, 37:02, 37:07, 37:26, 40:12, 44:130, 44:156, 48:18, 48:22, 49:25, 57:58, 58:12
								*07:115
		11						*08:01:01-08:02, 08:04-08:05, 08:07-08:10, 08:12:01-08:20, 08:22, 08:24, 08:26-08:39, 08:41-08:53:02, 08:55-08:68, 08:70-08:78, 08:80-08:93, 08:95-08:105, 13:06, 13:46, 13:53, 15:42, 15:50, 15:83, 15:86, 15:121, 15:188, 15:199, 15:218Q, 15:224, 27:15, 27:28, 27:62, 27:71, 35:35, 35:60, 35:87, 35:93, 35:213, 37:22, 39:12, 39:63, 39:72, 40:199, 41:01-41:16, 41:20-41:21, 41:23- 41:25, 44:04, 44:56N, 44:132, 44:163, 45:08, 46:03, 46:18, 46:21:01-46:21:02, 46:29, 47:08, 51:36, 51:143, 54:01:01- 54:01:03, 54:04-54:05N, 54:07-54:25, 54:27- 54:28, 55:01:01-55:05, 55:07, 55:11-55:21, 55:23, 55:25-55:50, 55:52-55:57, 56:10, 56:12, 56:18, 56:23, 56:32, 57:26, 58:05, 58:20, 58:35, 59:01:01:01-59:03, 59:05
		11			14			*08:03, 08:23, 08:54, 15:69, 37:01:01- 37:01:04, 37:01:06-37:01:09, 37:03N, 37:06, 37:08-37:10, 37:12-37:21, 37:23-37:25, 37:27-37:36, 38:02:03, 38:04, 38:06, 38:25, 41:22
		11						*08:69, 39:76, 41:18
9	10	11	12	13	14	15	16	Well No.

101.524-12 – including *Taq* polymerase, IFU-01 Rev. No. 03
 101.524-12u – without *Taq* polymerase, IFU-02 Rev. No. 03

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Lot No.: **06S**

Lot-specific information

Length of spec. PCR product(s)	265	185	210	85	135	95	260	250
				270	220	175		
Well No.	1	2	3	4	5	6	7	8
*13:15, 13:62, 51:01:01-51:01:18, 51:01:20-51:01:30, 51:01:32-51:01:38, 51:03, 51:07:01-51:09:02, 51:11N-51:14, 51:16, 51:19-51:20, 51:24:01-51:24:04, 51:26-51:28, 51:30-51:33, 51:35, 51:38-51:39, 51:41N, 51:43-51:44N, 51:48-51:53, 51:55, 51:57-51:58, 51:60-51:61:02, 51:63-51:80, 51:83-51:84, 51:86-51:89, 51:91, 51:95-51:100, 51:102-51:107, 51:109-51:115, 51:117-51:134, 51:136-51:138, 51:140-51:142, 51:145, 51:147, 52:01:01:01-52:01:10, 52:01:12-52:02, 52:04-52:10:02, 52:13-52:15, 52:17-52:23, 52:25, 52:28-52:31, 56:05:01-56:06, 56:21, 56:34, 58:08:01-58:08:02, 78:01:01-78:02:02, 78:05-78:06								
*15:09-15:10:02, 15:18:01-15:18:05, 15:23, 15:51-15:52, 15:72, 15:80, 15:90, 15:99, 15:108, 15:114-15:115, 15:119, 15:124, 15:133-15:134, 15:153, 15:161, 15:176, 15:197-15:198, 15:200, 15:221, 15:226N, 15:229, 15:238, 15:243, 15:263			3					
*15:21, 15:66, 35:82, 35:85, 35:135, 56:33			3					
*15:37			3				7	
*15:38:01-15:38:02, 15:185, 51:45, 51:135							7	
*15:44			3					
*15:93, 15:186, 15:252, 38:05			3					
*15:189, 35:26			3					
*18:01:01:01-18:01:01:02, 18:01:03-18:01:12, 18:01:14-18:01:15, 18:01:17-18:01:18, 18:05-18:08, 18:12, 18:15, 18:17N-18:20, 18:23N-18:24, 18:28, 18:31-18:34, 18:37-18:38, 18:40-18:43, 18:45-18:49, 18:51-18:53, 18:55, 18:59-18:60, 18:62-18:66, 18:71-18:79, 18:81-18:83							7	8
*18:01:02, 18:03, 18:29, 18:80							7	8
*18:01:13, 18:09, 18:25, 18:54, 18:67-18:68, 18:70							7	
*18:01:16, 18:02, 18:11, 18:14, 18:27, 18:39, 37:05, 37:11, 39:13:01-39:13:02, 39:20, 39:49, 42:11								8
Well No.	1	2	3	4	5	6	7	8

101.524-12 – including *Taq* polymerase, IFU-01 Rev. No. 03
 101.524-12u – without *Taq* polymerase, IFU-02 Rev. No. 03

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 “Instructions for Use” (IFU)

Lot No.: **06S**

Lot-specific information

160	180	135	230	210	190	100	90	Length of spec. PCR product(s)
						270	175	
9	10	11	12	13	14	15	16	Well No.
				13				*13:15, 13:62, 51:01:01-51:01:18, 51:01:20-51:01:30, 51:01:32-51:01:38, 51:03, 51:07:01-51:09:02, 51:11N-51:14, 51:16, 51:19-51:20, 51:24:01-51:24:04, 51:26-51:28, 51:30-51:33, 51:35, 51:38-51:39, 51:41N, 51:43-51:44N, 51:48-51:53, 51:55, 51:57-51:58, 51:60-51:61:02, 51:63-51:80, 51:83-51:84, 51:86-51:89, 51:91, 51:95-51:100, 51:102-51:107, 51:109-51:115, 51:117-51:134, 51:136-51:138, 51:140-51:142, 51:145, 51:147, 52:01:01-52:01:10, 52:01:12-52:02, 52:04-52:10:02, 52:13-52:15, 52:17-52:23, 52:25, 52:28-52:31, 56:05:01-56:06, 56:21, 56:34, 58:08:01-58:08:02, 78:01:01-78:02:02, 78:05-78:06
					14			*15:09-15:10:02, 15:18:01-15:18:05, 15:23, 15:51-15:52, 15:72, 15:80, 15:90, 15:99, 15:108, 15:114-15:115, 15:119, 15:124, 15:133-15:134, 15:153, 15:161, 15:176, 15:197-15:198, 15:200, 15:221, 15:226N, 15:229, 15:238, 15:243, 15:263
					14			*15:21, 15:66, 35:82, 35:85, 35:135, 56:33
					14			*15:37
		11						*15:38:01-15:38:02, 15:185, 51:45, 51:135
		11			14			*15:44
	10							*15:93, 15:186, 15:252, 38:05
								*15:189, 35:26
		11			14			*18:01:01:01-18:01:01:02, 18:01:03-18:01:12, 18:01:14-18:01:15, 18:01:17-18:01:18, 18:05-18:08, 18:12, 18:15, 18:17N-18:20, 18:23N-18:24, 18:28, 18:31-18:34, 18:37-18:38, 18:40-18:43, 18:45-18:49, 18:51-18:53, 18:55, 18:59-18:60, 18:62-18:66, 18:71-18:79, 18:81-18:83
		11						*18:01:02, 18:03, 18:29, 18:80
		11			14			*18:01:13, 18:09, 18:25, 18:54, 18:67-18:68, 18:70
		11			14			*18:01:16, 18:02, 18:11, 18:14, 18:27, 18:39, 37:05, 37:11, 39:13:01-39:13:02, 39:20, 39:49, 42:11
9	10	11	12	13	14	15	16	Well No.

101.524-12 – including *Taq* polymerase, IFU-01 Rev. No. 03
 101.524-12u – without *Taq* polymerase, IFU-02 Rev. No. 03

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Lot No.: **06S**

Lot-specific information

Length of spec. PCR product(s)	265	185	210	85	135	95	260	250
				270	220	175		
Well No.	1	2	3	4	5	6	7	8
*18:04, 56:31							7	
*18:13, 18:30				4			7	8
*18:22, 18:69								8
*18:26, 18:61							7	8
*18:36, 18:50, 18:57							7	8
*18:44:01-18:44:02	1							8
*35:21, 35:24:01-35:24:02, 35:81, 35:109, 53:02, 53:06, 53:28, 57:14, 58:09, C*15:39								
*35:96, 35:157, 35:188, 35:190								
*37:04:01-37:04:02								
*38:01:01-38:02:02, 38:02:04, 38:07, 38:09- 38:12, 38:15, 38:17-38:18, 38:20-38:21, 38:23-38:24, 38:27, 38:29, 38:31-38:32, 38:34N-38:40, 38:42		2						
*38:03, 38:13-38:14, 38:16, 38:26, 38:28, 38:41, 39:01:15		2						
*38:08, 38:22, 38:30		2						
*38:19		2				6		
*38:33			3					
*39:01:01:01-39:01:01:03, 39:01:03- 39:01:08, 39:01:10-39:01:14, 39:02:01, 39:06:01-39:06:02, 39:09, 39:14-39:15, 39:18, 39:19:02, 39:22, 39:25N-39:31, 39:34- 39:36, 39:38Q-39:39:01, 39:41-39:42, 39:44, 39:46, 39:51-39:54, 39:57-39:62, 39:64-39:71, 39:73, 39:75, 39:77, 39:79, 67:01:01, 67:03		2						8
*39:03, 39:24:01-39:24:02		2				6		8
*39:04			3					
*39:05:01-39:05:02, 39:07-39:08, 39:11, 39:55-39:56		2						8
*39:32		2					7	8
*39:37		2				6		8
*39:40:01N-39:40:02N		2			5			8
*39:48		2					7	8
*40:28								8
*40:51, 40:163							7	
*40:113, 51:06:01-51:06:02, 51:62							7	
Well No.	1	2	3	4	5	6	7	8

101.524-12 – including *Taq* polymerase, IFU-01 Rev. No. 03
 101.524-12u – without *Taq* polymerase, IFU-02 Rev. No. 03

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 “Instructions for Use” (IFU)

Lot No.: **06S**

Lot-specific information

160	180	135	230	210	190	100	90	Length of spec. PCR product(s)
						270	175	
9	10	11	12	13	14	15	16	Well No.
		11						*18:04, 56:31
		11			14			*18:13, 18:30
		11			14	15		*18:22, 18:69
		11		13	14			*18:26, 18:61
					14			*18:36, 18:50, 18:57
		11			14			*18:44:01-18:44:02
						15		*35:21, 35:24:01-35:24:02, 35:81, 35:109, 53:02, 53:06, 53:28, 57:14, 58:09, C*15:39
		11				15		*35:96, 35:157, 35:188, 35:190
		11			14	15		*37:04:01-37:04:02
		11			14			*38:01:01-38:02:02, 38:02:04, 38:07, 38:09- 38:12, 38:15, 38:17-38:18, 38:20-38:21, 38:23-38:24, 38:27, 38:29, 38:31-38:32, 38:34N-38:40, 38:42
		11						*38:03, 38:13-38:14, 38:16, 38:26, 38:28, 38:41, 39:01:15
					14			*38:08, 38:22, 38:30
		11			14			*38:19
	10	11			14			*38:33
		11						*39:01:01:01-39:01:01:03, 39:01:03- 39:01:08, 39:01:10-39:01:14, 39:02:01, 39:06:01-39:06:02, 39:09, 39:14-39:15, 39:18, 39:19:02, 39:22, 39:25N-39:31, 39:34- 39:36, 39:38Q-39:39:01, 39:41-39:42, 39:44, 39:46, 39:51-39:54, 39:57-39:62, 39:64-39:71, 39:73, 39:75, 39:77, 39:79, 67:01:01, 67:03
		11						*39:03, 39:24:01-39:24:02
	10	11						*39:04
		11			14			*39:05:01-39:05:02, 39:07-39:08, 39:11, 39:55-39:56
				13				*39:32
		11			14			*39:37
		11						*39:40:01N-39:40:02N
		11		13				*39:48
				13		15		*40:28
		11		13				*40:51, 40:163
				13				*40:113, 51:06:01-51:06:02, 51:62
9	10	11	12	13	14	15	16	Well No.

101.524-12 – including *Taq* polymerase, IFU-01 Rev. No. 03
 101.524-12u – without *Taq* polymerase, IFU-02 Rev. No. 03

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Lot No.: **06S**

Lot-specific information

Well No.	1	2	3	4	5	6	7	8
Length of spec. PCR product(s)	265	185	210	85	135	95	260	250
				270	220	175		
Well No.	1	2	3	4	5	6	7	8
*40:174								8
*42:06						6		8
*48:07						6		8
*51:04, 51:46, 51:56:01-51:56:02, 51:139								
*51:21, 51:101, 78:07								
*51:22, 78:03			3					
*51:29, 51:82, 52:24				4				
*51:116, 52:16, 52:27								
*57:11, 58:02, 58:06-58:07, 58:25, 58:38, C*01:35, C*03:17, C*03:71, C*14:20								
C*01:30	1			4				
C*07:102								W
C*08:08						6		
C*08:51				4			7	
C*12:87	1							
C*15:55								
HLA-B allele								
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*14 subtyping.

In addition, wells number 3 and 15 contain the primer pair giving rise to the shorter, 800 bp, internal positive control band in order to allow kit identification.

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

³The nucleotide position, in the 2nd or 3rd exon or 3rd intron, 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*14 alleles in bold lettering are listed as confirmed alleles on the IMGT/HLA web page www.ebi.ac.uk/imgt/hla, release 3.10.0, October 2012.

101.524-12 – including *Taq* polymerase, IFU-01 Rev. No. 03
 101.524-12u – without *Taq* polymerase, IFU-02 Rev. No. 03

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Lot No.: **06S**

Lot-specific information

9	10	11	12	13	14	15	16	Well No.
160	180	135	230	210	190	100	90	Length of spec. PCR product(s)
						270	175	
9	10	11	12	13	14	15	16	Well No.
				13				*40:174
		11						*42:06
					14			*48:07
				13		15		*51:04, 51:46, 51:56:01-51:56:02, 51:139
		11		13				*51:21, 51:101, 78:07
				13				*51:22, 78:03
				13				*51:29, 51:82, 52:24
				13	14			*51:116, 52:16, 52:27
			12					*57:11, 58:02, 58:06-58:07, 58:25, 58:38, C*01:35, C*03:17, C*03:71, C*14:20
								C*01:30
								C*07:102
								C*08:08
								C*08:51
								C*12:87
							16	C*15:55
9	10	11	12	13	14	15	16	HLA-B allele Well No.

⁵The B*14:08 and B*39:43 alleles will give rise to identical amplification patterns with the HLA-B*14 subtyping kit. These alleles can be distinguished by the HLA-B low resolution kit and/or the HLA-B*39 subtyping kit.

⁶The B*14:16 and B*14:23 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 16.

⁷Primer mix 4: Specific PCR fragment of 85 bp in the B*14:03 and the B*18:13, 18:30, 51:29, 51:82 and 52:24 and in the C*01:30 and C*08:51 alleles. Specific PCR fragment of 270 bp in the B*14:20 allele.

Primer mix 5: Specific PCR fragment of 135 bp in the B*14:07N and 39:40:01N-39:40:02N alleles. Specific PCR fragment of 220 bp in the B*14:04 allele.

Primer mix 6: Specific PCR fragment of 95 bp in the B*14:05 and the B*07:115, 08:69, 38:19, 39:03, 39:24:01-39:24:02, 39:37, 39:76, 41:18, 42:06 and 48:07 and in the C*08:08 alleles. Specific PCR fragment of 175 bp in the B*14:17 allele.

Primer mix 15: Specific PCR fragment of 100 bp in the B*14:15 allele. Specific PCR fragment of 270 bp in the B*14:10 and in the B*18:22, 18:69, 35:21, 35:24:01-35:24:02, 35:81, 35:96, 35:109, 35:157, 35:188, 35:190, 37:04:01-37:04:02, 40:28, 51:04, 51:46, 51:56:01-51:56:02, 51:139, 53:02, 53:06, 53:28, 57:14 and 58:09 and the C*15:39 alleles.

Primer mix 16: Specific PCR fragment of 90 bp in the B*14:23 and the C*15:55 alleles. Specific PCR fragment of 175 bp in the B*14:16 allele.

‘w’, might be weakly amplified.

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 101.524-12u – without *Taq* polymerase, IFU-02 Rev. No. 03

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Lot No.: **06S**

Lot-specific information

CELL LINE VALIDATION SHEET																				
HLA-B*14 SSP subtyping kit																				
					Well															
					1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
				Prod. No.:	201299301	201299302	201299303	201299304	201299305	201299306	201299307	201299308	201299309	201299310	201299311	201299312	201299313	201299314	201299315	201299316
	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	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	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

101.524-12 – including *Taq* polymerase, IFU-01 Rev. No. 03
101.524-12u – without *Taq* polymerase, IFU-02 Rev. No. 03

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

Lot No.: **06S**

Lot-specific information

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-B*14 SSP

Product number: 101.524-12 – including *Taq* polymerase
101.524-12u – without *Taq* polymerase
Lot number: 06S
Expiry date: 2015-August-01
Number of tests: 12
Number of wells per test: 16

Well specifications:

Well No.	Production No.	Well No.	Production No.
1	2012-993-01	9	2012-993-09
2	2012-993-02	10	2012-993-10
3	2012-993-03	11	2012-993-11
4	2012-993-04	12	2012-993-12
5	2012-993-05	13	2012-993-13
6	2012-993-06	14	2012-993-14
7	2012-993-07	15	2012-993-15
8	2012-993-08	16	2012-993-16

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

No DNAs carrying the alleles to be amplified by primer solution 4 to 6, 9, 15 and 16 were available. The specificities of the primers in primer solution 4 to 6, 15 and 16 were tested by separately adding additional 5'-primers respectively 3'-primers. In primer solution 9 it was only possible to test the 5'-primer, the 3'-primer was not possible to test. In primer solutions 4, 5 and 6, one 5'-primer was not possible to test, and in primer solutions 5, 12, 15 and 16 one 3'-primer was not possible to test.

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

Date of approval: 2013-May-02

Approved by:

Production Quality Control

101.524-12 – including *Taq* polymerase, IFU-01 Rev. No. 03
101.524-12u – without *Taq* polymerase, IFU-02 Rev. No. 03

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

Lot No.: **06S**

Lot-specific information

Declaration of Conformity

Product name: Olerup SSP® HLA-B*14
Product number: 101.524-12/12u
Lot number: 06S

Intended use: HLA-B*14 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.

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-May-02

Ann-Cathrin Jareman
Head of QA and Regulatory Affairs

101.524-12 – including *Taq* polymerase, IFU-01 Rev. No. 03
101.524-12u – without *Taq* polymerase, IFU-02 Rev. No. 03

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“Instructions for Use” (IFU)

Lot No.: **06S**

Lot-specific information

101.524-12 – including *Taq* polymerase, IFU-01 Rev. No. 03
101.524-12u – without *Taq* polymerase, IFU-02 Rev. No. 03

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

Lot No.: **06S**

Lot-specific information

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