

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.: **56N**

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:	56N
Expiry date:	2014-September-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. 56N.

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. 90K).

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.

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

Well	5'-primer	3'-primer	rationale
4	Added	-	5'-primer added for the B*14:20 allele.
10	Moved	Moved	Primer pair moved to well 15, to decrease primer oligomer formation.
15	Added	Added	Primer pair from well 10.
16	-	Added	3'-primer added for the B*14:23 allele.

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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*14:28 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. ‘56N’.

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, three B*13, several B*15, the B*18, twelve B*27, several B*35, the B*37, the B*38, the B*39, many B*40, the B*41, the B*42, five B*44, the B*45:08, five B*46, the B*47:08, the B*48, most B*51, most B*52, two B*53, most B*54, most B*55, ten B*56, three B*57, eleven B*58, most B*59, the B*67, the B*73, B*78 and 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 allele 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*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*14:28**, recognized by the HLA Nomenclature Committee in January 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 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.

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Lot-specific information

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*14:02:01-14:02:06 or the B*14:06:01-14:06:02 alleles.

¹HLA-B alleles listed on the IMGT/HLA web page 2012-January-12, release 3.7.0, 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
B*14:01:01	Confirmed	B*14:14	Unconfirmed
B*14:01:02	Unconfirmed	B*14:15	Unconfirmed
B*14:02:01	Confirmed	B*14:16	Unconfirmed
B*14:02:02	Confirmed	B*14:17	Unconfirmed
B*14:02:03	Unconfirmed	B*14:18	Confirmed
B*14:02:04	Unconfirmed	B*14:19	Confirmed
B*14:02:05	Unconfirmed	B*14:20	Confirmed
B*14:02:06	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*14:10	Confirmed		
B*14:11	Unconfirmed		
B*14:12	Confirmed		
B*14:13	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 35 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.

+++++---+ ---+----- *14:03, *14:07N = *14:07N, *14:20
 +++++---+ ---+----- *14:03, *14:12 = *14:03, *14:19 = *14:12, *14:20 = *14:19, *14:20

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

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+--+---+-	---+-----	*14:21 = *14:17, *14:17 = *14:17, *14:21
+--+---+-	---+-----	*14:06:01, *14:11 = *14:06:01, *14:28
+--+---+-	---+-----	*14:02:01, *14:06:01 = *14:06:01, *14:21
+--+-----	+++-----	*14:09, *14:11 = *14:09, *14:28
+--+-----	+++-----	*14:02:01, *14:09 = *14:09, *14:09 = *14:09, *14:21
+--+-----	+++-----	*14:11, *14:27 = *14:27, *14:28
+--+-----	+++-----	*14:11, *14:13 = *14:13, *14:28
+--+-----	+++-----	*14:11, *14:18 = *14:18, *14:28
+--+-----	+++-----	*14:11, *14:15 = *14:15, *14:28
+--+-----	+++-----	*14:11, *14:16 = *14:16, *14:28
+--+-----	+++-----	*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, *14:27 = *14:21, *14:27
+--+-----	---+-----	*14:02:01, *14:13 = *14:13, *14:21
+--+-----	---+-----	*14:02:01, *14:18 = *14:18, *14:18 = *14:18, *14:21
+--+-----	---+-----	*14:02:01, *14:15 = *14:15, *14:15 = *14:15, *14:21
+--+-----	---+-----	*14:02:01, *14:16 = *14:16, *14:16 = *14:16, *14:21
+--+-----	---+-----	*14:02:01, *14:02:01 = *14:02:01, *14:21
+-----	+++-----	*14:21, *14:28 = *14:28, *14:28

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

*14:02:01 = *14:02:01-14:02:06 and 14:22, 14:24 and 14:25

*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, 14:21-14:28	*18:44, C*01:30
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	*38:01:01-38:02:02, 38:03, 38:07-38:24, 38:26-38:32, 38:34N-38:37, 39:01:01:01-39:01:01:02L, 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, 39:24:01-39:44, 39:46-39:48, 39:50-39:62, 39:64-39:68, 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	*15:09-15:10:02, 15:18:01-15:18:04, 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, 35:26, 35:82, 35:85, 35:135, 38:05, 38:33, 39:04, 51:22, 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	*39:40N
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, 41:18, 42:06, 48:07, C*08:08
7	260 bp	1070 bp	*14:06:01-14:06:02, 14:08	*15:37-15:38:02, 15:185, 18:01:01-18:01:14, 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-

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				18:68, 39:32, 39:43, 39:48, 40:51, 40:113, 40:163, 51:06:01-51:06:02, 51:45, 51:62, 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	*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, 07:112-07:144, 15:68, 15:71, 15:175, 18:01:01-18:01:12, 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, 27:08, 27:12, 27:18, 27:26, 27:33, 27:40, 27:42, 27:44, 35:50, 35:84, 35:162, 37:05, 37:11, 39:01:01:01-39:01:01:02L, 39:01:03-39:03, 39:05:01-39:11, 39:13:01-39:20, 39:22-39:62, 39:64-39:68, 40:02:01-40:06:04, 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, 42:01:01-42:02, 42:04-42:16, 44:131, 48:01:01-48:17, 48:19-48:21, 48:23-48:27, 54:02, 55:10, 67:01:01-67:03, 73:01-73:02, 81:01-81:05, C*03:137, C*07:102^w
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	*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, 13:06, 13:46, 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,

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				18:01:01-18:09, 18:11-18:15, 18:17N-18:20, 18:22-18:34, 18:37- 18:49, 18:51-18:55, 18:59-18:68, 27:15, 27:28, 27:62, 27:71, 35:35, 35:60, 35:87, 35:93, 35:96, 35:157, 37:01:01-37:01:04, 37:01:06- 37:01:08, 37:03N-37:06, 37:08-37:25, 37:27-37:31, 38:01:01-38:07, 38:09- 38:21, 38:23-38:29, 38:31-38:37, 39:01:01:01-39:01:01:02L, 39:01:03- 39:20, 39:22-39:31, 39:34-39:46, 39:48-39:49, 39:51-39:68, 40:39, 40:51, 40:163, 41:01-41:16, 41:18, 42:01:01-42:02, 42:04-42:16, 44:04, 44:56N, 44:132, 45:08, 46:03, 46:18, 46:21:01-46:21:02, 46:29, 47:08, 51:21, 51:36, 51:101, 54:01:01-54:02, 54:04-54:05N, 54:07-54:24, 55:01:01- 55:05, 55:07, 55:10-55:21, 55:23, 55:25-55:50, 55:52-55:54, 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, C*01:35, C*03:17, C*03:71, C*14:20
13⁷	210 bp	1070 bp	*14:13	*13:15, 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, 51:03-51:04, 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, 51:109-51:126, 52:01:01:01-52:02, 52:04-52:10:02, 52:13-52:25, 52:27, 56:05:01-56:06, 56:21, 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, 15:18:01-15:18:04, 15:23, 15:29, 15:37, 15:47, 15:49, 15:51-15:52, 15:54, 15:62, 15:64, 15:68-15:69,

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15^{5,11}	100 bp, 270 bp	800 bp	*14:10, 14:15	*18:22, 35:21, 35:24:01-35:24:02, 35:81, 35:96, 35:109, 35:157, 37:04:01-37:04:02, 40:28, 51:04, 51:46, 51:56:01-51:56:02, 53:02, 53:06, 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 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.

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.

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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 allele 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*15:39 allele will be amplified by primer mix 15 and the C*15:55 allele will be amplified by primer mix 16.

The 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.

⁴For several HLA-B alleles 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 the introns are conserved within allelic groups.

⁵Short specific PCR fragments are less intense and not as sharp as longer specific bands.

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

⁷Primer mix 4, 13 and 14 may give rise to nonspecific amplifications.

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 220 bp in the B*14:20 allele.

⁹Primer mix 5: Specific PCR fragment of 135 bp in the B*14:07N and B*39:40N 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, 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.

¹²Primer 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, 35:21, 35:24:01-35:24:02, 35:81, 35:96, 35:109, 35:157, 37:04:01-37:04:02, 40:28, 51:04, 51:46, 51:56:01-51:56:02, 53:02, 53:06, 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*14:28 alleles								
	Well⁶							
	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	1	2						8
*14:02:01-14:02:06, 14:22, 14:24-14:25	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, 14:23	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*14:28 alleles							
Well ⁶							
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	3 rd 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					
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.: **56N**

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, 07:02:17-07:05:04, 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, 07:116-07:144, 15:71, 15:175, 27:08, 27:12, 27:18, 27:26, 27:33, 27:40, 27:42, 27:44, 35:50, 35:84, 40:02:01-40:06:04, 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, 44:131, 48:02:02, 73:01-73:02, 81:01-81:05, C*03:137								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, 48:03:01-48:06, 48:08-48:17, 48:19-48:21, 48:23-48:27								8
*07:19, 07:31, 07:34, 07:43, 39:01:09, 39:02:02, 39:10:01-39:10:02, 39:16-39:17, 39:19:01, 39:23, 39:45, 40:39, 42:01:01- 42:02, 42:04-42:05:02, 42:07-42:10, 42:12- 42:16, 54:02, 55:10, 67:01:02-67:02								8
Well No.	1	2	3	4	5	6	7	8

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Lot-specific information

160	180	135	230	210	190	100	90	Length of spec.
						270	175	PCR product(s)
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, 07:02:17-07:05:04, 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, 07:116-07:144, 15:71, 15:175, 27:08, 27:12, 27:18, 27:26, 27:33, 27:40, 27:42, 27:44, 35:50, 35:84, 40:02:01-40:06:04, 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, 44:131, 48:02:02, 73:01-73:02, 81:01-81:05, C*03:137
					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, 48:03:01-48:06, 48:08-48:17, 48:19-48:21, 48:23-48:27
		11						*07:19, 07:31, 07:34, 07:43, 39:01:09, 39:02:02, 39:10:01-39:10:02, 39:16-39:17, 39:19:01, 39:23, 39:45, 40:39, 42:01:01- 42:02, 42:04-42:05:02, 42:07-42:10, 42:12- 42:16, 54:02, 55:10, 67:01:02-67:02
9	10	11	12	13	14	15	16	Well No.

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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
*07:27, 07:38, 15:03:01-15:03:03, 15:29, 15:47, 15:49, 15:54, 15:62, 15:64, 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, 35:25, 35:124-35:125, 35:142, 37:01:05, 37:02, 37:07, 37:26, 40:12, 44:130, 48:18, 48:22, 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, 08:55-08:68, 08:70-08:78, 08:80, 13:06, 13:46, 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, 37:22, 39:12, 39:63, 41:01-41:16, 44:04, 44:56N, 44:132, 45:08, 46:03, 46:18, 46:21:01-46:21:02, 46:29, 47:08, 51:36, 54:01:01-54:01:02, 54:04-54:05N, 54:07-54:24, 55:01:01-55:05, 55:07, 55:11-55:21, 55:23, 55:25-55:50, 55:52-55:54, 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, 37:01:06-37:01:08, 37:03N, 37:06, 37:08-37:10, 37:12-37:21, 37:23-37:25, 37:27-37:31, 38:02:03, 38:04, 38:06, 38:25								
*08:69, 41:18						6		
*13:15, 51:01:01-51:01:18, 51:01:20-51:01:30, 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, 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, 51:117-51:126, 52:01:01:01-52:02, 52:04-52:10:02, 52:13-52:15, 52:17-52:23, 52:25, 56:05:01-56:06, 56:21, 58:08:01-58:08:02, 78:01:01-78:02:02, 78:05-78:06								
Well No.	1	2	3	4	5	6	7	8

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Lot No.: **56N**

Lot-specific information

160	180	135	230	210	190	100	90	Length of spec.
						270	175	PCR product(s)
9	10	11	12	13	14	15	16	Well No.
					14			*07:27, 07:38, 15:03:01-15:03:03, 15:29, 15:47, 15:49, 15:54, 15:62, 15:64, 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, 35:25, 35:124-35:125, 35:142, 37:01:05, 37:02, 37:07, 37:26, 40:12, 44:130, 48:18, 48:22, 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, 08:55-08:68, 08:70-08:78, 08:80, 13:06, 13:46, 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, 37:22, 39:12, 39:63, 41:01-41:16, 44:04, 44:56N, 44:132, 45:08, 46:03, 46:18, 46:21:01-46:21:02, 46:29, 47:08, 51:36, 54:01:01-54:01:02, 54:04-54:05N, 54:07-54:24, 55:01:01-55:05, 55:07, 55:11-55:21, 55:23, 55:25-55:50, 55:52-55:54, 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, 37:01:06-37:01:08, 37:03N, 37:06, 37:08-37:10, 37:12-37:21, 37:23-37:25, 37:27-37:31, 38:02:03, 38:04, 38:06, 38:25
		11						*08:69, 41:18
				13				*13:15, 51:01:01-51:01:18, 51:01:20-51:01:30, 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, 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, 51:117-51:126, 52:01:01:01-52:02, 52:04-52:10:02, 52:13-52:15, 52:17-52:23, 52:25, 56:05:01-56:06, 56:21, 58:08:01-58:08:02, 78:01:01-78:02:02, 78:05-78:06
9	10	11	12	13	14	15	16	Well No.

101.524-12 – including *Taq* polymerase, IFU-01 Rev. No. 03101. 524-12u – without *Taq* polymerase, IFU-02 Rev. No. 03Visit www.olerup-ssp.com for

“Instructions for Use” (IFU)

Lot No.: **56N**

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
*15:09-15:10:02, 15:18:01-15:18:04, 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			3					
*15:21, 15:66, 35:82, 35:85, 35:135			3					
*15:37			3				7	
*15:38:01-15:38:02, 15:185, 51:45							7	
*15:44			3					
*15:93, 15:186, 38:05			3					
*15:189, 35:26			3					
*18:01:01, 18:01:03-18:01:12, 18:01:14, 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							7	8
*18:01:02, 18:03, 18:29							7	8
*18:01:13, 18:09, 18:25, 18:54, 18:67-18:68							7	
*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
*18:04, 56:31							7	
*18:13, 18:30				4			7	8
*18:22								8
*18:26, 18:61							7	8
*18:36, 18:50, 18:57							7	8
*18:44	1							8
*35:21, 35:24:01-35:24:02, 35:81, 35:109, 53:02, 53:06, 57:14, 58:09, C*15:39								
*35:96, 35:157								
*37:04:01-37:04:02								
*38:01:01-38:02:02, 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-38:37		2						
*38:03, 38:13-38:14, 38:16, 38:26, 38:28		2						
*38:08, 38:22, 38:30		2						
*38:19		2				6		
*38:33			3					
Well No.	1	2	3	4	5	6	7	8

101.524-12 – including *Taq* polymerase, IFU-01 Rev. No. 03101. 524-12u – without *Taq* polymerase, IFU-02 Rev. No. 03Visit www.olerup-ssp.com for

“Instructions for Use” (IFU)

Lot No.: **56N**

Lot-specific information

160	180	135	230	210	190	100	90	Length of spec.
						270	175	PCR product(s)
9	10	11	12	13	14	15	16	Well No.
					14			*15:09-15:10:02, 15:18:01-15:18:04, 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
								*15:21, 15:66, 35:82, 35:85, 35:135
					14			*15:37
								*15:38:01-15:38:02, 15:185, 51:45
		11						*15:44
		11			14			*15:93, 15:186, 38:05
	10							*15:189, 35:26
		11			14			*18:01:01, 18:01:03-18:01:12, 18:01:14, 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
		11						*18:01:02, 18:03, 18:29
		11			14			*18:01:13, 18:09, 18:25, 18:54, 18:67-18:68
		11			14			*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
		11						*18:04, 56:31
		11			14			*18:13, 18:30
		11			14	15		*18:22
		11		13	14			*18:26, 18:61
					14			*18:36, 18:50, 18:57
		11			14			*18:44
						15		*35:21, 35:24:01-35:24:02, 35:81, 35:109, 53:02, 53:06, 57:14, 58:09, C*15:39
		11				15		*35:96, 35:157
		11			14	15		*37:04:01-37:04:02
		11			14			*38:01:01-38:02:02, 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-38:37
		11						*38:03, 38:13-38:14, 38:16, 38:26, 38:28
					14			*38:08, 38:22, 38:30
		11			14			*38:19
	10	11			14			*38:33
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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 “Instructions for Use” (IFU)

Lot No.: **56N**

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
*39:01:01:01-39:01:01:02L, 39:01:03-39:01:08, 39:01:10-39:02:01, 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, 39:41-39:42, 39:44, 39:46, 39:51-39:54, 39:57-39:62, 39:64-39:68, 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
*39:33, 39:47, 39:50		2						8
*39:37		2				6		8
*39:40N		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	
*40:174								8
*42:06						6		8
*48:07						6		8
*51:04, 51:46, 51:56:01-51:56:02								
*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, 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*15:55								
HLA-B allele								
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.: **56N**

Lot-specific information

160	180	135	230	210	190	100	90	Length of spec.
						270	175	PCR product(s)
9	10	11	12	13	14	15	16	Well No.
		11						*39:01:01:01-39:01:01:02L, 39:01:03-39:01:08, 39:01:10-39:02:01, 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, 39:41-39:42, 39:44, 39:46, 39:51-39:54, 39:57-39:62, 39:64-39:68, 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
								*39:33, 39:47, 39:50
		11			14			*39:37
		11						*39:40N
		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
				13				*40:174
		11						*42:06
					14			*48:07
				13		15		*51:04, 51:46, 51:56:01-51:56:02
		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, C*01:35, C*03:17, C*03:71, C*14:20
								C*01:30
								C*07:102
								C*08:08
								C*08:51
							16	C*15:55
9	10	11	12	13	14	15	16	HLA-B allele
								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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“Instructions for Use” (IFU)

Lot No.: 56N**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*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 3.7.0, January 2012.

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.

⁶Primer 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 220 bp in the B*14:20 allele.

Primer mix 5: Specific PCR fragment of 135 bp in the B*14:07N and B*39:40N 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, 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, 35:21, 35:24:01-35:24:02, 35:81, 35:96, 35:109, 35:157, 37:04:01-37:04:02, 40:28, 51:04, 51:46, 51:56:01-51:56:02, 53:02, 53:06, 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.

“Instructions for Use” (IFU)

Lot-specific information

CE
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101.524-12 – including *Taq* polymerase, IFU-01 Rev. No. 03101.524-12u – without *Taq* polymerase, IFU-02 Rev. No. 03Visit www.olerup-ssp.com for

“Instructions for Use” (IFU)

Lot No.: **56N**

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:

56N

Expiry date:

2014-September-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: 2012-March -22

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.: **56N**

Lot-specific information

Declaration of Conformity

Product name: Olerup SSP® HLA-B*14
Product number: 101.524-12/12u
Lot number: 56N

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 13485:2003, 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-March-22

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

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

Lot No.: **56N**

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

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Lot No.: **56N**

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.: **56N**

Lot-specific information

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For information on *Olerup* SSP distributors worldwide, contact **Olerup GmbH**.