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Lot No.: **76S** Lot-specific information

Olerup SSP® HLA-C*01

Product number: 101.621-12 – including *Taq* polymerase

101.621-12u - without *Taq* polymerase

Lot number: 76\$

Expiry date: 2016-January-01

Number of tests: 12 Number of wells per test: 24

Storage - pre-aliquoted primers: dark at -20°C

PCR Master Mix: -20°C
 Adhesive PCR seals
 Product Insert
 RT

This Product Description is only valid for Lot No. 76S.

CHANGES COMPARED TO THE PREVIOUS *OLERUP* SSP® HLA-C*01 Lot (75N)

The HLA-C*01 specificity and interpretation tables have been updated for the HLA-C alleles described since the previous *Olerup* SSP® HLA-C*01 lot was made (Lot No. 75N).

The HLA-C*01 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-C*01 including and without *Taq* polymerase is now described in one common Product Insert.

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

Well	5'-primer	3'-primer	rationale
7	Added	Added	Primer pair added for the C*01:67 allele.
14	-	Added	3'-primer added for the C*01:69N allele.
15	-	Added	3'-primer added for the C*01:73 allele.

July 2013 Rev. No.: 00

¹As described in section Uniquely Identified Alleles.

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18	Exchanged	-	5'-primer exchanged for the C*01:49 allele.
21	-	Added	3'-primer added for the C*01:69N allele.
24	Exchanged	-	5'-primer added for the C*01:49 allele.

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Lot No.: **76S** Lot-specific information

PRODUCT DESCRIPTION

HLA-C*01 SSP typing

CONTENT

The primer set contains 5'- and 3'-primers for identifying the C*01:02 to C*01:75 alleles.

PLATE LAYOUT

Each **HLA-C*01** test consists of 24 PCR reactions in a 24 well cut PCR plate.

1	2	3	4	5	6	7	8
9	10	11	12	13	14	15	16
17	18	19	20	21	22	23	24

The 24 well PCR plate is marked with 'HLA-C*01' in silver/gray ink.

Well No. 1 is marked with the Lot No. '76S'.

A faint row of numbers is seen between wells 1 and 2 or wells 7 and 8 of the PCR trays. These stem from the manufacture of the trays, and should be disregarded.

The PCR plates are heat-sealed with a PCR-compatible foil.

Please note: When removing each 24 well PCR plate, make sure that the remaining plates stay sealed. Use a scalpel or a similar instrument to carefully cut the foil between the plates.

INTERPRETATION

The interpretation of HLA-C*01 SSP subtypings will be influenced by the C*02:51, nine C*03, two C*04, five C*05, three C*06, four C*07, three C*08, three C*14, the C*15:37 and two C*16 alleles when present on the other haplotype. In addition, the A*01:01:33, A*02:01:29, A*11:01:40, A*26:01:09, A*32:01:09, A*33:01:07, A*68:01:06, B*07:02:21, B*13:02:03, B*27:05:06, B*40:01:10, B*40:02:11, B*44:03:08, B*51:01:24 and B*73:01-73:02 alleles will be amplified by primer mix 7, the A*01:24 allele will be amplified by primer mix 16, the B*07:77 allele will be amplified by primer mix 4, the B*15:33 and B*15:248 alleles will be amplified by primer mix 12, the B*51:129 allele will be amplified by primer mix 13.

UNIQUELY IDENTIFIED ALLELES

All the HLA-C*01 alleles, i.e. **C*01:02 to C*01:75**, recognized by the HLA Nomenclature Committee in January 2013¹ will be amplified by the primers in the HLA-C*01 SSP kit².

The HLA-C*01 kit enables separation of the confirmed HLA-C*01 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-C*01 alleles is listed below.

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Lot No.: **76S** Lot-specific information

The HLA-C*01 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-C*01 primer set cannot distinguish the following silent mutations: the C*01:02:01-01:02:18 alleles.

The C*01:06 and 01:38 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 5.

The C*01:10 and 01:52 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 9.

The C*01:17 and 01:41 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 14.

The C*01:18 and 01:42 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 15.

The C*01:43 and the C*01:19 and 01:58 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 16.

The C*01:25 and 01:59 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 17.

The C*01:27 and 01:45 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 19.

The C*01:28 and 01:56N alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 20.

The C*01:29 and 01:33 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 21.

The C*01:31 and 01:44 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 23.

The C*01:32 and 01:40 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 24.

¹HLA-C alleles listed on the IMGT/HLA web page 2013-January-11, release 3.11.0, www.ebi.ac.uk/imgt/hla.

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Lot No.: **76S** Lot-specific information

ALLELE CONFIRMATION STATUS

Allele	Status ¹	Allele	Status ¹	Allele	Status ¹	Allele	Status ¹
C*01:02:01	Confirmed	C*01:15	Unconfirmed	C*01:45	Confirmed	C*01:75	Unconfirmed
C*01:02:02	Unconfirmed	C*01:16	Confirmed	C*01:46	Unconfirmed		
C*01:02:03	Confirmed	C*01:17	Confirmed	C*01:47	Unconfirmed		
C*01:02:04	Confirmed	C*01:18	Unconfirmed	C*01:48	Unconfirmed		
C*01:02:05	Unconfirmed	C*01:19	Unconfirmed	C*01:49	Confirmed		
C*01:02:06	Unconfirmed	C*01:20	Unconfirmed	C*01:50	Confirmed		
C*01:02:07	Confirmed	C*01:21	Confirmed	C*01:51	Unconfirmed		
C*01:02:08	Confirmed	C*01:22	Confirmed	C*01:52	Confirmed		
C*01:02:09	Unconfirmed	C*01:23	Unconfirmed	C*01:53	Unconfirmed		
C*01:02:10	Unconfirmed	C*01:24	Unconfirmed	C*01:54	Confirmed		
C*01:02:11	Unconfirmed	C*01:25	Unconfirmed	C*01:55	Unconfirmed		
C*01:02:12	Unconfirmed	C*01:26	Confirmed	C*01:56N	Unconfirmed		
C*01:02:13	Unconfirmed	C*01:27	Confirmed	C*01:57	Unconfirmed		
C*01:02:14	Unconfirmed	C*01:28	Unconfirmed	C*01:58	Unconfirmed		
C*01:02:15	Unconfirmed	C*01:29	Unconfirmed	C*01:59	Confirmed		
C*01:02:16	Unconfirmed	C*01:30	Confirmed	C*01:60	Unconfirmed		
C*01:02:17	Unconfirmed	C*01:31	Unconfirmed	C*01:61	Unconfirmed		
C*01:02:18	Unconfirmed	C*01:32		C*01:62	Unconfirmed		
C*01:03	Confirmed	C*01:33	Unconfirmed	C*01:63	Unconfirmed		
C*01:04	Unconfirmed	C*01:34	Unconfirmed	C*01:64	Unconfirmed		
C*01:05	Unconfirmed	C*01:35	Unconfirmed	C*01:65	Unconfirmed		
C*01:06	Confirmed	C*01:36	Unconfirmed	C*01:66	Unconfirmed		
C*01:07	Unconfirmed	C*01:37N	Unconfirmed	C*01:67	Confirmed		
C*01:08	Confirmed	C*01:38	Unconfirmed	C*01:68	Unconfirmed		
C*01:09	Unconfirmed	C*01:39	Unconfirmed	C*01:69N	Unconfirmed		
C*01:10	Confirmed	C*01:40	Confirmed	C*01:70	Unconfirmed		
C*01:11	Unconfirmed	C*01:41	Confirmed	C*01:71	Unconfirmed		
C*01:12	Confirmed	C*01:42	Unconfirmed	C*01:72	Unconfirmed		
C*01:13	Confirmed	C*01:43	Unconfirmed	C*01:73	Unconfirmed		
C*01:14	Unconfirmed	C*01:44	Confirmed	C*01:74	Unconfirmed		

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

RESOLUTION IN HOMO- AND HETEROZYGOTES

A total of 91 alleles generate 42 amplification patterns that can be combined in 903 homozygous and heterozygous combinations. 625 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.

+	*01:36, *01:49 = *01:36, *01:50 = *01:49, *01:49 = *01:49, *01:50
	*01:12, *01:34 = *01:12, *01:36 = *01:34, *01:34 = *01:34, *01:36
-+	*01:03, *01:24 = *01:24, *01:24
++	*01:02:01, *01:32 = *01:02:01, *01:50 = *01:32, *01:32 = *01:32, *01:50
+	*01:02:01, *01:31 = *01:02:01, *01:54 = *01:31, *01:31 = *01:31, *01:54
+	*01:02:01, *01:30 = *01:30, *01:30
+	*01:02:01, *01:29 = *01:29, *01:29
+	*01:02:01, *01:28 = *01:28, *01:28
+	*01:02:01, *01:27 = *01:27, *01:27
+	*01:02:01, *01:26 = *01:02:01, *01:36 = *01:26, *01:26 = *01:26, *01:36
+	*01:02:01, *01:25 = *01:25, *01:25

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Lot No.: 76S		Latenacific information
+		Lot-specific information
+		*01:02:01, *01:19 = *01:19, *01:19
+		*01:02:01, *01:18 = *01:02:01, *01:73 = *01:18, *01:18 = *01:18, *01:73 *01:02:01, *01:17 = *01:02:01, *01:21 = *01:17, *01:17 = *01:17, *01:21
+		*01:02:01, *01:17 = *01:02:01, *01:21 = *01:17, *01:17 = *01:17, *01:21 *01:02:01, *01:13 = *01:13, *01:13
+		*01:02:01, *01:13 = *01:13, *01:13 *01:02:01, *01:12 = *01:02:01, *01:39 = *01:12, *01:39 = *01:39, *01:39
+		*01:02:01, *01:11 = *01:11, *01:11
+ ++		*01:02:01, *01:10 = *01:10, *01:10
+++		*01:02:01, *01:09 = *01:09, *01:09
++-		*01:02:01, *01:08 = *01:02:01, *01:67 = *01:08, *01:08 = *01:08, *01:67
++		*01:02:01, *01:07 = *01:02:01, *01:37N = *01:07, *01:07 = *01:07, *01:37N
++		*01:02:01, *01:06 = *01:06, *01:06
++		*01:02:01, *01:05 = *01:02:01, *01:16 = *01:05, *01:16 = *01:16, *01:16
+-+		*01:02:01, *01:14 = *01:14, *01:14
++		*01:02:01, *01:03 = *01:02:01, *01:15 = *01:03, *01:15 = *01:15, *01:15
		*01:12, *01:49 = *01:34, *01:49 = *01:34, *01:50
+++		*01:04, *01:04 = *01:04, *01:54
+		*01:31, *01:32 = *01:31, *01:50 = *01:32, *01:54
+		*01:30, *01:32 = *01:30, *01:50
+		*01:30, *01:31 = *01:30, *01:54
+		*01:29, *01:32 = *01:29, *01:50
+		*01:29, *01:31 = *01:29, *01:54
+		*01:28, *01:32 = *01:28, *01:50
+		*01:28, *01:31 = *01:28, *01:54 *04:27 *04:23 *04:27 *04:50
+		*01:27, *01:32 = *01:27, *01:50 *01:27 *01:21 = *01:27 *01:54
+		*01:27, *01:31 = *01:27, *01:54 *01:02:01 *01:40 = *01:26 *01:22 = *01:26 *01:40 = *01:26 *01:50 = *01:22 *01:26 =
1		*01:02:01, *01:49 = *01:26, *01:32 = *01:26, *01:49 = *01:26, *01:50 = *01:32, *01:36 = *01:32, *01:49
+	-++-	*01:26, *01:31 = *01:26, *01:54 = *01:31, *01:36
+		*01:26, *01:30 = *01:30, *01:36
+	-++	*01:26, *01:29 = *01:29, *01:36
+	-+-+	*01:26, *01:28 = *01:28, *01:36
+	-++	*01:26, *01:27 = *01:27, *01:36
+	++	*01:25, *01:32 = *01:25, *01:50
+	++-	*01:25, *01:31 = *01:25, *01:54
+		*01:25, *01:26 = *01:25, *01:36
++		*01:19, *01:32 = *01:19, *01:50
++		*01:19, *01:31 = *01:19, *01:54
++		*01:19, *01:26 = *01:19, *01:36
+		*01:18, *01:32 = *01:18, *01:50 = *01:32, *01:73 = *01:50, *01:73
+		*01:18, *01:31 = *01:18, *01:54 = *01:31, *01:73 = *01:54, *01:73
+		*01:18, *01:30 = *01:30, *01:73
+		*01:18, *01:29 = *01:29, *01:73
+		*01:18, *01:28 = *01:28, *01:73 *04:48 *04:27 = *04:27 *04:73
+		*01:18, *01:27 = *01:27, *01:73 *01:18, *01:26 = *01:18, *01:36 = *01:26, *01:73 = *01:36, *01:73
+		*01:18, *01:25 = *01:25, *01:73 = *01:36, *01:73
+++		*01:18, *01:19 = *01:19, *01:73
+	+	*01:17, *01:32 = *01:17, *01:50 = *01:21, *01:32
+		*01:17, *01:31 = *01:17, *01:54 = *01:21, *01:31
+	+	*01:17, *01:30 = *01:21, *01:30
+	+	*01:02:01, *01:69N = *01:17, *01:29 = *01:17, *01:69N = *01:21, *01:29 = *01:21, *01:69N
		= *01:29, *01:69N = *01:69N, *01:69N
+		*01:17, *01:28 = *01:21, *01:28
+	+	*01:17, *01:27 = *01:21, *01:27
+		*01:17, *01:26 = *01:17, *01:36 = *01:21, *01:26
+		*01:17, *01:25 = *01:21, *01:25
+++-+		*01:02:01, *01:23 = *01:17, *01:19 = *01:17, *01:23 = *01:19, *01:21 = *01:19, *01:23 =
		*01:21, *01:23 = *01:23, *01:23
++++-		*01:17, *01:18 = *01:17, *01:73 = *01:18, *01:21
+		*01:13, *01:32 = *01:13, *01:50
+		*01:13, *01:31 = *01:13, *01:54 *04:42 *04:26 = *04:43 *04:26
+++-+-		*01:13, *01:26 = *01:13, *01:36 *01:13 *01:18 = *01:13 *01:73
, ————————————————————————————————————		*01:13, *01:18 = *01:13, *01:73



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```
Lot No.: 76S
                                  Lot-specific information
                           *01:13, *01:17 = *01:13, *01:21
*01:12, *01:32 = *01:32, *01:39 = *01:39, *01:50
*01:12, *01:31 = *01:31, *01:39 = *01:39, *01:54
+----
+-----
+-----
+-----
                            *01:12, *01:30 = *01:30, *01:39
+----
                            *01:12, *01:29 = *01:29, *01:39
+----
                            *01:12, *01:28 = *01:28, *01:39
+----
                            *01:12, *01:27 = *01:27, *01:39
+-----
                            *01:02:01, *01:34 = *01:12, *01:26 = *01:26, *01:34 = *01:26, *01:39 = *01:34, *01:39 =
                            *01:36, *01:39
                            *01:12, *01:25 = *01:25, *01:39
+----- --+-+---
+----
                            *01:12, *01:19 = *01:19, *01:39
+----
                            *01:12, *01:18 = *01:12, *01:73 = *01:18, *01:39 = *01:39, *01:73
+----
                            *01:12, *01:17 = *01:17, *01:39 = *01:21, *01:39
                            *01:12, *01:13 = *01:13, *01:39
*01:11, *01:32 = *01:11, *01:50
+----
+----+
                            *01:11, *01:31 = *01:11, *01:54
+-----
+---- -+--+---
                            *01:11, *01:26 = *01:11, *01:36
+-----
                            *01:11, *01:18 = *01:11, *01:73
+-----
                            *01:11, *01:17 = *01:11, *01:21
+-----
                            *01:11, *01:12 = *01:11, *01:39
+----+
                            *01:10, *01:32 = *01:10, *01:50
*01:10, *01:31 = *01:10, *01:54
+-----
+---- +---+---
                            *01:10, *01:26 = *01:10, *01:36
+----- +---+- -----
                            *01:10, *01:18 = *01:10, *01:73
+-----
                            *01:10, *01:17 = *01:10, *01:21
+---- +-+-+--
                            *01:10, *01:12 = *01:10, *01:39
+----+
                            *01:09, *01:32 = *01:09, *01:50
+----+
                            *01:09, *01:31 = *01:09, *01:54
                            *01:09, *01:26 = *01:09, *01:36
+----+ ----+ -+---
+----+ ----+--
                            *01:09, *01:18 = *01:09, *01:73
+----+ ----++--
                            *01:09, *01:17 = *01:09, *01:21
+----+ --+---
                            *01:09, *01:12 = *01:09, *01:39
+----+ -+--+---
                            *01:02:01, *01:22 = *01:09, *01:11 = *01:09, *01:22 = *01:11, *01:22 = *01:22, *01:22
                            *01:08, *01:32 = *01:08, *01:50 = *01:32, *01:67 = *01:50, *01:67 *01:08, *01:31 = *01:08, *01:54 = *01:31, *01:67 = *01:54, *01:67
+----+
+----+
+----+-
                            *01:08, *01:30 = *01:30, *01:67
+----+- ----+---
                            *01:08, *01:29 = *01:29, *01:67
+----+- ----+---
                            *01:08, *01:28 = *01:28, *01:67
+----+
                            *01:08, *01:27 = *01:27, *01:67
                           *01:08, *01:26 = *01:08, *01:36 = *01:26, *01:67 = *01:36, *01:67 

*01:08, *01:25 = *01:25, *01:67 

*01:08, *01:19 = *01:19, *01:67
+----+- ----+---
+----+- ----+----
+----+
+----+
                            *01:08, *01:18 = *01:08, *01:73 = *01:18, *01:67
+----+
                            *01:08, *01:17 = *01:08, *01:21 = *01:17, *01:67
+----+
                            *01:08, *01:13 = *01:13, *01:67
                            *01:08, *01:12 = *01:08, *01:39 = *01:12, *01:67 = *01:39, *01:67
+----+- --+----
+----+- -+--+---
                            *01:08, *01:11 = *01:11, *01:67
*01:08, *01:10 = *01:10, *01:67
+----+ +---+---
+----+
                            *01:08, *01:09 = *01:09, *01:67
+---+
                            *01:07, *01:32 = *01:07, *01:50 = *01:32, *01:37N
+---+-
                            *01:07, *01:31 = *01:07, *01:54 = *01:31, *01:37N
                           *01:07, *01:30 = *01:30, *01:37N
*01:07, *01:29 = *01:29, *01:37N
*01:07, *01:28 = *01:28, *01:37N
+---+--
+---+--
+---+-- ----+---
+---+-- -----
                            *01:07, *01:27 = *01:27, *01:37N
                            *01:07, *01:26 = *01:07, *01:36 = *01:26, *01:37N
+----+-- -----
+----+-- +-----
                            *01:07, *01:25 = *01:25, *01:37N
+---+-
                            *01:07, *01:19 = *01:19, *01:37N
                           *01:07, *01:18 = *01:07, *01:73 = *01:18, *01:37N = *01:37N, *01:73 *01:07, *01:17 = *01:07, *01:21 = *01:17, *01:37N *01:07, *01:13 = *01:13, *01:37N
+---+-
+---+-- ----++--
+----+
+----+-- --+---
                            *01:07, *01:12 = *01:07, *01:39 = *01:37N, *01:39
+---+-- -+--+---
                            *01:07, *01:11 = *01:11, *01:37N
```

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Lot No.: 76S	Lot-specific information
++- ++	•
++++	*01:07, *01:10 = *01:10, *01:37N *01:07, *01:00 = *01:00, *01:27N
++++	*01:07, *01:09 = *01:09, *01:37N *01:07, *01:08 = *01:07, *01:67 = *01:08, *01:37N = *01:37N, *01:67
++	*01:06, *01:32 = *01:06, *01:50
++	*01:06, *01:31 = *01:06, *01:54
+++	*01:06, *01:26 = *01:06, *01:36
++	*01:06, *01:18 = *01:06, *01:73
++	*01:06, *01:17 = *01:06, *01:21
++	*01:06, *01:12 = *01:06, *01:39
++-	*01:02:01, *01:20 = *01:06, *01:08 = *01:06, *01:20 = *01:06, *01:67 = *01:08, *01:20 =
	*01:20, *01:20 = *01:20, *01:67
++	*01:06, *01:07 = *01:06, *01:37N
++	*01:05, *01:32 = *01:16, *01:32 = *01:16, *01:50
++	*01:05, *01:31 = *01:16, *01:31 = *01:16, *01:54
++	*01:05, *01:30 = *01:16, *01:30 *01:05, *01:29 = *01:16, *01:29
++	*01:05, *01:28 = *01:16, *01:28
++	*01:05, *01:27 = *01:16, *01:27
++	*01:05, *01:26 = *01:16, *01:26 = *01:16, *01:36
+++ +	*01:05, *01:25 = *01:16, *01:25
++	*01:05, *01:19 = *01:16, *01:19
++	*01:05, *01:18 = *01:05, *01:73 = *01:16, *01:18 = *01:16, *01:73
++	*01:05, *01:17 = *01:16, *01:17 = *01:16, *01:21
++	*01:05, *01:13 = *01:13, *01:16
++	*01:05, *01:39 = *01:12, *01:16 = *01:16, *01:39
++	*01:05, *01:11 = *01:11, *01:16
++ ++	*01:05, *01:10 = *01:10, *01:16
++	*01:05, *01:09 = *01:09, *01:16
++	*01:05, *01:08 = *01:05, *01:67 = *01:08, *01:16 = *01:16, *01:67
++	*01:05, *01:07 = *01:07, *01:16 = *01:16, *01:37N *01:05, *01:06 = *01:06, *01:16
+-+	*01:14, *01:32 = *01:14, *01:50
+-+	*01:14, *01:31 = *01:14, *01:54
+-+	*01:14, *01:26 = *01:14, *01:36
+-+	*01:14, *01:18 = *01:14, *01:73
+-+	*01:14, *01:17 = *01:14, *01:21
+-+	*01:12, *01:14 = *01:14, *01:39
+-++	*01:08, *01:14 = *01:14, *01:67
+-+++	*01:07, *01:14 = *01:14, *01:37N
+-++	*01:05, *01:14 = *01:14, *01:16
++	*01:03, *01:32 = *01:15, *01:32 = *01:15, *01:50
++	*01:03, *01:31 = *01:15, *01:31 = *01:15, *01:54 *01:03, *01:30 = *01:15, *01:30
++	*01:03, *01:29 = *01:15, *01:29
++	*01:03, *01:28 = *01:15, *01:28
++	*01:03, *01:27 = *01:15, *01:27
++	*01:03, *01:26 = *01:15, *01:26 = *01:15, *01:36
++	*01:02:01, *01:24 = *01:03, *01:25 = *01:15, *01:24 = *01:15, *01:25 = *01:24, *01:25
++	*01:03, *01:19 = *01:15, *01:19
++	*01:03, *01:18 = *01:03, *01:73 = *01:15, *01:18 = *01:15, *01:73
++	*01:03, *01:17 = *01:15, *01:17 = *01:15, *01:21
++	*01:03, *01:13 = *01:13, *01:15
+++-+	*01:03, *01:39 = *01:12, *01:15 = *01:15, *01:39
++ ++	*01:03, *01:11 = *01:11, *01:15
++++	*01:03, *01:10 = *01:10, *01:15 *01:03, *01:09 = *01:09, *01:15
++++	*01:03, *01:09 = *01:09, *01:15 *01:03, *01:08 = *01:03, *01:67 = *01:08, *01:15 = *01:15, *01:67
++++	*01:03, *01:07 = *01:07, *01:15 = *01:15, *01:37N
+++	*01:03, *01:06 = *01:06, *01:15
++-+	*01:03, *01:16 = *01:05, *01:15 = *01:15, *01:16
+++	*01:03, *01:14 = *01:14, *01:15
++	*01:18, *01:49 = *01:49, *01:73
++	*01:32, *01:69N = *01:50, *01:69N

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```
Lot No.: 76S
                               Lot-specific information
                         *01:31, *01:69N = *01:54, *01:69N
*01:26, *01:69N = *01:36, *01:69N
+-----
+-----
+----+
                          *01:23, *01:32 = *01:23, *01:50
                          *01:23, *01:31 = *01:23, *01:54
+-----
+----
                          *01:19, *01:69N = *01:23, *01:29 = *01:23, *01:69N
+----
                          *01:23, *01:26 = *01:23, *01:36
+----
                          *01:18, *01:69N = *01:69N, *01:73
                          *01:18, *01:23 = *01:23, *01:73
*01:32, *01:34 = *01:39, *01:49
+-----
+----+
                          *01:18, *01:34 = *01:34, *01:73
+-----
                          *01:12, *01:69N = *01:39, *01:69N
+----
+----
                          *01:12, *01:23 = *01:23, *01:39
+----+
                          *01:22, *01:32 = *01:22, *01:50
+----+ -+--+--
                          *01:02:01, *01:35 = *01:09, *01:35 = *01:11, *01:35 = *01:22, *01:31 = *01:22, *01:35 =
                          *01:22, *01:54 = *01:31, *01:35 = *01:35, *01:35 = *01:35, *01:54
                          *01:22, *01:26 = *01:22, *01:36
+----+ -+--+---
+----+ -+--+- ------
                          *01:18, *01:22 = *01:22, *01:73
+----+ -+--++-- ------
                          *01:17, *01:22 = *01:21, *01:22
+----+ -++-+---
                          *01:12, *01:22 = *01:22, *01:39
+----+
                          *01:08, *01:49 = *01:49, *01:67
+----+
                          *01:08, *01:69N = *01:67, *01:69N
*01:08, *01:23 = *01:23, *01:67
+----+
+----+
                          *01:08, *01:34 = *01:34, *01:67
+----+
                          *01:08, *01:22 = *01:22, *01:67
+---+--
                          *01:07, *01:69N = *01:37N, *01:69N
+---+-
                          *01:07, *01:23 = *01:23, *01:37N
+----+
                          *01:07, *01:22 = *01:22, *01:37N
+---+
                          *01:20, *01:32 = *01:20, *01:50
                          *01:20, *01:31 = *01:20, *01:54
+---+-
+---+-
                          *01:20, *01:26 = *01:20, *01:36
+---+-
                          *01:18, *01:20 = *01:20, *01:73
+---+-
                          *01:17, *01:20 = *01:20, *01:21
                         *01:12, *01:20 = *01:20, *01:39
*01:07, *01:20 = *01:20, *01:37N
*01:05, *01:69N = *01:16, *01:69N
+---+-
+---++- -----
+--+---
+--+---
                          *01:05, *01:23 = *01:16, *01:23
+--+--+ -+--+---
                          *01:05, *01:22 = *01:16, *01:22
+--++-+-
                          *01:05, *01:20 = *01:16, *01:20
+-+---+
                          *01:02:01, *01:04 = *01:04, *01:09 = *01:04, *01:14 = *01:04, *01:31
++-----
                          *01:18, *01:24 = *01:24, *01:73
++----
                          *01:03, *01:69N = *01:15, *01:69N
                          *01:03, *01:23 = *01:15, *01:23
++----
++----+ -+--+---
                          *01:03, *01:22 = *01:15, *01:22
++----+
                          *01:08, *01:24 = *01:24, *01:67
++--+--
                          *01:03, *01:20 = *01:15, *01:20
+----+
                          *01:32, *01:35 = *01:35, *01:50
+----+ -+--+--
                          *01:26, *01:35 = *01:35, *01:36
*01:18, *01:35 = *01:35, *01:73
+----+ -+--+- -----+-
+----+ -+--+--
                          *01:17, *01:35 = *01:21, *01:35
+----+ -++-+---
                          *01:12, *01:35 = *01:35, *01:39
+----+
                          *01:08, *01:35 = *01:35, *01:67
                          *01:07, *01:35 = *01:35, *01:37N
*01:05, *01:35 = *01:16, *01:35
*01:04, *01:18 = *01:04, *01:73
+---++ -+--+--
+--+--+ -+--+--
+-+---+
+-+---+ -+--+--
                          *01:04, *01:11 = *01:04, *01:22 = *01:04, *01:35 = *01:14, *01:35
+-+--++ ----+-
                          *01:04, *01:08 = *01:04, *01:67
++----+ -+--+---
                          *01:03, *01:35 = *01:15, *01:35
    *01:02:01 = *01:02:01-01:02:18 and 01:46-01:48, 01:51, 01:53, 01:57, 01:60-01:66, 01:68, 01:70-01:61
    01:72 and 01:74-01:75
```

*01:06 = *01:06 and 01:38 *01:10 = *01:10 and 01:52

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Lot-specific information

*01:17 = *01:17 and 01:41 *01:18 = *01:18 and 01:42 *01:19 = *01:19, 01:43 and 01:58 *01:25 = *01:25 and 01:59 *01:27 = *01:27 and 01:45 *01:28 = *01:28 and 01:56N *01:29 = *01:29 and 01:33 *01:31 = *01:31 and 01:44 *01:32 = *01:32 and 01:40

*01:36 = *01:36 and 01:55

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Lot-specific information SPECIFICITY TABLE

HLA-C*01 SSP subtyping

Specificities and sizes of the PCR products of the 24 primer mixes used for HLA-C*01 SSP subtyping

Primer Mix	Size of spec. PCR product ¹	Size of control band ²	Amplified HLA-C*01 alleles ³	Other amplified HLA Class I alleles ⁴				
1 ^{5,7}	90 bp	800 bp	*01:02:01-01:02:18, 01:06-01:11, 01:13- 01:20, 01:22-01:23, 01:25-01:33, 01:35, 01:38-01:48, 01:51- 01:53, 01:56N-01:75	*03:86, 03:94, 03:99, 07:177				
2 ^{5,8}	90 bp, 270 bp	1070 bp	*01:03, 01:15, 01:24	*03:58, 04:37, 05:85				
3 ⁹	150 bp, 265 bp	800 bp	*01:04, 01:14					
4 ¹⁰	210 bp, 240 bp	800 bp	*01:05, 01:16	*07:37, B*07:77				
5 ^{5,11}	105 bp, 150 bp, 200 bp	800 bp	*01:06, 01:20, 01:38					
6 ^{6,12}	195 bp, 235 bp	1070 bp	*01:07, 01:37N	*06:43:01, 14:24:02, 14:35N				
7 ^{5,6,13}	70 bp, 150 bp, 195 bp	1070 bp	*01:08, 01:20, 01:67	*03:03:10, 03:04:28, 04:01:11, 06:02:21, 07:02:36, A*01:01:33, A*02:01:29, A*11:01:40, A*26:01:09, A*32:01:09, A*33:01:07, A*68:01:06, B*07:02:21, B*13:02:03, B*27:05:06, B*40:01:10, B*40:02:11, B*44:03:08, B*51:01:24, B*73:01-73:02				
8	210 bp	1070 bp	*01:04, 01:09, 01:22, 01:35	*06:23, 07:177, 15:37				
9 ¹⁴	160 bp, 230 bp	800 bp	*01:10, 01:52					
10 ¹⁵	210 bp, 290 bp	1070 bp	*01:11, 01:22, 01:35	*07:177, 15:37				
11 ¹⁶	140 bp, 345 bp	800 bp	*01:12, 01:34, 01:39	,				
12	155 bp	1070 bp	*01:13	*02:51, 03:87, 05:09:01- 05:09:02, 05:17, 05:52, 07:130, 08:15:01- 08:15:02, 08:51, 16:27, B*15:33, B*15:248				

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			•	
13 ⁷	155 bp	800 bp	*01:02:01-01:20, 01:22- 01:66, 01:68-01:72, 01:74-01:75	B*54:18
14 ^{5,6,17}	120 bp, 240 bp	1070 bp	*01:17, 01:21, 01:23, 01:41, 01:69N	
15 ^{5,18}	115 bp, 230 bp	800 bp	*01:18, 01:42, 01:73	B*51:129
16 ¹⁹	130 bp, 255 bp, 295 bp	1070 bp	*01:19, 01:23, 01:43, 01:58	A*01:24
17 ^{5,20}	75 bp, 255 bp	800 bp	*01:24-01:25, 01:59	
18 ²¹	195 bp, 260 bp, 345 bp	800 bp	*01:26, 01:34, 01:36, 01:49, 01:55	
19 ^{5,22}	100 bp, 275 bp	1070 bp	*01:27, 01:45	
20 ^{5,23}	110 bp, 285 bp	800 bp	*01:28, 01:56N	*03:59, 03:123
21 ^{5,24}	125 bp, 245 bp	800 bp	*01:29, 01:33, 01:69N	
22	255 bp	1070 bp	*01:30	
23 ^{5,25}	90 bp, 120 bp, 235 bp	1070 bp	*01:04, 01:31, 01:35, 01:44, 01:54	*06:23, 14:45, 16:18
24 ^{5,26}	110 bp, 250 bp, 340 bp	1070 bp	*01:32, 01:40, 01:49- 01:50	

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-C*01 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 inherit 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-C*01 SSP subtyping.

In addition, wells number 3 to 5, 9, 11, 13, 15, 17, 18, 20 and 21 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.

³For 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.

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⁴Due to the sharing of sequence motifs between HLA Class I alleles some non-HLA-C*01 alleles will be amplified by primer mixes 1, 2, 4, 6 to 8, 10, 12, 20 and 23. In addition, the A*01:01:33, A*02:01:29, A*11:01:40, A*26:01:09, A*32:01:09, A*33:01:07, A*68:01:06, B*07:02:21, B*13:02:03, B*27:05:06, B*40:01:10, B*40:02:11, B*44:03:08, B*51:01:24 and B*73:01-73:02 alleles will be amplified by primer mix 7, the A*01:24 allele will be amplified by primer mix 16, the B*07:77 allele will be amplified by primer mix 4, the B*15:33 and B*15:248 alleles will be amplified by primer mix 12, the B*51:129 allele will be amplified by primer mix 15, and the B*54:18 allele will be amplified by primer mix 13.

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

⁶Primer mixes 6, 7, 14 and 18 may have tendencies of unspecific amplifications.

⁷Primer mixes 1 and 13 may give rise to a lower yield of HLA-specific PCR product than the other HLA-C*01 primer mixes.

⁸Primer mix 2: Specific PCR product of 90 bp in the C*01:03 and 01:24 and the C*03:58, 04:37 and 05:85 alleles. Specific PCR product of 270 bp in the C*01:15 allele.

⁹Primer mix 3: Specific PCR product of 150 bp in the C*01:04 allele. Specific PCR product of 265 bp in the C*01:14 allele.

¹⁰Primer mix 4: Specific PCR product of 210 bp in the C*01:05 and C*07:37 and the B*07:77 alleles. Specific PCR product of 240 bp in the C*01:16 allele.

¹Primer mix 5: Specific PCR product of 105 bp in the C*01:38 allele. Specific PCR product of 150 bp in the C*01:20 allele. Specific PCR product of 200 bp in the C*01:06 allele.

¹²Primer mix 6: Specific PCR product of 195 bp in the C*01:07 and the C*06:43:01 and 14:24:02 alleles. Specific PCR product of 235 bp in the C*01:37N and the C*14:35N alleles.

³Primer mix 7: Specific PCR product of 70 bp in the C*01:67 and the 03:03:10, 03:04:28, 04:01:11, 06:02:21 and 07:02:36 and in the A*01:01:33, A*02:01:29, A*11:01:40, A*26:01:09, A*32:01:09, A*33:01:07, A*68:01:06, B*07:02:21, B*13:02:03, B*27:05:06, B*40:01:10, B*40:02:11, B*44:03:08, B*51:01:24 and B*73:01-73:02 alleles. Specific PCR product of 150 bp in the C*01:20 allele. Specific PCR product of 195 bp in the C*01:08 allele.

¹⁴Primer mix 9: Specific PCR fragment of 160 bp in the C*01:52 allele. Specific PCR fragments of 230 bp in the C*01:10 allele.

¹⁵Primer mix 10: Specific PCR fragment of 210 bp in the C*01:22 and 01:35 and the C*07:177 and 15:37 alleles. Specific PCR fragments of 290 bp in the C*01:11 allele.

¹⁶Primer mix 11: Specific PCR product of 140 bp in the C*01:39 allele. Specific PCR product of 345 bp in the C*01:12 and 01:34 alleles.

¹⁷Primer mix 14: Specific PCR product of 120 bp in the C*01:41 allele. Specific PCR product of 240 bp in the C*01:17, 01:21, 01:23 and 01:69N alleles.

¹⁸Primer mix 15: Specific PCR product of 115 bp in the C*01:42 and 01:73 and in the B*51:129 alleles.

Specific PCR product of 230 bp in the C*01:18 allele.

19 Primer mix 16: Specific PCR product of 130 bp in the C*01:43 allele. Specific PCR product of 255 bp in the C*01:19 allele. Specific PCR product of 295 bp in the C*01:23, 01:58 and the A*01:24 alleles.

²¹Primer mix 17: Specific PCR fragment of 75 bp in the C*01:24 and 01:25 alleles. Specific PCR fragments of 255 bp in the C*01:59 allele.

²¹Primer mix 18: Specific PCR product of 195 bp in the C*01:26 allele. Specific PCR product of 260 bp in the C*01:34 allele. Specific PCR product of 345 bp in the C*01:36, 01:49 and 01:55 alleles.

²²Primer mix 19: Specific PCR fragment of 100 bp in the C*01:27 allele. Specific PCR fragments of

275 bp in the C*01:45 allele.

²³Primer mix 20: Specific PCR fragment of 110 bp in the C*01:28 and the C*03:59 and 03:123 alleles. Specific PCR fragments of 285 bp in the C*01:56N allele.

²⁴Primer mix 21: Specific PCR fragment of 125 bp in the C*01:33 allele. Specific PCR fragments of 245 bp in the C*01:29 and 01:69N alleles.

²⁵Primer mix 23: Specific PCR fragment of 90 bp in the C*01:04 and 01:54 and the C*06:23, 14:45 and 16:18 alleles. Specific PCR fragment of 120 bp in the C*01:44 allele. Specific PCR fragments of 235 bp in the C*01:31 and 01:35 alleles.

²⁶Primer mix 24: Specific PCR fragment of 110 bp in the C*01:40 allele. Specific PCR fragments of 250 bp in the C*01:32 allele. Specific PCR fragment of 335 bp in the C*01:49 and 01:50 alleles.

July 2013 For In Vitro Diagnostic Use Rev. No.: 00

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Lot No.: / 65	LOt	-spec	ITIC IN	rorma	tion							
IN	TER	PRE	TAT	ION	TAB	LE						
Н	LA-C	*01	SSP	sub	typi	ng						
Amplification p						C*01		lleles	5			
	Well ¹⁷											
	1	2	3	5	6	7	8	9	10	11	12	
Length of spec.	90	90	150	210	105	195	70	210	160	210	140	155
PCR product(s)		270	265	240	150	235	150		230	290	345	
					200		195					
Length of int.	800	1070	800	800	800	1070	1070	1070	800	1070	800	1070
pos. control ¹												
5'-primer(s) ²	368	368	89	89	368	363	89	368	368	368	101	485
			A	 A	G	A	 D		-9Tg ^{3'}	-9Tg ³ '	-CAT 3'	-CAA 3.
	-gTg	-gTg-	-gAA	-gAA	-gTg-	-TgA	-gAg	-gTg	-gT	-gT	Ϋ́	Ϋ́
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3'-primer(s) ³	419	419	312	287	430	559	117	538	488	539	201	601
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	-cgT	-CgA	-AgT	-TCg	-gCT	ပို	ပို	-CCA	ပို	1-	-стс	
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					-ccA ³		-ACA					
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Well No.	1	2	3	4	5	6	7	8	9	10	11	12
HLA-C allele ^{4,5}												
*01:02:01 -01:02:18, 01:46-01:48,												
01:51, 01:53, 01:57, 01:60-01:66,	1											
01:68, 01:70-01:72, 01:74-01:75												
*01:03		2										
*01:04			3	_				8				
*01:05	<u> </u>			4			_			4.5	4.	
Well No.	1	2	3	4	5	6	7	8	9	10	11	12

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	LOT	No.:	103					speci				
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											typir	_
				Ampl			atteri	ns of	the C	:*01:	02 to (C*01:75 alleles
					We	ell ¹⁷						
13	14	15	16	17	18	19	20	21	22	23	24	
155	120	115	130	75	195	100	110	125	255	90	110	Length of spec.
	240	230	255	255	260	275	285	245		120	250	PCR product(s)
			295		345					235	340	
800	1070	800	1070	800	800	1070	800	800	1070	1070	1070	Length of int.
												pos. control ¹
89	89	89	89	89	89	368	89	89	368	368	74	5'-primer(s) ²
.e 4	Б	.e 4	А 3.	э.	.e 4	 To	.e 4	.e	 D	.e.	-5-	,
-gAA ³	-gAA ³	-gAA ³'	-gAA	-gAA	-gAA ³'	-9Тg ^{з.}	-gAA	-gAA	-gTg	-gTg	ပု	
ŗ,	io.	io.	io.	52	52	ŗ,	o,	52	ĵo.	5	in .	
				806 ĕ	368 **		530 	368 **		3rd I ĕ	369 *	
				-ggA	-gTT		-99T	-gTg		-Cgg	-TAC	
				-G	رن		ر. دو	5.		٠,	- 'c	
				818	369						379	
				-ggc _{3.}	-TAC 3'						-ACg ³′	
				gc							¥	
				2	453						463	
											~	
					-AAT 3'						-TgA	
					້າດ						ũ	
201	170	164	176	302	244	427	331	172	583	419	142	3'-primer(s) ³
·e	₆	·6	3.	.e.	.e	'n	is _	·6	.e	<u>.</u>	'n	c pillion(e)
-CTC ³'	-Cgg	-gCA	-ACT	-ggT	-ств	-gTA ³'	-CTA	-CAT	-gTg	-Cgg	-TgA	
īo.	ī,	ία	52	5.	52	5.	ī,	5.	ŗ,	52	5	
	289 	165 .∞	301 ĕ	846 ∞	3rd I	601 ĕ	601 ĕ	295 		560 	3rd I ∞	
	-AgC	-T99	-gCA	-cAC	-АТ	-СТ	-CTC	-TCA		-ACA	-АТ	
	5A	.c.	5.	ئ -ر	5. -A	۶.	٠,			۶ -۸	- P	
	295	278	341					573		671		
	-TCA 3'	-ggT ³′	-cgT ³′					-AgA ³		-ggA ³'		
	₅ -۲(-9ć	Ç					5Aç		9		
13	14	15	16	17	18	19	20	21	22	23	24	Well No.
												HLA-C allele ^{4,5}
												*01:02:01 -01:02:18, 01:46-01:48,
13												01:51, 01:53, 01:57, 01:60-01:66,
												01:68, 01:70-01:72, 01:74-01:75
13												*01:03
13										23		*01:04
13												*01:05
13	14	15	16	17	18	19	20	21	22	23	24	Well No.

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Lot No.: **76S Lot-specific information**

LOUNO 7 00				Offila	1				i —			
Length of spec.	90	90	150	210	105	195	70	210	160	210	140	155
PCR product(s)		270	265	240	150	235	150		230	290	345	
					200		195					
Well No.	1	2	3	4	5	6	7	8	9	10	11	12
*01:06 , 01:38 ⁶	1				5							
*01:07	1					6						
*01:08	1						7					
*01:09	1							8				
*01:10, 01:52 ⁷	1								9			
*01:11	1									10		
*01:12											11	
*01:13	1											12
*01:14	1		3									
*01:15	1	2										
*01:16	1			4								
*01:17, 01:41 ⁸	1											
*01:18, 01:42 ⁹	1											
*01:19, 01:43, 01:58 ¹⁰	1											
*01:20	1				5		7					
*01:21												
*01:22	1							8		10		
*01:23	1											
*01:24		2										
*01:25, 01:59 ¹¹	1											
*01:26	1											
*01:27, 01:45 ¹²	1											
*01:28, 01:56N ¹³	1											
*01:29, 01:33 ¹⁴	1											
*01:30	1											
*01:31, 01:44 ¹⁵	1											
*01:32, 01:40 ¹⁶	1											
*01:34	<u> </u>										11	
*01:35	1							8		10		
*01:36, 01:55								U		10		
*01:37N						6						
*01:39	1										11	
*01:49												
*01:50												
*01:54												
*01:67	1						7					
*01:69N	1											
*01:73	1											
Well No.	1	2	3	4	5	6	7	8	9	10	11	12

July 2013 Rev. No.: 00

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Lot No.: **76S Lot-specific information**

155	120	115	130	75	195	100	110	125	255	90	110	Length of spec.
100	240	230	255	255	260	275	285	245	200	120	250	PCR product(s)
	240	200	295	200	345	210	200	240		235	340	1 ON product(s)
13	14	15	16	17	18	19	20	21	22	23	24	Well No.
13												* 01:06 , 01:38 ⁶
13												*01:07
13												*01:08
13												*01:09
13												*01:10, 01:52 ⁷
13												*01:11
13												*01:12
13												*01:13
13												*01:14
13												*01:15
13												*01:16
13	14											*01:17, 01:41 ⁸
13		15										*01:18, 01:42 ⁹
13		10	16									*01:19, 01:43, 01:58 ¹⁰
13			10									*01:20
13	14											*01:21
13	17											*01:22
13	14		16									*01:23
13	• •			17								*01:24
13				17								*01:25, 01:59 ¹¹
13					18							*01:26
13						19						*01:27, 01:45 ¹²
13							20					*01:28, 01:56N ¹³
13								21				*01:29, 01:33 ¹⁴
13									22			*01:30
13									LL	23		*01:31, 01:44 ¹⁵
										23	24	
13					40						24	*01:32, 01:40 ¹⁶
13					18					23		*01:34
13					18					23		*01:35
13 13					10							*01:36, 01:55 *01:37N
13												*01:37N
13					18						24	*01:49
13					.5						24	*01:50
13										23		*01:54
												*01:67
13	14							21				*01:69N
		15										*01:73
13	14	15	16	17	18	19	20	21	22	23	24	Well No.
	July	2013				_			CE	_		For <i>In Vitro</i> Diagnostic Use

July 2013 Rev. No.: 00

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Lot No.: 76S Lot-specific information

Length of spec.	90	90	150	210	105	195	70	210	160	210	140	155
PCR product(s)		270	265	240	150	235	150		230	290	345	
					200		195					
Well No.	1	2	3	4	5	6	7	8	9	10	11	12
*02:51, 03:87, 05:09:01-05:09:02,												
05:17, 05:52, 07:130, 08:15:01-												12
08:15:02, 08:51, 16:27, <i>B*15:33</i> ,												
B*15:248												
*03:03:10, 03:04:28, 04:01:11,												
06:02:21, 07:02:36, <i>A*01:01:33</i> ,												
A*02:01:29, A*11:01:40,												
A*26:01:09, A*32:01:09,							_					
A*33:01:07, A*68:01:06,							7					
B*07:02:21, B*13:02:03,												
B*27:05:06, B*40:01:10,												
B*40:02:11, B*44:03:08,												
B*51:01:24, B*73:01-73:02												
*03:58, 04:37, 05:85		2										
*03:59, 03:123	_											
*03:86, 03:94, 03:99	1							_				
*06:23						_		8				
*06:43:01, 14:24:02, 14:35N						6						
*07:37, <i>B</i> *07:77				4								
*07:177	1							8		10		
*14:45, 16:18												
*15:37								8		10		
A*01:24												
B*51:129												
B*54:18												
HLA-C allele ^{4,5}												
Well No.	1	2	3	4	5	6	7	8	9	10	11	12

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-C*01 SSP subtyping.

In addition, wells number 3, 4, 5, 9, 11, 13, 15, 17, 18, 20 and 21 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, 3rd or 4th exon or the 3rd intron, 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.

3 The nucleotide position, in the 2nd, 3rd or 4th exon or the 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.

⁴The HLA-Cw*0101 nucleotide sequence has been shown to be identical to C*01:02:01.

⁵HLA-C*01 alleles in bold lettering are listed as confirmed alleles on the IMGT/HLA web page www.ebi.ac.uk/imgt/hla, release 3.11.0, January 2013.

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Lot No.: 76S **Lot-specific information**

155	120	115	130	75	195	100	110	125	255	90	110	Length of spec.
	240	230	255	255	260	275	285	245		120	250	PCR product(s)
			295		345					235	340	
13	14	15	16	17	18	19	20	21	22	23	24	Well No.
												*02:51, 03:87, 05:09:01-05:09:02,
												05:17, 05:52, 07:130, 08:15:01-
												08:15:02, 08:51, 16:27, <i>B*15:33,</i>
												B*15:248
												*03:03:10, 03:04:28, 04:01:11,
												06:02:21, 07:02:36, <i>A*01:01:33,</i>
												A*02:01:29, A*11:01:40,
												A*26:01:09, A*32:01:09,
												A*33:01:07, A*68:01:06,
												B*07:02:21, B*13:02:03,
												B*27:05:06, B*40:01:10,
												B*40:02:11, B*44:03:08,
												B*51:01:24, B*73:01-73:02
												*03:58, 04:37, 05:85
							20					*03:59, 03:123
												*03:86, 03:94, 03:99
										23		*06:23
												*06:43:01, 14:24:02, 14:35N
												*07:37, <i>B</i> *07:77
												*07:177
										23		*14:45, 16:18
												*15:37
			16									A*01:24
		15										B*51:129
13												B*54:18
												HLA-C allele ^{4,5}
13	14	15	16	17	18	19	20	21	22	23	24	Well No.

⁶The C*01:06 and 01:38 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 5. ⁷The C*01:10 and 01:52 alleles can be distinguished by the different sizes of the specific PCR

products generated by primer mix 9. The C*01:17 and 01:41 alleles can be distinguished by the different sizes of the specific PCR

products generated by primer mix 14. The C*01:18 and 01:42 alleles can be distinguished by the different sizes of the specific PCR

products generated by primer mix 15. ¹⁰The C*01:43 and the C*01:19 and 01:58 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 16.

11 The C*01:25 and 01:59 alleles can be distinguished by the different sizes of the specific PCR

products generated by primer mix 17.

12The C*01:27 and 01:45 alleles can be distinguished by the different sizes of the specific PCR

products generated by primer mix 19.

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Lot No.: 76S Lot-specific information

¹³The C*01:28 and 01:56N alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 20. ¹⁴The C*01:29 and 01:33 alleles can be distinguished by the different sizes of the specific PCR

products generated by primer mix 21.

⁵The C*01:31 and 01:44 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 23. ¹⁶The C*01:32 and 01:40 alleles can be distinguished by the different sizes of the specific PCR

products generated by primer mix 24. ¹⁷Primer mix 2: Specific PCR product of 90 bp in the C*01:03 and 01:24 and the C*03:58, 04:37

and 05:85 alleles. Specific PCR product of 270 bp in the C*01:15 allele.

Primer mix 3: Specific PCR product of 150 bp in the C*01:04 allele. Specific PCR product of 265 bp in the C*01:14 allele.

Primer mix 4: Specific PCR product of 210 bp in the C*01:05 and C*07:37 and the B*07:77 alleles. Specific PCR product of 240 bp in the C*01:16 allele.

Primer mix 5: Specific PCR product of 105 bp in the C*01:38 allele. Specific PCR product of 150 bp in the C*01:20 allele. Specific PCR product of 200 bp in the C*01:06 allele.

Primer mix 6: Specific PCR product of 195 bp in the C*01:07 and the C*06:43:01 and 14:24:02 alleles. Specific PCR product of 235 bp in the C*01:37N and the C*14:35N alleles.

Primer mix 7: Specific PCR product of 70 bp in the C*01:67 and the 03:03:10, 03:04:28, 04:01:11, 06:02:21 and 07:02:36 and in the A*01:01:33, A*02:01:29, A*11:01:40, A*26:01:09, A*32:01:09, A*33:01:07, A*68:01:06, B*07:02:21, B*13:02:03, B*27:05:06, B*40:01:10, B*40:02:11, B*44:03:08, B*51:01:24 and B*73:01-73:02 alleles. Specific PCR product of 150 bp in the C*01:20 allele. Specific PCR product of 195 bp in the C*01:08 allele.

Primer mix 9: Specific PCR fragment of 160 bp in the C*01:52 allele. Specific PCR fragments of 230 bp in the C*01:10 allele.

Primer mix 10: Specific PCR fragment of 210 bp in the C*01:22 and 01:35 and the C*07:177 and 15:37 alleles. Specific PCR fragments of 290 bp in the C*01:11 allele.

Primer mix 11: Specific PCR product of 140 bp in the C*01:39 allele. Specific PCR product of 345 bp in the C*01:12 and 01:34 alleles.

Primer mix 14: Specific PCR product of 120 bp in the C*01:41 allele. Specific PCR product of 240 bp in the C*01:17, 01:21, 01:23 and 01:69N alleles.

Primer mix 15: Specific PCR product of 115 bp in the C*01:42 and 01:73 and in the B*51:129 alleles. Specific PCR product of 230 bp in the C*01:18 allele.

Primer mix 16: Specific PCR product of 130 bp in the C*01:43 allele. Specific PCR product of 255 bp in the C*01:19 allele. Specific PCR product of 295 bp in the C*01:23, 01:58 and the A*01:24 alleles.

Primer mix 17: Specific PCR fragment of 75 bp in the C*01:24 and 01:25 alleles. Specific PCR fragments of 255 bp in the C*01:59 allele.

Primer mix 18: Specific PCR product of 195 bp in the C*01:26 allele. Specific PCR product of 260 bp in the C*01:34 allele. Specific PCR product of 345 bp in the C*01:36, 01:49 and 01:55 alleles.

Primer mix 19: Specific PCR fragment of 100 bp in the C*01:27 allele. Specific PCR fragments of 275 bp in the C*01:45 allele.

Primer mix 20: Specific PCR fragment of 110 bp in the C*01:28 and the C*03:59 and 03:123 alleles. Specific PCR fragments of 285 bp in the C*01:56N allele.

Primer mix 21: Specific PCR fragment of 125 bp in the C*01:33 allele. Specific PCR fragments of 245 bp in the C*01:29 and 01:69N alleles.

Primer mix 23: Specific PCR fragment of 90 bp in the C*01:04 and 01:54 and the C*06:23, 14:45 and 16:18 alleles. Specific PCR fragment of 120 bp in the C*01:44 allele. Specific PCR fragments of 235 bp in the C*01:31 and 01:35 alleles.

Primer mix 24: Specific PCR fragment of 110 bp in the C*01:40 allele. Specific PCR fragments of 250 bp in the C*01:32 allele. Specific PCR fragment of 335 bp in the C*01:49 and 01:50 alleles.

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	CELL LINE VALIDATION SHEET																			
	HLA-C*01 SSP primer set																			
												We	ell ¹							
					1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
				٠.	5	22	33	4	25	90	22	80	60	9	7	7	13	4	5	16
				Prod. No.:	201070701	201070702	201070703	201182604	201201405	201182606	201318907	201201408	201201409	201201410	201182611	201070712	201070713	201318914	201318915	201182616
				od.	107	101	101	2	12(118	73	12(12(12(112	107	107	13,	73	112
					20	8	8	2	2	2	2	2	20	8	8	2	2	8	2	8
		VC cell line		<u>C*</u>																
1	9001		*07:02 *07:01	*45.05	-	-	-	-	-	-	÷	-	-	-	-	-	-	-	-	<u> </u>
3		LK707 E4181324	*12:02	*15:05	Ė	-		-	-	-	+	-	-		-	-	-	-	-	-
4		GU373	*03:04	*04:01	H	÷	÷	÷		Ė	÷	-	-		-	-	-	÷	-	÷
5		KAS011	*06:02	04.01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
6	9353		*03:04	*07:02	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
7	9020		*05:01	01.02	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
8	9007		*04:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
9	9026		*12:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
10	9107		*01:02		+	-	-	-	-	-	-	-	-	-	-	-	+	-	-	-
11	9051	PITOUT	*16:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
12	9052	DBB	*06:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
13	9004	JESTHOM	*01:02		+	-	-	-	-	-	-	-	-	-	-	-	+	-	-	-
14	9071	OLGA	*01:02	*03:04	+	-	-	-	-	-	-	-	-	-	-	-	+	-	-	-
15	9075	DKB	*03:04		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
16	9037	SWEIG007	*02:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
17	9282	CTM3953540	*03:03	*07:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
18	9257	32367	*01:02	*07:05	+	-	-	-	-	-	-	-	-	-	-	-	+	-	-	-
19		BM16	*07:01		-	-	-	-	-	-	Ŀ	-	-	-	-	-	-	-	-	-
20		SLE005	*03:04		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
21		AMALA	*03:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
22		KOSE	*12:03		<u> </u>	-	-	-	-	-	Ŀ	-	-	-	-	-	-	-	-	-
23	9124		*01:02	*15:02	+	-		•	•	-	Ŀ	-	-	•	-	•	+	-	•	•
24		JBUSH	*12:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
25		IBW9	*08:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
26		WT49	*07:01	*45.05	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
27		CH1007	*07:04	*15:05	-	-	-	-	-	-	Ŀ	-	-	-	-	-	-	-	-	-
28		BEL5GB	*05:01 *16:01	*16:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
29 30	9050 9021		*17:01		-	-	-	-	-	-	÷	-	-		-	-	-	-	-	-
31		DUCAF	*05:01		H	-	H	-	-	-	-	-	-	-	-		-	-	-	÷
32		HAG	*17:01	*17:03	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
33		MT14B	*03:04	17.03	-	-	-	-	-	-		-	-	-	-	-	-	-	-	-
34	9104		*12:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
35		SSTO	*05:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
36		KT17	*03:03	*04:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
37		HHKB	*07:02	0 1.01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
38	9099		*03:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
39	9315		*02:02	*07:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
40		WHONP199	*01:02	*06:02	+	-	-	-	-	-	-	-	-	-	-	-	+	-	-	-
41		H0301	*08:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
42	9066	TAB089	*01:02		+	-	-	-	-	-	-	-	-	-	-	-	+	-	-	-
43	9076	T7526	*01:02	*08:01	+	-	-	-	-	-	-	-	-	-	-	-	+	-	-	-
44	9057	TEM	*12:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
45		SHJO	*06:02	*17:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
46	9013	SCHU	*07:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
47		TUBO	*07:04	*15:02	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
48	9303	TER-ND	*04:01	*16:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

¹The B*73:01 allele is weakly amplified by primer mix 7 in the 9280 (LK707) cell line.

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	Lot No.: 765 Lot-specific information											
	CELL LINE VALIDATION SHEET HLA-C*01 SSP primer set											
		HLA-	C*01 S	SP prin	ner	SE	Σ					
								W				
					17	18	19	20	21	22	23	24
					7	ω	6	0	Σ.	Ŋ	က္လ	4
				Prod. No.	201201417	201318918	201182619	201201420	201318921	201201422	201201423	201318924
				<u> </u>	20	3	20	20	3	20	20	3
				Pro	201	201	201	201	201	201	201	201
	IHV	VC cell line		C*	Ė	- 1		<u> </u>		- 1	<u> </u>	Ť
1	9001		*07:02		-	-	-	-	-	-	-	-
2	9280	LK707	*07:01	*15:05	-	-	-	-	-	-	-	-
3	9011	E4181324	*12:02		-	-	-	-	-	-	-	-
4		GU373	*03:04	*04:01	-	-	-	-	-	-	-	-
5	9009	KAS011	*06:02		-	-	-	-	-	-	-	-
6	9353	SM	*03:04	*07:02	-	-	-	-	-	-	-	-
7	9020		*05:01		-	-	-	-	-	-	-	-
8	9007		*04:01		-	-	-	-	-	-	-	-
9	9026		*12:03		-	-	-	-	-	-	-	-
10	9107	_	*01:02		-	-	-	-	-	-	-	-
11		PITOUT	*16:01		<u> </u>	-	-	-	-	-	-	-
12	9052		*06:02		<u> </u>	-	-	-	-	-	-	-
13		JESTHOM	*01:02		-	-	-	-	-	-	-	-
14		OLGA	*01:02	*03:04	-	-	-	-	-	-	-	-
15	9075		*03:04		-	-	-	-	-	-	-	-
16		SWEIG007	*02:02		-	-	-	-	-	-	-	-
17		CTM3953540	*03:03	*07:01	-	-	-	-	-	-	-	-
18		32367	*01:02	*07:05	-	-	-	-	-	-	-	-
19		BM16	*07:01		_	-	-	-	-	-	-	_
20		SLE005	*03:04		<u> </u>	-	-	-	-	-	-	-
21		AMALA	*03:03		-	-	-	-	-	-	-	-
22	9124	KOSE	*12:03 *01:02	*15:02	Ŀ	-	-	-	-	-	-	-
24		JBUSH	*12:03	15.02	H	H	E	-	E	E	E	H
25	9033		*08:02		H	H	E	-	E	E	E	H
26		WT49	*07:01			-		-		-	-	-
27		CH1007	*07:04	*15:05				-		-		
28		BEL5GB	*05:01	*16:01	-	-	-	-	-	-	-	-
29	9050		*16:01	10.01	-	-	-	-	-	-	-	-
30	9021		*17:01		-	-	-	-	-	-	-	-
31		DUCAF	*05:01		-	-	-	-	-	-	-	-
32	9297		*17:01	*17:03	-	-	-	-	-	-	-	-
33		MT14B	*03:04		-	-	-	-	-	-	-	-
34	9104		*12:03		-	-	-	-	-	-	-	-
35		SSTO	*05:01		-	-	-	-	-	-	-	-
36		KT17	*03:03	*04:01	-	-	-	-	-	-	-	-
37	9065	HHKB	*07:02		-	-	-	-	-	-	-	-
38	9099	LZL	*03:03		-	-	-	-	-	-	-	-
39	9315		*02:02	*07:01	-	-	-	-	-	-	-	-
40	9134	WHONP199	*01:02	*06:02	-	Ŀ	Ŀ	-	Ŀ		_	-
41	9055	H0301	*08:02		-	-	-	-	-	-	-	-
42	9066	TAB089	*01:02		-	-	-	-	-	-	-	-
43	9076	T7526	*01:02	*08:01	-	-	-	-	-	-	-	-
44	9057		*12:03		-	-	-	-	-	-	-	-
45	9239	SHJO	*06:02	*17:01	-	-	-	-	-	-	-	-
46		SCHU	*07:02		-	-	-	-	-	-	-	-
47		TUBO	*07:04	*15:02	-	-	-	-	-	-	-	-
48	9303	TER-ND	*04:01	*16:01	-	-	-	-	-	-	-	-

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Lot No.: **76S** Lot-specific information

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-C*01 SSP

Product number: 101.621-12 – including *Taq* polymerase

101.621-12u - without *Taq* polymerase

Lot number: 76S

Expiry date: 2016-January-01

Number of tests: 12 Number of wells per test: 24

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2010-707-01	9	2012-014-09	17	2012-014-17
2	2010-707-02	10	2012-014-10	18	2013-189-18
3	2010-707-03	11	2011-826-11	19	2011-826-19
4	2011-826-04	12	2010-707-12	20	2012-014-20
5	2012-014-05	13	2010-707-13	21	2013-189-21
6	2011-826-06	14	2013-189-14	22	2012-014-22
7	2013-189-07	15	2013-189-15	23	2012-014-23
8	2012-014-08	16	2011-826-16	24	2013-189-24

The specificity of each primer solution of the HLA-C*01 primer set has been tested against 48 well characterized IHWC cell line DNAs.

No DNAs carrying the alleles to be amplified by primer solutions 2 to 6, 8 to 12 and 14 to 24 were available. The specificity of the primers in primer solutions 2 to 5, 8 to 12, 14 to 18, 20 and 22 to 24 were tested by adding additional 5'-primers respectively 3'-primers. In primer solution 6, it was only possible to test the 3'-primer, the 5'-primer was not possible to test. In primer solutions 19 and 21 it was only possible to test the 5'-primers, the 3'-primers were not possible to test. In primer solutions 11, 17, 20 and 24 one or two of the 5'-primers were not possible to test. In primer solutions 2, 4, 5, 7, 9, 10, 14, 15, 16, 18, 20 and 23 one or two of the 3'-primers were not possible to test. In primer solution 7 one additional 5'-primer was tested by separately adding one additional 3'-primer.

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

Date of approval: 2013-July-23

Approved by:

Production Quality Control

Visit <u>www.olerup-ssp.com</u> for "Instructions for Use" (IFU)

Lot No.: **76S** Lot-specific information

Declaration of Conformity

Product name: Olerup SSP® HLA-C*01

Product number: 101.621-12/12u

Lot number: 76S

Intended use: HLA-C*01 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 III, as transposed into the national laws of the Member States of the European Union.

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

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

Stockholm, Sweden 2013-July-23

Åsa Olausson Production Quality Control

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Lot No.: **76S** Lot-specific information

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