

101.621-12 – including *Taq* pol., IFU-01 Rev. No. 03
 101.621-12u – without *Taq* pol., IFU-02 Rev. No. 03

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

Lot No.: **75N**

Lot-specific information
Olerup SSP[®] HLA-C*01

Product number:	101.621-12 – including <i>Taq</i> polymerase 101.621-12u – without <i>Taq</i> polymerase
Lot number:	75N
Expiry date:	2014-November-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	RT
- Product Insert	RT

This Product Description is only valid for Lot No. 75N.

**CHANGES COMPARED TO THE PREVIOUS *OLERUP SSP[®]*
 HLA-C*01 Lot (09L)**

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. 09L).

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.

¹As described in section Uniquely Identified Alleles.

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

Well	5'-primer	3'-primer	rationale
5	Modified	-	Increased yield of HLA-specific PCR product.
8	Modified	-	Increased yield of HLA-specific PCR product.
9	-	Added	Primer added for the C*01:52 allele.

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10	Modified	-	Increased yield of HLA-specific PCR product.
17	Added	Added	Primer pair added for the C*01:59 allele.
20	Added	Added	Primer pair added for the C*01:56N allele.
22	Modified	-	Increased yield of HLA-specific PCR product.
23	-	Added	Primer added for the C*01:54 allele.
24	Added	-	Primer pair added for the C*01:50 allele.

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PRODUCT DESCRIPTION

HLA-C*01 SSP typing

CONTENT

The primer set contains 5'- and 3'-primers for identifying the C*01:02 to C*01:66 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. '75N'.

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, seven C*03, the C*04:37, four C*05, two C*06, three C*07, three C*08, the C*14:35N, the C*15:37 and two C*16 alleles when present on the other haplotype.

In addition, 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 allele will be amplified by primer mix 12 and the B*54:18 allele will be amplified by primer mix 13.

UNIQUELY IDENTIFIED ALLELES

All the HLA-C*01 alleles, i.e. **C*01:02 to C*01:66**, recognized by the HLA Nomenclature Committee in April 2012¹ 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.

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

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The HLA-C*01 primer set cannot distinguish the following silent mutations: the C*01:02:01-01:02:15 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*01:19, 01:43 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 2012-April-12, release 3.8.0, www.ebi.ac.uk/imgt/hla.

²The HLA-C*01 primer set cannot separate the C*01:49 and B*54:18 alleles. These alleles can be distinguished by the HLA-B low resolution kit and/or the HLA-B*54 high resolution kit.

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ALLELE CONFIRMATION STATUS

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

¹Allele status “confirmed” or “unconfirmed” as listed on the IMGT/HLA web page 2012-April-12, release 3.8.0, www.ebi.ac.uk/imgt/hla.

RESOLUTION IN HOMO- AND HETEROZYGOTES

A total of 79 alleles generate 39 amplification patterns that can be combined in 780 homozygous and heterozygous combinations. 517 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.

- +-----+ *01:49, *01:50 = *01:50, *01:50
- +-----+ *01:49, *01:54 = *01:54, *01:54
- +-----+ *01:36, *01:36 = *01:36, *01:49
- +-----+ *01:12, *01:12 = *01:12, *01:49
- +-----+ *01:37N, *01:37N = *01:37N, *01:49
- +-----+ *01:05, *01:05 = *01:05, *01:49
- +-----+ *01:03, *01:03 = *01:03, *01:49
- +-----+ *01:02:01, *01:02:01 = *01:02:01, *01:49
- +-----+ *01:12, *01:34 = *01:12, *01:36 = *01:34, *01:34 = *01:34, *01:36 = *01:34, *01:49
- +-----+ *01:03, *01:24 = *01:24, *01:24 = *01:24, *01:49
- +-----+ *01:02:01, *01:32 = *01:02:01, *01:50 = *01:32, *01:32 = *01:32, *01:49 = *01:32, *01:50
- +-----+ *01:02:01, *01:31 = *01:02:01, *01:54 = *01:31, *01:31 = *01:31, *01:49 = *01:31, *01:54
- +-----+ *01:02:01, *01:30 = *01:30, *01:30 = *01:30, *01:49
- +-----+ *01:02:01, *01:29 = *01:29, *01:29 = *01:29, *01:49
- +-----+ *01:02:01, *01:28 = *01:28, *01:28 = *01:28, *01:49



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+-----	-----	-----	*01:02:01, *01:27 = *01:27, *01:27 = *01:27, *01:49
+-----	-----	-----	*01:02:01, *01:26 = *01:02:01, *01:36 = *01:26, *01:26 = *01:26, *01:36 = *01:26, *01:49
+-----	-----	-----	*01:02:01, *01:25 = *01:25, *01:25 = *01:25, *01:49
+-----	-----	-----	*01:02:01, *01:19 = *01:19, *01:19 = *01:19, *01:49
+-----	-----	-----	*01:02:01, *01:18 = *01:18, *01:18 = *01:18, *01:49
+-----	-----	-----	*01:02:01, *01:17 = *01:02:01, *01:21 = *01:17, *01:17 = *01:17, *01:21 = *01:17, *01:49
+-----	-----	-----	*01:02:01, *01:13 = *01:13, *01:13 = *01:13, *01:49
+-----	-----	-----	*01:02:01, *01:12 = *01:02:01, *01:39 = *01:12, *01:39 = *01:39, *01:39 = *01:39, *01:49
+-----	-----	-----	*01:02:01, *01:11 = *01:11, *01:11 = *01:11, *01:49
+-----	-----	-----	*01:02:01, *01:10 = *01:10, *01:10 = *01:10, *01:49
+-----	-----	-----	*01:02:01, *01:09 = *01:09, *01:09 = *01:09, *01:49
+-----	-----	-----	*01:02:01, *01:08 = *01:08, *01:08 = *01:08, *01:49
+-----	-----	-----	*01:02:01, *01:07 = *01:02:01, *01:37N = *01:07, *01:07 = *01:07, *01:37N = *01:07, *01:49
+-----	-----	-----	*01:02:01, *01:06 = *01:06, *01:06 = *01:06, *01:49
+-----	-----	-----	*01:02:01, *01:05 = *01:02:01, *01:16 = *01:05, *01:16 = *01:16, *01:16 = *01:16, *01:49
+-----	-----	-----	*01:02:01, *01:14 = *01:14, *01:14 = *01:14, *01:49
+-----	-----	-----	*01:02:01, *01:03 = *01:02:01, *01:15 = *01:03, *01:15 = *01:15, *01:15 = *01:15, *01:49
+-----	-----	-----	*01:04, *01:04 = *01:04, *01:49 = *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
+-----	-----	-----	*01:27, *01:32 = *01:27, *01:50
+-----	-----	-----	*01:27, *01:31 = *01:27, *01:54
+-----	-----	-----	*01:26, *01:32 = *01:26, *01:50 = *01:32, *01:36
+-----	-----	-----	*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
+-----	-----	-----	*01:18, *01:31 = *01:18, *01:54
+-----	-----	-----	*01:18, *01:26 = *01:18, *01:36
+-----	-----	-----	*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
+-----	-----	-----	*01:17, *01:29 = *01:21, *01:29
+-----	-----	-----	*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



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+-----	-----++	-----	*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 = *01:23, *01:49
+-----	-----++	-----	*01:17, *01:18 = *01:18, *01:21
+-----	-----++	-----	*01:13, *01:32 = *01:13, *01:50
+-----	-----++	-----	*01:13, *01:31 = *01:13, *01:54
+-----	-----++	-----	*01:13, *01:26 = *01:13, *01:36
+-----	-----++	-----	*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 = *01:18, *01:39
+-----	-----++	-----	*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, *01:17 = *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, *01:17 = *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, *01:17 = *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 = *01:22, *01:49
+-----	-----++	-----	*01:08, *01:32 = *01:08, *01:50
+-----	-----++	-----	*01:08, *01:31 = *01:08, *01:54
+-----	-----++	-----	*01:08, *01:26 = *01:08, *01:36
+-----	-----++	-----	*01:08, *01:17 = *01:08, *01:21
+-----	-----++	-----	*01:08, *01:12 = *01:08, *01:39
+-----	-----++	-----	*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 = *01:18, *01:37N
+-----	-----++	-----	*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



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+-----+--	-+-----	-----	*01:07, *01:11 = *01:11, *01:37N
+-----+--	+-----	-----	*01:07, *01:10 = *01:10, *01:37N
+-----++	-----	-----	*01:07, *01:09 = *01:09, *01:37N
+-----+--	-----	-----	*01:07, *01:08 = *01:08, *01:37N
+-----+--	-----	-----+	*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, *01:17 = *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 = *01:08, *01:20 = *01:20, *01:20 = *01:20, *01:49
+-----+--	-----	-----	*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 = *01:16, *01:18
+-----+--	-----	-----	*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 = *01:08, *01:16
+-----+--	-----	-----	*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, *01:17 = *01:14, *01:21
+-----+--	-----	-----	*01:12, *01:14 = *01:14, *01:39
+-----+--	-----	-----	*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 = *01:15, *01:18
+-----+--	-----	-----	*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, *01:08 = *01:08, *01:15



101.621-12 – including *Taq* pol., IFU-01 Rev. No. 03
 101.621-12u– without *Taq* pol., IFU-02 Rev. No. 03

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Lot No.: 75N

Lot-specific information

++-----	-----	-----	*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
+-----	-----	-----	*01:23, *01:32 = *01:23, *01:50
+-----	-----	-----	*01:23, *01:31 = *01:23, *01:54
+-----	-----	-----	*01:23, *01:26 = *01:23, *01:36
+-----	-----	-----	*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, *01:49 = *01:35, *01:54
+-----	-----	-----	*01:22, *01:26 = *01:22, *01:36
+-----	-----	-----	*01:17, *01:22 = *01:21, *01:22
+-----	-----	-----	*01:12, *01:22 = *01:22, *01:39
+-----	-----	-----	*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
+-----	-----	-----	*01:17, *01:20 = *01:20, *01:21
+-----	-----	-----	*01:12, *01:20 = *01:20, *01:39
+-----	-----	-----	*01:07, *01:20 = *01:20, *01:37N
+-----	-----	-----	*01:05, *01:23 = *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
++-----	-----	-----	*01:03, *01:23 = *01:15, *01:23
++-----	-----	-----	*01:03, *01:22 = *01:15, *01:22
++-----	-----	-----	*01:03, *01:20 = *01:15, *01:20
+-----	-----	-----	*01:32, *01:35 = *01:35, *01:50
+-----	-----	-----	*01:26, *01:35 = *01:35, *01:36
+-----	-----	-----	*01:17, *01:35 = *01:21, *01:35
+-----	-----	-----	*01:12, *01:35 = *01:35, *01:39
+-----	-----	-----	*01:07, *01:35 = *01:35, *01:37N
+-----	-----	-----	*01:05, *01:35 = *01:16, *01:35
+-----	-----	-----	*01:04, *01:11 = *01:04, *01:22 = *01:04, *01:35 = *01:14, *01:35
++-----	-----	-----	*01:03, *01:35 = *01:15, *01:35

*01:02:01 = *01:02:01-01:02:15 and the 01:46-01:48, 01:51, 01:53, 01:57 and 01:60-01:66

*01:06 = *01:06 and 01:38

*01:10 = *01:10 and 01:52

*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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 101.621-12u– without *Taq* pol., IFU-02 Rev. No. 03

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Lot No.: **75N**

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
1⁵	90 bp	800 bp	*01:02:01-01:02:15, 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-01:66	*03:86, 03:94, 03:99, 07:177
2^{5,7}	90 bp, 270 bp	1070 bp	*01:03, 01:15, 01:24	*03:58, 04:37
3⁸	150 bp, 265 bp	800 bp	*01:04, 01:14	
4⁹	210 bp, 240 bp	800 bp	*01:05, 01:16	*07:37, B*07:77
5^{5,10}	105 bp, 150 bp, 200 bp	800 bp	*01:06, 01:20, 01:38	
6^{6,11}	195 bp, 235 bp	1070 bp	*01:07, 01:37N	*06:43, 14:35N
7^{6,12}	150 bp, 195 bp	1070 bp	*01:08, 01:20	
8	210 bp	1070 bp	*01:04, 01:09, 01:22, 01:35	*06:23, 07:177, 15:37
9¹³	160 bp, 230 bp	800 bp	*01:10, 01:52	
10¹⁴	210 bp, 290 bp	1070 bp	*01:11, 01:22, 01:35	*07:177, 15:37
11¹⁵	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
13	155 bp	800 bp	*01:02:01-01:20, 01:22-01:66	B*54:18
14^{5,6,16}	120 bp, 240 bp	1070 bp	*01:17, 01:21, 01:23, 01:41	
15^{5,17}	115 bp, 230 bp	800 bp	*01:18, 01:42	
16¹⁸	130 bp, 255 bp, 295 bp	1070 bp	*01:19, 01:23, 01:43, 01:58	A*01:24
17^{5,19}	75 bp, 255 bp	800 bp	*01:24-01:25, 01:59	

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Lot No.: 75N		Lot-specific information	
18 ²⁰	195 bp, 260 bp, 345 bp	800 bp	*01:26, 01:34, 01:36, 01:55
19 ^{5,21}	100 bp, 275 bp	1070 bp	*01:27, 01:45
20 ^{5,22}	110 bp, 285 bp	800 bp	*01:28, 01:56N *03:59, 03:123
21 ^{5,23}	125 bp, 245 bp	800 bp	*01:29, 01:33
22	255 bp	1070 bp	*01:30
23 ^{5,24}	90 bp, 120 bp, 235 bp	1070 bp	*01:04, 01:31, 01:35, 01:44, 01:54 *06:23, 16:18
24 ^{5,25}	110 bp, 250 bp, 335 bp	1070 bp	*01:32, 01:40, 01:50

¹ Alleles 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 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.

² The 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.

³ For several HLA-C*01 alleles 4th exon or 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 4th exon or in introns are conserved within allelic groups.

⁴ Due 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, 8, 10, 12, 20 and 23. In addition, 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 allele will be amplified by primer mix 12 and the B*54:18 allele will be amplified by primer mix 13.

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

⁶ Primer mixes 6, 7 and 14 may have a tendency of giving rise to nonspecific amplifications.

⁷ Primer mix 2: Specific PCR product of 90 bp in the C*01:03 and 01:24 and the C*03:58 and 04:37 alleles. Specific PCR product of 270 bp in the C*01:15 allele.

⁸ 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.

⁹ 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.

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Lot No.: 75N**Lot-specific information**

¹⁰Primer 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.

¹¹Primer mix 6: Specific PCR product of 195 bp in the C*01:07 and the C*06:43 alleles. Specific PCR product of 235 bp in the C*01:37N and the C*14:35N alleles.

¹²Primer mix 7: Specific PCR product of 150 bp in the C*01:20 allele. Specific PCR product of 195 bp in the C*01:08 allele.

¹³Primer 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.

¹⁴Primer 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.

¹⁵Primer 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.

¹⁶Primer 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 and 01:23 alleles.

¹⁷Primer mix 15: Specific PCR product of 115 bp in the C*01:42 allele. Specific PCR product of 230 bp in the C*01:18 allele.

¹⁸Primer 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.

¹⁹Primer 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.

²⁰Primer 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 and 01:55 alleles.

²¹Primer 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.

²²Primer 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.

²³Primer 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 allele.

²⁴Primer mix 23: Specific PCR fragment of 90 bp in the C*01:04 and 01:54 and the C*06:23 and 16:18 allele. 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.

²⁵Primer 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*01:50 allele.

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Lot No.: 75N

Lot-specific information

INTERPRETATION TABLE												
HLA-C*01 SSP subtyping												
Amplification patterns of the C*01:02 to C*01:66 alleles												
	Well¹⁸											
	1	2	3	4	5	6	7	8	9	10	11	12
Length of spec.	90	90	150	210	105	195	150	210	160	210	140	155
PCR product(s)		270	265	240	150	235	195		230	290	345	
					200							
Length of int.	800	1070	800	800	800	1070	1070	1070	800	1070	800	1070
pos. control¹												
5'-primer(s)²	368	368	89	89	368	363	368	368	368	368	101	485
	5'-gTg ^{3'}	5'-gTg ^{3'}	5'-gAA ^{3'}	5'-gAA ^{3'}	5'-gTg ^{3'}	5'-TgA ^{3'}	5'-gTg ^{3'}	5'-gTg ^{3'}	5'-gTg ^{3'}	5'-gTg ^{3'}	5'-CAT ^{3'}	5'-CAA ^{3'}
			368	368		406					368	
			5'-gTg ^{3'}	5'-gTC ^{3'}		5'-gCA ^{3'}					5'-gTA ^{3'}	
3'-primer(s)³	419	419	312	287	430	559	479	538	488	539	201	601
	5'-CgT ^{3'}	5'-CgA ^{3'}	5'-AgT ^{3'}	5'-TCg ^{3'}	5'-gCT ^{3'}	5'-CgT ^{3'}	5'-CCA ^{3'}	5'-CCA ^{3'}	5'-CCA ^{3'}	5'-TCA ^{3'}	5'-CTC ^{3'}	5'-CTC ^{3'}
		595	477	538	479		523	539	559	619	3 ¹	
		5'-CCT ^{3'}	5'-gCA ^{3'}	5'-CCg ^{3'}	5'-CCA ^{3'}		5'-ACA ^{3'}	5'-TCA ^{3'}	5'-CTC ^{3'}	5'-TTT ^{3'}	5'-ATg ^{3'}	
					527							
					5'-CCA ^{3'}							
Well No.	1	2	3	4	5	6	7	8	9	10	11	12
HLA-C allele^{4,5}												
*01:02:01-01:02:15, 01:46-01:48, 01:51, 01:53, 01:57, 01:60-01:66	1											
*01:03		2										
*01:04			3					8				
*01:05				4								
Well No.	1	2	3	4	5	6	7	8	9	10	11	12

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Lot No.: **75N**

Lot-specific information

INTERPRETATION TABLE												
HLA-C*01 SSP subtyping												
Amplification patterns of the C*01:02 to C*01:66 alleles												
Well ¹⁸												
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. PCR product(s)
	240	230	255	255	260	275	285	245		120	250	
			295		345					235	335	
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
5'-gAA ^{3'}	5'-gAA ^{3'}	5'-gAA ^{3'}	5'-gAA ^{3'}	5'-gAA ^{3'}	5'-gAA ^{3'}	5'-gTg ^{3'}	5'-gAA ^{3'}	5'-gAA ^{3'}	5'-gTg ^{3'}	5'-gTg ^{3'}	5'-C ^{3'}	
				806	368		530	368		3 rd I	379	
				5'-ggA ^{3'}	5'-gTT ^{3'}		5'-ggT ^{3'}	5'-gTg ^{3'}		5'-Cgg ^{3'}	5'-ACg ^{3'}	
				818	420						420	
				5'-ggC ^{3'}	5'-TTC ^{3'}						5'-TTC ^{3'}	
					453						463	
					5'-AAT ^{3'}						5'-TgA ^{3'}	
201	170	164	176	302	244	427	331	172	583	419	142	3'-primer(s) ³
5'-CTC ^{3'}	5'-Cgg ^{3'}	5'-gCA ^{3'}	5'-ACT ^{3'}	5'-ggT ^{3'}	5'-CTg ^{3'}	5'-gTA ^{3'}	5'-CTA ^{3'}	5'-CAT ^{3'}	5'-gTg ^{3'}	5'-Cgg ^{3'}	5'-TgA ^{3'}	
	289	278	301	846	3 rd I	601	601	573		560	3 rd I	
	5'-AgC ^{3'}	5'-ggT ^{3'}	5'-gCA ^{3'}	5'-CAC ^{3'}	5'-ATg ^{3'}	5'-CTg ^{3'}	5'-CTC ^{3'}	5'-AgA ^{3'}		5'-ACA ^{3'}	5'-ATg ^{3'}	
			341							671		
			5'-CgT ^{3'}							5'-ggA ^{3'}		
13	14	15	16	17	18	19	20	21	22	23	24	Well No.
												HLA-C allele ^{4,5}
13												*01:02:01-01:02:15, 01:46-01:48, 01:51, 01:53, 01:57, 01:60-01:66
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.: **75N**

Lot-specific information

Length of spec.	90	90	150	210	105	195	150	210	160	210	140	155
PCR product(s)		270	265	240	150	235	195		230	290	345	
					200							
Well No.	1	2	3	4	5	6	7	8	9	10	11	12
*01:06, 01:38⁷	1				5							
*01:07	1					6						
*01:08	1						7					
*01:09	1							8				
*01:10, 01:52⁸	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, 01:41⁹	1											
*01:18, 01:42 ¹⁰	1											
*01:19, 01:43, 01:58 ¹¹	1											
*01:20	1				5		7					
*01:21												
*01:22	1							8		10		
*01:23	1											
*01:24		2										
*01:25, 01:59 ¹²	1											
*01:26	1											
*01:27, 01:45¹³	1											
*01:28, 01:56N ¹⁴	1											
*01:29, 01:33 ¹⁵	1											
*01:30	1											
*01:31, 01:44 ¹⁶	1											
*01:32, 01:40¹⁷	1											
*01:34											11	
*01:35	1							8		10		
*01:36, 01:55												
*01:37N						6						
*01:39	1										11	
*01:49, B*54:18⁶												
*01:50												
*01:54												
Well No.	1	2	3	4	5	6	7	8	9	10	11	12

101.621-12 – including *Taq* pol., IFU-01 Rev. No. 03
 101.621-12u– without *Taq* pol., IFU-02 Rev. No. 03

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Lot No.: **75N**

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	335	
13	14	15	16	17	18	19	20	21	22	23	24	Well No.
13												*01:06, 01:38 ⁷
13												*01:07
13												*01:08
13												*01:09
13												*01:10, 01:52 ⁸
13												*01:11
13												*01:12
13												*01:13
13												*01:14
13												*01:15
13												*01:16
13	14											*01:17, 01:41 ⁹
13		15										*01:18, 01:42 ¹⁰
13			16									*01:19, 01:43, 01:58 ¹¹
13												*01:20
	14											*01:21
13												*01:22
13	14		16									*01:23
13				17								*01:24
13				17								*01:25, 01:59 ¹²
13					18							*01:26
13						19						*01:27, 01:45 ¹³
13							20					*01:28, 01:56N ¹⁴
13								21				*01:29, 01:33 ¹⁵
13									22			*01:30
13										23		*01:31, 01:44 ¹⁶
13											24	*01:32, 01:40 ¹⁷
13					18							*01:34
13										23		*01:35
13					18							*01:36, 01:55
13												*01:37N
13												*01:39
13												*01:49, B*54:18 ⁶
13											24	*01:50
13										23		*01:54
13	14	15	16	17	18	19	20	21	22	23	24	Well No.

101.621-12 – including **Taq pol.**, IFU-01 Rev. No. 03
 101.621-12u– without **Taq pol.**, IFU-02 Rev. No. 03

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Lot No.: **75N**

Lot-specific information

Length of spec.	90	90	150	210	105	195	150	210	160	210	140	155
PCR product(s)		270	265	240	150	235	195		230	290	345	
					200							
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- 08:15:02, 08:51, 16:27, B*15:33												12
*03:58, 04:37		2										
*03:59, 03:123												
*03:86, 03:94, 03:99	1											
*06:23								8				
*06:43, 14:35N						6						
*07:37, B*07:77				4								
*07:177	1							8		10		
*15:37								8		10		
*16:18												
A*01:24												
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.

³The 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 3.8.0, April 2012.

⁶The HLA-C*01 primer set cannot separate the C*01:49 and B*54:18 alleles. These alleles can be distinguished by the HLA-B low resolution kit and/or the HLA-B*54 high resolution kit.

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

⁸The C*01:10 and 01:52 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 9.

⁹The C*01:17 and 01:41 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 14.

¹⁰The C*01:18 and 01:42 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 15.

¹¹The C*01:19, 01:43 and 01:58 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 16.

101.621-12 – including **Taq pol.**, IFU-01 Rev. No. 03
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Lot No.: 75N**Lot-specific information**

¹²The C*01:25 and 01:59 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 17.

¹³The C*01:27 and 01:45 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 19.

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

¹⁵The C*01:29 and 01:33 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 21.

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

¹⁷The C*01:32 and 01:40 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 24.

¹⁸Primer mix 2: Specific PCR product of 90 bp in the C*01:03 and 01:24 and the C*03:58 and 04:37 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 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 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 and 01:23 alleles.

Primer mix 15: Specific PCR product of 115 bp in the C*01:42 allele. 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 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 allele.

Primer mix 23: Specific PCR fragment of 90 bp in the C*01:04 and 01:54 and the C*06:23 and 16:18 allele. 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*01:50 allele.

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Lot No.: **75N**

Lot-specific information

CELL LINE VALIDATION SHEET																				
HLA-C*01 SSP primer set																				
				Well																
				1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	
				Prod. No.:	201070701	201070702	201070703	201182604	201201405	201182606	201070707	201201408	201201409	201201410	201182611	201070712	201070713	201182614	201182615	201182616
IHWC cell line		C*																		
1	9001	SA	*07:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2	9280	LK707	*07:01	*15:05	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
3	9011	E4181324	*12:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
4	9275	GU373	*03:04	*04:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
5	9009	KAS011	*06:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
6	9353	SM	*03:04	*07:02	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
7	9020	QBL	*05:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
8	9007	DEM	*04:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
9	9026	YAR	*12:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
10	9107	LKT3	*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	9038	BM16	*07:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
20	9059	SLE005	*03:04		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
21	9064	AMALA	*03:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
22	9056	KOSE	*12:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
23	9124	IHL	*01:02	*15:02	+	-	-	-	-	-	-	-	-	-	-	-	+	-	-	-
24	9035	JBUSH	*12:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
25	9049	IBW9	*08:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
26	9285	WT49	*07:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
27	9191	CH1007	*07:04	*15:05	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
28	9320	BEL5GB	*05:01	*16:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
29	9050	MOU	*16:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
30	9021	RSH	*17:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
31	9019	DUCAF	*05:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
32	9297	HAG	*17:01	*17:03	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
33	9098	MT14B	*03:04		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
34	9104	DHIF	*12:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
35	9302	SSTO	*05:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
36	9024	KT17	*03:03	*04:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
37	9065	HHKB	*07:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
38	9099	LZL	*03:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
39	9315	CML	*02:02	*07:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
40	9134	WHONP199	*01:02	*06:02	+	-	-	-	-	-	-	-	-	-	-	-	+	-	-	-
41	9055	H0301	*08:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
42	9066	TAB089	*01:02		+	-	-	-	-	-	-	-	-	-	-	-	+	-	-	-
43	9076	T7526	*01:02	*08:01	+	-	-	-	-	-	-	-	-	-	-	-	+	-	-	-
44	9057	TEM	*12:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
45	9239	SHJO	*06:02	*17:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
46	9013	SCHU	*07:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
47	9045	TUBO	*07:04	*15:02	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
48	9303	TER-ND	*04:01	*16:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-



101.621-12 – including **Taq** pol., IFU-01 Rev. No. 03
 101.621-12u– without **Taq** pol., IFU-02 Rev. No. 03

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Lot No.: **75N**

Lot-specific information

CELL LINE VALIDATION SHEET												
HLA-C*01 SSP primer set												
				Well								
				17	18	19	20	21	22	23	24	
				Prod. No.:	201201417	201201418	201182619	201201420	201070721	201201422	201201423	201201424
IHWC cell line		C*										
1	9001	SA	*07:02		-	-	-	-	-	-	-	-
2	9280	LK707	*07:01	*15:05	-	-	-	-	-	-	-	-
3	9011	E4181324	*12:02		-	-	-	-	-	-	-	-
4	9275	GU373	*03:04	*04:01	-	-	-	-	-	-	-	-
5	9009	KAS011	*06:02		-	-	-	-	-	-	-	-
6	9353	SM	*03:04	*07:02	-	-	-	-	-	-	-	-
7	9020	QBL	*05:01		-	-	-	-	-	-	-	-
8	9007	DEM	*04:01		-	-	-	-	-	-	-	-
9	9026	YAR	*12:03		-	-	-	-	-	-	-	-
10	9107	LKT3	*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	9038	BM16	*07:01		-	-	-	-	-	-	-	-
20	9059	SLE005	*03:04		-	-	-	-	-	-	-	-
21	9064	AMALA	*03:03		-	-	-	-	-	-	-	-
22	9056	KOSE	*12:03		-	-	-	-	-	-	-	-
23	9124	IHL	*01:02	*15:02	-	-	-	-	-	-	-	-
24	9035	JBUSH	*12:03		-	-	-	-	-	-	-	-
25	9049	IBW9	*08:02		-	-	-	-	-	-	-	-
26	9285	WT49	*07:01		-	-	-	-	-	-	-	-
27	9191	CH1007	*07:04	*15:05	-	-	-	-	-	-	-	-
28	9320	BEL5GB	*05:01	*16:01	-	-	-	-	-	-	-	-
29	9050	MOU	*16:01		-	-	-	-	-	-	-	-
30	9021	RSH	*17:01		-	-	-	-	-	-	-	-
31	9019	DUCAF	*05:01		-	-	-	-	-	-	-	-
32	9297	HAG	*17:01	*17:03	-	-	-	-	-	-	-	-
33	9098	MT14B	*03:04		-	-	-	-	-	-	-	-
34	9104	DHIF	*12:03		-	-	-	-	-	-	-	-
35	9302	SSTO	*05:01		-	-	-	-	-	-	-	-
36	9024	KT17	*03:03	*04:01	-	-	-	-	-	-	-	-
37	9065	HHKB	*07:02		-	-	-	-	-	-	-	-
38	9099	LZL	*03:03		-	-	-	-	-	-	-	-
39	9315	CML	*02:02	*07:01	-	-	-	-	-	-	-	-
40	9134	WHONP199	*01:02	*06:02	-	-	-	-	-	-	-	-
41	9055	H0301	*08:02		-	-	-	-	-	-	-	-
42	9066	TAB089	*01:02		-	-	-	-	-	-	-	-
43	9076	T7526	*01:02	*08:01	-	-	-	-	-	-	-	-
44	9057	TEM	*12:03		-	-	-	-	-	-	-	-
45	9239	SHJO	*06:02	*17:01	-	-	-	-	-	-	-	-
46	9013	SCHU	*07:02		-	-	-	-	-	-	-	-
47	9045	TUBO	*07:04	*15:02	-	-	-	-	-	-	-	-
48	9303	TER-ND	*04:01	*16:01	-	-	-	-	-	-	-	-

101.621-12 – including *Taq* pol., IFU-01 Rev. No. 03
 101.621-12u– without *Taq* pol., IFU-02 Rev. No. 03

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Lot No.: **75N**

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: 75N
Expiry date: 2014-November-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	2012-014-18
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	2010-707-21
6	2011-826-06	14	2011-826-14	22	2012-014-22
7	2010-707-07	15	2011-826-15	23	2012-014-23
8	2012-014-08	16	2011-826-16	24	2012-014-24

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 12 and 14 to 24 were available. The specificity of the primers in primer solutions 2 to 5, 8 to 12, 14, 16 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 7, 15, 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, 9, 10, 14, 16, 18, 20 and 23 one or two of the 3'-primers were not possible to test.

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

Date of approval: 2012-June-07

Approved by:

Production Quality Control

101.621-12 – including **Taq pol.**, IFU-01 Rev. No. 03
101.621-12u– without **Taq pol.**, IFU-02 Rev. No. 03

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Lot No.: **75N**

Lot-specific information

Declaration of Conformity

Product name: *Olerup SSP*[®] HLA-C*01
Product number: 101.621-12/12u
Lot number: 75N

Intended use: HLA-C*01 high resolution histocompatibility testing

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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 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
2012-June-07

Ann-Cathrin Jareman
Head of QA and Regulatory Affairs

101.621-12 – including **Taq pol.**, IFU-01 Rev. No. 03
101.621-12u– without **Taq pol.**, IFU-02 Rev. No. 03

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

Lot No.: **75N**

Lot-specific information

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