

101.613-12– including *Taq* polymerase, IFU-01 Rev. No. 03101.613-12u – without *Taq* polymerase, IFU-02 Rev. No. 03Visit [www.olerup-ssp.com](http://www.olerup-ssp.com) for

“Instructions for Use” (IFU)

Lot No.: **47N**

Lot-specific information

**Olerup SSP<sup>®</sup> HLA-C\*05**

Product number:	101.613-12 – including <i>Taq</i> polymerase 101.613-12u – without <i>Taq</i> polymerase
Lot number:	47N
Expiry date:	2014-September-01
Number of tests:	12
Number of wells per test:	32
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. 47N.**

**CHANGES COMPARED TO THE PREVIOUS OLERUP SSP<sup>®</sup>  
HLA-C\*05 LOT**

The HLA-C\*05 kit is updated for new alleles to enable separation of:

- Confirmed<sup>1</sup> 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

Two wells have been added to the HLA-C\*05 kit, wells **31 and 32**.

The Lot-specific information for HLA-C\*05 including and without *Taq* polymerase is now described in one common Product Insert.

<sup>1</sup>As described in section Uniquely Identified Alleles.

The HLA-C\*05 specificity and interpretation tables have been updated for the HLA-C alleles described since the previous *Olerup SSP<sup>®</sup>* HLA-C\*05 lot was made (**Lot No. 57K**).

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

Well	5'-primer	3'-primer	rationale
8	-	Added	3'-primer added for the C*05:55 allele.
30	Added	Added	Primer pair added for the C*05:53 allele.
31	New	New	New primer pairs for the C*05:18:02 and 05:18:03 alleles.
32	New	New	New primer pairs for the C*05:48N and 05:51Q allele.

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## PRODUCT DESCRIPTION

### HLA-C\*05 SSP subtyping

#### CONTENT

The primer set contains 5'- and 3'-primers for identifying the C\*05:01 to C\*05:72 alleles.

#### PLATE LAYOUT

Each test consists of 32 PCR reactions in a 32 well 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
25	26	27	28	29	30	31	32

The 32 well cut PCR plate is marked with ‘HLA-C\*05’ in silver/gray ink.

Well No. 1 is marked with the Lot No. ‘47N’.

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 32 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\*05 SSP subtypings will be influenced by two C\*01, the C\*02:51, the C\*03:87, the C\*04:78, four C\*06, several C\*07, the C\*08, two C\*12, the C\*16:27 and the C\*17:05 alleles when present on the other haplotype. In addition, the A\*29:10 and A\*68:69 alleles will be amplified by primer mix 6, the A\*80 will be weakly amplified by primer mix 11 and the B\*15:33 allele will be amplified by primer mixes 3, 10 and 26.

#### UNIQUELY IDENTIFIED ALLELES

All the HLA-C\*05 alleles, i.e. **C\*05:01 to C\*05:72**, recognized by the HLA Nomenclature Committee in January 2012<sup>1</sup> will be amplified by the primers in the HLA-C\*05 subtyping kit<sup>2</sup>.

The HLA-C\*05 kit enables separation of the confirmed HLA-C\*05 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\*05 alleles is listed below.

The HLA-C\*05 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\*05 subtyping kit cannot distinguish the following silent mutations: the C\*05:01:01:01-05:01:18, the C\*05:09:01-05:09:02, the C\*05:18:02-05:18:03 and the C\*05:22:01-05:22:02 alleles.

The C\*05:06 and C\*05:55 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 8.

The C\*05:08 and C\*05:30 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 10.

The C\*05:10 and C\*05:38 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 12.

The C\*05:21 and C\*05:26 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 20.

The C\*05:24 and C\*05:36 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 23.

The C\*05:25 and C\*05:33 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 11.

The C\*05:28 and C\*05:39 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 26.

The C\*05:35 and C\*05:40 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 25.

The C\*05:37 and C\*05:41 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 29.

<sup>1</sup>HLA-C alleles listed on the IMGT/HLA web page 2012-January-12, release 3.7.0, [www.ebi.ac.uk/imgt/hla](http://www.ebi.ac.uk/imgt/hla).

<sup>2</sup>The C\*05:18:01 and C\*08:10 and the C\*05:29 and C\*08:25 alleles will give rise to identical amplification patterns with the HLA-C\*05 subtyping kit. These alleles can be distinguished by the HLA-C low resolution kit and/or the C\*08 subtyping kit.

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### ALLELE CONFIRMATION STATUS

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

<sup>1</sup>Allele status “confirmed” or “unconfirmed” as listed on the IMGT/HLA web page 2012-January-12, release 3.7.0, [www.ebi.ac.uk/imgt/hla](http://www.ebi.ac.uk/imgt/hla).

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**RESOLUTION IN HOMO- AND HETEROZYGOTES**

A total of 94 alleles generate 42 amplification patterns that can be combined in 903 homozygous and heterozygous combinations. 407 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.

++++--+-	-----	-----	-----	*05:03, *05:09:01 = *05:03, *05:44
++++--+-	-----	-----+--	-----	*05:04, *05:09:01 = *05:04, *05:44
++++--+-	-----	-----	-----	*05:09:01, *05:31 = *05:31, *05:44
++++--+-	-----	-----	-----	*05:05, *05:44 = *05:09:01, *05:16 = *05:16, *05:44
++++--+-	-----	-----	-----	*05:06, *05:09:01 = *05:06, *05:44
++++--+-	+-----	-----	-----	*05:07N, *05:09:01 = *05:07N, *05:44
++++--+-	-+-----	-----	-----	*05:08, *05:17 = *05:11, *05:52
++++--+-	-+-----	-----+	-----	*05:29, *05:52 = *05:43, *05:52
++++--+-	-+-----	-----	-----+	*05:48N, *05:52 = *05:51Q, *05:52
++++--+-	-+-----	-----	-----	*05:01:01:01, *05:52 = *05:08, *05:09:01 = *05:08, *05:44 = *05:08, *05:52 = *05:44, *05:52
++++--+-	--+-----	-----	--+-----	*05:09:01, *05:42 = *05:42, *05:44
++++--+-	--+-----	-----	-----	*05:09:01, *05:25 = *05:25, *05:44
++++--+-	---+-----	-----	-----	*05:09:01, *05:10 = *05:10, *05:44
++++--+-	---+-----	-----+	-----	*05:17, *05:29 = *05:17, *05:43
++++--+-	---+-----	-----	-+-----	*05:09:01, *05:27 = *05:17, *05:27 = *05:17, *05:28 = *05:27, *05:44
++++--+-	---+-----	-----	-----+	*05:17, *05:48N = *05:17, *05:51Q
++++--+-	---+-----	-----	-----	*05:01:01:01, *05:17 = *05:09:01, *05:11 = *05:11, *05:17 = *05:11, *05:44 = *05:17, *05:44
++++--+-	---+-----	-----	-----	*05:09:01, *05:15 = *05:15, *05:44
++++--+-	---+-----	-----	-----+--	*05:09:01, *05:34 = *05:34, *05:44
++++--+-	---+-----	-----	-----	*05:09:01, *05:13 = *05:13, *05:44
++++--+-	---+-----	-----	-----	*05:09:01, *05:14 = *05:14, *05:44
++++--+-	---+-----	-----	-----	*05:09:01, *05:19 = *05:19, *05:44
++++--+-	---+-----	-----	-----	*05:09:01, *05:20 = *05:20, *05:44
++++--+-	---+-----	-----	-----	*05:09:01, *05:21 = *05:21, *05:44
++++--+-	---+-----	-----	-----	*05:09:01, *05:22:01 = *05:22:01, *05:44
++++--+-	---+-----	-----	-----	*05:09:01, *05:23 = *05:23, *05:44
++++--+-	---+-----	-----	-----	*05:09:01, *05:24 = *05:24, *05:44
++++--+-	---+-----	-----	-----+	*05:09:01, *05:29 = *05:09:01, *05:43 = *05:29, *05:44 = *05:43, *05:44
++++--+-	---+-----	-----	+-----	*05:09:01, *05:35 = *05:35, *05:44
++++--+-	---+-----	-----	-+-----	*05:09:01, *05:28 = *05:28, *05:44
++++--+-	---+-----	-----	--+-----	*05:09:01, *05:46 = *05:44, *05:46
++++--+-	---+-----	-----	---+-----	*05:09:01, *05:45 = *05:44, *05:45
++++--+-	---+-----	-----	---+-----	*05:09:01, *05:37 = *05:37, *05:44
++++--+-	---+-----	-----	---+-----	*05:09:01, *05:32 = *05:32, *05:44
++++--+-	---+-----	-----	-----+	*05:09:01, *05:48N = *05:09:01, *05:51Q = *05:44, *05:48N = *05:44, *05:51Q
++++--+-	---+-----	-----	-----	*05:01:01:01, *05:09:01 = *05:01:01:01, *05:44 = *05:09:01, *05:44 = *05:44, *05:44 = *05:44, *05:61
++-+--+-	-----	-----	-----	*05:03, *05:05 = *05:03, *05:16
++-+--+-	-----	-----+	-----	*05:03, *05:29 = *05:03, *05:43
++-+--+-	-----	-----	-----+	*05:03, *05:48N = *05:03, *05:51Q
++-+--+-	-----	-----	-----	*05:01:01:01, *05:03 = *05:03, *05:03 = *05:03, *05:61
++-+--+-	-----	-----	-----	*05:04, *05:05 = *05:04, *05:16
++-+--+-	-----	-----	-----	*05:05, *05:31 = *05:16, *05:31
++-+--+-	-----	-----+--	-----	*05:04, *05:29 = *05:04, *05:43
++-+--+-	-----	-----+--	-----+	*05:04, *05:48N = *05:04, *05:51Q



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++-+-+--	-----	-----+	-----	*05:01:01:01, *05:04 = *05:04, *05:04 = *05:04, *05:22:01 = *05:04, *05:31 = *05:04, *05:61 = *05:22:01, *05:31
++-+-+--	-----	-----+	-----	*05:29, *05:31 = *05:31, *05:43
++-+-+--	-----	-----	-----+	*05:31, *05:48N = *05:31, *05:51Q
++-+-+--	-----	-----	-----	*05:01:01:01, *05:31 = *05:31, *05:31 = *05:31, *05:61
++-+-+--	-----	-----	-----	*05:05, *05:06 = *05:06, *05:16
++-+-+--	+-----	-----	-----	*05:05, *05:07N = *05:07N, *05:16
++-+-+--	-+-----	-----	-----	*05:05, *05:08 = *05:08, *05:16
++-+-+--	--+-----	-----	--+-----	*05:05, *05:42 = *05:16, *05:42
++-+-+--	--+-----	-----	-----	*05:05, *05:25 = *05:16, *05:25
++-+-+--	---+-----	-----	-----	*05:05, *05:10 = *05:10, *05:16
++-+-+--	---+-----	-----	-+-----	*05:05, *05:27 = *05:16, *05:27
++-+-+--	---+-----	-----	-----	*05:05, *05:11 = *05:11, *05:16
++-+-+--	---+-----	+-----	-----	*05:05, *05:12 = *05:12, *05:16
++-+-+--	---+-----	-----	-----	*05:05, *05:15 = *05:15, *05:16
++-+-+--	---+-----	-----	---+-----	*05:05, *05:34 = *05:16, *05:34
++-+-+--	---+-----	-----	-----	*05:05, *05:13 = *05:13, *05:16
++-+-+--	---+-----	+-----	-----	*05:05, *05:14 = *05:14, *05:16
++-+-+--	---+-----	+-----	-----	*05:05, *05:18:01 = *05:16, *05:18:01
++-+-+--	---+-----	-+-----	-----	*05:05, *05:19 = *05:16, *05:19
++-+-+--	---+-----	--+-----	-----	*05:05, *05:20 = *05:16, *05:20
++-+-+--	---+-----	---+-----	-----	*05:05, *05:21 = *05:16, *05:21
++-+-+--	---+-----	---+-----	-----	*05:05, *05:22:01 = *05:16, *05:22:01
++-+-+--	---+-----	---+-----	-----	*05:05, *05:23 = *05:16, *05:23
++-+-+--	---+-----	---+-----	-----	*05:05, *05:24 = *05:16, *05:24
++-+-+--	---+-----	---+-----	-----	*05:05, *05:29 = *05:05, *05:43 = *05:16, *05:29 = *05:16, *05:43
++-+-+--	-----	-----	+-----	*05:05, *05:35 = *05:16, *05:35
++-+-+--	-----	-----	-+-----	*05:05, *05:28 = *05:16, *05:28
++-+-+--	-----	-----	--+-----	*05:05, *05:46 = *05:16, *05:46
++-+-+--	-----	-----	---+-----	*05:05, *05:45 = *05:16, *05:45
++-+-+--	-----	-----	---+-----	*05:05, *05:37 = *05:16, *05:37
++-+-+--	-----	-----	---+-----	*05:05, *05:32 = *05:16, *05:32
++-+-+--	-----	-----	---+-----	*05:05, *05:18:02 = *05:16, *05:18:02
++-+-+--	-----	-----	---+-----	*05:05, *05:48N = *05:05, *05:51Q = *05:16, *05:48N = *05:16, *05:51Q
++-+-+--	-----	-----	-----	*05:01:01:01, *05:05 = *05:01:01:01, *05:16 = *05:05, *05:16 = *05:16, *05:16 = *05:16, *05:61
++-+-+--	-----	-----	-----	*05:05, *05:05 = *05:05, *05:61
++-+-+--	-----	-----+	-----	*05:06, *05:29 = *05:06, *05:43
++-+-+--	-----	-----	-----+	*05:06, *05:48N = *05:06, *05:51Q
++-+-+--	-----	-----	-----	*05:01:01:01, *05:06 = *05:06, *05:06 = *05:06, *05:61
++-+-+--	+-----	-----+	-----	*05:07N, *05:29 = *05:07N, *05:43
++-+-+--	+-----	-----	-----+	*05:07N, *05:48N = *05:07N, *05:51Q
++-+-+--	+-----	-----	-----	*05:01:01:01, *05:07N = *05:07N, *05:07N = *05:07N, *05:61
++-+-+--	-+-----	-----+	-----	*05:08, *05:29 = *05:08, *05:43
++-+-+--	-+-----	-----	-----+	*05:08, *05:48N = *05:08, *05:51Q
++-+-+--	-+-----	-----	-----	*05:01:01:01, *05:08 = *05:08, *05:08 = *05:08, *05:61
++-+-+--	--+-----	-----+	--+-----	*05:29, *05:42 = *05:42, *05:43
++-+-+--	--+-----	-----+	-----	*05:25, *05:29 = *05:25, *05:43
++-+-+--	--+-----	-----	--+-----	*05:42, *05:48N = *05:42, *05:51Q
++-+-+--	--+-----	-----	--+-----	*05:01:01:01, *05:42 = *05:25, *05:42 = *05:25, *05:46 = *05:42, *05:42 = *05:42, *05:46 = *05:42, *05:61
++-+-+--	--+-----	-----	-----+	*05:25, *05:48N = *05:25, *05:51Q
++-+-+--	--+-----	-----	-----	*05:01:01:01, *05:25 = *05:25, *05:25 = *05:25, *05:61
++-+-+--	---+-----	-----+	-----	*05:10, *05:29 = *05:10, *05:43
++-+-+--	---+-----	-----	-----+	*05:10, *05:48N = *05:10, *05:51Q







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++-----+	-----	-----	+-----+	*05:35, *05:48N = *05:35, *05:51Q
++-----+	-----	-----	+-----+	*05:01:01:01, *05:35 = *05:35, *05:35 = *05:35, *05:61
++-----+	-----	-----	+-----+	*05:28, *05:48N = *05:28, *05:51Q
++-----+	-----	-----	+-----+	*05:01:01:01, *05:28 = *05:28, *05:28 = *05:28, *05:61
++-----+	-----	-----	+-----+	*05:46, *05:48N = *05:46, *05:51Q
++-----+	-----	-----	+-----+	*05:01:01:01, *05:46 = *05:46, *05:46 = *05:46, *05:61
++-----+	-----	-----	+-----+	*05:45, *05:48N = *05:45, *05:51Q
++-----+	-----	-----	+-----+	*05:01:01:01, *05:45 = *05:45, *05:45 = *05:45, *05:61
++-----+	-----	-----	+-----+	*05:37, *05:48N = *05:37, *05:51Q
++-----+	-----	-----	+-----+	*05:01:01:01, *05:37 = *05:37, *05:37 = *05:37, *05:61
++-----+	-----	-----	+-----+	*05:32, *05:48N = *05:32, *05:51Q
++-----+	-----	-----	+-----+	*05:01:01:01, *05:32 = *05:32, *05:32 = *05:32, *05:61
++-----+	-----	-----	+-----+	*05:18:02, *05:48N = *05:18:02, *05:51Q
++-----+	-----	-----	+-----+	*05:01:01:01, *05:18:02 = *05:18:02, *05:61
++-----+	-----	-----	+-----+	*05:01:01:01, *05:48N = *05:01:01:01, *05:51Q = *05:48N, *05:51Q = *05:48N, *05:61 = *05:51Q, *05:51Q = *05:51Q, *05:61
++-----+	-----	-----	+-----+	*05:01:01:01, *05:01:01:01 = *05:01:01:01, *05:61
-+-----	-+-----	-----	-----	*05:09:01, *05:52 = *05:52, *05:52
-+-----	-----	-----	-----	*05:09:01, *05:17 = *05:17, *05:17
-+-----	-----	+-----	-----	*05:12, *05:12 = *05:12, *05:18:01

- \*05:01:01:01 = \*05:01:01:01-05:01:18 and the 05:47, 05:49-05:50, 05:54, 05:56-05:60, 05:63-05:67, 05:69 and 05:71-05:72
- \*05:06 = \*05:06, 05:55
- \*05:08 = \*05:08 and \*05:30
- \*05:10 = \*05:10 and \*05:38
- \*05:11 = \*05:11, 05:68, 05:70
- \*05:18:02 = \*05:18:02-05:18:03
- \*05:21 = \*05:21 and \*05:26
- \*05:22:01 = \*05:22:01-05:22:02
- \*05:23 = \*05:23, 05:62
- \*05:24 = \*05:24 and \*05:36
- \*05:25 = \*05:25 and \*05:33
- \*05:28 = \*05:28 and \*05:39
- \*05:32 = \*05:32, 05:53
- \*05:35 = \*05:35 and \*05:40
- \*05:37 = \*05:37 and \*05:41



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Lot-specific information  
**SPECIFICITY TABLE**

**HLA-C\*05 SSP subtyping**

Specificities and sizes of the PCR products of the 32 primer mixes used for HLA-C\*05 SSP subtyping

Primer Mix	Size of spec. PCR product <sup>1</sup>	Size of control band <sup>2</sup>	Amplified HLA-C*05 alleles <sup>3,4</sup>	Other amplified HLA Class I alleles <sup>5</sup>
<b>1</b>	155 bp	<b>800 bp</b>	*05:01:01:01-05:01:18, 05:03-05:08, 05:10-05:11, 05:13-05:16, 05:19-05:51Q, 05:53-05:72	*07:41, 08:02:01-08:02:07, 08:04-08:05, 08:07, 08:12-08:13, 08:17-08:19, 08:23, 08:25, 08:28-08:32, 08:34, 08:37, 08:43, 08:45, 08:47-08:49, 08:52N-08:53, 08:55N
<b>2</b>	165 bp	1070 bp	*05:01:01:01-05:01:18, 05:03-05:28, 05:30-05:47, 05:49-05:72	*06:05, 06:67, 08:10, 12:21, 12:33, 17:05
<b>3</b>	150 bp	1070 bp	*05:09:01-05:09:02, 05:17, 05:44, 05:52	*01:13, 02:51, 03:87, 07:130, 08:15:01-08:15:02, 08:51, 16:27, <b>B*15:33</b>
<b>4<sup>6</sup></b>	120 bp	<b>800 bp</b>	*05:03	*07:52
<b>5<sup>8</sup></b>	225 bp, 285 bp	1070 bp	*05:04, 05:31	*07:68, 08:09, 08:11
<b>6</b>	270 bp	1070 bp	*05:05, 05:16	*08:12, <b>A*29:10, A*68:69</b>
<b>7</b>	265 bp	1070 bp	*05:01:01:01-05:01:18, 05:03-05:04, 05:06-05:08, 05:10-05:16, 05:18:01-05:51Q, 05:53-05:60, 05:62-05:72	*07:04:01-07:04:07, 07:11-07:12, 07:41, 07:63, 07:68, 07:101, 07:139, 07:142, 07:181, 07:199, 08:01:01-08:14, 08:16-08:50, 08:52N-08:56
<b>8<sup>6,9</sup></b>	85 bp, 210 bp	<b>800 bp</b>	*05:06, 05:55	
<b>9</b>	285 bp	1070 bp	*05:07N	
<b>10<sup>6,10</sup></b>	95 bp, 195 bp	1070 bp	*05:08, 05:30, 05:52	*02:51, 08:29, 08:31, <b>B*15:33</b>
<b>11<sup>6,11</sup></b>	115 bp, 205 bp	1070 bp	*05:25, 05:33, 05:42	*06:05, 06:67, 07:101, 07:148, 07:161, 08:28, <b>A*80:01<sup>w</sup>-80:02<sup>w</sup></b>

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<b>12</b> <sup>12</sup>	225 bp, 285 bp	1070 bp	*05:10, 05:38	*08:44
<b>13</b> <sup>6</sup>	95 bp	1070 bp	*05:11, 05:17, 05:27, 05:68, 05:70	*03:87, 07:130, 08:04, 08:13
<b>14</b> <sup>6</sup>	120 bp	1070 bp	*05:12, 05:15	
<b>15</b> <sup>13</sup>	185 bp, 240 bp	1070 bp	*05:13, 05:34	*06:13
<b>16</b>	195 bp	1070 bp	*05:14	
<b>17</b>	155 bp	1070 bp	*05:12, 05:18:01	*08:01:01-08:01:05, 08:03:01-08:03:02, 08:06, 08:08-08:11, 08:14, 08:16, 08:20-08:22, 08:24, 08:26N-08:27, 08:33:02, 08:35-08:36N, 08:38- 08:42, 08:44, 08:46, 08:50, 08:54, 08:56
<b>18</b>	235 bp	1070 bp	*05:19	
<b>19</b>	175 bp	<b>800 bp</b>	*05:20	*01:43, 07:101, 07:148, 07:161, 08:01:01-08:09, 08:11-08:12, 08:14- 08:15:02, 08:17, 08:19- 08:24, 08:26N-08:54, 08:56
<b>20</b> <sup>14</sup>	205 bp, 390 bp	1070 bp	*05:21, 05:26	
<b>21</b>	230 bp	1070 bp	*05:04, 05:22:01- 05:22:02	*07:04:01-07:04:07, 07:11- 07:12, 07:63, 07:68, 07:101, 07:139, 07:142, 07:181, 07:199, 08:09, 08:11
<b>22</b> <sup>6</sup>	100 bp	<b>800 bp</b>	*05:23, 05:62	*08:07, 08:47
<b>23</b> <sup>6,15</sup>	85 bp, 135 bp	1070 bp	*05:24, 05:36	*07:148
<b>24</b> <sup>16</sup>	185 bp, 265 bp	1070 bp	*05:29, 05:43	*08:13, 08:16, 08:25, 08:37
<b>25</b> <sup>6,17</sup>	105 bp, 205 bp	1070 bp	*05:35, 05:40	
<b>26</b> <sup>6,18</sup>	115 bp, 185 bp	1070 bp	*05:27-05:28, 05:39	*03:87, 06:64, <b>B*15:33</b>
<b>27</b>	155 bp	1070 bp	*05:42, 05:46	*06:67, 07:101, 07:148, 07:161, 08:05, 08:21, 17:05
<b>28</b> <sup>7</sup>	200 bp	<b>800 bp</b>	*05:45	

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<b>29</b> <sup>19</sup>	140 bp, 185 bp, 260 bp	1070 bp	*05:34, 05:37, 05:41	*04:78, 06:13
<b>30</b> <sup>6,20</sup>	70 bp, 175 bp	1070 bp	*05:32, 05:53	
<b>31</b>	155 bp	1070 bp	*05:18:02-05:18:03	*07:04:01-07:04:07, 07:11- 07:12, 07:63, 07:68, 07:101, 07:139, 07:142, 07:181, 07:199, 08:33:01
<b>32</b> <sup>6,21</sup>	105 bp, 175 bp	1070 bp	*05:48N, 05:51Q	

<sup>1</sup>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\*05 SSP subtypings.

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.

<sup>2</sup>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\*05 subtyping.

In addition, wells number 4, 8 19, 22 and 28 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.

<sup>3</sup>The C\*05:18:01 and C\*08:10 and the C\*05:29 and C\*08:25 alleles will give rise to identical amplification patterns with the HLA-C\*05 subtyping kit. These alleles can be distinguished by the HLA-C low resolution kit and/or the C\*08 subtyping kit.

<sup>4</sup>For several HLA-C\*05 alleles nucleotide sequences are only available from the 2<sup>nd</sup> and 3<sup>rd</sup> exon. 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 4<sup>th</sup> exon and in the introns are conserved within allelic groups.

<sup>5</sup>Due to the sharing of sequence motifs between HLA-C alleles non-HLA-C\*05 alleles will be amplified by primer mixes 1 to 7, 10 to 13, 15, 17, 19, 21 to 24, 26, 27, 29 and 31. In addition, the A\*29:10 and A\*68:69 alleles will be amplified by primer mix 6, the A\*80 will be weakly amplified by primer mix 11 and the B\*15:33 allele will be amplified by primer mixes 3, 10 and 26.

<sup>6</sup>Specific PCR fragments shorter than 125 base pairs have a lower intensity than longer PCR bands.

<sup>7</sup>Primer mix 28 may give rise to primer oligomer formation.

<sup>8</sup>Primer mix 5: Specific PCR fragment of 225 bp in the C\*05:04 and in the C\*07:68, 08:09 and 08:11 alleles. Specific PCR fragment of 285 bp in the C\*05:31 allele.

<sup>9</sup>Primer mix 8: Specific PCR fragment of 85 bp in the C\*05:06 allele. Specific PCR fragment of 210 bp in the C\*05:55 allele.

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<sup>10</sup>Primer mix 10: Specific PCR fragment of 95 bp in the C\*05:08 and 05:52 and the C\*02:51, 08:29 and 08:31 and in the B\*15:33 alleles. Specific PCR fragment of 195 bp in the C\*05:30 allele.

<sup>11</sup>Primer mix 11: Specific PCR fragment of 115 bp in the C\*05:33 allele. Specific PCR fragment of 205 bp in the C\*05:25 and 05:42 and the C\*06:05, 06:67, 07:101, 07:148, 07:161 and 08:28 and in the A\*80:01<sup>w</sup>-80:02<sup>w</sup> alleles.

<sup>12</sup>Primer mix 12: Specific PCR fragment of 225 bp in the C\*05:38 allele. Specific PCR fragment of 285 bp in the C\*05:10 and the C\*08:44 alleles.

<sup>13</sup>Primer mix 15: Specific PCR fragment of 185 bp in the C\*05:34 and in the C\*06:13 alleles. Specific PCR fragment of 240 bp in the C\*05:13 allele.

<sup>14</sup>Primer mix 20: Specific PCR fragment of 205 bp in the C\*05:26 allele. Specific PCR fragment of 390 bp in the C\*05:21 allele.

<sup>15</sup>Primer mix 23: Specific PCR fragment of 85 bp in the C\*05:24 allele. Specific PCR fragment of 135 bp in the C\*05:36 and in the C\*07:148 alleles.

<sup>16</sup>Primer mix 24: Specific PCR fragment of 185 bp in the C\*05:43 and the C\*08:37 alleles. Specific PCR fragment of 265 bp in the C\*05:29 and in the C\*08:13, 08:16 and 08:25 alleles.

<sup>17</sup>Primer mix 25: Specific PCR fragment of 105 bp in the C\*05:40 allele. Specific PCR fragment of 205 bp in the C\*05:35 allele.

<sup>18</sup>Primer mix 26: Specific PCR fragment of 115 bp in the C\*05:27 and 05:39 and in the C\*03:87 and in the B\*15:33 alleles. Specific PCR fragment of 185 bp in the C\*05:28 and the C\*06:64 alleles.

<sup>19</sup>Primer mix 29: Specific PCR fragment of 140 bp in the C\*05:41 and the C\*04:78 alleles. Specific PCR fragment of 185 bp in the C\*05:34 and in the C\*06:13 alleles. Specific PCR fragment of 260 bp in the C\*05:37 allele.

<sup>20</sup>Primer mix 30: Specific PCR fragment of 70 bp in the C05:53 allele. Specific PCR fragment of 175 bp in the C\*05:32 allele.

<sup>21</sup>Primer mix 32: Specific PCR fragment of 105 bp in the C\*05:51Q allele. Specific PCR fragment of 175 bp in the C\*05:48N allele.

'w', might be weakly amplified.

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Lot-specific information

<b>INTERPRETATION TABLE</b>																
<b>HLA-C*05 subtyping</b>																
<b>Amplification patterns of the C*05:01 to 05:72 alleles</b>																
	Well <sup>17</sup>															
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
Length of spec. PCR product(s)	155	165	150	120	225	270	265	85	285	95	115	225	95	120	185	195
Length of int. pos. control <sup>1</sup>	800	1070	1070	800	1070	1070	1070	800	1070	1070	1070	1070	1070	1070	1070	1070
5'-primer(s) <sup>2</sup>	485	176	485	3 <sup>rd</sup> I	355	361	379	176	355	1 <sup>st</sup> I	176	355	485	176	115	446
	5'-CAA 3'	5'-gCA 3'	5'-CAA 3'	5'-ggA 3'	5'-TCC 3'	5'-AgT 3'	5'-ACC 3'	5'-gCA 3'	5'-CC 3'	5'-CgA 3'	5'-gCA 3'	5'-TCA 3'	5'-CAA 3'	5'-gCA 3'	5'-ggA 3'	5'-CgT 3'
					419	379				485		416		453	2 <sup>nd</sup> I	
					5'-gTC 3'	5'-ACg 3'				5'-CAA 3'		5'-CCg 3'		5'-AAT 3'	5'-CCA 3'	
3'-primer(s) <sup>3</sup>	601	302	595	668	601	601	601	221	601	106	248	601	538	256	312	601
	5'-CTT 3'	5'-ggT 3'	5'-CCT 3'	5'-TgA 3'	5'-CTT 3'	5'-CTT 3'	5'-CTT 3'	5'-ACC 3'	5'-CTT 3'	5'-CAT 3'	5'-AAC 3'	5'-CTT 3'	5'-Cag 3'	5'-CCA 3'	5'-AgT 3'	5'-CTT 3'
			601					343		538	341			527	475	
			5'-CTC 3'				5'-T 3'			5'-CCA 3'	5'-CgT 3'			5'-CCA 3'	5'-ggT 3'	
Well No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
HLA-C allele <sup>4,5</sup>																
*05:01:01:01- 05:01:18, 05:47, 05:49-05:50, 05:54, 05:56-05:60, 05:63-05:67, 05:69, 05:71-05:72	1	2					7									
*05:03	1	2		4			7									
*05:04	1	2			5		7									
*05:05	1	2				6										
*05:06, 05:55 <sup>6</sup>	1	2					7	8								
*05:07N	1	2					7		9							
*05:08, 05:30 <sup>7</sup>	1	2					7			10						
*05:09:01-05:09:02		2	3													
Well No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16

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Lot-specific information

INTERPRETATION TABLE																
HLA-C*05 subtyping																
Amplification patterns of the C*05:01 to 05:72 alleles																
Well <sup>17</sup>																
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	
155	235	175	205	230	100	85	185	105	115	155	200	140	70	155	105	Length of spec. PCR product(s)
			390			135	265	205	185			185	175		175	
1070	1070	800	1070	1070	800	1070	1070	1070	1070	1070	800	1070	1070	1070	1070	Length of int. pos. control <sup>1</sup>
486	406	176	1 <sup>st</sup>	412	453	176	1 <sup>st</sup>	176	158	176	2 <sup>nd</sup>	2 <sup>nd</sup>	176	486	166	
5'-ACg <sup>3'</sup>	5'-gCC <sup>3'</sup>	5'-gCA <sup>3'</sup>	5'-CgA <sup>3'</sup>	5'-ATg <sup>3'</sup>	5'-AAT <sup>3'</sup>	5'-gCA <sup>3'</sup>	5'-CgA <sup>3'</sup>	5'-gCA <sup>3'</sup>	5'-ggg <sup>3'</sup>	5'-gCA <sup>3'</sup>	5'-CCA <sup>3'</sup>	5'-CCA <sup>3'</sup>	5'-gCA <sup>3'</sup>	5'-ACC <sup>3'</sup>	5'-CgT <sup>3'</sup>	
			322						485			629	3 <sup>rd</sup>		485	3'-primer(s) <sup>3</sup>
			5'-gCC <sup>3'</sup>						5'-CAA <sup>3'</sup>			5'-Aag <sup>3'</sup>	5'-gga <sup>3'</sup>		5'-CAA <sup>3'</sup>	
601	601	311	118	601	512	218	97	241	302	289	488	430	311	601	302	3'-primer(s) <sup>3</sup>
5'-CTT <sup>3'</sup>	5'-CTT <sup>3'</sup>	5'-ggT <sup>3'</sup>	5'-gCT <sup>3'</sup>	5'-CTT <sup>3'</sup>	5'-CCA <sup>3'</sup>	5'-gCC <sup>3'</sup>	5'-gTC <sup>3'</sup>	5'-CgA <sup>3'</sup>	5'-ggT <sup>3'</sup>	5'-AgC <sup>3'</sup>	5'-CCT <sup>3'</sup>	5'-gCA <sup>3'</sup>	5'-gTC <sup>3'</sup>	5'-CTT <sup>3'</sup>	5'-ggT <sup>3'</sup>	
			419			270	175	341	559	289		475	621		550	
			5'-CgA <sup>3'</sup>			5'-TAG <sup>3'</sup>	5'-CCg <sup>3'</sup>	5'-CgA <sup>3'</sup>	5'-CAG <sup>3'</sup>	5'-AgC <sup>3'</sup>		5'-ggT <sup>3'</sup>	5'-Tgg <sup>3'</sup>		5'-CAG <sup>3'</sup>	
												846				
												5'-CAC <sup>3'</sup>				
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	Well No. HLA-C allele <sup>4,5</sup>
																*05:01:01:01- 05:01:18, 05:47, 05:49-05:50, 05:54, 05:56-05:60, 05:63-05:67, 05:69, 05:71-05:72
				21												*05:03
																*05:04
																*05:05
																*05:06, 05:55 <sup>6</sup>
																*05:07N
																*05:08, 05:30 <sup>7</sup>
																*05:09:01-05:09:02
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	Well No.

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Lot-specific information

Length of spec. PCR product(s)	155	165	150	120	225	270	265	85	285	95	115	225	95	120	185	195
					285			210		195	205	285			240	
Well No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
*05:10, 05:38 <sup>8</sup>	1	2					7					12				
*05:11, 05:68, 05:70	1	2					7						13			
*05:12		2					7							14		
*05:13	1	2					7								15	
*05:14	1	2					7									16
*05:15	1	2					7							14		
*05:16	1	2				6	7									
*05:17		2	3										13			
*05:18:01, 08:10 <sup>15</sup>		2					7									
*05:18:02-05:18:03		2					7									
*05:19	1	2					7									
*05:20	1	2					7									
*05:21, 05:26 <sup>9</sup>	1	2					7									
*05:22:01-05:22:02	1	2					7									
*05:23, 05:62	1	2					7									
*05:24, 05:36 <sup>10</sup>	1	2					7									
*05:25, 05:33 <sup>11</sup>	1	2					7				11					
*05:27	1	2					7						13			
*05:28, 05:39 <sup>12</sup>	1	2					7									
*05:29, 08:25 <sup>16</sup>	1						7									
*05:31	1	2			5		7									
*05:32, 05:53	1	2					7									
*05:34	1	2					7								15	
*05:35, 05:40 <sup>13</sup>	1	2					7									
*05:37, 05:41 <sup>14</sup>	1	2					7									
*05:42	1	2					7				11					
*05:43	1	2					7									
*05:44	1	2	3				7									
*05:45	1	2					7									
*05:46	1	2					7									
*05:48N	1						7									
*05:51Q	1	2					7									
*05:52		2	3							10						
*05:61	1	2														
*01:13, 16:27			3													
*01:43																
*02:51			3							10						
*03:87			3										13			
Well No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16



101.613-12– including *Taq* polymerase, IFU-01 Rev. No. 03  
 101.613-12u – without *Taq* polymerase, IFU-02 Rev. No. 03

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 “Instructions for Use” (IFU)

Lot No.: **47N**

Lot-specific information

155	235	175	205	230	100	85	185	105	115	155	200	140	70	155	105	Length of spec. PCR product(s)
			390			135	265	205	185			185	175		175	
												260				
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	Well No.
																*05:10, 05:38 <sup>8</sup>
																*05:11, 05:68, 05:70
17																*05:12
																*05:13
																*05:14
																*05:15
																*05:16
																*05:17
17																*05:18:01, 08:10 <sup>15</sup>
														31		*05:18:02-05:18:03
	18															*05:19
		19														*05:20
			20													*05:21, 05:26 <sup>9</sup>
				21												*05:22:01-05:22:02
					22											*05:23, 05:62
						23										*05:24, 05:36 <sup>10</sup>
																*05:25, 05:33 <sup>11</sup>
									26							*05:27
									26							*05:28, 05:39 <sup>12</sup>
							24									*05:29, 08:25 <sup>16</sup>
																*05:31
														30		*05:32, 05:53
												29				*05:34
								25								*05:35, 05:40 <sup>13</sup>
												29				*05:37, 05:41 <sup>14</sup>
										27						*05:42
							24									*05:43
																*05:44
											28					*05:45
										27						*05:46
															32	*05:48N
															32	*05:51Q
																*05:52
																*05:61
																*01:13, 16:27
		19														*01:43
																*02:51
									26							*03:87
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	Well No.



101.613-12– including *Taq* polymerase, IFU-01 Rev. No. 03Visit [www.olerup-ssp.com](http://www.olerup-ssp.com) for101.613-12u – without *Taq* polymerase, IFU-02 Rev. No. 03

“Instructions for Use” (IFU)

Lot No.: **47N**

Lot-specific information

Length of spec. PCR product(s)	155	165	150	120	225 285	270	265	85 210	285	95 195	115 205	225 285	95	120	185 240	195
Well No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
*04:78																
*06:05		2									11					
*06:13															15	
*06:64																
*06:67		2									11					
*07:04:01-07:04:07, 07:11-07:12, 07:63, 07:139, 07:142, 07:181, 07:199							7									
*07:41, 08:18, 08:55N	1						7									
*07:52				4												
*07:68					5		7									
*07:101							7				11					
*07:130			3										13			
*07:148											11					
*07:161											11					
*08:01:01-08:01:05, 08:03:01-08:03:02, 08:06, 08:08, 08:14, 08:20, 08:22, 08:24, 08:26N-08:27, 08:33:02, 08:35- 08:36N, 08:38-08:42, 08:46, 08:50, 08:54, 08:56							7									
*08:02:01-08:02:07, 08:17, 08:19, 08:23, 08:30, 08:32, 08:34, 08:43, 08:45, 08:48- 08:49, 08:52N-08:53	1						7									
*08:04	1						7						13			
*08:05	1						7									
*08:07, 08:47	1						7									
*08:09, 08:11					5		7									
*08:12	1					6	7									
*08:13	1						7						13			
*08:15:01-08:15:02, 08:51			3													
*08:16							7									
*08:21							7									
Well No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16

101.613-12– including *Taq* polymerase, IFU-01 Rev. No. 03  
 101.613-12u – without *Taq* polymerase, IFU-02 Rev. No. 03

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 “Instructions for Use” (IFU)

Lot No.: **47N**

Lot-specific information

155	235	175	205	230	100	85	185	105	115	155	200	140	70	155	105	Length of spec. PCR product(s)
			390			135	265	205	185			185	175		175	
												260				
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	Well No.
												29				*04:78
																*06:05
												29				*06:13
									26							*06:64
										27						*06:67
				21										31		*07:04:01-07:04:07, 07:11-07:12, 07:63, 07:139, 07:142, 07:181, 07:199
																*07:41, 08:18, 08:55N
																*07:52
				21										31		*07:68
		19		21						27				31		*07:101
																*07:130
		19				23				27						*07:148
		19								27						*07:161
17		19														*08:01:01-08:01:05, 08:03:01-08:03:02, 08:06, 08:08, 08:14, 08:20, 08:22, 08:24, 08:26N-08:27, 08:33:02, 08:35- 08:36N, 08:38-08:42, 08:46, 08:50, 08:54, 08:56
		19														*08:02:01-08:02:07, 08:17, 08:19, 08:23, 08:30, 08:32, 08:34, 08:43, 08:45, 08:48- 08:49, 08:52N-08:53
		19														*08:04
		19								27						*08:05
		19			22											*08:07, 08:47
17		19		21												*08:09, 08:11
		19														*08:12
							24									*08:13
		19														*08:15:01-08:15:02, 08:51
17							24									*08:16
17		19								27						*08:21
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	Well No.

101.613-12– including *Taq* polymerase, IFU-01 Rev. No. 03101.613-12u – without *Taq* polymerase, IFU-02 Rev. No. 03Visit [www.olerup-ssp.com](http://www.olerup-ssp.com) for

“Instructions for Use” (IFU)

Lot No.: **47N**

Lot-specific information

Length of spec. PCR product(s)	155	165	150	120	225	270	265	85	285	95	115	225	95	120	185	195
Well No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
					285			210		195	205	285			240	
*08:28	1						7				11					
*08:29, 08:31	1						7			10						
*08:33:01							7									
*08:37	1						7									
*08:44							7					12				
*12:21, 12:33		2														
*17:05		2														
A*29:10, A*68:69						6										
A*80:01-80:02											w					
B*15:33			3							10						
Well No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16

<sup>1</sup>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\*05 subtyping.

In addition, wells number 4, 8, 19, 22 and 28 contain the primer pair giving rise to the shorter, 800 bp, internal positive control band in order to allow kit identification.

<sup>2</sup>The nucleotide position, in the 2<sup>nd</sup>, 3<sup>rd</sup> or 4<sup>th</sup> exon or the 1<sup>st</sup>, 2<sup>nd</sup> and 3<sup>rd</sup> intron, matching the specificity-determining 3'-end of the primer is given. Nucleotide numbering as on the [www.ebi.ac.uk/imgt/hla](http://www.ebi.ac.uk/imgt/hla) web site. The sequence of the 3 terminal nucleotides of the primer is given.

<sup>3</sup>The nucleotide position, in the 2<sup>nd</sup>, 3<sup>rd</sup> or 4<sup>th</sup> exon, matching the specificity-determining 3'-end of the primer is given in the anti-sense direction. Nucleotide numbering as on the [www.ebi.ac.uk/imgt/hla](http://www.ebi.ac.uk/imgt/hla) web site. The sequence of the 3 terminal nucleotides of the primer is given.

<sup>4</sup>The HLA-Cw\*0502 nucleotide sequence has been deleted as it is identical to C\*05:09.

<sup>5</sup>HLA-C\*05 alleles in bold lettering are listed as confirmed alleles on the IMGT/HLA web page [www.ebi.ac.uk/imgt/hla](http://www.ebi.ac.uk/imgt/hla), release 3.7.0, January 2012.

<sup>6</sup>The C\*05:06 and C\*05:55 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 8.

<sup>7</sup>The C\*05:08 and C\*05:30 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 10.

<sup>8</sup>The C\*05:10 and C\*05:38 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 12.

<sup>9</sup>The C\*05:21 and C\*05:26 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 20.

<sup>10</sup>The C\*05:24 and C\*05:36 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 23.

<sup>11</sup>The C\*05:25 and C\*05:33 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 11.

<sup>12</sup>The C\*05:28 and C\*05:39 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 26.

<sup>13</sup>The C\*05:35 and C\*05:40 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 25.

<sup>14</sup>The C\*05:37 and C\*05:41 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 29.

<sup>15</sup>The C\*05:18:01 and C\*08:10 alleles will give rise to identical amplification patterns with the HLA-C\*05 subtyping kit. These alleles can be distinguished by the HLA-C low resolution kit and/or the C\*08 subtyping kit.

101.613-12– including *Taq* polymerase, IFU-01 Rev. No. 03  
 101.613-12u – without *Taq* polymerase, IFU-02 Rev. No. 03

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Lot No.: **47N**

Lot-specific information

155	235	175	205	230	100	85	185	105	115	155	200	140	70	155	105	Length of spec. PCR product(s)
			390			135	265	205	185			185	175		175	
												260				
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	Well No.
		19														*08:28
		19														*08:29, 08:31
		19												31		*08:33:01
		19					24									*08:37
17		19														*08:44
																*12:21, 12:33
										27						*17:05
																A*29:10, A*68:69
																A*80:01-80:02
									26							B*15:33
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	Well No.

<sup>16</sup>The C\*05:29 and C\*08:25 alleles will give rise to identical amplification patterns with the HLA-C\*05 subtyping kit. These alleles can be distinguished by the HLA-C low resolution kit and/or the C\*08 subtyping kit.

<sup>17</sup>Primer mix 5: Specific PCR fragment of 225 bp in the C\*05:04 and in the C\*07:68, 08:09 and 08:11 alleles. Specific PCR fragment of 285 bp in the C\*05:31 allele.

Primer mix 8: Specific PCR fragment of 85 bp in the C\*05:06 allele. Specific PCR fragment of 210 bp in the C\*05:55 allele.

Primer mix 10: Specific PCR fragment of 95 bp in the C\*05:08 and 05:52 and the C\*02:51, 08:29 and 08:31 and in the B\*15:33 alleles. Specific PCR fragment of 195 bp in the C\*05:30 allele.

Primer mix 11: Specific PCR fragment of 115 bp in the C\*05:33 allele. Specific PCR fragment of 205 bp in the C\*05:25 and 05:42 and the C\*06:05, 06:67, 07:101, 07:148, 07:161 and 08:28 and in the A\*80:01<sup>w</sup>-80:02<sup>w</sup> alleles.

Primer mix 12: Specific PCR fragment of 225 bp in the C\*05:38 allele. Specific PCR fragment of 285 bp in the C\*05:10 and the C\*08:44 alleles.

Primer mix 15: Specific PCR fragment of 185 bp in the C\*05:34 and in the C\*06:13 alleles. Specific PCR fragment of 240 bp in the C\*05:13 allele.

Primer mix 20: Specific PCR fragment of 205 bp in the C\*05:26 allele. Specific PCR fragment of 390 bp in the C\*05:21 allele.

Primer mix 23: Specific PCR fragment of 85 bp in the C\*05:24 allele. Specific PCR fragment of 135 bp in the C\*05:36 and in the C\*07:148 alleles.

Primer mix 24: Specific PCR fragment of 185 bp in the C\*05:43 and the C\*08:37 alleles. Specific PCR fragment of 265 bp in the C\*05:29 and in the C\*08:13, 08:16 and 08:25 alleles.

Primer mix 25: Specific PCR fragment of 105 bp in the C\*05:40 allele. Specific PCR fragment of 205 bp in the C\*05:35 allele.

Primer mix 26: Specific PCR fragment of 115 bp in the C\*05:27 and 05:39 and in the C\*03:87 and in the B\*15:33 alleles. Specific PCR fragment of 185 bp in the C\*05:28 and the C\*06:64 alleles.

Primer mix 29: Specific PCR fragment of 140 bp in the C\*05:41 and the C\*04:78 alleles. Specific PCR fragment of 185 bp in the C\*05:34 and in the C\*06:13 alleles. Specific PCR fragment of 260 bp in the C\*05:37 allele.

Primer mix 30: Specific PCR fragment of 70 bp in the C05:53 allele. Specific PCR fragment of 175 bp in the C\*05:32 allele.

Primer mix 32: Specific PCR fragment of 105 bp in the C\*05:51Q allele. Specific PCR fragment of 175 bp in the C\*05:48N allele.

'w', might be weakly amplified.

101.613-12– including *Taq* polymerase, IFU-01 Rev. No. 03  
 101.613-12u – without *Taq* polymerase, IFU-02 Rev. No. 03

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 “Instructions for Use” (IFU)

Lot No.: **47N**

Lot-specific information

<b>CELL LINE VALIDATION SHEET</b>																				
<b>HLA-C*05 SSP subtyping kit</b>																				
				Well																
				1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	
			Prod. No.:	201077801	201077802	201077803	201077804	201077805	201077806	201077807	201298408	201077809	201077810	201077811	201077812	201077813	201077814	201077815	201077816	
	<b>IHWC cell line</b>		<b>C*</b>																	
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	9025 DEU		*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	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-



101.613-12– including *Taq* polymerase, IFU-01 Rev. No. 03  
 101.613-12u – without *Taq* polymerase, IFU-02 Rev. No. 03

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Lot No.: **47N**

Lot-specific information

<b>CELL LINE VALIDATION SHEET</b>																				
<b>HLA-C*05 SSP subtyping kit</b>																				
				<b>Well</b>																
				17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	
				Prod. No.:	201077817	201077818	201077819	201077820	201077821	201077822	201077823	201077824	201077825	201077826	201077827	201077828	201077829	201298430	201298431	201298432
<b>IHWC cell line</b>			<b>C*</b>																	
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	9025	DEU	*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	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	



101.613-12– including *Taq* polymerase, IFU-01 Rev. No. 03  
 101.613-12u – without *Taq* polymerase, IFU-02 Rev. No. 03

Visit [www.olerup-ssp.com](http://www.olerup-ssp.com) for  
 “Instructions for Use” (IFU)

Lot No.: **47N**

Lot-specific information

## CERTIFICATE OF ANALYSIS

### Olerup SSP® HLA-C\*05 SSP

Product number: 101.613-12 – including *Taq* polymerase  
 101.613-12u – without *Taq* polymerase  
 Lot number: 47N  
 Expiry date: 2014-September-01  
 Number of tests: 12  
 Number of wells per test: 32

#### Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2010-778-01	13	2010-778-13	25	2010-778-25
2	2010-778-02	14	2010-778-14	26	2010-778-26
3	2010-778-03	15	2010-778-15	27	2010-778-27
4	2010-778-04	16	2010-778-16	28	2010-778-28
5	2010-778-05	17	2010-778-17	29	2010-778-29
6	2010-778-06	18	2010-778-18	30	2012-984-30
7	2010-778-07	19	2010-778-19	31	2012-984-31
8	2012-984-08	20	2010-778-20	32	2012-984-32
9	2010-778-09	21	2010-778-21		
10	2010-778-10	22	2010-778-22		
11	2010-778-11	23	2010-778-23		
12	2010-778-12	24	2010-778-24		

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

No DNAs carrying the alleles to be amplified by primer solutions 4 to 6, 8 to 12, 14 to 16, 18, 20, 22 to 30 and 32 were available. The specificities of the primers in primer solutions 5, 6, 8, 10 to 12, 14, 15, 20, 22 to 24, 26, 27, 29 and 32 were tested by separately adding additional 5'-primers respectively 3'-primers. In primer solutions 4, 25, 28 and 30 it was only possible to test the 5'-primers, the 3'-primers were not possible to test. In primer solutions 9, 16 and 18 it was only possible to test the 3'-primer, the 5'-primer was not possible to test. In primer solutions 8, 10, 11, 14, 15, 20, 23, 29 and 32 one or two 3'-primers were not possible to test. In primer solutions 12, 15, 20, 26, 29 and 32 one 5'-primer was not possible to test. One additional 3'-primer in primer solution 3 was tested by separately adding one 5'-primer.

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

**Date of approval:** 2012-March-09

**Approved by:**

#### Production Quality Control



101.613-12– including *Taq* polymerase, IFU-01 Rev. No. 03  
101.613-12u – without *Taq* polymerase, IFU-02 Rev. No. 03

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Lot No.: **47N**

Lot-specific information

## Declaration of Conformity

**Product name:** *Olerup* SSP® HLA-C\*05  
**Product number:** 101.613-12/12u  
**Lot number:** 47N

**Intended use:** HLA-C\*05 high resolution histocompatibility testing

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

We, *Olerup* SSP AB, hereby declare that this product, to which this Declaration of Conformity relates is in conformity with the following Standard(s) and other normative document(s) ISO 9001:2008 and ISO 13485:2003, following the provisions of the 98/79/EC Directive on *in vitro* diagnostic medical devices, Annex 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.

Stockholm, Sweden  
2012-March-09

Ann-Cathrin Jareman  
Head of QA and Regulatory Affairs

101.613-12– including *Taq* polymerase, IFU-01 Rev. No. 03  
101.613-12u – without *Taq* polymerase, IFU-02 Rev. No. 03

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Lot No.: **47N**

Lot-specific information

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