

101.612-12 – including *Taq* pol., IFU-01  
101.612-12u– without *Taq* pol., IFU-02

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“Instructions for Use” (IFU)

Lot No.: 86S

Lot-specific information  
**Olerup SSP® HLA-C\*04**

Product number:	101.612-12 – including <i>Taq</i> polymerase
	101.612-12u – without <i>Taq</i> polymerase
Lot number:	86S
Expiry date:	2016-May-01
Number of tests:	12
Number of wells per test:	48
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. 86S.**

**CHANGES COMPARED TO THE PREVIOUS OLERUP SSP®  
HLA-C\*04 LOT (60R)**

The HLA-C\*04 specificity and interpretation tables have been updated for the HLA-C alleles described since the previous *Olerup SSP® HLA-C\*04* lot was made (**Lot No. 60R**).

The HLA-C\*04 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

The Lot-specific information for HLA-C\*04 including and without *Taq* polymerase is described in one common Product Insert.

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

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

Well	5'-primer	3'-primer	rationale
3	-	Added	3'-primer added for the C*04:01:42 allele.
4	-	Added	3'-primer added for the C*04:03:02 allele.
6	-	Added	3'-primer added for the C*04:112 allele.
15	Added		5'-primer added for the C*04:112 allele.
22	Added	Modified	5'-primers added for the C*04:96 and C*04:140 alleles, 5'-primer added from well 24, 3'-primer modified for improved specificity of amplification.
23	Added		5'-primer added for the C*04:144 allele.
24	Moved	Modified	5'-primer moved to wells 24 and 45 for decreased tendencies of primer oligomer formation, 3'-primer modified to decrease unspecific amplification.
31	Added	-	5'-primer added for the C*04:139 allele.
45	Added	Modified	5'-primer added from well 24, 3'-primer modified to decrease unspecific amplification.
47	Added	Added	Primer pair added for the C*04:146 allele.
48	-	Modified	Exchanged control primer pair, for decreased tendencies of primer oligomer formation, 3'-primer modified for increased yield of HLA-specific PCR product.

Change in revision R01 compared to R00:

1. The HLA-C\*04:15:02 and 04:17 and the C\*03:13:01, 03:35, 08:01:07, 08:02:07 and 08:33:02 alleles are amplified by primer mix 16. This has been corrected in the Specificity and Interpretation Tables.

Change in revision R02 compared to R01:

1. Primer mixes 5 and 8 do not amplify the B\*58:02 allele. This has been corrected in the Specificity and Interpretation Tables.

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**Lot-specific information**  
**PRODUCT DESCRIPTION**

### HLA-C\*04 SSP subtyping

#### CONTENT

The primer set contains 5'- and 3'-primers for identifying the HLA-C\*04:01 to HLA-C\*04:152 alleles.

#### PLATE LAYOUT

Each test consists of 48 PCR reactions in a 48 well PCR plate.

<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>6</b>	<b>7</b>	<b>8</b>
<b>9</b>	<b>10</b>	<b>11</b>	<b>12</b>	<b>13</b>	<b>14</b>	<b>15</b>	<b>16</b>
<b>17</b>	<b>18</b>	<b>19</b>	<b>20</b>	<b>21</b>	<b>22</b>	<b>23</b>	<b>24</b>
<b>25</b>	<b>26</b>	<b>27</b>	<b>28</b>	<b>29</b>	<b>30</b>	<b>31</b>	<b>32</b>
<b>33</b>	<b>34</b>	<b>35</b>	<b>36</b>	<b>37</b>	<b>38</b>	<b>39</b>	<b>40</b>
<b>41</b>	<b>42</b>	<b>43</b>	<b>44</b>	<b>45</b>	<b>46</b>	<b>47</b>	<b>48</b>

The 48 well cut PCR plate is marked with ‘HLA-C\*04’ in silver/gray ink.

Well No. 1 is marked with the Lot No. ‘86S’.

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 48 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\*04 SSP subtypings will be influenced by other HLA-C alleles, as primer mixes 1, 2, 4 to 8, 10 to 12, 15 to 20, 22 to 25, 27, 30, 33, 34, 38, 39, 41, 42, 44, 47 and 48 amplify non-HLA-C\*04 alleles. In addition, the A\*01:118, A\*02:109 and A\*33:52 alleles will be amplified by primer mix 20, the A\*24:96 and A\*24:146 alleles will be amplified by primer mix 15, the A\*68:46 allele will be amplified by primer mix 47, the B\*07:90 allele will be amplified by primer mix 30, the B\*15:27:01-15:27:03 and 15:109 alleles will be amplified by primer mixes 18 and 25, the B\*15:78:03 allele will be amplified by primer mixes 16 and 44 and the B\*40:100 allele will be amplified by primer mixes 32 and 33.

#### UNIQUELY IDENTIFIED ALLELES

All the HLA-C\*04 alleles, i.e. C\*04:01 to C\*04:152, recognized by the HLA Nomenclature Committee in July 2013<sup>1</sup> will be amplified by the primers in the HLA-C\*04 kit<sup>2</sup>.

The HLA-C\*04 kit enables separation of the confirmed HLA-C\*04 alleles as listed in the IMGT/HLA database. An HLA allele is listed as confirmed by IMGT/HLA if

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it has been sequenced by more than a single laboratory or from multiple sources. Current allele confirmation status for HLA-C\*04 alleles is listed below.

The HLA-C\*04 kit also enables identification of polymorphisms in exons outside of the region encoding the peptide binding domain and of null and alternatively expressed alleles.

The HLA-C\*04 primer set cannot distinguish the following silent mutations: the C\*04:01:01:01-04:01:09, 04:01:11-04:01:22, 04:01:24-04:01:27, 04:01:29-04:01:33 and 04:01:35-04:01:52 alleles, the C\*04:01:10 and 04:01:23 alleles, the \*04:03:01-04:03:02 alleles, the C\*04:04:01-04:04:02 alleles, the C\*04:15:01 and 04:15:03 alleles, the C\*04:64:01-04:64:02 and the C\*04:94:01-04:94:02 alleles.

The C\*04:05 and C\*04:112 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 6.

The C\*C\*04:44 and C\*04:47 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 20.

The C\*04:23, C\*04:38 and C\*04:39 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 21.

The C\*04:25, C\*04:40 and C\*04:41 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 23.

The C\*04:46 and C\*04:50 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 27.

The C\*04:48 and C\*04:75 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 28.

The C\*04:54 and C\*04:105N alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 41.

The C\*04:56 and C\*04:64:01-04:64:02 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 40.

The C\*04:59Q and C\*04:78 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 32.

The C\*04:61 and C\*04:96 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 34.

The C\*04:62 and C\*04:76 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 35.

The C\*04:65 and C\*04:72 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 33.

The C\*04:67 and C\*04:93N alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 46.

The C\*04:81 and C\*04:88N alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 43.

The C\*04:84 and C\*04:106 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 48.

The C\*04:114 and 04:146 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 47.

<sup>1</sup>HLA-C alleles listed on the IMGT/HLA web page 2013-July-25, release 3.13.1, [www.ebi.ac.uk/imgt/hla](http://www.ebi.ac.uk/imgt/hla).

<sup>2</sup>The HLA-C\*04 primer set cannot separate the C\*04:03:01-04:03:02 and 02:49 alleles or the C\*04:107 and the C\*02:12 and 02:55 alleles. These alleles can be distinguished by the HLA-C low resolution kit and/or the HLA-C\*02 high resolution kit.



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### **RESOLUTION IN HOMO- AND HETEROZYGOTES**

A total of 211 alleles generate 87 amplification patterns that can be combined in 3828 homozygous and heterozygous combinations. 2052 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.



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**SPECIFICITY TABLE**

**HLA-C\*04 SSP subtyping**

**Specificities and sizes of the PCR products of the 48 primer mixes used for HLA-C\*04 SSP subtyping**

Primer Mix	Size of spec. PCR product <sup>1</sup>	Size of control band <sup>2</sup>	Amplified HLA-C*04 alleles <sup>3</sup>	Other amplified HLA Class I alleles <sup>4</sup>
1 <sup>7</sup>	250 bp	800 bp	*04:01:01:01- 04:01:33, 04:01:34 <sup>w</sup> , 04:01:35-04:01:52, 04:03:01-04:03:02, 04:05, 04:07-04:12, 04:15:01-04:18, 04:19 <sup>w</sup> , 04:20, 04:23- 04:33, 04:35-04:57, 04:59Q-04:67, 04:69- 04:94:02, 04:95N <sup>w</sup> , 04:96-04:109, 04:110 <sup>7</sup> , 04:112- 04:121, 04:123N- 04:152	*01:02:01-01:21, 01:23-01:34, 01:36-01:78, 02:02:01-02:02:03, 02:02:05-02:02:26, 02:04-02:15, 02:17, 02:19-02:40, 02:42-02:68, 05:01:01:01-05:01:27, 05:03-05:10, 05:12-05:16, 05:18:01-05:26, 05:28- 05:50, 05:52-05:61, 05:63-05:67, 05:69, 05:71-05:78, 05:80-05:94, 06:02:01:01-06:02:01:02, 06:02:03- 06:03:02, 06:05-06:39, 06:41-06:78, 06:80-06:102, 08:02:01-08:02:10, 08:05, 08:07, 08:12, 08:15:01- 08:15:02, 08:17-08:19, 08:23, 08:25, 08:27-08:35, 08:37, 08:43, 08:45, 08:47-08:49, 08:51-08:53, 08:55N, 08:62-08:63, 08:67-08:71, 08:73- 08:77, 12:02:01-12:13, 12:15-12:17, 12:21-12:82, 12:84N-12:99, 14:02:01-14:05, 14:07N-14:14, 14:16-14:52, 15:08, 16:04:01, 16:29, 16:33, 16:42, 16:53, 16:55, 17:17, 18:01-18:07N
2	220 bp	1070 bp	*04:01:01:01- 04:01:27, 04:01:29- 04:01:52, 04:04:01- 04:05, 04:07-04:09N, 04:12 <sup>w</sup> , 04:13- 04:15:03, 04:17- 04:20, 04:23-04:35, 04:37-04:41, 04:43- 04:54, 04:56-04:70, 04:72-04:79, 04:81- 04:102, 04:104- 04:106, 04:108- 04:139, 04:141- 04:146,	*07:64



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			04:148-04:152	
<b>3</b>	145 bp	1070 bp	*04:01:01:01- 04:01:52, 04:04:01- 04:05, 04:08- 04:15:03, 04:17- 04:20, 04:23-04:26, 04:28-04:41, 04:43- 04:79, 04:81-04:86, 04:88N, 04:90- 04:102, 04:104- 04:106, 04:108- 04:139, 04:141- 04:146, 04:148- 04:152	
<b>4<sup>7</sup></b>	210 bp	1070 bp	*04:03:01-04:03:02, 04:06, 04:80, 04:107, 04:147	*02:12, 02:49, 02:55
<b>5<sup>7</sup></b>	250 bp	1070 bp	*04:04:01-04:04:02, 04:06, 04:13, 04:34, 04:58, 04:122	*01:22, 01:35, 02:03, 02:16:01- 02:16:02, 02:18, 05:11, 05:17, 05:27, 05:68, 05:79, 06:04, 08:01:01-08:01:10, 08:03:01- 08:04:03, 08:06, 08:08-08:11, 08:13- 08:14, 08:16:01-08:16:02, 08:20- 08:22, 08:24, 08:26N, 08:36N, 08:38-08:42, 08:44, 08:46, 08:50, 08:54, 08:56-08:61, 08:65-08:66, 08:72:01-08:72:02, 08:78, 12:14:01- 12:14:02, 12:18:01-12:18:02, 12:20, 12:83, 14:06, 14:15, 15:02:01-15:07, 15:09-15:13, 15:15-15:19, 15:21- 15:24, 15:26-15:50, 15:52-15:71, 16:35, 16:40, 16:48, 17:01:01-01- 17:16, 17:18-17:19
<b>6<sup>5,9</sup></b>	95 bp, 215 bp	1070 bp	*04:05, 04:112	*15:36
<b>7<sup>6</sup></b>	145 bp	1070 bp	*04:07, 04:27, 04:32, 04:77, 04:89	*03:34, 03:142, 05:78, 07:64, 14:25, 15:36, 18:03
<b>8</b>	270 bp	1070 bp	*04:08, 04:34, 04:147	*01:35, 02:58, 05:27, 05:39, 06:96, 08:41, 12:83, 14:20, 15:15, 17:07
<b>9<sup>5,10</sup></b>	110 bp, 180 bp, 220 bp	<b>800 bp</b>	*04:09N, 04:30, 04:35	
<b>10<sup>11</sup></b>	195 bp, 220 bp	1070 bp	*04:10-04:11, 04:31, 04:36, 04:55	*05:78, 15:36



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<b>11<sup>7</sup></b>	180 bp	1070 bp	*04:01:01:01- 04:01:09, 04:01:11- 04:01:22, 04:01:24- 04:01:52, 04:03:01- 04:10, 04:12-04:20, 04:23-04:26, 04:28- 04:32, 04:34-04:51, 04:53-04:54, 04:56- 04:106, 04:108- 04:115N, 04:117- 04:129, 04:131-04:152	*02:49, 05:25, 05:42, 06:05, 06:76:02, 07:02:09, 08:28, 12:28, 15:25, 15:62, 16:26, 16:46, 16:55
<b>12<sup>5,12</sup></b>	125 bp, 165 bp	1070 bp	*04:11, 04:29, 04:33, 04:36, 04:55	*07:125
<b>13<sup>13</sup></b>	225 bp, 270 bp	1070 bp	*04:12, 04:52, 04:55	
<b>14<sup>14</sup></b>	155 bp, 185 bp	1070 bp	*04:16, 04:18	
<b>15<sup>15</sup></b>	180 bp, 235 bp	1070 bp	*04:14, 04:28, 04:68, 04:144	*03:171, 05:93, 06:73, 08:20, 08:40, 16:45, <b>A*24:96, A*24:146</b>
<b>16<sup>5,16</sup></b>	85 bp, 130 bp	1070 bp	*04:15:01-04:15:03, 04:17, 04:37, 04:123N	*03:05, 03:13:01, 03:25, 03:27, 03:35, 03:135, 03:167, 08:01:07, 08:02:07, 08:33:02, 14:09, 14:45, 18:07N, <b>B*15:78:03</b>
<b>17</b>	320 bp	1070 bp	*04:17, 04:80, 04:100	*01:50
<b>18<sup>5,17</sup></b>	125 bp, 220 bp	1070 bp	*04:19, 04:70, 04:94:01-04:94:02	*06:101, 12:10:01-12:10:02, 18:03, <b>B*15:27:01-15:27:03, B*15:109</b>
<b>19<sup>5,18</sup></b>	120 bp, 155 bp	1070 bp	*04:20, 04:35, 04:37	*03:135, 14:45
<b>20<sup>19</sup></b>	165 bp, 250 bp, 545 bp	1070 bp	*04:15:02, 04:17, 04:44, 04:47, 04:100	*05:78, 15:36, <b>A*01:118, A*02:109,</b> <b>A*33:52</b>
<b>21<sup>5,20</sup></b>	85 bp, 145 bp, 240 bp	1070 bp	*04:23, 04:38-04:39, 04:108	
<b>22<sup>5,21</sup></b>	120 bp, 170 bp	1070 bp	*04:24, 04:26, 04:139-04:140	*07:125
<b>23<sup>5,22</sup></b>	85 bp, 145 bp, 225 bp	1070 bp	*04:25, 04:40-04:41, 04:144	*03:171, 05:93, 06:73, 08:20, 08:40
<b>24<sup>6</sup></b>	170 bp	1070 bp	*04:30, 04:42	*07:125
<b>25</b>	200 bp	1070 bp	*04:43, 04:94:01- 04:94:02	*06:101, 12:10:01-12:10:02, 18:03, <b>B*15:27:01-15:27:03, B*15:109</b>
<b>26<sup>7</sup></b>	215 bp	<b>800 bp</b>	*04:45	
<b>27<sup>5,23</sup></b>	125 bp, 280 bp	<b>800 bp</b>	*04:46, 04:50, 04:120	*05:64:01-05:64:02, 08:19



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28 <sup>5,24</sup>	120 bp, 215 bp	1070 bp	*04:48, 04:75	
29 <sup>5,25</sup>	105 bp, 185 bp	1070 bp	*04:49, 04:82	
30 <sup>5</sup>	75 bp	1070 bp	*04:53	*05:49, <b>B*07:90</b>
31 <sup>6,26</sup>	130 bp, 180 bp	1070 bp	*04:51, 04:95N, 04:139	
32 <sup>5,27</sup>	105 bp, 235 bp, 275 bp	1070 bp	*04:59Q, 04:77-04:78	<b>B*40:100</b>
33 <sup>5,28</sup>	80 bp, 180 bp	1070 bp	*04:58, 04:65, 04:72	*07:08, 07:108, <b>B*40:100</b>
34 <sup>5,29</sup>	75 bp, 200 bp, 275 bp	1070 bp	*04:13, 04:58, 04:61, 04:68, 04:96, 04:120	*05:64:01-05:64:02, 07:08, 07:108, 08:19
35 <sup>5,30</sup>	85 bp, 145 bp, 175 bp	1070 bp	*04:62, 04:76, 04:115N	
36 <sup>5</sup>	115 bp	1070 bp	*04:57, 04:63	
37 <sup>5,31</sup>	110 bp, 135 bp	1070 bp	*04:63, 04:73-04:74	
38 <sup>5,32</sup>	95 bp, 135 bp	1070 bp	*04:74, 04:83, 04:123N	*18:07N
39 <sup>33</sup>	135 bp, 330 bp	1070 bp	*04:71, 04:79, 04:95N	*01:21
40 <sup>34</sup>	140 bp, 270 bp	<b>800 bp</b>	*04:56, 04:64:01- 04:64:02	
41 <sup>6,35</sup>	135 bp, 280 bp	1070 bp	*04:54, 04:105N	*01:04, 01:54, 14:02:01-14:24:01, 14:25, 14:27-14:52
42 <sup>5</sup>	95 bp	1070 bp	*04:69, 04:82	*16:12
43 <sup>7,36</sup>	145 bp, 170 bp, 260 bp	1070 bp	*04:81, 04:88N, 04:115N	
44 <sup>5,37</sup>	90 bp, 135 bp	1070 bp	*04:60, 04:108	*03:81, 03:175, <b>B*15:78:03</b>
45 <sup>38</sup>	135 bp, 165 bp	1070 bp	*04:16, 04:26, 04:66, 04:103	
46 <sup>5,39</sup>	125 bp, 300 bp	1070 bp	*04:67, 04:93N	
47 <sup>5,7,40</sup>	50 bp, 295 bp	<b>800 bp</b>	*04:114, 04:146	*01:59, 02:65, 03:130, 03:140, 05:20, 06:82, 07:49, 07:210, 07:238, 07:247, 12:54, 14:04, 16:57, <b>A*68:46</b>
48 <sup>41</sup>	155 bp, 240 bp	<b>800 bp</b>	*04:84, 04:106	*07:167, 08:78

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### Lot-specific information

<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\*04 SSP typings.

When the primers in a primer mix can give rise to HLA-specific PCR products of more than one length this is indicated if the size difference is more than 20 base pairs. Size differences of 20 base pairs or less are not given. For high resolution SSP kits the respective lengths of the HLA-specific PCR product(s) are given for the alleles amplified by these primer mixes.

Nonspecific amplifications, i.e. a ladder or a smear of bands, may sometimes be seen. GC-rich primers have a higher tendency of giving rise to nonspecific amplifications than other primers.

PCR fragments longer than the control bands may sometimes be observed. Such bands should be disregarded and do not influence the interpretation of the SSP typings.

PCR fragments migrating faster than the control bands, but slower than a 400 bp fragment may be seen in some gel read-outs. Such bands can be disregarded and do not influence the interpretation of the SSP typings.

Some primers may give rise to primer oligomer artifacts. Sometimes this phenomenon is an inherit feature of the primer pair(s) of a primer mix. More often it is due to other factors such as too low amount of DNA in the PCR reactions, taking too long time in setting up the PCR reactions, working at elevated room temperature or using thermal cyclers that are not pre-heated.

<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\*04 subtyping.

In addition, wells number 9, 26, 27, 40, 47 and 48 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>For several HLA Class I alleles 1<sup>st</sup> and/or 4<sup>th</sup> exon(s) and beyond, as well as intron nucleotide sequences, are not available. In these instances it is not known whether some of the primers of the SSP sets are completely matched with the target sequences or not. We assume that unknown sequences in these regions are conserved within allelic groups.

<sup>4</sup>Due to the sharing of sequence motifs between HLA-C alleles non-HLA-C\*04 alleles will be amplified by primer mixes 1, 2, 4 to 8, 10 to 12, 15 to 20, 22 to 25, 27, 30, 33, 34, 38, 39, 41, 42, 44, 47 and 48. In addition, the A\*01:118, A\*02:109 and A\*33:52 alleles will be amplified by primer mix 20, the A\*24:96 and A\*24:146 alleles will be amplified by primer mix 15, the A\*68:46 allele will be amplified by primer mix 47, the B\*07:90 allele will be amplified by primer mix 30, the B\*15:27:01-15:27:03 and 15:109 alleles will be amplified by primer mixes 18 and 25, the B\*15:78:03 allele will be amplified by primer mixes 16 and 44 and the B\*40:100 allele will be amplified by primer mixes 32 and 33.

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

<sup>6</sup>Primer mixes 7, 24, 31 and 41 have a tendency to giving rise to primer oligomer formation.

<sup>7</sup>Primer mixes 1, 4, 5, 11, 26, 43 and 47 may have tendencies of unspecific amplification.

<sup>8</sup>Primer mix, 28 may give rise to a long unspecific amplification product of approximately 500 bp. This should be disregarded when interpreting the C\*04 typings.

<sup>9</sup>Primer mix 6: Specific PCR fragment of 95 bp in the C\*04:05 allele. Specific PCR fragment of 215 bp in the C\*04:112 and the C\*15:36 allele.

<sup>10</sup>Primer mix 9: Specific PCR fragment of 110 bp in the C\*04:35 allele. Specific PCR fragment of 180 bp in the C\*04:30 allele. Specific PCR fragment of 220 bp in the C\*04:09N allele.

<sup>11</sup>Primer mix 10: Specific PCR fragment of 195 bp in the C\*04:31 allele. Specific PCR fragment of 220 bp in the C\*04:10-04:11, 04:36 and 04:55 and the C\*05:78 and 15:36 alleles.

<sup>12</sup>Primer mix 12: Specific PCR fragment of 125 bp in the C\*04:29, 04:36 and 04:55 and the C\*07:125 alleles. Specific PCR fragment of 165 bp in the C\*04:33 allele. Specific PCR fragment of 125 and 165 bp in the C\*04:11 allele.

<sup>13</sup>Primer mix 13: Specific PCR fragment of 225 bp in the C\*04:12 allele. Specific PCR fragment of 270 bp in the C\*04:52 and 04:55 alleles.

<sup>14</sup>Primer mix 14: Specific PCR fragment of 155 bp in the C\*04:16 allele. Specific PCR fragment of 185 bp in the C\*04:18 allele.

**101.612-12 – including Taq pol., IFU-01**  
**101.612-12u– without Taq pol., IFU-02**

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## Lot No.: 86S

### Lot-specific information

- <sup>15</sup>Primer mix 15: Specific PCR fragment of 180 bp in the C\*04:14, 04:28 and 04:68 and the C\*16:45 and in the A\*24:96 and A\*24:146 alleles. Specific PCR fragment of 235 bp in the C\*04:144 and the C\*03:171, 05:93, 06:73, 08:20 and 08:40 alleles.
- <sup>16</sup>Primer mix 16: Specific PCR fragment of 85 bp in the C\*04:123N and the C\*18:07N allele. Specific PCR fragment of 130 bp in the C\*04:15:01-04:15:03, 04:17 and 04:37 and the C\*03:05, 03:13:01, 03:25, 03:27, 03:35, 03:135, 03:167, 08:01:07, 08:02:07, 08:33:02, 14:09 and 14:45 and in the B\*15:78:03 alleles.
- <sup>17</sup>Primer mix 18: Specific PCR fragment of 125 bp in the C\*04:70 allele. Specific PCR fragment of 220 bp in the C\*04:19 and 04:94:01-04:94:02 and the C\*06:101, 12:10:01-12:10:02 and 18:03 and in the B\*15:27:01-15:27:03 and B\*15:109 alleles.
- <sup>18</sup>Primer mix 19: Specific PCR fragment of 120 bp in the C\*04:35 and 04:37 and the C\*14:45 alleles. Specific PCR fragment of 155 bp in the C\*04:20 and the C\*03:135 alleles.
- <sup>19</sup>Primer mix 20: Specific PCR fragment of 165 bp in the C\*04:44 allele. Specific PCR fragment of 250 bp in the C\*04:47 allele. Specific PCR fragment of 545 bp in the C\*04:15:02, 04:17 and 04:100 and in the C\*05:78 and 15:36 and in the A\*01:118, A\*02:109 and A\*33:52 alleles.
- <sup>20</sup>Primer mix 21: Specific PCR fragment of 85 bp in the C\*04:23 and 04:108 alleles. Specific PCR fragment of 145 bp in the C\*04:38 allele. Specific PCR fragment of 240 bp in the C\*04:39 allele.
- <sup>21</sup>Primer mix 22: Specific PCR fragment of 120 bp in the C\*04:24, 04:139 and 04:140 and the C\*07:125 alleles. Specific PCR fragment of 170 bp in the C\*04:26 allele.
- <sup>22</sup>Primer mix 23: Specific PCR fragment of 85 bp in the C\*04:25 allele. Specific PCR fragment of 145 bp in the C\*04:40 allele. Specific PCR fragment of 225 bp in the C\*04:41, 04:144 and the C\*03:171, 05:93, 06:73, 08:20 and 08:40 alleles.
- <sup>23</sup>Primer mix 27: Specific PCR fragment of 125 bp in the C\*04:50 allele. Specific PCR fragment of 280 bp in the C\*04:46 and 04:120 and the C\*05:64:01-05:64:02 and 08:19 alleles.
- <sup>24</sup>Primer mix 28: Specific PCR fragment of 120 bp in the C\*04:75 allele. Specific PCR fragment of 215 bp in the C\*04:48 allele.
- <sup>25</sup>Primer mix 29: Specific PCR fragment of 105 bp in the C\*04:82 allele. Specific PCR fragment of 185 bp in the C\*04:49 allele.
- <sup>26</sup>Primer mix 31: Specific PCR fragment of 130 bp in the C\*04:95N and 04:139 alleles. Specific PCR fragment of 180 bp in the C\*04:51 allele.
- <sup>27</sup>Primer mix 32: Specific PCR fragment of 105 bp in the C\*04:78 allele. Specific PCR fragment of 235 bp in the C\*04:59Q allele. Specific PCR fragment of 275 bp in the C\*04:77 and in the B\*40:100 alleles.
- <sup>28</sup>Primer mix 33: Specific PCR fragment of 80 bp in the C\*04:72 allele. Specific PCR fragment of 180 bp in the C\*04:58 and 04:65 and the C\*07:08 and 07:108 and in the B\*40:100 alleles.
- <sup>29</sup>Primer mix 34: Specific PCR fragment of 75 bp in the C\*04:96 allele. Specific PCR fragment of 200 bp in the C\*04:13, 04:58, 04:61 and 04:68 and the C\*07:08 and 07:108 alleles. Specific PCR fragment of 275 bp in the C\*04:120 and the C\*05:64:01-05:64:02 and 08:19 alleles.
- <sup>30</sup>Primer mix 35: Specific PCR fragment of 85 bp in the C\*04:62 allele. Specific PCR fragment of 145 bp in the C\*04:115N allele. Specific PCR fragment of 175 bp in the C\*04:76 allele.
- <sup>31</sup>Primer mix 37: Specific PCR fragment of 110 bp in the C\*04:63 and 04:73 alleles. Specific PCR fragment of 135 bp in the C\*04:74 allele.
- <sup>32</sup>Primer mix 38: Specific PCR fragment of 95 bp in the C\*04:83 and 04:123N and the C\*18:07N alleles. Specific PCR fragment of 135 bp in the C\*04:74 allele.
- <sup>33</sup>Primer mix 39: Specific PCR fragment of 135 bp in the C\*04:71 and 04:95N and the C\*01:21 alleles. Specific PCR fragment of 330 bp in the C\*04:79 allele.
- <sup>34</sup>Primer mix 40: Specific PCR fragment of 140 bp in the C\*04:56 allele. Specific PCR fragment of 270 bp in the C\*04:64:01-04:64:02 alleles.
- <sup>35</sup>Primer mix 41: Specific PCR fragment of 135 bp in the C\*04:105N allele. Specific PCR fragment of 280 bp in the C\*04:54 and the C\*01:04, 01:54, 14:02:01-14:24:01, 14:25 and 14:27-14:52 alleles.
- <sup>36</sup>Primer mix 43: Specific PCR fragment of 145 bp in the C\*04:115N allele. Specific PCR fragment of 170 bp in the C\*04:81 allele. Specific PCR fragment of 260 bp in the C\*04:88N allele.
- <sup>37</sup>Primer mix 44: Specific PCR fragment of 90 bp in the C\*04:108 and in the C\*03:81, 03:175 and in the B\*15:78:03 alleles. Specific PCR fragment of 135 bp in the C\*04:60 allele.
- <sup>38</sup>Primer mix 45: Specific PCR fragment of 135 bp in the C\*04:66 allele. Specific PCR fragment of 165 bp in the C\*04:16, 04:26 and 04:103 alleles.



**101.612-12 – including *Taq pol.*, IFU-01**  
**101.612-12u– without *Taq pol.*, IFU-02**

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**Lot No.: 86S****Lot-specific information**

<sup>39</sup>Primer mix 46: Specific PCR fragment of 125 bp in the C\*04:93N allele. Specific PCR fragment of 300 bp in the C\*04:67 allele.

<sup>40</sup>Primer mix 47: Specific PCR fragment of 50 bp in the C\*04:114 and the C\*01:59, 02:65, 03:130, 03:140, 05:20, 06:82, 07:49, 07:210, 07:238, 07:247, 12:54, 14:04, 16:57 and in the A\*68:46 alleles. Specific PCR fragment of 295 bp in the C \*04:146 allele.

<sup>41</sup>Primer mix 48: Specific PCR fragment of 155 bp in the C\*04:84 and the C\*07:167 alleles. Specific PCR fragment of 240 bp in the C\*04:106 and the C\*08:78 allele.

‘w’, may be weakly amplified.



















101.612-12 – including *Taq pol.*, IFU-01  
 101.612-12u– without *Taq pol.*, IFU-02

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## Lot No.: 86S

## Lot-specific information

Length of spec.	250	220	145	210	250	215	95	145	270	220	180	110	220	195	180	165	125	270	225	185	155	235	180	130	85	320	220	125	155	120	545	250	165	240	145	85	225	145	85	170
PCR product(s)																																								
Well No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24																
*01:02:01-01:03, 01:05-01:20, 01:23-01:34, 01:36-01:49, 01:51-01:53, 01:55-01:58, 01:60-01:78, 02:02:01-02:02:03, 02:02:05-02:02:26, 02:04-02:11, 02:13-02:15, 02:17, 02:19-02:40, 02:42-02:48, 02:50-02:54, 02:56-02:57, 02:59-02:64, 02:66-02:68, 05:01:01:01-05:01:27, 05:03-05:10, 05:12-05:16, 05:18:01-05:19, 05:21-05:24, 05:26, 05:28-05:38, 05:40-05:41, 05:43-05:48N, 05:50, 05:52-05:61, 05:63, 05:65-05:67, 05:69, 05:71-05:77, 05:80-05:92N, 05:94, 06:02:01:01-06:02:01:02, 06:02:03-06:03:02, 06:06-08:33:01, 08:33:03-06:39, 06:41-06:72, 06:74Q-06:76:01, 06:77-06:78, 06:80-06:81, 06:83-06:95, 06:97-06:100, 06:102, 08:02:01-08:02:06, 08:02:08-08:02:10, 08:05, 08:07, 08:12, 08:15:01-08:15:02, 08:17-08:18, 08:23, 08:25, 08:27, 08:29-08:35, 08:37, 08:43, 08:45, 08:47-08:49, 08:51-08:53, 08:55N, 08:62-08:63, 08:67-08:71, 08:73-08:77, 12:02:01-12:09, 12:11-12:13, 12:15-12:17, 12:21-12:27, 12:29-12:53, 12:55-12:82, 12:84N-12:99, 14:24:02, 14:26, 15:08, 16:04:01, 16:29, 16:33, 16:42, 16:53, 17:17, 18:01-18:02, 18:04-18:06	1																																							
*01:04, 01:54, 14:02:01-14:03, 14:05, 14:07N-14:08, 14:10-14:14, 14:16-14:19, 14:21N-14:24:01, 14:27-14:44, 14:46-14:52	1																																							
Well No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24																













101.612-12 – including *Taq pol.*, IFU-01  
101.612-12u– without *Taq pol.*, IFU-02

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**Lot No.: 86S****Lot-specific information**

- <sup>9</sup>The C\*04:44 and C\*04:47 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 20.
- <sup>10</sup>The C\*04:23, C\*04:38 and C\*04:39 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 21.
- <sup>11</sup>The C\*04:25, C\*04:40 and C\*04:41 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 23.
- <sup>12</sup>The C\*04:46 and C\*04:50 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 27.
- <sup>13</sup>The C\*04:48 and C\*04:75 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 28.
- <sup>14</sup>The C\*04:54 and C\*04:105N alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 41.
- <sup>15</sup>The C\*04:56 and C\*04:64:01-04:64:02 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 40.
- <sup>16</sup>The C\*04:59Q and C\*04:78 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 32.
- <sup>17</sup>The C\*04:61 and C\*04:96 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 34.
- <sup>18</sup>The C\*04:62 and C\*04:76 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 35.
- <sup>19</sup>The C\*04:65 and C\*04:72 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 33.
- <sup>20</sup>The C\*04:67 and C\*04:93N alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 46.
- <sup>21</sup>The C\*04:81 and C\*04:88N alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 43.
- <sup>22</sup>The C\*04:84 and C\*04:106 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 48.
- <sup>23</sup>The C\*04:114 and 04:146 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 47.
- <sup>24</sup>Primer mix 6: Specific PCR fragment of 95 bp in the C\*04:05 allele. Specific PCR fragment of 215 bp in the C\*04:112 and the C\*15:36 allele.  
Primer mix 9: Specific PCR fragment of 110 bp in the C\*04:35 allele. Specific PCR fragment of 180 bp in the C\*04:30 allele. Specific PCR fragment of 220 bp in the C\*04:09N allele.  
Primer mix 10: Specific PCR fragment of 195 bp in the C\*04:31 allele. Specific PCR fragment of 220 bp in the C\*04:10-04:11, 04:36 and 04:55 and the C\*05:78 and 15:36 alleles.  
Primer mix 12: Specific PCR fragment of 125 bp in the C\*04:29, 04:36 and 04:55 and the C\*07:125 alleles. Specific PCR fragment of 165 bp in the C\*04:33 allele. Specific PCR fragment of 125 and 165 bp in the C\*04:11 allele.  
Primer mix 13: Specific PCR fragment of 225 bp in the C\*04:12 allele. Specific PCR fragment of 270 bp in the C\*04:52 and 04:55 alleles.  
Primer mix 14: Specific PCR fragment of 155 bp in the C\*04:16 allele. Specific PCR fragment of 185 bp in the C\*04:18 allele.  
Primer mix 15: Specific PCR fragment of 180 bp in the C\*04:14, 04:28 and 04:68 and the C\*16:45 and in the A\*24:96 and 24:146 alleles. Specific PCR fragment of 235 bp in the C\*04:144 and the C\*03:171, 05:93, 06:73, 08:20 and 08:40 alleles.  
Primer mix 16: Specific PCR fragment of 85 bp in the C\*04:123N and the C\*18:07N allele. Specific PCR fragment of 130 bp in the C\*04:15:01-04:15:03, 04:17 and 04:37 and the C\*03:05, 03:13:01, 03:25, 03:27, 03:35, 03:135, 03:167, 08:01:07, 08:02:07, 08:33:02, 14:09 and 14:45 and in the B\*15:78:03 alleles.  
Primer mix 18: Specific PCR fragment of 125 bp in the C\*04:70 allele. Specific PCR fragment of 220 bp in the C\*04:19 and 04:94:01-04:94:02 and the C\*06:101, 12:10:01-12:10:02 and 18:03 and in the B\*15:27:01-15:27:03 and B\*15:109 alleles.  
Primer mix 19: Specific PCR fragment of 120 bp in the C\*04:35 and 04:37 and the C\*14:45 alleles. Specific PCR fragment of 155 bp in the C\*04:20 and the C\*03:135 alleles.

**101.612-12 – including *Taq pol.*, IFU-01**  
**101.612-12u– without *Taq pol.*, IFU-02**

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**Lot No.: 86S****Lot-specific information**

Primer mix 20: Specific PCR fragment of 165 bp in the C\*04:44 allele. Specific PCR fragment of 250 bp in the C\*04:47 allele. Specific PCR fragment of 545 bp in the C\*04:15:02, 04:17 and 04:100 and in the C\*05:78 and 15:36 and in the A\*01:118, A\*02:109 and A\*33:52 alleles.

Primer mix 21: Specific PCR fragment of 85 bp in the C\*04:23 and 04:108 alleles. Specific PCR fragment of 145 bp in the C\*04:38 allele. Specific PCR fragment of 240 bp in the C\*04:39 allele.

Primer mix 22: Specific PCR fragment of 120 bp in the C\*04:24, 04:139 and 04:140 and the C\*07:125 alleles. Specific PCR fragment of 170 bp in the C\*04:26 allele.

Primer mix 23: Specific PCR fragment of 85 bp in the C\*04:25 allele. Specific PCR fragment of 145 bp in the C\*04:40 allele. Specific PCR fragment of 225 bp in the C\*04:41, 04:144 and the C\*03:171, 05:93, 06:73, 08:20 and 08:40 alleles.

Primer mix 27: Specific PCR fragment of 125 bp in the C\*04:50 allele. Specific PCR fragment of 280 bp in the C\*04:46 and 04:120 and the C\*05:64:01-05:64:02 and 08:19 alleles.

Primer mix 28: Specific PCR fragment of 120 bp in the C\*04:75 allele. Specific PCR fragment of 215 bp in the C\*04:48 allele.

Primer mix 29: Specific PCR fragment of 105 bp in the C\*04:82 allele. Specific PCR fragment of 185 bp in the C\*04:49 allele.

Primer mix 31: Specific PCR fragment of 130 bp in the C\*04:95N and 04:139 alleles. Specific PCR fragment of 180 bp in the C\*04:51 allele.

Primer mix 32: Specific PCR fragment of 105 bp in the C\*04:78 allele. Specific PCR fragment of 235 bp in the C\*04:59Q allele. Specific PCR fragment of 275 bp in the C\*04:77 and in the B\*40:100 alleles.

Primer mix 33: Specific PCR fragment of 80 bp in the C\*04:72 allele. Specific PCR fragment of 180 bp in the C\*04:58 and 04:65 and the C\*07:08 and 07:108 and in the B\*40:100 alleles.

Primer mix 34: Specific PCR fragment of 75 bp in the C\*04:96 allele. Specific PCR fragment of 200 bp in the C\*04:13, 04:58, 04:61 and 04:68 and the C\*07:08 and 07:108 alleles. Specific PCR fragment of 275 bp in the C\*04:120 and the C\*05:64:01-05:64:02 and 08:19 alleles.

Primer mix 35: Specific PCR fragment of 85 bp in the C\*04:62 allele. Specific PCR fragment of 145 bp in the C\*04:115N allele. Specific PCR fragment of 175 bp in the C\*04:76 allele.

Primer mix 37: Specific PCR fragment of 110 bp in the C\*04:63 and 04:73 alleles. Specific PCR fragment of 135 bp in the C\*04:74 allele.

Primer mix 38: Specific PCR fragment of 95 bp in the C\*04:83 and 04:123N and the C\*18:07N alleles. Specific PCR fragment of 135 bp in the C\*04:74 allele.

Primer mix 39: Specific PCR fragment of 135 bp in the C\*04:71 and 04:95N and the C\*01:21 alleles. Specific PCR fragment of 330 bp in the C\*04:79 allele.

Primer mix 40: Specific PCR fragment of 140 bp in the C\*04:56 allele. Specific PCR fragment of 270 bp in the C\*04:64:01-04:64:02 alleles.

Primer mix 41: Specific PCR fragment of 135 bp in the C\*04:105N allele. Specific PCR fragment of 280 bp in the C\*04:54 and the C\*01:04, 01:54, 14:02:01-14:24:01, 14:25 and 14:27-14:52 alleles.

Primer mix 43: Specific PCR fragment of 145 bp in the C\*04:115N allele. Specific PCR fragment of 170 bp in the C\*04:81 allele. Specific PCR fragment of 260 bp in the C\*04:88N allele.

Primer mix 44: Specific PCR fragment of 90 bp in the C\*04:108 and in the C\*03:81, 03:175 and in the B\*15:78:03 alleles. Specific PCR fragment of 135 bp in the C\*04:60 allele.

Primer mix 45: Specific PCR fragment of 135 bp in the C\*04:66 allele. Specific PCR fragment of 165 bp in the C\*04:16, 04:26 and 04:103 alleles.

Primer mix 46: Specific PCR fragment of 125 bp in the C\*04:93N allele. Specific PCR fragment of 300 bp in the C\*04:67 allele.

Primer mix 47: Specific PCR fragment of 50 bp in the C\*04:114 and the C\*01:59, 02:65, 03:130, 03:140, 05:20, 06:82, 07:49, 07:210, 07:238, 07:247, 12:54, 14:04, 16:57 and in the A\*68:46 alleles. Specific PCR fragment of 295 bp in the C\*04:146 allele.

Primer mix 48: Specific PCR fragment of 155 bp in the C\*04:84 and the C\*07:167 alleles. Specific PCR fragment of 240 bp in the C\*04:106 and the C\*08:78 allele.  
‘w’, may be weakly amplified.









101.612-12 – including *Taq* pol., IFU-01  
 101.612-12u – without *Taq* pol., IFU-02

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Lot No.: 86S

Lot-specific information  
**CERTIFICATE OF ANALYSIS**

**Olerup SSP® HLA-C\*04 SSP**

<b>Product number:</b>	101.612-12 – including <i>Taq</i> polymerase
	101.612-12u – without <i>Taq</i> polymerase
<b>Lot number:</b>	86S
<b>Expiry date:</b>	2016-May-01
<b>Number of tests:</b>	12
<b>Number of wells per test:</b>	48

**Well specifications:**

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2013-247-01	17	2013-247-17	33	2013-247-33
2	2013-247-02	18	2013-247-18	34	2013-247-34
3	2013-247-03	19	2013-247-19	35	2013-247-35
4	2013-247-04	20	2013-247-20	36	2013-247-36
5	2013-247-05	21	2013-247-21	37	2013-247-37
6	2013-247-06	22	2013-247-22	38	2013-247-38
7	2013-247-07	23	2013-247-23	39	2013-247-39
8	2013-247-08	24	2013-247-24	40	2013-247-40
9	2013-247-09	25	2013-247-25	41	2013-247-41
10	2013-247-10	26	2013-247-26	42	2013-247-42
11	2013-247-11	27	2013-247-27	43	2013-247-43
12	2013-247-12	28	2013-247-28	44	2013-247-44
13	2013-247-13	29	2013-247-29	45	2013-247-45
14	2013-247-14	30	2013-247-30	46	2013-247-46
15	2013-247-15	31	2013-247-31	47	2013-247-47
16	2013-247-16	32	2013-247-32	48	2013-247-48

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

No DNAs carrying the alleles to be amplified by primer solutions 6, 8, 10, 12 to 15, 17, 19 to 24, 26 to 40 and 42 to 48 were available. The specificity of the primers in primer solutions 6, 8, 10, 12 to 15, 17, 19 to 22, 24, 27, 28, 31 to 34, 39, 42, 44, 45, 47 and 48 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer. In primer solutions 26, 29, 35, 40 and 43 it was only possible to test the 5'-primers, the 3'-primers were not possible to test. In primer solutions 23, 30, 36 to 38 and 46 it was only possible to test the 3'-primers, the 5'-primers were not possible to test. In primer solutions 9, 15, 16, 18, 19, 22, 28, 31, 41, 44 and 45 one, two or three of the 5'-primers were not possible to test, and in primer solutions 3, 4, 6, 9, 10, 13, 14, 18, 20, 21, 24, 25, 27, 28, 31 to 34, 39, 42, 47 and 48 one or two of the 3'-primers were not possible to test. Additional primers in primer solutions 7, 9, 16, 18 and 41 were tested by separately adding one 5'-primer and/or one 3'-primer.



101.612-12 – including *Taq pol.*, IFU-01  
101.612-12u– without *Taq pol.*, IFU-02

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**Lot No.: 86S**

**Lot-specific information**

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

**Date of approval:** 2013-November-15

**Approved by:**

**Production Quality Control**

101.612-12 – including *Taq pol.*, IFU-01  
101.612-12u– without *Taq pol.*, IFU-02

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**Lot No.: 86S**

**Lot-specific information**  
**Declaration of Conformity**

**Product name:** Olerup SSP® HLA-C\*04

**Product number:** 101.612-12/12u

**Lot number:** 86S

**Intended use:** HLA-C\*04 high resolution histocompatibility testing

**Manufacturer:** Olerup SSP AB  
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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 13485:2012, following the provisions of the 98/79/EC Directive on *in vitro* diagnostic medical devices, Annex III, as transposed into the national laws of the Member States of the European Union.

The Technical Documentation File is maintained at Olerup SSP AB,  
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The Authorized Representative located within the Community is: Olerup SSP AB.

Stockholm, Sweden

Daniel Malica  
Head of QA and Regulatory Affairs

101.612-12 – including *Taq pol.*, IFU-01  
101.612-12u– without *Taq pol.*, IFU-02

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

**Lot No.: 86S**

Lot-specific information

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