HLA-C\*08 Product Insert Page 1 of 20

101.623-12 – including *Taq* polymerase

General "Instructions for Use" IFU-01 Rev. No. 01 can be downloaded from

Lot No.: 41K Lot-specific information www.olerup-ssp.com

## Olerup SSP® HLA-C\*08

Product number: 101.623-12 – including *Taq* polymerase

Lot number: 41K

Expiry date: 2012-September-01

Number of tests: 12 Number of wells per test: 23

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

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

## This Product Description is only valid for Lot No. 41K.

# CHANGES COMPARED TO THE PREVIOUS OLERUP SSP® HLA-C\*08 LOT

The HLA-C\*08 specificity and interpretation tables have been updated for the HLA-C alleles described since the previous *Olerup* SSP® HLA-C\*08 lot was made (Lot No. 79F).

Seven wells have been added to the HLA-C\*08 kit, wells **17 to 23**. The amplification patterns for some rare HLA-C\*08 alleles only differ by the length of the specific PCR products.

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

Well	5'-primer	3'-primer	rationale
6	-	-	Exchanged positive control primer pair.
8	Added	-	Primer added for the C*08:34 allele.
9	Added	Added	Primer pair added for the C*08:24 allele.
13	Exchanged	-	Improved specificity of primer pair.
16	-	Added	Increased yield of specific PCR product.
17	New	New	New primer pairs for the C*08:25 and C*08:28
			alleles.
18	New	New	New primer pairs for the C*08:26N and
			C*08:31 alleles.
19	New	New	New primer pairs for the C*08:29, C*08:30 and
			C*08:32 alleles.
20	New	New	New primer pair for the C*08:35 allele.
21	New	New	New primer pair for the C*08:27 allele.
22	New	New	New primer pair for the C*08:33 allele.
23	New	New	New primer pair for the C*08:36N allele.

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## PRODUCT DESCRIPTION

## **HLA-C\*08 SSP typing**

#### CONTENT

The primer set contains 5'- and 3'-primers for identifying the C\*08:01 to C\*08:36N alleles.

#### PLATE LAYOUT

Each HLA-C\*08 test consists of 23 PCR reactions in a 24 well cut PCR plate. Well 24 is empty.

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

The 24 well PCR plate is marked with 'HLA-C\*08' in silver/gray ink.

Well No. 1 is marked with the Lot No. '41K'.

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

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

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

#### INTERPRETATION

The interpretation of HLA-C\*08 SSP subtypings will be influenced by other HLA-C alleles, as primer mixes 1, 3, 5, 7, 8, 11 to 13, 15 to 17 and 19 to 22 amplify non-HLA-C\*08 alleles. In addition, primer mix 1 will amplify the B\*58:02 allele, primer mix 5 will amplify the B\*15:33 allele and primer mix 16 will amplify the B\*67:02 allele.

#### UNIQUELY IDENTIFIED ALLELES

All the HLA-C\*08 alleles, i.e. **C\*08:01 to C\*08:36N**, recognized by the HLA Nomenclature Committee in July 2010<sup>1</sup> will be amplified by the primers in the HLA-C\*08 SSP kit.

The HLA-C\*08 subtyping kit cannot distinguish the C\*08:01:01-08:01:02 alleles, the 08:02:01-08:02:04 alleles or the 08:03:01-08:03:02 alleles.

The HLA-C\*08 subtyping kit cannot separate the C\*08:15 and C\*07:148 alleles. These two alleles can be distinguished by the HLA-C low resolution and/or HLA-C\*07 kits.

The C\*08:30 and C\*08:32 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 19.

<sup>1</sup>HLA-B alleles listed on the IMGT/HLA web page 2009-May-09, release 2.25.2, www.ebi.ac.uk/imgt/hla.

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

A total of 41 alleles generate 35 amplification patterns that can be combined in 630 homozygous and heterozygous combinations. 236 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.

```
++++-+-- ---++--- *08:02:01, *08:06 = *08:03:01, *08:23 = *08:06, *08:23
++++-+-- *08:06, *08:27 = *08:06, *08:29
++++---- *08:14, *08:27 = *08:14, *08:29
++++---- *08:03:01, *08:27 = *08:03:01, *08:29
+++-+-- *08:05, *08:11 = *08:21, *08:34

++--- +--+-- *08:05, *08:10 = *08:05, *08:24

++--- +--+-- *08:05, *08:20 = *08:12, *08:24
+++-+-- *08:05, *08:08 = *08:18, *08:21
+++-+-- ---++-+- +---+- *08:05, *08:16 = *08:19, *08:21 = *08:21, *08:25
+++-+-- ---- +---+--- *08:01:01, *08:05 = *08:02:01, *08:21 = *08:05, *08:21 = *08:21, *08:28
+++-+-- ---- +-+--- *08:21, *08:27 = *08:21, *08:29
+++--+-- +--++--- *08:10, *08:23 = *08:23, *08:24
+++---+ +--++--- *08:07, *08:10 = *08:07, *08:24
+++---+ +--++--- *08:10, *08:34 = *08:24, *08:34
+++---+ -+-++--- *08:02:01, *08:09 = *08:09, *08:17 = *08:09, *08:34 = *08:11, *08:17
+++---+ --+++--- *08:11, *08:12 = *08:20, *08:34
+++---+ ---+++-- ---+-- *08:08, *08:34 = *08:11, *08:18
+++---+ ---++-+- *08:11, *08:19 = *08:16, *08:34
+++---+ ---++--- *08:01:01, *08:34 = *08:02:01, *08:11 = *08:11, *08:34
+++---+ ---+--- *08:11, *08:27 = *08:11, *08:29
+++---- ++-++-- *08:10. *08:17 = *08:17. *08:24
+++---- +-+++--- *08:10, *08:12 = *08:12, *08:24
+++---- +--++-+- ----+- *08:10, *08:19 = *08:19, *08:24
+++---- +--++--- +---+-- *08:10, *08:28 = *08:24, *08:28
+++---- +--++-- *08:10, *08:30 = *08:24, *08:30
+++---- +--++-- *08:10, *08:35 = *08:24, *08:35
+++---- +--++-- *08:10, *08:33 = *08:24, *08:33
+++---- +--++--- *08:02:01, *08:10 = *08:02:01, *08:24
+++---- +--+-- -++-+-- *08:10, *08:31 = *08:24, *08:31
+++---- +--+--- *08:10, *08:27 = *08:10, *08:29 = *08:24, *08:27 = *08:24, *08:29 

+++---- +--+--- *08:04, *08:10 = *08:04, *08:24 

+++---- +-+++-- ---+-- *08:04, *08:12 = *08:18, *08:20
+++---- *08:12, *08:16 = *08:19, *08:20
+++---- --+++--- *08:01:01, *08:12 = *08:02:01, *08:20 = *08:12, *08:20
+++---- *08:20, *08:27 = *08:20, *08:29
+++---- *08:01:01, *08:18 = *08:02:01, *08:08 = *08:08, *08:18

+++---- *08:01:01, *08:18 = *08:02:01, *08:08 = *08:08, *08:18

++---- *08:01:01, *08:25 = *08:16, *08:28

++---- *08:01:01, *08:19 = *08:02:01, *08:16 = *08:16, *08:19
+++---- *08:08, *08:27 = *08:08, *08:29
+++---- *08:16, *08:27 = *08:16, *08:29
+++---- *08:01:01, *08:13 = *08:04, *08:16
+++---- *08:22, *08:27 = *08:22, *08:29
+++---- ---+-+-+ *08:27, *08:36N = *08:29, *08:36N
+++---- *08:01:01, *08:27 = *08:01:01, *08:29
++-+-- +--+-- *08:06, *08:10 = *08:06, *08:24
++-+-- *08:06, *08:14 = *08:06, *08:22
++-+-- ---- *08:01:01, *08:06 = *08:03:01, *08:06 = *08:06, *08:06
++-+--- +--+--- *08:10, *08:14 = *08:14, *08:24
++-+--- +--+-- *08:03:01, *08:10 = *08:03:01, *08:24
++-+--- *08:01:01, *08:14 = *08:03:01, *08:14 = *08:03:01, *08:22 = *08:14, *08:14 =
                              *08:14, *08:22
++-+--- *08:01:01, *08:03:01 = *08:03:01, *08:03:01
++--+-- +--+-- +--+-- *08:10, *08:21 = *08:21, *08:24
++--+-- +--+--- *08:10, *08:15 = *08:15, *08:24
++--+-- +---+-- +---+-- *08:01:01, *08:21 = *08:15, *08:21 = *08:21, *08:21
++----+ ++-+---- *08:09, *08:10 = *08:09, *08:24
```

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```
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                                                      www.olerup-ssp.com
++----+ +--+--- *08:10, *08:11 = *08:11, *08:24
++----+ -+-+--- *08:01:01, *08:09 = *08:09, *08:09 = *08:09, *08:11
++----+ **--+--- *08:01:01, *08:11 = *08:11, *08:11
++---- +-++--- *08:10, *08:20 = *08:20, *08:24
++----- +--+-+-- *08:08, *08:10 = *08:08, *08:24
++----- +--+---+ ----+ *08:10, *08:22 = *08:22, *08:24
++----- +--+--- -+--+-- *08:10, *08:26N = *08:24, *08:26N
++----- +--+-- *08:10, *08:36N = *08:24, *08:36N
++----- +--+--- *08:01:01, *08:10 = *08:01:01, *08:24 = *08:10, *08:24 = *08:24, *08:24
++----- *08:01:01, *08:08 = *08:08, *08:08
++----- *08:01:01, *08:22 = *08:22, *08:22
++----- *08:01:01, *08:26N = *08:26N, *08:26N
++---- *08:01:01, *08:36N = *08:36N, *08:36N
+-+---- *08:04, *08:25 = *08:13, *08:28
+-+---- *08:02:01, *08:13 = *08:04, *08:19 = *08:13, *08:19
--+-+--- *08:05, *08:19 = *08:05, *08:25 = *08:15, *08:25
--+-+--- *08:05, *08:29 = *08:05, *08:30
--+-+--- \quad ---++--- \quad *08:02:01, \ *08:05 = *08:05, \ *08:05 = *08:05, \ *08:15 = *08:05, \ *08:28 = *08:15,
                        *08:28
--+--+-- *08:23, *08:29 = *08:23, *08:30
--+--+-- *08:02:01, *08:23 = *08:23, *08:23
--+--+ *08:07, *08:29 = *08:07, *08:30
--+---+ *--++--- *08:29, *08:34 = *08:30, *08:34
--+---+ **---+ **08:02:01, *08:34 = *08:34, *08:34
--+---- *08:17, *08:29 = *08:17, *08:30
--+---- *08:02:01, *08:17 = *08:17, *08:17
--+---- *08:12, *08:29 = *08:12, *08:30
--+---- *08:02:01. *08:12 = *08:12. *08:12
--+---- *08:18, *08:29 = *08:18, *08:30
--+---- *08:25, *08:29 = *08:25, *08:30
--+---
                        *08:02:01, *08:25 = *08:19, *08:25 = *08:19, *08:28 = *08:25, *08:28
--+---- *08:19, *08:29 = *08:19, *08:30
--+---- *08:02:01, *08:19 = *08:19, *08:19
--+---- *08:28, *08:29 = *08:28, *08:30
--+---- *08:02:01, *08:28 = *08:28, *08:28
--+---- *08:02:01, *08:31 = *08:30, *08:31
--+---- *08:27, *08:35 = *08:29, *08:35 = *08:30, *08:35
--+---- *08:02:01, *08:27 = *08:27, *08:30
--+---- *08:29, *08:33 = *08:30, *08:33
--+---- *08:02:01, *08:29 = *08:02:01, *08:30 = *08:29, *08:30 = *08:30, *08:30
--+---- *08:02:01, *08:35 = *08:35, *08:35
--+---- *08:02:01, *08:33 = *08:33, *08:33
--+---- *08:29, *08:31 = *08:31, *08:31
--+---- *08:27, *08:27 = *08:27, *08:29
*08:01:01 = *08:01:01-08:01:02
*08:02:01 = *08:02:01-08:02:04
*08:03:01 = *08:03:01-08:03:02
```

\*08:30 = \*08:30 and \*08:32

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#### **SPECIFICITY TABLE**

## **HLA-C\*08 SSP subtyping**

Specificities and sizes of the PCR products of the 23 primer mixes used for HLA-C\*08 SSP subtyping

Primer Mix	Size of spec. PCR product <sup>1</sup>	Size of control band <sup>2</sup>	Amplified HLA- C*08 alleles <sup>3</sup>	Other amplified HLA Class I alleles <sup>4</sup>
1	250 bp	800 bp	*08:01:01-08:01:02, 08:03:01-08:04, 08:06, 08:08-08:11, 08:13-08:14, 08:16, 08:20-08:22, 08:24, 08:26N, 08:36N	*01:22, 01:35, 02:03, 02:16:01-02:16:02, 02:18, 04:04:01-04:04:02, 04:06, 04:13, 04:34, 04:58, 05:11, 05:17, 05:27, 06:04, 12:14:01-12:14:02, 12:18, 12:20, 14:06, 14:15, 15:02:01-15:07, 15:09-15:13, 15:15-15:24, 15:26-15:35, 17:01:01:01-17:07, <b>B*58:02</b>
<b>2</b> <sup>5</sup>	115 bp	1070 bp	*08:01:01-08:01:02, 08:03:01-08:03:02, 08:06, 08:08-08:11, 08:14, 08:16, 08:20- 08:22, 08:24, 08:26N, 08:36N	
<b>3</b> <sup>5</sup>	115 bp	800 bp	*08:02:01-08:02:04, 08:04-08:05, 08:07, 08:12-08:13, 08:17-08:19, 08:23, 08:25, 08:27-08:35	*05:01:01:01-05:01:13, 05:03- 05:08, 05:10-05:11, 05:13- 05:16, 05:18-05:45, 07:41
<b>4</b> <sup>5</sup>	110 bp	1070 bp	*08:03:01-08:03:02, 08:06, 08:14	
5	155 bp	1070 bp	*08:05, 08:15, 08:21	*01:13, 03:87, 05:09, 05:17, 05:42, 07:101, 07:130, 07:148, 17:05, <b>B</b> *15:33
<b>6</b> <sup>8</sup>	270 bp, 310 bp	800 bp	*08:06, 08:23	
<b>7</b> <sup>5</sup>	100 bp	1070 bp	*08:07	*05:23
<b>8</b> <sup>9</sup>	225 bp, 290 bp	1070 bp	*08:09, 08:11, 08:34	*05:04, 07:68
9 <sup>10</sup>	385 bp, 495 bp	1070 bp	*08:10, 08:24	
10 <sup>5,11</sup>	110 bp, 140 bp	800 bp	*08:09, 08:17	
11 <sup>6,12</sup>	280 bp, 465 bp	800 bp	*08:12, 08:20	*05:16

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			Lot specific information	· ·
12	165 bp	800 bp	*08:01:01-08:09, 08:11-08:12, 08:14- 08:15, 08:17, 08:19- 08:24, 08:26N- 08:36N	*07:101, 07:148
13 <sup>5</sup>	105 bp	800 bp	*08:02:01-08:02:04, 08:05, 08:07, 08:12, 08:17-08:19, 08:23, 08:25, 08:28, 08:30, 08:32-08:35	*05:01:01:01-05:01:13, 05:03-05:07N, 05:10, 05:12-05:16, 05:18-05:26, 05:28-05:45, 07:41
14 <sup>13</sup>	170 bp, 280 bp	1070 bp	*08:08, 08:18	
15 <sup>14</sup>	265 bp, 490 bp	1070 bp	*08:13, 08:16, 08:19, 08:25	*05:29
16 <sup>5,6,15</sup>	100 bp, 540 bp	1070 bp	*08:14, 08:22	*01:21, 06:05, 07:02:09, 12:16, 15:29, <b>B*67:02</b>
17 <sup>16</sup>	375 bp, 430 bp	1070 bp	*08:05, 08:21, 08:25, 08:28	*05:25, 05:42
18 <sup>5,17</sup>	80 bp, 200 bp	1070 bp	*08:26N, 08:31	
19 <sup>5,7,18</sup>	115 bp, 250 bp	800 bp	*08:27, 08:29-08:32	*05:08
<b>20</b> <sup>5</sup>	110 bp	1070 bp	*08:35	*05:44
21 <sup>6</sup>	195 bp	1070 bp	*08:01:01-08:01:02, 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, 08:35-08:36N	*01:02:06, 01:04, 01:21, 02:02:05, 02:02:13, 02:05-02:06, 02:10, 02:12, 02:14, 02:16:01, 02:17, 02:27:02, 02:33, 04:01:01:01-04:01:06, 04:01:09-04:01:21, 04:03-04:20, 04:23-04:70, 05:12, 05:18, 06:02:01:01-06:02:01:02, 06:02:03-06:15, 06:17-06:40, 06:42-06:45, 12:02:01-12:13, 12:14:02-12:31, 12:33-12:44, 14:02:01-14:02:04, 14:03-14:16, 14:18-14:21N, 15:02:01-15:02:04, 15:02:06-15:13, 15:15-15:35, 16:01:01-16:02:02, 16:02:04, 16:04:01, 16:06-16:26, 17:01:01:01-17:05, 17:07, 18:01-18:03
22	155 bp	1070 bp	*08:33	*07:04:01-07:04:04, 07:11- 07:12, 07:63, 07:68, 07:101, 07:139, 07:142
23 <sup>5</sup>	95 bp	1070 bp	*08:36N	·

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<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\*08 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 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\*08 SSP subtyping.

In addition, wells number 3, 6, 10 to 13 and 19 contain the primer pair giving rise to the shorter, 800 bp, internal positive control band.

In the presence of a specific amplification the intensity of the control band often decreases.

<sup>3</sup>The C\*08:30 and C\*08:32 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 19.

The HLA-C\*08 subtyping kit cannot separate the C\*08:15 and C\*07:148 alleles. These two alleles can be distinguished by the HLA-C low resolution and/or HLA-C\*07 kits.

<sup>4</sup>Due to the sharing of sequence motifs between HLA-C alleles some non-HLA-C\*08 alleles will be amplified by primer mixes 1, 3, 5, 7, 8, 11 to 13, 15 to 17 and 19 to 22. In addition, primer mix 1 will amplify the B\*58:02 allele, primer mix 5 will amplify the B\*15:33 allele and primer mix 16 will amplify the B\*67:02 allele.

<sup>5</sup>Short specific PCR fragments are less intense and not as sharp as longer specific bands.

<sup>6</sup>Primer mixes 11, 16 and 21 have a tendency of giving rise to non-specific amplifications.

<sup>7</sup>Primer mixes 19 may give rise to primer oligomer formation.

<sup>8</sup>Primer mix 6: Specific PCR fragment of 270 bp in the C\*08:06 allele. Specific PCR fragment of 310 bp in the C\*08:23 allele.

<sup>9</sup>Primer mix 8: Specific PCR fragment of 225 bp in the C\*08:09 and 08:11 and in the C\*05:04 and 07:68 alleles. Specific PCR fragment of 290 bp in the C\*08:34 allele.

<sup>10</sup>Primer mix 9: Specific PCR fragment of 385 bp in the C\*08:24 allele. Specific PCR fragment of 495 bp in the C\*08:10 allele.

<sup>11</sup>Primer mix 10: Specific PCR fragment of 110 bp in the C\*08:09 allele. Specific PCR fragment of 140 bp in the C\*08:17 allele.

<sup>12</sup>Primer mix 11: Specific PCR fragment of 280 bp in the C\*08:12 and in the C\*05:16 allele. Specific PCR fragment of 465 bp in the C\*08:20 allele.

<sup>13</sup>Primer mix 14: Specific PCR fragment of 170 bp in the C\*08:18 allele. Specific PCR fragment of 280 bp in the C\*08:08 allele.

<sup>14</sup>Primer mix 15: Specific PCR fragment of 265 bp in the C\*08:13, 08:16 and 08:25 and the C\*05:29 alleles. Specific PCR fragment of 490 bp in the C\*08:19 allele.

<sup>15</sup>Primer mix 16: Specific PCR fragment of 100 bp in the C\*08:14 and the C\*01:21, 06:05, 07:02:09 and 12:16 and in the B\*67:02 allele. Specific PCR fragment of 540 bp in the C\*08:22 and in the 15:29 alleles.

<sup>16</sup>Primer mix 17: Specific PCR fragment of 375 bp in the C\*08:05, 08:21 and 08:25 alleles. Specific PCR fragment of 430 bp in the C\*08:28 and C\*05:25 alleles. Specific PCR fragment of 375 and 430 bp in the C\*05:42 allele.

<sup>17</sup>Primer mix 18: Specific PCR fragment of 80 bp in the C\*08:31 allele. Specific PCR fragment of 200 bp in the C\*08:26N allele.

<sup>18</sup>Primer mix 19: Specific PCR fragment of 115 bp in the C\*08:27 and 08:29-08:31 and in the C\*05:08 alleles. Specific PCR fragment of 250 bp in the C\*08:32 allele.

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#### INTERPRETATION TABLE **HLA-C\*08 SSP subtyping** Amplification patterns of the HLA-C\*08:01 to 08:36N alleles Well<sup>6</sup> Length of spec. PCR product(s) Length of int. 1070 800 1070 1070 800 1070 1070 pos. control<sup>1</sup> 5'-primer<sup>2</sup> 2<sup>nd</sup> I 2<sup>nd</sup> I 5' -TAC 3' s -gCA ۶′ -AgT -CCA 5' -TAC <sup>5′</sup> -TgA -CCA 5' -AAT -CAA -gTC <sup>3</sup> -CAA 3. 5' -TAC 3' -CCA 3'-primer<sup>3</sup> -CTT ³ €TT7 -CgT ³ 5' -CTT 3' s -cgc ع ۶ -CCA FTCA -gCA -CCT L T 956 598 ۶′ -CAg -CTC 3 ° -CTC 3 Well No. **HLA-C** allele \*08:01:01-08:01:02 \*08:02:01-08:02:04 \*08:03:01-08:03:02 \*08:04 \*08:05 \*08:06 \*08:07 \*08:08 \*08:09 \*08:10 Well No.

CE

Lot No.: 41K Lot-specific information www.olerup-ssp.com

		110				INT		-		TIO	N TABLE
					<u>'</u>						ıbtyping
			Amr	olifica	ation						C*08:01 to 08:36N alleles
			, <u>r</u>		Well <sup>6</sup>	_		<del> </del>			
13	14	15	16	17	18	19	20	21	22	23	
105	170	265	100	375	80	115	110	195	155	95	Length of spec.
	280	490	540	430	200	250			.00		PCR product(s)
800							1070	1070	1070	1070	Length of int.
											pos. control <sup>1</sup>
539	173	1 <sup>st</sup> I	142	1 <sup>st</sup> I	441	391	527	2 <sup>nd</sup> I	486	246	5'-primer <sup>2</sup>
				8							3-primer
-gCg ³'	-cgc ³	-CgA 3'	-TCT <sup>3"</sup>	-CgA	-TAg ³'	-ACT ³'	-TgA ³'	-ccA ³	-ACC 3.	-CAg ³'	
ŗ,	ίο	ù	52	5.	ù	5.	īo.	2.		25	
	363	176	972		560	520					
	-AgC ³	-gCA ³'	-ста ³'		-CgA ³	-cgc ³					
	<sub>5</sub> A	 	<sub>5</sub> C		္	္န					
						539					
						 Di					
						<sup>5'</sup> -gТg <sup>3'</sup>					
601	302	175	201	289	601	601	595	485	601	302	3'-primer <sup>3</sup>
-CTT 3'	င့	-CCg 3.	٦ 3.	اد ء.	 -	-CTT ³′	 T	-ccg ³'	 -	C 3.	
CT	5' -ggC	<sub>5</sub> -د	⁵′ -СТТ	AgC	·cTT	<sub>5</sub> СТ	° -ccT	<sub>-</sub> -در	5' -CTT	<sup>5'</sup> -ggC <sup>3</sup>	
r.	601	387	1034	341	5.	LC.	LO.	r.	ro.	3	
	÷.	- <del>-</del>	3.								
	-cT	-TCC	-AgT	-CgT ³'							
	ما	īo.	2.								
13	14	15	16	17	18	19	20	21	22	23	Well No.
	4 -7	10	10		10	10	_0	<u>- '</u>			HLA-C allele
								21			*08:01:01-08:01:02
13											*08:02:01-08:02:04
								21			*08:03:01-08:03:02
											*08:04
13				17							*08:05
								21			*08:06
13											*08:07
	14							21			*08:08
								21			*08:09
								21			*08:10
13	14	15	16	17	18	19	20	21	22	23	Well No.

Page 10 of 20 General "Instructions for Use" HLA-C\*08 **Product Insert** 101.623-12 – including *Taq* polymerase

IFU-01 Rev. No. 01 can be downloaded from

Lot No.: 41K Lot-specific information www.olerup-ssp.com

Lot No.: 41K	ot-specific information						wwv	v.oler	up-ss	ssp.com		
Length of spec.	250	115	115	110	155	270	100	225	385	110	280	165
PCR product(s)						310		290	495	140	465	
Well No.	1	2	3	4	5	6	7	8	9	10	11	12
*08:11	1	2						8				12
*08:12			3								11	12
*08:13	1		3									
*08:14	1	2		4								12
*08:15, 07:148 <sup>4</sup>					5							12
*08:16	1	2										
*08:17			3							10		12
*08:18			3									
*08:19			3									12
*08:20	1	2									11	12
*08:21	1	2			5							12
*08:22	1	2										12
*08:23			3			6						12
*08:24	1	2							9			12
*08:25			3									
*08:26N	1	2										12
*08:27			3									12
*08:28			3									12
*08:29			3									12
*08:30, 08:32 <sup>5</sup>			3									12
*08:31			3									12
*08:33			3									12
*08:34			3					8				12
*08:35			3									12
*08:36N	1	2										12
*01:02:06, 01:04, 02:02:05, 02:02:13,												
02:05-02:06, 02:10, 02:12, 02:14,												
02:17, 02:27:02, 02:33, 04:01:01:01-												
04:01:06, 04:01:09-04:01:21, 04:03,												
04:05, 04:07-04:12, 04:14-04:20,												
04:23-04:33, 04:35-04:57, 04:59Q-												
04:70, 06:02:01:01-06:02:01:02,												
06:02:03-06:03, 06:06-06:15, 06:17-												
06:40, 06:42-06:45, 12:02:01-12:13,												
12:15, 12:17, 12:19, 12:21-12:31,												
12:33-12:44, 14:02:01-14:02:04,												
14:03-14:05, 14:07N-14:14, 14:16,												
14:18-14:21N, 15:08, 15:25, 16:01:01	-											
16:02:02, 16:02:04, 16:04:01, 16:06-												
16:26, 18:01-18:03												
Well No.	1	2	3	4	5	6	7	8	9	10	11	12
	1	CE	_		1							
November 2010		(	•			For II	n Vitro	Diag	nostic	Use		

105	170	265	100	375	80	115	110	195	155	95	Length of spec.
	280	490	540	430	200	250					PCR product(s)
13	14	15	16	17	18	19	20	21	22	23	Well No.
								21			*08:11
13											*08:12
		15									*08:13
			16					21			*08:14
											*08:15, 07:148 <sup>4</sup>
		15						21			*08:16
13											*08:17
13	14										*08:18
13		15									*08:19
								21			*08:20
				17				21			*08:21
			16					21			*08:22
13											*08:23
								21			*08:24
13		15		17							*08:25
					18			21			*08:26N
						19		21			*08:27
13				17							*08:28
						19					*08:29
13						19					*08:30, 08:32 <sup>5</sup>
					18	19					*08:31
13									22		*08:33
13											*08:34
13							20	21			*08:35
								21		23	*08:36N
											*01:02:06, 01:04, 02:02:05, 02:02:13,
											02:05-02:06, 02:10, 02:12, 02:14,
											02:17, 02:27:02, 02:33, 04:01:01:01-
											04:01:06, 04:01:09-04:01:21, 04:03,
											04:05, 04:07-04:12, 04:14-04:20,
											04:23-04:33, 04:35-04:57, 04:59Q-
											04:70, 06:02:01:01-06:02:01:02,
								21			06:02:03-06:03, 06:06-06:15, 06:17-
											06:40, 06:42-06:45, 12:02:01-12:13,
											12:15, 12:17, 12:19, 12:21-12:31,
											12:33-12:44, 14:02:01-14:02:04,
											14:03-14:05, 14:07N-14:14, 14:16,
											14:18-14:21N, 15:08, 15:25, 16:01:01-
											16:02:02, 16:02:04, 16:04:01, 16:06-
											16:26, 18:01-18:03
13	14	15	16	17	18	19	20	21	22	23	Well No.

HLA-C\*08 Product Insert Page 12 of 20 101.623-12 – including *Taq* polymerase General "Instructions for Use"

IFU-01 Rev. No. 01 can be downloaded from

Length of spec.	250	115	115	110	155	270	100	225	385	110	280	165
PCR product(s)						310		290	495	140	465	
Well No.	1	2	3	4	5	6	7	8	9	10	11	12
*01:13, 03:87, 05:09, 07:130, <i>B*15:33</i>					5							
*01:21, 06:05, 12:16												
*01:22, 01:35, 02:03, 02:16:02, 02:18,	1											
12:14:01, 15:02:05, 17:06, <i>B*58:0</i> 2	<u>'</u>											
*02:16:01, 04:04:01-04:04:02, 04:06,												
04:13, 04:34, 04:58, 06:04, 12:14:02,												
12:18, 12:20, 14:06, 14:15, 15:02:01-												
15:02:04, 15:02:06-15:07, 15:09-	1											
15:13, 15:15-15:24, 15:26-15:28,												
15:30-15:35, 17:01:01:01-17:04,												
17:07												
*05:01:01:01-05:01:13, 05:03, 05:05-												
05:07N, 05:10, 05:13-05:15, 05:19-			3									
05:22, 05:24, 05:26, 05:28, 05:30-			၁									
05:41, 05:43, 05:45, 07:41												
*05:04			3					8				
*05:08			3									
*05:11, 05:27	1		3									
*05:12												
*05:16			3								11	
*05:17	1				5							
*05:18			3									
*05:23			3				7					
*05:25			3									
*05:29			3									
*05:42			3		5							
*05:44			3									
*07:02:09, <i>B</i> *67:02												
*07:04:01-07:04:04, 07:11-07:12,												
07:63, 07:139, 07:142												
*07:68								8				
*07:101					5							12
*15:29	1											
*17:05	1				5							
HLA-C allele												
Well No.	1	2	3	4	5	6	7	8	9	10	11	12
	<u> </u>		<u> </u>	т			•			. •		

		140						<u></u>		www.olerup-ssp.com					
105	170	265	100	375	80	115	110	195	155	95	Length of spec.				
	280	490	540	430	200	250					PCR product(s)				
13	14	15	16	17	18	19	20	21	22	23	Well No.				
											*01:13, 03:87, 05:09, 07:130, <i>B*15:33</i>				
			16					21			*01:21, 06:05, 12:16				
											<b>*01:22, 01:35, 02:03, 02:16:02, 02:18,</b>				
											12:14:01, 15:02:05, 17:06, <i>B*58:0</i> 2				
											<b>*02:16:01, 04:04:01-04:04:02, 04:06,</b>				
											04:13, 04:34, 04:58, 06:04, 12:14:02,				
											12:18, 12:20, 14:06, 14:15, 15:02:01-				
								21			15:02:04, 15:02:06-15:07, 15:09-				
											15:13, 15:15-15:24, 15:26-15:28,				
											15:30-15:35, 17:01:01:01-17:04,				
											17:07				
											*05:01:01:01-05:01:13, 05:03, 05:05-				
13											05:07N, 05:10, 05:13-05:15, 05:19-				
13											05:22, 05:24, 05:26, 05:28, 05:30-				
											05:41, 05:43, 05:45, 07:41				
13											*05:04				
						19					*05:08				
											*05:11, 05:27				
13								21			*05:12				
13											*05:16				
											*05:17				
13								21			*05:18				
13											*05:23				
13				17							*05:25				
13		15									*05:29				
13				17							*05:42				
13							20				*05:44				
			16								*07:02:09, <i>B*67:0</i> 2				
									00		*07:04:01-07:04:04, 07:11-07:12,				
									22		07:63, 07:139, 07:142				
									22		*07:68				
									22		*07:101				
			16					21			*15:29				
								21			*17:05				
											HLA-C allele				
13	14	15	16	17	18	19	20	21	22	23	Well No.				
.,			. 0		. 0		20			20	11GII 140.				

**Product Insert** HLA-C\*08 Page 14 of 20 101.623-12 - including Tag polymerase General "Instructions for Use"

IFU-01 Rev. No. 01 can be downloaded from

Lot No.: 41K **Lot-specific information** www.olerup-ssp.com

<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\*08 SSP subtyping.

In addition, wells number 3, 6, 10 to 13 and 19 contain the primer pair giving rise to the shorter, 800 bp. internal positive control band.

<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> or 2<sup>nd</sup> intron, matching the specificitydetermining 3'-end of the primer is given. Nucleotide numbering as on the www.ebi.ac.uk/imgt/hla web site. The sequence of the 3 terminal nucleotides of the primer is given.

<sup>3</sup>The nucleotide position, in the 2<sup>nd</sup>,3<sup>rd</sup> or 5<sup>th</sup> exon, matching the specificity-determining 3'-end of the primer is given in the anti-sense direction. The sequence of the 3 terminal nucleotides of the primer is given.

<sup>4</sup>The HLA-C\*08 subtyping kit cannot separate the C\*08:15 and C\*07:148 alleles. These two alleles can be distinguished by the HLA-C low resolution and/or HLA-C\*07 kits.

<sup>5</sup>The C\*08:30 and C\*08:32 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 19. <sup>6</sup>Primer mix 6: Specific PCR fragment of 270 bp in the C\*08:06 allele. Specific PCR fragment of 310 bp

in the C\*08:23 allele.

Primer mix 8: Specific PCR fragment of 225 bp in the C\*08:09 and 08:11 and in the C\*05:04 and 07:68 alleles. Specific PCR fragment of 290 bp in the C\*08:34 allele.

Primer mix 9: Specific PCR fragment of 385 bp in the C\*08:24 allele. Specific PCR fragment of 495 bp in the C\*08:10 allele.

Primer mix 10: Specific PCR fragment of 110 bp in the C\*08:09 allele. Specific PCR fragment of 140 bp in the C\*08:17 allele.

Primer mix 11: Specific PCR fragment of 280 bp in the C\*08:12 and in the C\*05:16 allele. Specific PCR fragment of 465 bp in the C\*08:20 allele.

Primer mix 14: Specific PCR fragment of 170 bp in the C\*08:18 allele. Specific PCR fragment of 280 bp in the C\*08:08 allele.

Primer mix 15: Specific PCR fragment of 265 bp in the C\*08:13, 08:16 and 08:25 and the C\*05:29 alleles. Specific PCR fragment of 490 bp in the C\*08:19 allele.

Primer mix 16: Specific PCR fragment of 100 bp in the C\*08:14 and the C\*01:21, 06:05, 07:02:09 and 12:16 and in the B\*67:02 allele. Specific PCR fragment of 540 bp in the C\*08:22 and in the 15:29 alleles.

Primer mix 17: Specific PCR fragment of 375 bp in the C\*08:05, 08:21 and 08:25 alleles. Specific PCR fragment of 430 bp in the C\*08:28 and C\*05:25 alleles. Specific PCR fragment of 375 and 430 bp in the C\*05:42 allele.

Primer mix 18: Specific PCR fragment of 80 bp in the C\*08:31 allele. Specific PCR fragment of 200 bp in the C\*08:26N allele.

Primer mix 19: Specific PCR fragment of 115 bp in the C\*08:27 and 08:29-08:31 and in the C\*05:08 alleles. Specific PCR fragment of 250 bp in the C\*08:32 allele.

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Lot No.: 41K Lot-specific information www.olerup-ssp.com

	CELL LINE VALIDATION SHEET																			
HLA-C*08 SSP primer set																				
												W	ell							
					1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
					801	802	803	804	805	806	807	808	308	810	81	812	813	814	815	816
				Z	75	)75	75	75	75	175	175	175	75	175	175	75	75	75	)75	)75
				Prod. No.:	201075801	201075802	201075803	201075804	201075805	201075806	201075807	201075808	201075809	201075810	201075811	201075812	201075813	201075814	201075815	201075816
					2	7	7	7	7	7	7	7	2	7	7	7	7	7	7	7
	9001	VC cell line		<u>C*</u>																
2		LK707	*07:02 *07:01	*15:05	-	-	-	-		÷	-	-			-	-	-	-	-	-
3		E4181324	*12:02	15.05	+		-	-		÷		÷	H		-	-	-	-	-	
4		GU373	*03:04	*04:01	-	-	-	-			-	-	-	-		-	-	-	-	-
5		KAS011	*06:02	04.01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	_
6	9353		*03:04	*07:02	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
7	9020		*05:01	002	-	-	+	-	-	-	-	-	-	-	-	-	+	-	-	-
8	9007		*04:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
9	9026		*12:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
10	9107	LKT3	*01:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
11	9051	PITOUT	*16:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
12	9052		*06:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
13	9004	JESTHOM	*01:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
14		OLGA	*01:02	*03:04	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
15	9075		*03:04		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
16		SWEIG007	*02:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
17		CTM3953540	*03:03	*07:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
18		32367	*01:02	*07:05	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
19		BM16	*07:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
20		SLE005 AMALA	*03:04		Ŀ	-	-	-	•	-	-	-	H	-	÷	•	-	-	-	-
22		KOSE	*03:03 *12:03			-	-	-	-	-		÷		-		-	-	-	-	-
23	9124		*01:02	*15:02	+	-	-	-		÷		-			E	-	-	-	-	-
24		JBUSH	*12:03	13.02	-	-	-	-	-		-	-	-	-	-	-	-	-	-	-
25	9049		*08:02		-	-	+	-	-	-	-	-	-	-	-	+	+	-	-	-
26		WT49	*07:01		-	-	÷	-	-	-	-	-	-	-	-		÷	-	-	-
27		CH1007	*07:04	*15:05	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
28	9320	BEL5GB	*05:01	*16:01	-	-	+	-	-	-	-	-	-	-	-	-	+	-	-	- 1
29	9050	MOU	*16:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
30	9021	RSH	*17:01		+	-	-	-	-		-		•	-	-	-	-	-	-	-
31	9019	DUCAF	*05:01		-	-	+	-	-	-	-	-	-	-	-	-	+	-	-	-
32	9297		*17:01	*17:03	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
33		MT14B	*03:04		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
34	9104		*12:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
35		SSTO	*05:01	*0 1 0 :	-	-	+	-	-	-	-	-	<u> </u>	-	-	-	+	-	-	-
36		KT17	*03:03	*04:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
37		HHKB	*07:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
38 39	9099		*03:03	*07:01	-	-	-	-	-	÷	-	-	-		-	-	-	-	-	
40	9315	WHONP199	*02:02 *01:02	*06:02		-	-	-	-		-		H	-	÷	-	-	-	-	
41		H0301	*08:02	00.02	÷	-	+	-	-	-	-	-	÷	-	-	+	+	-	-	-
42		TAB089	*01:02		-	-	-	-	-	-	-	-	-	-	-	-	т -	-	-	_
43		T7526	*01:02	*08:01	+	+	-	-	-	-	-	-	-	-	-	+	-	-	-	-
44	9057		*12:03	11.01	Ė		-	-	-	-	-	-	-	-	-	-	-	-	-	-
45		SHJO	*06:02	*17:01	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
46		SCHU	*07:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
47		TUBO	*07:04	*15:02	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
48		TER-ND	*04:01	*16:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

CELL LINE VALIDATION SHEET												
	HLA-C*08 SSP primer set											
							\	Иe	1			
					17	18	19	20	21	22	23	
					7	æ	0			CI.	3	
				.: <u>o</u>	201075817	201075818	201075819	201075820	201075821	201075822	201075823	
				2	375	375	375	375	375	375	375	
				Prod. No.	010	9	9	9	9	9	9	
	11.114	VC a a II lina		C*	2	N	7	7	7	7	7	
1	9001	VC cell line		<u>ن</u> ا								
2		LK707	*07:02 *07:01	*15:05	-	-	-	-	-	-	-	
3		E4181324	*12:02	15.05	-	÷	-	-	+	E	Ε	
4		GU373	*03:04	*04:01			-		+	E		
5		KAS011	*06:02	04.01	_		-	-	+		-	
6	9353		*03:04	*07:02	_	_	-	-	÷	_	_	
7	9020		*05:01	01.02	-	-	-	-	-	-	-	
8	9007		*04:01		-	-	-	-	+	-	-	
9	9026		*12:03		-	-	-	-	÷	-	-	
10		LKT3	*01:02		-	-	-	-	Ė	-	-	
11		PITOUT	*16:01		-	-	-	-	+	-	-	
12	9052	DBB	*06:02		-	-	-	-	+	-	-	
13	9004	JESTHOM	*01:02		-	-	-	-	-	-	-	
14	9071	OLGA	*01:02	*03:04	-	-	-	-	-	-	-	
15	9075	DKB	*03:04		-	-	-	-	-	-	-	
16	9037	SWEIG007	*02:02		-	-	-	-	-	-	-	
17	9282	CTM3953540	*03:03	*07:01	-	-	-	-	-	-	-	
18	9257	32367	*01:02	*07:05	-	-	-	-	-	-	-	
19		BM16	*07:01		-	-	-	-	-	-	-	
20		SLE005	*03:04		-	-	-	-	-	-	-	
21		AMALA	*03:03		-	-	-	-	-	-	-	
22		KOSE	*12:03		-	-	-	-	+	-	-	
23	9124		*01:02	*15:02	-	-	-	-	+	-	-	
24		JBUSH	*12:03		-	-	-	-	+	-	-	
25		IBW9	*08:02		-	-	-	-	-	-	-	
26		WT49	*07:01	*45.05	-	-	-	-	-	-	-	
27		CH1007	*07:04	*15:05	-	-	-	-	+	+	-	
28 29		BEL5GB	*05:01	*16:01	Ŀ	Ë	-	-	+	-	Ë	
30	9050 9021		*16:01 *17:01		-	-	-	-	+		-	
31		DUCAF	*05:01		Ë	÷	-	-	+	÷	Ë	
32		HAG	*17:01	*17:03	-	Ė	Ė	H	+	E	÷	
33		MT14B	*03:04	17.03	-	Ė	-	-	÷	Ė		
34	9104		*12:03		-	-	-	-	+	-	-	
35		SSTO	*05:01		-	-	-	-	÷	-	-	
36		KT17	*03:03	*04:01	-	-	-	-	+	-	-	
37		HHKB	*07:02		-	-	-	-	Ė	-	-	
38	9099		*03:03		-	-	-	-	-	-	-	
39	9315		*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	-	-	-	-	+	-	-	

HLA-C\*08 Product Insert Page 17 of 20

**101.623-12 – including** *Taq* **polymerase** 

General "Instructions for Use" IFU-01 Rev. No. 01 can be downloaded from

Lot No.: 41K Lot-specific information www.olerup-ssp.com

#### **CERTIFICATE OF ANALYSIS**

Olerup SSP® HLA-C\*08 SSP

Product number: 101.623-12 – including *Taq* polymerase

Lot number: 41K

Expiry date: 2012-September-01

Number of tests: 12 Number of wells per test: 23

#### Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2010-758-01	9	2010-758-09	17	2010-758-17
2	2010-758-02	10	2010-758-10	18	2010-758-18
3	2010-758-03	11	2010-758-11	19	2010-758-19
4	2010-758-04	12	2010-758-12	20	2010-758-20
5	2010-758-05	13	2010-758-13	21	2010-758-21
6	2010-758-06	14	2010-758-14	22	2010-758-22
7	2010-758-07	15	2010-758-15	23	2010-758-23
8	2010-758-08	16	2010-758-16		

The specificity of each primer solution of the HLA-C\*08 primer set has been tested against 48 well characterized cell line DNAs.

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

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

Date of approval: 2010-November-24

Approved by:

**Quality Control, Supervisor** 

HLA-C\*08 Product Insert Page 18 of 20 101.623-12 – including *Taq* polymerase General "Instructions for Use"

IFU-01 Rev. No. 01 can be downloaded from

Lot No.: 41K Lot-specific information www.olerup-ssp.com

## **Declaration of Conformity**

**Product name:** Olerup SSP® HLA-C\*08

**Product number:** 101.623-12

Lot number: 41K

Intended use: HLA-C\*08 high resolution histocompatibility testing

Manufacturer: Olerup SSP AB

Hasselstigen 1

SE-133 33 Saltsjöbaden, 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, Hasselstigen 1, SE-133 33 Saltsjöbaden, Sweden.

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

Saltsjöbaden, Sweden 2010-November-24

Olle Olerup Managing Director HLA-C\*08 Product Insert Page 19 of 20 101.623-12 – including *Taq* polymerase General "Instructions for Use"

IFU-01 Rev. No. 01 can be downloaded from

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IFU-01 Rev. No. 01 can be downloaded from

Lot No.: 41K Lot-specific information www.olerup-ssp.com

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**Tel:** 1-877-OLERUP1 **Fax:** 610-344-7989

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Web page: <a href="http://www.olerup.com">http://www.olerup.com</a>

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