HLA-C*08 Product Insert Page 1 of 24

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

General "Instructions for Use" IFU-01 Rev. No. 03 can be downloaded from

Lot No.: 55M Lot-specific information www.olerup-ssp.com

Olerup SSP® HLA-C*08

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

Lot number: 55M

Expiry date: 2014-February-01

Number of tests: 12 Number of wells per test: 29

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. 55M.

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. 41K)**.

Six wells have been added to the HLA-C*08 kit, wells **24 to 29**. 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
9	-	Modified	Improved specificity of primer pair.
22	Added	-	Primer added for the C*08:41 allele.
24	New	New	New primer pair for the C*08:37 allele.
25	New	New	New primer pair for the C*08:39 allele.
26	New	New	New primer pair for the C*08:42 allele.
27	New	New	New primer pair for the C*08:43 allele.
28	New	New	New primer pair for the C*08:44 allele.
29	New	New	New primer pair for the C*08:38 allele.

CE

September 2011

Rev. No.: 00

101.623-12 – including *Taq* polymerase

General "Instructions for Use" IFU-01 Rev. No. 03 can be downloaded from

Lot No.: 55M Lot-specific information www.olerup-ssp.com

PRODUCT DESCRIPTION

HLA-C*08 SSP typing

CONTENT

The primer set contains 5'- and 3'-primers for identifying the C*08:01 to C*08:44 alleles.

PLATE LAYOUT

Each HLA-C*08 test consists of 29 PCR reactions in a 32 well cut PCR plate. Wells 30 to 32 are empty.

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	empty	empty	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. '55M'.

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, 19 to 22, 24, 25 and 28 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, primer mix 16 will amplify the B*67:02 allele and primer mix 25 will amplify the A*29:10 allele.

UNIQUELY IDENTIFIED ALLELES

All the HLA-C*08 alleles, i.e. **C*08:01 to C*08:44**, recognized by the HLA Nomenclature Committee in October 2010¹ will be amplified by the primers in the HLA-C*08 SSP kit.

The HLA-C*08 subtyping kit cannot distinguish the C*08:01:01-08:01:03 alleles, the 08:02:01-08:02:05 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.

¹HLA-B alleles listed on the IMGT/HLA web page 2010-October-20, release 3.2.0, www.ebi.ac.uk/imgt/hla.

September 2011 Rev. No.: 00 Lot No.: 55M Lot-specific information www.olerup-ssp.com

RESOLUTION IN HOMO- AND HETEROZYGOTES

A total of 65 alleles generate 41 amplification patterns that can be combined in 861 homozygous and heterozygous combinations. 288 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.

```
++++-+- --+++--- ----+---
                                *08:06, *08:12 = *08:23, *08:40
++++-+-- ---++--- ----+---
                                *08:02:01, *08:06 = *08:03:01, *08:23 = *08:06, *08:23
++++-+-- ---+--- --+-+---
                                *08:06, *08:27 = *08:06, *08:29
++++--- --+++--- ----+---
                                *08:02:01, *08:40 = *08:03:01, *08:12 = *08:12, *08:40
++++---- --++---- -----
                                *08:27, *08:40 = *08:29, *08:40
++++---
                                *08:14, *08:27 = *08:14, *08:29
++++---
                                *08:27, *08:38 = *08:29, *08:38
++++--- ---+--- --+---
                                *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, *08:21
+++-+-- ---+++-- +---+---
                                *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,
+++---+ -+-+--- --+-+---
                                *08:09, *08:27 = *08:09, *08:29
+++---+ --+++--- ----+---
                                *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, *08:37 = *08:24, *08:37
+++---- +--++--- ---+---
                                *08:10, *08:43 = *08:24, *08:43
+++---- +--++--- ------
                                *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
+++---- --+++-- ----+---
                                *08:08, *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, *08:25 = *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
```



General "Instructions for Use"

IFU-01 Rev. No. 03 can be downloaded from

Lot No.: **55M** Lot-specific information www.olerup-ssp.com +++---- ---+--- -++-+---*08:01:01, *08:31 = *08:26N, *08:27 = *08:26N, *08:29 = *08:26N, *08:31 +++----*08:27, *08:41 = *08:29, *08:41 +++----*08:27, *08:36N = *08:29, *08:36N +++---- ---+--- --+--- -+---*08:27, *08:42 = *08:29, *08:42 +++---- ---+---*08:27, *08:44 = *08:29, *08:44 +++---- ---+--- --+-+---*08:01:01. *08:27 = *08:01:01. *08:29 ++-+-- +--+--- -----*08:06, *08:10 = *08:06, *08:24 ++-+-- --++--- -----*08:06, *08:20 = *08:06, *08:40 ++-+-+- ---+ ----+ ----*08:06, *08:14 = *08:06, *08:22 ++-+-+-- ---+--- ----+---*08:01:01, *08:06 = *08:03:01, *08:06 = *08:06, *08:06 ++-+--- +-++---- ----+---*08:10, *08:40 = *08:24, *08:40 ++-+--- +--+--+ ----+---*08:10, *08:14 = *08:14, *08:24 ++-+--- +--+---*08:10, *08:38 = *08:24, *08:38 ++-+--- +--+--- ----+---*08:03:01, *08:10 = *08:03:01, *08:24 ++-+--- --++---+ ----+---*08:14, *08:20 = *08:14, *08:40 = *08:22, *08:40 *08:20, *08:38 = *08:38, *08:40 ++-+---++-+--- --++---*08:01:01, *08:40 = *08:03:01, *08:20 = *08:03:01, *08:40 = *08:20, *08:40 = *08:40, *08:40 ++-+---*08:14, *08:38 = *08:22, *08:38 ++-+--- ---+ ----+ ----*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, *08:38 = *08:03:01, *08:38 = *08:38, *08:38 ++-+--- ---+--- -----*08:01:01, *08:03:01 = *08:03:01, *08:03:01 ++--+-- +--+--- +---+---*08:10, *08:21 = *08:21, *08:24 ++--+-- ---+--- +---+---*08:01:01, *08:21 = *08:21, *08:21 ++----+ ++-+---- ----+---*08:09, *08:10 = *08:09, *08:24 ++----+ +--+---*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, *08:41 = *08:24, *08:41 ++---- +--+---*08:10, *08:36N = *08:24, *08:36N ++---- +--+--- ----+--- +----*08:10, *08:39 = *08:24, *08:39 ++---- +--+--- ----+--- -+---*08:10, *08:42 = *08:24, *08:42 ++---- +--+--*08:10, *08:44 = *08:24, *08:44 ++---- +--+--- ----+---*08:01:01, *08:10 = *08:01:01, *08:24 = *08:10, *08:24 = *08:24, *08:24 *08:01:01, *08:20 = *08:20, *08:20 *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, *08:41 = *08:41, *08:41 ++----*08:01:01, *08:36N = *08:36N, *08:36N ++----- ---+--- ---+---*08:01:01, *08:42 = *08:42, *08:42 ++----- ---+---*08:01:01, *08:44 = *08:44, *08:44 +-+---- ---++-+- +-----*08:04, *08:25 = *08:13, *08:28 +-+---- ---++-+- -----*08:02:01, *08:13 = *08:04, *08:19 = *08:13, *08:19 +-+---- ---+--- --+---*08:27, *08:39 = *08:29, *08:39 --+-+--- ---++-+- +------*08:05, *08:19 = *08:05, *08:25 --+-+--- ---++--- +-+----*08:05, *08:29 = *08:05, *08:30 --+-+--- ---++--- +-----*08:02:01, *08:05 = *08:05, *08:05 = *08:05, *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 --+---+ *08:02:01, *08:07 = *08:07, *08:07



Lot No.: 55M	Lot-specific information	www.olerup-ssp.com
+++++	*08:29, *08:34 = *08:30, *08:34	
++++	*08:02:01, *08:34 = *08:34, *08:34	4
+	*08:17, *08:29 = *08:17, *08:30	
+	*08:02:01, *08:17 = *08:17, *08:1	7
+	*08:12, *08:29 = *08:12, *08:30	
+	*08:02:01, *08:12 = *08:12, *08:12	2
+	*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	5 = *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	Ð
+++ +-+	*08:28, *08:29 = *08:28, *08:30	
++ +	*08:02:01, *08:28 = *08:28, *08:28	
+++++	*08:02:01, *08:31 = *08:30, *08:3	
+	*08:27, *08:35 = *08:29, *08:35 =	
+	*08:02:01, *08:27 = *08:27, *08:30)
+	*08:29, *08:37 = *08:30, *08:37	
+++	*08:29, *08:43 = *08:30, *08:43	
++++	*08:02:01, *08:29 = *08:02:01, *08	3:30 = *08:29, *08:30 =
	*08:30, *08:30	
+	*08:02:01, *08:35 = *08:35, *08:35	
+	*08:02:01, *08:37 = *08:37, *08:3	
++	*08:02:01, *08:43 = *08:43, *08:43	3
+	*08:29, *08:31 = *08:31, *08:31	
+	*08:27, *08:27 = *08:27, *08:29	
*08:01:01 = *08:01:01-08:01:03 *08:02:01 = *08:02:01-08:02:05 *08:03:01 = *08:03:01-08:03:02		

Lot No.: 55M Lot-specific information www.olerup-ssp.com

SPECIFICITY TABLE

HLA-C*08 SSP subtyping

Specificities and sizes of the PCR products of the 29 primer mixes used for HLA-C*08 SSP subtyping

Primer Mix	Size of spec. PCR product ¹	Size of control band ²	Amplified HLA-C*08 alleles ³	Other amplified HLA Class I alleles ⁴
1	250 bp	800 bp	*08:01:01-08:01:03, 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, 08:38-08:42, 08:44	*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, 15:26-15:45, 17:01:01:01-17:08, B*58:02
2 ⁵	115 bp	1070 bp	*08:01:01-08:01:03, 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, 08:38, 08:40-08:42, 08:44	
3 ⁵	115 bp	800 bp	*08:02:01-08:02:05, 08:04-08:05, 08:07, 08:12-08:13, 08:17-08:19, 08:23, 08:25, 08:27-08:35, 08:37, 08:43	*05:01:01:01-05:01:15, 05:03- 05:08, 05:10-05:11, 05:13- 05:16, 05:18-05:51Q, 07:41
4 ⁵	110 bp	1070 bp	*08:03:01-08:03:02, 08:06, 08:14, 08:38, 08:40	
5	155 bp	1070 bp	*08:05, 08:15, 08:21	*01:13, 03:87, 05:09, 05:17, 05:42, 05:46, 07:101, 07:130, 07:148, 16:27, 17:05, B*15:33
6 ⁸	270 bp, 310 bp	800 bp	*08:06, 08:23	
7 ⁵	100 bp	1070 bp	*08:07	*05:23
8 ⁹	225 bp, 290 bp	1070 bp	*08:09, 08:11, 08:34	*05:04, 07:68
9 ¹⁰	385 bp, 505 bp	1070 bp	*08:10, 08:24	

			11 O-01 INEV. IN	o. U3 can be downloaded from
Lot No.:	55M	Lo	t-specific information	www.olerup-ssp.com
10 ^{5,11}	110 bp, 140 bp	800 bp	*08:09, 08:17	
11 ^{6,7,12}	280 bp, 470 bp	800 bp	*08:12, 08:20, 08:40	*05:16
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-08:44	*01:43, 07:101, 07:148
13 ⁵	105 bp	800 bp	*08:02:01-08:02:05, 08:05, 08:07, 08:12, 08:17-08:19, 08:23, 08:25, 08:28, 08:30, 08:32-08:35, 08:37, 08:43	*05:01:01:01-05:01:15, 05:03- 05:07N, 05:10, 05:12-05:16, 05:18-05:26, 05:28-05:51Q, 07:41
14 ¹³	170 bp, 280 bp	1070 bp	*08:08, 08:18	
15 ¹⁴	265 bp, 500 bp	1070 bp	*08:13, 08:16, 08:19, 08:25	*05:29
16 ^{5,6,15}	100 bp, 545 bp	1070 bp	*08:14, 08:22	*01:21, 02:42, 06:05, 07:02:09, 12:16, 15:29, B*67:02
17 ¹⁶	375 bp, 430 bp	1070 bp	*08:05, 08:21, 08:25, 08:28	*05:25, 05:42, 05:46
18 ^{5,17}	80 bp, 200 bp	1070 bp	*08:26N, 08:31	
19 ^{5,7,18}	115 bp, 250 bp	800 bp	*08:27, 08:29-08:32	*05:08
20 ⁵	110 bp	1070 bp	*08:35	*05:44
21 ⁶	195 bp	1070 bp	*08:01:01-08:01:03, 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, 08:38-08:42, 08:44	*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, 04:01:09-04:01:26, 04:03-04:20, 04:23-04:81, 05:12, 05:18, 06:02:01:01-06:02:01:02, 06:02:03-06:15, 06:17-06:40, 06:42-06:55, 12:02:01-12:13, 12:14:02-12:31, 12:33-12:50, 14:02:01-14:02:04, 14:02:06-14:16, 14:18-14:25, 15:02:01-15:02:04, 15:02:06-15:06:02, 15:07-15:13, 15:15-15:45, 16:01:01-16:02:02, 16:02:04-16:02:05, 16:04:01, 16:06-16:26, 16:28-16:32,

Page 8 of 24

Lot No.: **55M Lot-specific information** www.olerup-ssp.com

				17:01:01:01-17:05, 17:07- 17:08, 18:01-18:04
22 ^{5,19}	80 bp, 155 bp	1070 bp	*08:33, 08:41	*05:27, 05:39, 07:04:01- 07:04:04, 07:11-07:12, 07:63, 07:68, 07:101, 07:139, 07:142
23 ⁵	95 bp	1070 bp	*08:36N	
24	145 bp	1070 bp	*08:37	*02:14, 04:42, 05:43, 06:05, 07:02:09, 12:16, 15:23, 16:21
25 ⁵	115 bp	1070 bp	*08:39	*05:12, A*29:10
26 ⁵	125 bp	1070 bp	*08:42	
27 ⁵	100 bp	1070 bp	*08:43	
28 ⁷	285 bp	1070 bp	*08:44	*05:10
29	200 bp	1070 bp	*08:38	

¹Alleles are assigned by the presence of specific PCR product(s). However, the sizes of the specific PCR products may be helpful in the interpretation of HLA-C*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.

²The internal positive control primer pairs amplify segments of the human growth hormone gene. The two different control primer pairs give rise to either an internal positive control band of 1070 base pairs, for most wells, or a band of 800 base pairs, for some wells.

Well number 1 contains the primer pair giving rise to the shorter, 800 bp, internal positive control band in order to help in the correct orientation of the HLA-C*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.

³The 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.

⁴Due 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, 19 to 22, 24, 25 and 28. In addition, primer mix 1 will amplify the B*58:02 allele, primer mix 5 will amplify the B*15:33 allele, primer mix 16 will amplify the B*67:02 allele and primer mix 25 will amplify the A*29:10 allele.

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

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.



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

⁷Primer mixes 11, 19 and 28 may give rise to primer oligomer formation.

⁸Primer 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.

HLA-C*08 Product Insert Page 9 of 24 101.623-12 – including *Taq* polymerase General "Instructions for Use"

IFU-01 Rev. No. 03 can be downloaded from

¹⁰Primer mix 9: Specific PCR fragment of 385 bp in the C*08:24 allele. Specific PCR fragment of 505 bp in the C*08:10 allele.

¹¹Primer 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.

¹²Primer mix 11: Specific PCR fragment of 280 bp in the C*08:12 and in the C*05:16 allele. Specific PCR fragment of 470 bp in the C*08:20 and 08:40 alleles.

¹³Primer 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.

¹⁴Primer 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 500 bp in the C*08:19 allele.

¹⁵Primer mix 16: Specific PCR fragment of 100 bp in the C*08:14 and the C*01:21, 02.42, 06:05, 07:02:09 and 12:16 and in the B*67:02 allele. Specific PCR fragment of 545 bp in the C*08:22 and in the C*15:29 alleles.

¹⁶Primer mix 17: Specific PCR fragment of 375 bp in the C*08:05, 08:21 and 08:25 and the C*05:46 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.

¹⁷Primer 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.

¹⁸Primer 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.

¹⁹Primer mix 22: Specific PCR fragment of 80 bp in the C*08:41 and in the C*05:27 and 05:39 alleles. Specific PCR fragment of 155 bp in the C*08:33 and in the C*07:04:01-07:04:04, 07:11-07:12, 07:63, 07:68, 07:101, 07:139 and 07:142 alleles.

HLA-C*08 Product Insert Page 10 of 24 101.623-12 – including *Taq* polymerase General "Instructions for Use"

IFU-01 Rev. No. 03 can be downloaded from

Lot No.: 55M Lot-specific information www.olerup-ssp.com

INTERPRETATION TABLE **HLA-C*08 SSP subtyping** Amplification patterns of the HLA-C*08:01 to 08:44 alleles Well⁶ 4 8 10 11 12 13 14 15 16 2 5 6 7 9 115 110 270 225 165 105 170 265 155 100 Length of spec. 310 140 280 200 290 545 PCR product(s) 1070 1070 1070 1070 1070 800 800 Length of int. pos. control¹ 312 142 539 453 5'-primer² 527 527 527 2nd 351 361 2nd ^{5'} -TAC ^{3'} 5' -gCA 3' -CCA ³ 5. -gCA 3. ^{5′} -TgA ^{3′} -gCA 3. 5' -CgA 3' 5' -TAC 3' -cac 3. 5' -TCT 3' 5' -CAA 3 -AAT ₃ 736 176 485 419 652 972 363 527 5' -gCA 3' 5' -CTA 3' -CAA 3. 539 595 512 289 559 526 302 302 60 277 601 601 601 201 3'-primer³ -TCA 3 5. -CgC 3. 5' -gCA 3' ° A⊃⊃ -CgT 3. ⁵ -CCg 5' -CTT 3' -CTT 3 -CTT 3 -CTT 3 5' -CTT 3' -CTT 3 ECCT 599 598 926 289 387 601 5. -AgT 3" ٠CTT ، -CAg ³ ٠TCC ع 5' -AgC 3' FCC 3 601 ° CTC Well No. 5 7 10 11 12 13 14 15 16 1 2 3 4 6 **HLA-C** allele *08:01:01-08:01:03 1 12 2 *08:02:01-08:02:05 12 13 3 *08:03:01-08:03:02 1 2 4 12 *08:04 1 12 3 3 Well No. 2 7 10 11 12 13 14 15 16 4 5 6

CE

General "Instructions for Use" IFU-01 Rev. No. 03 can be downloaded from

							NT	ER	PR	E7	ΓΑΊ	ΓΙΟ	NTABLE
													ubtyping
			An	npli				tter	ns c	of th	ne H	LA-	C*08:01 to 08:44 alleles
						Vell							
17			20								28		
375	80	115	110	195	80	95	145	115	125	100	285	200	Length of spec.
430	200	250		_	155								PCR product(s)
1070	1070	800	1070	1070	1070	1070	1070	1070	1070	1070	1070	1070	Length of int.
													pos. control ¹
1 st I	441	391	527	2 nd I	486	246	97	527	2 nd I	527	355	368	5'-primer ²
5' -CgA 3'	^{5'} -ТАg ^{3'}	5' -ACT 3'	^{5'} -TgA ^{3'}	5' -CCA 3'	5' -ACC 3'	^{5'} -CAg ^{3'}	^{5.} -TCg ^{3.}	° -TgT ³'	5' -CCA 3'	5' -TgA 3'	^{5′} -TCA ^{3′}	^{5′} -gтс ^{3′}	
	260	520			260								
	5' -CgA 3'	₅ -cgc ³'			5′ -ССТ 3′								
	u,	539			L)								
		^{5'} -gТg ^{3'}											
289	601	601	295	485	601	302	201	601	412	584	601	526	3'-primer ³
5' -AgC 3'	5' -CTT 3'	^{5′} -СТТ ³′	5' -CCT 3'	₅ ددو	5' -СТТ 3'	^{5′} -ggC ^{3′}	5' -CTT 3'	⁵ -СТТ ³′	5' -CTT 3'	5' -ggC 3'	⁵′ -СТТ ³′	^{5′} -сgт ^{3′}	
341													
^{5'} -сgТ ^{3'}													
17	18	19	20	21	22	23	24	25	26	27	28	29	Well No.
			_0			_0	_7				_5		HLA-C allele
				21									*08:01:01-08:01:03
													*08:02:01-08:02:05
				21									*08:03:01-08:03:02
													*08:04
17	18	19	20	21	22	23	24	25	26	27	28	29	Well No.

HLA-C*08 Product Insert 101.623-12 – including *Taq* polymerase Gener

Page 12 of 24 General "Instructions for Use"

IFU-01 Rev. No. 03 can be downloaded from

Lot No.: 55M Lot-specific information www.olerup-ssp.com

Length of spec.	250	115	115	110	155	270	100					165	105			
PCR product(s)						310		290	505	140	470			280	500	545
Well No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
*08:05			3		5							12	13			
*08:06	1	2		4		6						12				
*08:07			3				7					12	13			
*08:08	1	2										12		14		
*08:09	1	2						8		10		12				
*08:10	1	2							9							
*08:11	1	2						8				12				
*08:12			3								11	12	13			
*08:13	1		3												15	
*08:14	1	2		4								12				16
*08:15, 07:148 ⁴					5							12				
*08:16	1	2													15	
*08:17			3							10		12	13			
*08:18			3										13	14		
*08:19			3									12	13		15	
*08:20	1	2									11	12				
*08:21	1	2			5							12				
*08:22	1	2										12				16
*08:23			3			6						12	13			
*08:24	1	2							9			12				
*08:25			3										13		15	
*08:26N	1	2										12				
*08:27			3									12				
*08:28			3									12	13			
*08:29			3									12				
*08:30, 08:32 ⁵			3									12	13			
*08:31			3									12				
*08:33			3									12	13			
*08:34			3					8				12	13			
*08:35			3									12	13			
*08:36N	1	2										12				
*08:37			3									12	13			
*08:38	1	2		4								12				
*08:39	1											12				
*08:40	1	2		4							11	12				
*08:41	1	2										12				
*08:42	1	2										12				
*08:43			3										13			
*08:44	1	2	-									12				
Well No.	1	2	3	4	5	6	7	8	9	10	11		13	14	15	16

((

	OL IN											HOIII	· ·
	80		110	195		95	145	115	125	100	285	200	Length of spec.
	200				155								PCR product(s)
_	18	19	20	21	22	23	24	25	26	27	28	29	Well No.
17													*08:05
				21									*08:06
													*08:07
				21									*08:08
				21									*08:09
				21									*08:10
				21									*08:11
													*08:12
													*08:13
				21									*08:14
													*08:15, 07:148 ⁴
				21									*08:16
													*08:17
													*08:18
													*08:19
				21									*08:20
17				21									*08:21
				21									*08:22
													*08:23
				21									*08:24
17													*08:25
	18			21									*08:26N
		19		21									*08:27
17													*08:28
		19											*08:29
		19											*08:30, 08:32 ⁵
	18												*08:31
	10	13			22								*08:33
					22								*08:34
			20	21									*08:35
			20	21		23							*08:36N
				Z I		23	24						
				24			24					20	*08:37
				21				25				29	*08:38
				21				∠5					*08:39
				21	22								*08:40 *09:44
				21	22				20				*08:41
				21					26	27			*08:42
				04						27	20		*08:43
4-7	40	40	00	21	00	00	0.4	05	00	^=	28	00	*08:44
1/	18	19	20	21	22	23	24	25	26	2/	28	29	Well No.

HLA-C*08 Product Insert Page 14 of 24 101.623-12 – including *Taq* polymerase General "Instructions for Use"

IFU-01 Rev. No. 03 can be downloaded from

Lot No.: 55IVI				intor		_				/WW.	_			_	_	
Length of spec.	250	115	115	110	155		100			110			105			
PCR product(s)	4	_	_	4	_	310	_			140			4.0			545
Well No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
*01:02:06, 01:04, 02:02:05,																
02:02:13, 02:05-02:06, 02:10,																
02:12, 02:17, 02:27:02, 02:33,																
04:01:01:01-04:01:06, 04:01:09-																
04:01:26, 04:03, 04:05, 04:07-																
04:12, 04:14-04:20, 04:23-04:33,																
04:35-04:41, 04:43-04:57, 04:59Q-																
04:81, 06:02:01:01-06:02:01:02,																
06:02:03-06:03, 06:06-06:15,																
06:17-06:40, 06:42-06:55,																
12:02:01-12:13, 12:15, 12:17,																
12:19, 12:21-12:31, 12:33-12:50,																
14:02:01-14:02:04, 14:02:06-																
14:05, 14:07N-14:14, 14:16, 14:18-																
14:25, 15:08, 15:25, 16:01:01-																
16:02:02, 16:02:04-16:02:05,																
16:04:01, 16:06-16:20, 16:22-																
16:26, 16:28-16:32, 18:01-18:04																
*01:13, 03:87, 05:09, 07:130,					5											
16:27, <i>B*15:</i> 33					Э											
*01:21																16
*01:22, 01:35, 02:03, 02:16:02,																
02:18, 12:14:01, 15:02:05,	1															
15:06:03, 17:06, <i>B*58:02</i>																
*01:43												12				
*02:14, 04:42, 16:21																
*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,	_															
15:02:06-15:06:02, 15:07, 15:09-	1															
15:13, 15:15-15:22, 15:24, 15:26-																
15:28, 15:30-15:45, 17:01:01:01-																
17:04, 17:07-17:08																
*02:42, <i>B</i> *67:02																16
*05:01:01:01-05:01:15, 05:03,																
05:05-05:07N, 05:13-05:15, 05:19-																
05:22, 05:24, 05:26, 05:28, 05:30-			3										13			
05:38, 05:40-05:41, 05:45, 05:47-																
05:51Q, 07:41																
Well No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
110111101					J	J	1	J	9	. 0		14			13	. 0

Page 15 of 24 General "Instructions for Use" IFU-01 Rev. No. 03 can be downloaded from

													*01:02:06, 01:04, 02:02:05,
													02:02:13, 02:05-02:06, 02:10,
													02:12, 02:17, 02:27:02, 02:33,
													04:01:01:01-04:01:06, 04:01:09-
													04:01:26, 04:03, 04:05, 04:07-
													04:12, 04:14-04:20, 04:23-04:33,
													04:35-04:41, 04:43-04:57, 04:59Q-
													04:81, 06:02:01:01-06:02:01:02,
				21									06:02:03-06:03, 06:06-06:15,
													06:17-06:40, 06:42-06:55,
													12:02:01-12:13, 12:15, 12:17,
													12:19, 12:21-12:31, 12:33-12:50,
													14:02:01-14:02:04, 14:02:06- 14:05, 14:07N-14:14, 14:16, 14:18-
													14:25, 15:08, 15:25, 16:01:01-
													16:02:02, 16:02:04-16:02:05,
													16:04:01, 16:06-16:20, 16:22-
													16:26, 16:28-16:32, 18:01-18:04
													*01:13, 03:87, 05:09, 07:130,
													16:27, <i>B*15:</i> 33
				21									*01:21
													*01:22, 01:35, 02:03, 02:16:02,
													02:18, 12:14:01, 15:02:05,
													15:06:03, 17:06, <i>B*58:02</i>
													*01:43
				21			24						*02:14, 04:42, 16:21
													*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,
				21									14:15, 15:02:01-15:02:04,
				~ I									15:02:06-15:06:02, 15:07, 15:09-
													15:13, 15:15-15:22, 15:24, 15:26-
													15:28, 15:30-15:45, 17:01:01:01-
													17:04, 17:07-17:08
													*02:42, <i>B</i> *67:02
													*05:01:01:01-05:01:15, 05:03,
													05:05-05:07N, 05:13-05:15, 05:19-
													05:22, 05:24, 05:26, 05:28, 05:30-
													05:38, 05:40-05:41, 05:45, 05:47-
			•	-									05:51Q, 07:41
17	18	19	20	71	ソフ	73	74	ンち	76	77	7) 🛛	70	Well No.

Length of spec.	250	115	115	110	155	270	100	225	385	110	280	165	105	170	265	100
PCR product(s)						310		290	505	140	470			280	500	545
Well No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
*05:04			3					8					13			
*05:08			3													
*05:10			3										13			
*05:11	1		3													
*05:12													13			
*05:16			3								11		13			
*05:17	1				5											
*05:18			3										13			
*05:23			3				7						13			
*05:25			3										13			
*05:27	1		3													
*05:29			3										13		15	
*05:39			3										13			
*05:42, 05:46			3		5								13			
*05:43			3										13			
*05:44			3										13			
*06:05, 12:16																16
*07:02:09																16
*07:04:01-07:04:04, 07:11-07:12,																
07:63, 07:139, 07:142																
*07:68								8								
*07:101					5							12				
*15:23	1															
*15:29	1															16
*17:05	1				5											
A*29:10																
HLA-C allele																
Well No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16

¹The internal positive control primer pairs amplify segments of the human growth hormone gene. The two different control primer pairs give rise to either an internal positive control band of 1070 base pairs, for most wells, or a band of 800 base pairs, for some wells.

Well number 1 contains the primer pair giving rise to the shorter, 800 bp, internal positive control band in order to help in the correct orientation of the HLA-C*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. ²The nucleotide position, in the 2nd, 3rd or 4th exon or the 1st or 2nd 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.

The nucleotide position, in the 2nd, 3rd, 5th or 6th 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.

Length of spec	200	285	100	125	115	145	95	80	195	110	115	80	375
PCR product(s								155			250	200	430
Well No	29	28	27	26	25	24	23	22	21	20	19	18	17
*05:0													
*05:0											19		
*05:1		28											
*05:1													
*05:1					25				21				
*05:1													
*05:1													
*05:1									21				
*05:2													
*05:2													17
*05:2								22					
*05:2													
*05:3								22					
*05:42, 05:4													17
*05:4						24							
*05:4										20			
*06:05, 12:1						24			21				
*07:02:0						24							
*07:04:01-07:04:04, 07:11-07:12								22					
07:63, 07:139, 07:14								22					
*07:6								22					
*07:10								22					
*15:2						24			21				
*15:2									21				
*17:0									21				
A*29:10					25								
HLA-C allel													
Well No	29	28	27	26	25	24	23	22	21	20	19	18	17
Well INC						_				_		. 5	• •

⁴The 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.

⁵The 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.

generated by primer mix 19. ⁶Primer 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 505 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 470 bp in the C*08:20 and 08:40 alleles.

HLA-C*08 Product Insert Page 18 of 24 101.623-12 – including *Taq* polymerase General "Instructions for Use"

IFU-01 Rev. No. 03 can be downloaded from

Lot No.: 55M Lot-specific information www.olerup-ssp.com

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 500 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, 02.42, 06:05, 07:02:09 and 12:16 and in the B*67:02 allele. Specific PCR fragment of 545 bp in the C*08:22 and in the C*15:29 alleles.

Primer mix 17: Specific PCR fragment of 375 bp in the C*08:05, 08:21 and 08:25 and the C*05:46 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.

Primer mix 22: Specific PCR fragment of 80 bp in the C*08:41 and in the C*05:27 and 05:39 alleles. Specific PCR fragment of 155 bp in the C*08:33 and in the C*07:04:01-07:04:04, 07:11-07:12, 07:63, 07:68, 07:101, 07:139 and 07:142 alleles.

CE

Lot No.: 55M Lot-specific information www.olerup-ssp.com

				INIE \/	Λ.	ır)	TI	C	\I	211					v.01				
		C	ELL L										<u> </u>							
HLA-C*08 SSP primer set Well																				
					1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
					Ľ			_			_									
				.:	301	201075802	201075803	201075804	201075805	201075806	201075807	201075808	201189809	201075810	201075811	201075812	201075813	201075814	201075815	201075816
				Prod. No.:	201075801	758	758	758	758	758	758	175	898	758	758	758	758	75	758	75
				ľoď	9	96	9	9	96	9	9	9	01	96	96	96	9	9	9	15
					2	7	7	7	0	7	7	7	2	7	7	7	7	0	0	7
4		VC cell line		<u>C*</u>																
1	9001	LK707	*07:02	*45.05	L.	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
3		E4181324	*07:01 *12:02	*15:05	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
4		GU373	*03:04	*04:01	H	-	-	-	-	-	-	-	H	-	-	-	-	-	-	-
5		KAS011	*06:02	04.01	H	-	-	H	H	-	-	H		H	-	H	H	-	H	H
6	9353		*03:04	*07:02	H	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
7	9020		*05:04	07.02	<u>-</u>	-	+	-	-	-	-	-	-	H	-	-	+	-	-	-
8	9007		*04:01		-	-	-	-	-	-	-	-	-		-	-	-	-	-	-
9	9026		*12:03		-	-	-	-	-	-	-	-			-	-	-	-	-	-
10		LKT3	*01:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
11		PITOUT	*16:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
12	9052		*06:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
13		JESTHOM	*01:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
14		OLGA	*01:02	*03:04	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
15	9075		*03:04		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
16	9037	SWEIG007	*02:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
17		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		CH1007	*07:04	*15:05	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
28		BEL5GB	*05:01	*16:01	-	-	+	-	-	-	-	-	-	-	-	-	+	-	-	-
29	9050		*16:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
30	9021	_	*17:01		+	•	-	-	-	-	-	-	-	-	•	-	-	•	-	-
31		DUCAF	*05:01		-	-	+	-	-	-	-	-	-	-	-	-	+	-	-	-
32	9297		*17:01	*17:03	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
33		MT14B	*03:04		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
34	9104		*12:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
35		SSTO	*05:01	*0 * 0 :	-	-	+	-	-	-	-	-	-	-	-	-	+	-	-	-
36		KT17	*03:03	*04:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
37		HHKB	*07:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
38	9099		*03:03	*07.04	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
39	9315		*02:02	*07:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
40		WHONP199	*01:02	*06:02	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
41		H0301	*08:02		-	-	+	-	-	-	-	-	-	-	-	+	+	-	-	-
42 43		TAB089 T7526	*01:02 *01:02	*00.01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
43	9076		*12:03	*08:01	+	+	-	-	-	-	-	-	-	-	-	+	-	-	-	-
44		SHJO	*06:02	*17:01	-	-	-	Ē	Ē	-	-	-	H	H	-	Ė	Ė	-	-	-
46		SCHU	*07:02	17.01	+	-	-	-	-	-	-		-	H	-	-		-	-	-
46		TUBO	*07:02	*15:02				<u> </u>				Ė		_		Ė		-		
48		TER-ND	*04:01	*16:01	+	-	-	-	-	-	-		-	-	-	-	-	-	-	-

September 2011 Rev. No.: 00

HLA-C*08 SSP primer set Well	25 20 301183825	201189827	201189828	201189829
IHWC cell line	201189825	201189827	201189828	201189829
HWC cell line C*	201189825	201189827	201189828	201189829
IHWC cell line		-	-	- - -
IHWC cell line		-	-	- - -
IHWC cell line		-	-	- - -
IHWC cell line		-	-	- - -
IHWC cell line		-	- - -	- - -
1 9001 SA *07:02		-	- - -	- - -
2 9280 LK707 *07:01 *15:05 +		-	-	-
4 9275 GU373 *03:04 *04:01 - - - + -	 	-	-	-
5 9009 KAS011 *06:02 +		-	-	
6 9353 SM *03:04 *07:02 -		-	-	-
7 9020 QBL *05:01	 	-	-	
8 9007 DEM *04:01 +	 	_		-
9 9026 YAR *12:03 +		-	-	-
10 9107 LKT3 *01:02			-	-
11 9051 PITOUT *16:01 + 1		-	-	-
12 9052 DBB *06:02 + 13 9004 JESTHOM *01:02 14 9071 OLGA *01:02 *03:04 15 9075 DKB *03:04		-	-	-
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 - - - - - - - -		-	-	-
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 DHF *12:03 +		_	-	-
35 9302 SSTO *05:01		_	-	-
36 9024 KT17 *03:03 *04:01 +		_	-	-
37 9065 HHKB *07:02 -		_	-	-
		_	-	-
		_	-	-
44 0055 10004 100 00		_	H	-
40 0000 TADOO		_		
42 9066 TAB089			H	
44 9057 TEM *12:03 +		_		
44 9037 TEW 12.03 + 45 9239 SHJO *06:02 *17:01 +		_	H	
46 9013 SCHU *07:02			H	-
47 9045 TUBO *07:04 *15:02 + +		_	H	H
48 9303 TER-ND *04:01 *16:01 +		_	-	

HLA-C*08 Product Insert Page 21 of 24

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

General "Instructions for Use" IFU-01 Rev. No. 03 can be downloaded from

Lot No.: 55M 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: 55M

Expiry date: 2014-February-01

Number of tests: 12 Number of wells per test: 29

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2010-758-01	11	2010-758-11	21	2010-758-21
2	2010-758-02	12	2010-758-12	22	2011-898-22
3	2010-758-03	13	2010-758-13	23	2010-758-23
4	2010-758-04	14	2010-758-14	24	2011-898-24
5	2010-758-05	15	2010-758-15	25	2011-898-25
6	2010-758-06	16	2010-758-16	26	2011-898-26
7	2010-758-07	17	2010-758-17	27	2011-898-27
8	2010-758-08	18	2010-758-18	28	2011-898-28
9	2011-898-09	19	2010-758-19	29	2011-898-29
10	2010-758-10	20	2010-758-20		

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 to 29 were available. The specificity of the primers in primer solutions 5, 7 to 9, 11, 14, 15, 17 to 20, 24, 25, 28 and 29 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer. In primer solutions 6, 10, 26 and 27 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 was tested by separately adding one 3'-primer.

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

Date of approval: 2011-September-16

Approved by:

Quality Control, Supervisor

((

HLA-C*08 Product Insert Page 22 of 24 101.623-12 – including *Taq* polymerase General "Instructions for Use"

IFU-01 Rev. No. 03 can be downloaded from

Lot No.: 55M Lot-specific information www.olerup-ssp.com

Declaration of Conformity

Product name: Olerup SSP® HLA-C*08

Product number: 101.623-12

Lot number: 55M

Intended use: HLA-C*08 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.

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

Stockholm, Sweden 2011-September-16

Ann-Cathrin Jareman
Head of QA and Regulatory Affairs

HLA-C*08 Product Insert Page 23 of 24 101.623-12 – including *Taq* polymerase General "Instructions for Use"

IFU-01 Rev. No. 03 can be downloaded from

HLA-C*08 Product Insert Page 24 of 24 **101.623-12 – including** *Taq* **polymerase** General "Instructions for Use"

IFU-01 Rev. No. 03 can be downloaded from

Lot No.: **55M** Lot-specific information www.olerup-ssp.com

Addresses:

Manufacturer:

Olerup SSP AB, Franzengatan 5, SE-112 51 Stockholm, Sweden.

Tel: +46-8-717 88 27 Fax: +46-8-717 88 18

E-mail: info-ssp@olerup.com

Web page: http://www.olerup-ssp.com

Distributed by:

Olerup GmbH, Löwengasse 47 / 6, AT-1030 Vienna, Austria.

Tel: +43-1-710 15 00 Fax: +43-1-710 15 00 10

E-mail: support-at@olerup.com Web page: http://www.olerup.com

Olerup Inc., 901 S. Bolmar St., Suite R, West Chester, PA 19382

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

E-mail: info.us@olerup.com

Web page: http://www.olerup.com

For information on *Olerup* SSP distributors worldwide, contact **Olerup GmbH**.