

Olerup SSP[®] HLA-C*15

Product number:	101.626-12 – including <i>Taq</i> polymerase
Lot number:	03K
Expiry date:	2012-May-01
Number of tests:	12
Number of wells per test:	16
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. 03K.

CHANGES COMPARED TO THE PREVIOUS *OLERUP SSP*[®] HLA-C*15 Lot

The HLA-C*15 specificity and interpretation tables have been updated for the HLA-C alleles described since the previous *Olerup SSP*[®] HLA-C*15 lot was made (**Lot No. 75F**).

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	Primer added for the C*15:28 allele.
5	Modified	-	Primer modified for improved yield of specific PCR product.
6	Added	Exchanged	Exchanged 3'-primer, primers added for the C*15:22 and C*15:26 alleles.
9	Added	-	Primer added for the C*15:23 allele.
12	-	Modified, added	3'-primer modified for improved specificity, primer added for the C*15:28 allele.
13	Added	Added	Primer pair added for the C*15:24 allele.
16	Added	Added	Primer pair added for the C*15:27 allele.

PRODUCT DESCRIPTION

HLA-C*15 SSP typing

CONTENT

The primer set contains 5'- and 3'-primers for identifying the C*15:02 to C*15:28 alleles.

PLATE LAYOUT

Each HLA-C*15 test consists of 16 PCR reactions in a 16 well cut PCR plate.

1	2	3	4	5	6	7	8
9	10	11	12	13	14	15	16

The 16 well PCR plate is marked with 'HLA-C*15' in silver/gray ink.

Well No. 1 is marked with the Lot No. '03K'.

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 16 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*15 SSP subtypings will be influenced by HLA-C*01, HLA-C*02, HLA-C*03, HLA-C*04, HLA-C*05, HLA-C*06, HLA-C*07, HLA-C*08, HLA-C*12, HLA-C*14, HLA-C*16 and HLA-C*17 alleles, when present on the other haplotype. In addition, primer mix 7 amplifies the B*35:08:02 and B*67:02 alleles, primer mix 8 weakly amplifies the B*07:78, B*13:18, B*13:31, B*15:73, B*54:10, B*54:20, B*55:09, B*55:21 and B*55:37 alleles and primer mix 14 amplifies the B*46:11, B*46:18, B*56:08 and B*56:14 alleles.

UNIQUELY IDENTIFIED ALLELES

All the HLA-C*15 alleles, i.e. **C*15:02 to C*15:28**, recognized by the HLA Nomenclature Committee in April 2010¹ will be amplified by the primers in the HLA-C*15 SSP kit.

The HLA-C*15 subtyping kit cannot distinguish the C*15:02:01 to C*15:02:05 alleles, the C*15:05:01 to C*15:05:04 alleles, the C*15:06:01 to C*15:06:02 alleles or the C*15:10:01 and C*15:10:02 alleles.

¹HLA-C alleles listed on the IMGT/HLA web page 2010-April-01, release 3.0.0, www.ebi.ac.uk/imgt/hla.

RESOLUTION IN HOMO- AND HETEROZYGOTES

The twenty-six phenotypically different HLA-C*15 alleles can be combined in 351 homozygous and heterozygous combinations. 231 of these genotypes do not give rise to unique amplification patterns. The different lengths of the specific PCR products generated by primer mixes 3, 6, 8, 9, 12 to 14 and 16 were not considered in these calculations.

++++----- --+-----15:04, 15:28 = 15:09, 15:28 = 15:20, 15:28
++++----- --+-----15:04, 15:16 = 15:09, 15:16
++++----- --+-----15:03, 15:04 = 15:03, 15:09 = 15:03, 15:20
+++----- --+-----15:06, 15:28 = 15:26, 15:28
+++----- --+-----15:06, 15:16 = 15:16, 15:26
+++----- --+-----15:03, 15:06 = 15:03, 15:26
+++----- --+-----15:13, 15:25 = 15:16, 15:21
+++----- --+-----15:02, 15:25 = 15:03, 15:07 = 15:03, 15:21 = 15:03, 15:25
= 15:07, 15:28 = 15:21, 15:25 = 15:21, 15:28 =
15:25, 15:28
+++----- +-+-----15:03, 15:11 = 15:16, 15:18
+++----- --+-----15:12, 15:28 = 15:24, 15:28
+++----- --+-----15:13, 15:28 = 15:16, 15:28 = 15:17, 15:28
+++----- --+-----15:02, 15:28 = 15:03, 15:28 = 15:28, 15:28
+++----- --+-----15:12, 15:16 = 15:16, 15:24
+++----- --+-----15:03, 15:12 = 15:03, 15:24
+++----- --+-----15:02, 15:16 = 15:03, 15:13 = 15:03, 15:16 = 15:03, 15:17
= 15:13, 15:16
+++----- --+-----15:02, 15:03 = 15:03, 15:03
++-+----- --+-----15:04, 15:22 = 15:09, 15:22 = 15:20, 15:22
++-+----- +-+-----15:04, 15:23 = 15:09, 15:23 = 15:20, 15:23
++-+----- --+-----15:04, 15:05 = 15:05, 15:09 = 15:05, 15:20
++-+----- --+-----15:04, 15:26 = 15:09, 15:26 = 15:20, 15:26
++-+----- --+-----15:04, 15:06 = 15:06, 15:09 = 15:06, 15:20
++-+----- --+-----15:07, 15:19 = 15:19, 15:21
++-+----- --+-----15:04, 15:07 = 15:04, 15:21 = 15:07, 15:09 = 15:09, 15:21
= 15:20, 15:21
++-+----- --+-----15:13, 15:19 = 15:17, 15:19
++-+----- --+-----15:08, 15:27 = 15:15, 15:19
++-+----- --+-----15:02, 15:19 = 15:04, 15:08 = 15:08, 15:09 = 15:08, 15:19
= 15:08, 15:20
++-+----- --+-----15:04, 15:19 = 15:09, 15:19 = 15:19, 15:19 = 15:19, 15:20
++-+----- +-+-----15:04, 15:11 = 15:09, 15:11
++-+----- +-+-----15:04, 15:18 = 15:09, 15:18 = 15:18, 15:20
++-+----- --+-----15:04, 15:10 = 15:09, 15:10
++-+----- --+-----15:04, 15:12 = 15:09, 15:12 = 15:12, 15:20
++-+----- --+-----15:04, 15:13 = 15:04, 15:17 = 15:09, 15:13 = 15:09, 15:17
= 15:13, 15:20
++-+----- --+-----15:02, 15:27 = 15:04, 15:15 = 15:09, 15:15 = 15:15, 15:20
= 15:15, 15:27
++-+----- --+-----15:02, 15:04 = 15:02, 15:09 = 15:02, 15:20
++-+----- --+-----15:04, 15:24 = 15:09, 15:24 = 15:20, 15:24
++-+----- --+-----15:04, 15:27 = 15:09, 15:27
++-+----- --+-----15:04, 15:09 = 15:04, 15:20 = 15:09, 15:09 = 15:09, 15:20
++-+----- --+-----15:07, 15:22 = 15:21, 15:22
++-+----- +-+-----15:18, 15:22 = 15:23, 15:26
++-+----- +-+-----15:06, 15:23 = 15:22, 15:23
++-+----- --+-----15:13, 15:22 = 15:17, 15:22

SPECIFICITY TABLE

HLA-C*15 SSP subtyping

Specificities and sizes of the PCR products of the 16 primer mixes used for HLA-C*15 SSP subtyping

Primer Mix	Size of spec. PCR product ¹	Size of control band ²	Amplified HLA-C*15 alleles	Other amplified HLA Class I alleles ³
1	325 bp	800 bp	*15:02:01-15:03, 15:05:01-15:13, 15:15-15:24, 15:26-15:28	*02:06, 02:23, 02:36, 03:81, 12:15, 16:20
2	175 bp	1070 bp	*15:02:01-15:09, 15:12-15:13, 15:15, 15:18-15:19, 15:21-15:24, 15:26, 15:28	*03:08, 03:29, 03:31, 07:20, 07:96
3 ^{4,7}	70 bp, 195 bp	1070 bp	*15:03, 15:16, 15:25 ^w , 15:28	*02:12 ^w , 03:15, 03:27 ^w , 03:38:01 ^w -03:38:02 ^w , 03:69 ^w , 04:03, 04:06, 04:16, 07:20 ^w , 07:96 ^w
4	315 bp	1070 bp	*15:04, 15:09, 15:19-15:20, 15:27	*01:04, 01:21, 02:02:01-02:02:03, 02:02:05-02:05, 02:08-02:18, 02:20-02:21, 02:24-02:36, 03:02:01-03:02:06, 03:14-03:16, 03:33, 03:36, 03:40, 03:42-03:43:02, 03:60, 03:71, 03:84, 04:54, 05:04, 06:02:01:01-06:02:01:02, 06:02:03-06:08, 06:10-06:33, 06:35-06:37, 07:01:01-07:03, 07:05-07:10, 07:14-07:27:02, 07:30-07:33N, 07:35-07:40, 07:42-07:44, 07:46-07:62, 07:64-07:99, 08:09, 08:11, 12:02:01-12:14:02, 12:16-12:30, 12:32-12:35, 14:02:01-14:19, 16:01:01-16:02:04, 16:04:01, 16:06-16:09, 16:11-16:21
5 ^{4,5}	100 bp	1070 bp	*15:05:01-15:05:04, 15:22-15:23	

Lot No.: **03K**

Lot-specific information

www.olerup-ssp.com

6⁸	305 bp, 345 bp, 370 bp	1070 bp	*15:06:01-15:06:02, 15:22, 15:26	
7⁴	140 bp	800 bp	*15:07, 15:21, 15:25	*01:21, 02:12, 02:27, 04:11, 04:29, 04:36, 04:55, 07:02:09, 08:01:01-08:09, 08:11-08:31, 12:02:01-12:03:03, 12:03:05-12:03:08, 12:03:10-12:03:11, 12:06-12:08, 12:10:01-12:20, 12:22-12:26, 12:28-12:32, 12:34-12:35, 14:02:03, 14:03, 14:08, 14:10, 16:01:01, 16:01:03-16:01:04, 16:04:01, 16:06-16:08, 16:10-16:11, 16:13-16:18, 16:20-16:21, B*35:08:02, B*67:02
8^{6,9}	160 bp, 185 bp	1070 bp	*15:08, 15:19	*02:06, 12:15, B*07:78^w, B*13:18^w, B*13:31^w, B*15:73^w, B*54:10^w, B*54:20^w, B*55:09^w, B*55:21^w, B*55:37^w
9^{4,10}	135 bp, 305 bp	1070 bp	*15:11, 15:18, 15:23	*02:02:01-02:02:03, 02:02:05-02:20, 02:22-02:25Q, 02:27-02:36, 04:03, 04:06, 04:42, 05:26, 06:05, 07:02:09, 12:16, 16:21
10	170 bp	1070 bp	*15:10:01-15:10:02	*02:08, 03:18, 03:64, 04:01:01:01-04:01:02, 04:01:04-04:01:16, 04:04:01-04:05, 04:07-04:15:02, 04:17-04:20, 04:23-04:62, 05:01:01:01-05:01:13, 05:03-05:42, 06:28, 07:64, 07:73, 07:92, 08:01:01-08:13, 08:15-08:31, 12:02:01-12:15, 12:17-12:35, 14:02:01-14:02:04, 14:04-14:09, 14:11-14:17, 14:19, 16:01:01-16:02:04, 16:04:01, 16:06-16:21, 17:01:01:01-17:06

Lot No.: **03K**

Lot-specific information

www.olerup-ssp.com

11	315 bp	800 bp	*15:02:01-15:03, 15:07-15:08, 15:10:01-15:13, 15:15-15:18, 15:21, 15:26, 15:28	*02:06, 03:12, 03:19, 12:15
12 ^{4,11}	100 bp, 240 bp	1070 bp	*15:07, 15:21, 15:25, 15:28	*02:12, 02:27, 03:02:01- 03:04:16, 03:04:18-03:06, 03:08-03:14, 03:16- 03:17, 03:19-03:38:02, 03:40-03:44, 03:46- 03:66, 03:68-03:84, 07:96
13 ^{4,6,12}	125 bp, 185 bp	1070 bp	*15:12, 15:24	*04:52, 04:55, 14:10
14 ^{4,13}	130 bp, 440 bp	800 bp	*15:11, 15:13, 15:16-15:17	*02:06, 03:12, 03:19, 12:15, B*46:11, B*46:18, B*56:08, B*56:14
15 ^{4,5}	85 bp	1070 bp	*15:02:01-15:06:02, 15:08-15:10:02, 15:12-15:13, 15:15, 15:18-15:19, 15:21- 15:24, 15:26, 15:28	*03:29, 05:36, 07:07, 07:09
16 ^{4,14}	90 bp, 165 bp	1070 bp	*15:15, 15:27	

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 C*15 high resolution SSP typings. When the primers in a primer mix can give rise to specific PCR products of more than one length this is indicated if the size difference is 20 base pairs or more. Size differences shorter than 20 base pairs are not given. For high resolution SSP kits the respective lengths of the specific PCR product(s) of the alleles amplified by these primer mixes are given.

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

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

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

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

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*15 SSP subtyping.

In addition, wells number 7, 11 and 14 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.

³Due to the sharing of sequence motifs between HLA Class I alleles non-HLA-C*15 alleles will be amplified by most primer mixes. In addition, primer mix 7 amplifies the B*35:08:02 and B*67:02 alleles, primer mix 8 weakly amplifies the B*07:78, B*13:18, B*13:31, B*15:73, B*54:10, B*54:20,

Lot No.: **03K**

Lot-specific information

www.olerup-ssp.com

B*55:09, B*55:21 and B*55:37 alleles and primer mix 14 amplifies the B*46:11, B*46:18, B*56:08 and B*56:14 alleles.

⁴Short specific PCR fragments are less intense and not as sharp as longer specific bands.

⁵Primer mixes 5 and 15 may give a lower yield of specific PCR products than the other HLA-C*15 primer mixes.

⁶Primer mix 13 may have tendencies of primer oligomer formation.

⁷Primer mix 3: Specific PCR fragment of 70 bp in the C*15:28 allele. Specific PCR fragment of 195 bp in the C*15:03, 15:16 and 15:25^w and in the C*02:12^w, 03:15, 03:27^w, 03:38:01^w-03:38:02^w, 03:69^w, 04:03, 04:06, 04:16, 07:20 and C*07:96 alleles.

⁸Primer mix 6: Specific PCR fragment of 305 bp in the C*15:06:01 and 15:06:02 alleles. Specific PCR fragment of 345 bp in the C*15:26 allele. Specific PCR fragment of 370 bp in the C*15:22 allele.

⁹Primer mix 8: Specific PCR fragment of 160 bp in the C*15:08 and the C*02:06 and 12:15 and in the B*07:78^w, B*13:18^w, 13:31^w, B*15:73^w, B*54:10^w, B*54:20^w, B*55:09^w, B*55:21^w and B*55:37^w alleles. Specific PCR fragment of 185 bp in the C*15:19 allele.

¹⁰Primer mix 9: Specific PCR fragment of 135 bp in the C*15:11 and 15:23 and in the C*02:02:01-02:02:03, 02:02:05-02:20, 02:22-02:25Q, 02:27-02:36, 04:03, 04:06, 04:42, 05:26, 06:05, 07:02:09, 12:16 and 16:21 alleles. Specific PCR fragment of 305 bp in the C*15:18 allele.

¹¹Primer mix 12: Specific PCR fragment of 100 bp in the C*15:28 allele. Specific PCR fragment of 240 bp in the C*15:07, 15:21 and 15:25 and in the C*02:12, 02:27, 03:02:01-03:04:16, 03:04:18-03:06, 03:08-03:14, 03:16-03:17, 03:19-03:38:02, 03:40-03:44, 03:46-03:66, 03:68-03:84 and 07:96 alleles.

¹²Primer mix 13: Specific PCR fragment of 125 bp in the C*15:24 allele. Specific PCR fragment of 185 bp in the C*15:12 and C*04:52, 04:55 and 14:10 alleles.

¹³Primer mix 14: Specific PCR fragment of 130 bp in the C*15:13 allele. Specific PCR fragment of 440 bp the C*15:11 and 15:16-15:17 and the C*02:06, 03:12, 03:19 and 12:15 and the B*46:11, B*46:18, B*56:08 and B*56:14 alleles.

¹⁴Primer mix 16: Specific PCR fragment of 90 bp in the C*15:27 allele. Specific PCR fragment of 165 bp in the C*15:15 allele.

'w', might be weakly amplified.

INTERPRETATION TABLE

HLA-C*15 SSP subtyping

Amplification patterns of the HLA-C*15:02 to 15:28 alleles

	Well ⁵							
	1	2	3	4	5	6	7	8
Length of spec.	325	175	70	315	100	305	140	160
PCR product			195			345		185
						370		
Length of int.	800	1070	1070	1070	1070	1070	800	1070
pos. control ¹								
5'-primer ²	409	134	134	419	420	355	201	125
	5'-ggC 3'	5'-CCA 3'	5'-CCA 3'	5'-gTC 3'	5'-TTC 3'	5'-CCC 3'	5'-CCA 3'	5'-CgA 3'
						379		420
						5'-ACg 3'		5'-TTA 3'
						419		
						5'-gTA 3'		
3'-primer ³	3 rd I	270	164	3 rd I	477	3 rd I	302	270
	5'-CTC 3'	5'-TAG 3'	5'-gCA 3'	5'-CTC 3'	5'-gCg 3'	5'-ggA 3'	5'-ggC 3'	5'-TAG 3'
			289				302	539
			5'-AgC 3'				5'-ggC 3'	5'-TCC 3'
Well No.	1	2	3	4	5	6	7	8
HLA-C allele ⁴								
*15:02:01-15:02:05	1	2						
*15:03	1	2	3					
*15:04		2		4				
*15:05:01-15:05:04	1	2			5			
*15:06:01-15:06:02	1	2				6		
*15:07	1	2					7	
*15:08	1	2						8
*15:09	1	2		4				
*15:10:01-15:10:02	1							
*15:11	1							
*15:12	1	2						
*15:13	1	2						
*15:15	1	2						
*15:16	1		3					
*15:17	1							
*15:18	1	2						
Well No.	1	2	3	4	5	6	7	8

INTERPRETATION TABLE								
HLA-C*15 SSP subtyping								
Amplification patterns of the HLA-C*15:02 to 15:28 alleles								
Well ⁵								
9	10	11	12	13	14	15	16	
135	170	315	100	125	130	85	90	Length of spec. PCR product
305			240	185	440		165	
1070	1070	800	1070	1070	800	1070	1070	Length of int. pos. control ¹
97	1st I	420	105	201	270	270	261	5'-primer ²
5' -TCg 3'	5' -CgA 3'	5' -TTA 3'	5' -gCT 3'	5' -CCA 3'	5' -AAg 3'	5' -AAC 3'	5' -AAC 3'	
118				2nd I	757		560	
5' -CCA 3'				5' -CCA 3'	5' -CCC 3'		5' -CCT 3'	
430								
5' -ACC 3'								
201	134	3rd I	164	343	420	312	312	3'-primer ³
5' -CTT 3'	5' -AgC 3'	5' -CTC 3'	5' -gCA 3'	5' -T 3'	5' -gCT 3'	5' -AgT 3'	5' -AgT 3'	
3rd I			302	412	846		3rd I	
5' -CTC 3'			5' -ggC 3'	5' -gTT 3'	5' -CAC 3'		5' -ggA 3'	
			302					
			5' -ggC 3'					
9	10	11	12	13	14	15	16	Well No. HLA-C allele ⁴
		11				15		*15:02:01-15:02:05
		11				15		*15:03
						15		*15:04
						15		*15:05:01-15:05:04
						15		*15:06:01-15:06:02
		11	12					*15:07
		11				15		*15:08
						15		*15:09
	10	11				15		*15:10:01-15:10:02
9		11			14			*15:11
		11		13		15		*15:12
		11			14	15		*15:13
		11				15	16	*15:15
		11			14			*15:16
		11			14			*15:17
9		11				15		*15:18
9	10	11	12	13	14	15	16	Well No.

Lot No.: **03K**

Lot-specific information

www.olerup-ssp.com

Length of spec.	325	175	70	315	100	305	140	160
PCR product			195			345		185
						370		
Well No.	1	2	3	4	5	6	7	8
*15:19	1	2		4				8
*15:20	1			4				
*15:21	1	2					7	
*15:22	1	2			5	6		
*15:23	1	2			5			
*15:24	1	2						
*15:25			w				7	
*15:26	1	2				6		
*15:27	1			4				
*15:28	1	2	3					
*01:04, 02:21, 02:26:01- 02:26:02, 06:02:01:01- 06:02:01:02, 06:02:03-06:04, 06:06-06:08, 06:10-06:27, 06:29-06:33, 06:35-06:37, 07:01:01-07:02:08, 07:02:10- 07:03, 07:05-07:06, 07:08, 07:10, 07:14-07:19, 07:21- 07:27:02, 07:30-07:33N, 07:35-07:40, 07:42-07:44, 07:46-07:62, 07:65-07:72, 07:74-07:91, 07:93-07:95, 07:97-07:99, 14:18				4				
*01:21, 14:03				4			7	
*02:02:01-02:02:03, 02:02:05- 02:05, 02:09-02:11, 02:13- 02:18, 02:20, 02:24-02:25Q, 02:28-02:35, 06:05				4				
*02:06	1							8
*02:07, 02:19, 02:22								
*02:08				4				
*02:12			w	4			7	
*02:23	1							
*02:27				4			7	
*02:36	1			4				
*03:02:01-03:02:06, 03:14, 03:16, 03:33, 03:36, 03:40, 03:42-03:43:02, 03:60, 03:71, 03:84				4				
Well No.	1	2	3	4	5	6	7	8

Lot No.: **03K**

Lot-specific information

www.olerup-ssp.com

135	170	315	100	125	130	85	90	Length of spec. PCR product
305			240	185	440		165	
9	10	11	12	13	14	15	16	Well No.
						15		*15:19
								*15:20
		11	12			15		*15:21
						15		*15:22
9						15		*15:23
				13		15		*15:24
			12					*15:25
		11				15		*15:26
							16	*15:27
		11	12			15		*15:28
								*01:04, 02:21, 02:26:01-02:26:02, 06:02:01:01-06:02:01:02, 06:02:03-06:04, 06:06-06:08, 06:10-06:27, 06:29-06:33, 06:35-06:37, 07:01:01-07:02:08, 07:02:10-07:03, 07:05-07:06, 07:08, 07:10, 07:14-07:19, 07:21-07:27:02, 07:30-07:33N, 07:35-07:40, 07:42-07:44, 07:46-07:62, 07:65-07:72, 07:74-07:91, 07:93-07:95, 07:97-07:99, 14:18
								*01:21, 14:03
9								*02:02:01-02:02:03, 02:02:05-02:05, 02:09-02:11, 02:13-02:18, 02:20, 02:24-02:25Q, 02:28-02:35, 06:05
9		11			14			*02:06
9								*02:07, 02:19, 02:22
9	10							*02:08
9			12					*02:12
9								*02:23
9			12					*02:27
9								*02:36
			12					*03:02:01-03:02:06, 03:14, 03:16, 03:33, 03:36, 03:40, 03:42-03:43:02, 03:60, 03:71, 03:84
9	10	11	12	13	14	15	16	Well No.



Lot No.: **03K**

Lot-specific information

www.olerup-ssp.com

Length of spec.	325	175	70	315	100	305	140	160
PCR product			195			345		185
						370		
Well No.	1	2	3	4	5	6	7	8
*03:03:01-03:04:16, 03:04:18-03:06, 03:09-03:11:02, 03:13, 03:17, 03:20N-03:26, 03:28, 03:30, 03:32, 03:34-03:35, 03:37, 03:41, 03:44, 03:46-03:59, 03:61-03:63, 03:65-03:66, 03:68, 03:70, 03:72-03:80, 03:82-03:83								
*03:08, 03:31		2						
*03:12, 03:19								
*03:15			3	4				
*03:18, 04:01:01:01-04:01:02, 04:01:04-04:01:16, 04:04:01-04:05, 04:07-04:10, 04:12-04:15:02, 04:17-04:20, 04:23-04:28, 04:30-04:35, 04:37-04:41, 04:43-04:51, 04:53, 04:56-04:62, 05:01:01:01-05:01:13, 05:03, 05:05-05:25, 05:27-05:35, 05:37-05:42, 08:10, 17:01:01:01-17:06								
*03:27, 03:38:01-03:38:02, 03:69			w					
*03:29		2						
*03:64								
*03:81	1							
*04:03, 04:06			3					
*04:11, 04:29, 04:36, 08:01:01-08:08, 08:12-08:13, 08:15-08:31, 12:31, 16:10							7	
*04:16			3					
*04:42, 05:26								
*04:52								
Well No.	1	2	3	4	5	6	7	8

Lot No.: **03K**

Lot-specific information

www.olerup-ssp.com

135	170	315	100	125	130	85	90	Length of spec.
305			240	185	440		165	PCR product
9	10	11	12	13	14	15	16	Well No.
			12					*03:03:01-03:04:16, 03:04:18-03:06, 03:09-03:11:02, 03:13, 03:17, 03:20N-03:26, 03:28, 03:30, 03:32, 03:34-03:35, 03:37, 03:41, 03:44, 03:46-03:59, 03:61-03:63, 03:65-03:66, 03:68, 03:70, 03:72-03:80, 03:82-03:83
			12					*03:08, 03:31
		11	12		14			*03:12, 03:19
								*03:15
	10							*03:18, 04:01:01:01-04:01:02, 04:01:04-04:01:16, 04:04:01-04:05, 04:07-04:10, 04:12-04:15:02, 04:17-04:20, 04:23-04:28, 04:30-04:35, 04:37-04:41, 04:43-04:51, 04:53, 04:56-04:62, 05:01:01:01-05:01:13, 05:03, 05:05-05:25, 05:27-05:35, 05:37-05:42, 08:10, 17:01:01:01-17:06
			12					*03:27, 03:38:01-03:38:02, 03:69
			12			15		*03:29
	10		12					*03:64
			12					*03:81
9								*04:03, 04:06
	10							*04:11, 04:29, 04:36, 08:01:01-08:08, 08:12-08:13, 08:15-08:31, 12:31, 16:10
								*04:16
9	10							*04:42, 05:26
	10			13				*04:52
9	10	11	12	13	14	15	16	Well No.

Lot No.: **03K**

Lot-specific information

www.olerup-ssp.com

Length of spec.	325	175	70	315	100	305	140	160
PCR product			195			345		185
						370		
Well No.	1	2	3	4	5	6	7	8
*04:54, 05:04, 06:28, 07:64, 07:73, 07:92, 12:03:04, 12:03:09, 12:04:01-12:05, 12:09, 12:21, 12:27, 12:33, 14:02:01-14:02:02, 14:02:04, 14:04-14:07N, 14:09, 14:11- 14:17, 14:19, 16:01:02, 16:02:01-16:02:04, 16:09, 16:12, 16:19				4				
*04:55							7	
*05:36								
*07:02:09, 12:16				4			7	
*07:07, 07:09				4				
*07:20		2	w	4				
*07:96		2	w	4				
*08:09, 08:11, 12:02:01- 12:03:03, 12:03:05-12:03:08, 12:03:10-12:03:11, 12:06- 12:08, 12:10:01-12:14:02, 12:17-12:20, 12:22-12:26, 12:28-12:30, 12:32, 12:34- 12:35, 14:02:03, 14:08, 16:01:01, 16:01:03-16:01:04, 16:04:01, 16:06-16:08, 16:11, 16:13-16:18				4			7	
*08:14, B*35:08:02, B*67:02							7	
*12:15	1						7	8
*14:10				4			7	
*16:20	1			4			7	
*16:21				4			7	
B*07:78, B*13:18, B*13:31, B*15:73, B*54:10, B*54:20, B*55:09, B*55:21, B*55:37								w
B*46:11, B*46:18, B*56:08, B*56:14								
Well No.	1	2	3	4	5	6	7	8

Lot No.: **03K**

Lot-specific information

www.olerup-ssp.com

135	170	315	100	125	130	85	90	Length of spec.
305			240	185	440		165	PCR product
9	10	11	12	13	14	15	16	Well No.
	10							*04:54, 05:04, 06:28, 07:64, 07:73, 07:92, 12:03:04, 12:03:09, 12:04:01-12:05, 12:09, 12:21, 12:27, 12:33, 14:02:01-14:02:02, 14:02:04, 14:04-14:07N, 14:09, 14:11- 14:17, 14:19, 16:01:02, 16:02:01-16:02:04, 16:09, 16:12, 16:19
	10			13				*04:55
	10					15		*05:36
9								*07:02:09, 12:16
						15		*07:07, 07:09
								*07:20
			12					*07:96
	10							*08:09, 08:11, 12:02:01- 12:03:03, 12:03:05-12:03:08, 12:03:10-12:03:11, 12:06- 12:08, 12:10:01-12:14:02, 12:17-12:20, 12:22-12:26, 12:28-12:30, 12:32, 12:34- 12:35, 14:02:03, 14:08, 16:01:01, 16:01:03-16:01:04, 16:04:01, 16:06-16:08, 16:11, 16:13-16:18
								*08:14, B*35:08:02, B*67:02
	10	11			14			*12:15
				13				*14:10
	10							*16:20
9	10							*16:21
								B*07:78, B*13:18, B*13:31, B*15:73, B*54:10, B*54:20, B*55:09, B*55:21, B*55:37
					14			B*46:11, B*46:18, B*56:08, B*56:14
9	10	11	12	13	14	15	16	Well No.

Lot No.: **03K**

Lot-specific information

www.olerup-ssp.com

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*15 SSP subtyping.

In addition, wells number 7, 11 and 14 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 specificity-determining 3'-end of the primer is given. Nucleotide numbering as on the www.ebi.ac.uk/imgt/hla web site. The sequence of the 3 terminal nucleotides of the primer is given.

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

⁴The HLA-C*15:01 nucleotide sequence has been shown to be identical to C*15:02.

The HLA-C*15:14 nucleotide sequence has been renamed C*15:10:02.

⁵Primer mix 3: Specific PCR fragment of 70 bp in the C*15:28 allele. Specific PCR fragment of 195 bp in the C*15:03, 15:16 and 15:25^w and in the C*02:12^w, 03:15, 03:27^w, 03:38:01^w-03:38:02^w, 03:69^w, 04:03, 04:06, 04:16, 07:20 and C*07:96 alleles.

Primer mix 6: Specific PCR fragment of 305 bp in the C*15:06:01 and 15:06:02 alleles. Specific PCR fragment of 345 bp in the C*15:26 allele. Specific PCR fragment of 370 bp in the C*15:22 allele.

Primer mix 8: Specific PCR fragment of 160 bp in the C*15:08 and the C*02:06 and 12:15 and in the B*07:78^w, B*13:18^w, 13:31^w, B*15:73^w, B*54:10^w, B*54:20^w, B*55:09^w, B*55:21^w and B*55:37^w alleles. Specific PCR fragment of 185 bp in the C*15:19 allele.

Primer mix 9: Specific PCR fragment of 135 bp in the C*15:11 and 15:23 and in the C*02:02:01-02:02:03, 02:02:05-02:20, 02:22-02:25Q, 02:27-02:36, 04:03, 04:06, 04:42, 05:26, 06:05, 07:02:09, 12:16 and 16:21 alleles. Specific PCR fragment of 305 bp in the C*15:18 allele.

Primer mix 12: Specific PCR fragment of 100 bp in the C*15:28 allele. Specific PCR fragment of 240 bp in the C*15:07, 15:21 and 15:25 and in the C*02:12, 02:27, 03:02:01-03:04:16, 03:04:18-03:06, 03:08-03:14, 03:16-03:17, 03:19-03:38:02, 03:40-03:44, 03:46-03:66, 03:68-03:84 and 07:96 alleles.

Primer mix 13: Specific PCR fragment of 125 bp in the C*15:24 allele. Specific PCR fragment of 185 bp in the C*15:12 and C*04:52, 04:55 and 14:10 alleles.

Primer mix 14: Specific PCR fragment of 130 bp in the C*15:13 allele. Specific PCR fragment of 440 bp the C*15:11 and 15:16-15:17 and the C*02:06, 03:12, 03:19 and 12:15 and the B*46:11, B*46:18, B*56:08 and B*56:14 alleles.

Primer mix 16: Specific PCR fragment of 90 bp in the C*15:27 allele. Specific PCR fragment of 165 bp in the C*15:15 allele.

'w', might be weakly amplified.

CELL LINE VALIDATION SHEET																				
HLA-C*15 SSP primer set																				
				Prod. No.:	Well															
					1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
					201071801	201071802	201071803	201071804	201071805	201071806	201071807	201071808	201071809	201071810	201071811	201071812	201071813	201071814	201071815	201071816
	IHWC cell line		C*																	
1	9001 SA		*07:02		-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-
2	9280 LK707		*07:01	*15:05	+	+	-	+	+	-	-	-	-	-	-	-	-	-	+	-
3	9011 E4181324		*12:02		-	-	-	+	-	-	+	-	-	+	-	-	-	-	-	-
4	9275 GU373		*03:04	*04:01	-	-	-	-	-	-	-	-	-	+	-	+	-	-	-	-
5	9009 KAS011		*06:02		-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-
6	9353 SM		*03:04	*07:02	-	-	-	+	-	-	-	-	-	-	-	+	-	-	-	-
7	9020 QBL		*05:01		-	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-
8	9025 DEU		*04:01		-	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-
9	9026 YAR		*12:03		-	-	-	+	-	-	+	-	-	+	-	-	-	-	-	-
10	9107 LKT3		*01:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
11	9051 PITOUT		*16:01		-	-	-	+	-	-	+	-	-	+	-	-	-	-	-	-
12	9052 DBB		*06:02		-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-
13	9004 JESTHOM		*01:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
14	9071 OLGA		*01:02	*03:04	-	-	-	-	-	-	-	-	-	-	-	+	-	-	-	-
15	9075 DKB		*03:04		-	-	-	-	-	-	-	-	-	-	-	+	-	-	-	-
16	9037 SWEIG007		*02:02		-	-	-	+	-	-	-	-	+	-	-	-	-	-	-	-
17	9282 CTM3953540		*03:03	*07:01	-	-	-	+	-	-	-	-	-	-	-	+	-	-	-	-
18	9257 32367		*01:02	*07:05	-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-
19	9038 BM16		*07:01		-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-
20	9059 SLE005		*03:04		-	-	-	-	-	-	-	-	-	-	-	+	-	-	-	-
21	9064 AMALA		*03:03		-	-	-	-	-	-	-	-	-	-	-	+	-	-	-	-
22	9056 KOSE		*12:03		-	-	-	+	-	-	+	-	-	+	-	-	-	-	-	-
23	9124 IHL		*01:02	*15:02	+	+	-	-	-	-	-	-	-	-	+	-	-	-	+	-
24	9035 JBUSH		*12:03		-	-	-	+	-	-	+	-	-	+	-	-	-	-	-	-
25	9049 IBW9		*08:02		-	-	-	-	-	-	+	-	-	+	-	-	-	-	-	-
26	9285 WT49		*07:01		-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-
27	9191 CH1007		*07:04	*15:05	+	+	-	-	+	-	-	-	-	-	-	-	-	-	+	-
28	9320 BEL5GB		*05:01	*16:01	-	-	-	+	-	-	+	-	-	+	-	-	-	-	-	-
29	9050 MOU		*16:01		-	-	-	+	-	-	+	-	-	+	-	-	-	-	-	-
30	9021 RSH		*17:01		-	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-
31	9019 DUCAF		*05:01		-	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-
32	9297 HAG		*17:01	*17:03	-	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-
33	9098 MT14B		*03:04		-	-	-	-	-	-	-	-	-	-	-	+	-	-	-	-
34	9104 DHIF		*12:03		-	-	-	+	-	-	+	-	-	+	-	-	-	-	-	-
35	9302 SSTO		*05:01		-	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-
36	9024 KT17		*03:03	*04:01	-	-	-	-	-	-	-	-	-	+	-	+	-	-	-	-
37	9065 HHKB		*07:02		-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-
38	9099 LZL		*03:03		-	-	-	-	-	-	-	-	-	-	-	+	-	-	-	-
39	9315 CML		*02:02	*07:01	-	-	-	+	-	-	-	-	+	+	-	-	-	-	-	-
40	9134 WHONP199		*01:02	*06:02	-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-
41	9055 H0301		*08:02		-	-	-	-	-	-	-	+	-	-	+	-	-	-	-	-
42	9066 TAB089		*01:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
43	9076 T7526		*01:02	*08:01	-	-	-	-	-	-	-	+	-	-	+	-	-	-	-	-
44	9057 TEM		*12:03		-	-	-	+	-	-	+	-	-	+	-	-	-	-	-	-
45	9239 SHJO		*06:02	*17:01	-	-	-	+	-	-	-	-	-	+	-	-	-	-	-	-
46	9013 SCHU		*07:02		-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-
47	9045 TUBO		*07:04	*15:02	+	+	-	-	-	-	-	-	-	-	+	-	-	-	+	-
48	9303 TER-ND		*04:01	*16:01	-	-	-	+	-	-	+	-	-	+	-	-	-	-	-	-



CERTIFICATE OF ANALYSIS

Olerup SSP[®] HLA-C*15 SSP

Product number: 101.626-12 – including *Taq* polymerase
Lot number: 03K
Expiry date: 2012-May-01
Number of tests: 12
Number of wells per test: 16

Well specifications:

Well No.	Production No.	Well No.	Production No.
1	2010-718-01	9	2010-718-09
2	2010-718-02	10	2010-718-10
3	2010-718-03	11	2010-718-11
4	2010-718-04	12	2010-718-12
5	2010-718-05	13	2010-718-13
6	2010-718-06	14	2010-718-14
7	2010-718-07	15	2010-718-15
8	2010-718-08	16	2010-718-16

The specificity of each primer solution of the HLA-C*15 primer set has been tested against 48 well characterized cell line DNAs.

No DNAs carrying the alleles to be amplified by primer solutions 6, 8, 13, 14 and 16 were available. The specificity of the primers in primer solutions 6, 8, 13, 14 and 16 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer. In primer mixes 8, 9 and 14 one of the 5'-primers could not be tested, and in primer mixes 3 and 12 one of the 5'-primers could not be tested. In addition, one 5'-primer and one 3'-primer in primer solution 9 were tested by separately adding one 3'-primer respectively one 5'-primer.

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

Date of approval: 2010-November-24

Approved by:

Quality Control, Supervisor

Lot No.: **03K**

Lot-specific information

www.olerup-ssp.com

Declaration of Conformity

Product name: *Olerup* SSP® HLA-C*15
Product number: 101.626-12
Lot number: 03K

Intended use: HLA-C*15 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

Lot No.: **03K**

Lot-specific information

www.olerup-ssp.com

ADDRESSES:

Manufacturer:

Olerup SSP AB, Hasselstigen 1, SE-133 33 Saltsjöbaden, 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**.