HLA-C*06 Product Insert Page 1 of 24 101.614-12 - including *Taq* polymerase General "Instructions for Use"

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

Lot No.: **08K Lot-specific information** www.olerup-ssp.com

Olerup SSP® HLA-C*06

Product number: 101.614-12 – including *Taq* polymerase

Lot number: 08K

2012-June-01 Expiry date:

Number of tests: 12 Number of wells per test: 24

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

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

This Product Description is only valid for Lot No. 08K.

CHANGES COMPARED TO THE PREVIOUS OLERUP SSP® **HLA-C*06 LOT**

The HLA-C*06 specificity and interpretation tables have been updated for the HLA-C alleles described since the previous Olerup SSP® HLA-C*06 lot was made (Lot No. 95F).

Eight wells have been added to the HLA-C*06 kit,

wells 17 to 24.

The amplification patterns for some rare HLA-C*06 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	-	Modified	Improved specificity of primer pair.
7	Added	-	Primer added for the C*06:33 allele.
16	Added	-	Primer added for the C*06:21 allele.
17	New	New	Primer pairs for the C*06:24 and C*06:37 alleles.
18	New	New	Primer pair for the C*06:26 allele.
19	New	New	Primer pairs for the C*06:28 and C*06:32 alleles.
20	New	New	Primer pairs for the C*06:27 and C*06:29 alleles.

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21	New	New	Primer pairs for the C*06:25 and C*06:36
			alleles.
22	New	New	Primer pair for the C*06:30 allele.
23	New	New	Primer pair for the C*06:31 allele.
24	New	New	Primer pairs for the C*06:34 and C*06:35
			alleles.

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101.614-12 – including *Taq* **polymerase**

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PRODUCT DESCRIPTION

HLA-C*06 SSP subtyping

CONTENT

The primer set contains 5'- and 3'-primers for identifying the HLA-C*06:02 to HLA-C*06:37 alleles.

PLATE LAYOUT

Each test consists of 24 PCR reactions in a 24 well PCR plate.

1	2	3	4	5	6	7	8
9	10	11	12	13	14	15	16
17	18	19	20	21	22	23	24

The 24 well cut PCR plate is marked with 'HLA-C*06' in silver/gray ink.

Well No. 1 is marked with the Lot No. '08K'.

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 covered with a PCR-compatible foil.

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

INTERPRETATION

The interpretation of HLA-C*06 SSP subtypings will be influenced by the C*01, six C*02, the C*03, most C*04, the C*05, several C*07, the C*08, most C*12, the C*14, the C*15, the C*16:04:01 allele, the C*17 and the C*18 alleles when present on the other haplotype. In addition, the B*58:02 allele will be amplified by primer mix 4, the B*15:137 will be amplified by the primer mix 9, the B*08:56, B*15:142 and B*51:68 alleles will be amplified by primer mix 19 and the B*13:31, B*15:58, B*15:73, B*15:137, B*39:36 and B*39:36 alleles will be amplified by primer mix 24.

UNIQUELY IDENTIFIED ALLELES

All the HLA-C*06 alleles, i.e. **C*06:02 to C*06:37**, recognized by the HLA Nomenclature Committee in April 2010¹ will give rise to unique amplification patterns by the primers in the HLA-C*06 subtyping kit.

The HLA-C*06 SSP subtyping kit cannot distinguish the C*06:02:01:01, 06:02:01:02 and the C*06:02:03 to 06:02:05 alleles.

The C*06:07 and C*06:33 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 7.

The C*06:16N and C*06:21 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 16.

The C*06:24 and C*06:37 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 17.

The C*06:25 and C*06:36 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 21.

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The C*06:27 and C*06:29 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 20.

The C*06:28 and C*06:32 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 19.

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 36 HLA-C*06 alleles will generate 30 patterns, as some alleles have patterns that only differ in size of specific PCR product. These can be combined in 465 homozygous and heterozygous combinations. 119 of these genotypes do not give rise to unique amplification patterns. The different lengths of the specific PCR products generated by primer mixes 5, 7, 9, 11, 12, 16, 17, 19 to 21 and 24 were not considered in these calculations.

+++-+	06:03,06:05 = 06:05,06:18 = 06:06,06:18
+++-+	06:03,06:23 = 06:17,06:18 = 06:18,06:23
+++-+	06:18,06:34 = 06:18,06:35
+++-+	06:02,06:18 = 06:03,06:18 = 06:18,06:18
++++	06:03,06:34 = 06:03,06:35
+++ +	06:05,06:17 = 06:05,06:23 = 06:06,06:23
++++	06:09,06:23 = 06:23,06:34 = 06:23,06:35
+++	06:02,06:23 = 06:17,06:23 = 06:23,06:23
+++	06:07,06:20 = 06:16N,06:19 = 06:19,06:20
+++	06:19,06:34 = 06:19,06:35
++	06:02,06:19 = 06:07,06:12 = 06:07,06:19 =
	06:12,06:19 = 06:19,06:19
+++	06:07,06:34 = 06:07,06:35
++	06:02,06:07 = 06:07,06:07
+++	06:08,06:34 = 06:08,06:35
+++	06:02,06:08 = 06:08,06:08
+++	06:02,06:09 = 06:09,06:09 = 06:09,06:17 =
	06:09,06:34 = 06:09,06:35 = 06:17,06:34 =
	06:17,06:35
+++	06:22,06:34 = 06:22,06:35
++	06:02,06:22 = 06:10,06:11 = 06:10,06:22 =
	06:11,06:22 = 06:22,06:22
+++	06:10,06:34 = 06:10,06:35
++	06:02,06:10 = 06:10,06:10
+++	06:11,06:34 = 06:11,06:35
++	06:02,06:11 = 06:11,06:11
+++	06:20,06:34 = 06:20,06:35
++	06:02,06:20 = 06:12,06:16N = 06:12,06:20
	= 06:16N,06:20 = 06:20,06:20
+++	06:12,06:34 = 06:12,06:35
++	06:02,06:12 = 06:12,06:12
+++	06:13,06:34 = 06:13,06:35
++	06:02,06:13 = 06:13,06:13
+++	06:15,06:34 = 06:15,06:35
++	06:02,06:15 = 06:15,06:15
+++	06:16N,06:34 = 06:16N,06:35

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Lot No.: 08K
                   Lot-specific information
                                      www.olerup-ssp.com
++----- 06:02,06:16N = 06:16N,06:16N
++----- +----+ 06:24,06:34 = 06:24,06:35
++----- +----- 06:02,06:24 = 06:24,06:24
++----- ----- -+---+ 06:26,06:34 = 06:26,06:35
++---- 06:02,06:26 = 06:26,06:26
++----- 06:28,06:34 = 06:28,06:35
++---- 06:02,06:28 = 06:28,06:28
++----- -06:27,06:34 = 06:27,06:35
++---- 06:02,06:27 = 06:27,06:27
++----- 06:25,06:34 = 06:25,06:35
++---- 06:02,06:25 = 06:25,06:25
++----- -06:02,06:30 = 06:30,06:30
++----++06:31,06:34=06:31,06:35
++----- ------ ----+- 06:02,06:31 = 06:31,06:31
++----- -----+ 06:02,06:34 = 06:02,06:35 = 06:34,06:34
                     = 06:34,06:35
+---++-- ----- 06:05,06:05 = 06:05,06:06
06:02 = 06:02:01:01, 06:02:01:02, 06:02:03-06:02:05
06:07 = 06:07 and 06:33
06:16N = 06:16N and 06:21
06:24 = 06:24 \text{ and } 06:37
06:25 = 06:25 \text{ and } 06:36
06:27 = 06:27 \text{ and } 06:29
06:28 = 06:28 \text{ and } 06:32
```

Lot No.: 08K Lot-specific information www.olerup-ssp.com

SPECIFICITY TABLE

HLA-C*06 SSP subtyping

Specificities and sizes of the PCR products of the 24 primer mixes used for $HLA-C^*06$ SSP subtyping

Primer Mix	Size of spec. PCR product ¹	Size of control band ²	Amplified HLA- C*06 alleles ³	Other amplified HLA Class I alleles ⁴
1	240 bp	800 bp	*06:02:01:01- 06:02:01:02, 06:02:03-06:02:05, 06:04-06:16N, 06:18-06:37	*03:39, 03:67, 04:42, 12:16, 16:21
2	220 bp	800 bp	*06:02:01:01- 06:02:01:02, 06:02:03-06:03, 06:07-06:13, 06:15-06:34, 06:36-06:37	*01:04, 01:09, 02:05, 02:17, 12:03:01:01-12:07, 12:11- 12:13, 12:15, 12:23, 12:25- 12:26, 12:28-12:29, 12:31- 12:35, 14:16, 16:04:01
3 ⁵	135 bp	1070 bp	*06:03, 06:18	*03:02:01-03:04:14, 03:04:16-03:17, 03:19- 03:38:02, 03:40-03:66, 03:67 ^w , 03:68-03:84, 07:96
4	250 bp	1070 bp	*06:04	*01:22, 01:35, 05:11, 05:17, 05:27, 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, 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, 15:26-15:28, 17:01:01:01-17:06, B*58:02
5 ⁷	165 bp, 220 bp	800 bp	*06:05, 06:18, 06:23	*01:04, 01:09, 02:21, 05:01:01:01-05:01:13, 05:03-05:28, 05:30-05:42, 08:10, 12:21, 12:33, 17:05
6	250 bp	1070 bp	*06:05-06:06	*01:02:01-01:03, 01:05- 01:08, 01:10-01:20, 01:23- 01:34, 01:36-01:37N, 02:32, 04:01:01:01-04:01:16, 04:03, 04:05, 04:07-04:12, 04:15:01- 04:20, 04:23-04:33, 04:35- 04:47, 04:49-04:57, 04:59Q- 04:62, 05:01:01:01-05:01:13,

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	OOK		-specific information	www.oierup-ssp.com
				05:03-05:07N, 05:09-05:10, 05:12-05:16, 05:18-05:26, 05:28-05:42, 08:02:01-08:02:03, 08:05, 08:07, 08:12, 08:15, 08:17-08:19, 08:23, 08:25, 08:28, 08:30, 12:09, 12:24, 14:02:01-14:05, 14:07N-14:14, 14:17-14:19, 15:08, 18:01-18:02
7 ^{5,8}	110 bp, 185 bp, 235 bp	1070 bp	*06:07, 06:19, 06:33	
8	240 bp	1070 bp	*06:08	*01:10, 02:05, 02:17
	•	•		, , ,
99	165 bp, 210 bp, 435 bp	1070 bp	*06:09, 06:17, 06:23	*01:04, 01:09, 02:22, 05:08, 07:07, 07:09, 07:76, 08:27, 08:29, 08:31, 12:31, 18:01-18:03, B*15:137
10 ⁶	190 bp	800 bp	*06:10, 06:22	· ·
11 ^{5,10}	130 bp, 185 bp	1070 bp	*06:11, 06:22	*07:04:01-07:04:03, 07:11- 07:12, 07:45, 07:63, 07:68, 12:03:09
12 ¹¹	185 bp, 205 bp, 275 bp	1070 bp	*06:12, 06:19- 06:20	*01:32, 07:81
13	155 bp	1070 bp	*06:13	
14	305 bp	1070 bp	*06:14	*03:32, 03:45, 07:43, 15:25
15	360 bp	800 bp	*06:15	
16 ¹²	235 bp, 275 bp, 340 bp	1070 bp	*06:16N, 06:20- 06:21	*01:32, 07:81
17 ¹³	160 bp, 225 bp	1070 bp	*06:24, 06:37	*01:20
18	220 bp	1070 bp	*06:26	
19 ^{5,14}	85 bp, 160 bp	800 bp	*06:28, 06:32	*02:14, 03:67, 04:42, 07:20, 07:73, 15:23, 16:21, B*08:56, B*15:142, B*51:68
20 ^{5,15}	115 bp, 275 bp	1070 bp	*06:27, 06:29	,
21 ¹⁶	190 bp, 380 bp	1070 bp	*06:25, 06:36	
22	170 bp	1070 bp	*06:30	*12:03:09
23	205 bp	1070 bp	*06:31	*16:04:01
24 ¹⁷	160 bp, 210 bp	1070 bp	*06:09, 06:34- 06:35	*02:22, 05:08, 08:27, 08:29, 08:31, 12:31, 18:03, B*13:31, B*15:58, B*15:73, B*15:137, B*39:36, B*55:21

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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*06 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 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*06 subtyping.

In addition, wells number 2, 5, 10, 15 and 19 contain the primer pair giving rise to the shorter, 800 bp, internal positive control in order to allow kit identification.

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

³The HLA-C*06 SSP subtyping kit cannot distinguish the C*06:02:01:01, 06:02:01:02 and the C*06:02:03 to 06:02:05 alleles. The C*06:07 and C*06:33 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 7. The C*06:16N and C*06:21 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 16. The C*06:24 and C*06:37 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 17. The C*06:25 and C*06:36 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 21. The C*06:27 and C*06:29 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 20. The C*06:28 and C*06:32 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 19.

⁴Due to the sharing of sequence motifs between HLA-C alleles non-HLA-C*06 alleles will be amplified by primer mixes 1 to 6, 8, 9, 11, 12, 14, 16, 17, 19 and 22 to 24. In addition, the B*58:02 allele will be amplified by primer mix 4, the B*15:137 will be amplified by the primer mix 9, the B*08:56, B*15:142 and B*51:68 alleles will be amplified by primer mix 19 and the B*13:31, B*15:58, B*15:73, B*15:137, B*39:36 and B*39:36 alleles will be amplified by primer mix 24.

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

⁶Primer mix 10 has a tendency of giving rise to non-specific amplifications.

⁷Primer mix 5: Specific PCR fragment of 165 bp in the C*06:05 and the C*05:01:01:01-05:01:13, 05:03-05:28, 05:30-05:42, 08:10, 12:21, 12:33 and 17:05 alleles. Specific PCR fragment of 220 bp in the C*06:18 and 06:23 and the C*01:04, 01:09 and 02:21 alleles.

⁸Primer mix 7: Specific PCR fragment of 110 bp in the C*06:07 allele. Specific PCR fragment of 185 bp in the C*06:19 allele. Specific PCR fragment of 235 bp in the C*06:33 allele.

⁹Primer mix 9: Specific PCR fragment of 165 bp in the C*06:09 and in the C*02:22, 05:08, 08:27, 08:29, 08:31 and 12:31 alleles, and in addition in the B*15:137 allele.

Specific PCR fragment of 210 bp in the C*06:23, 01:04, 01:09 alleles.

Specific PCR fragment of 435 bp in the C*06:17, 07:07, 07:09, 07:76, 18:01-18:02 alleles. Specific PCR fragments of 165 and 435 bp in the C*18:03 allele.

10 Primer mix 11: Specific PCR fragment of 130 bp in the C*06:11 and C*07:04:01 to 07:04:03,

07:11, 07:12, 07:45, 07:63, 07:68 and 12:03:09 alleles. Specific PCR fragment of 185 bp in the C*06:22 allele.

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¹¹Primer mix 12: Specific PCR fragment of 185 bp in the C*06:19 allele. Specific PCR fragment of 205 bp in the C*06:12 allele. Specific PCR fragment of 275 bp in the C*06:20 and in the C*01:32 and 07:81 alleles.

¹²Primer mix 16: Specific PCR fragment of 235 bp in the C*06:16N allele. Specific PCR fragment of 275 bp in the C*06:20 and in the C*01:32 and 07:81 alleles. Specific PCR fragment of 340 bp in the C*06:21 allele.

¹³Primer mix 17: Specific PCR fragment of 160 bp in the C*06:37 and in the C*01:20 alleles. Specific PCR fragment of 225 bp in the C*06:24 allele.

¹⁴Primer mix 19: Specific PCR fragment of 85 bp in the C*06:28 and in the C*02:14, 03:67, 04:42. 07:20. 07:73. 15:23 and 16:21 alleles, and in addition in the B*08:56. B*15:142 and B*51:68 alleles. Specific PCR fragment of 160 bp in the C*06:32 allele.

¹⁵Primer mix 20: Specific PCR fragment of 115 bp in the C*06:29 allele. Specific PCR fragment

of 275 bp in the C*06:27 allele.

16 Primer mix 21: Specific PCR fragment of 190 bp in the C*06:36 allele. Specific PCR fragment of 380 bp in the C*06:25 allele.

The state of 160 bp in the C*06:09 and 06:34 and in the C*02:22, and 06:34 and 06:34 and in the C*02:22, and 06:34 and 06:

05:08, 08:27, 08:29, 08:31, 12:31 and 18:03 alleles, and in addition in the B*13:31, B*15:58, 15:73, 15:137, B*39:36, B*55:21 alleles. Specific PCR fragment of 210 bp in the C*06:35 allele. 'w', may be weakly amplified.

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	NTER			TION		BLE			ici up-			
	HLA-	C*06	SSI	P su	btyp	ing						
Amplification							6:37	allele	:S			
						We	:II ¹¹					
	1	2	3	4	5	6	7	8	9	10	11	12
Length of spec.	240	220	135	250	165	250	110	240	165	190	130	185
PCR product(s)					220		185		210		185	
							235		435			275
Length of int.	800	800	1070	1070	800	1070	1070	1070	1070	800	1070	1070
pos. control ¹												
5'-primer(s) ²	28	361	105	2 nd I	113	2 nd I	107	361	47	142	213	157
	٠ ۲	-	F -	h <	F 4	H <	≪	F -	F D	ני	ני	h et
	-TCA T	-AgT	-gCT F	-CCA	-CCA T	-CCA	-CgA	-AgT	-A99	-100	222	-TgA
	la la	la .	113	la .	176	la .	157	ja .	368	^₄ 419	419	463
										L	h	h
			-CCA F		-gCA T		-TgA "		-gTg-	-gTC	-gTC	-TgA
			h'		le .		la .		h	la	la	la
					368		232		412			529
					-gTg r		-AgA *		-ATA			-AgA *
					P P		4 h		4			ų ų
3'-primer(s) ³	97	538	201	539	302	538	302	559	312	302	302	302
	H-	k «	h U	h ď	F	H Di	h L	ь	⊩	h L	h (1	E.
	-gTC *	-CCA	-CTC	-TCA	-99T	r-ccg r	- 19g-	-cTC	-AgT	-99T	-99C	-99T
	La .	la .	la .	la	538	la .	h	ia .	538	ь 565	565	3 rd I
					-				,	h	h	la la
					CCA				-ccA	-CAT	-CAT	-CTC
			_		h	_			h	la	h	h
Well No.	1	2	3	4	5	6	7	8	9	10	11	12
HLA-C allele ⁴												
*06:02:01:01-06:02:01:02,	1	2										
06:02:03-06:02:05												
*06:03		2	3									
*06:04	1			4	F	^						
*06:05	1				5	6						
*06:06		_				O	-					
*06:07, 06:33 ⁵	1	2					7					
*06:08	1	2						8	_			
*06:09	1	2							9	40		
*06:10 *06:44	1	2								10	44	
*06:11	1	2	9	A		c	7	0	0	40	11	40
Well No.	1		3	4	5	6	1	8	9	10	11	12

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Lot No.: 08K Lot-specific information www.olerup-ssp.com

INTERPRETATION TABLE **HLA-C*06 SSP subtyping** Amplification patterns of the C*06:02 to C*06:37alleles Well¹¹ 16 17 18 19 22 24 13 14 15 20 21 23 155 305 360 235 160 220 85 115 190 170 205 160 Length of spec. PCR product(s) 275 225 160 275 380 210 340 1070 1070 1070 1070 800 1070 800 1070 1070 1070 1070 1070 Length of int. pos. control¹ 376 397 122 97 361 341 361 97 28 213 361 368 5'-primer(s)² r -TCg r -gTC r -CCT * -TCg * F -TCA F r-AgT r -000 -9gA -AgT -ģCT -gCT 388 463 361 419 -CCA TTę--AgT 501 7 O... 3'-primer(s)³ 3rd I 3rd I 475 353 479 302 142 172 239 341 527 538 -CTC * -CTC T -CAT * r -ccg r -CCA T " -TgC " -CCA 7 -gCT F -TgA -9gT r -C99 -<u>9</u> 547 214 595 538 -CCA -CCA -gTg -CCA 14 16 17 18 22 Well No. 13 15 19 20 21 23 24 HLA-C allele4 *06:02:01:01-06:02:01:02, 06:02:03-06:02:05 *06:03 *06:04 *06:05 *06:06 *06:07, 06:33⁵ *06:08 24 *06:09 *06:10 *06:11 23 14 15 16 17 18 19 20 24 13 21 Well No.

Length of spec.	240	220	135	250	165	250	110	240	165	190	130	185
PCR product(s)					220		185		210		185	205
							235		435			275
Well No.	1	2	3	4	5	6	7	8	9	10	11	12
*06:12	1	2										12
*06:13	1	2										
*06:14	1											
*06:15	1	2										
*06:16N, 06:21 ⁶	1	2										
*06:17		2							9			
*06:18	1	2	3		5							
*06:19	1	2					7					12
*06:20	1	2										12
*06:22	1	2								10	11	
*06:23	1	2			5				9			
*06:24, 06:37 ⁷	1	2										
*06:25, 06:36 ⁸	1	2										
*06:26	1	2										
*06:27, 06:29 ⁹	1	2										
*06:28, 06:32 ¹⁰	1	2										
*06:30	1	2										
*06:31	1	2										
*06:34	1	2										
*06:35	1											
*01:02:01-01:03, 01:05-01:08,												
01:11-01:19, 01:23-01:31, 01:33												
01:34, 01:36-01:37N, 02:32,												
04:01:01:01-04:01:16, 04:03,												
04:05, 04:07-04:12, 04:15:01-												
04:20, 04:23-04:33, 04:35-												
04:41, 04:43-04:47, 04:49-						6						
04:57, 04:59Q-04:62, 05:29,												
08:02:01-08:02:03, 08:05,												
08:07, 08:12, 08:15, 08:17-												
08:19, 08:23, 08:25, 08:28,												
08:30, 12:09, 12:24, 14:02:01-												
14:05, 14:07N-14:14, 14:17-												
14:19, 15:08												
*01:04, 01:09		2			5				9			
*01:10						6		8				
*01:20						6						
Well No.	1	2	3	4	5	6	7	8	9	10	11	12

HLA-C*06 Product Insert Page 13 of 24 101.614-12 – including *Taq* polymerase General "Instructions for Use"

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								Specia			-	www.oicrup 33p.com
155	305	360	235	160	220	85	115	190	170	205	210	Length of spec.
			275	225		160	275	380			160	PCR product(s)
			340									
13	14	15	16	17	18	19	20	21	22	23	24	Well No.
												*06:12
13												*06:13
	14											*06:14
		15										*06:15
			16									*06:16N, 06:21 ⁶
												*06:17
												*06:18
												*06:19
			16									*06:20
												*06:22
												*06:23
				17								*06:24, 06:37 ⁷
								21				*06:25, 06:36 ⁸
					18							*06:26
							20					*06:27, 06:29 ⁹
						19						*06:28, 06:32 ¹⁰
									22			*06:30
										23		*06:31
											24	*06:34
											24	*06:35
												*01:02:01-01:03, 01:05-01:08,
												01:11-01:19, 01:23-01:31, 01:33-
												01:34, 01:36-01:37N, 02:32,
												04:01:01:01-04:01:16, 04:03,
												04:05, 04:07-04:12, 04:15:01-
												04:20, 04:23-04:33, 04:35-
												04:41, 04:43-04:47, 04:49-
												04:57, 04:59Q-04:62, 05:29,
												08:02:01-08:02:03, 08:05,
												08:07, 08:12, 08:15, 08:17-
												08:19, 08:23, 08:25, 08:28,
												08:30, 12:09, 12:24, 14:02:01-
												14:05, 14:07N-14:14, 14:17-
												14:19, 15:08
												*01:04, 01:09
												*01:10
				17								*01:20
13	14	15	16	17	18	19	20	21	22	23	24	Well No.

Langth of anal		220				250	440	240	405	400	420	405
Length of spec.	240	220	135	250		250	110	240		190		185
PCR product(s)					220		185		210		185	205
Mall No.	4			4			235	_	435	40	4.4	275
Well No.	1	2	3	4	5	6	7	8	9	10	11	12
*01:22, 01:35, 08:01:01-												
08:01:02, 08:03:01-08:04,												
08:06, 08:08-08:09, 08:11,												
08:13-08:14, 08:16, 08:20-												
08:22, 08:24, 08:26N, 12:14:01-				4								
12:14:02, 12:18, 12:20, 14:06,												
14:15, 15:02:01-15:07, 15:09-												
15:13, 15:15-15:22, 15:24,												
15:26-15:28, 17:01:01:01-												
17:04, 17:06, <i>B*58:02</i>												
*01:32						6						12
*02:05, 02:17		2						8				
*02:14, 07:20, 07:73, <i>B*08:56,</i>												
B*15:142, B*51:68												
*02:21, 12:21					5							
*02:22, 08:27, 08:29, 08:31,									9			
18:03, <i>B*15:137</i>									9			
*03:02:01-03:04:14, 03:04:16-												
03:17, 03:19-03:31, 03:33-			•									
03:38:02, 03:40-03:44, 03:46-			3									
03:66, 03:68-03:84, 07:96												
*03:32, 03:45			3									
*03:39, 12:16	1											
*03:67	1		w									
*04:42	1					6						
*05:01:01:01-05:01:13, 05:03-												
05:07N, 05:09-05:10, 05:12-					_							
05:16, 05:18-05:26, 05:28,					5	6						
05:30-05:42												
*05:08					5				9			
*05:11, 05:17, 05:27, 08:10,					_							
17:05				4	5							
*07:04:01-07:04:03, 07:11-												
07:12, 07:45, 07:63, 07:68											11	
*07:07, 07:09, 07:76									9			
*07:43, 15:25									_			
*07:81												12
Well No.	1	2	3	4	5	6	7	8	9	10	11	12
				-		_	•			. •		

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								•				
155	305	360			220	85	115		170	205	210	Length of spec.
			275	225		160	275	380			160	PCR product(s)
			340									
13	14	15	16	17	18	19	20	21	22	23	24	Well No.
												*01:22, 01:35, 08:01:01-
												08:01:02, 08:03:01-08:04,
												08:06, 08:08-08:09, 08:11,
												08:13-08:14, 08:16, 08:20-
												08:22, 08:24, 08:26N, 12:14:01-
												12:14:02, 12:18, 12:20, 14:06,
												14:15, 15:02:01-15:07, 15:09-
												15:13, 15:15-15:22, 15:24,
												15:26-15:28, 17:01:01:01-
												17:04, 17:06, <i>B*58:0</i> 2
			16									*01:32
												*02:05, 02:17
												*02:14, 07:20, 07:73, <i>B</i> *08:56,
						19						B*15:142, B*51:68
												*02:21, 12:21
												*02:22, 08:27, 08:29, 08:31,
											24	18:03, <i>B*15:137</i>
												*03:02:01-03:04:14, 03:04:16-
												03:17, 03:19-03:31, 03:33-
												03:38:02, 03:40-03:44, 03:46-
												03:66, 03:68-03:84, 07:96
	14											*03:32, 03:45
												*03:39, 12:16
						19						*03:67
						19						*04:42
												*05:01:01:01-05:01:13, 05:03-
												05:07N, 05:09-05:10, 05:12-
												05:16, 05:18-05:26, 05:28,
												05:30-05:42
											24	*05:08
											_ •	*05:11, 05:17, 05:27, 08:10,
												17:05
												*07:04:01-07:04:03, 07:11-
												07:12, 07:45, 07:63, 07:68
												*07:07, 07:09, 07:76
	14											*07:43, 15:25
			16									*07:43, 13:23
13	14	15	16	17	18	19	20	21	22	23	24	Well No.
			. 0		.0							770/1140.

HLA-C*06 Product Insert Page 16 of 24 101.614-12 - including *Taq* polymerase General "Instructions for Use"

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

Lot No.: **08K** Lot-specific information www.olerup-ssp.com

Length of spec.	240	220	135	250	165	250	110	240	165	190	130	185
PCR product(s)					220		185		210		185	205
							235		435			275
Well No.	1	2	3	4	5	6	7	8	9	10	11	12
*12:03:01:01-12:03:08,												
12:03:10-12:07, 12:11-12:13,												
12:15, 12:23, 12:25-12:26,		2										
12:28-12:29, 12:32, 12:34-												
12:35, 14:16												
*12:03:09		2									11	
*12:31		2							9			
*12:33		2			5							
*15:23				4								
*16:04:01		2										
*16:21	1											
*18:01-18:02						6			9			
B*13:31, B*15:58, 15:73,												
B*39:36, B*55:21												
HLA-C allele ⁴												
Well No.	1	2	3	4	5	6	7	8	9	10	11	12

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*06 subtyping.

In addition, wells number 2, 5, 10, 15 and 19 contain the primer pair giving rise to the shorter, 800 bp,

internal positive control in order to allow kit identification. ²The nucleotide position, in the 1st, 2nd or 3rd exons or the the 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.

³The nucleotide position, in the 2nd or 3rd exons 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 sequence of the C*06:01 allele has been shown to be identical to C*06:02.

The sequence of the C*06:02:02 allele has been renamed to C*06:17.

⁵The C*06:07 and C*06:33 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 7.

The C*06:16N and C*06:21 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 16.

The C*06:24 and C*06:37 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 17.

The C*06:25 and C*06:36 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 21.

The C*06:27 and C*06:29 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 20.

 $^{\circ}$ The C*06:28 and C*06:32 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 19.

101.614-12 - including Tag polymerase

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Lot No.: **08K** Lot-specific information www.olerup-ssp.com

155	305	360	235	160	220	85	115	190	170	205	210	Length of spec.
			275	225		160	275	380			160	PCR product(s)
			340									
13	14	15	16	17	18	19	20	21	22	23	24	Well No.
												*12:03:01:01-12:03:08,
												12:03:10-12:07, 12:11-12:13,
												12:15, 12:23, 12:25-12:26,
												12:28-12:29, 12:32, 12:34-
												12:35, 14:16
									22			*12:03:09
											24	*12:31
												*12:33
						19						*15:23
										23		*16:04:01
						19						*16:21
												*18:01-18:02
											24	B*13:31, B*15:58, 15:73,
											24	B*39:36, B*55:21
												HLA-C allele ⁴
13	14	15	16	17	18	19	20	21	22	23	24	Well No.

¹¹Primer mix 5: Specific PCR fragment of 165 bp in the C*06:05 and the C*05:01:01:01-05:01:13, 05:03-05:28, 05:30-05:42, 08:10, 12:21, 12:33 and 17:05 alleles. Specific PCR fragment of 220 bp in the C*06:18 and 06:23 and the C*01:04, 01:09 and 02:21 alleles.

Primer mix 7: Specific PCR fragment of 110 bp in the C*06:07 allele. Specific PCR fragment of 185 bp in the C*06:19 allele. Specific PCR fragment of 235 bp in the C*06:33 allele.

Primer mix 9: Specific PCR fragment of 165 bp in the C*06:09 and in the C*02:22, 05:08, 08:27, 08:29, 08:31 and 12:31 alleles, and in addition in the B*15:137 allele.

Specific PCR fragment of 210 bp in the C*06:23, 01:04, 01:09 alleles.

Specific PCR fragment of 435 bp in the C*06:17, 07:07, 07:09, 07:76, 18:01-18:02 alleles. Specific PCR fragments of 165 and 435 bp in the C*18:03 allele.

Primer mix 11: Specific PCR fragment of 130 bp in the C*06:11 and C*07:04:01 to 07:04:03, 07:11, 07:12, 07:45, 07:63, 07:68 and 12:03:09 alleles. Specific PCR fragment of 185 bp in the C*06:22 allele.

Primer mix 12: Specific PCR fragment of 185 bp in the C*06:19 allele. Specific PCR fragment of 205 bp in the C*06:12 allele. Specific PCR fragment of 275 bp in the C*06:20 and in the C*01:32 and 07:81 alleles.

Primer mix 16: Specific PCR fragment of 235 bp in the C*06:16N allele. Specific PCR fragment of 275 bp in the C*06:20 and in the C*01:32 and 07:81 alleles. Specific PCR fragment of 340 bp in the C*06:21 allele.

Primer mix 17: Specific PCR fragment of 160 bp in the C*06:37 and in the C*01:20 alleles. Specific PCR fragment of 225 bp in the C*06:24 allele.

Primer mix 19: Specific PCR fragment of 85 bp in the C*06:28 and in the C*02:14, 03:67, 04:42, 07:20, 07:73, 15:23 and 16:21 alleles, and in addition in the B*08:56, B*15:142 and B*51:68 alleles. Specific PCR fragment of 160 bp in the C*06:32 allele.

Primer mix 20: Specific PCR fragment of 115 bp in the C*06:29 allele. Specific PCR fragment of 275 bp in the C*06:27 allele.

Primer mix 21: Specific PCR fragment of 190 bp in the C*06:36 allele. Specific PCR fragment of 380 bp in the C*06:25 allele.

Primer mix 24: Specific PCR fragment of 160 bp in the C*06:09 and 06:34 and in the C*02:22, 05:08, 08:27, 08:29, 08:31, 12:31 and 18:03 alleles, and in addition in the B*13:31, B*15:58, 15:73, 15:137, B*39:36, B*55:21 alleles. Specific PCR fragment of 210 bp in the C*06:35 allele 'w', may be weakly amplified.

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Lot No.: **08K** Lot-specific information www.olerup-ssp.com

CELL LINE VALIDATION SHEET																				
HLA-C*06 SSP subtyping kit																				
									•			W	ell							
					1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
					7	2	33	4	5	90	7(8	60	0	_	2	3	4	2	9
				Prod. No.:	200960501	200734402	200960503	200734404	200960505	201072406	201072407	200734408	201072409	200960510	200960511	200960512	200734413	200734414	201072415	201072416
				<u>6</u>	960)73	960)73	960	107	107)73	107	960	960	960)73)73	107	107
				Pro	20	20	20(200	200	20,	20	200	Ś	20	200	200	200	200	20	20
	IHV	VC cell line		C*																
1	9001		*07:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2		LK707	*07:01	*15:05	-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-
3		E4181324	*12:02	*04.04	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
4		GU373	*03:04	*04:01	ļ.	-	+	-	-	+	-	-	-	-	-	-	-	-	-	-
5	9353	KAS011	*06:02 *03:04	*07.00	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
6 7	9020		*05:01	*07:02	H	-	+	-	+	+	-	-	-	-	-	-	-	-	-	-
8	9025		*04:01		-	-	-	-	-	+	-	-	-	-	-	-	-	-	-	-
9		YAR	*12:03		١.	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
10		LKT3	*01:02		-		-	-	-	+	-	-	-	-	-	-	-	-	-	-
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		32367	*01:02	*07:05	-	-	-	-	-	+	-	-	-	-	-	-	-	-	-	-
19		BM16	*07:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
20		SLE005	*03:04		-	-	+	-	-	-	-	-	-	-	-	-	-	•	-	-
21		AMALA	*03:03		ļ-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-
22		KOSE	*12:03		<u> </u>	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
23	9124		*01:02	*15:02	-	-	-	+	-	+	-	-	-	-	-	-	-	-	-	-
24		JBUSH	*12:03		-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
25		IBW9	*08:02		-	-	-	-	-	+	-	-	-	-	-	-	-	-	-	-
26 27		WT49 CH1007	*07:01 *07:04	*15:05	ļ-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
28		BEL5GB	*05:01	*16:01	-	-		+	-	-	-	-	-	-	+	-	-	-	-	-
29		MOU	*16:01	10.01	H	H	H	-	+	+		-	-	H	-		-	-	-	-
30	9021		*17:01		-	-	-	+	-	-	-	-	_	H	-	-	-	-	-	-
31		DUCAF	*05:01		Η-	-	-	-	+	+	-	-	-	-	-	-	-	-	-	-
32		HAG	*17:01	*17:03	١.	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-
33		MT14B	*03:04	17.00	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-
34	9104		*12:03		-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
35		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		WHONP199	*01:02	*06:02	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
41		H0301	*08:02		-	-	-	-	-	+	-	-	-	-	-	-	-	-	-	-
42		TAB089	*01:02		-	-	-	-	-	+	-	-	-	-	-	-	-	-	-	-
43		T7526	*01:02	*08:01	-	-	-	+	-	+	-	-	-	-	-	-	-	-	-	-
44	9057		*12:03		-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
45		SHJO	*06:02	*17:01	+	+	-	+	-	-	-	-	-	-	-	-	-	-	-	-
46		SCHU	*07:02	***	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
47		TUBO	*07:04	*15:02	ļ-	-	-	+	-	-	-	-	-	-	+	-	-	-	-	-
48	9303	TER-ND	*04:01	*16:01	-	-	-	-	-	+	-	-	-	-	-	-	-	-	-	-

HLA-C*06

CELL LINE VALIDATION SHEET												
HLA-C*06 SSP subtyping kit												
		Well										
					17	18	19	20	21	22	23	24
					7	ω	စ	0	Σ.	Ŋ	က္လ	4
				Prod. No.	201072417	201072418	201072419	201072420	201072421	201072422	201072423	201072424
				<u> </u>	107	107	107	107	107	107	101	107
				Pro	201	201	201	201	201	201	201	201
	IHV	VC cell line		C*								
1	9001	SA	*07:02		-	-	-	-	-	-	-	-
2	9280	LK707	*07:01	*15:05	-	-	-	-	-	-	-	-
3	9011	E4181324	*12:02		-	-	-	-	-	-	-	-
4		GU373	*03:04	*04:01	-	-	-	-	-	-	-	-
5		KAS011	*06:02		-	-	-	-	-	-	-	-
6	9353	-	*03:04	*07:02	-	-	-	-	-	-	-	-
7	9020		*05:01		-	-	-	-	-	-	-	-
8	9025		*04:01		-	-	-	-	-	-	-	-
9	9026		*12:03		-	-	-	-	-	-	-	-
10	9107		*01:02		-	-	-	-	-	-	-	-
11		PITOUT	*16:01		-	-	-	-	-	-	-	-
12	9052		*06:02		-	-	-	-	-	-	-	-
13		JESTHOM	*01:02	400 5 1	-	-	-	-	-	-	-	_
14		OLGA	*01:02	*03:04	-	-	-	-	-	-	-	-
15	9075		*03:04		-	-	-	-	-	-	-	-
16		SWEIG007	*02:02	+0= 04	-	-	-	-	-	-	•	-
17		CTM3953540	*03:03	*07:01	-	-	-	-	-	-	-	-
18	9257	32367	*01:02	*07:05	<u> </u>	-	-	-	-	-	-	-
19		BM16	*07:01		<u> </u>	-	-	-	-	-	-	_
20		SLE005	*03:04		-	-	-	-	-	-	•	-
21		AMALA	*03:03		-	-	-	-	-	-	-	-
22	9056	KOSE	*12:03 *01:02	*45.00	-	-	-	-	-	-	-	-
24		JBUSH	*12:03	*15:02	-		-	-				
25		IBW9	*08:02				-	-				
26		WT49	*07:01		-	-	-	-	-	-	-	-
27	9191		*07:04	*15:05	HĒ	-	_	-	_	_		<u> </u>
28		BEL5GB	*05:01	*16:01	-	-	-	-	-	-		-
29	9050		*16:01	10.01				-			-	
30	9021		*17:01		-	-	-	-	-	-	-	-
31		DUCAF	*05:01		-	-	-	-	-	-	-	-
32	9297		*17:01	*17:03	-	-	-	-	-	-	-	-
33		MT14B	*03:04	17.00	-	-	-	-	-	-	-	-
34	9104		*12:03		-	-	-	-	-	-	-	-
35		SSTO	*05:01		-	-	-	-	-	-	-	-
36		KT17	*03:03	*04:01	-	-	-	-	-	-	-	-
37		HHKB	*07:02		-	-	-	-	-	-	-	-
38	9099		*03:03		-	-	-	-	-	-	-	-
39	9315		*02:02	*07:01	-	-	-	-	-	-	-	-
40		WHONP199	*01:02	*06:02	-	-	-	-	-	-	-	-
41		H0301	*08:02		-	-	-	-	-	-	-	-
42		TAB089	*01:02		-	-	-	-	-	-	-	-
43		T7526	*01:02	*08:01	-	-	-	-	-	-	-	-
44	9057		*12:03		-	-	-	-	-	-	-	-
45		SHJO	*06:02	*17:01	-	-	-	-	-	-	-	-
46		SCHU	*07:02	1	-	-	-	-	-	-	-	-
47		TUBO	*07:04	*15:02	-	-	-	-	-	-	-	-
48		TER-ND	*04:01	*16:01	-	-	-	-	-	-	-	-

HLA-C*06 Product Insert Page 20 of 24

101.614-12 – including *Taq* polymerase

General "Instructions for Use"

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

Lot No.: 08K Lot-specific information www.olerup-ssp.com

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-C*06 SSP

Product number: 101.614-12 – including *Taq* polymerase

Lot number: 08K

Expiry date: 2012-June-01

Number of tests: 12 Number of wells per test: 24

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2009-605-01	9	2010-724-09	17	2010-724-17
2	2007-344-02	10	2009-605-10	18	2010-724-18
3	2009-605-03	11	2009-605-11	19	2010-724-19
4	2007-344-04	12	2009-605-12	20	2010-724-20
5	2009-605-05	13	2007-344-13	21	2010-724-21
6	2010-724-06	14	2007-344-14	22	2010-724-22
7	2010-724-07	15	2010-724-15	23	2010-724-23
8	2007-344-08	16	2010-724-16	24	2010-724-24

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

No DNAs carrying the alleles to be amplified by primer solutions 7, 8, 10, 12 to 22 and 24 were available. The specificity of the primers in primer solutions 8, 10, 12, 14, 19, 21, 22 and 24 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer. In primer solutions 13, 17 and 20 it was only possible to test the 5'-primer, the 3'-primer was not possible to test. In primer solutions 7, 15 and 18 it was only possible to test the 3'-primer, the 5'-primer was not possible to test. In primer solution 3, 5, 10, 12, 16 and 21 one or two 5'-primers was not possible to test, and in primer solutions 10, 11, 19 and 21 one 3'-primer was not possible to test. Additional primers in primers solutions 5 and 9 were tested by separately adding one 5'-primer or one 3'-primer.

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

Date of approval: 2010-November-24

Approved by:

Quality Control, Supervisor

HLA-C*06 Product Insert Page 21 of 24 101.614-12 – including *Taq* polymerase General "Instructions for Use"

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

Lot No.: 08K Lot-specific information www.olerup-ssp.com

Declaration of Conformity

Product name: Olerup SSP® HLA-C*06

Product number: 101.614-12

Lot number: 08K

Intended use: HLA-C*06 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 Construction 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.

(E

Saltsjöbaden, Sweden 2010-November-24

Olle Olerup

HLA-C*06 Product Insert Page 22 of 24 101.614-12 – including *Taq* polymerase General "Instructions for Use"

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

Lot No.: **08K** Lot-specific information www.olerup-ssp.com

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E-mail: info.us@olerup.com

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

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