101.628-06– including *Taq* polymerase, IFU-01 Rev. No. 03
101. 628-06u – without *Taq* polymerase, IFU-02 Rev. No. 03

Visit www.olerup-ssp.com for **"Instructions for Use" (IFU)**

Lot No.: 17N **Lot-specific information**

Olerup SSP® HLA-C*17

Product number:	**101.628-06 – including *Taq* polymerase** **101.628-06u – without *Taq* polymerase**
Lot number:	**17N**
Expiry date:	**2014-August-01**
Number of tests:	**6**
Number of wells per test:	**12**
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. 17N.

CHANGES COMPARED TO THE PREVIOUS *OLERUP* SSP® HLA-C*17 LOT

The HLA-C*17 specificity and interpretation tables have been updated for the HLA-C alleles described since the previous *Olerup* SSP® HLA-C*17 lot was made **(Lot No. 64K)**.

The HLA-C*17 kit is updated for new alleles to enable separation of:

- Confirmed[1] alleles as listed in the IMGT/HLA database
- Polymorphisms in exons outside of the region encoding the peptide binding domain
- Null and Alternatively expressed alleles

Four wells have been added to the HLA-C*17 kit, wells **9 to 12**.

The Lot-specific information for HLA-C*17 including and without *Taq* polymerase is now described in one common Product Insert.

[1]As described in section Uniquely Identified Alleles.

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101. 628-06u – without *Taq* polymerase, IFU-02 Rev. No. 03 **"Instructions for Use" (IFU)**

Lot No.: 17N **Lot-specific information**

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	New	New	New primer pair for the C*17:08 allele.
10	New	New	New primer pair for the C*17:09 allele.
11	New	New	New primer pair for the C*17:10 allele.
12	New	New	New primer pair for the C*17:11 allele.

101.628-06– including *Taq* polymerase, IFU-01 Rev. No. 03
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Lot No.: 17N **Lot-specific information**

Lot No.: 17N **Lot-specific information**

PRODUCT DESCRIPTION

HLA-C*17 SSP typing

CONTENT

The primer set contains 5'- and 3'-primers for identifying the C*17:01 to C*17:11 alleles.

PLATE LAYOUT

Each HLA-C*17 test consists of 12 PCR reactions in a 16 well cut PCR plate.
Wells 13 to 16 are empty.

1	**2**	**3**	**4**	**5**	**6**	**7**	**8**
9	**10**	**11**	**12**	**empty**	**empty**	**empty**	**empty**

The 16 well PCR plate is marked with 'C17' in silver/gray ink.
Well No. 1 is marked with the Lot No. '17N'.
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*17 SSP subtypings will be influenced by the C*01:43, C*03:129, C*05:01:12, C*06:67, C*07:101, C*07:148 and C*07:161 alleles when present on the other haplotype. In addition, the B*15:116, B*40:63 and B*40:92 will be amplified by primer mix 8.

UNIQUELY IDENTIFIED ALLELES

All the HLA-C*17 alleles, i.e. **C*17:01 to C*17:11**, recognized by the HLA Nomenclature Committee in January 2012[1] will be amplified by the primers in the HLA-C*17 SSP kit.
The HLA-C*17 kit enables separation of the confirmed HLA-C*17 alleles as listed in the IMGT/HLA database. An HLA allele is listed as confirmed by IMGT/HLA if it has been sequenced by more than a single laboratory or from multiple sources. Current allele confirmation status for HLA-C*17 alleles is listed below.

The HLA-C*17 kit also enables identification of polymorphisms in exons outside of the region encoding the peptide binding domain and of null and alternatively expressed alleles

The HLA-C*17 subtyping kit cannot distinguish the following silent mutations: the C*17:01:01:01 to 17:01:07 alleles.

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101. 628-06u – without *Taq* polymerase, IFU-02 Rev. No. 03 **"Instructions for Use" (IFU)**

Lot No.: 17N **Lot-specific information**

[1]HLA-C alleles listed on the IMGT/HLA web page 2012-January-12, release 3.7.0, www.ebi.ac.uk/imgt/hla.

ALLELE CONFIRMATION STATUS

Allele	Status[1]	Allele	Status[1]
C*17:01:01:01	**Confirmed**	C*17:03	Unconfirmed
C*17:01:01:02	Unconfirmed	C*17:04	Unconfirmed
C*17:01:02	Unconfirmed	C*17:05	Unconfirmed
C*17:01:03	**Confirmed**	C*17:06	Unconfirmed
C*17:01:04	**Confirmed**	**C*17:07**	**Confirmed**
C*17:01:05	Unconfirmed	C*17:08	Unconfirmed
C*17:01:06	Unconfirmed	C*17:09	Unconfirmed
C*17:01:07	Unconfirmed	C*17:10	Unconfirmed
C*17:02	Unconfirmed	C*17:11	Unconfirmed

[1]Allele status "confirmed" or "unconfirmed" as listed on the IMGT/HLA web page 2012-January-12, release 3.7.0, www.ebi.ac.uk/imgt/hla.

RESOLUTION IN HOMO- AND HETEROZYGOTES

A total of 18 alleles generate 11 amplification patterns that can be combined in 66 homozygous and heterozygous combinations. 2 of these genotypes do not give rise to unique amplification patterns.

+−−+−+−− −−−− *17:01:01:01, *17:05 = *17:05, *17:05

*17:01:01:01 = 17:01:01:01-17:01:07

101.628-06– including *Taq* polymerase, IFU-01 Rev. No. 03
101. 628-06u – without *Taq* polymerase, IFU-02 Rev. No. 03
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Lot No.: 17N **Lot-specific information**

SPECIFICITY TABLE

HLA-C*17 SSP subtyping

Specificities and sizes of the PCR products of the 12 primer mixes used for HLA-C*17 SSP subtyping

Primer Mix	Size of spec. PCR product[1]	Size of control band[2]	Amplified HLA-C*17 alleles[3]	Other amplified HLA-C alleles[4]
1	350 bp	**800 bp**	*17:01:01:01-17:01:07, 17:03, 17:04[?], 17:05, 17:06[?]-17:11[?]	
2[5]	70 bp	1070 bp	*17:02, 17:04[?], 17:06[?]-17:11[?]	
3	300 bp	1070 bp	*17:03, 17:04[?], 17:06[?]-17:11[?]	
4[5]	90 bp	1070 bp	*17:01:01:01-17:01:07, 17:04[?], 17:05, 17:06[?]-17:11[?]	
5	155 bp	1070 bp	*17:04	
6[5]	65 bp	1070 bp	*17:05	*01:43, 05:01:12, 06:67, 07:101, 07:148, 07:161
7[5]	125 bp	**800 bp**	*17:06	
8[5]	100 bp	1070 bp	*17:07	*03:129, **B*15:116, B*40:63, B*40:92**
9	135 bp	1070 bp	*17:08	
10[5]	95 bp	1070 bp	*17:09	
11	160 bp	1070 bp	*17:10	
12	450 bp	1070 bp	*17:11	

[1]Alleles are assigned by the presence of specific PCR product(s). However, the sizes of the specific PCR products may be helpful in the interpretation of HLA-C*17 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.
[2]The internal positive control primer pairs amplify segments of the human growth hormone gene. The two different control primer pairs give rise to either an internal positive control band of 1070 base pairs, for most wells, or a band of 800 base pairs, for some wells.

101.628-06– including *Taq* polymerase, IFU-01 Rev. No. 03 Visit www.olerup-ssp.com for
101. 628-06u – without *Taq* polymerase, IFU-02 Rev. No. 03 **"Instructions for Use" (IFU)**

Lot No.: 17N **Lot-specific information**

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*17 SSP subtyping. In addition, well number 7 contains the primer pair giving rise to the shorter, 800 bp, internal positive control band in order to allow kit identification.

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

[3]For several HLA-C*17 alleles 1st, 5th, 6th and 7th exon nucleotide sequences are not available. In these instances it is not known whether some of the primers of the SSP sets are completely matched with the target sequences or not. We assume that unknown sequences in the 1st, 5th, 6th and 7th exons are conserved within allelic groups.

[4]Due to the sharing of sequence motifs between HLA-C alleles some non-HLA-C*17 alleles will be amplified by primer mixes 6 and 8. In addition, the B*15:116, B*40:63 and B*40:92 will be amplified by primer mix 8.

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

'?', nucleotide sequence information not available for the primer matching sequence.

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Lot No.: 17N **Lot-specific information**

INTERPRETATION TABLE

HLA-C*17 SSP subtyping

Amplification patterns of the HLA-C*17:01 to C*17:11 alleles

	Well							
	1	2	3	4	5	6	7	8
Length of spec. PCR product	350	70	300	90	155	65	125	100
Length of int. pos. control[1]	800	1070	1070	1070	1070	1070	800	1070
5'-primer[2]	20	28	70	20	126	176	412	499
	5' -CCA 3'	5' -TCA 3'	5' -ggA 3'	5' -CCA 3'	5' -ggA 3'	5' -gCA 3'	5' -ATA 3'	5' -TCT 3'
3'-primer[3]	201	59	201	70	239	201	495	559
	5' -CTC 3'	5' -CgA 3'	5' -CTC 3'	5' -ggC 3'	5' -gCg 3'	5' -CTC 3'	5' -ATA 3'	5' -CAg 3'
	201							
	5' -CTT 3'							
Well No.	1	2	3	4	5	6	7	8
HLA-C allele[4]								
***17:01:01:01**-17:01:07	1			4				
*17:02		2						
*17:03	1		3					
*17:04	?	?	?	?	5			
*17:05	1			4		6		
*17:06	?	?	?	?			7	
***17:07**	?	?	?	?				8
*17:08	?	?	?	?				
*17:09	?	?	?	?				
*17:10	?	?	?	?				
*17:11	?	?	?	?				
*01:43, 05:01:12, 06:67, 07:101, 07:148, 07:161						6		
*03:129, *B*15:116, B*40:63, B*40:92*								8
HLA-C allele								
Well No.	1	2	3	4	5	6	7	8

[1]The internal positive control primer pairs amplify segments of the human growth hormone gene. The two different control primer pairs give rise to either an internal positive control band of 1070 base pairs, for most wells, or a band of 800 base pairs, for some wells.
Well number 1 contains the primer pair giving rise to the shorter, 800 bp, internal positive control band in order to help in the correct orientation of the HLA-C*17 SSP subtyping. In addition, well number 7 contains the primer pair giving rise to the shorter, 800 bp, internal positive control band in order to allow kit identification.
[2]The nucleotide position, in the 1st, 2nd or 3rd exon, 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.

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Lot No.: 17N **Lot-specific information**

INTERPRETATION TABLE				
HLA-C*17 SSP subtyping				
Amplification patterns of the HLA-C*17 alleles				
Well				
9	10	11	12	
135	95	160	450	Length of spec.
				PCR product
1070	1070	1070	1070	Length of int.
				pos. control[1]
406	445	80	341	5'-primer[2]
5' -gCA 3'	5' -TCA 3'	5' -CCg 3'	5' -ggA 3'	
499	499	201	499	3'-primer[3]
5' -ggA 3'	5' -ggA 3'	5' -CTC 3'	5' -ggA 3'	
9	10	11	12	Well No.
				HLA-C allele[4]
				***17:01:01:01**-17:01:07
				*17:02
				*17:03
				*17:04
				*17:05
				*17:06
				***17:07**
9				*17:08
	10			*17:09
		11		*17:10
			12	*17:11
				*01:43, 05:01:12, 06:67, 07:101, 07:148, 07:161
				*03:129, *B*15:116, B*40:63, B*40:92*
				HLA-C allele
9	10	11	12	Well No.

[3]The nucleotide position, in the 1st, 2nd or 3rd exon, 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.

[4]HLA-C*17 alleles in bold lettering are listed as confirmed alleles on the IMGT/HLA web page www.ebi.ac.uk/imgt/hla, release 3.7.0, January 2012.

'?', nucleotide sequence information not available for the primer matching sequence.

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Lot No.: 17N **Lot-specific information**

CELL LINE VALIDATION SHEET

HLA-C*17 SSP primer set

					Well											
					1	2	3	4	5	6	7	8	9	10	11	12
				Prod. No.:	201078601	200847302	200847303	200847304	200847305	200963706	201078607	201078608	201195409	201195410	201195411	201195412
	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	+	-	+	w	-	-	-	-	-	-	-	-
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	-	-	-	-	-	-	-	-	-	-	-	-

Lot No.: 17N **Lot-specific information**

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-C*17 SSP

Product number: **101.628-06 – including *Taq* polymerase**
101.628-06u – without *Taq* polymerase
Lot number: **17N**
Expiry date: **2014-August-01**
Number of tests: **6**
Number of wells per test: **12**

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2010-786-01	5	2008-473-05	9	2011-954-09
2	2008-473-02	6	2009-637-06	10	2011-954-10
3	2008-473-03	7	2010-786-07	11	2011-954-11
4	2008-473-04	8	2010-786-08	12	2011-954-12

The specificity of each primer solution of the HLA-C*17 primer set has been tested against 48 well characterized IHWC cell line DNAs.

No DNAs carrying the alleles to be amplified by primer solutions 2 and 5 to 12 were available. The specificity of the primers in primer solutions 2, 6, 8 and 12 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer. In primer solutions 5 and 7 it was only possible to test the 5'-primer, the 3'-primer was not possible to test. In primer solutions 9 to 11 it was only possible to test the 3'-primer, the 5'-primer was not possible to test. One additional 3'-primer in primer solution 1 was tested by separately adding one 5'-primer.

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

Date of approval: 2012-February-16

Approved by:

Production Quality Control

Lot No.: 17N **Lot-specific information**

Declaration of Conformity

Product name: *Olerup* SSP® HLA-C*17
Product number: 101.628-06
Lot number: 17N

Intended use: HLA-C*17 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.

Stockholm, Sweden
2012-February-16

Ann-Cathrin Jareman
Head of QA and Regulatory Affairs

101.628-06– including *Taq* polymerase, IFU-01 Rev. No. 03
101. 628-06u – without *Taq* polymerase, IFU-02 Rev. No. 03

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Lot No.: 17N **Lot-specific information**

Lot No.: 17N **Lot-specific information**

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**.