

Lot No.: **52S**

Lot-specific information

Olerup SSP[®] HLA-C*04:09N

Product number:	101.861-12 – including <i>Taq</i> polymerase 101.861-12u – without <i>Taq</i> polymerase
Lot number:	52S
Expiry date:	2015-November-01
Number of tests:	12
Number of wells per test:	2
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. 52S.

CHANGES COMPARED TO THE PREVIOUS OLERUP SSP[®] HLA-C*04:09N LOT (41R)

The Lot-specific information for HLA-C*04:09N including and without *Taq* polymerase is described in one common Product Insert.

The HLA-C*04:09N specificity and interpretation tables has been updated for the HLA-C alleles described since the previous *Olerup SSP[®]* HLA-C*04:09N lot (**Lot No. 41R**) was made.

The HLA-C*04:09N primer set is unchanged compared to the previous lot.

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PRODUCT DESCRIPTION

HLA-C*04:09N SSP subtyping

CONTENT

The primer set contains 5'- and 3'-primers for identifying the HLA-C*04:09N allele.

PLATE LAYOUT

Each test consists of 2 PCR reactions in an 8 well PCR plate. Wells 3 to 8 are empty.

1	2	empty	empty	empty	empty	empty	empty
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The 8 well cut PCR plate is marked with the Lot No. '52S' in silver/gray ink.

Well No. 1 is marked with the Lot No. '52S'.

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 8 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*04:09N SSP subtypings will be influenced by the other C*04 alleles, the C*05:78 allele and the C*16:34 allele, when present on the other haplotype.

UNIQUELY IDENTIFIED ALLELES

The HLA-C*04:09N allele will give rise to a unique amplification pattern by the primers in the HLA-C*04:09N kit¹.

¹HLA-C alleles listed on the IMGT/HLA web page 2013-January-11, release 3.11.0, www.ebi.ac.uk/imgt/hla.

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SPECIFICITY TABLE

HLA-C*04:09N SSP subtyping

Specificities and sizes of the PCR products of the 2 primer mixes used for HLA-C*04:09N SSP subtyping

Primer Mix	Size of spec. PCR product ¹	Size of control band ²	Amplified HLA-C alleles ³
1	220 bp	800 bp	*04:09N
2	255 bp, 360 bp	1070 bp	*04:01:01:01-04:01:48, 04:03-04:20, 04:23-04:144, 05:78, 16:34

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*04:09N SSP typings. 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*04:09N subtyping.

³For several HLA Class I alleles 1st and/or 4th exon(s) and beyond, as well as intron 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 these regions are conserved within allelic groups.

INTERPRETATION TABLE		
HLA-C*04:09N SSP typing		
	Well	
	1	2
Length of spec.	220	255
PCR product		360
Length of int.	800	1070
pos. control ¹		
5'-primer(s) ²	1018	28
	5' -gTg 3'	5' -TCA 3'
3'-primer(s) ³	1092	112
	5' -TTA 3'	5' -CCA 3'
		118
		5' -gCT 3'
		218
		5' -gCT 3'
Well No.	1	2
HLA-C allele		
*04:09N	1	2
*04:01:01:01-04:01:48, 04:03-04:08, 04:10-04:20, 04:23-04:144, 05:78, 16:34		2
HLA-C allele		
Well No.	1	2

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*04:09N subtyping.

²The nucleotide position, in the 1st or 6th 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.

³The nucleotide position, in the 2nd or 7th 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.

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CELL LINE VALIDATION SHEET						
HLA-C*04:09N SSP kit						
					Well	
					1	2
					201208401	201208402
					Lot No.:	
IHC 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	9007	DEM	*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	-	+



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CERTIFICATE OF ANALYSIS

Olerup SSP[®] HLA-C*04:09N SSP

Product number: 101.861-12 – including *Taq* polymerase
101.861-12u – without *Taq* polymerase

Lot number: 52S

Expiry date: 2015-November-01

Number of tests: 12

Number of wells per test: 2

Well specifications:

Well No.	Production No.
1	2012-084-01
2	2012-084-02

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

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

Date of approval: 2013-May-16

Approved by:

Production Quality Control

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Declaration of Conformity

Product name: Olerup SSP® HLA-C*04:09N
Product number: 101.861-12/12u
Lot number: 52S

Intended use: HLA-C*04:09N histocompatibility testing

Manufacturer: Olerup SSP AB
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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 13485:2012, 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
2013-May-16

Ann-Cathrin Jareman
Head of QA and Regulatory Affairs

HLA-C*04:09N
101.861-12 – including *Taq* polymerase, IFU-01
101.861-12u – without *Taq* polymerase, IFU-02

Product Insert

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Visit www.olerup-ssp.com for
“Instructions for Use” (IFU)

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