HLA-Cw*0409N Product Insert Page 1 of 8 101.861-12 – including *Taq* polymerase General "Instructions for Use"

IFU-01 Rev. No. 00 can be downloaded from

Lot No.: 19G Lot-specific information www.olerup.com

Olerup SSP® HLA-Cw*0409N

Product number: 101.861-12 – including *Taq* polymerase

Lot number: 19G

Expiry date: 2011-July-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. 19G.

CHANGES COMPARED TO THE PREVIOUS OLERUP SSP® HLA-Cw*0409N Lot

The HLA-Cw*0409N specificity and interpretation tables has been updated for the HLA-C alleles described since the previous *Olerup* SSP® HLA-Cw*0409N lot **(Lot No. 74E)** was made.

The plate layout of the HLA-Cw*0409 kit has been changed to 2 PCR reactions in an 8 well plate.

The HLA-Cw*0409N primer set is unchanged compared to the previous lot.

HLA-Cw*0409N Product Insert Page 2 of 8

101.861-12 – including *Taq* **polymerase**General "Instructions for Use"

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PRODUCT DESCRIPTION

HLA-CW*0409N SSP subtyping

CONTENT

The primer set contains 5'- and 3'-primers for identifying the HLA-Cw*0409N 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 empty

The 8 well cut PCR plate is marked with the Lot No. '19G' in silver/gray ink.

Well No. 1 is marked with the Lot No. '19G'.

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-Cw*0409N SSP subtypings will be influenced by the other Cw*04 alleles.

UNIQUELY IDENTIFIED ALLELES

The HLA-Cw*0409N allele will give rise to a unique amplification pattern by the primers in the HLA-Cw*0409N kit¹.

¹HLA-Cw alleles listed on the IMGT/HLA web page 2009-May-11, release 2.25.2, www.ebi.ac.uk/imgt/hla.

101.861-12 – including *Taq* polymerase

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SPECIFICITY TABLE

HLA-Cw*0409N SSP subtyping

Specificities and sizes of the PCR products of the 2 primer mixes used for HLA-Cw*0409N SSP subtyping

Primer Mix	Size of spec. PCR product ¹	Size of control band ²	Amplified HLA-Cw alleles
1	205 bp	800 bp	0409N
2	255, 360 bp	1070 bp	04010101-0440

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-Cw*0409N 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 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-Cw*0409N subtyping.

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HLA-Cw*0409N SSP typing				
	Well			
	1	2		
Length of spec.	205	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-Cw allele				
*0409N	1	2		
*04010101-040106, 0403-				
0408, 0410-0420, 0423-0438,		2		
0440				
HLA-Cw 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-Cw*0409N subtyping.

²The nucleotide position, in the 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 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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HLA-Cw*0409N SSP kit			115 1/41 1	DATI	- LOI-5p		
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1 9001 SA *0702	-	ILIV	VC cell line			2	2
2 9280 LK707	1				,W "	_	_
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45 9239 SHJO *0602 *1701 -	44				İ	-	-
	45				*1701	-	-
				*0702		-	-
47 9045 TUBO *0704 *1502 -				_	*1502	-	-
48 9303 TER-ND *0401 *1601 -	_					-	+

HLA-Cw*0409N Product Insert Page 6 of 8 101.861-12 – including *Taq* polymerase General "Instructions for Use"

IFU-01 Rev. No. 00 can be downloaded from

Lot No.: 19G Lot-specific information www.olerup.com

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-Cw*0409N SSP

Product number: 101.861-12 – including *Taq* polymerase

Lot number: 19G

Expiry date: 2011-July-01

Number of tests: 12 Number of wells per test: 2

Well specifications:

Well No.	Production No.	
1	2008-478-01	
2	2008-478-02	

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: 2009-July-11

Approved by:

Quality Control, Supervisor

HLA-Cw*0409N Product Insert Page 7 of 8 101.861-12 – including *Taq* polymerase General "Instructions for Use"

IFU-01 Rev. No. 00 can be downloaded from

Lot No.: 19G Lot-specific information www.olerup.com

Declaration of Conformity

Product name: Olerup SSP® HLA-Cw*0409N

Product number: 101.861-12

Lot number: 19G

Intended use: HLA-Cw*0409N 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 9001:2003, ISO 17025:1999 and ISO 13485:2003, following the provisions of the 98/79/EC Directive on *in vitro* diagnostic medical devices, Annex III.

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.

CE

Saltsjöbaden, Sweden 2009-July-11

Olle Olerup Managing Director HLA-Cw*0409N Product Insert Page 8 of 8 101.861-12 – including *Taq* polymerase General "Instructions for Use"

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Lot No.: 19G Lot-specific information www.olerup.com

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July 2009

Rev. No.: 00

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