101.842-12 – including *Taq* polymerase, IFU-01 Rev. No. 03
101.842-12u – without *Taq* polymerase, IFU-02 Rev. No. 03

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

Lot No.: 21N **Lot-specific information**

Olerup SSP® HLA-A*11 Add-on

Product number:	**101.842-12 – including *Taq* polymerase** **101.842-12u – without *Taq* polymerase**
Lot number:	**21N**
Expiry date:	**2014-August-01**
Number of tests:	**12**
Number of wells per test:	**3**
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. 21N.

The Lot-specific information for HLA-A*11 Add-on including and without *Taq* polymerase is described in one common Product Insert.

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Lot No.: 21N **Lot-specific information**

PRODUCT DESCRIPTION

HLA-A*11 Add-on SSP subtyping

CONTENT

The primer set contains 5'- and 3'-primers for distinguishing the HLA-A*11:77 and 11:110 alleles from HLA-A*11:02.

PLATE LAYOUT

Each test consists of 3 PCR reactions in an 8 well cut PCR plate. Wells 4 to 8 are empty.

1	**2**	**3**	**empty**	**empty**	**empty**	**empty**	**empty**

The 8 well cut PCR plate is marked with the Lot No. '21N' in silver/gray ink.
Well No. 1 is marked with the Lot No. '21N'.
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-A*11 Add-on SSP subtypings will be influenced by the A*02:294, the A*03:26, the A*66:08 in addition to a few A*11 alleles, when present on the other haplotype.

UNIQUELY IDENTIFIED ALLELES

The HLA-A*11:02[1], 11:77 and 11:110 alleles give different patterns in the HLA-A*11 Add-on kit[2].

[1]The HLA-A*11 add-on kit cannot distinguish the silent mutations in the A*11:02:01-11:02:03 alleles.

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

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Lot No.: 21N **Lot-specific information**

SPECIFICITY TABLE

HLA-A*11 Add-on SSP subtyping

Specificities and sizes of the PCR products of the 3 primer mixes used for HLA-A*11 Add-on SSP subtyping

Primer Mix	Size of spec. PCR product[1]	Size of control band[2]	Amplified HLA-A*11:02/11:77/11:110 alleles	Other amplified HLA-A alleles[3,4]
1	270 bp	**800 bp**	*11:02:01-11:02:03, 11:77, 11:110	*11:14, 11:16, 11:38, 11:57, 11:101
2	210 bp	1070 bp	11:110	*02:294, 66:08
3	170 bp	1070 bp	11:77	*03:26

[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-A*11 Add-on 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.
[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.
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-A*11 Add-on subtyping.
[3]For several HLA-A alleles 1st, 4th or 5th 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 these exons are conserved within allelic groups.
[4]Due to the sharing of sequence motifs between HLA-A alleles some non-HLA-A*11 alleles will be amplified by primer mixes 2 and 3.

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Lot No.: 21N **Lot-specific information**

INTERPRETATION TABLE

HLA-A*11 Add-on SSP typing

	Well		
	1	**2**	**3**
Length of spec.	**270**	**210**	**170**
PCR product			
Length of int.	**800**	**1070**	**1070**
pos. control[1]			
5'-primer[2]	**28**	**831**	**874**
	5' -TCC 3'	**5' -gAg 3'**	**5' -CCg 3'**
3'-primer[3]	**127**	**899**	**899**
	5' -CTT 3'	**5' -ACg 3'**	**5' -ACA 3'**
Well No.	**1**	**2**	**3**
HLA-A allele			
***11:02:01-11:02:03, 11:14, 11:16, 11:38, 11:57, 11:101**	**1**		
***11:77**	**1**		**3**
***11:110**	**1**	**2**	
***02:294, 66:08**		**2**	
***03:26**			**3**
HLA-A allele			
Well No.	**1**	**2**	**3**

[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-A*11 Add-on subtyping.
[2]The nucleotide position, in the 1st or 4th 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.
[3]The nucleotide position, in the 2nd or 5th 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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Lot No.: 21N **Lot-specific information**

CELL LINE VALIDATION SHEET

HLA-A*11 Add-on SSP kit

					Well		
					1	2	3
				Lot No.:	201295901	201295902	201295903
	IHWC cell line		A*	A*			
1	9001	SA	*24:02		-	-	-
2	9280	LK707	*02:01		-	-	-
3	9011	E4181324	*01:01		-	-	-
4	9275	GU373	*30:01		-	-	-
5	9009	KAS011	*01:01		-	-	-
6	9353	SM	*02:01	*26:03	-	-	-
7	9020	QBL	*26:01		-	-	-
8	9025	DEU	*31:01		-	-	-
9	9026	YAR	*26:01		-	-	-
10	9107	LKT3	*24:02		-	-	-
11	9051	PITOUT	*29:02		-	-	-
12	9052	DBB	*02:01		-	-	-
13	9004	JESTHOM	*02:01		-	-	-
14	9071	OLGA	*31:01		-	-	-
15	9075	DKB	*24:02		-	-	-
16	9037	SWEIG007	*29:02		-	-	-
17	9282	CTM3953540	*03:01	*80:01	-	-	-
18	9257	32367	*33:03	*74:01	-	-	-
19	9038	BM16	*02:01		-	-	-
20	9059	SLE005	*02:01		-	-	-
21	9064	AMALA	*02:17		-	-	-
22	9056	KOSE	*02:01		-	-	-
23	9124	IHL	*02:01	*34:01	-	-	-
24	9035	JBUSH	*32:01		-	-	-
25	9049	IBW9	*33:01		-	-	-
26	9285	WT49	*02:05		-	-	-
27	9191	CH1007	*24:10	*29:01	-	-	-
28	9320	BEL5GB	*02:01	*29:02	-	-	-
29	9050	MOU	*29:02		-	-	-
30	9021	RSH	*30:01	*68:02	-	-	-
31	9019	DUCAF	*30:02		-	-	-
32	9297	HAG	*02:01		-	-	-
33	9098	MT14B	*31:01		-	-	-
34	9104	DHIF	*31:01		-	-	-
35	9302	SSTO	*32:01		-	-	-
36	9024	KT17	*02:06	*11:01	-	-	-
37	9065	HHKB	*03:01		-	-	-
38	9099	LZL	*02:17		-	-	-
39	9315	CML	*01:01	*03:01	-	-	-
40	9134	WHONP199	*02:07	*30:01	-	-	-
41	9055	H0301	*03:01		-	-	-
42	9066	TAB089	*02:07		-	-	-
43	9076	T7526	*02:06	*02:07	-	-	-
44	9057	TEM	*66:01		-	-	-
45	9239	SHJO	*23:01	*24:02	-	-	-
46	9013	SCHU	*03:01		-	-	-
47	9045	TUBO	*02:16	*03:01	-	-	-
48	9303	TER-ND	*02:01	*11:01	-	-	-

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Lot No.: 21N **Lot-specific information**

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-A*11 Add-on SSP

Product number: **101.842-12 – including *Taq* polymerase**
101.842-12u – without *Taq* polymerase
Lot number: **21N**
Expiry date: **2014-August-01**
Number of tests: **12**
Number of wells per test: **3**

Well specifications:

Well No.	Production No.
1	2012-959-01
2	2012-959-02
3	2012-959-03

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 2 and 3 were available. The specificities of the primers in primer solution 2 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer. In primer solution 3 it was only possible to test the 5'-primer, the 3'-primer was not possible to test.

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

Date of approval: 2012-March-02

Approved by:

Production Quality Control

Lot No.: 21N **Lot-specific information**

Declaration of Conformity

Product name: *Olerup* SSP® HLA-A*11 Add-on
Product number: 101.842-12/12u
Lot number: 21N

Intended use: HLA-A*11 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 II List B, 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.

Notified Body: Lloyd's Register Quality Assurance Limited, Hiramford, Middlemarch Office Village, Siskin Drive, Coventry CV3 4FJ, United Kingdom. (Notified Body number: 0088.)

Stockholm, Sweden
2012-May-10

Ann-Cathrin Jareman
Head of QA and Regulatory Affairs

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Lot No.: 21N **Lot-specific information**

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