

101.434-06 – including *Taq* polymerase, IFU-01
 101.434-06u – without *Taq* polymerase, IFU-02

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

Lot No.: **03S**

Lot-specific information

Olerup SSP[®] HLA-A*80

Product number:	101.434-06 – including <i>Taq</i> polymerase 101.434-06u – without <i>Taq</i> polymerase
Lot number:	03S
Expiry date:	2015-August-01
Number of tests:	6
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. 03S.

CHANGES COMPARED TO THE PREVIOUS *OLERUP SSP[®]* HLA-A*80 LOT (70M)

The HLA-A*80 kit is updated for new alleles to enable separation of:

- Confirmed¹ 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

The Lot-specific information for HLA-A*80 including and without *Taq* polymerase is now described in one common Product Insert.

¹As described in section Uniquely Identified Alleles.

The HLA-A*80 specificity and interpretation tables have been updated for the HLA-A alleles described since the previous *Olerup SSP[®]* HLA-A*80 lot was made (**Lot No. 70M**).

The primers of the wells detailed below have been exchanged, added or modified compared to the previous lot.

Well	5'-primer	3'-primer	rationale
3	-	Modified	3'-primer modified for improved specificity.

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PRODUCT DESCRIPTION

HLA-A*80 SSP subtyping

CONTENT

The primer set contains 5'- and 3'-primers for identifying the HLA-A*80:01 to A*80:02 alleles.

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
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The 8 well cut PCR plate is marked with 'A80' in silver/gray ink.

Well No. 1 is marked with the Lot No. '03S'.

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*80 SSP subtyping will be influenced by the A*30:56 allele. Thus, the interpretation of HLA-A*80 subtypings is only marginally influenced by other groups of HLA-A genes.

UNIQUELY IDENTIFIED ALLELES

The HLA-A*80 alleles, i.e. **HLA-A*80:01** and **HLA-A*80:02**, recognized by the HLA Nomenclature Committee in October 2012¹ will be amplified by the primers in the HLA-A*80 subtyping kit.

The HLA-A*80kit enables separation of the confirmed HLA-A*80 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-A*80 alleles is listed below.

The HLA-A*80 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-A*80 subtyping kit cannot distinguish the silent mutations in the A*80:01:01:01 and 80:01:01:02 alleles.

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¹HLA-A alleles listed on the IMGT/HLA web page 2012-October-14, release 3.10.0, www.ebi.ac.uk/imgt/hla.

²The A*80:02 and the A*30:56 alleles give rise to identical amplification patterns with the HLA-A*80 primer set. These alleles can be distinguished by the HLA-A low resolution and/or the HLA-A*30 kits.

ALLELE CONFIRMATION STATUS

Allele	Status ¹
A*80:01:01:01	Confirmed
A*80:01:01:02	Unconfirmed
A*80:02	Unconfirmed

¹Allele status “confirmed” or “unconfirmed” as listed on the IMGT/HLA web page 2012-October-14, release 3.10.0, www.ebi.ac.uk/imgt/hla.

RESOLUTION IN HOMO- AND HETEROZYGOTES

The two HLA-A*80 alleles can be combined in 3 homozygous and heterozygous combinations. All these genotypes give rise to unique amplification patterns.

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Lot-specific information

SPECIFICITY TABLE

HLA-A*80 SSP subtyping

Specificities and sizes of the PCR products of the 3 primer mixes used for HLA-A*80 SSP subtyping

Primer Mix	Size of spec. PCR product ¹	Size of control band ²	Amplified HLA-A*80 alleles	Other amplified HLA Class I alleles ³
1	135 bp	800 bp	*80:01:01:01-80:02	*30:56
2	155 bp	1070 bp	*80:01:01:01- 80:01:01:02	
3	165 bp	1070 bp	*80:02	*30:56

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-A*80 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-A*80 SSP subtyping.

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

³Due to the sharing of sequence motifs between HLA-A alleles non-HLA-A*80 alleles will be amplified by primer mixes 1 and 3.

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INTERPRETATION TABLE			
HLA-A*80 SSP typing			
	Well		
	1	2	3
Length of spec.	135	155	165
PCR product			
Length of int.	800	1070	1070
pos. control¹			
5'-primer²	176	176	176
	5' -gCA 3'	5' -gCA 3'	5' -gCA 3'
3'-primer³	270	292	299
	5' -ACA 3'	5' -gTT 3'	5' -CCA 3'
Well No.	1	2	3
HLA-A allele⁴			
*80:01:01:01-80:01:01:02	1	2	
*80:02, 30:56⁵	1		3
HLA-A allele			
Well No.	1	2	3

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-A*80 subtyping. .

²The nucleotide position, in the 2nd 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 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.

⁴HLA-A*80 alleles in bold lettering are listed as confirmed alleles on the IMGT/HLA web page www.ebi.ac.uk/imgt/hla, release 3.10.0, October 2012.

⁵The A*80:02 and the A*30:56 alleles give rise to identical amplification patterns with the HLA-A*80 primer set. These alleles can be distinguished by the HLA-A low resolution and/or the HLA-A*30 kits.

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CELL LINE VALIDATION SHEET							
HLA-A*80 SSP kit							
					Well		
					1	2	3
				Lot No.:	201072301	201072302	201315303
	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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CERTIFICATE OF ANALYSIS

Olerup SSP[®] HLA-A*80 SSP

Product number: 101.434-06 – including *Taq* polymerase
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Lot number: 03S

Expiry date: 2015-August-01

Number of tests: 6

Number of wells per test: 3

Well specifications:

Well No.	Production No.
1	2010-723-01
2	2010-723-02
3	2013-153-03

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 solution 3 were available. The specificities of the primers in primer solution 3 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer.

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

Date of approval: 2013-February-26

Approved by:

Production Quality Control

101.434-06 – including *Taq* polymerase, IFU-01
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Declaration of Conformity

Product name: *Olerup* SSP® HLA-A*80
Product number: 101.434-06/06u
Lot number: 03S

Intended use: HLA-A*80 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 13485:2012, following the provisions of the 98/79/EC Directive on *in vitro* diagnostic medical devices, Annex II List B, conformity assessed using Annex IV, 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
2013-February-26

Åsa Olausson
Production Quality Control

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