101. 411-24/06 – including *Taq* polymerase, IFU-01 Rev. No. 03
101. 411-24u/06u – without *Taq* polymerase, IFU-02 Rev. No. 03

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

Lot No.: 06N **Lot-specific information**

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-A*01 SSP

Product number: **101.411-24/06 – including *Taq* pol.**
101.411-24u/06u – without *Taq* pol.

Lot number: **06N**

Expiry date: **2014-July-01**

Number of tests: **24 test – Product No. 101.411-24/24u**
6 tests – Product No. 101.411-06/06u

Number of wells per test: **48**

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2009-629-01	17	2009-629-17	33	2010-792-33
2	2009-629-02	18	2009-629-18	34	2010-792-34
3	2009-629-03	19	2009-629-19	35	2010-792-35
4	2009-629-04	20	2009-629-20	36	2010-792-36
5	2009-629-05	21	2010-792-21	37	2012-938-37
6	2010-792-06	22	2009-629-22	38	2010-792-38
7	2009-629-07	23	2009-629-23	39	2012-938-39
8	2012-938-08	24	2009-629-24	40	2010-792-40
9	2009-629-09	25	2010-792-25	41	2010-792-41
10	2009-629-10	26	2012-938-26	42	2012-938-42
11	2009-629-11	27	2012-938-27	43	2012-938-43
12	2012-938-12	28	2009-629-28	44	2012-938-44
13	2009-629-13	29	2010-792-29	45	2012-938-45
14	2010-792-14	30	2012-938-30	46	2012-938-46
15	2009-629-15	31	2010-792-31	47	2010-792-47
16	2010-792-16	32	2010-792-32	48	2012-938-48

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 6, 8 to 11, 14, 16, 19 to 23, 25 to 32 and 34 to 48 were available. The specificities of primers in primer solutions 8, 10, 11, 14, 19 to 21, 23, 25, 30, 32, 38, 44 to 46 and 48 were tested by separately adding additional 5'-primers, respectively additional 3'-primers. In primer solution 6, 31, 34, 37, 39 and 40 it was only possible to test the 3'-primer, the 5'-primer was not possible to test. In primer solutions 9, 16, 22, 26 to 29, 35, 36, 41 to 43 and 47 it was only possible to test the 5'-primers, the 3'-primers were not possible to test. In primer solutions 8, 10, 11, 14, 16, 20, 25, 30, 32, 38 and 46 one or two of the 3'-primers was not possible to test, and in primer solutions 10, 19, 21, 44, 45 and 48 one of the 5'-primers was not possible to test. An additional 3'-primer in primer solutions 15 was tested by separately adding one 5'-primer.

Lot No.: 06N **Lot-specific information**

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

Date of approval: 2012-January-17

Approved by:

Åsa Olausson

Production Quality Control

Lot No.: 06N **Lot-specific information**

Declaration of Conformity

Product name:	*Olerup* SSP® HLA-A*01
Product number:	101.411-24/06 101.411-24u/06u
Lot number:	06N
Intended use:	HLA-A*01 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 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-January-17

Ann-Cathrin Jareman
Head of QA and Regulatory Affairs