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101.416-12u/04u – without *Taq* polymerase   General "Instructions for Use"
                                              IFU-02 Rev. No. 03 can be downloaded from
Lot No.: **16M**   Lot-specific information   www.olerup-ssp.com

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-A*11 SSP

Product number:	101.416-12u/04u – without *Taq* pol.
Lot number:	16M
Expiry date:	2013-October-01
Number of tests:	12 tests – Product No. 101.416-12u
	4 tests – Product No. 101.416-04u
Number of wells per test:	48

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2007-368-01	17	2007-368-17	33	2011-838-33
2	2007-368-02	18	2010-704-18	34	2011-838-34
3	2008-533-03	19	2011-838-19	35	2011-838-35
4	2007-368-04	20	2010-704-20	36	2011-838-36
5	2011-838-05	21	2011-838-21	37	2011-838-37
6	2010-704-06	22	2010-704-22	38	2011-838-38
7	2007-368-07	23	2007-368-23	39	2011-838-39
8	2010-704-08	24	2010-704-24	40	2011-838-40
9	2010-704-09	25	2010-704-25	41	2011-838-41
10	2010-704-10	26	2010-704-26	42	2011-838-42
11	2010-704-11	27	2010-704-27	43	2011-838-43
12	2007-368-12	28	2010-704-28	44	2011-838-44
13	2010-704-13	29	2010-704-29	45	2011-838-45
14	2007-368-14	30	2010-704-30	46	2011-838-46
15	2008-533-15	31	2010-704-31	47	2011-838-47
16	2010-704-16	32	2010-704-32	48	2011-838-48

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

No DNAs carrying the alleles to be amplified by primer solutions 5, 8, 9, 13, 16, 19, 23, 28, 30, 31, 33 to 40 and 42 to 48 were available. The specificities of the primers in primer solutions 5, 9, 13, 23, 28, 31, 40, 43 and 47 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer. In primer solutions 19, 30, 34, 35, 37, 38 and 42 it was only possible to test the 5'-primers, the 3'-primers were not possible to test. In primer solutions 8, 16, 33, 36, 39, 44 to 46 and 48 it was only possible to test the 3'-primers, the 5'-primers were not possible to test. In primer solutions 6, 10, 13, 20, 28 and 31 one or two of the 5'-primers were not possible to test. In primer solutions 5, 20, 22, 24, 26 to 28, 31, 32, 40 and 43 one or two of the 3'primers were not possible to test. Additional primers in primer solutions 3, 10, 18, 20, 24, 25, 27 and 32 were tested by separately adding one additional 5'-primer or one additional 3'-primer.

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Lot No.: **16M**   **Lot-specific information**   **www.olerup-ssp.com**

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

Date of approval: 2012-January-24

Approved by:

Åsa Olausson

Production Quality Control

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Lot No.: **16M**   Lot-specific information   www.olerup-ssp.com

Declaration of Conformity

Product name: *Olerup* SSP® HLA-A*11
Product number: 101.416-12u/04u
Lot number: 16M

Intended use: HLA-A*11 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, 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
2012-January-24

Ann-Cathrin Jareman
Head of QA and Regulatory Affairs