101.416-12/04 – including *Taq* pol., IFU-01
101.416-12u/04u – without *Taq* polymerase, IFU-02

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Lot No.: 09S **Lot-specific information**

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-A*11 SSP

Product number: **101.416-12/04 – including *Taq* pol.**
101.416-12u/04u – without *Taq* pol.

Lot number: **09S**
Expiry date: **2015-October-01**
Number of tests: **12 tests – Product No. 101.416-12/12u**
4 tests – Product No. 101.416-04/04u
Number of wells per test: **64**

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2012-999-01	25	2012-999-25	49	2012-999-49
2	2012-999-02	26	2012-999-26	50	2012-999-50
3	2012-999-03	27	2012-999-27	51	2012-999-51
4	2012-999-04	28	2012-999-28	52	2012-999-52
5	2012-999-05	29	2012-999-29	53	2012-999-53
6	2012-999-06	30	2012-999-30	54	2012-999-54
7	2012-999-07	31	2012-999-31	55	2012-999-55
8	2012-999-08	32	2012-999-32	56	2012-999-56
9	2012-999-09	33	2012-999-33	57	2013-159-57
10	2012-999-10	34	2012-999-34	58	2013-159-58
11	2012-999-11	35	2012-999-35	59	2013-159-59
12	2012-999-12	36	2012-999-36	60	2013-159-60
13	2012-999-13	37	2012-999-37	61	2013-159-61
14	2012-999-14	38	2012-999-38	62	2013-159-62
15	2012-999-15	39	2012-999-39	63	2013-159-63
16	2012-999-16	40	2012-999-40	64	2013-159-64
17	2012-999-17	41	2012-999-41		
18	2012-999-18	42	2012-999-42		
19	2012-999-19	43	2013-159-43		
20	2013-159-20	44	2012-999-44		
21	2012-999-21	45	2012-999-45		
22	2012-999-22	46	2012-999-46		
23	2013-159-23	47	2012-999-47		
24	2012-999-24	48	2012-999-48		

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, 42 to 54, 56 to 61, 63 and 64 were available. The specificities of the primers in primer solutions 5, 9, 13, 23, 28, 31, 40, 43, 44, 47, 52 to 54 and 61 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer. In primer solutions 19, 30, 34, 35, 37, 38,

Lot No.: 09S **Lot-specific information**

42, 49, 51, 58, 60 and 63 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, 45, 46, 48, 50, 56, 57, 59 and 64 it was only possible to test the 3'-primers, the 5'-primers were not possible to test. In primer solutions 6, 10, 28, 31, 44, 52, 54 and 64 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, 44, 52, 54 and 55 one or two of the 3'primers were not possible to test.
Additional primers in primer solutions 3, 10, 18, 24, 25, 27 and 55 were tested by separately adding one additional 5'-primer and/or one additional 3'-primer.

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

Date of approval: 2013-June-17

Approved by:

Kurvin Mathiesen

Production Quality Control

101.416-12/04 – including *Taq* pol., IFU-01
101.416-12u/04u – without *Taq* polymerase, IFU-02

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Lot No.: 09S

Lot-specific information

Declaration of Conformity

Product name: *Olerup* SSP® HLA-A*11
Product number: 101.416-12/12u, -04/04u
Lot number: 09S

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 13485:2012, 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
2015-February-09

Daniel Malica
Head of QA and Regulatory Affairs