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

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

Lot No.: 62N **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: **62N**
Expiry date: **2014-November-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: **56**

Well specifications:

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

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 and 56 were available. The specificities of the primers in primer solutions 5, 9, 13, 23, 28, 31, 40, 43, 44, 47 and 52 to 54 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer. In primer solutions 19, 30, 34, 35, 37, 38, 42, 49 and 51 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 and 56 it was only possible to test the 3'-primers, the 5'-primers were not possible to test. In primer solutions 6, 10, 20, 28, 31, 44, 52 and 54 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.

Lot No.: 62N **Lot-specific information**

Additional primers in primer solutions 3, 10, 18, 20, 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: 2012-June-04

Approved by:

Kurin Clattsson

Production Quality Control

Lot No.: 62N **Lot-specific information**

Declaration of Conformity

Product name: *Olerup* SSP® HLA-A*11
Product number: 101.416-12/12u, -04/04u
Lot number: 62N

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
2014-October-07

Daniel Malica
Head of QA and Regulatory Affairs