Lot No.: 89S **Lot-specific information**

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-B low resolution screening SSP

Product number: **101.503-48/12 – including *Taq* pol.**
101.503-48u/12u – without *Taq* pol.
Lot number: **89S**
Expiry date: **2016-April-01**
Number of tests: **48 tests – Product No. 101.503-48/48u**
12 tests – Product No. 101.503-12/12u
Number of wells per test: **47 + 1**

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2013-187-01	17	2013-187-17	33	2013-187-33
2	2013-187-02	18	2013-218-18	34	2013-187-34
3	2013-218-03	19	2013-187-19	35	2013-187-35
4	2013-187-04	20	2013-187-20	36	2013-187-36
5	2013-187-05	21	2013-187-21	37	2013-187-37
6	2013-208-06	22	2013-208-22	38	2013-187-38
7	2013-187-07	23	2013-208-23	39	2013-187-39
8	2013-221-08	24	2013-208-24	40	2013-187-40
9	2013-264-09	25	2013-187-25	41	2013-187-41
10	2013-187-10	26	2013-187-26	42	2013-218-42
11	2013-264-11	27	2013-187-27	43	2013-187-43
12	2013-187-12	28	2013-187-28	44	2013-187-44
13	2013-187-13	29	2013-264-29	45	2013-187-45
14	2013-187-14	30	2013-187-30	46	2013-187-46
15	2013-187-15	31	2013-187-31	47	2013-187-47
16	2013-187-16	32	2013-187-32		

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

Additional 5'-primers and 3'-primers in primer solutions 3, 6, 14, 19, 29, 31 and 40 were tested by separately adding one additional 3'-primer, respectively one additional 5'-primer. Additional 3'-primers in primer solutions 2, 8, 11, 13, 15 and 18 were tested by separately adding one additional 5'-primer. Additional 5'-primers in primer solutions 1, 21 and 25 were tested by separately adding one additional 3'-primer.
In primer mixes 31, 42 and 43 one 5'-primer was not possible to test, and in primer mixes 29, 38 and 42 one or two 3'-primer was not possible to test.

The negative control primer pairs, **Production No. 2013-271-01**, can detect contamination with PCR products diluted 10^{-7}.

Lot No.: 89S **Lot-specific information**

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

Date of approval: 2013-November-08

Approved by:

Åsa Olauss

Production Quality Control

Lot No.: 89S **Lot-specific information**

Declaration of Conformity

Product name: *Olerup* SSP® HLA-B low resolution screening
Product number: 101.503-48/48u, -12/12u
Lot number: 89S

Intended use: HLA-B low resolution screening histocompatibility testing

Manufacturer: *Olerup* SSP AB
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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-November-08

Ann-Cathrin Jareman
Head of QA and Regulatory Affairs