

Lot No.: **98M**

Lot-specific information

www.olerup-ssp.com

CERTIFICATE OF ANALYSIS

Olerup SSP[®] HLA-B low resolution SSP

Product number: 101.501-48u/12u – without Taq pol.

Lot number: 98M

Expiry date: 2014-July-01

Number of tests: 48 tests – Product No. 101.501-48u

12 tests – Product No. 101.501-12u

Number of wells per test: 47 + 1

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2011-900-01	17	2011-900-17	33	2011-900-33
2	2011-900-02	18	2011-900-18	34	2011-900-34
3	2011-900-03	19	2011-900-19	35	2011-900-35
4	2011-900-04	20	2011-955-20	36	2011-900-36
5	2011-900-05	21	2011-900-21	37	2011-900-37
6	2011-900-06	22	2011-900-22	38	2011-900-38
7	2011-900-07	23	2011-900-23	39	2011-900-39
8	2011-900-08	24	2011-900-24	40	2011-900-40
9	2011-900-09	25	2011-900-25	41	2011-900-41
10	2011-900-10	26	2011-900-26	42	2011-900-42
11	2011-900-11	27	2011-900-27	43	2011-900-43
12	2011-900-12	28	2011-900-28	44	2011-900-44
13	2011-900-13	29	2011-900-29	45	2011-900-45
14	2011-900-14	30	2011-900-30	46	2011-900-46
15	2011-900-15	31	2011-900-31	47	2011-900-47
16	2011-900-16	32	2011-900-32		

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, 13, 15 and 35 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 solution 31, one 5'-primer was not possible to test, in primer solution 38, one 3'-primer was not possible to test, and in primer solution 42, one 5'-primer and one 3'-primer was not possible to test.

The negative control primer pairs, **Production No. 2011-917-01**, can detect contamination with PCR products diluted 10⁻⁷.

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

Date of approval: 2012-January-09

Approved by:

Production Quality Control

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Declaration of Conformity

Product name: Olerup SSP® HLA-B low resolution
Product number: 101.501-48u/12u
Lot number: 98M

Intended use: HLA-B low 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-09



Ann-Cathrin Jareman
Head of QA and Regulatory Affairs