

101.501-48/12 – including *Taq* polymerase, IFU-01
 101.501-48u/12u – without *Taq* polymerase, IFU-02

Visit www.olerup-ssp.com for
 “Instructions for Use” (IFU)

Lot No.: **54R**

Lot-specific information

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-B low resolution SSP

Product number: 101.501-48/12 – including *Taq* pol.
 101.501-48u/12u – without *Taq* pol.
Lot number: 54R
Expiry date: 2015-May-01
Number of tests: 48 tests – Product No. 101.501-48/48u
 12 tests – Product No. 101.501-12/12u
Number of wells per test: 63 + 1

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2012-042-01	25	2012-042-25	49	2011-924-49
2	2012-042-02	26	2012-042-26	50	2011-924-50
3	2012-042-03	27	2012-042-27	51	2011-924-51
4	2012-042-04	28	2012-042-28	52	2011-924-52
5	2012-042-05	29	2012-042-29	53	2011-924-53
6	2012-042-06	30	2012-042-30	54	2012-040-54
7	2012-042-07	31	2012-042-31	55	2011-924-55
8	2012-042-08	32	2012-042-32	56	2011-924-56
9	2011-924-09	33	2012-042-33	57	2011-924-57
10	2012-042-10	34	2012-042-34	58	2011-924-58
11	2012-042-11	35	2012-042-35	59	2012-040-59
12	2012-042-12	36	2012-042-36	60	2011-924-60
13	2012-042-13	37	2012-042-37	61	2011-924-61
14	2012-042-14	38	2012-042-38	62	2011-924-62
15	2012-042-15	39	2012-042-39	63	2012-040-63
16	2012-042-16	40	2012-042-40		
17	2012-042-17	41	2012-042-41		
18	2012-042-18	42	2012-042-42		
19	2012-100-19	43	2012-042-43		
20	2012-042-20	44	2012-042-44		
21	2012-042-21	45	2012-981-45		
22	2012-042-22	46	2012-042-46		
23	2012-042-23	47	2012-042-47		
24	2012-124-24	48	2012-042-48		

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

Additional 3'-primers in primer solutions 2, 3, 6, 13 to 15, 19, 29, 31, 35, 40, 58 were tested by separately adding additional 5'-primers.

Additional 5'-primers in primer solutions 1, 3, 6, 14, 19, 21, 25, 29, 31, 40, 48, 54, 58, 59 and 61 were tested by separately adding additional 3'-primers.

In primer solutions 31, 42 and 63 one 5'-primer was not possible to test and in primer solutions 38, 42, 54 and 61 one 3'-primer was not possible to test.

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The negative control primer pairs, **Production No. 2012-085-01**, can detect contamination with PCR products diluted 10^{-7} .

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

Date of approval: 2012-December-10

Approved by:

Karin Mattsson

Production Quality Control

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Declaration of Conformity

Product name: Olerup SSP® HLA-B low resolution
Product number: 101.501-48/48u, -12/12u
Lot number: 54R

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
2015-January-21



Daniel Malica
Head of QA and Regulatory Affairs