

101.503-48/12 – including *Taq* pol., IFU-01
101.503-48u/12u – without *Taq* pol., IFU-02

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

Lot No.: **8E4**

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: 8E4
Expiry date: 2019-07-01
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	2016-736-01	17	2016-736-17	33	2016-736-33
2	2016-736-02	18	2016-736-18	34	2016-736-34
3	2016-736-03	19	2016-736-19	35	2016-736-35
4	2016-736-04	20	2016-736-20	36	2016-736-36
5	2016-736-05	21	2017-767-21	37	2016-736-37
6	2016-736-06	22	2016-736-22	38	2016-736-38
7	2016-736-07	23	2016-736-23	39	2016-736-39
8	2016-736-08	24	2016-736-24	40	2016-736-40
9	2017-767-09	25	2016-736-25	41	2017-767-41
10	2017-767-10	26	2016-736-26	42	2016-736-42
11	2017-767-11	27	2016-736-27	43	2016-736-43
12	2016-736-12	28	2016-736-28	44	2016-736-44
13	2016-736-13	29	2016-736-29	45	2016-736-45
14	2016-736-14	30	2016-736-30	46	2016-736-46
15	2016-736-15	31	2016-736-31	47	2016-736-47
16	2016-736-16	32	2016-736-32		

The negative control primer pairs, **Production No. 2016-695-01**, can detect contamination with PCR products diluted 10^{-7} .

Results of Quality Control: No false positive or false negative amplifications obtained.

Date of approval: 170301

Approved by:



Production Quality Control

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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: 8E4

Intended use: HLA-B low resolution screening 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 EN 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, 1 Trinity Park, Bickenhill Lane, Birmingham B37 7ES, United Kingdom.
(Notified Body number: 0088.)

Stockholm, Sweden
2017-Mar-07



Daniel Malica
Head of QA and Regulatory Affairs