

101.903-24 – including *Taq* polymerase, IFU-01 Visit www.olerup-ssp.com for
101.903-24u – without *Taq* polymerase, IFU-02 “Instructions for Use” (IFU)

Lot No.: **3E2**

Lot-specific information

CERTIFICATE OF ANALYSIS

Olerup SSP® DQA1*02,05;DQB1*02,03:02 SSP

Product number: 101.903-24 – including *Taq* polymerase
101.903-24u – without *Taq* polymerase
Lot number: 3E2
Expiry date: 2019-04-01
Number of tests: 24
Number of wells per test: 20+ 1

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2015-490-01	9	2016-716-09	17	2015-490-15
2	2015-490-02	10	2015-490-09	18	2015-490-16
3	2015-490-03	11	2015-490-10	19	2015-490-17
4	2016-716-04	12	2015-490-10B	20	2016-716-20
5	2015-490-06	13	2015-490-11		
6	2015-490-07	14	2015-490-12		
7	2015-490-08	15	2015-490-13		
8	2016-716-08	16	2015-490-14		

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:

161028

Approved by:



Production Quality Control

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Lot-specific information

Declaration of Conformity

Product name: Olerup SSP® DQA1*02,05;DQB1*02,03:02

Product number: 101.903-24/24u

Lot number: 3E2

Intended use: DQA1*02, DQA1*05, DQB1*02 and DQB1*03 medium resolution histocompatibility testing

Manufacturer: Olerup SSP AB
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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 III, 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.

The Authorized Representative located within the Community is: Olerup SSP AB.

Stockholm, Sweden
2016-Oct-28



Daniel Malica
Head of QA and Regulatory Affairs

