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

Lot No.: 07Y **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: **07Y**
Expiry date: **2017-August-01**
Number of tests: **24**
Number of wells per test: **17+ 1**

Well specifications:

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

The negative control primer pairs, **Production No. 2015-499-01**, can detect contamination with PCR products diluted 10^{-7}.

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

Date of approval: 2015-February-27

Approved by:

Karin Mattsson

Production Quality Control

CE

For *In Vitro* Diagnostic Use.

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

Lot No.: 07Y **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: 07Y

Intended use: DQA1*02, DQA1*05, DQB1*02 and DQB1*03 medium 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 13485:2012, 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
2015-March-02

Daniel Malica
Head of QA and Regulatory Affairs

CE

For *In Vitro* Diagnostic Use.