**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.: 4D0** **Lot-specific information**

# CERTIFICATE OF ANALYSIS

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

| | |
|---|---|
| **Product number:** | **101.903-24 – including *Taq* polymerase**<br>**101.903-24u – without *Taq* polymerase** |
| **Lot number:** | **4D0** |
| **Expiry date:** | **2018-07-01** |
| **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. 2015-617-01**, can detect contamination with PCR products diluted $10^{-7}$.

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

***Date of approval:*** 2016-07-22

***Approved by:***

**Production Quality Control**

**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.: 4D0** **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:** 4D0

**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 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-Feb-22

Daniel Malica
Head of QA and Regulatory Affairs



CE

For *In Vitro* Diagnostic Use.