101.901-24 – including *Taq* polymerase, IFU-01
101.901-24u – without *Taq* polymerase, IFU-02

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

Lot No.: 47X **Lot-specific information**

CERTIFICATE OF ANALYSIS

Olerup SSP® DQB1*06:02,DQA1*01:02 - SSP

Product number:	**101.901-24 – including *Taq* polymerase** **101.901-24u- without *Taq* polymerase**
Lot number:	**47X**
Expiry date:	**2017-September-01**
Number of tests:	**24**
Number of wells per test:	**7+1**

Well specifications:

Well No.	Production No.
1	2014-431-01B
2	2014-431-01
3	2014-431-02
4	2014-431-04
5	2014-431-05
6	2014-431-06
7	2015-502-03

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-April-17

Approved by:

Kurin Mattsson

Production Quality Control

CE

For *In Vitro* Diagnostic Use

101.901-24 – including *Taq* polymerase, IFU-01
101.901-24u – without *Taq* polymerase, IFU-02

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

Lot No.: 47X **Lot-specific information**
Declaration of Conformity

Product name: *Olerup* SSP® DQB1*06:02,DQA1*01:02
Product number: 101.901-24/24u
Lot number: 47X

Intended use: DQB1*06:02,DQA1*01:02, DRB1*15:XX 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.

Stockholm, Sweden
2015-April-21

Daniel Malica
Head of QA and Regulatory Affairs