

101.901-24 – including *Taq* polymerase, IFU-01

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

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

Lot No.: **4G6**

Lot-specific information

CERTIFICATE OF ANALYSIS

Olerup SSP[®] DQB1*06:02,DQA1*01:02

Product number:	101.901-24 – including <i>Taq</i> polymerase 101.901-24u – without <i>Taq</i> polymerase
Lot number:	4G6
Expiry date:	2021-01-01
Number of tests:	24
Number of wells per test:	7+1

Well specifications:

Well No.	Production No.
1	2018-927-01
2	2014-431-01
3	2014-431-02
4	2014-431-04
5	2014-431-05
6	2014-431-06
7	2018-927-07

The negative control primer pairs, **Production No. 2017-845-01**, can detect contamination with PCR products diluted 10^{-7} .

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

Date of approval: 2018-09-07

Approved by: Rebecca Salme

Production Quality Control



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

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Lot No.: **4G6**

Lot-specific information
Declaration of Conformity

Product name: Olerup SSP® DQB1*06:02,DQA1*01:02
Product number: 101.901-24/24u
Lot number: 4G6

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


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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.

Stockholm, Sweden

2018-09-10


Terese Wasell
Head of Regulatory Affairs