

101.811-12 – including *Taq* polymerase, IFU-01

101.811-12u – without *Taq* polymerase, IFU-02

Lot No.: 23Y

Visit www.olerup-ssp.com for

“Instructions for Use” (IFU)

CERTIFICATE OF ANALYSIS

Olerup SSP® DRB4*01:03:01:02N SSP

Product number: 101.811-12 – including *Taq* polymerase
101.811-12u – without *Taq* polymerase
Lot number: 23Y
Expiry date: 2017-September-01
Number of tests: 12
Number of wells per test: 2+1

Well specifications:

Well No.	Production No.
1	2013-275-01
2	2013-275-02

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-March-16

Approved by:

Karin Ollatsoen

Production Quality Control

101.811-12 – including *Taq* polymerase, IFU-01

101.811-12u – without *Taq* polymerase, IFU-02

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Declaration of Conformity

Product name: Olerup SSP® DRB4*01:03:01:02N

Product number: 101.811-12

Lot number: 23Y

Intended use: DRB4*01:03:01:02N 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 ISO 13485:2012, following the provisions of the 98/79/EC Directive on *in vitro* diagnostic medical devices, Annex II List B, 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.

Notified Body: Lloyd's Register Quality Assurance Limited, Hiramford, Middlemarch Office Village, Siskin Drive, Coventry CV3 4FJ, United Kingdom.
(Notified Body number: 0088.)

Stockholm, Sweden
2015-March-16



Daniel Malica
Head of QA and Regulatory Affairs