

101.811-12 – including *Taq* polymerase, IFU-01Visit <https://labproducts.caredx.com> for101.811-12u – without *Taq* polymerase, IFU-02

“Instructions for Use” (IFU)

Lot No.: **6F3****CERTIFICATE OF ANALYSIS****Olerup SSP® DRB4\*01:03:01:02N**

**Product number:** 101.811-12 – including *Taq* polymerase  
101.811-12u – without *Taq* polymerase

**Lot number:** 6F3

**Expiry date:** 2021-10-01

**Number of tests:** 12

**Number of wells per test:** 2+1

**Well specifications:**

Well No.	Production No.
1	2017-844-01
2	2017-844-02

The negative control primer pairs, **Production No. 2016-746-01**, can detect contamination with PCR products diluted  $10^{-7}$ .

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

**Date of approval:** 2019-08-28

**Approved by:** *Rebecca Selmer*

**Production Quality Control**

**0088**For *In Vitro* Diagnostic Use

MA100 v02 CoA\_DoC IVD Annex II List B

Date: August 2019, Rev. No: 01

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

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

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Lot No.: **6F3**

## Declaration of Conformity

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

**Product number:** 101.811-12

**Lot number:** 6F3

**Intended use:** DRB4\*01:03:01:02N 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) EN ISO 13485:2016, following the provisions of the 98/79/EC Directive on *in vitro* diagnostic medical devices, Annex II List B, conformity assessed using Annex IV, 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.

Notified Body: Lloyd's Register Quality Assurance Limited, 1 Trinity Park, Bickenhill Lane, Birmingham B37 7ES, United Kingdom.  
(Notified Body number: 0088.)

Stockholm, Sweden

Date:

2019-08-29

Quality Assurance



Change in revision R01 compared to R00:

1. The expiration date has been altered due to extension of shelf-life.



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