101.851-12 – including *Taq* polymerase
101.851-12u – without *Taq* polymerase

Visit https://labproducts.caredx.com for **"Instructions for Use" (IFU)**

Lot No.: 4F3

Lot-specific Information

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-B*51:11N SSP

Product number:	**101.851-12 – including *Taq* polymerase** **101.851-12u – without *Taq* polymerase**
Lot number:	**4F3**
Expiry date:	**2021-07-01**
Number of tests:	**12**
Number of wells per test:	**2+1**

Well specifications:

Well No.	Production No.
1	2017-821-01
2	2017-821-02

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: 2019-08-23

Approved by: Rebecka Fleur

Production Quality Control

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MA100 v02 CoA_DoC IVD Annex II List B
Date: August 2019, Rev. No: 01

101.851-12 – including *Taq* polymerase
101.851-12u – without *Taq* polymerase

Visit https://labproducts.caredx.com for **"Instructions for Use" (IFU)**

Lot No.: 4F3

Lot-specific Information

Declaration of Conformity

Product name: *Olerup* SSP® HLA-B*51:11N
Product number: 101.851-12/12u
Lot number: 4F3

Intended use: HLA-B*51:11N histocompatibility testing

Manufacturer:
Olerup SSP AB
Franzengatan 5
SE-112 51 Stockholm, Sweden
Phone: +46-8-508 939 00
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: 2019-09-13

Quality Assurance

Changes in revision R01 compared to R00:
1. The expiry date has been altered due to extension of shelf-life.

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