101.403.48/12 – including *Taq* pol., IFU-01
101.403.48u/12u – without *Taq* pol., IFU-02

Visit www.labproducts.caredx.com for "Instructions for Use" (IFU)

Lot No.: **2H8** Lot-specific information

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-A low resolution screening

Product number:	**101.403-48/12 – including *Taq* polymerase** **101.403-48u/12u – without *Taq* polymerase**
Lot number:	**2H8**
Expiry date:	**2021-09-01**
Number of tests:	**48 tests – Product No. 101.403-48/48u** **12 tests – Product No. 101.403-12/12u**
Number of wells per test:	**23+1**

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2019-008-01	9	2019-008-09	17	2019-008-17
2	2019-008-02	10	2019-008-10	18	2019-008-18
3	2019-008-03	11	2019-008-11	19	2019-008-19
4	2019-008-04	12	2019-008-12	20	2019-008-20
5	2019-008-05	13	2019-008-13	21	2019-008-21
6	2019-008-06	14	2019-008-14	22	2019-008-22
7	2019-008-07	15	2019-008-15	23	2019-008-23
8	2019-008-08	16	2019-008-16		

The negative control primer pairs, **Production No. 2018-947-01**, can detect contamination with PCR products diluted 10^{-7}.

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

Date of approval: 2019-03-15

Approved by: Rebecka Salonen

Production Quality Control

CE
0088
For *In Vitro* Diagnostic Use
MA100 v02 CoA_DoC IVD Annex II List B
Date: March 2019, Rev. No: 00

101.403.48/12 – including *Taq* pol., IFU-01
101.403.48u/12u – without *Taq* pol., IFU-02

Visit www.labproducts.caredx.com for **"Instructions for Use" (IFU)**

Lot No.: 2H8 **Lot-specific information**

Declaration of Conformity

Product name: *Olerup* SSP® HLA-A low resolution screening
Product number: 101.403-48/48u, -12/12u
Lot number: 2H8

Intended use: HLA-A low resolution screening 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: 20190321

Emil Jonsson
Head of Quality Assurance

CE
0088
For *In Vitro* Diagnostic Use
MA100 v02 CoA_DoC IVD Annex II List B
Date: March 2019, Rev. No: 00