101.903-24 – including *Taq* polymerase, IFU-01
101.903-24u – without *Taq* polymerase, IFU-02

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

Lot No.: 1K1 **Lot-specific information**

CERTIFICATE OF ANALYSIS

Olerup SSP® DQA1*02,05;DQB1*02,03:02

Product number:	**101.903-24 – including *Taq* polymerase** **101.903-24u – without *Taq* polymerase**
Lot number:	**1K1**
Expiry date:	**2022-01-01**
Number of tests:	**24**
Number of wells per test:	**22+ 1**

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2017-841-01	9	2017-841-09	17	2017-841-15
2	2015-490-02	10	2017-841-21	18	2018-915-17
3	2017-841-03	11	2018-915-11	19	2018-915-18
4	2017-841-04	12	2017-841-10	20	2017-841-18
5	2017-841-05	13	2017-841-11	21	2018-915-20
6	2017-841-06	14	2017-841-12	22	2017-841-20
7	2017-841-07	15	2017-841-13		
8	2017-841-08	16	2017-841-14		

The negative control primer pairs, **Production No. 2019-076-01**, can detect contamination with PCR products diluted 10^{-7}.

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

Date of approval:

Approved by:

Production Quality Control

CE

For *In Vitro* Diagnostic Use
MA099 v01 CoA_DoC General IVDs
Date: July 2019, Rev. No: 00

101.903-24 – including *Taq* polymerase, IFU-01
101.903-24u – without *Taq* polymerase, IFU-02

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

Lot No.: 1K1

Lot-specific information

Declaration of Conformity

Product name:	*Olerup* SSP® DQA1*02,05;DQB1*02,03:02
Product number:	101.903-24/24u
Lot number:	1K1
Intended use:	DQA1*02, DQA1*05, DQB1*02 and DQB1*03 medium resolution histocompatibility testing
Manufacturer:	*Olerup* SSP AB Franzéngatan 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 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, Franzéngatan 5, SE-112 51 Stockholm, Sweden.

The Authorized Representative located within the Community is: *Olerup* SSP AB.

Stockholm, Sweden
Date: 20170725

Quality Assurance

CE