101.213.24 – including *Taq* pol., IFU-01.
101.213.24u – without *Taq* pol., IFU-02.

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

Lot No.: 7H7 **Lot-specific information**

CERTIFICATE OF ANALYSIS

Olerup SSP® DQB1*02

Product number:	**101.213-24 – including *Taq* polymerase** **101.213-24u – without *Taq* polymerase**
Lot number:	**7H7**
Expiry date:	**2021-11-01**
Number of tests:	**24**
Number of wells per test:	**31+1**

Well specifications:

Well No.	Production No.	Well No.	Production No.
1	2015-581-01	17	2015-581-17
2	2015-581-02	18	2019-057-18
3	2014-438-03	19	2017-772-19
4	2014-438-04	20	2017-772-20
5	2018-945-05	21	2017-772-21
6	2014-438-06	22	2019-057-22
7	2014-438-07	23	2015-581-23
8	2019-057-08	24	2017-772-24
9	2014-438-09	25	2017-772-25
10	2014-438-10	26	2018-945-26
11	2018-945-11	27	2017-772-27
12	2017-772-12	28	2018-945-28
13	2014-438-13	29	2017-772-29
14	2015-581-14	30	2017-772-30
15	2017-772-15	31	2017-772-31
16	2015-581-16		

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: 2019-06-03

Approved by: Rebecka Salmé

Production Quality Control

CE

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

101.213.24 – including *Taq* pol., IFU-01.
101.213.24u – without *Taq* pol., IFU-02.

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

Lot No.: 7H7

Lot-specific information

Declaration of Conformity

Product name: *Olerup* SSP® DQB1*02
Product number: 101.213-24/24u
Lot number: 7H7

Intended use: DQB1*02 high 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: 2019-06-07

Quality Assurance

CE

For *In Vitro* Diagnostic Use