

101.211-24 – including *Taq* pol., IFU-01
 101.211-24u – without *Taq* pol., IFU-02

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

Lot No.: **7K2**

Lot-specific information

CERTIFICATE OF ANALYSIS

Olerup SSP[®] DQB1*05

Product number:	101.211-24 – including <i>Taq</i> polymerase 101.211-24u – without <i>Taq</i> polymerase
Lot number:	7K2
Expiry date:	2024-01-01
Number of tests:	24
Number of wells per test:	31+1

Well specifications:

Well No.	Production No.	Well No.	Production No.
1	2020-147-01	17	2017-795-17
2	2020-147-02	18	2020-147-18
3	2015-600-03	19	2017-795-19
4	2020-147-04	20	2017-795-20
5	2015-600-05	21	2017-795-21
6	2015-600-06	22	2017-795-22
7	2017-795-07	23	2017-795-23
8	2017-795-08	24	2017-795-24
9	2015-600-09	25	2020-147-25
10	2015-600-10	26	2017-795-26
11	2017-795-11	27	2017-795-27
12	2017-795-12	28	2017-795-28
13	2017-795-13	29	2017-795-29
14	2017-795-14	30	2017-795-30
15	2015-600-15	31	2017-795-31
16	2020-147-16		

The negative control primer pairs, **Production No. 2019-109-01**, can detect contamination with PCR products diluted 10⁻⁷.

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

Date of approval: 2020-02-19

Approved by: *Rebecka Salome*

Production Quality Control



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Lot-specific information

Declaration of Conformity

Product name: *Olerup* SSP® DQB1*05
Product number: 101.211-24/24u
Lot number: 7K2

Intended use: DQB1*05 resolution histocompatibility testing

Manufacturer: *CareDx* AB
 Franzéngatan 5
 SE-112 51 Stockholm, Sweden
Phone: +46-8-508 939 00
Fax: +46-8-717 88 18

We, *CareDx* 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 *CareDx* AB, Franzéngatan 5, SE-112 51 Stockholm, Sweden.

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

Stockholm, Sweden

Date:

2020-02-20

Quality Assurance


