

101.201-48/12 – including *Taq* pol., IFU-01
101.201-48u/12u – without *Taq* pol., IFU-02

Visit <https://labproducts.caredx.com> for
“Instructions for Use” (IFU)

Lot No.: **5N9**

Lot-specific information

CERTIFICATE OF ANALYSIS

Olerup SSP[®] DQ low

Product number:

101.201-48/12 – including *Taq* pol.

101.201-48u/12u – without *Taq* pol.

Lot number:

5N9

Expiry date:

2025-12-01

Number of tests:

48 tests – Product No. 101.201-48/48u

12 tests – Product No. 101.201-12/12u

Number of wells per test:

15+1

Well specifications:

Well No.	Production No.	Well No.	Production No.
1	2020-203-01	9	2020-203-09
2	2021-359-02	10	2020-203-10
3	2020-203-03	11	2020-203-11
4	2020-203-04	12	2020-203-12
5	2021-335-05	13	2021-359-13
6	2020-203-06	14	2020-203-14
7	2020-203-07	15	2020-203-15
8	2020-203-08		

The negative control primer pairs, **Production No. 2021-336-01**, can detect contamination with PCR products diluted 10^{-7} .

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

Date of approval: 2022-01-19

Approved by:



Production Quality Control



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Lot No.: **5N9**

Lot-specific information

Declaration of Conformity

Product name: *Olerup* SSP® DQ low
Product number: 101.201-48/48u, -12/12u
Lot number: 5N9

Intended use: DQB1 low resolution histocompatibility testing

Manufacturer: *CareDx* AB
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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, Franzégatan 5, SE-112 51 Stockholm, Sweden.

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

Stockholm, Sweden

Date:

2022-01-29

Quality Assurance

