

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.: **4L6**

Lot-specific information

CERTIFICATE OF ANALYSIS

Olerup SSP® DQB1*02

Product number:	101.213-24 – including <i>Taq</i> polymerase 101.213-24u – without <i>Taq</i> polymerase
Lot number:	4L6
Expiry date:	2024-10-01
Number of tests:	24
Number of wells per test:	31+1

Well specifications:

Well No.	Production No.	Well No.	Production No.
1	2020-231-01	17	2020-231-17
2	2020-231-02	18	2020-231-18
3	2020-231-03	19	2020-231-19
4	2020-231-04	20	2020-231-20
5	2020-231-05	21	2020-231-21
6	2020-231-06	22	2020-231-22
7	2020-231-07	23	2020-231-23
8	2020-231-08	24	2020-231-24
9	2020-231-09	25	2020-231-25
10	2020-231-10	26	2020-231-26
11	2020-231-11	27	2020-231-27
12	2020-231-12	28	2020-231-28
13	2020-231-13	29	2020-231-29
14	2020-231-14	30	2020-231-30
15	2020-231-15	31	2020-231-31
16	2020-231-16		

The negative control primer pairs, **Production No. 2020-205-01**, can detect contamination with PCR products diluted 10^{-7} .

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

Date of approval: 2020-11-13

Approved by:



Production Quality Control



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Lot-specific information

Declaration of Conformity

Product name: *Olerup* SSP® DQB1*02
Product number: 101.213-24/24u
Lot number: 4L6

Intended use: DQB1*02 high 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, Franzéngatan 5, SE-112 51 Stockholm, Sweden.

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

Stockholm, Sweden

Date:

2020-11-13

Quality Assurance


