

101.231-24/04 – including *Taq* pol., IFU-01
101.231-24u/04u – without *Taq* pol., IFU-02

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

Lot No.: 7H1

Lot-specific information

CERTIFICATE OF ANALYSIS

Olerup SSP® DQA1

Product number:

101.231-24/04 – including *Taq* pol.

101.231-24u/04u – without *Taq* pol.

Lot number:

7H1

Expiry date:

2021-12-01

Number of tests:

24 tests – Product No. 101.231-24/24u

4 tests – Product No. 101.231-04/04u

Number of wells per test:

31+1

Well specifications:

Well No.	Production No.	Well No.	Production No.
1	2019-052-01	17	2019-052-17
2	2019-052-02	18	2019-052-18
3	2019-052-03	19	2019-052-19
4	2019-052-04	20	2019-052-20
5	2019-052-05	21	2019-052-21
6	2019-052-06	22	2019-052-22
7	2019-052-07	23	2019-052-23
8	2019-052-08	24	2019-052-24
9	2019-052-09	25	2016-052-25
10	2019-052-10	26	2019-052-26
11	2019-052-11	27	2019-052-27
12	2019-052-12	28	2019-052-28
13	2019-052-13	29	2019-052-29
14	2019-052-14	30	2019-052-30
15	2019-052-15	31	2019-052-31
16	2019-052-16		

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: 2019-07-04

Approved by: Rebecca Selme

Production Quality Control



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Lot-specific information

Declaration of Conformity

Product name: Olerup SSP® DQA1

Product number: 101.231-24/04

Lot number: 7H1

Intended use: HLA-DQA1 high resolution histocompatibility testing

Manufacturer: Olerup SSP AB
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SE-112 51 Stockholm, Sweden
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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:

2019-07-04

Quality Assurance


