

101.215-12 – including *Taq* pol., IFU-01
 101.215-12u – without *Taq* pol., IFU-02

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

Lot No.: **7H9**

Lot-specific Information

CERTIFICATE OF ANALYSIS

Olerup SSP® DQB1*04

Product number: 101.215-12 – including *Taq* polymerase
 101.215-12u – without *Taq* polymerase
Lot number: 7H9
Expiry date: 2021-11-01
Number of tests: 12
Number of wells per test: 20+1

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2015-507-01	9	2014-321-09	17	2016-737-17
2	2015-507-02	10	2014-321-10	18	2016-737-18
3	2015-507-03	11	2018-936-11	19	2018-936-19
4	2014-321-04	12	2015-507-12	20	2018-936-20
5	2014-321-05	13	2014-321-13		
6	2015-507-06	14	2014-321-14		
7	2015-507-07	15	2018-936-15		
8	2014-321-08	16	2016-737-16		

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: 2019-06-17

Approved by: *Roseck Sa Amg*

Production Quality Control



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Lot-specific Information

Declaration of Conformity

Product name: *Olerup* SSP® DQB1*04
Product number: 101.215-12/12u
Lot number: 7H9

Intended use: DQB1*04 high resolution histocompatibility testing

Manufacturer: *Olerup* SSP AB
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 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: 2019-06-18

Quality Assurance 

