

101.214-24/06 – including *Taq* polymerase
101.214-24u/06u – without *Taq* polymerase

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

Lot No.: **6S3**

Lot-specific information

CERTIFICATE OF ANALYSIS

Olerup SSP® DQB1*03

Product number:

101.214-24/06 – including *Taq* pol.
101.214-24u/06u – without *Taq* pol.

Lot number:

6S3

Expiry date:

2027-10-01

Number of tests:

24 test – Product No. 101.214-24/24u

6 tests – Product No. 101.214-06/06u

Number of wells per test:

63+1

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2023-519-01	25	2023-519-25	49	2023-519-49
2	2023-519-02	26	2023-519-26	50	2023-519-50
3	2023-519-03	27	2023-519-27	51	2023-519-51
4	2023-519-04	28	2023-519-28	52	2023-519-52
5	2023-519-05	29	2023-519-29	53	2023-519-53
6	2023-519-06	30	2023-519-30	54	2023-519-54
7	2023-519-07	31	2023-519-31	55	2023-519-55
8	2023-519-08	32	2023-519-32	56	2023-519-56
9	2023-519-09	33	2023-519-33	57	2023-519-57
10	2023-519-10	34	2023-519-34	58	2023-519-58
11	2023-519-11	35	2023-519-35	59	2023-519-59
12	2023-519-12	36	2023-519-36	60	2023-519-60
13	2023-519-13	37	2023-519-37	61	2023-519-61
14	2023-519-14	38	2023-519-38	62	2023-519-62
15	2023-519-15	39	2023-519-39	63	2023-519-63
16	2023-519-16	40	2023-519-40		
17	2023-519-17	41	2023-519-41		
18	2023-519-18	42	2023-519-42		
19	2023-519-19	43	2023-519-43		
20	2023-519-20	44	2023-519-44		
21	2023-519-21	45	2023-519-45		
22	2023-519-22	46	2023-519-46		
23	2023-519-23	47	2023-519-47		
24	2023-519-24	48	2023-519-48		

The negative control primer pairs, **Production No. 2023-544-01**, can detect contamination with PCR products diluted 10⁻⁷.



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Lot-specific information

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

Date of approval: 2023-11-29



Approved by:

Production Quality Control



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Lot-specific information

Declaration of Conformity

Product name: *Olerup* SSP® DQB1*03
Product number: 101.214-24/06, -24u/06u
Lot number: 6S3

Intended use: DQB1*03 high 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:

2023-12-05

Susan B

Quality Assurance



