

Certificates

101.221-12 – including *Taq* pol., IFU-01
 101.221-12u – without *Taq* pol., IFU-02

Visit www.labproducts.caredx.com for
 "Instructions for Use" (IFU)

Lot No.: **9H7**

Lot-specific information

CERTIFICATE OF ANALYSIS

Olerup SSP® DQB1 high resolution for frequent alleles

Product number: 101.221-12 – including *Taq* polymerase
 101.221-12u – without *Taq* polymerase
Lot number: 9H7
Expiry date: 2023-11-01
Number of tests: 12 tests
Number of wells per test: 95+ 1

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2019-077-01	33	2019-077-33	65	2019-077-65
2	2019-077-02	34	2019-077-34	66	2019-077-66
3	2019-077-03	35	2019-077-35	67	2019-077-67
4	2019-077-04	36	2019-077-36	68	2019-077-68
5	2019-077-05	37	2019-077-37	69	2019-077-69
6	2019-077-06	38	2019-077-38	70	2019-077-70
7	2019-077-07	39	2019-077-39	71	2019-077-71
8	2019-077-08	40	2019-077-40	72	2019-077-72
9	2019-077-09	41	2019-077-41	73	2019-077-73
10	2019-077-10	42	2019-077-42	74	2019-077-74
11	2019-077-11	43	2019-077-43	75	2019-077-75
12	2019-077-12	44	2019-077-44	76	2019-077-76
13	2019-077-13	45	2019-077-45	77	2019-077-77
14	2019-077-14	46	2019-077-46	78	2019-077-78
15	2019-077-15	47	2019-077-47	79	2019-077-79
16	2019-077-16	48	2019-077-48	80	2019-077-80
17	2019-077-17	49	2019-077-49	81	2019-077-81
18	2019-077-18	50	2019-077-50	82	2019-077-82
19	2019-077-19	51	2019-077-51	83	2019-077-83
20	2019-077-20	52	2019-077-52	84	2019-077-84
21	2019-077-21	53	2019-077-53	85	2019-077-85
22	2019-077-22	54	2019-077-54	86	2019-077-86
23	2019-077-23	55	2019-077-55	87	2019-077-87
24	2019-077-24	56	2019-077-56	88	2019-077-88
25	2019-077-25	57	2019-077-57	89	2019-077-89
26	2019-077-26	58	2019-077-58	90	2019-077-90
27	2019-077-27	59	2019-077-59	91	2019-077-91
28	2019-077-28	60	2019-077-60	92	2019-077-92
29	2019-077-29	61	2019-077-61	93	2019-077-93
30	2019-077-30	62	2019-077-62	94	2019-077-94
31	2019-077-31	63	2019-077-63	95	2019-077-95
32	2019-077-32	64	2019-077-64		



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Lot-specific information

The negative control primer pairs, **Production No. 2019-078-01**, can detect contamination with PCR products diluted 10^{-7} .

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

Date of approval: 2019-11-26

Approved by: Rebecca Salve

Production Quality Control



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Lot No.: **9H7**

Lot-specific information
Declaration of Conformity

Product name: *Olerup* SSP® DQB1 High
Product number: 101.221-12/12u
Lot number: 9H7

Intended use: DQB1 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, Franzégatan 5, SE-112 51 Stockholm, Sweden.

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

Stockholm, Sweden

Date: 2019-11-28

Quality Assurance

