

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.: 2F4

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: 2F4

Expiry date: 2021-07-01

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	2016-682-01	33	2017-803-33	65	2016-682-65
2	2016-682-02	34	2017-803-34	66	2017-803-66
3	2015-500-03	35	2017-803-35	67	2017-803-67
4	2015-500-04	36	2016-682-36	68	2015-500-68
5	2017-803-05	37	2015-500-37	69	2017-803-69
6	2015-500-06	38	2017-803-38	70	2015-500-70
7	2015-500-07	39	2017-803-39	71	2017-803-71
8	2016-682-08	40	2017-803-40	72	2017-803-72
9	2015-500-09	41	2017-803-41	73	2017-803-73
10	2017-803-10	42	2017-803-42	74	2017-803-74
11	2015-500-11	43	2015-500-43	75	2017-803-75
12	2017-803-12	44	2017-803-44	76	2017-803-76
13	2017-803-13	45	2017-803-45	77	2017-803-77
14	2016-682-14	46	2015-500-46	78	2017-803-78
15	2017-803-15	47	2015-500-47	79	2017-803-79
16	2015-500-16	48	2015-500-48	80	2017-803-80
17	2017-803-17	49	2017-803-49	81	2016-682-81
18	2017-803-18	50	2017-803-50	82	2015-500-82
19	2015-500-19	51	2017-803-51	83	2015-500-83
20	2015-500-20	52	2015-500-52	84	2017-803-84
21	2017-803-21	53	2016-682-53	85	2017-803-85
22	2015-500-22	54	2017-803-54	86	2017-803-86
23	2015-500-23	55	2016-682-55	87	2017-803-87
24	2016-682-24	56	2017-803-56	88	2017-803-88
25	2017-803-25	57	2016-682-57	89	2016-682-89
26	2015-500-26	58	2017-803-58	90	2017-803-90
27	2015-500-27	59	2016-682-59	91	2017-803-91
28	2015-500-28	60	2016-682-60	92	2017-803-92
29	2015-500-29	61	2017-803-61	93	2016-682-93
30	2017-803-30	62	2017-803-62	94	2017-803-94
31	2015-500-31	63	2017-803-63	95	2015-500-95
32	2015-500-32	64	2016-682-64		



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

"Instructions for Use" (IFU)

Lot No.: 2F4

Lot-specific information

The negative control primer pairs, **Production No. 2016-746-01**, can detect contamination with PCR products diluted 10^{-7} .

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

Date of approval: 2019-05-02

Approved by: *Rebecca Salme*

Production Quality Control



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Lot No.: **2F4**

Lot-specific information

Declaration of Conformity

Product name: Olerup SSP® DQB1 High

Product number: 101.221-12/12u

Lot number: 2F4

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

The Authorized Representative located within the Community is: Olerup SSP AB.

Stockholm, Sweden

Date:

20190502

Emil Jonsson

Head of Quality Assurance

Change in revision R01 compared to R00:

1. The expiration date has been altered due to extension of shelf-life.

