

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.: **4H0**

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: 4H0
Expiry date: 2021-09-01
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	2019-023-65
2	2016-682-02	34	2017-803-34	66	2019-023-66
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	2019-023-38	70	2015-500-70
7	2019-023-07	39	2017-803-39	71	2019-023-71
8	2016-682-08	40	2017-803-40	72	2019-023-72
9	2015-500-09	41	2017-803-41	73	2019-023-73
10	2017-803-10	42	2017-803-42	74	2017-803-74
11	2015-500-11	43	2015-500-43	75	2019-023-75
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	2019-023-47	79	2017-803-79
16	2015-500-16	48	2015-500-48	80	2019-023-80
17	2019-023-17	49	2017-803-49	81	2016-682-81
18	2019-023-18	50	2019-023-50	82	2015-500-82
19	2015-500-19	51	2019-023-51	83	2019-023-83
20	2015-500-20	52	2015-500-52	84	2017-803-84
21	2017-803-21	53	2019-023-53	85	2017-803-85
22	2015-500-22	54	2017-803-54	86	2019-023-86
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	2019-023-26	58	2017-803-58	90	2019-023-90
27	2015-500-27	59	2016-682-59	91	2017-803-91
28	2015-500-28	60	2016-682-60	92	2019-023-92
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	2019-023-64		



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

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Lot No.: **4H0**

Lot-specific information

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: 2019-04-11

Approved by: *Rebecca Palung*

Production Quality Control



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Lot No.: 4H0**Lot-specific information****Declaration of Conformity**

Product name: *Olerup* SSP® DQB1 High
Product number: 101.221-12/12u
Lot number: 4H0

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: 20190411



Emil Jonsson
Head of Quality Assurance

