

Lot No.: 9G8

Lot-specific information

CERTIFICATE OF ANALYSIS

Olerup SSP® DPB1

Product number:

**101.311-24/04 – including *Taq* pol.
 101.311-24u/04u – without *Taq* pol.**

Lot number:

9G8

Expiry date:

2021-08-01

Number of tests:

24 tests – Product No. 101.311-24/24u

4 tests – Product No. 101.311-04/04u

Number of wells per test:

95+1

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2016-683-01	33	2016-683-33	65	2017-863-65
2	2016-683-02	34	2016-683-34	66	2018-982-66
3	2017-776-03	35	2016-683-35	67	2018-982-67
4	2016-683-04	36	2016-683-36	68	2018-982-68
5	2016-683-05	37	2018-982-37	69	2018-982-69
6	2016-683-06	38	2018-982-38	70	2018-982-70
7	2016-683-07	39	2016-683-39	71	2016-683-71
8	2016-683-08	40	2017-863-40	72	2018-982-72
9	2016-683-09	41	2016-683-41	73	2017-776-73
10	2017-863-10	42	2016-683-42	74	2017-863-74
11	2016-683-11	43	2016-683-43	75	2016-683-75
12	2017-863-12	44	2018-982-44	76	2018-982-76
13	2016-683-13	45	2016-683-45	77	2018-982-77
14	2017-776-14	46	2016-683-46	78	2018-982-78
15	2018-982-15	47	2016-683-47	79	2018-982-79
16	2016-683-16	48	2016-683-48	80	2018-982-80
17	2016-683-17	49	2017-863-49	81	2016-683-81
18	2016-683-18	50	2016-683-50	82	2016-683-82
19	2016-683-19	51	2017-776-51	83	2016-683-83
20	2016-683-20	52	2017-776-52	84	2017-863-84
21	2016-683-21	53	2018-982-53	85	2017-776-85
22	2016-683-22	54	2018-982-54	86	2018-982-86
23	2016-683-23	55	2017-776-55	87	2018-982-87
24	2016-683-24	56	2017-863-56	88	2016-683-88
25	2016-683-25	57	2016-683-57	89	2017-776-89
26	2018-982-26	58	2016-683-58	90	2018-982-90
27	2017-863-27	59	2017-863-59	91	2018-982-91
28	2016-683-28	60	2018-982-60	92	2018-982-92
29	2018-982-29	61	2016-683-61	93	2018-982-93
30	2016-683-30	62	2016-683-62	94	2017-863-94
31	2016-683-31	63	2018-982-63	95	2016-683-95
32	2016-683-32	64	2017-863-64		



101.311-24/04 – including *Taq* pol., IFU-01

Visit www.labproducts.caredx.com for

101.311-24/04u – without *Taq* pol., IFU-02

“Instructions for Use” (IFU)

Lot No.: **9G8**

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: 2019-03-25

Approved by: Rebecca Salome

Production Quality Control



101.311-24/04 – including *Taq* pol., IFU-01Visit www.labproducts.caredx.com for101.311-24/04u – without *Taq* pol., IFU-02

“Instructions for Use” (IFU)

Lot No.: **9G8**

Lot-specific information

Declaration of Conformity

Product name: Olerup SSP® DPB1
Product number: 101.311-24/04, -24u/04u
Lot number: 9G8

Intended use: DPB1 high resolution histocompatibility testing

Manufacturer: Olerup SSP AB
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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:

20190328



Emil Jonsson
Head of Quality Assurance

