

101.612-12 – including *Taq* pol., IFU-01
101.612-12u – without *Taq* pol., IFU-02

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

Lot No.: 0F2

Lot-specific information
CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-C*04 SSP

Product number: 101.612-12 – including *Taq* polymerase
101.612-12u – without *Taq* polymerase
Lot number: 0F2
Expiry date: 2021-05-01
Number of tests: 12
Number of wells per test: 63+1

Well specifications:

Well No.	Production No.	Well No.	Production No.
1	2017-782-01	25	2017-782-25
2	2017-782-02	26	2017-782-26
3	2017-782-03	27	2017-782-27
4	2017-782-04	28	2017-782-28
5	2017-782-05	29	2017-782-29
6	2017-782-06	30	2017-782-30
7	2017-782-07	31	2017-782-31
8	2017-782-08	32	2017-782-32
9	2017-782-09	33	2017-782-33
10	2017-782-10	34	2017-782-34
11	2017-782-11	35	2017-782-35
12	2017-782-12	36	2017-782-36
13	2017-782-13	37	2017-782-37
14	2017-782-14	38	2017-782-38
15	2017-782-15	39	2017-782-39
16	2017-782-16	40	2017-782-40
17	2017-782-17	41	2017-782-41
18	2017-782-18	42	2017-782-42
19	2017-782-19	43	2017-782-43
20	2017-782-20	44	2017-782-44
21	2017-782-21	45	2017-782-45
22	2017-782-22	46	2017-782-46
23	2017-782-23	47	2017-782-47
24	2017-782-24	48	2017-782-48
49	2017-782-49	50	2017-782-50
51	2017-782-51	52	2017-782-52
53	2017-782-53	54	2017-782-54
55	2017-782-55	56	2017-782-56
57	2017-782-57	58	2017-782-58
59	2017-782-59	60	2017-782-60
61	2017-782-61	62	2017-782-62
63	2017-782-63		

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 Palmer

Production Quality Control



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Lot No.: **0F2**

Lot-specific information
Declaration of Conformity

Product name: Olerup SSP® HLA-C*04
Product number: 101.612-12/12u
Lot number: 0F2

Intended use: HLA-C*04 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: 20190506



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.

