

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.: 7H3

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: 7H3
Expiry date: 2022-01-01
Number of tests: 12
Number of wells per test: 63+1

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2017-782-01	25	2017-782-25	49	2017-782-49
2	2017-782-02	26	2017-782-26	50	2017-782-50
3	2017-782-03	27	2017-782-27	51	2017-782-51
4	2017-782-04	28	2017-782-28	52	2017-782-52
5	2017-782-05	29	2017-782-29	53	2019-054-53
6	2017-782-06	30	2017-782-30	54	2019-054-54
7	2017-782-07	31	2017-782-31	55	2017-782-55
8	2017-782-08	32	2019-054-32	56	2017-782-56
9	2017-782-09	33	2017-782-33	57	2017-782-57
10	2017-782-10	34	2017-782-34	58	2017-782-58
11	2017-782-11	35	2019-054-35	59	2017-782-59
12	2017-782-12	36	2019-054-36	60	2017-782-60
13	2017-782-13	37	2017-782-37	61	2017-782-61
14	2017-782-14	38	2017-782-38	62	2019-054-62
15	2017-782-15	39	2017-782-39	63	2017-782-63
16	2019-054-16	40	2017-782-40		
17	2017-782-17	41	2017-782-41		
18	2017-782-18	42	2017-782-42		
19	2019-054-19	43	2017-782-43		
20	2019-054-20	44	2017-782-44		
21	2017-782-21	45	2017-782-45		
22	2017-782-22	46	2019-054-46		
23	2017-782-23	47	2017-782-47		
24	2017-782-24	48	2017-782-48		

The negative control primer pairs, **Production No. 2019-076-01**, can detect contamination with PCR products diluted 10^{-7} .

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

Date of approval: 2019-07-10

Approved by:

Production Quality Control



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Lot-specific information

Declaration of Conformity

Product name: Olerup SSP® HLA-C*04

Product number: 101.612-12/12u

Lot number: 7H3

Intended use: HLA-C*04 high resolution histocompatibility testing

Manufacturer: Olerup SSP AB
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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: 2019-07-11

Quality Assurance


