101.624-12– including *Taq* polymerase, IFU-01
101.624-12u – without *Taq* polymerase, IFU-02

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

Lot No.: **1H9** Lot-specific Information

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-C*12 SSP

Product number: 101.624-12 – including *Taq* polymerase
101.624-12u – without *Taq* polymerase

Lot number: 1H9
Expiry date: 2021-08-01
Number of tests: 12
Number of wells per test: 47+1

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2014-320-01	17	2017-796-17	33	2018-001-33
2	2014-320-02	18	2017-796-18	34	2017-796-34
3	2018-001-03	19	2014-320-19	35	2015-610-35
4	2014-320-04	20	2017-796-20	36	2017-796-36
5	2014-462-05	21	2014-320-21	37	2017-796-37
6	2014-320-06	22	2017-796-22	38	2017-796-38
7	2017-796-07	23	2018-001-23	39	2017-796-39
8	2014-320-08	24	2015-610-24	40	2015-610-40
9	2014-320-09	25	2017-796-25	41	2017-796-41
10	2018-001-10	26	2017-796-26	42	2015-610-42
11	2017-796-11	27	2017-796-27	43	2015-610-43
12	2014-320-12	28	2018-001-28	44	2018-001-44
13	2015-610-13	29	2018-001-29	45	2017-796-45
14	2014-320-14	30	2018-001-30	46	2018-001-46
15	2014-320-15	31	2017-796-31	47	2017-796-47
16	2014-320-16	32	2015-610-32		

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: 2019-02-22

Approved by: Rebecka Dahlme

Production Quality Control

CE

101.624-12– including *Taq* polymerase, IFU-01
101.624-12u – without *Taq* polymerase, IFU-02

Visit www.labproducts.caredx.com for **"Instructions for Use" (IFU)**

Lot No.: 1H9 **Lot-specific Information**

Declaration of Conformity

Product name: *Olerup* SSP® HLA-C*12
Product number: 101.624-12/12u
Lot number: 1H9

Intended use: HLA-C*12 high resolution histocompatibility testing

Manufacturer: *Olerup* SSP AB
Franzéngatan 5
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, Franzéngatan 5, SE-112 51 Stockholm, Sweden.

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

Stockholm, Sweden
Date: 20190228

Emil Jonsson
Head of Quality Assurance

CE