Lot No.: 6H1 **Lot-specific information**

CERTIFICATE OF ANALYSIS

Olerup SSP® DPA1

Product number: **101.331-24/06 – including *Taq* pol.**
101.331-24u/06u – without *Taq* pol.

Lot number: **6H1**

Expiry date: **2023-05-01**

Number of tests: **24 tests – Product No. 101.331-24/24u**
6 tests – Product No. 101.331-06/06u

Number of wells per test: **21+1**

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2016-706-01	9	2016-706-09	17	2018-933-17
2	2016-706-02	10	2016-706-10	18	2019-042-18
3	2019-042-03	11	2016-706-11	19	2018-933-19
4	2016-706-04	12	2016-706-12	20	2019-042-20
5	2016-706-05	13	2019-042-13	21	2019-042-21
6	2016-706-06	14	2016-706-14		
7	2019-042-07	15	2016-706-15		
8	2016-706-08	16	2019-042-16		

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: 2021-04-09

Approved by:

Production Quality Control

CE

Lot No.: 6H1 **Lot-specific information**

Declaration of Conformity

Product name: *Olerup* SSP® DPA1
Product number: 101.331-24/24u, -06/06u
Lot number: 6H1

Intended use: HLA-DPA1 high resolution histocompatibility testing

Manufacturer: *CareDx* AB
Franzéngatan 5
SE-112 51 Stockholm, Sweden
Phone: +46-8-508 939 00
Fax: +46-8-717 88 18

We, CareDx 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 *CareDx* AB, Franzéngatan 5, SE-112 51 Stockholm, Sweden.

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

Stockholm, Sweden
Date: 2021-04-13

Quality Assurance

Changes in revision R01 compared to R00:
1. The expiration date has been altered due to shelf-life extension.

CE