

Lot No.: 5R1

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: 5R1  
Expiry date: 2026-12-01  
Number of tests: 24 tests – Product No. 101.331-24/24u  
6 tests – Product No. 101.331-06/06u  
Number of wells per test: 22+1

### Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2022-464-01	9	2022-464-09	17	2022-464-17
2	2022-464-02	10	2022-464-10	18	2022-464-18
3	2022-464-03	11	2022-464-11	19	2022-464-19
4	2022-464-04	12	2022-464-12	20	2022-464-20
5	2022-464-05	13	2022-464-13	21	2022-464-21
6	2022-464-06	14	2022-464-14	22	2022-464-22
7	2022-464-07	15	2022-464-15		
8	2022-464-08	16	2022-464-16		

The negative control primer pairs, **Production No. 2021-336-01**, can detect contamination with PCR products diluted  $10^{-7}$ .

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

**Date of approval:** 2022-12-13

**Approved by:**

**Production Quality Control**



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## Declaration of Conformity

**Product name:** Olerup SSP® DPA1

**Product number:** 101.331-24/24u, -06/06u

**Lot number:** 5R1

**Intended use:** HLA-DPA1 high resolution histocompatibility testing

**Manufacturer:** CareDx AB  
Franzégatan 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, Franzégatan 5, SE-112 51 Stockholm, Sweden.

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

Stockholm, Sweden

Date: 2022-12-13

Quality Assurance

