Lot No.: **5K8** Lot-specific Information

# CERTIFICATE OF ANALYSIS

## *Olerup* SSP® HLA-A*01

**Product number:** 101.411-24/06 – including *Taq* pol.
101.411-24u/06u – without *Taq* pol.

**Lot number:** 5K8

**Expiry date:** 2024-05-01

**Number of tests:** 24 tests – Product No. 101.411-24/24u
6 tests – Product No. 101.411-06/06u

**Number of wells per test:** 62+1

**Well specifications:**

| Well No. | Production No. | Well No. | Production No. | Well No. | Production No. |
|---|---|---|---|---|---|
| 1 | 2020-131-01 | 25 | 2020-131-25 | 49 | 2020-131-49 |
| 2 | 2020-131-02 | 26 | 2020-131-26 | 50 | 2020-131-50 |
| 3 | 2020-131-03 | 27 | 2020-131-27 | 51 | 2020-131-51 |
| 4 | 2020-131-04 | 28 | 2020-131-28 | 52 | 2020-131-52 |
| 5 | 2020-131-05 | 29 | 2020-131-29 | 53 | 2020-131-53 |
| 6 | 2020-131-06 | 30 | 2020-131-30 | 54 | 2020-131-54 |
| 7 | 2020-131-07 | 31 | 2020-131-31 | 55 | 2020-131-55 |
| 8 | 2020-131-08 | 32 | 2020-131-32 | 56 | 2020-131-56 |
| 9 | 2020-131-09 | 33 | 2020-131-33 | 57 | 2020-131-57 |
| 10 | 2020-131-10 | 34 | 2020-131-34 | 58 | 2020-131-58 |
| 11 | 2020-131-11 | 35 | 2020-131-35 | 59 | 2020-131-59 |
| 12 | 2020-131-12 | 36 | 2020-131-36 | 60 | 2020-131-60 |
| 13 | 2020-131-13 | 37 | 2020-131-37 | 61 | 2020-131-61 |
| 14 | 2020-131-14 | 38 | 2020-131-38 | 62 | 2020-131-62 |
| 15 | 2020-131-15 | 39 | 2020-131-39 | | |
| 16 | 2020-131-16 | 40 | 2020-131-40 | | |
| 17 | 2020-131-17 | 41 | 2020-131-41 | | |
| 18 | 2020-131-18 | 42 | 2020-131-42 | | |
| 19 | 2020-131-19 | 43 | 2020-131-43 | | |
| 20 | 2020-131-20 | 44 | 2020-131-44 | | |
| 21 | 2020-131-21 | 45 | 2020-131-45 | | |
| 22 | 2020-131-22 | 46 | 2020-131-46 | | |
| 23 | 2020-131-23 | 47 | 2020-131-47 | | |
| 24 | 2020-131-24 | 48 | 2020-131-48 | | |

The negative control primer pairs, **Production No. 2019-145-01**, can detect contamination with PCR products diluted $10^{-7}$.

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

***Date of approval:*** 2020-06-05

***Approved by:*** Romero

**Production Quality Control**

CE
**0197**
For *In Vitro* Diagnostic Use
MA100 v04 CoA_DoC IVD Annex II List B
Date: June 2020, Rev. No: 00

**Lot No.: 5K8** **Lot-specific Information**

# Declaration of Conformity

**Product name:** *Olerup* SSP® HLA-A*01
**Product number:** 101.411-24/06
101.411-24u/06u
**Lot number:** 5K8

**Intended use:** HLA-A*01 high resolution histocompatibility testing

**Manufacturer:** CareDx AB
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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 II List B, conformity assessed using Annex IV, as transposed into the national laws of the Member States of the European Union.

The Technical Documentation File is maintained at *CareDx* AB, Franzengatan 5, SE-112 51 Stockholm, Sweden.

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

Notified Body: TÜV Rheinland LGA products, Tillystrasse 2, D-90431 Nürnberg, Germany. (Notified Body number: 0197.)

Stockholm, Sweden
Date: 2020-06-05

Quality Assurance

CE
**0197**
For *In Vitro* Diagnostic Use
MA100 v04 CoA_DoC IVD Annex II List B
Date: June 2020, Rev. No: 00