Lot No.: 8L0 **Lot-specific information**

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA - Negative Control SSP

Product number:	**102.102-01 – including *Taq* polymerase** **102.102-01u – without *Taq* polymerase**
Lot number:	**8L0**
Expiry date:	**2025-01-01**
Number of tests:	**96**
Number of wells per test:	**1**

Well specification:

Well No.	Production No.
1	2020-205-01

The negative control primer solution has been tested in a dilution series of the corresponding PCR products, 1 to 10^3 down to 1 to 10^9.

The HLA-Wipe test and the HLA-Negative Control contain the same primer mix.
The 8 well cut PCR plate is marked with 'WT' in silver/gray ink.
The inner box is labelled with HLA - Wipetest – Negative Control SSP.

Results: The negative control primer pairs can detect contamination with the corresponding PCR products diluted 1 to 10^7.

Date of approval: 2021-02-26

Approved by:

Romero

Production Quality Control

See also 102.101-01 HLA-Wipe Test lot 8L0

CE

Lot No.: 8L0 **Lot-specific information**

Declaration of Conformity

Product name: *Olerup* SSP® HLA - Negative Control
Product number: 102.102-01/01u
Lot number: 8L0

Intended use: Negative Control in *Olerup* SSP® HLA typings.

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: 2021-03-01

Quality Assurance

CE