

Lot No.: **4S4**

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: 4S4
 Expiry date: 2027-10-01
 Number of tests: 96
 Number of wells per test: 1

Well specification:

Well No.	Production No.
1	2023-544-01

The negative control primer solution has been tested in a dilution series of the corresponding PCR products, 1 to 10³ down to 1 to 10⁹.

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 – Wipe Test – Negative Control SSP.

Results: The negative control primer pairs can detect contamination with the corresponding PCR products diluted 1 to 10⁷.

Date of approval: 2023-11-16

Approved by:



Production Quality Control

See also 102.101-01 HLA-Wipe Test lot 4S4



Lot No.: **4S4**

Lot-specific information

Declaration of Conformity

Product name: *Olerup* SSP® HLA - Negative Control
Product number: 102.102-01/01u
Lot number: 4S4

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

Manufacturer: *CareDx* AB
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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 lot documentation 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:

2023-11-16

Quality Assurance


