

Lot No.: **5N2**

Lot-specific information

## CERTIFICATE OF ANALYSIS

### Olerup SSP<sup>®</sup> HLA - Negative Control SSP

Product number: 102.102-01 – including *Taq* polymerase  
102.102-01u – without *Taq* polymerase  
Lot number: 5N2  
Expiry date: 2025-10-01  
Number of tests: 96  
Number of wells per test: 1

#### Well specification:

Well No.	Production No.
1	2021-336-01

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

The HLA-Wipe test and the HLA-Negative Control contain the same primer mix.

The 8 well cut PCR plate is marked with '5N2' 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 10<sup>7</sup>.

**Date of approval:** 2021-11-18

**Approved by:**



**Production Quality Control**

See also 102.101-01 HLA-Wipe Test lot 5N2



Lot No.: **5N2**

Lot-specific information

## Declaration of Conformity

**Product name:** Olerup SSP<sup>®</sup> HLA - Negative Control

**Product number:** 102.102-01/01u

**Lot number:** 5N2

**Intended use:** Negative Control in Olerup SSP<sup>®</sup> 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 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:

2021-11-18



Quality Assurance

