

Lot No.: **3K2**

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: 3K2  
 Expiry date: 2023-10-01  
 Number of tests: 96  
 Number of wells per test: 1

#### Well specification:

Well No.	Production No.
1	2019-078-01

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 ‘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<sup>7</sup>.

**Date of approval:** 2019-10-18

**Approved by:** Rebecca Selmer

### Production Quality Control

See 102.101-01 HLA-Wipe Test lot 3K2



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## Declaration of Conformity

**Product name:** *Olerup* SSP® HLA - Negative Control  
**Product number:** 102.102-01/01u  
**Lot number:** 3K2

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

**Manufacturer:** *CareDx* AB  
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**Phone:** +46-8-508 939 00  
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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, Franzégatan 5, SE-112 51 Stockholm, Sweden.

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

Stockholm, Sweden

Date: 2019.10.29

Quality Assurance


