

102.101-01 – including *Taq* polymerase, IFU-01  
 102.101-01u – without *Taq* polymerase, IFU-02

Visit <https://labproducts.caredx.com>  
 for "Instructions for Use" (IFU)

Lot No.: **8L0**

Lot-specific information

## CERTIFICATE OF ANALYSIS

### Olerup SSP® HLA Wipe Test – Negative Control

Product number: 102.101-01 – including *Taq* polymerase  
 Product number: 102.101-01u – without *Taq* polymerase  
 Lot number: 8L0  
 Expiry date: 2023-08-01  
 Number of tests: 96  
 Number of wells per test: 1-2

#### Well specification:

Well No.	Production No.
1	2020-289-01

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 Positive Control DNA has been tested with the HLA Wipe Test kit and gives rise to PCR amplicons.

The negative control primer pairs can detect contamination with the corresponding PCR products diluted 1 to 10<sup>8</sup>, equivalent to 0.1 ng starting material.

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

**Date of approval:** 2021-02-24

**Approved by:** 

#### Production Quality Control



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## Declaration of Conformity

**Product name:** Olerup SSP® HLA Wipe Test – Negative Control  
**Product number:** 102.101-01/01u  
**Lot number:** 8L0

**Intended use:** Detection of contamination with HLA amplicons.

**Manufacturer:** CareDx AB  
Franzégatan 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, Franzégatan 5, SE-112 51 Stockholm, Sweden.

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

Stockholm, Sweden

Date:

2021-03-07

Quality Assurance

