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.: 5N2 **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:	**5N2**
Expiry date:	**2025-10-01**
Number of tests:	**96**
Number of wells per test:	**1-2**

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 10^3 down to 1 to 10^9. 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 10^8, equivalent to 0.1 ng starting material.

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

Date of approval: 2021-11-18

Approved by:

Romero

Production Quality Control

CE

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.: 5N2

Lot-specific information

Declaration of Conformity

Product name: *Olerup* SSP® HLA Wipe Test – Negative Control
Product number: 102.101-01/01u
Lot number: 5N2

Intended use: Detection of contamination with HLA amplicons.

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: 2021-11-18

Quality Assurance

CE

For *In Vitro* Diagnostic Use
MA099 v03 CoA_DoC General IVDs
Date: October 2021, Rev. No: 00