

101.532-48 – including *Taq* polymerase, IFU-01
101.532-48u – without *Taq* polymerase, IFU-02

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

Lot No.: 4L0

Lot-specific information

CERTIFICATE OF ANALYSIS

Olerup SSP[®] HLA-B*27 – bulk

Product number: 101.532-48 – including *Taq* polymerase
101.532-48u – without *Taq* polymerase
Lot number: 4L0
Expiry date: 2022-08-01
Number of tests: 48
Number of wells per test: 2

Well specifications:

| Well No. | Production No. |
|----------|----------------|
| 1 | 2020-204-01 |
| 2 | 2020-204-02 |

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

Date of approval: 2020-09-14

Approved by:



Production Quality Control



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For In Vitro Diagnostic Use
MA100 v04 CoA_DoC IVD Annex II List B
Date: September 2020, Rev. No: 00

101.532-48 – including *Taq* polymerase, IFU-01
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Declaration of Conformity

Product name: Olerup SSP[®] HLA-B*27 - bulk
Product number: 101.532-48/48u
Lot number: 4L0

Intended use: HLA-B*27 low resolution histocompatibility testing

Manufacturer: CareDx AB
Franzengatan 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 II List B, conformity assessed using Annex IV, as transposed into the national laws of the Member States of the European Union.

The Technical Documentation File is maintained at CareDx AB, Franzengatan 5, SE-112 51 Stockholm, Sweden.

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

Notified Body: TÜV Rheinland LGA products, Tillystrasse 2, D-90431 Nürnberg, Germany. (Notified Body number: 0197.)

Stockholm, Sweden

Date:

2020-09-17

Quality Assurance



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