

101.546-06 – including *Taq* pol., IFU-01

Visit <https://labproducts.caredx.com/> for

101.546-06u – without *Taq* pol., IFU-02

“Instructions for Use” (IFU)

Lot No.: **3K3**

Lot-specific information

CERTIFICATE OF ANALYSIS

Olerup SSP[®] HLA-B*48

Product number:

101.546-06 – including *Taq* polymerase

101.546-06u – without *Taq* polymerase

Lot number:

3K3

Expiry date:

2023-10-01

Number of tests:

6

Number of wells per test:

19+1

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2019-075-01	9	2019-075-09	17	2019-075-17
2	2019-075-02	10	2019-075-10	18	2019-075-18
3	2019-075-03	11	2019-075-11	19	2019-075-19
4	2019-075-04	12	2019-075-12		
5	2019-075-05	13	2019-075-13		
6	2019-075-06	14	2019-075-14		
7	2019-075-07	15	2019-075-15		
8	2019-075-08	16	2019-075-16		

The negative control primer pairs, **Production No. 2019-078-01**, can detect contamination with PCR products diluted 10^{-7} .

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

Date of approval: 20191018

Approved by: 

Production Quality Control



0197

For *In Vitro* Diagnostic Use

MA100 v03 CoA_DoC IVD Annex II List B

Date: October 2019, Rev. No: 00

101.546-06 – including *Taq* pol., IFU-01

Visit <https://labproducts.caredx.com/> for

101.546-06u – without *Taq* pol., IFU-02

"Instructions for Use" (IFU)

Lot No.: **3K3**

Lot-specific information

Declaration of Conformity

Product name: Olerup SSP® HLA-B*48

Product number: 101.546-06/06u

Lot number: 3K3

Intended use: HLA-B*48 high resolution histocompatibility testing

Manufacturer: CareDx SSP 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:

2019-10-24

Quality Assurance




0197

For *In Vitro* Diagnostic Use

MA100 v03 CoA_DoC IVD Annex II List B

Date: October 2019, Rev. No: 00