OLERUP SSP

HLA-B*50 Certificates Page 1 of 2

101.548-06 – including *Taq* pol., IFU-01 **101.548-06**u – without *Taq* pol., IFU-02

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

Lot No.: 1K7

Lot-specific information

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-B*50

Product number: 101.548-06 – including *Taq* polymerase

101.548-06u – without *Tag* polymerase

Lot number: 1K7

Expiry date: 2023-08-01

Number of tests: 6 Number of wells per test: 23+1

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2016-630-01	9	2017-859-09	17	2016-630-17
2	2016-630-02	10	2016-630-10	18	2016-630-18
3	2016-630-03	11	2016-630-11	19	2016-630-19
4	2016-630-04	12	2016-630-12	20	2016-630-20
5	2016-630-05	13	2016-630-13	21	2016-630-21
6	2017-859-06	14	2016-630-14	22	2017-859-22
7	2016-630-07	15	2016-630-15	23	2017-859-23
8	2017-859-08	16	2016-630-16		

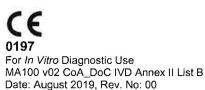
The negative control primer pairs, **Production No. 2019-076-01**, can detect contamination with PCR products diluted 10⁻⁷.

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

Date of approval: 2019-09-19

Approved by: Reservasione

Production Quality Control



ELERUP SSP

HLA-B*50 Certificates Page 2 of 2

101.548-06 – including *Taq* pol., IFU-01 **101.548-06**u – without *Taq* pol., IFU-02

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

Lot No.: 1K7

Lot-specific information

Declaration of Conformity

Product name:

Olerup SSP® HLA-B*50

Product number:

101.548-06/06u

Lot number:

1K7

Intended use:

HLA-B*50 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

2019.09.20

Date:

Quality Assurance

0197
For In Vitro Diagnostic Use
MA100 v02 CoA_DoC IVD Annex II List B
Date: August 2019, Rev. No: 00