

101.628-06 – including *Taq* polymerase, IFU-01
101.628-06u – without *Taq* polymerase, IFU-02

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

Lot No.: **6K3**

Lot-specific information
CERTIFICATE OF ANALYSIS

Olerup SSP[®] HLA-C*17

Product number: 101.628-06 – including *Taq* polymerase
101.628-06u – without *Taq* polymerase
Lot number: 6K3
Expiry date: 2023-12-01
Number of tests: 6
Number of wells per test: 15+1

Well specifications:

Well No.	Production No.	Well No.	Production No.
1	2018-910-01	9	2018-910-09
2	2018-910-02	10	2018-910-10
3	2018-910-03	11	2018-910-11
4	2018-910-04	12	2018-910-12
5	2018-910-05	13	2018-910-13
6	2018-910-06	14	2018-910-14
7	2018-910-07	15	2018-910-15
8	2018-910-08		

The negative control primer pairs, **Production No. 2019-109-01**, can detect contamination with PCR products diluted 10^{-7} .

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

Date of approval: 2020-01-16

Approved by: Rebekka Salme

Production Quality Control



101.628-06 – including *Taq* polymerase, IFU-01
101.628-06u – without *Taq* polymerase, IFU-02

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

Lot No.: **6K3**

Lot-specific information

Declaration of Conformity

Product name: *Olerup* SSP[®] HLA-C*17
Product number: 101.628-06/06u
Lot number: 6K3

Intended use: HLA-C*17 high resolution histocompatibility testing

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: 2020-01-16

Quality Assurance


