101.519-12 – including *Taq* pol., IFU-01
101.519-12u – without *Taq* pol., IFU-02

Visit www.labproducts.caredx.com for **"Instructions for Use" (IFU)**

Lot No.: 8F2 **Lot-specific information**

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-B*18

Product number: **101.519-12 – including *Taq* polymerase**
101.519-12u – without *Taq* polymerase
Lot number: **8F2**
Expiry date: **2021-11-01**
Number of tests: **12**
Number of wells per test: **37+1**

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2016-631-01	17	2016-631-17	33	2017-869-33
2	2014-439-02	18	2016-631-18	34	2017-869-34
3	2014-439-03	19	2014-439-19	35	2017-869-35
4	2014-439-04	20	2016-631-20	36	2017-869-36
5	2014-439-05	21	2014-439-21	37	2017-869-37
6	2016-631-06	22	2017-869-22		
7	2014-439-07	23	2014-439-23		
8	2014-439-08	24	2017-869-24		
9	2014-439-09	25	2016-631-25		
10	2016-631-10	26	2016-631-26		
11	2017-869-11	27	2016-631-27		
12	2014-439-12	28	2016-631-28		
13	2014-439-13	29	2016-631-29		
14	2016-631-14	30	2017-869-30		
15	2017-869-15	31	2014-439-31		
16	2014-439-16	32	2017-869-32		

The negative control primer pairs, **Production No. 2017-845-01**, can detect contamination with PCR products diluted 10^{-7}.

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

Date of approval: 2020-01-10

Approved by:

Production Quality Control

CE
0197
For *In Vitro* Diagnostic Use
MA100 v03 CoA_DoC IVD Annex II List B
Date: January 2020, Rev. No: 01

101.519-12 – including *Taq* pol., IFU-01
101.519-12u – without *Taq* pol., IFU-02

Visit www.labproducts.caredx.com for **"Instructions for Use" (IFU)**

Lot No.: 8F2

Lot-specific information

Declaration of Conformity

Product name: *Olerup* SSP® HLA-B*18
Product number: 101.519-12/12u
Lot number: 8F2

Intended use: HLA-B*18 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: 2020-01-10

Quality Assurance

Changes in revision R01 compared to R00:
1. The expiration date has been altered due to extension of shelf-life.

CE
0197
For *In Vitro* Diagnostic Use
MA100 v03 CoA_DoC IVD Annex II List B
Date: January 2020, Rev. No: 01