101.568-06 – including *Taq* polymerase, IFU-01
101.568-06u – without *Taq* polymerase, IFU-02

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

Lot No.: 2N1 **Lot-specific information**

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-B*58

Product number:	**101.568-06 – including *Taq* polymerase** **101.568-06u – without *Taq* polymerase**
Lot number:	**2N1**
Expiry date:	**2025-05-01**
Number of tests:	**6**
Number of wells per test:	**31+1**

Well specifications:

Well No.	Production No.	Well No.	Production No.
1	2021-313-01	17	2017-860-17
2	2017-860-02	18	2017-860-18
3	2017-860-03	19	2017-860-19
4	2021-313-04	20	2017-860-20
5	2017-860-05	21	2017-860-21
6	2017-860-06	22	2017-860-22
7	2017-860-07	23	2017-860-23
8	2017-860-08	24	2017-860-24
9	2017-860-09	25	2017-860-25
10	2017-860-10	26	2017-860-26
11	2017-860-11	27	2021-313-27
12	2017-860-12	28	2017-860-28
13	2017-860-13	29	2017-860-29
14	2017-860-14	30	2021-313-30
15	2017-860-15	31	2017-860-31
16	2017-860-16		

The negative control primer pairs, **Production No. 2020-289-01**, can detect contamination with PCR products diluted 10^{-7}.

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

Results: No false positive or false negative amplifications were obtained.

Date of approval: 2021-06-14

Approved by:

Romeo

Production Quality Control

CE
0197
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Date: May 2021, Rev. No: 00

101.568-06 – including *Taq* polymerase, IFU-01
101.568-06u – without *Taq* polymerase, IFU-02

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

Lot No.: 2N1 **Lot-specific information**

Declaration of Conformity

Product name: *Olerup* SSP® HLA-B*58
Product number: 101.568-06/06u
Lot number: 2N1

Intended use: HLA-B*58 high 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: 2021-06-16

Quality Assurance

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