

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

Visit [www.labproducts.caredx.com](http://www.labproducts.caredx.com) for  
“Instructions for Use” (IFU)

Lot No.: 7F4

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:

7F4

Expiry date:

2022-10-01

Number of tests:

6

Number of wells per test:

31+1

### Well specifications:

| Well No. | Production No. | Well No. | Production No. |
|----------|----------------|----------|----------------|
| 1        | 2017-860-01    | 17       | 2017-860-17    |
| 2        | 2017-860-02    | 18       | 2017-860-18    |
| 3        | 2017-860-03    | 19       | 2017-860-19    |
| 4        | 2017-860-04    | 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       | 2017-860-27    |
| 12       | 2017-860-12    | 28       | 2017-860-28    |
| 13       | 2017-860-13    | 29       | 2017-860-29    |
| 14       | 2017-860-14    | 30       | 2017-860-30    |
| 15       | 2017-860-15    | 31       | 2017-860-31    |
| 16       | 2017-860-16    |          |                |

The negative control primer pairs, **Production No. 2018-947-01**, 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:** 20200121

**Approved by:**



### Production Quality Control



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For *In Vitro* Diagnostic Use  
MA100 v03 CoA\_DoC IVD Annex II List B  
Date: January 2020, Rev. No: 01

101.568-06 – including *Taq* polymerase, IFU-01  
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Lot-specific information

## Declaration of Conformity

**Product name:** Olerup SSP® HLA-B\*58

**Product number:** 101.568-06/06u

**Lot number:** 7F4

**Intended use:** HLA-B\*58 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: 20200121

Quality Assurance



Changes in revision R01 compared to R00:

1. The expiration date has been altered due to extension of shelf-life.



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For *In Vitro* Diagnostic Use  
MA100 v03 CoA\_DoC IVD Annex II List B  
Date: January 2020, Rev. No: 01