

101.565-12 – including *Taq* pol., IFU-01  
 101.565-12u – without *Taq* pol., IFU-02

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

Lot No.: **4K7**

Lot-specific information

**CERTIFICATE OF ANALYSIS**

**Olerup SSP® HLA-B\*38**

**Product number:** 101.565-12 – including *Taq* polymerase  
 101.565-12u – without *Taq* polymerase  
**Lot number:** 4K7  
**Expiry date:** 2023-11-01  
**Number of tests:** 12  
**Number of wells per test:** 29+1

**Well specifications:**

Well No.	Production No.	Well No.	Production No.
1	2014-440-01	17	2014-440-17
2	2014-440-02	18	2019-121-18
3	2014-440-03	19	2016-738-19
4	2014-440-04	20	2014-440-20
5	2016-738-05	21	2014-440-21
6	2019-043-06	22	2016-738-22
7	2019-043-07	23	2016-738-23
8	2014-440-08	24	2016-738-27
9	2014-440-09	25	2017-850-25
10	2014-440-10	26	2016-738-26
11	2014-440-11	27	2019-043-27
12	2014-440-12	28	2017-850-28
13	2016-738-13	29	2017-850-29
14	2014-440-14		
15	2014-440-15		
16	2014-440-16		

The negative control primer pairs, **Production No. 2019-078-01**, can detect contamination with PCR products diluted 10<sup>-7</sup>.

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

**Date of approval:** 2019-12-09

**Approved by:** *Rebeka Selman*

**Production Quality Control**



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For *In Vitro* Diagnostic Use  
 MA100 v03 CoA\_DoC IVD Annex II List B  
 Date: November 2019, Rev. No: 00

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## Declaration of Conformity

**Product name:** Olerup SSP® HLA-B\*38  
**Product number:** 101.565-12/12u  
**Lot number:** 4K7

**Intended use:** HLA-B\*38 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: 2019-12-12

Quality Assurance




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