

101.545-06 – including *Taq* pol., IFU-01

Visit <https://labproducts.caredx.com> for

101.545-06u – without *Taq* pol., IFU-02

“Instructions for Use” (IFU)

Lot No.: **7H6**

Lot-specific Information

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-B*47

Product number:

101.545-06 – including *Taq* polymerase

101.545-06u – without *Taq* polymerase

Lot number:

7H6

Expiry date:

2021-11-01

Number of tests:

6

Number of wells per test:

10+1

Well specifications:

Well No.	Production No.	Well No.	Production No.
1	2018-946-01	9	2018-946-09
2	2018-946-02	10	2018-946-10
3	2018-946-03		
4	2018-946-04		
5	2018-946-05		
6	2018-946-06		
7	2018-946-07		
8	2018-946-08		

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.

Date of approval: 2019-05-24

Approved by: *Rebecca Salome*

Production Quality Control



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For *In Vitro* Diagnostic Use

MA100 v02 CoA_DoC IVD Annex II List B

Date: April 2019, Rev. No: 00

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Lot-specific Information

Declaration of Conformity

Product name: Olerup SSP® HLA-B*47

Product number: 101.545-06

Lot number: 7H6

Intended use: HLA-B*47 high resolution histocompatibility testing

Manufacturer: Olerup SSP AB
Franzengatan 5
SE-112 51 Stockholm, Sweden
Phone: +46-8-508 939 00
Fax: +46-8-717 88 18

We, Olerup SSP 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 Olerup SSP AB, Franzengatan 5, SE-112 51 Stockholm, Sweden.

The Authorized Representative located within the Community is: Olerup SSP AB.

Notified Body: Lloyd's Register Quality Assurance Limited, 1 Trinity Park, Bickenhill Lane, Birmingham B37 7ES, United Kingdom.
(Notified Body number: 0088.)

Stockholm, Sweden

Date: 2019-05-24

Terese Wasell
Head of Regulatory Affairs



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