

101.549-06 – including *Taq* polymerase, IFU-01

101.549-06u – without *Taq* polymerase, IFU-02

Visit www.olerup.com for
“Instructions for Use” (IFU)

Lot No.: 8H0

Lot-specific information

CERTIFICATE OF ANALYSIS

Olerup SSP[®] HLA-B*53

Product number:

101.549-06 – including *Taq* polymerase

101.549-06u – without *Taq* polymerase

Lot number:

8H0

Expiry date:

2021-12-01

Number of tests:

6

Number of wells per test:

23+1

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2019-060-01	9	2019-060-09	17	2019-060-17
2	2019-060-02	10	2019-060-10	18	2019-060-18
3	2019-060-03	11	2019-060-11	19	2019-060-19
4	2019-060-04	12	2019-060-12	20	2019-060-20
5	2019-060-05	13	2019-060-13	21	2019-060-21
6	2019-060-06	14	2019-060-14	22	2019-060-22
7	2019-060-07	15	2019-060-15	23	2019-060-23
8	2019-060-08	16	2019-060-16		

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.

Date of approval: 2019-07-10

Approved by:



Production Quality Control



0088

For In Vitro Diagnostic Use

MA100 v02 CoA_DoC IVD Annex II List B

Date: July 2019, Rev. No: 00

101.549-06 – including *Taq* polymerase, IFU-01
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Lot No.: 8H0

Lot-specific information

Declaration of Conformity

Product name: Olerup SSP® HLA-B*53

Product number: 101.549-06/06u

Lot number: 8H0

Intended use: HLA-B*53 high resolution histocompatibility testing

Manufacturer: Olerup SSP AB
Franzengatan 5
SE-112 51 Stockholm, Sweden
Phone: +46-8-717 88 27
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:

2019-07-11

Quality Assurance




0088

For *In Vitro* Diagnostic Use
MA100 v02 CoA_DoC IVD Annex II List B
Date: July 2019, Rev. No: 00