

Lot No.: 5G7

Lot-specific information

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-B*46

Product number:

101.544-06 – including Taq polymerase

101.544-06u – without Taq polymerase

Lot number:

5G7

Expiry date:

2021-01-01

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	2017-766-01	9	2017-766-09	17	2017-766-17
2	2017-766-02	10	2017-766-10	18	2017-766-18
3	2017-766-03	11	2017-766-11	19	2017-766-19
4	2017-766-04	12	2017-766-12	20	2018-938-20
5	2017-766-05	13	2017-766-13	21	2017-766-21
6	2018-938-06	14	2017-766-14	22	2018-938-22
7	2017-766-07	15	2017-766-15	23	2017-766-23
8	2017-766-08	16	2017-766-16		

The negative control primer pairs, **Production No. 2017-845-01**, can detect contamination with PCR products diluted 10^{-7} .

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

Date of approval: 2018-09-06

Approved by: Rebecca Salove

Production Quality Control

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Declaration of Conformity

Product name: *Olerup* SSP® HLA-B*46

Product number: 101.544-06/06u

Lot number: 5G7

Intended use: HLA-B*46 high resolution histocompatibility testing

Manufacturer: *Olerup* SSP AB
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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) ISO 9001:2008 and EN ISO 13485:2012, 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.

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

Stockholm, Sweden

SEPT 07 2018



Terese Wasell
 Head of Regulatory Affairs