

101.621-12 – including *Taq* pol., IFU-01
101.621-12u – without *Taq* pol., IFU-02

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

Lot No.: **4G0**

Lot-specific information

CERTIFICATE OF ANALYSIS

Olerup SSP[®] HLA-C*01

Product number: 101.621-12 – including *Taq* polymerase
101.621-12u – without *Taq* polymerase
Lot number: 4G0
Expiry date: 2020-11-01
Number of tests: 12
Number of wells per test: 31+1

Well specifications:

Well No.	Production No.	Well No.	Production No.
1	2016-708-01	17	2016-708-17
2	2014-311-02	18	2018-920-18
3	2016-708-03	19	2014-311-19
4	2016-708-04	20	2015-518-20
5	2014-311-05	21	2014-311-21
6	2014-311-06	22	2018-920-22
7	2014-311-07	23	2016-708-23
8	2018-920-08	24	2018-920-24
9	2014-311-09	25	2016-708-25
10	2014-311-10	26	2016-708-26
11	2018-920-11	27	2016-708-27
12	2016-708-12	28	2018-920-28
13	2015-518-13	29	2016-708-29
14	2014-311-14	30	2016-708-30
15	2016-708-15	31	2016-708-31
16	2014-311-16		

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: 2018-09-07

Approved by: *Rebecca Salene*

Production Quality Control



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Declaration of Conformity

Product name: *Olerup* SSP® HLA-C*01

Product number: 101.621-12/12u

Lot number: 4G0

Intended use: HLA-C*01 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) ISO 9001:2008 and EN ISO 13485:2012, following the provisions of the 98/79/EC Directive on *in vitro* diagnostic medical devices, Annex III, 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.

Stockholm, Sweden

SEPT. 07 2018

Terese Wasell
Head of Regulatory Affairs

