

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

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

Lot No.: **37Y**

Lot-specific information

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-C*01 SSP

Product number: 101.621-12 – including *Taq* polymerase
 101.621-12u – without *Taq* polymerase
Lot number: 37Y
Expiry date: 2017-November-01
Number of tests: 12
Number of wells per test: 31+1

Well specifications:

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

The negative control primer pairs, **Production No. 2015-499-01**, can detect contamination with PCR products diluted 10⁻⁷.

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

Date of approval: 20150620

Approved by:



Production Quality Control



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Lot-specific information

Declaration of Conformity

Product name: *Olerup* SSP® HLA-C*01
Product number: 101.621-12/12u
Lot number: 37Y

Intended use: HLA-C*01 high resolution histocompatibility testing

Manufacturer: *Olerup* SSP AB
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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
2015-Jun-30



Daniel Malica
Head of QA and Regulatory Affairs