

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.: **40V**

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: 40V
Expiry date: 2016-October-01
Number of tests: 12
Number of wells per test: 23+1

Well specifications:

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

The negative control primer pairs, **Production No. 2013-271-01**, can detect contamination with PCR products diluted 10⁻⁷.

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

Date of approval: 2014-April-16

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: 40V

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 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
 2014-April-16

Ann-Cathrin Jareman
 Head of QA and Regulatory Affairs