

101.622-12 – including *Taq* pol., IFU-01
 101.622-12u – without *Taq* pol., IFU-02

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

Lot No.: **81X**

Lot-specific information

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-C*02 SSP

Product number: 101.622-12 – including *Taq* polymerase
 101.622-12u –without *Taq* polymerase
Lot number: 81X
Expiry date: 2017-August-01
Number of tests: 12
Number of wells per test: 31+1

Well specifications:

Well No.	Production No.	Well No.	Production No.
1	2014-466-01	17	2014-466-17
2	2014-466-02	18	2014-466-18
3	2014-466-03	19	2014-466-19
4	2014-466-04	20	2014-466-20
5	2014-466-05	21	2014-466-21
6	2014-466-06	22	2014-466-22
7	2014-466-07	23	2014-466-23
8	2014-466-08	24	2014-466-24
9	2014-466-09	25	2014-466-25
10	2014-466-10	26	2014-466-26
11	2014-466-11	27	2014-466-27
12	2014-466-12	28	2014-466-28
13	2014-466-13	29	2014-466-29
14	2011-844-14	30	2014-466-30
15	2014-466-15	31	2014-466-31
16	2014-466-16		

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: 2015-March-13

Approved by:

Karin Mattsson

Production Quality Control

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Lot-specific information

Declaration of Conformity

Product name: *Olerup SSP*® HLA-C*02
Product number: 101.622-12/12u
Lot number: 81X

Intended use: HLA-C*02 high resolution histocompatibility testing

Manufacturer: *Olerup SSP AB*
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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
 2015-March-16

Daniel Malica
 Head of QA and Regulatory Affairs