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.: 96Y

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: **96Y**
Expiry date: **2018-April-01**
Number of tests: **12**
Number of wells per test: **36+1**

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2014-466-01	17	2014-466-17	33	2015-579-33
2	2014-466-02	18	2014-466-18	34	2015-579-34
3	2014-466-03	19	2014-466-19	35	2015-579-35
4	2014-466-04	20	2015-579-20	36	2015-579-36
5	2015-579-05	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	2015-579-26		
11	2014-466-11	27	2015-579-27		
12	2014-466-12	28	2014-466-28		
13	2014-466-13	29	2014-466-29		
14	2014-466-14	30	2015-579-30		
15	2015-579-15	31	2014-466-31		
16	2014-466-16	32	2015-579-32		

The negative control primer pairs, **Production No. 2015-545-01**, can detect contamination with PCR products diluted 10^{-7}.

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

Date of approval: 2015-10-20

Approved by:

Production Quality Control

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.: 96Y

Lot-specific information

Declaration of Conformity

Product name: *Olerup* SSP® HLA-C*02
Product number: 101.622-12/12u
Lot number: 96Y

Intended use: HLA-C*02 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
2015-Oct-20

Daniel Malica
Head of QA and Regulatory Affairs