101.603-24/12 – including *Taq* pol., IFU-01
101.603-24u/12u – without *Taq* pol., IFU-02

Visit www.olerup-ssp.com for **"Instructions for Use" (IFU)**

Lot No.: 27Y **Lot-specific information**

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-C low resolution screening SSP

Product number: **101.603-24/12 – including *Taq* pol.**
101.603-24u/12u – without *Taq* pol.
Lot number: **27Y**
Expiry date: **2017-October-01**
Number of tests: **24 tests – Product No. 101.603-24/24u**
12 tests – Product No. 101.603-12/12u
Number of wells per test: **23 + 1**

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2015-508-01	9	2013-222-09	17	2013-222-17
2	2013-222-02	10	2013-222-10	18	2015-508-18
3	2013-222-03	11	2013-222-11	19	2014-339-19
4	2013-222-04	12	2013-222-12	20	2013-222-20
5	2013-222-05	13	2015-508-13	21	2013-222-21
6	2013-222-06	14	2013-305-14	22	2013-222-22
7	2013-222-07	15	2014-418-15	23	2015-508-23
8	2013-222-08	16	2014-358-16		

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: 2015-06-08

Approved by:

Karin Mattsson

Production Quality Control

101.603-24/12 – including *Taq* pol., IFU-01
101.603-24u/12u – without *Taq* pol., IFU-02

Visit www.olerup-ssp.com for **"Instructions for Use" (IFU)**

Lot No.: 27Y **Lot-specific information**

Declaration of Conformity

Product name: *Olerup* SSP® HLA-C low resolution screening
Product number: 101.603-24/24u, -12/12u
Lot number: 27Y

Intended use: HLA-C low 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.

Stockholm, Sweden
2015-Jun-08

Daniel Malica
Head of QA and Regulatory Affairs