101.601-24/12 – including *Taq* pol., IFU-01
101.601-24u/12u – without *Taq* pol., IFU-02

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

Lot No.: 8D8 **Lot-specific information**

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-C low resolution SSP

Product number: **101.601-24/12 – including *Taq* pol.**
101.601-24u/12u – without *Taq* pol.

Lot number: **8D8**

Expiry date: **2018-10-01**

Number of tests: **24 tests – Product No. 101.601-24/24u**
12 tests – Product No. 101.601-12/12u

Number of wells per test: **31 + 1**

Well specifications:

Well No.	Production No.	Well No.	Production No.
1	2015-531-01	17	2015-531-17
2	2015-531-02	18	2015-531-18
3	2015-531-03	19	2015-531-19
4	2015-531-04	20	2016-672-20
5	2015-531-05	21	2015-531-21
6	2015-531-06	22	2015-531-22
7	2015-531-07	23	2016-672-23
8	2015-613-08	24	2016-672-24
9	2015-531-09	25	2016-672-25
10	2015-531-10	26	2016-672-26
11	2016-672-11	27	2016-672-27
12	2015-531-12	28	2014-358-28
13	2015-531-13	29	2016-672-29
14	2016-672-14	30	2016-672-30
15	2016-672-15	31	2016-672-31
16	2015-531-16		

The negative control primer pairs, **Production No. 2015-617-01**, can detect contamination with PCR products diluted 10^{-7}.

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

Date of approval: 2016-05-24

Approved by:

Production Quality Control

101.601-24/12 – including *Taq* pol., IFU-01
101.601-24u/12u – without *Taq* pol., IFU-02

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

Lot No.: 8D8

Lot-specific information

Declaration of Conformity

Product name: *Olerup* SSP® HLA-C low resolution
Product number: 101.601-24/24u, -12/12u
Lot number: 8D8

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 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.

Stockholm, Sweden
2016-May-25

Daniel Malica
Head of QA and Regulatory Affairs