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.: 41S **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: **41S**
Expiry date: **2015-November-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.	Well No.	Production No.
1	2013-192-01	13	2013-192-13	25	2012-003-25
2	2013-192-02	14	2013-192-14	26	2012-079-26
3	2013-192-03	15	2013-192-15	27	2012-003-27
4	2013-192-04	16	2013-192-16	28	2012-003-28
5	2013-192-05	17	2013-192-17	29	2012-079-29
6	2013-192-06	18	2013-192-18	30	2012-079-30
7	2013-192-07	19	2013-192-19	31	2012-079-31
8	2013-192-08	20	2013-192-20		
9	2013-192-09	21	2013-192-21		
10	2013-192-10	22	2013-192-22		
11	2013-192-11	23	2012-003-23		
12	2013-192-12	24	2013-192-24		

The specificity of each primer solution of the kit has been tested against 48 well characterized IHWC cell line DNAs.

Additional 5'-primers and 3'-primers in primer solutions 1, 2, 7, 14 to 16, 22, 24 and 28 to 29 were tested by separately adding one additional 3'-primer, respectively one additional 5'-primer. Additional 3'-primers in primer solution 18 and 19 were tested by separately adding one additional 5'-primer. Additional 5'-primers in primer solutions 6, 13 and 26 were tested by separately adding one additional 3'-primer.
In primer solution 23 one 5'-primer was not possible to test, and in primer solutions 3, 11, 12, 14, 16 and 18 one or two 3'-primers were not possible to test.

The negative control primer pairs, **Production No. 2013-165-01**, can detect contamination with PCR products diluted 10^{-7}.

Lot No.: 41S **Lot-specific information**

Results: No false positive or false negative amplifications were obtained.

Date of approval: 2013-May-16

Approved by:

Production Quality Control

Lot No.: 41S **Lot-specific information**

Declaration of Conformity

Product name: *Olerup* SSP® HLA-C low resolution
Product number: 101.601-24/24u, -12/12u
Lot number: 41S

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
2013-May-16

Ann-Cathrin Jareman
Head of QA and Regulatory Affairs