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.: 36R **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: **36R**
Expiry date: **2015-March-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	2012-079-01	13	2012-043-13	25	2012-003-25
2	2011-888-02	14	2012-043-14	26	2012-079-26
3	2011-888-03	15	2012-003-15	27	2012-003-27
4	2011-888-04	16	2012-003-16	28	2012-003-28
5	2011-888-05	17	2012-003-17	29	2012-079-29
6	2012-003-06	18	2011-888-18	30	2012-079-30
7	2012-003-07	19	2011-888-19	31	2012-079-31
8	2012-003-08	20	2011-888-20		
9	2011-888-09	21	2011-888-21		
10	2011-888-10	22	2011-888-22		
11	2011-888-11	23	2012-003-23		
12	2012-003-12	24	2012-003-24		

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

Additional 5'-primers in primer solution 1, 2, 6, 7, 13 to 16, 22, 26, and 28 to 30 were tested by separately adding one 3'-primer. Additional 3'-primers in primer solutions 1, 2, 7, 10, 14 to 16, 18, 19, 22, 26, 28 and 29 were tested by separately adding one 5'-primer.

In primer solutions 3, 11, 12, 14 and 18, one or two 3'-primers were not possible to test, and in primer solution 23 one 5'-primer was not possible to test.

The negative control primer pairs, **Production No. 2012-002-01**, can detect contamination with PCR products diluted 10^{-7}.

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

Date of approval: 2012-October-01

Approved by:

Ilsa Olausson

Production Quality Control

101.601.24/12 – including *Taq* pol., IFU-01
101.601.24u/12u – without *Taq* pol., IFU-02

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Lot No.: 36R **Lot-specific information**

Declaration of Conformity

Product name: *Olerup* SSP® HLA-C low resolution
Product number: 101.601-24/12
Lot number: 36R

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 13485:2004, 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
2012-October-01

Ann-Cathrin Jareman
Head of QA and Regulatory Affairs