

101.601.24/12 – including *Taq* pol., IFU-01 Rev. No. 03
 101.601.24u/12u – without *Taq* pol., IFU-02 Rev. No. 03

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

Lot No.: **64N**

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: 64N
Expiry date: 2014-October-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	2011-888-01	13	2012-003-13	25	2012-003-25
2	2011-888-02	14	2011-888-14	26	2012-003-26
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	2012-003-29
6	2012-003-06	18	2011-888-18	30	2012-003-30
7	2012-003-07	19	2011-888-19	31	2012-003-31
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 2, 6, 7, 13 to 16, 22, 26, 28 and 30 were tested by separately adding one 3'-primer. Additional 3'-primers in primer solutions 2, 7, 10, 14 to 16, 18, 19, 22, 26 and 28 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. 2010-928-01**, can detect contamination with PCR products diluted 10^{-7} .

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

Date of approval: 2012-April-20

Approved by:



Production Quality Control



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Lot-specific information

Declaration of Conformity

Product name: Olerup SSP® HLA-C low resolution
Product number: 101.601-24/24u, -12/12u
Lot number: 64N

Intended use: HLA-C low resolution histocompatibility testing

Manufacturer: Olerup SSP AB
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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-May-23



Ann-Cathrin Jareman
Head of QA and Regulatory Affairs