101.621-12 – including *Taq* pol., IFU-01 Rev. No. 03
101.621-12u– without *Taq* pol., IFU-02 Rev. No. 03

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

Lot No.: **75N** Lot-specific information

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-C*01 SSP

Product number: **101.621-12 – including *Taq* polymerase**
101.621-12u – without *Taq* polymerase
Lot number: **75N**
Expiry date: **2014-November-01**
Number of tests: **12**
Number of wells per test: **24**

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2010-707-01	9	2012-014-09	17	2012-014-17
2	2010-707-02	10	2012-014-10	18	2012-014-18
3	2010-707-03	11	2011-826-11	19	2011-826-19
4	2011-826-04	12	2010-707-12	20	2012-014-20
5	2012-014-05	13	2010-707-13	21	2010-707-21
6	2011-826-06	14	2011-826-14	22	2012-014-22
7	2010-707-07	15	2011-826-15	23	2012-014-23
8	2012-014-08	16	2011-826-16	24	2012-014-24

The specificity of each primer solution of the HLA-C*01 primer set has been tested against 48 well characterized IHWC cell line DNAs.

No DNAs carrying the alleles to be amplified by primer solutions 2 to 12 and 14 to 24 were available. The specificity of the primers in primer solutions 2 to 5, 8 to 12, 14, 16 to 18, 20 and 22 to 24 were tested by adding additional 5'-primers respectively 3'-primers. In primer solution 6, it was only possible to test the 3'-primer, the 5'-primer was not possible to test. In primer solutions 7, 15, 19 and 21 it was only possible to test the 5'-primers, the 3'-primers were not possible to test. In primer solutions 11, 17, 20 and 24 one or two of the 5'-primers were not possible to test. In primer solutions 2, 4, 5, 9, 10, 14, 16, 18, 20 and 23 one or two of the 3'-primers were not possible to test.

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

Date of approval: 2012-June-07

Approved by:

Production Quality Control

Lot No.: 75N

Lot-specific information

Declaration of Conformity

Product name: *Olerup* SSP® HLA-C*01
Product number: 101.621-12/12u
Lot number: 75N

Intended use: HLA-C*01 high 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 13485:2003, 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.

The Authorized Representative located within the Community is: *Olerup* SSP AB.

Stockholm, Sweden
2012-June-07

Ann-Cathrin Jareman
Head of QA and Regulatory Affairs