Lot No.: **82N** Lot-specific information

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-C*18 SSP

Product number: **101.629-06 – including *Taq* polymerase**
101.629-06u – without *Taq* polymerase

Lot number: **82N**
Expiry date: **2014-November-01**
Number of tests: **6**
Number of wells per test: **7**

Well specifications:
HLA-C*18

Well No.	Production No.
1	2009-647-01
2	2009-647-02
3	2009-647-03
4	2009-647-04
5	2009-647-05
6	2011-816-06
7	2012-023-07

The specificity of each primer solution of the HLA-C*18 primer set has been tested against 48 well characterized IHWC cell line DNAs.

No DNAs carrying the alleles to be amplified by primer solutions 5 to 7 were available. The specificities of the primers in primer solutions 5 to 7 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer.

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

Date of approval: 2012-May-07

Approved by:

Åsa Olausson

Production Quality Control

101.629-06– including *Taq* polymerase, IFU-01 Rev. No. 03
101. 629-06u – without *Taq* polymerase, IFU-02 Rev. No. 03

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

Lot No.: 82N

Lot-specific information

Declaration of Conformity

Product name: *Olerup* SSP® HLA-C*18
Product number: 101.629-06/06u
Lot number: 82N

Intended use: HLA-C*18 high resolution histocompatibility testing

Manufacturer:
Olerup SSP AB
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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, ISO 17025:1999 and ISO 13485:2000, following the provisions of the 98/79/EC Directive on *in vitro* diagnostic medical devices, Annex III.

The Technical Documentation File is maintained at *Olerup* SSP AB, Franzengatan 5, SE-112 51 Stockholm, Sweden.

Stockholm, Sweden
2012-May-07

Ann-Cathrin Jareman
Head of QA and Regulatory Affairs