CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-C*04:09N SSP

Product number: 101.861-12 – including *Taq* polymerase
101.861-12u – without *Taq* polymerase

Lot number: 52S
Expiry date: 2015-November-01
Number of tests: 12
Number of wells per test: 2

Well specifications:

Well No.	Production No.
1	2012-084-01
2	2012-084-02

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

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

Date of approval: 2013-May-16

Approved by:

Production Quality Control

Declaration of Conformity

Product name: *Olerup* SSP® HLA-C*04:09N
Product number: 101.861-12/12u
Lot number: 52S

Intended use: HLA-C*04:09N 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 13485:2012, 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.

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

Stockholm, Sweden
2013-May-16

Ann-Cathrin Jareman
Head of QA and Regulatory Affairs