CERTIFICATE OF ANALYSIS

Olerup SSP® HLA Wipe Test – Negative Control

Product number: **102.101-01 – including *Taq* polymerase**
Product number: **102.101-01u – without *Taq* polymerase**
Lot number: **88S**
Expiry date: **2016-March-01**
Number of tests: **96**
Number of wells per test: **1-2**

Well specification:

Well No.	Production No.
1	2013-165-01

The negative control primer solution has been tested in a dilution series of the corresponding PCR products, 1 to 10^3 down to 1 to 10^9.
The Positive Control DNA has been tested with the HLA Wipe Test kit and gives rise to PCR amplicons.

Results: The negative control primer pairs can detect contamination with the corresponding PCR products diluted 1 to 10^7.

Date of approval: 2013-September-11

Approved by:

Åsa Claesson

Production Quality Control

Lot No.: 88S **Lot-specific information** **www.olerup-ssp.com**

Declaration of Conformity

Product name: *Olerup* SSP® HLA Wipe Test – Negative Control
Product number: 102.101-01/01u
Lot number: 88S

Intended use: Detection of contamination with HLA amplicons.

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.

Stockholm, Sweden
2013-September-11

Ann-Cathrin Jareman
Head of QA and Regulatory Affairs