CERTIFICATE OF ANALYSIS

Olerup SSP® HLA - Negative Control SSP

Product number:	**102.102-01u – without *Taq* polymerase**
Lot number:	**81M**
Expiry date:	**2014-April-01**
Number of tests:	**96**
Number of wells per test:	**1**

Well specification:

Well No.	Production No.
1	2011-928-01

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.

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

Date of approval: 2011-November-09

Approved by:

Åsa Olsson

Production Quality Control

Declaration of Conformity

Product name: *Olerup* SSP® HLA - Negative Control
Product number: 102.102-01u
Lot number: 81M

Intended use: Negative Control in *Olerup* SSP® HLA typings.

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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 13485:2003, 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.

Stockholm, Sweden
2011-November-09

Ann-Cathrin Jareman
Head of QA and Regulatory Affairs