

Lot No.: **81M**

Lot-specific Information

www.olerup-ssp.com

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA - Negative Control SSP

Product number: 102.102-01 – including *Taq* polymerase
Lot number: 81M
Expiry date: 2014-April-01
Number of tests: 96
Number of wells per test: 1

Well specification:

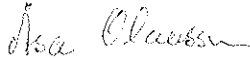
Well No.	Production No.
1	2011-928-01

The negative control primer solution has been tested in a dilution series of the corresponding PCR products, 1 to 10³ down to 1 to 10⁹.

Results: The negative control primer pairs can detect contamination with the corresponding PCR products diluted 1 to 10⁷.

Date of approval: 2011-November-09

Approved by:



Production Quality Control

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Declaration of Conformity

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

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

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.

Stockholm, Sweden
2011-November-09



Ann-Cathrin Jareman
Head of QA and Regulatory Affairs