

Lot No.: 51R

Lot-specific information

www.olerup-ssp.com

CERTIFICATE OF ANALYSIS

Olerup SSP[®] HLA - Negative Control SSP

Product number: 102.102-01 – including Taq polymerase
102.102-01u – without Taq polymerase
Lot number: 51R
Expiry date: 2015-April-01
Number of tests: 96
Number of wells per test: 1

Well specification:

| Well No. | Production No. |
|----------|----------------|
| 1 | 2012-085-01 |

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: 2012-November-16

Approved by:



Production Quality Control

Lot No.: **51R**

Lot-specific information

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Declaration of Conformity

Product name: *Olerup* SSP® HLA - Negative Control
Product number: 102.102-01/01u
Lot number: 51R

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
2012-November-16



Ann-Cathrin Jareman
Head of QA and Regulatory Affairs