

102.101-01 – including Taq polymerase, IFU-01
102.101-01u – without Tag polymerase, IFU-02

Visit www.olerup-ssp.com for
 “Instructions for Use” (IFU)

Lot No.: 37X

Lot-specific information

www.olerup-ssp.com

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: 37X
Expiry date: 2017-March-01
Number of tests: 96
Number of wells per test: 1-2

Well specification:

Well No.	Production No.
1	2014-382-01

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.
 The Positive Control DNA has been tested with the HLA Wipe Test kit and gives rise to PCR amplicons.

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

Results of Quality Control: No false positive or false negative amplifications obtained.

Date of approval: 2014-November-04

Approved by:

Karin Mattsson

Production Quality Control

102.101-01 – including *Taq* polymerase, IFU-01

102.101-01u – without *Taq* polymerase, IFU-02

Visit www.olerup-ssp.com for

“Instructions for Use” (IFU)

Lot No.: **37X**

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: 37X

Intended use: Detection of contamination with HLA amplicons.

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 13485:2012, 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
 2014-November-10

Daniel Malica
 Head of QA and Regulatory Affairs