

Lot No.: **05X**

Lot-specific information

[www.olerup-ssp.com](http://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:** 05X  
**Expiry date:** 2017-March-01  
**Number of tests:** 96  
**Number of wells per test:** 1

#### 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 10<sup>3</sup> down to 1 to 10<sup>9</sup>.

**Results:** The negative control primer pairs can detect contamination with the corresponding PCR products diluted 1 to 10<sup>7</sup>.

**Date of approval:** 2014-September-12

**Approved by:**

*Karin Mattsson*

**Production Quality Control**

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## Declaration of Conformity

**Product name:** Olerup SSP® HLA - Negative Control  
**Product number:** 102.102-01/01u  
**Lot number:** 05X

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

**Manufacturer:** Olerup SSP AB  
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 SE-112 51 Stockholm, Sweden  
**Phone:** +46-8-717 88 27  
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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

2014-September-16



Daniel Malica  
 Head of QA and Regulatory Affairs