

Lot No.: 43K

Lot-specific Information

www.olerup-ssp.com

## CERTIFICATE OF ANALYSIS

### Olerup SSP® HLA - Negative Control SSP

Product number: 102.102-01u – without Taq polymerase  
Lot number: 43K  
Expiry date: 2013-April-01  
Number of tests: 96  
Number of wells per test: 1

#### Well specification:

Well No.	Production No.
1	2010-760-01

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:** 2011-February-04

**Approved by:**



**Quality Control, Supervisor**

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## Declaration of Conformity

**Product name:** Olerup SSP® HLA - Negative Control  
**Product number:** 102.102-01u  
**Lot number:** 43K

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

**Manufacturer:** Olerup SSP AB  
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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, Hasselstigen 1, SE-133 33 Saltsjöbaden, Sweden.

The Authorized Representative located within the Community is: Olerup SSP AB.

Saltsjöbaden, Sweden  
2011-February-04



Olle Olerup  
Managing Director