

## CERTIFICATE OF ANALYSIS

### Olerup SSP® HLA-A\*36 SSP

Product number: 101.419-06 – including *Taq* polymerase  
Lot number: 98K  
Expiry date: 2013-August-01  
Number of tests: 6  
Number of wells per test: 7

#### Well specifications:

| Well No. | Production No. |
|----------|----------------|
| 1        | 2009-635-01    |
| 2        | 2009-635-02    |
| 3        | 2009-635-03    |
| 4        | 2009-635-04    |
| 5        | 2009-635-05    |
| 6        | 2009-635-06    |
| 7        | 2011-817-07    |

The specificity of each primer solution of the kit has been tested against 48 well characterized cell line DNAs.

No DNAs carrying the alleles to be amplified by primer solution 7 was available. The specificities of the 5'-primer in primer solutions 7 was tested by separately adding one additional 3'-primer, the 3'-primer was not possible to test.

**Results:** No false positive or false negative amplifications were obtained.

**Date of approval:** 2011-February-16

**Approved by:**



**Quality Control, Supervisor**

Lot No.: **98K**

Lot-specific Information

[www.olerup-ssp.com](http://www.olerup-ssp.com)

## Declaration of Conformity

**Product name:** *Olerup* SSP® HLA-A\*36  
**Product number:** 101.419-06  
**Lot number:** 98K

**Intended use:** HLA-A\*36 high resolution histocompatibility testing

**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 II List B, conformity assessed using Annex IV, 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.

Notified Body: Lloyd's Register Quality Assurance Limited, Hiramford, Middlemarch Office Village, Siskin Drive, Coventry CV3 4FJ, United Kingdom. (Notified Body number: 0088.)

Saltsjöbaden, Sweden  
2011-February-16



Olle Olerup  
Managing Director