

Lot No.: **37M**

Lot-specific information

www.olerup-ssp.com

CERTIFICATE OF ANALYSIS

Olerup SSP[®] HLA-C*04:09N SSP

Product number: 101.861-12u – without *Taq* polymerase
Lot number: 37M
Expiry date: 2013-December-01
Number of tests: 12
Number of wells per test: 2

Well specifications:

Well No.	Production No.
1	2010-705-01
2	2010-705-02

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

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

Date of approval: 2011-June-17

Approved by:



Quality Control, Supervisor

Lot No.: **37M**

Lot-specific information

www.olerup-ssp.com

Declaration of Conformity

Product name: *Olerup* SSP® HLA-C*04:09N
Product number: 101.861-12u
Lot number: 37M

Intended use: HLA-C*04:09N histocompatibility testing

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 13485:2003, 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, Franzengatan 5, SE-112 51 Stockholm, Sweden.

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

Stockholm, Sweden
2011-June-17



Olle Olerup
Managing Director