

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-C*18 SSP

Product number: 101.629-06 – including Taq polymerase
Lot number: 97K
Expiry date: 2013-August-01
Number of tests: 6
Number of wells per test: 6

Well specifications:

HLA-C*18

Well No.	Production No.
1	2009-647-01
2	2009-647-02
3	2009-647-03
4	2009-647-04
5	2009-647-05
6	2011-816-06

The specificity of each primer solution of the HLA-C*18 primer set has been tested against 48 well characterized IHWC cell line DNAs.

No DNAs carrying the alleles to be amplified by primer solutions 5 and 6 were available. The specificities of the primers in primer solutions 5 and 6 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer.

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

Date of approval: 2011-February-16

Approved by:



Quality Control, Supervisor

Lot No.: **97K**

Lot-specific information

www.olerup-ssp.com

Declaration of Conformity

Product name: *Olerup* SSP® HLA-C*18
Product number: 101.629-06
Lot number: 97K

Intended use: HLA-C*18 high resolution histocompatibility testing

Manufacturer: *Olerup* SSP AB
Hasselstigen 1
SE-133 33 Saltsjöbaden, 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, ISO 17025:1999 and ISO 13485:2000, following the provisions of the 98/79/EC Directive on *in vitro* diagnostic medical devices, Annex III.

The Technical Construction 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-16



Olle Olerup
Managing Director