**Product Insert** 

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General "Instructions for Use" IFU-02 Rev. No. 02 can be downloaded from

Lot No.:97K

Lot-specific information

www.olerup-ssp.com

## CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-C\*18 SSP

Product number:

101.629-06u - without Tag 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

HLA-C\*18 Product Insert Page 7 of 8
101.629-06u – without Tag polymerase General "Instructions for Use"

IFU-02 Rev. No. 02 can be downloaded from

Lot No.:97K

Lot-specific information

www.olerup-ssp.com

## **Declaration of Conformity**

Product name:

Olerup SSP® HLA-C\*18

Product number:

101.629-06u

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