

101.629-06 – including *Taq* polymerase, IFU-01
 101.629-06u – without *Taq* polymerase, IFU-02

Visit www.olerup-ssp.com for
 "Instructions for Use" (IFU)

Lot No.: **83S**

Lot-specific information

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-C*18 SSP

Product number: 101.629-06 – including *Taq* polymerase
 101.629-06u – without *Taq* polymerase
Lot number: 83S
Expiry date: 2016-March-01
Number of tests: 6
Number of wells per test: 8

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
7	2013-244-07
8	2013-244-08

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 to 8 were available. The specificities of the primers in primer solutions 5 to 7 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer. In primer solution 8 it was only possible to test the 3'-primer, the 5'-primer was not possible to test. In primer mix 7, one 5'-primer was not possible to test.

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

Date of approval: 2013-October-09

Approved by:



Production Quality Control

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Declaration of Conformity

Product name: *Olerup* SSP® HLA-C*18
Product number: 101.629-06/06u
Lot number: 83S

Intended use: HLA-C*18 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 13485:2012, 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, Franzengatan 5, SE-112 51 Stockholm, Sweden.

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

Stockholm, Sweden
2013-October-09



Ann-Cathrin Jareman
Head of QA and Regulatory Affairs