

101.625-06 – including *Taq* polymerase, IFU-01
101.625-06u – without *Taq* polymerase, IFU-02

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

Lot No.: **19X**

Lot-specific information

www.olerup-ssp.com

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-C*14 SSP

Product number: **101.625-06 – including *Taq* polymerase**
101.625-06u – without *Taq* polymerase

Lot number: **19X**

Expiry date: **2017-March-01**

Number of tests: **6**

Number of wells per test: **28+1**

Well specifications:

Well No.	Production No.	Well No.	Production No.
1	2013-162-01	17	2013-162-17
2	2013-162-02	18	2014-402-18
3	2013-162-03	19	2014-402-19
4	2013-162-04	20	2013-162-20
5	2013-162-05	21	2013-162-21
6	2013-162-06	22	2013-162-22
7	2013-162-07	23	2013-162-23
8	2013-162-08	24	2014-402-24
9	2013-162-09	25	2014-402-25
10	2013-162-10	26	2014-402-26
11	2013-162-11	27	2014-402-27
12	2013-162-12	28	2014-402-28
13	2013-162-13		
14	2013-162-14		
15	2013-162-15		
16	2013-162-16		

The negative control primer pairs, **Production No. 2014-382-01**, can detect contamination with PCR products diluted 10^{-7} .

Results of Quality Control: No false positive or false negative amplifications obtained.

Date of approval: 2014-October-09

Approved by:

Karin Mattsson

Production Quality Control

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Declaration of Conformity

Product name: *Olerup* SSP® HLA-C*14
Product number: 101.625-06/06u
Lot number: 19X

Intended use: HLA-C*14 high resolution 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 13485:2012, 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
2014-October-09



Daniel Malica
Head of QA and Regulatory Affairs