

101.613-12– including *Taq* polymerase, IFU-01
101.613-12u – without *Taq* polymerase, IFU-02

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

Lot No.: **02Y**

Lot-specific information

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-C*05 SSP

Product number: 101.613-12 – including *Taq* polymerase
101.613-12u – without *Taq* polymerase
Lot number: 02Y
Expiry date: 2017-October-01
Number of tests: 12
Number of wells per test: 31+1

Well specifications:

Well No.	Production No.	Well No.	Production No.
1	2014-485-01	17	2014-485-17
2	2014-485-02	18	2014-485-18
3	2014-485-03	19	2014-485-19
4	2014-485-04	20	2014-485-20
5	2014-485-05	21	2014-485-21
6	2014-485-06	22	2014-485-22
7	2014-485-07	23	2014-485-23
8	2014-485-08	24	2014-485-24
9	2014-485-09	25	2014-485-25
10	2014-485-10	26	2014-485-26
11	2014-485-11	27	2014-485-27
12	2014-485-12	28	2014-485-28
13	2014-485-13	29	2014-485-29
14	2014-485-14	30	2014-485-30
15	2014-485-15	31	2014-485-31
16	2014-485-16		

The negative control primer pairs, **Production No. 2015-499-01**, can detect contamination with PCR products diluted 10^{-7} .

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

Date of approval: 2015-April-24

Approved by:

Karin Mattsson

Production Quality Control

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Lot-specific information

Declaration of Conformity

Product name: *Olerup* SSP® HLA-C*05
Product number: 101.613-12/12u
Lot number: 02Y

Intended use: HLA-C*05 high resolution histocompatibility testing

Manufacturer: *Olerup* SSP AB
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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.

Stockholm, Sweden
2015-April-24



Daniel Malica
Head of QA and Regulatory Affairs