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.: 0E3 **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:	**0E3**
Expiry date:	**2019-03-01**
Number of tests:	**12**
Number of wells per test:	**35+1**

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2014-485-01	17	2014-485-17	33	2016-685-33
2	2014-485-02	18	2014-485-18	34	2016-685-34
3	2014-485-03	19	2014-485-19	35	2016-685-35
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	2016-685-30		
15	2014-485-15	31	2016-685-31		
16	2014-485-16	32	2016-685-32		

The negative control primer pairs, **Production No. 2016-695-01**, can detect contamination with PCR products diluted 10^{-7}.

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

Date of approval: 2016-09-23

Approved by:

Production Quality Control

CE

For *In Vitro* Diagnostic Use

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.: 0E3

Lot-specific information

Declaration of Conformity

Product name: *Olerup* SSP® HLA-C*05
Product number: 101.613-12/12u
Lot number: 0E3

Intended use: HLA-C*05 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) EN 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
2016-Sep-23

Daniel Malica
Head of QA and Regulatory Affairs