101.612-12 – including *Taq* pol., IFU-01
101.612-12u– without *Taq* pol., IFU-02

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

Lot No.: 67X

Lot-specific information

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-C*04 SSP

Product number: **101.612-12 – including *Taq* polymerase**
101.612-12u – without *Taq* polymerase

Lot number: **67X**
Expiry date: **2017-May-01**
Number of tests: **12**
Number of wells per test: **52+1**

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2013-247-01	25	2014-403-25	49	2014-403-49
2	2014-403-02	26	2014-403-26	50	2014-403-50
3	2014-403-03	27	2013-247-27	51	2014-403-51
4	2013-247-04	28	2013-247-28	52	2014-403-52
5	2013-247-05	29	2014-403-29		
6	2013-247-06	30	2013-247-30		
7	2013-247-07	31	2013-247-31		
8	2013-247-08	32	2014-403-32		
9	2013-247-09	33	2013-247-33		
10	2014-403-10	34	2013-247-34		
11	2013-247-11	35	2014-403-35		
12	2013-247-12	36	2014-403-36		
13	2014-403-13	37	2014-403-37		
14	2014-403-14	38	2014-403-38		
15	2013-247-15	39	2014-403-39		
16	2013-247-16	40	2014-403-40		
17	2013-247-17	41	2014-403-41		
18	2013-247-18	42	2013-247-42		
19	2013-247-19	43	2014-403-43		
20	2014-403-20	44	2014-403-44		
21	2014-403-21	45	2014-403-45		
22	2014-403-22	46	2014-403-46		
23	2013-247-23	47	2014-403-47		
24	2014-403-24	48	2014-448-48		

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-November-14

Approved by:
Karin Olafsson
Production Quality Control

CE

For In Vitro Diagnostic Use

101.612-12 – including *Taq* pol., IFU-01
101.612-12u– without *Taq* pol., IFU-02

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

Lot No.: 67X **Lot-specific information**

Declaration of Conformity

Product name: *Olerup* SSP® HLA-C*04
Product number: 101.612-12/12u
Lot number: 67X

Intended use: HLA-C*04 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-November-17

Daniel Malica
Head of QA and Regulatory Affairs