

101.611-12 – including *Taq* polymerase, IFU-01
 101.611-12u – without *Taq* polymerase, IFU-02

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

Lot No.: **63Y**

Lot-specific information

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-C*03 SSP

Product number: 101.611-12 – including *Taq* polymerase
 101.611-12u – without *Taq* polymerase
Lot number: 63Y
Expiry date: 2018-January-01
Number of tests: 12
Number of wells per test: 47+1

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2012-994-01	17	2014-340-17	33	2015-546-33
2	2015-546-02	18	2014-340-18	34	2015-546-34
3	2012-994-03	19	2015-546-19	35	2015-546-35
4	2012-994-04	20	2015-546-20	36	2015-546-36
5	2012-994-05	21	2012-994-21	37	2012-994-37
6	2012-994-06	22	2015-546-22	38	2015-546-38
7	2015-546-07	23	2015-546-23	39	2015-546-39
8	2015-546-08	24	2015-546-24	40	2015-546-40
9	2012-994-09	25	2015-546-25	41	2014-340-41
10	2015-546-10	26	2015-546-26	42	2015-546-42
11	2015-546-11	27	2015-546-27	43	2015-546-43
12	2015-546-12	28	2015-546-28	44	2015-546-44
13	2012-994-13	29	2015-546-29	45	2014-340-45
14	2013-143-14	30	2015-546-30	46	2013-143-46
15	2012-994-15	31	2014-340-31	47	2015-546-47
16	2015-546-16	32	2015-546-32		

The negative control primer pairs, **Production No. 2015-545-01**, can detect contamination with PCR products diluted 10⁻⁷.

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

Date of approval: 20150902

Approved by:

Kevin Mattsson

Production Quality Control

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Lot-specific information

Declaration of Conformity

Product name: *Olerup* SSP® HLA-C*03

Product number: 101.611-12/12u

Lot number: 63Y

Intended use: HLA-C*03 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 EN 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-Sep-02

Daniel Malica
 Head of QA and Regulatory Affairs