**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.: 64V** **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:** **64V**
**Expiry date:** **2016-October-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 | 2014-340-33 |
| 2 | 2012-994-02 | 18 | 2014-340-18 | 34 | 2012-994-34 |
| 3 | 2012-994-03 | 19 | 2014-340-19 | 35 | 2014-330-35 |
| 4 | 2012-994-04 | 20 | 2014-340-20 | 36 | 2014-340-36 |
| 5 | 2012-994-05 | 21 | 2012-994-21 | 37 | 2012-994-37 |
| 6 | 2012-994-06 | 22 | 2014-340-22 | 38 | 2014-340-38 |
| 7 | 2012-994-07 | 23 | 2012-994-23 | 39 | 2014-340-39 |
| 8 | 2013-143-08 | 24 | 2014-340-24 | 40 | 2012-994-40 |
| 9 | 2012-994-09 | 25 | 2014-340-25 | 41 | 2014-340-41 |
| 10 | 2012-994-10 | 26 | 2012-994-26 | 42 | 2014-340-42 |
| 11 | 2012-994-11 | 27 | 2014-340-27 | 43 | 2014-340-43 |
| 12 | 2012-994-12 | 28 | 2012-994-28 | 44 | 2014-340-44 |
| 13 | 2012-994-13 | 29 | 2012-994-29 | 45 | 2014-340-45 |
| 14 | 2013-143-14 | 30 | 2012-994-30 | 46 | 2013-143-46 |
| 15 | 2012-994-15 | 31 | 2014-340-31 | 47 | 2012-994-47 |
| 16 | 2014-340-16 | 32 | 2014-340-32 | | |

The negative control primer pairs, **Production No. 2013-271-01**, 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-May-23

***Approved by:***

**Production Quality Control**

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

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**Lot No.: 64V**

**Lot-specific information**

# Declaration of Conformity

**Product name:** *Olerup* SSP® HLA-C*03
**Product number:** 101.611-12/12u
**Lot number:** 64V

**Intended use:** HLA-C*03 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.

Stockholm, Sweden
2014-May-23

Ann-Cathrin Jareman
Head of QA and Regulatory Affairs