101.624-12 – including *Taq* polymerase, IFU-01
101.624-12u – without *Taq* polymerase, IFU-02

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

Lot No.: 1F8

Lot-specific information

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-C*12 SSP

Product number: **101.624-12 – including *Taq* polymerase**
101.624-12u – without *Taq* polymerase

Lot number: **1F8**
Expiry date: **2020-01-01**
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	2014-320-01	17	2017-796-17	33	2017-796-33
2	2014-320-02	18	2017-796-18	34	2017-796-34
3	2014-320-03	19	2014-320-19	35	2015-610-35
4	2014-320-04	20	2017-796-20	36	2017-796-36
5	2014-462-05	21	2014-320-21	37	2017-796-37
6	2014-320-06	22	2017-796-22	38	2017-796-38
7	2017-796-07	23	2017-796-23	39	2017-796-39
8	2014-320-08	24	2015-610-24	40	2015-610-40
9	2014-320-09	25	2017-796-25	41	2017-796-41
10	2014-320-10	26	2017-796-26	42	2015-610-42
11	2017-796-11	27	2017-796-27	43	2015-610-43
12	2014-320-12	28	2014-320-28	44	2015-610-44
13	2015-610-13	29	2017-796-29	45	2017-796-45
14	2014-320-14	30	2017-796-30	46	2017-796-46
15	2014-320-15	31	2017-796-31	47	2017-796-47
16	2014-320-16	32	2015-610-32		

The negative control primer pairs, **Production No. 2016-746-01**, can detect contamination with PCR products diluted 10^{-7}.

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

Date of approval: 170724

Approved by:

Production Quality Control

101.624-12 – including *Taq* polymerase, IFU-01
101.624-12u – without *Taq* polymerase, IFU-02

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

Lot No.: 1F8 **Lot-specific information**

Declaration of Conformity

Product name: *Olerup* SSP® HLA-C*12
Product number: 101.624-12/12u
Lot number: 1F8

Intended use: HLA-C*12 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 EN ISO 13485:2012, following the provisions of the 98/79/EC Directive on *in vitro* diagnostic medical devices, Annex II List B, conformity assessed using Annex IV, 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

Emil Jonsson
Head of QA

July 26th 2017