101.231-24/04– including *Taq* pol., IFU-01
101.231-24u/04u– without *Taq* pol., IFU-02

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

Lot No.: 17V **Lot-specific information**

CERTIFICATE OF ANALYSIS

Olerup SSP® DQA1 SSP

Product number: **101.231-24/04 – including *Taq* pol.**
101.231-24u/04u – without *Taq* pol.

Lot number: **17V**

Expiry date: **2016-July-01**

Number of tests: **24 tests – Product No. 101.231-24/24u**
4 tests – Product No. 101.231-04/04u

Number of wells per test: **31+1**

Well specifications:

Well No.	Production No.	Well No.	Production No.
1	2009-609-01	17	2009-609-17
2	2013-129-02	18	2009-609-18
3	2009-609-03	19	2009-609-19
4	2009-609-04	20	2009-609-20
5	2013-129-05	21	2013-284-21
6	2009-609-06	22	2013-129-22
7	2009-609-07	23	2013-284-23
8	2009-609-08	24	2009-609-24
9	2009-609-09	25	2009-609-25
10	2009-609-10	26	2011-891-26
11	2009-609-11	27	2013-129-27
12	2009-609-12	28	2009-609-28
13	2009-609-13	29	2013-284-29
14	2009-609-14	30	2011-891-30
15	2009-609-15	31	2009-609-32
16	2013-284-16		

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-January-22

Approved by:

Production Quality Control

CE

For *In Vitro* Diagnostic Use.

101.231-24/04– including *Taq* pol., IFU-01
101.231-24u/04u– without *Taq* pol., IFU-02

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

Lot No.: 17V

Lot-specific information

Declaration of Conformity

Product name: *Olerup* SSP® DQA1
Product number: 101.231-24/04
Lot number: 17V

Intended use: HLA-DQA1 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.

Notified Body: Lloyd's Register Quality Assurance Limited, Hiramford, Middlemarch Office Village, Siskin Drive, Coventry CV3 4FJ, United Kingdom.
(Notified Body number: 0088.)

Stockholm, Sweden
2014-January-22

Ann-Cathrin Jareman
Head of QA and Regulatory Affairs

CE

For *In Vitro* Diagnostic Use.