101.331.24/06 – including *Taq* pol., IFU-01
101.331.24u/06u – without *Taq* pol., IFU-02

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

Lot No.: **40R**

Lot-specific information

CERTIFICATE OF ANALYSIS

Olerup SSP® DPA1 SSP

Product number: 101.331-24/06 – including *Taq* pol.
101.331-24u/06u – without *Taq* pol.

Lot number: 40R

Expiry date: 2015-May-01

Number of tests: 24 test – Product No. 101.331-24/24u
6 tests – Product No. 101.331-06/06u

Number of wells per test: 16

Well specifications:

Well No.	Production No.	Well No.	Production No.
1	2009-682-01	9	2009-682-09
2	2009-682-02	10	2009-682-10
3	2010-774-03	11	2009-682-11
4	2009-682-04	12	2009-682-12
5	2009-682-05	13	2009-682-13
6	2009-682-06	14	2012-083-14
7	2009-682-07	15	2009-682-15
8	2009-682-08	16	2009-682-16

The specificity of each primer solution of the kit has been tested against 48 well characterized IHWC cell line DNAs.

No DNAs carrying the allele to be amplified by primer solutions 6, 13, 14 and 16 were available. The specificities of the primers in primer solutions 6 and 14 were tested by separately adding one additional 5'-primer and one additional 3'-primer, respectively. In primer solutions 13 and 16 it was only possible to test the 3'-primers, the 5'-primers were not possible to test. In primer solution 6 one 5'-primer was not possible to test, and in primer solutions 6 and 14 one 3'-primer was not possible to test.

Results: No false positive or false negative amplifications were obtained.

Date of approval: 2012-November-29

Approved by:

Åsa Clauss

Production Quality Control

CE

For *In Vitro* Diagnostic Use.

101.331.24/06 – including *Taq* pol., IFU-01
101.331.24u/06u – without *Taq* pol., IFU-02

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

Lot No.: 40R **Lot-specific information**

Declaration of Conformity

Product name: *Olerup* SSP® DPA1
Product number: 101.331-24/24u, -06/06u
Lot number: 40R

Intended use: HLA-DPA1 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 13485:2003, 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
2012-November-29

Ann-Cathrin Jareman
Head of QA and Regulatory Affairs