101.122-24/06 – including *Taq* pol., IFU-01
101.122-24u/06u – without *Taq* pol., IFU-02

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

Lot No.: 67S **Lot-specific information**

CERTIFICATE OF ANALYSIS

Olerup SSP® DRB4 SSP

Product number: **101.122-24/06 – including *Taq* pol.**
101.122-24/06u – without *Taq* pol.
Lot number: **67S**
Expiry date: **2016-February-01**
Number of tests: **24 test – Product No. 101.122-24**
6 tests – Product No. 101.122-06
Number of wells per test: **13**

Well specifications:

Well No.	Production No.	Well No.	Production No.
1	2012-027-01	9	2012-027-09
2	2012-027-02	10	2012-027-10
3	2012-027-03	11	2012-027-11
4	2012-027-04	12	2012-027-12
5	2012-027-05	13	2012-027-13
6	2012-027-06		
7	2012-027-07		
8	2012-027-08		

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

No DNAs carrying the alleles to be amplified by primer solutions 6 and 9 to 13 were available. The specificities of the primers in primer solutions 6 and 9 were tested by separately adding one additional 5'-primer, respectively, one additional 3'-primer. In primer solutions 10 and 11 it was only possible to test the 3'-primers, the 5'-primers were not possible to test. In primer solutions 12 and 13 it was only possible to test the 5'-primer, the 3'-primer was not possible to test. One additional 3'-primer in primer solution 1 was tested by adding one additional 5'-primer.

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

Date of approval: 2013-August-23

Approved by:

Åsa Claesson

Production Quality Control

CE
0088

101.122-24/06 – including *Taq* pol., IFU-01
101.122-24u/06u – without *Taq* pol., IFU-02

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

Lot No.: 67S **Lot-specific information**

Declaration of Conformity

Product name: *Olerup* SSP® DRB4
Product number: 101.122-24/24u, -06/06u
Lot number: 67S

Intended use: DRB4 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 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.

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
2013-August-23

Ann-Cathrin Jareman
Head of QA and Regulatory Affairs