

101.812-12 – including *Taq* polymerase, IFU-01 Rev. No. 03
101.812-12u – without *Taq* polymerase, IFU-02 Rev. No. 03

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

Lot No.: **44N**

Lot-specific information

CERTIFICATE OF ANALYSIS

Olerup SSP[®] DRB5*01:08N SSP

Product number: 101.812-12 – including *Taq* polymerase
101.812-12u – without *Taq* polymerase
Lot number: 44N
Expiry date: 2014-August-01
Number of tests: 12
Number of wells per test: 2

Well specifications:

Well No.	Production No.
1	2008-479-01
2	2009-649-02

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

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

Date of approval: 2012-March-01

Approved by:



Production Quality Control

101.812-12 – including *Taq* polymerase, IFU-01 Rev. No. 03
101.812-12u – without *Taq* polymerase, IFU-02 Rev. No. 03

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

Lot No.: **44N**

Lot-specific information

Declaration of Conformity

Product name: *Olerup* SSP® DRB5*01:08N
Product number: 101.812-12
Lot number: 44N

Intended use: DRB5*01:08N 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 II List B, 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
2012-March-01



Ann-Cathrin Jareman
Head of QA and Regulatory Affairs