

Lot No.: **93K**

Lot-specific information

www.olerup-ssp.com

CERTIFICATE OF ANALYSIS

Olerup SSP® DRB4*01:03:01:02N SSP

Product number: 101.811-12 – including *Taq* polymerase
Lot number: 93K
Expiry date: 2013-July-01
Number of tests: 12
Number of wells per test: 2

Well specifications:

Well No.	Production No.
1	2008-477-01
2	2008-477-02

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: 2011-January-31

Approved by:



Quality Control, Supervisor

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Declaration of Conformity

Product name: *Olerup* SSP® DRB4*01:03:01:02N
Product number: 101.811-12
Lot number: 93K

Intended use: DRB4*01:03:01:02N histocompatibility testing

Manufacturer: *Olerup* SSP AB
Hasselstigen 1
SE-133 33 Saltsjöbaden, Sweden
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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, Hasselstigen 1, SE-133 33 Saltsjöbaden, Sweden.

The Authorized Representative located within the Community is: *Olerup* SSP AB.

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

Saltsjöbaden, Sweden
2011-January-31



Olle Olerup
Managing Director