

Lot No.: **94K**

Lot-specific information

[www.olerup-ssp.com](http://www.olerup-ssp.com)

## CERTIFICATE OF ANALYSIS

### **Olerup SSP® DRB5\*01:08N SSP**

Product number: 101.812-12u – without *Taq* polymerase  
Lot number: 94K  
Expiry date: 2013-July-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:** 2011-January-31

**Approved by:**



Quality Control, Supervisor

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## Declaration of Conformity

**Product name:** *Olerup* SSP® DRB5\*01:08N  
**Product number:** 101.812-12u  
**Lot number:** 94K  
  
**Intended use:** DRB5\*01:08N histocompatibility testing  
  
**Manufacturer:** *Olerup* SSP AB  
Hasselstigen 1  
SE-133 33 Saltsjöbaden, 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, 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