Lot No.: **52F**
Lot-specific information

CERTIFICATE OF ANALYSIS

Olerup SSP® DRA SSP

Product number: 101.131-24u – without Taq polymerase
Lot number: 52F
Expiry date: 2011-February-01
Number of tests: 24
Number of wells per test: 2

Well specifications:

Well No.	Production No.
1	2008-557-01
2	2008-557-02

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: 2009-May-25

Approved by:

Quality Control, Supervisor

Lot No.: 52F

Lot-specific information

Declaration of Conformity

Product name: *Olerup* SSP® DRA
Product number: 101.131-24u
Lot number: 52F

Intended use: DRA high resolution 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 9001:2000 and ISO 13485:2003, 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, 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
2009-May-25

Olle Olerup
Managing Director