CERTIFICATE OF ANALYSIS

Olerup SSP® DR low resolution

Product number: **101.101-48/12 – including *Taq* pol.**
Lot number: **05L**
Expiry date: **2013-July-01**
Number of tests: **48 tests – Product No. 101.101-48**
12 tests – Product No. 101.101-12
Number of wells per test: **23 + 1**

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2010-789-01	9	2010-689-09	17	2010-789-17
2	2010-689-02	10	2010-689-10	18	2010-689-18
3	2011-822-03	11	2011-822-11	19	2010-689-19
4	2010-789-04	12	2010-689-12	20	2010-689-20
5	2010-689-05	13	2010-689-13	21	2010-789-21
6	2010-689-06	14	2010-689-14	22	2010-689-22
7	2010-689-07	15	2010-789-15	23	2010-689-23
8	2010-689-08	16	2010-789-16		

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

The reactivities of additional 3'-primers in primer solutions 1, 3, 4, 9 to 12, 18 and 20 were tested by separately adding another 5'-primer.
Additional 5'-primers in primer solutions 6, 9, 11, 15, 16 and 18 were tested by separately adding another 3'-primer.
One or more of the 5'-primers in primer solutions 1, 3, 4, 8 to 10, 13, 15 and 16 and one or two of the 3'-primers in primer solutions 1, 3, 4, 13 and 22 were not possible to test.

The negative control primer pairs, **Production No. 2010-760-01**, can detect contamination with PCR products diluted 10^{-7}.

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

Date of approval: 2011-June-22

Approved by:

Production Quality Control

Declaration of Conformity

Product name: *Olerup* SSP® DR low resolution
Product number: 101.101-48/12
Lot number: 05L

Intended use: DRB1 low resolution histocompatibility testing

Manufacturer: *Olerup* SSP AB
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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, 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.

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.)

Stockholm, Sweden
2011-June-22

Ann-Cathrin Jareman
Head of QA and Regulatory Affairs