CERTIFICATE OF ANALYSIS

Olerup SSP® DRB1*01 SSP

Product number: 101.111-24/06 – including *Taq* pol.
Lot number: 28M
Expiry date: 2013-November-01
Number of tests: 24 test – Product No. 101.111-24
6 tests – Product No. 101.111-06
Number of wells per test: 22

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2008-424-01	9	2008-555-09	17	2010-703-17
2	2008-424-02	10	2008-424-10	18	2010-703-18
3	2008-424-03	11	2010-703-11	19	2010-703-19
4	2008-424-04	12	2010-703-12	20	2011-869-20
5	2010-703-05	13	2010-703-13	21	2011-869-21
6	2010-703-06	14	2010-703-14	22	2011-869-22
7	2010-703-07	15	2010-703-15		
8	2010-703-08	16	2010-703-16		

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

No DNAs carrying the alleles to be amplified by primer solutions 5, 6 and 8 to 22 were available. The specificities of the primers in primer solutions 5, 6 and 9 to 16 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer. In primer solution 8 and 17 to 20 it was only possible to test the 3'-primer, the 5'-primer was not possible to test. In primer solution 21 and 22 it was only possible to test the 5'-primer, the 3'-primer was not possible to test. In primer solutions 6 and 12 to 16 one or two 3'-primers were not possible to test. Additional 3'-primers in primer solution 7 were tested by separately adding one additional 5'-primer.

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

Date of approval: 2011-June-10
Approved by:

Quality Control, Supervisor

Declaration of Conformity

Product name: *Olerup* SSP® DRB1*01
Product number: 101.111-24/06
Lot number: 28M

Intended use: DRB1*01 high 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-10

Olle Olerup
Managing Director