CERTIFICATE OF ANALYSIS

Olerup SSP® DRB3 SSP

Product number: 101.121-24/04 – including *Taq* pol.
Lot number: 71M
Expiry date: 2014-March-01
Number of tests: 24 tests – Product No. 101.121-24
4 tests – Product No. 101.121-04
Number of wells per test: 30

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2011-908-01	11	2010-805-11	21	2010-805-21
2	2010-805-02	12	2010-805-12	22	2011-908-22
3	2010-805-03	13	2010-805-13	23	2011-908-23
4	2010-805-04	14	2010-805-14	24	2010-805-24
5	2010-805-05	15	2010-805-15	25	2011-908-25
6	2010-805-06	16	2011-908-16	26	2010-805-26
7	2011-908-07	17	2010-805-17	27	2010-805-27
8	2010-805-08	18	2010-805-18	28	2011-908-28
9	2010-805-09	19	2010-805-19	29	2011-908-29
10	2010-805-10	20	2010-805-20	30	2011-908-30

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

No DNAs carrying the alleles to be amplified by primer solutions 4 to 8, 16 to 19, 21 to 23 and 25 to 30 were available. The specificities of the primers in primer solutions 5, 7, 8, 16 to 19, 21, 25, 26, 28 and 29 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer. In primer solutions 4, 6, 22, 23, 27 and 30 it was only possible to test the 3'-primer, the 5'-primer was not possible to test. One or two of the 3'-primers in primer solutions 1 to 3, 5, 7, 12, 15, 17, 19, 21 and 25 were not possible to test. In primer solutions 2, 3, 4, 6, 22, 23, 27 and 30 one or two of the 5'-primers was not possible to test. Additional 3'-primers in primer solutions 15, 20 and 24 were tested by separately adding one 5'-primer.

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

Date of approval: 2011- October-11

Approved by:

Åsa Olausson

Quality Control, Supervisor

Declaration of Conformity

Product name: *Olerup* SSP® DRB3
Product number: 101.121-24/04
Lot number: 71M

Intended use: DRB3 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.

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-October-11

Ann-Cathrin Jareman
Head of QA and Regulatory Affairs