CERTIFICATE OF ANALYSIS

OLERUP SSP® DQB1*06 SSP

Product number: 101.212-24/04 – including *Taq* pol.
Lot number: 40K
Expiry date: 2012-September-01
Number of tests: 24 test – Product No. 101.212-24
4 tests – Product No. 101.212-04
Number of wells per test: 30

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2010-757-01	11	2010-757-11	21	2010-757-21
2	2010-757-02	12	2010-757-12	22	2010-757-22
3	2010-757-03	13	2010-757-13	23	2010-757-23
4	2010-757-04	14	2010-757-14	24	2010-757-24
5	2010-757-05	15	2010-757-15	25	2010-757-25
6	2010-757-06	16	2010-757-16	26	2010-757-26
7	2010-757-07	17	2010-757-17	27	2010-757-27
8	2010-757-08	18	2010-757-18	28	2010-757-28
9	2010-757-09	19	2010-757-19	29	2010-757-29
10	2010-757-10	20	2010-757-20	30	2010-757-30

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

No DNAs carrying the alleles to be amplified by primer solutions 10, 12 to 20, 22 and 26 to 28 were available. The specificities of the primers in primer solutions 10, 12 to 15, 17, 19, 22 and 26 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer. In primer solutions 16, 18 and 28 it was only possible to test the 5'-primers, the 3'-primers were not possible to test. In primer solutions 20 and 27 it was only possible to test the 3'-primer, the 5'-primer was not possible to test. In primer solution 19, one 3'-primer was not possible to test, and in primer solution 22 one 5'-primer was not possible to test.

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

Date of approval: 2011-October-06

Approved by:

Åsa Claesson

Quality Control, Supervisor

CE

For *In Vitro* Diagnostic Use.

Declaration of Conformity

Product name: *Olerup* SSP™ DQB1*06
Product number: 101.212-24/04
Lot number: 40K

Intended use: DQB1*06 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 III, 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.

Stockholm, Sweden
2011-October-06

Ann-Cathrin Jareman
Head of QA and Regulatory Affairs