Lot No.: **56K**

Lot-specific Information

CERTIFICATE OF ANALYSIS

Olerup SSP® DQB1*03 SSP

Product number: 101.214-24u/06u – without *Taq* pol.
Lot number: 56K
Expiry date: 2013-April-01
Number of tests: 24 test – Product No. 101.214-24u
6 tests – Product No. 101.214-06u
Number of wells per test: 24

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2009-630-01	9	2009-630-09	17	2009-630-17
2	2009-630-02	10	2009-630-10	18	2009-630-18
3	2009-630-03	11	2009-630-11	19	2009-630-19
4	2009-630-04	12	2009-630-12	20	2009-630-20
5	2009-630-05	13	2009-630-13	21	2009-630-21
6	2009-630-06	14	2009-630-14	22	2009-630-22
7	2009-630-07	15	2009-630-15	23	2009-630-23
8	2009-630-08	16	2009-630-16	24	2010-777-24

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 7 to 10, 13, 17, 20, 21, 23 and 24 were available. The specificities of the primers in primer solutions 7, 9 and 10 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer. In primer solutions 8, 17, 20 and 21 it was only possible to test the 3'-primer, the 5'-primers were not possible to test. In primer solutions 13, 23 and 24 it was only possible to test the 3'-primers, the 5'-primers were not possible to test. In primer solutions 10 and 14 one of the 3'-primers was not possible to test, and in primer solution 6 one of the 5'-primers was not possible to test.

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

Date of approval: 2010-November-24

Approved by:

Quality Control, Supervisor

CE

For *In Vitro* Diagnostic Use.

Declaration of Conformity

Product name: *Olerup* SSP® DQB1*03
Product number: 101.214-24u/06u
Lot number: 56K

Intended use: DQB1*03 high resolution histocompatibility testing

Manufacturer: *Olerup* SSP AB
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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 9001:2008 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, Hasselstigen 1, SE-133 33 Saltsjöbaden, Sweden.

The Authorized Representative located within the Community is: *Olerup* SSP AB.

Saltsjöbaden, Sweden
2010-November-24

Olle Olerup
Managing Director