CERTIFICATE OF ANALYSIS

Olerup SSP® DQB1*06:02,DQA1*01:02 - SSP

Product number: 101.901-24 – including *Taq* polymerase
Lot number: 64M
Expiry date: 2014-May-01
Number of tests: 24
Number of wells per test: 8

Well specifications:

Well No.	Production No.
1	2011-901-01
2	2011-901-02
3	2011-901-03
4	2011-901-04
5	2011-901-05
6	2011-901-06
7	2011-901-07
8	2011-901-08

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 and 7 were available. The specificities of the primers in primer solutions 7 were tested by separately adding one additional 5'-primer, respectively, one additional 3'-primer. In primer solution 5 it was only possible to test the 5'-primer, the 3'-primer was not possible to test. In primer solutions 6 and 8 one 3'-primer was not possible to test, and in primer solution 7 two 5'-primers were not possible to test.

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

Date of approval: 2011-December-02

Approved by:

Åsa Olausson

Production Quality Control

Declaration of Conformity

Product name: *Olerup* SSP® DQB1*06:02,DQA1*01:02
Product number: 101.901-24
Lot number: 64M

Intended use: DQB1*06:02,DQA1*01:02 histocompatibility testing

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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-December-02

Ann-Cathrin Jareman
Head of QA and Regulatory Affairs