CERTIFICATE OF ANALYSIS

Olerup SSP® DQA1 SSP

Product number: 101.231-24/04 – including *Taq* pol.
Lot number: 58M
Expiry date: 2014-March-01
Number of tests: 24 tests – Product No. 101.231-24
4 tests – Product No. 101.231-04
Number of wells per test: 32

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2009-609-01	13	2009-609-13	25	2009-609-25
2	2009-609-02	14	2009-609-14	26	2011-891-26
3	2009-609-03	15	2009-609-15	27	2009-609-27
4	2009-609-04	16	2009-609-16	28	2009-609-28
5	2009-609-05	17	2009-609-17	29	2009-609-29
6	2009-609-06	18	2009-609-18	30	2011-891-30
7	2009-609-07	19	2009-609-19	31	2009-609-31
8	2009-609-08	20	2009-609-20	32	2009-609-32
9	2009-609-09	21	2009-609-21		
10	2009-609-10	22	2011-891-22		
11	2009-609-11	23	2009-609-23		
12	2009-609-12	24	2009-609-24		

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, 16, 20, 26 to 29 and 31 were available. In primer solutions 7, 26, 29 and 31 the 5'-primers were tested by adding one additional 3'-primer, the 3'-primers were not possible to test. In primer solutions 16, 20, 27 and 28 the 3'-primers were tested by adding one additional 5'-primer, the 5'-primers were not possible to test. In primer solution 25, one 3'-primer was not possible to test, and one additional 5'-primer was tested by separately adding one 3'-primer. In primer solution 30, one 5'-primer was not possible to test, and one additional 3'-primer was tested by separately adding one 5'-primer.

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

Date of approval: 2011-October-06

Approved by:

Åsa Olausson

Quality Control, Supervisor

Declaration of Conformity

Product name: *Olerup* SSP® DQA1
Product number: 101.231-24/04
Lot number: 58M

Intended use: HLA-DQA1 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.

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-06

Ann-Cathrin Jareman
Head of QA and Regulatory Affairs