Lot No.: 69K

Lot-specific Information

CERTIFICATE OF ANALYSIS

Olerup SSP® DQA1 SSP

Product number: 101.231-24/04 – including *Taq* pol.
Lot number: 69K
Expiry date: 2013-May-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	2010-794-26
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	2009-609-30
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	2009-609-22		
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 and 26 to 32 were available. In primer solutions 7, 25, 26, 29, 31 and 3 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, 28 and 30 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.

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® DQA1
Product number: 101.231-24/04
Lot number: 69K

Intended use: HLA-DQA1 high resolution histocompatibility testing

Manufacturer:
Olerup SSP AB
Hasselstigen 1
SE-133 33 Saltsjöbaden, Sweden
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 Construction 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