

CERTIFICATE OF ANALYSIS**Olerup SSP® DQA1 SSP****Product number:****101.231-24u/04u – without Taq pol.****Lot number:****69K****Expiry date:****2013-May-01****Number of tests:****24 tests – Product No. 101.231-24u****4 tests – Product No. 101.231-04u****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



Declaration of Conformity

Product name: Olerup SSP® DQA1

Product number: 101.231-24u/04u

Lot number: 69K

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 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

