

101.212.24/04 – including *Taq* pol., IFU-01
 101.212.24u/04u – without *Taq* pol., IFU-02

Visit www.olerup-ssp.com for
 “Instructions for Use” (IFU)

Lot No.: **26R**

Lot-specific information

CERTIFICATE OF ANALYSIS

OLERUP SSP® DQB1*06 SSP

Product number:

101.212-24/04 – including *Taq* pol.

101.212-24u/04u – without *Taq* pol.

Lot number:

26R

Expiry date:

2015-April-01

Number of tests:

24 test – Product No. 101.212-24/24u

4 tests – Product No. 101.212-04/04u

Number of wells per test:

32

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2010-757-01	13	2012-067-13	25	2012-067-25
2	2010-757-02	14	2010-757-14	26	2012-942-26
3	2010-757-03	15	2010-757-15	27	2010-757-27
4	2010-757-04	16	2012-067-16	28	2012-067-28
5	2010-757-05	17	2012-067-17	29	2010-757-29
6	2010-757-06	18	2010-757-18	30	2012-067-30
7	2010-757-07	19	2010-757-19	31	2012-942-31
8	2010-757-08	20	2010-757-20	32	2012-067-32
9	2010-757-09	21	2010-757-21		
10	2010-757-10	22	2010-757-22		
11	2010-757-11	23	2010-757-23		
12	2010-757-12	24	2012-942-24		

The specificity of each primer solution of the kit has been tested against 48 well characterized cell line IHWC DNAs.

No DNAs carrying the alleles to be amplified by primer solutions 10, 12 to 20, 22, 26 to 28 and 31 were available. The specificities of the primers in primer solutions 10, 12 to 17, 19, 22 and 26 were tested by separately adding additional 5'-primers, respectively additional 3'-primers. In primer solutions 18, 28 and 31 it was only possible to test the 5'-primers, the 3'-primers were not possible to test. In primer solutions 20 and 27 it was only possible to test the 3'-primer, the 5'-primer was not possible to test.

In primer solution 16 and 19, one 3'-primer was not possible to test, and in primer solutions 16, 22 and 25 one 5'-primer was not possible to test.

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

Date of approval: 2012-October-22

Approved by:

Karin Mattsson

Production Quality Control

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Lot-specific information

Declaration of Conformity

Product name: Olerup SSP® DQB1*06
Product number: 101.212-24/24u, -04/04u
Lot number: 26R

Intended use: DQB1*06 high resolution histocompatibility testing

Manufacturer: Olerup SSP AB
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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, Franzengatan 5, SE-112 51 Stockholm, Sweden.

Stockholm, Sweden
2014-September-02



Daniel Malica
Head of QA and Regulatory Affairs