

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

Visit [www.olerup-ssp.com](http://www.olerup-ssp.com) for  
 “Instructions for Use” (IFU)

Lot No.: **53S**

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:** 53S  
**Expiry date:** 2016-January-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:** 44

### Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2010-757-01	17	2013-205-17	33	2013-205-33
2	2010-757-02	18	2010-757-18	34	2013-205-34
3	2010-757-03	19	2010-757-19	35	2013-205-35
4	2010-757-04	20	2013-205-20	36	2013-205-36
5	2010-757-05	21	2010-757-21	37	2013-205-37
6	2010-757-06	22	2010-757-22	38	2013-205-38
7	2010-757-07	23	2010-757-23	39	2013-205-39
8	2013-205-08	24	2013-205-24	40	2013-205-40
9	2010-757-09	25	2012-067-25	41	2013-205-41
10	2012-116-10	26	2012-942-26	42	2013-205-42
11	2010-757-11	27	2013-205-27	43	2013-205-43
12	2013-205-12	28	2012-067-28	44	2013-205-44
13	2012-067-13	29	2010-757-29		
14	2010-757-14	30	2013-205-30		
15	2010-757-15	31	2012-942-31		
16	2012-067-16	32	2013-205-32		

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, 31, 33 and 35 to 44 were available. The specificities of the primers in primer solutions 10, 12 to 17, 19, 22, 26 and 33 were tested by separately adding additional 5'-primers, respectively additional 3'-primers. In primer solutions 18, 28, 31, 35 to 40 and 42 it was only possible to test the 5'-primers, the 3'-primers were not possible to test. In primer solutions 20, 27, 41, 43 and 44 it was only possible to test the 3'-primer, the 5'-primer was not possible to test.

In primer solution 8, 12, 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.

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

**Date of approval:** 2013-July-23

**Approved by:**

*Karin Mattsson*

**Production Quality Control**

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## Declaration of Conformity

**Product name:** Olerup SSP® DQB1\*06  
**Product number:** 101.212-24/24u, -04/04u  
**Lot number:** 53S

**Intended use:** DQB1\*06 high resolution histocompatibility testing

**Manufacturer:** Olerup SSP AB  
Franzengatan 5  
SE-112 51 Stockholm, 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 13485:2012, 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