

CERTIFICATE OF ANALYSIS

Olerup SSP® DQ-DR SSP Combi Tray

Product number: 101.704-48/12 – including Taq pol.
Lot number: 11M
Expiry date: 2013-November-01
Number of tests: 48 tests – Product No. 101.704-48
12 tests – Product No. 101.704-12
Number of wells per test: 31 + 1

Well specifications:

Well No.	Production No.
1	2011-852-01
2	2011-852-02
3	2011-852-03
4	2011-852-04
5	2011-852-05
6	2011-852-06
7	2011-852-07
8	2011-852-08

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
9	2011-851-01	17	2011-851-09	25	2011-851-17
10	2011-851-02	18	2011-851-10	26	2011-851-18
11	2011-851-03	19	2011-851-11	27	2011-851-19
12	2011-851-04	20	2011-851-12	28	2011-851-20
13	2011-851-05	21	2011-851-13	29	2011-851-21
14	2011-851-06	22	2011-851-14	30	2011-851-22
15	2011-851-07	23	2011-851-15	31	2011-851-23
16	2011-851-08	24	2011-851-16		

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

The reactivities of one additional 5'-primer and one or more 3'-primers in primer solution 17, 19 and 26 were tested by separately adding another 5'-primer or 3'-primer.

One or more additional 3'-primers in primer solution 9, 11, 12, 18, 20 and 28 were tested by separately adding another 5'-primer.

One additional 5'-primer in primer solutions 2, 8, 14, 23 and 24 was tested by separately adding another 3'-primer.

In primer solutions 9, 11, 12, 21 and 30 one or more 3'-primers were not possible to test, and in primer solutions 9, 11, 12, 16 to 18, 21, 23 and 24 one or more 5'-primers were not possible to test.

The negative control primer pairs, Production No. 2010-760-01, can detect contamination with PCR products diluted 10^{-7} .

Lot No.: **11M**

Lot-specific information

www.olerup-ssp.com

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

Date of approval: 2011-May-26

Approved by:



Quality Control Supervisor

Lot No.: **11M**

Lot-specific information

www.olerup-ssp.com

Declaration of Conformity

Product name: *Olerup* SSP® DQ-DR SSP Combi Tray
Product number: 101.704-48/12
Lot number: 11M

Intended use: DQB1 and DRB1 low 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 II List B, conformity assessed using Annex IV, 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.

The Authorized Representative located within the Community is: *Olerup* SSP AB.

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-May-26


Olle Olerup
Managing Director