

Lot No.: **71G**

Lot-specific information

www.olerup-ssp.com

## CERTIFICATE OF ANALYSIS

### Olerup SSP® DPB1-DQ-DR SSP Combi Tray

Product number: 101.709-24/06 – including *Taq* pol.  
 Lot number: 71G  
 Expiry date: 2012-January-01  
 Number of tests: 24 tests – Product No. 101.709-24  
 6 tests – Product No. 101.709-06  
 Number of wells per test: 95 + 1

#### Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2009-655-01	17	2007-375-17	33	2009-655-33
2	2007-375-02	18	2007-375-18	34	2007-375-34
3	2007-375-03	19	2007-375-19	35	2007-375-35
4	2008-532-04	20	2007-375-20	36	2007-375-36
5	2007-375-05	21	2007-375-21	37	2007-375-37
6	2009-655-06	22	2007-375-22	38	2009-655-38
7	2007-375-07	23	2007-375-23	39	2007-375-39
8	2007-375-08	24	2007-375-24	40	2009-655-40
9	2007-375-09	25	2007-375-25	41	2007-375-41
10	2007-375-10	26	2009-655-26	42	2009-678-42
11	2007-375-11	27	2007-375-27	42	2007-375-43
12	2009-655-12	28	2009-655-28	43	2009-655-44
13	2007-375-13	29	2007-375-29	45	2007-375-45
14	2007-375-14	30	2007-375-30	46	2007-375-46
15	2009-655-15	31	2007-375-31	47	2008-532-47
16	2007-375-16	32	2007-375-32	48	2009-655-48

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
49	2009-666-01	57	2009-630-01	65	2009-630-12
50	2009-666-02	58	2009-630-05	66	2009-679-66
51	2009-666-03	59	2009-630-06	67	2009-630-14
52	2009-666-04	60	2009-630-07	68	2009-630-16
53	2009-666-05	61	2009-630-08	69	2009-679-69
54	2009-666-06	62	2009-630-09	70	2009-630-18
55	2009-666-07	63	2009-630-10	71	2009-630-19
56	2009-666-08	64	2009-630-11	72	2009-630-22

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
73	2009-685-01	81	2009-603-09	89	2009-603-17
74	2009-603-02	82	2009-603-10	90	2009-685-18
75	2009-685-03	83	2009-603-11	91	2009-634-19
76	2009-603-04	84	2009-603-12	92	2009-603-20
77	2009-634-05	85	2009-603-13	93	2009-685-21
78	2009-603-06	86	2009-603-14	94	2009-603-22
79	2009-603-07	87	2009-603-15	95	2009-603-23
80	2009-634-08	88	2009-603-16		

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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 pairs in solutions 38, 41, 42, 44, 46, 60 to 63, 66 and 69 were available. The specificity of most of the primers in these solutions was tested by separately adding one or more additional 5'-primer, respectively one or more additional 3'-primer.

In primer solutions 44 and 61 the 5'-primers were not possible to test.

In primer solutions 41, 42 and 46 the 3'-primers were not possible to test.

Additional 5'-primers or 3'-primers in primer solutions 40, 43, 47, 50, 73, 75, 78, 81 to 84, 87, 88, 90, 92 and 93 were tested by separately adding one or more additional 3'-primer, respectively one or more additional 5'-primer.

In primer solutions 15, 25, 32, 33, 38, 59, 66, 69, 75, 76, 81, 82, 85 and 88 one or more of the 5'-primers were not possible to test. In primer solutions 8, 24, 28, 48, 63, 66, 67, 69, 73, 75 and 85 one or more of the 3'-primers were not possible to test.

The negative control primer pairs, **Production No. 2009-614-01**, can detect contamination with PCR products diluted  $10^{-7}$ .

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

**Date of approval:** 2010-July-02

**Approved by:**



**Quality Control Supervisor**

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## Declaration of Conformity

**Product name:** Olerup SSP® DPB1-DQ-DR SSP Combi Tray  
**Product number:** 101.709-24/06  
**Lot number:** 71G

**Intended use:** DPB1, DQB1 and DRB1 low 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 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, Hasselstigen 1, SE-133 33 Saltsjöbaden, 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.)

Saltsjöbaden, Sweden  
2010-July-02



Olle Olerup  
Managing Director