

## CERTIFICATE OF ANALYSIS

### Olerup SSP® DRB1\*14 SSP

**Product number:** 101.117-12/03 – including Taq pol.  
**Lot number:** 76K  
**Expiry date:** 2013-May-01  
**Number of tests:** 12 tests – Product No. 101.117-12  
 3 tests – Product No. 101.117-03  
**Number of wells per test:** 48

#### Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2007-373-01	17	2007-373-17	33	2010-799-33
2	2007-373-02	18	2007-373-18	34	2008-520-34
3	2010-799-03	19	2007-373-19	35	2008-520-35
4	2007-373-04	20	2010-799-20	36	2009-650-36
5	2007-373-05	21	2007-373-21	37	2008-520-37
6	2007-373-06	22	2007-373-22	38	2010-799-38
7	2007-373-07	23	2007-373-23	39	2008-520-39
8	2009-650-08	24	2010-799-24	40	2008-520-40
9	2009-650-09	25	2007-373-25	41	2010-799-41
10	2007-373-10	26	2010-799-26	42	2008-520-42
11	2007-373-11	27	2007-373-27	43	2010-799-43
12	2007-373-12	28	2010-799-28	44	2009-650-44
13	2010-799-13	29	2010-799-29	45	2009-650-45
14	2009-650-14	30	2007-373-30	46	2010-799-46
15	2007-373-15	31	2007-373-31	47	2010-799-47
16	2007-373-16	32	2007-373-32	48	2010-799-48

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 10, 14, 15, 19, 24, 27 to 29, 31, 38 to 46 and 48 were available.

The specificities of the primers in primer solutions 10, 14, 15, 19, 24, 27 to 29, 31, 38, 39, 42, 43, 45 and 48 were tested by separately adding one additional 5'-primer, respectively, one or several additional 3'-primers.

In primer solutions 40 and 47 it was only possible to test the 5'-primers, the 3'-primers were not possible to test.

In primer solution 44 it was only possible to test the 3'-primer, the 5'-primer was not possible to test.

In primer solutions 9, 10 and 14 one of the 5'-primers was not possible to test, and in primer solutions 17, 24, 25, 28, 29, 37, 41 and 48 one or more of the 3'-primers were not possible to test.

Additional primers in primer solutions 11, 20, 21, 25, 30, 32 and 41 were tested by separately adding one 5'-primer and/or one 3'-primer.

Lot No.: **76K**

Lot-specific information

[www.olerup-ssp.com](http://www.olerup-ssp.com)

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

**Date of approval:** 2010-December-10

**Approved by:**



**Quality Control, Supervisor**

Lot No.: **76K**

Lot-specific information

[www.olerup-ssp.com](http://www.olerup-ssp.com)

## Declaration of Conformity

**Product name:** *Olerup SSP*® DRB1\*14**Product number:** 101.117-12/03**Lot number:** 76K**Intended use:** DRB1\*14 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 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-December-10



Olle Olerup  
Managing Director