DRB1*14
101.117-12u/03u – without *Taq* polymerase

Product Insert

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General "Instructions for Use"
IFU-02 Rev. No. 02 can be downloaded from

Lot No.: **76K**

Lot-specific information

www.olerup-ssp.com

CERTIFICATE OF ANALYSIS

Olerup SSP® DRB1*14 SSP

Product number:	101.117-12u/03u – without *Taq* pol.
Lot number:	76K
Expiry date:	2013-May-01
Number of tests:	12 tests – Product No. 101.117-12u
	3 tests – Product No. 101.117-03u
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.

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101.117-12u/03u – without *Taq* polymerase

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General **"Instructions for Use"**
IFU-02 Rev. No. 02 can be downloaded from

Lot No.: **76K**   Lot-specific information   **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

December 2010
Rev. No.: 00u

CE
0088

For *In Vitro* Diagnostic Use.

DRB1*14
101.117-12u/03u – without *Taq* polymerase

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General **"Instructions for Use"**
IFU-02 Rev. No. 02 can be downloaded from
www.olerup-ssp.com

Lot No.: 76K

Lot-specific information

Declaration of Conformity

Product name: *Olerup* SSP® DRB1*14
Product number: 101.117-12u/03u
Lot number: 76K

Intended use: DRB1*14 high 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-December-10

Olle Olerup
Managing Director

December 2010
Rev. No.: 00u

CE
0088

For *In Vitro* Diagnostic Use.