

CERTIFICATE OF ANALYSIS

Olerup SSP® DRB1*04 SSP

Product number: 101.114-24u/03u – without Taq pol.
Lot number: 40M
Expiry date: 2014-February-01
Number of tests: 24 tests – Product No. 101.114-24u
3 tests – Product No. 101.114-03u
Number of wells per test: 45

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2011-881-01	17	2011-881-17	33	2011-881-33
2	2011-881-02	18	2011-881-18	34	2011-881-34
3	2011-881-03	19	2011-881-19	35	2011-881-35
4	2011-881-04	20	2011-881-20	36	2011-881-36
5	2011-881-05	21	2011-881-21	37	2011-881-37
6	2011-881-06	22	2011-881-22	38	2011-881-38
7	2011-881-07	23	2011-881-23	39	2011-881-39
8	2011-881-08	24	2011-881-24	40	2011-881-40
9	2011-881-09	25	2011-881-25	41	2011-881-41
10	2011-881-10	26	2011-881-26	42	2011-881-42
11	2011-881-11	27	2011-881-27	43	2011-881-43
12	2011-881-12	28	2011-881-28	44	2011-881-44
13	2011-881-13	29	2011-881-29	45	2011-881-45
14	2011-881-14	30	2011-881-30		
15	2011-881-15	31	2011-881-31		
16	2011-881-16	32	2011-881-32		

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 11, 13, 15, 17 to 20, 22, 23, 25 and 33 to 45 were available. The specificities of the primers in primer solutions 11, 13, 17 to 20, 35, 37 to 39, 42 and 45 were tested by separately adding one additional 5'-primer, respectively, one additional 3'-primer.

In primer solutions 15, 25, 34 and 36 it was only possible to test the 3'-primers, the 5'-primers were not possible to test.

In primer solutions 22, 23, 33, 40, 41, 43 and 44 it was only possible to test the 5'-primers, the 3'-primers were not possible to test.

One or two of the 3'-primers in primer solutions 10, 12 to 14, 17, 19, 20, 21, 26, 32, 35, 38, 39 and 42 was not possible to test, and in primer solution 27, 29 and 31 one or two 5'-primers was not possible to test.

One additional 3'-primer in primer solution 21 was tested by separately adding one additional 5'-primer.

Lot No.: **40M**

Lot-specific information

www.olerup-ssp.com

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

Date of approval: 2011-August-18

Approved by:



Quality Control, Supervisor

Lot No.: **40M**

Lot-specific information

www.olerup-ssp.com

Declaration of Conformity

Product name: *Olerup* SSP® DRB1*04
Product number: 101.114-24u/03u
Lot number: 40M

Intended use: DRB1*04 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, 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
2010-August-20



Ann-Cathrin Jareman
Head of QA and Regulatory Affairs