

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-B*07 SSP

Product number: 101.512-24u/03u – without *Taq* pol.
Lot number: 03L
Expiry date: 2013-August-01
Number of tests: 24 tests – Product No. 101.512-24u
 3 tests – Product No. 101.512-03u
Number of wells per test: 72

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2009-675-01	25	2011-821-25	49	2009-675-49
2	2009-675-02	26	2009-675-26	50	2009-675-50
3	2009-675-03	27	2011-821-27	51	2009-675-51
4	2009-675-04	28	2009-675-28	52	2011-821-52
5	2009-675-05	29	2011-821-29	53	2009-675-53
6	2009-675-06	30	2009-675-30	54	2011-821-54
7	2009-675-07	31	2009-675-31	55	2009-675-55
8	2009-675-08	32	2009-675-32	56	2009-675-56
9	2009-675-09	33	2009-675-33	57	2011-821-57
10	2009-675-10	34	2009-675-34	58	2011-821-58
11	2009-675-11	35	2009-675-35	59	2011-821-59
12	2009-675-12	36	2009-675-36	60	2009-675-60
13	2009-675-13	37	2009-675-37	61	2011-821-61
14	2011-821-14	38	2011-821-38	62	2009-675-62
15	2009-675-15	39	2009-675-39	63	2009-675-63
16	2009-675-16	40	2009-675-40	64	2009-675-64
17	2009-675-17	41	2009-675-41	65	2011-821-65
18	2009-675-18	42	2009-675-42	66	2009-675-66
19	2009-675-19	43	2009-675-43	67	2009-675-67
20	2009-675-20	44	2009-675-44	68	2011-821-68
21	2009-675-21	45	2009-675-45	69	2011-821-69
22	2009-675-22	46	2009-675-46	70	2011-821-70
23	2009-675-23	47	2009-675-47	71	2011-821-71
24	2009-675-24	48	2009-675-48	72	2011-821-72

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

No DNAs carrying the alleles to be amplified by primer solutions 7, 12, 13, 15, 17, 18, 20 to 23, 25, 27 to 29, 33 to 36, 38, 40 to 42, 48 to 55, 57 to 61, 63, 65, 68 and 70 to 72 were available.

The specificities of the primers in primer solutions 7, 12, 13, 15, 17, 18, 20, 23, 25, 27, 29, 36, 38, 40, 48, 51, 53, 57, 59, 60, 68, 70 and 72 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer. In primer solutions 33, 50, 54, 58, 61, 65 and 71 it was only possible to test the 5'-primer, the 3'-primer were not possible to test. In primer solutions 21, 22, 28, 34, 35, 41, 42, 49, 52, 55 and 63 it was only possible to test the 3'-primers, the 5'-primers were not possible to test. In primer solutions 7, 27, 29,

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Lot-specific Information

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48 and 57 one or two 5'-primers were not possible to test, and in primer solutions 8 to 11, 15, 17, 19, 20, 24 to 26, 38, 40, 51, 56, 59, 68 and 69 one or two 3'-primers were not possible to test. Additional primers in primer solutions 8, 10, 11, 19, 24, 26, 31 and 69 were tested by separately adding one additional 5'-primer, or one additional 3'-primer.

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

Date of approval: 2011-February-24

Approved by:



Quality Control, Supervisor

Lot No.: **03L**

Lot-specific Information

www.olerup-ssp.com

Declaration of Conformity

Product name: Olerup SSP® HLA-B*07
Product number: 101.512-24u/03u
Lot number: 03L

Intended use: HLA-B*07 high resolution histocompatibility testing

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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
2011-February-24



Olle Olerup
Managing Director