

Lot No.: **07M**

Lot-specific information

www.olerup-ssp.com

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-B*40 SSP

Product number: 101.523-24/03 – including *Taq* pol.
Lot number: 07M
Expiry date: 2013-September-01
Number of tests: 24 tests – Product No. 101.523-24
3 tests – Product No. 101.523-03
Number of wells per test: 72

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2008-525-01	25	2008-525-25	49	2008-525-49
2	2011-848-02	26	2008-525-26	50	2008-525-50
3	2010-699-03	27	2008-525-27	51	2008-525-51
4	2008-525-04	28	2008-525-28	52	2008-525-52
5	2008-525-05	29	2008-525-29	53	2008-525-53
6	2008-525-06	30	2011-848-30	54	2008-525-54
7	2008-525-07	31	2008-525-31	55	2008-525-55
8	2008-525-08	32	2008-525-32	56	2010-699-56
9	2008-525-09	33	2008-525-33	57	2008-525-57
10	2008-525-10	34	2008-525-34	58	2008-525-58
11	2008-525-11	35	2008-525-35	59	2008-525-59
12	2008-525-12	36	2008-525-36	60	2008-525-60
13	2008-525-13	37	2008-525-37	61	2008-525-61
14	2008-525-14	38	2008-525-38	62	2008-525-62
15	2008-525-15	39	2008-525-39	63	2008-525-63
16	2008-525-16	40	2008-525-40	64	2008-525-64
17	2008-525-17	41	2008-525-41	65	2011-848-65
18	2008-525-18	42	2008-525-42	66	2008-525-66
19	2008-525-19	42	2008-525-43	67	2008-525-67
20	2008-525-20	43	2008-525-44	68	2008-525-68
21	2008-525-21	45	2008-525-45	69	2010-699-69
22	2008-525-22	46	2010-699-46	70	2008-525-70
23	2008-525-23	47	2008-525-47	71	2008-525-71
24	2008-525-24	48	2008-525-48	72	2010-699-72

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, 16, 23, 24, 25, 27, 34, 37, 38, 42 to 45, 47 to 57, 59 to 63, 67 to 69, and 71 were available. The specificities of the primers in primer solutions 11, 16, 25, 34, 37, 38, 42, 43, 45, 48 to 50, 52, 61, 69 and 71 were tested by separately adding one or two additional 5'-primers, respectively one or two additional 3'-primers. In primer solutions 27, 44, 53, 54, 56, 62, 63, 67 and 68 it was only possible to test the 5'-primers, the 3'-primers were not possible to test.

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In primer solutions 23, 24, 47, 51, 55, 57, 59 and 60 it was only possible to test the 3'-primers, the 5'-primers were not possible to test.

One of the 3'-primers in primer solutions 3 and 6 and one of the 5'-primers in primer solutions 16, 30, 45 and 65 were not possible to test.

One additional 3'-primer in primer solution 6 was tested by separately adding one additional 5'-primer.

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

Date of approval: 2011-April-21

Approved by:



Quality Control, Supervisor

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Declaration of Conformity

Product name: *Olerup* SSP® HLA-B*40
Product number: 101.523-24/03
Lot number: 07M

Intended use: HLA-B*40 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.)

Stockholm, Sweden
2013-September-16


Ann-Cathrin Jareman
Head of QA and Regulatory Affairs