

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-B*51 SSP

Product number: 101.561-24/03 – including *Taq* pol.
Lot number: 48M
Expiry date: 2014-February-01
Number of tests: 24 tests – Product No. 101.561-24
3 tests – Product No. 101.561-03
Number of wells per test: 64

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2010-731-01	25	2010-731-25	49	2010-731-49
2	2010-731-02	26	2010-731-26	50	2010-731-50
3	2010-731-03	27	2010-731-27	51	2010-731-51
4	2010-731-04	28	2010-731-28	52	2010-731-52
5	2010-731-05	29	2010-731-29	53	2010-731-53
6	2010-731-06	30	2011-891-30	54	2010-731-54
7	2010-731-07	31	2010-731-31	55	2010-731-55
8	2010-731-08	32	2010-731-32	56	2010-731-56
9	2010-731-09	33	2010-731-33	57	2010-731-57
10	2010-731-10	34	2010-731-34	58	2010-731-58
11	2010-731-11	35	2010-731-35	59	2010-731-59
12	2010-731-12	36	2010-731-36	60	2010-731-60
13	2010-731-13	37	2010-731-37	61	2010-731-61
14	2010-731-14	38	2010-731-38	62	2010-731-62
15	2010-731-15	39	2010-731-39	63	2010-731-63
16	2010-731-16	40	2010-731-40	64	2010-731-64
17	2010-731-17	41	2010-731-41		
18	2010-731-18	42	2010-731-42		
19	2010-731-19	43	2010-731-43		
20	2010-731-20	44	2010-731-44		
21	2010-731-21	45	2010-731-45		
22	2010-731-22	46	2010-731-46		
23	2010-731-23	47	2010-731-47		
24	2010-731-24	48	2010-731-48		

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 5, 13, 17, 20, 21, 25, 27, 32, 33, 36, 37, 39, 42 to 46, 51 to 53, 55 and 57 to 64 were available. The specificities of the primers in primer solutions 5, 17, 27, 32, 37, 39, 42, 44, 46, 51, 57 and 61 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer. In primer solutions 13, 20, 21, 25, 33, 43, 45, 53, 55, 59, 60 and 62 it was only possible to test the 5'-primer, the 3'-primer was not possible to test. In primer solutions 36, 52, 58, 63 and 64

Lot No.: **48M**

Lot-specific Information

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it was only possible to test the 3'-primer, the 5'-primer was not possible to test. In primer solutions 9, 16, 25, 39, 41, 42 and 44 one or two of the 5'-primers were not possible to test. In primer solution 15, 18, 26 to 28, 37, 42, 51, 57 and 61 one or two of the 3'-primers were not possible to test. Additional primers in primer solutions 18, 26, 28, 31, 41, 47 and 48 were tested by separately adding one 5'-primer or one 3'-primer.

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

Date of approval: 2011-August-18

Approved by:



Quality Control, Supervisor

Lot No.: **48M**

Lot-specific Information

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Declaration of Conformity

Product name: Olerup SSP® HLA-B*51
Product number: 101.561-24/03
Lot number: 48M

Intended use: HLA-B*51 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
2011-August-18



Ann-Cathrin Jareman
Head of QA and Regulatory Affairs