

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-B*44 SSP

Product number: 101.563-24u/03u – without Tag pol.

Lot number: 15M

Expiry date: 2013-December-01

Number of tests: 24 tests – Product No. 101.563-24u

3 tests – Product No. 101.563-03u

Number of wells per test: 48

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2011-856-01	17	2011-856-17	33	2011-856-33
2	2011-856-02	18	2011-856-18	34	2011-856-34
3	2011-856-03	19	2011-856-19	35	2011-856-35
4	2011-856-04	20	2011-856-20	36	2011-856-36
5	2011-856-05	21	2011-856-21	37	2011-856-37
6	2011-856-06	22	2011-856-22	38	2011-856-38
7	2011-856-07	23	2011-856-23	39	2011-856-39
8	2011-856-08	24	2011-856-24	40	2011-856-40
9	2011-856-09	25	2011-856-25	41	2011-856-41
10	2011-856-10	26	2011-856-26	42	2011-856-42
11	2011-856-11	27	2011-856-27	43	2011-856-43
12	2011-856-12	28	2011-856-28	44	2011-856-44
13	2011-856-13	29	2011-856-29	45	2011-856-45
14	2011-856-14	30	2011-856-30	46	2011-856-46
15	2011-856-15	31	2011-856-31	47	2011-856-47
16	2011-856-16	32	2011-856-32	48	2011-856-48

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

No DNAs carrying the alleles to be amplified by primer solutions 5, 10, 13, 18, 19, 21, 22, 24, 26, 28, 29, 33, 35 and 43 to 48 were available. The specificities of the primers in primer solutions 5, 10, 18, 21, 26, 29, 33, 35 and 44 to 46 were tested by separately adding one or two additional 5'-primers, respectively one or two additional 3'-primers. In primer solutions 13, 19, 22, 28, 43, 47 and 48 it was only possible to test the 5'-primer, the 3'-primer was not possible to test. In primer solutions 5, 6, 18, 21, 26, 31, 33, 37, 45 and 46 one or two of the 5'-primers were not possible to test. In primer solutions 1, 7, 8, 10, 17, 35, 44 and 46 one or more of the 3'-primers were not possible to test. In primer solution 24 neither the 5'-primer nor the 3'-primer was possible to test. Additional primers in primer solutions 6 to 8, 27, 31 and 42 were tested by separately adding one 5'-primer or one 3'-primer.

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

Lot No.: **15M**

Lot-specific Information

www.olerup-ssp.com**Date of approval:** 2011-June-29**Approved by:****Quality Control, Supervisor**

Lot No.: **15M**

Lot-specific Information

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Declaration of Conformity

Product name: *Olerup* SSP® HLA-B*44**Product number:** 101.563-24u/03u**Lot number:** 15M**Intended use:** HLA-B*44 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, 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-June-29



Olle Olerup
Managing Director