

Lot No.: 23L

Lot-specific information

www.olerup-ssp.com

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-B*15 SSP

Product number: 101.516-24/04 – including Taq pol.
 Lot number: 23L
 Expiry date: 2013-September-01
 Number of tests: 24 tests – Product No. 101.516-24
 4 tests – Product No. 101.516-04
 Number of wells per test: 96

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2009-672-01	33	2011-840-33	65	2008-499-65
2	2009-672-02	34	2008-499-34	66	2009-672-66
3	2008-499-03	35	2008-499-35	67	2011-840-67
4	2009-672-04	36	2009-672-36	68	2008-499-68
5	2008-499-05	37	2008-499-37	69	2008-499-69
6	2008-499-06	38	2008-499-38	70	2011-840-70
7	2009-672-07	39	2008-499-39	71	2011-840-71
8	2008-499-08	40	2009-672-40	72	2011-840-72
9	2008-499-09	41	2008-499-41	73	2008-499-73
10	2011-840-10	42	2008-499-42	74	2008-499-74
11	2008-499-11	43	2008-499-43	75	2011-840-75
12	2008-499-12	44	2009-672-44	76	2008-499-76
13	2009-672-13	45	2009-672-45	77	2008-499-77
14	2011-840-14	46	2008-499-46	78	2008-499-78
15	2008-499-15	47	2008-499-47	79	2011-840-79
16	2008-499-16	48	2008-499-48	80	2009-672-80
17	2008-499-17	49	2008-499-49	81	2009-672-81
18	2008-499-18	50	2011-840-50	82	2009-672-82
19	2008-499-19	51	2009-672-51	83	2009-672-83
20	2008-499-20	52	2008-499-52	84	2011-840-84
21	2009-672-21	53	2008-499-53	85	2011-840-85
22	2008-499-22	54	2011-840-54	86	2011-840-86
23	2008-499-23	55	2008-499-55	87	2011-840-87
24	2011-840-24	56	2008-499-56	88	2009-672-88
25	2008-499-25	57	2008-499-57	89	2009-672-89
26	2008-499-26	58	2008-499-58	90	2011-840-90
27	2008-499-27	59	2011-840-59	91	2011-840-91
28	2008-499-28	60	2008-499-60	92	2009-672-92
29	2008-499-29	61	2009-672-61	93	2009-672-93
30	2008-499-30	62	2008-499-62	94	2009-672-94
31	2008-499-31	63	2008-499-63	95	2011-840-95
32	2011-840-32	64	2008-499-64	96	2009-672-96

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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 4, 10, 18, 24 to 27, 30 to 34, 36, 39, 49 to 65, 67 to 75, 77 to 80 and 82 to 89 and 91 to 96 were available. The specificities of the primers in primer solutions 10, 18, 24 to 27, 30, 31, 33, 34, 36, 49, 53, 59, 61, 65, 67, 70, 73, 85, 87, 91, 94 and 95 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer.

In primer solutions 4, 32, 39, 50 to 52, 54 to 56, 60, 62 to 64, 68, 69, 71, 77, 79, 82, 86, 88, 89, 92, 93 and 96 it was only possible to test the 5'-primers, the 3'-primers were not possible to test. In primer solutions 57, 58, 72, 74, 75, 78, 80, 83 and 84 it was only possible to test the 3'-primers, the 5'-primers were not possible to test.

In primer solutions 3, 12, 13, 19, 21, 24, 25, 33, 36, 59, 67, 70, 85, 87, 90, 91, 94 and 95 one or two 3'-primers were not possible to test. In primer solutions 10, 14, 20, 30, 31, 59, 61, 91 and 94 one or two 5'-primers were not possible to test.

Additional primers in primer solutions 16, 40, 42 and 90 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-April-08

Approved by:



Quality Control, Supervisor

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Declaration of Conformity

Product name: Olerup SSP® HLA-B*15**Product number:** 101.516-24/04**Lot number:** 23L**Intended use:** HLA-B*15 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.)

Saltsjöbaden, Sweden
2011-April-08



Olle Olerup