CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-A*02 SSP

Product number: **101.412-24u/04u – without *Taq* pol.**
Lot number: **65M**
Expiry date: **2014-April-01**
Number of tests: **24 tests – Product No. 101.412-24u**
4 tests – Product No. 101.412-04u
Number of wells per test: **96**

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2011-902-01	33	2011-902-33	65	2011-902-65
2	2011-902-02	34	2011-902-34	66	2011-902-66
3	2011-902-03	35	2011-902-35	67	2011-902-67
4	2011-902-04	36	2011-902-36	68	2011-902-68
5	2011-902-05	37	2011-902-37	69	2011-902-69
6	2011-902-06	38	2011-902-38	70	2011-902-70
7	2011-902-07	39	2011-902-39	71	2011-902-71
8	2011-902-08	40	2011-902-40	72	2011-902-72
9	2011-902-09	41	2011-902-41	73	2011-902-73
10	2011-902-10	42	2011-902-42	74	2011-902-74
11	2011-902-11	43	2011-902-43	75	2011-902-75
12	2011-902-12	44	2011-902-44	76	2011-902-76
13	2011-902-13	45	2011-902-45	77	2011-902-77
14	2011-902-14	46	2011-902-46	78	2011-902-78
15	2011-902-15	47	2011-902-47	79	2011-902-79
16	2011-902-16	48	2011-902-48	80	2011-902-80
17	2011-902-17	49	2011-902-49	81	2011-902-81
18	2011-902-18	50	2011-902-50	82	2011-902-82
19	2011-902-19	51	2011-902-51	83	2011-902-83
20	2011-902-20	52	2011-902-52	84	2011-902-84
21	2011-902-21	53	2011-902-53	85	2011-902-85
22	2011-902-22	54	2011-902-54	86	2011-902-86
23	2011-902-23	55	2011-902-55	87	2011-902-87
24	2011-902-24	56	2011-902-56	88	2011-902-88
25	2011-902-25	57	2011-902-57	89	2011-902-89
26	2011-902-26	58	2011-902-58	90	2011-902-90
27	2011-902-27	59	2011-902-59	91	2011-902-91
28	2011-902-28	60	2011-902-60	92	2011-902-92
29	2011-902-29	61	2011-902-61	93	2011-902-93
30	2011-902-30	62	2011-902-62	94	2011-902-94
31	2011-902-31	63	2011-902-63	95	2011-902-95
32	2011-902-32	64	2011-902-64	96	2011-902-96

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 15, 20, 21, 24, 26, 29, 30, 32, 33, 38, 40, 44, 46 to 48, 50, 52, 54, 56, 57, 59, 63 to 74, 76 to 90 and 92 to 96 were available.
The specificities of the primers in primer solutions 15, 20, 26, 30, 32, 33, 40, 46, 52, 56, 57, 69, 72, 77, 78, 80, 82, 84, 88 and 92 to 95 were tested by separately adding additional 5'-prime, respectively additional 3'-primers.
In primer solutions 21, 24, 29, 47, 54, 59, 65, 68, 70, 71, 73, 76, 79, 81, 85 to 87, 89 and 96 it was only possible to test the 5'-primer, the 3'-primer were not possible to test.
In primer solutions 38, 44, 48, 63, 64, 66, 67, 74 and 90 it was only possible to test the 3'-primer, the 5'-primer was not possible to test.
In primer solutions 50 and 83 neither the 5'-primers nor the 3'-primers were possible to test.
In primer solutions 4, 8, 12, 15, 17, 18, 26, 28, 30, 32, 33, 35 to 37, 39, 40, 43, 45, 46, 56, 57, 69, 72, 75, 77, 78, 80, 82, 84, 88, 92 and 94 one or several of the 3'-primers were not possible to test.
In primer solutions 11, 13, 14, 23, 30, 34, 41, 46, 77, 78, 80, 82, 84, 91, 93 and 94 one or more of the 5'-primers were not possible to test.
Additional primers in primer solutions 10 to 13, 17, 23, 27, 31, 34 and 41 were tested by separately adding either one additional 3'-primer or one additional 5'-primer.

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

Date of approval: 2011-November-09

Approved by:

Åsa Olausson

Production Quality Control

Declaration of Conformity

Product name: *Olerup* SSP® HLA-A*02
Product number: 101.412-24u/04u
Lot number: 65M

Intended use: HLA-A*02 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, 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.

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-November-09

Ann-Cathrin Jareman
Head of QA and Regulatory Affairs