

101.412-24/04 – including *Taq* pol., IFU-01
 101.412-24u/04u – without *Taq* polymerase, IFU-02

Visit www.olerup-ssp.com for
 “Instructions for Use” (IFU)

Lot No.: **93N**

Lot-specific information

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-A*02 SSP

Product number:

101.412-24/04 – including *Taq* pol.

101.412-24u/04u – without *Taq* pol.

Lot number:

93N

Expiry date:

2014-December-01

Number of tests:

24 tests – Product No. 101.412-24/24u

4 tests – Product No. 101.412-04/04u

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	2012-033-02	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	2012-033-16	48	2011-902-48	80	2011-902-80
17	2011-902-17	49	2011-902-49	81	2012-033-81
18	2012-033-18	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	2012-033-86
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

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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 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'-primers respectively 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: 2012-June-15

Approved by:



Production Quality Control

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Lot-specific information

Declaration of Conformity

Product name: Olerup SSP® HLA-A*02
Product number: 101.412-24/24u, -04/04u
Lot number: 93N

Intended use: HLA-A*02 high resolution histocompatibility testing

Manufacturer: Olerup SSP AB
Franzengatan 5
SE-112 51 Stockholm, Sweden
Phone: +46-8-717 88 27
Fax: +46-8-717 88 18

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
2012-June-15

Ann-Cathrin Jareman
Head of QA and Regulatory Affairs