

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

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

Lot No.: 15V

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: 15V
Expiry date: 2016-July-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: 95+1

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2013-282-01	33	2011-902-33	65	2013-282-65
2	2012-033-02	34	2013-180-34	66	2013-282-66
3	2012-066-03	35	2013-282-35	67	2013-282-67
4	2011-902-04	36	2011-902-36	68	2013-282-68
5	2013-282-05	37	2012-066-37	69	2012-066-69
6	2011-902-06	38	2013-180-38	70	2013-282-70
7	2011-902-07	39	2013-282-39	71	2013-282-71
8	2011-902-08	40	2013-282-40	72	2011-902-72
9	2011-902-09	41	2011-902-41	73	2012-066-73
10	2011-902-10	42	2011-902-42	74	2012-066-74
11	2011-902-11	43	2011-902-43	75	2013-282-75
12	2011-902-12	44	2013-282-44	76	2013-282-76
13	2013-180-13	45	2011-902-45	77	2013-180-77
14	2011-902-14	46	2013-180-46	78	2012-066-78
15	2011-902-15	47	2012-066-47	79	2013-282-79
16	2012-033-16	48	2011-902-48	80	2012-066-80
17	2011-902-17	49	2012-066-49	81	2012-066-81
18	2013-180-18	50	2011-902-50	82	2013-180-82
19	2012-066-19	51	2011-902-51	83	2013-282-83
20	2013-282-20	52	2011-902-52	84	2012-066-84
21	2012-066-21	53	2011-902-53	85	2013-180-85
22	2011-902-22	54	2011-902-54	86	2012-066-86
23	2011-902-23	55	2012-066-55	87	2013-180-87
24	2013-282-24	56	2011-902-56	88	2013-282-88
25	2013-282-25	57	2011-902-57	89	2013-282-89
26	2011-902-26	58	2011-902-58	90	2013-282-90
27	2013-282-27	59	2012-066-59	91	2012-066-91
28	2011-902-28	60	2011-902-60	92	2013-282-92
29	2011-902-29	61	2011-902-61	93	2011-902-93
30	2011-902-30	62	2011-902-62	94	2013-282-94
31	2011-902-31	63	2013-180-63	95	2011-902-95
32	2011-902-32	64	2012-066-64		

The negative control primer pairs, **Production No. 2013-271-01**, can detect contamination with PCR products diluted 10⁻⁷.

101.412-24/04 – including *Taq* polymerase, IFU-01
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Lot No.: **15V**

Lot-specific information

Results of Quality Control: No false positive or false negative amplifications
obtained.

Date of approval: 2014-February-06

Approved by:



Production Quality Control

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Lot No.: **15V**

Lot-specific information

Declaration of Conformity

Product name: *Olerup* SSP® HLA-A*02
Product number: 101.412-24/24u, -04/04u
Lot number: 15V

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 13485:2012, 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
2014-February-06

Ann-Cathrin Jareman
Head of QA and Regulatory Affairs