101.702.24/06– including *Taq* pol., IFU-01
101.702.24u/06u – without *Taq* pol., IFU-02

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

Lot No.: 02R Lot-specific information

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-A-B-C SSP Combi Tray

Product number: 101.702-24/06 – including *Taq* pol.
101.702-24u/06u – without *Taq* pol.

Lot number: 02R
Expiry date: 2015-February-01
Number of tests: 24 tests – Product No. 101.702-24/24u
6 tests – Product No. 101.702-06/06u
Number of wells per test: 95 + 1

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2011-931-01	9	2012-019-09	17	2012-019-17
2	2012-019-02	10	2012-041-10	18	2012-019-18
3	2011-931-03	11	2012-019-11	19	2012-019-19
4	2012-019-04	12	2012-019-12	20	2012-019-20
5	2012-019-05	13	2012-019-13	21	2012-019-21
6	2012-019-06	14	2012-041-14	22	2012-019-22
7	2012-019-07	15	2012-019-15	23	2012-019-23
8	2012-019-08	16	2012-019-16	24	2011-931-24

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

Additional 5'- and 3'-primers in primer solutions 4, 5, 7, 8, 12, 14 to 17 and 20 to 23 were tested by separately adding one 3'-primer, respectively one 5'-primer. Additional 5'-primers in primer solutions 1 and 10 were tested by separately adding one 3'-primer. Additional 3'-primers in primer solutions 3, 6, 18 and 19 were tested by separately adding one 5'-primer.
In primer solutions 2, 9, 10, 11 and 15 one or two 5'-primers were not possible to test, and in primer solutions 3, 8, 18 and 19 one 3'-primer was not possible to test.

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
25	2012-042-01	41	2012-042-17	57	2012-042-33
26	2012-042-02	42	2012-042-18	58	2012-042-34
27	2012-042-03	43	2012-042-19	59	2012-042-35
28	2012-042-04	44	2012-042-20	60	2012-042-36
29	2012-042-05	45	2012-042-21	61	2012-042-37
30	2012-042-06	46	2012-042-22	62	2012-042-38
31	2012-042-07	47	2012-042-23	63	2012-042-39
32	2012-042-08	48	2012-042-24	64	2012-042-40
33	2012-042-09	49	2012-042-25	65	2012-042-41
34	2012-042-10	50	2012-042-26	66	2012-042-42
35	2012-042-11	51	2012-042-27	67	2012-042-43
36	2012-042-12	52	2012-042-28	68	2012-042-44
37	2012-042-13	53	2012-042-29	69	2012-042-45
38	2012-042-14	54	2012-042-30	70	2012-042-46
39	2012-042-15	55	2012-042-31	71	2012-042-47
40	2012-042-16	56	2012-042-32	72	2012-042-48

Lot No.: 02R **Lot-specific information**

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

Additional 5'-primers and 3'-primers in primer solutions 27, 30, 38, 43, 53, 55 and 64 were tested by separately adding one additional 3'-primer, respectively one additional 5'-primer. Additional 3'-primers in primer solutions 26, 37, 39 and 59 were tested by separately adding one additional 5'-primer. Additional 5'-primers in primer solutions 25, 45, 49 and 72 were tested by separately adding one additional 3'-primer.
In primer mixes 55 and 66 one 5'-primer was not possible to test, and in primer mixes 62 and 66 one 3'-primer was not possible to test.

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
73	2011-888-01	81	2011-888-09	89	2012-003-17
74	2011-888-02	82	2011-888-10	90	2011-888-18
75	2011-888-03	83	2011-888-11	91	2011-888-19
76	2011-888-04	84	2012-003-12	92	2011-888-20
77	2011-888-05	85	2012-043-13	93	2011-888-21
78	2012-003-06	86	2012-043-14	94	2011-888-22
79	2012-003-07	87	2011-888-15	95	2012-043-23
80	2011-888-08	88	2012-003-16		

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

Additional 5'-primers and 3'-primers in primer solutions 74, 79, 84, 86 to 88 and 94 were tested by separately adding one additional 3'-primer, respectively one additional 5'-primer. Additional 3'-primers in primer solution 82, 90 and 91 were tested by separately adding one additional 5'-primer. Additional 5'-primers in primer solutions 78, 85 and 95 were tested by separately adding one additional 3'-primer.
In primer solution 95 one 5'-primer was not possible to test, and in primer solutions 75, 83, 84, 86 and 90 one or two 3'-primers were not possible to test.

The negative control primer pairs, **Production No. 2011-917-01**, can detect contamination with PCR products diluted 10^{-7}.

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

Date of approval: 2012-September-06

Approved by:

Kurin Olattsson

Production Quality Control

101.702.24/06– including *Taq* pol., IFU-01
101.702.24u/06u – without *Taq* pol., IFU-02

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Lot No.: 02R **Lot-specific information**

Declaration of Conformity

Product name: *Olerup* SSP® HLA-A-B-C SSP Combi Tray
Product number: 101.702-24/24u, -06/06u
Lot number: 02R

Intended use: HLA-A, HLA-B and HLA-C low resolution histo-compatibility 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, 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
2015-January-20

Daniel Malica
Head of QA and Regulatory Affairs