

101.708-24 – including *Taq* polymerase, IFU-01101.708-24u – without *Taq* polymerase, IFU-02Visit www.olerup-ssp.com for

“Instructions for Use” (IFU)

Lot No.: 70S

Lot-specific information

CERTIFICATE OF ANALYSIS**Olerup SSP® HLA-A-B-DR-DQ SSP Combi Tray**

Product number: 101.708-24 – including *Taq* pol.
 101.708-24u – without *Taq* pol.

Lot number: 70S

Expiry date: 2016-March-01

Number of tests: 24 tests

Number of wells per test: 95 +1

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2013-217-01	9	2012-117-10	17	2013-217-18
2	2012-117-02	10	2012-117-11	18	2013-217-19
3	2013-217-03	11	2013-217-12	19	2012-117-20
4	2012-117-04	12	2012-117-13	20	2013-217-21
5	2012-117-06	13	2013-217-14	21	2012-117-23
6	2012-117-07	14	2013-217-15		
7	2012-117-08	15	2012-117-16		
8	2012-117-09	16	2012-117-17		

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, 6, 7, 11, 13 to 16 and 19 to 21 were tested by separately adding one 3'-primer, respectively one 5'-primer. Additional 5'-primers in primer solution 1 and 18 were tested by separately adding one 3'-primer. Additional 3'-primers in primer solutions 3 and 17 were tested by separately adding one 5'-primer.

In primer solutions 2, 10, 11 and 14 one or two 5'-primers were not possible to test, and in primer solutions 3, 5, 7, 11, 12, 15 and 17 one 3'-primer was not possible to test.

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
22	2013-218-48	38	2013-218-18	54	2013-187-36
23	2013-187-02	39	2013-187-19	55	2013-187-37
24	2013-218-03	40	2013-187-20	56	2013-187-38
25	2013-187-04	41	2013-187-21	57	2013-187-39
26	2013-187-05	42	2013-208-22	58	2013-187-40
27	2013-208-06	43	2013-208-23	59	2013-187-41
28	2013-187-07	44	2013-208-24	60	2013-218-42
29	2013-218-08	45	2013-187-25	61	2013-187-44
30	2013-218-09	46	2013-187-27	62	2013-187-45
31	2013-187-10	47	2013-187-28	63	2013-187-46
32	2013-187-11	48	2013-229-29	64	2013-187-47
33	2013-187-13	49	2013-187-31		
34	2013-187-14	50	2013-187-32		
35	2013-187-15	51	2013-187-33		
36	2013-187-16	52	2013-187-34		
37	2013-187-17	53	2013-187-35		

101.708-24 – including *Taq* polymerase, IFU-01101.708-24u – without *Taq* polymerase, IFU-02Visit www.olerup-ssp.com for

“Instructions for Use” (IFU)

Lot No.: 70S**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 24, 27, 34, 39, 48, 49 and 58 were tested by separately adding one additional 3'-primer, respectively one additional 5'-primer. Additional 3'-primers in primer solutions 23, 29, 33, 35, 38 and 53 were tested by separately adding one additional 5'-primer. Additional 5'-primers in primer solutions 22, 41 and 45 were tested by separately adding one additional 3'-primer.

In primer mixes 49 and 60 one 5'-primer was not possible to test, and in primer mixes 24, 56 and 60 one or two 3'-primer was not possible to test.

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
65	2013-219-01	73	2012-090-09	81	2012-090-17
66	2012-090-02	74	2012-090-10	82	2012-090-18
67	2012-090-03	75	2012-090-11	83	2012-090-19
68	2012-090-04	76	2012-090-12	84	2013-219-20
69	2012-090-05	77	2012-090-13	85	2012-088-29
70	2012-090-06	78	2012-090-14	86	2012-088-30
71	2012-090-07	79	2012-090-15	87	2012-088-31
72	2012-090-08	80	2012-090-16		

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 73, 75 and 82 were tested by separately adding one 3'-primer, respectively one 5'-primer.

Additional 5'-primers in primer solutions 70, 76, 79 and 80 were tested by separately adding one 3'-primer. Additional 3'-primers in primer solutions 65, 67, 68, 74 and 84 were tested by separately adding one 5'-primer.

One, two or three of the 5'-primers in primer solution 65, 67, 68, 72 to 74, 77, 79, 80 and 84 were not possible to test. One or two of the 3'-primers in primer solution 65, 67, 68, 77, 79 and 86 were not possible to test.

Well No.	Production No.
88	2013-231-01
89	2013-231-02
90	2013-231-03
91	2013-231-04
92	2013-161-05
93	2013-161-06
94	2013-231-07
95	2013-231-08

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

One additional 5'-primer in primer solutions 89 and 94 were tested by separately adding one additional 3'-primer.

In primer mixes 88, 89 and 90 one 5'-primer was not possible to test, and in primer mixes 89, 91 and 94 one 3'-primer was not possible to test.

101.708-24 – including *Taq* polymerase, IFU-01
101.708-24u – without *Taq* polymerase, IFU-02

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

Lot No.: **70S**

Lot-specific information

The negative control primer pairs, **Production No. 2013-165-01**, can detect contamination with PCR products diluted 10^{-7} .

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

Date of approval: 2013-September-25

Approved by

Karin Olsson

Production Quality Control

101.708-24 – including *Taq* polymerase, IFU-01
101.708-24u – without *Taq* polymerase, IFU-02

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

Lot No.: **70S**

Lot-specific information

Declaration of Conformity

Product name: Olerup SSP® HLA-A-B-DR-DQ SSP Combi Tray
Product number: 101.708-24/24u
Lot number: 70S

Intended use: HLA-A, HLA-B, HLA-DR and HLA-DQ 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 13485:2012, 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.

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-December-18

Daniel Malica
Head of QA and Regulatory Affairs