

101.522-24/03– including *Taq* pol., IFU-01
 101.522-24u/03u – without *Taq* pol., IFU-02

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

Lot No.: **54S**

Lot-specific information

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-B*35 SSP

Product number:

**101.522-24/03 – including *Taq* pol.
 101.522-24u/03u – without *Taq* pol.**

Lot number:

54S

Expiry date:

2016-February-01

Number of tests:

**24 tests – Product No. 101.522-24/24u
 3 tests – Product No. 101.522-03/03u**

Number of wells per test:

79

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2012-058-01	31	2012-058-31	61	2012-058-61
2	2012-058-02	32	2012-058-32	62	2012-058-62
3	2012-058-03	33	2012-058-33	63	2012-058-63
4	2012-058-04	34	2012-058-34	64	2012-058-64
5	2012-058-05	35	2012-058-35	65	2012-058-65
6	2012-058-06	36	2013-206-36	66	2012-058-66
7	2012-058-07	37	2012-058-37	67	2012-058-67
8	2012-058-08	38	2012-058-38	68	2012-058-68
9	2012-058-09	39	2012-058-39	69	2012-058-69
10	2012-058-10	40	2012-058-40	70	2013-206-70
11	2012-058-11	41	2013-206-41	71	2012-058-71
12	2012-058-12	42	2012-058-42	72	2012-058-72
13	2012-058-13	43	2012-058-43	73	2012-058-73
14	2012-058-14	44	2012-058-44	74	2012-058-74
15	2012-058-15	45	2012-058-45	75	2012-058-75
16	2012-058-16	46	2013-206-46	76	2012-058-76
17	2013-206-17	47	2012-058-47	77	2013-206-77
18	2012-058-18	48	2012-058-48	78	2012-058-78
19	2013-206-19	49	2013-206-49	79	2012-058-79
20	2012-058-20	50	2013-206-50		
21	2012-058-21	51	2012-058-51		
22	2012-058-22	52	2012-058-52		
23	2012-058-23	53	2012-058-53		
24	2012-058-24	54	2013-206-54		
25	2012-058-25	55	2012-058-55		
26	2012-058-26	56	2012-058-56		
27	2012-058-27	57	2012-058-57		
28	2012-058-28	58	2012-058-58		
29	2012-058-29	59	2012-058-59		
30	2012-058-30	60	2012-058-60		

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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 10, 35, 36, 41 to 44, 50 to 71, 74 and 76 to 79 were available.

The specificities of the primers in primer solutions 10, 35, 36, 41, 43, 44, 50, 58, 61, 63, 64, 68, 69 and 77 were tested by separately adding one or two additional 5'-primers, respectively one or two additional 3'-primers.

In primer solutions 42, 52 to 55, 57, 62, 67 and 74 it was only possible to test the 5'-primers, the 3'-primers were not possible to test.

In primer solutions 51, 56, 59, 60, 65, 66, 70, 71, 76, 78 and 79 it was only possible to test the 3'-primers, the 5'-primers were not possible to test.

In primer solutions 10, 16, 33, 35, 36, 43, 64, 69 and 77 one, two or three of the 5'-primers were not possible to test, and in primer solutions 10, 12, 41, 43, 44, 49, 50, 58, 61, 64, 69, 75 and 77 one or two of the 3'-primers were not possible to test.

Additional primers in primer solutions 3, 22, 26, 31 and 33 were tested by separately adding one 5'-primer and/or one 3'-primer.

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

Date of approval: 2013-September-04

Approved by:



Production Quality Control

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Lot-specific information

Declaration of Conformity

Product name: Olerup SSP® HLA-B*35
Product number: 101.522-24/24u, -03/03u
Lot number: 54S

Intended use: HLA-B*35 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, 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-DEC-18

Daniel Malica
Head of QA and Regulatory Affairs