

101. 516-24/04 – including *Taq* polymerase, IFU-01  
 101. 516-24u/04u – without *Taq* polymerase, IFU-02

Visit [www.olerup-ssp.com](http://www.olerup-ssp.com) for  
 “Instructions for Use” (IFU)

Lot No.: **94N**

Lot-specific information

## CERTIFICATE OF ANALYSIS

**Olerup SSP® HLA-B\*15 SSP**

Product number:

101.516-24/04 – including *Taq* pol.

101.516-24u/04u – without *Taq* pol.

Lot number:

94N

Expiry date:

2015-January-01

Number of tests:

24 tests – Product No. 101.516-24/24u

4 tests – Product No. 101.516-04/04u

Number of wells per test:

96

### Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2009-672-01	33	2011-840-33	65	2008-499-65
2	2009-672-02	34	2008-499-34	66	2009-672-66
3	2008-499-03	35	2008-499-35	67	2011-840-67
4	2009-672-04	36	2009-672-36	68	2008-499-68
5	2008-499-05	37	2008-499-37	69	2008-499-69
6	2008-499-06	38	2008-499-38	70	2011-840-70
7	2009-672-07	39	2008-499-39	71	2011-840-71
8	2008-499-08	40	2009-672-40	72	2012-034-72
9	2012-034-09	41	2008-499-41	73	2012-034-73
10	2012-034-10	42	2008-499-42	74	2008-499-74
11	2012-034-11	43	2008-499-43	75	2011-840-75
12	2008-499-12	44	2009-672-44	76	2008-499-76
13	2009-672-13	45	2009-672-45	77	2008-499-77
14	2011-840-14	46	2008-499-46	78	2008-499-78
15	2008-499-15	47	2008-499-47	79	2012-034-79
16	2008-499-16	48	2008-499-48	80	2009-672-80
17	2008-499-17	49	2012-034-49	81	2009-672-81
18	2008-499-18	50	2012-034-50	82	2009-672-82
19	2008-499-19	51	2009-672-51	83	2009-672-83
20	2008-499-20	52	2012-034-52	84	2012-034-84
21	2009-672-21	53	2008-499-53	85	2011-840-85
22	2008-499-22	54	2011-840-54	86	2011-840-86
23	2008-499-23	55	2012-034-55	87	2011-840-87
24	2011-840-24	56	2012-034-56	88	2012-034-88
25	2008-499-25	57	2008-499-57	89	2012-034-89
26	2008-499-26	58	2008-499-58	90	2012-034-90
27	2008-499-27	59	2011-840-59	91	2011-840-91
28	2008-499-28	60	2012-034-60	92	2009-672-92
29	2008-499-29	61	2009-672-61	93	2012-034-93
30	2008-499-30	62	2008-499-62	94	2009-672-94
31	2008-499-31	63	2008-499-63	95	2011-840-95
32	2011-840-32	64	2008-499-64	96	2012-034-96

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**Lot-specific information**

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 4, 10, 11, 18, 24 to 27, 30 to 34, 36, 39, 49 to 65, 67 to 72, 74, 75, 77 to 80, 82 to 89 and 91 to 96 were available. The specificities of the primers in primer solutions 9, 10, 18, 24 to 27, 30, 31, 33, 34, 36, 49, 53, 59, 61, 65, 67, 70, 72, 85, 87, 91 and 94 to 96 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer.

In primer solutions 4, 32, 39, 50 to 52, 54 to 56, 62 to 64, 68, 69, 71, 77, 79, 82, 86, 88, 89, 92 and 93 it was only possible to test the 5'-primers, the 3'-primers were not possible to test.

In primer solutions 57, 58, 74, 75, 78, 80, 83 and 84 it was only possible to test the 3'-primers, the 5'-primers were not possible to test.

In primer solutions 3, 12, 13, 19, 21, 24, 25, 33, 36, 59, 67, 70, 72, 85, 87, 90, 91 and 94 to 96 one or two 3'-primers were not possible to test.

In primer solutions 10, 14, 20, 30, 31, 59, 61, 72, 91, 94 and 96 one or two 5'-primers were not possible to test.

Additional primers in primer solutions 16, 40, 42, 60, 73 and 90 were tested by separately adding one additional 5'-primer or one additional 3'-primer.

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

**Date of approval:** 2012-July-13

**Approved by:**



**Production Quality Control**

101. 516-24/04 – including *Taq* polymerase, IFU-01  
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## Declaration of Conformity

**Product name:** Olerup SSP® HLA-B\*15  
**Product number:** 101.516-24/24u, -04/04u  
**Lot number:** 94N

**Intended use:** HLA-B\*15 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, 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, Middlesbrough Office Village, Siskin Drive, Coventry CV3 4FJ, United Kingdom.  
(Notified Body number: 0088.)

Stockholm, Sweden  
2012-July-13

Ann-Cathrin Jareman  
Head of QA and Regulatory Affairs