

101.563-24/03 – including *Taq* pol., IFU-01
 101.563-24u/03u – without *Taq* pol., IFU-02

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

Lot No.: **69R**

Lot-specific information

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-B*44 SSP

Product number:

101.563-24/03 – including *Taq* pol.
 101.563-24u/03u – without *Taq* pol.
69R

Lot number:

2015-July-01

Expiry date:

Number of tests:

24 tests – Product No. 101.563-24/24u

3 tests – Product No. 101.563-03/03u

Number of wells per test:

56

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2011-856-01	21	2012-989-21	41	2011-856-41
2	2013-115-02	22	2011-856-22	42	2011-856-42
3	2011-856-03	23	2011-856-23	43	2011-856-43
4	2011-856-04	24	2011-856-24	44	2011-856-44
5	2013-115-05			45	2011-856-45
6	2011-856-06	25	2011-856-25	46	2011-856-46
7	2011-856-07	26	2011-856-26	47	2011-856-47
8	2011-856-08	27	2011-856-27	48	2011-856-48
		28	2011-856-28		
9	2013-115-09	29	2013-115-29	49	2013-115-49
10	2011-856-10	30	2011-856-30	50	2013-115-50
11	2013-115-11	31	2011-856-31	51	2012-989-51
12	2011-856-12	32	2011-856-32	52	2013-115-52
13	2011-856-13			53	2012-989-53
14	2011-856-14	33	2011-856-33	54	2013-115-54
15	2011-856-15	34	2013-115-34	55	2013-115-55
16	2011-856-16	35	2011-856-35	56	2013-115-56
		36	2013-115-36		
17	2011-856-17	37	2011-856-37		
18	2013-115-18	38	2011-856-38		
19	2011-856-19	39	2011-856-39		
20	2011-856-20	40	2011-856-40		

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, 18, 19, 21, 22, 24, 26, 28, 33 and 43 to 56 were available. The specificities of the primers in primer solutions 10, 18, 21, 26, 33, 44 to 46, 50, 55 and 56 were tested by separately adding one or two additional 5'-primers, respectively one or two additional 3'-primers. In primer solutions 19, 22, 28, 43, 47, 48 and 54 it was only possible to test the 5'-primer, the 3'-primer was not possible to test. In primer solutions 49 and 51 to 53 it was only possible to test the 3'-primer, the 5'-primer was not possible to test. In primer solution 24 neither the 5'-primer nor the 3'-primer was possible to test.

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In primer solutions 5, 6, 18, 21, 26, 31, 33, 37, 45 and 46 one or two of the 5'-primers were not possible to test. In primer solutions 1, 2, 7, 8, 10, 17, 35, 36, 44, 46, 50 and 56 one or more of the 3'-primers were not possible to test.

Additional primers in primer solutions 6 to 8, 27, 29, 31, 35, 36 and 42 were tested by separately adding one 5'-primer or one 3'-primer.

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

Date of approval: 2013-February-11

Approved by:

Karin Clattorze

Production Quality Control

101.563-24/03 – including *Taq* pol., IFU-01
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Lot-specific information

Declaration of Conformity

Product name: Olerup SSP® HLA-B*44
Product number: 101.563-24/24u, -03/03u
Lot number: 69R

Intended use: HLA-B*44 high resolution histocompatibility testing

Manufacturer: Olerup SSP AB
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SE-112 51 Stockholm, Sweden
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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
2015-January-19

Daniel Malica
Head of QA and Regulatory Affairs