

Lot No.: 14L

Lot-specific information

www.olerup-ssp.com

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-A*26 SSP

Product number: 101.424-12 – including Taq polymerase
Lot number: 14L
Expiry date: 2013-September-01
Number of tests: 12
Number of wells per test: 43

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2011-831-01	17	2010-727-17	33	2011-831-33
2	2010-727-02	18	2011-831-18	34	2011-831-34
3	2010-727-03	19	2010-727-19	35	2011-831-35
4	2010-727-04	20	2010-727-20	36	2011-831-36
5	2010-727-05	21	2010-727-21	37	2011-831-37
6	2010-727-06	22	2010-727-22	38	2011-831-38
7	2010-727-07	23	2011-831-23	39	2011-831-39
8	2010-727-08	24	2010-727-24	40	2011-831-40
9	2010-727-09	25	2010-727-25	41	2011-831-41
10	2010-727-10	26	2010-727-26	42	2011-831-42
11	2010-727-11	27	2010-727-27	43	2011-831-43
12	2010-727-12	28	2010-727-28		
13	2010-727-13	29	2010-727-29		
14	2010-727-14	30	2011-831-30		
15	2010-727-15	31	2010-727-31		
16	2010-727-16	32	2011-831-32		

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 6, 8 to 11, 13, 18 to 23, 26, 27, 29 to 31, 33, 34, 36-41 and 43 were available.

The specificities of the primers in primer solutions 6, 8 to 11, 18, 19, 21, 29, 34, 36, 37, 39 and 43 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer. In primer solutions 23, 26, 30, 40 and 41 it was only possible to test the 5'-primers. In primer solutions 13, 20, 22, 27 and 31 it was only possible to test the 3'-primer. In primer solutions 1, 6, 8, 16, 21, 29, 32 34 36, 37 and 39 one or two of the 3'-primers were not possible to test. In primer solutions 4, 10, 11, 18, 19, 21 35 and 37 one of the 5'-primers was not possible to test. Additional primers in primer solutions 7 and 12 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer.

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

Date of approval: 2012-May-10

Approved by:



Production Quality Control

Declaration of Conformity

Product name: Olerup SSP® HLA-A*26
Product number: 101.424-12
Lot number: 14L

Intended use: HLA-A*26 high resolution histocompatibility testing

Manufacturer: Olerup SSP AB
Hasselstigen 1
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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, Hasselstigen 1, SE-133 33 Saltsjöbaden, 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
2012-May-10


Ann-Cathrin Jareman
Head of QA and Regulatory Affairs