

Lot No.: 85K

Lot-specific Information

www.olerup-ssp.com

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-C*03 SSP

Product number: 101.611-12u – without Taq polymerase
Lot number: 85K
Expiry date: 2013-July-01
Number of tests: 12
Number of wells per test: 48

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2007-370-01	17	2010-807-17	33	2009-662-33
2	2007-370-02	18	2010-807-18	34	2010-807-34
3	2007-370-03	19	2010-807-19	35	2010-807-35
4	2008-542-04	20	2010-807-20	36	2009-662-36
5	2007-370-05	21	2010-807-21	37	2009-662-37
6	2009-662-06	22	2009-662-22	38	2010-807-38
7	2009-662-07	23	2010-807-23	39	2010-807-39
8	2008-542-08	24	2010-807-24	40	2010-807-40
9	2007-370-09	25	2009-662-25	41	2010-807-41
10	2007-370-10	26	2009-662-26	42	2010-807-42
11	2010-807-11	27	2009-662-27	43	2010-807-43
12	2007-370-12	28	2009-662-28	44	2010-807-44
13	2007-370-13	29	2010-807-29	45	2010-807-45
14	2007-370-14	30	2010-807-30	46	2010-807-46
15	2010-807-15	31	2009-662-31	47	2010-807-47
16	2007-370-16	32	2010-807-32	48	2010-807-48

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

No DNAs carrying the alleles to be amplified by primer solutions 8, 11, 12, 17 to 21, 23 to 26, 29, 31 to 36, 38 to 45, 47 and 48 were available. The specificities of the primers in primer solutions 8, 11, 12, 17, 18, 21, 23, 25, 26, 29, 32, 33, 35, 39, 41 to 43, 47 and 48 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer. In primer solutions 20, 31, 36 and 45 it was only possible to test the 3'-primers, the 5'-primers were not possible to test. In primer solutions 19, 24, 34, 38, 40 and 44 it was only possible to test the 5'-primer, the 3'-primer was not possible to test. In primer solutions 8, 17, 18, 21, 22, 41 and 43 it was not possible to test one or two of the 5'-primers and in primer solutions 17, 29, 30, 32, 33, 35, 39, 41 and 42 one, two or three 3'-primers were not possible to test. Finally, additional primers in primer solutions 6, 22 and 30 were tested by separately adding an additional 5'- or 3'-primer.

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

Date of approval: 2011-January-31

Approved by:



Quality Control, Supervisor

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Declaration of Conformity

Product name: Olerup SSP® HLA-C*03

Product number: 101.611-12u

Lot number: 85K

Intended use: HLA-C*03 high resolution histocompatibility testing

Manufacturer: Olerup SSP AB
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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 III, 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.

Saltsjöbaden, Sweden
2011- January-31



Olle Olerup
Managing Director