

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-C*07 SSP

Product number: 101.615-24u/04u – without *Taq* pol.
Lot number: 03M
Expiry date: 2013-October-01
Number of tests: 24 tests – Product No. 101.615-24u
 4 tests – Product No. 101.615-04u
Number of wells per test: 48

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2010-698-01	17	2010-698-17	33	2011-841-33
2	2010-698-02	18	2010-698-18	34	2010-698-34
3	2011-841-03	19	2010-698-19	35	2010-698-35
4	2010-698-04	20	2010-698-20	36	2010-698-36
5	2010-698-05	21	2010-698-21	37	2010-698-37
6	2010-698-06	22	2010-698-22	38	2010-698-38
7	2010-698-07	23	2011-841-23	39	2010-698-39
8	2010-698-08	24	2010-698-24	40	2010-698-40
9	2010-698-09	25	2010-698-25	41	2010-698-41
10	2010-698-10	26	2010-698-26	42	2010-698-42
11	2010-698-11	27	2010-698-27	43	2010-698-43
12	2010-698-12	28	2011-841-28	44	2010-698-44
13	2010-698-13	29	2011-841-29	45	2010-698-45
14	2010-698-14	30	2011-841-30	46	2011-841-46
15	2010-698-15	31	2010-698-31	47	2011-841-47
16	2010-698-16	32	2010-698-32	48	2010-698-48

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 5, 10, 11, 13 to 15, 18 to 20, 23 to 31, 34 to 39, 41 to 44 and 46 to 48 were available. The specificities of the primers in primer solutions 5, 10, 11, 13 to 15, 18 to 20, 24 to 27, 31, 35 to 38, 44 and 46 to 48 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer. In primer solution 43 it was only possible to test the 5'-primer, the 3'-primer were not possible to test. In primer solutions 23, 28 to 30, 34, 39, 41 and 42 it was only possible to test the 3'-primers, the 5'-primers were not possible to test. In primer solutions 8, 11, 20, 22, 24, 26, 33, 37, 38, 44 and 46 to 48 one or two 5'-primers were not possible to test, and in primer solutions 5, 9, 13, 15, 18, 19, 21, 25, 32, 35, 38, 40 and 46 to 48 one or two 3'-primers were not possible to test. Additional primers in primer solutions 2, 8, 9, 21 and 33 were tested by separately adding either one 5'-primer or one 3'-primer.

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Lot-specific Information

www.olerup-ssp.com

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

Date of approval: 2012-June-11

Approved by:

Isa Olsson

Production Quality Control

Lot No.: **03M**

Lot-specific Information

www.olerup-ssp.com

Declaration of Conformity

Product name: Olerup SSP® HLA-C*07
Product number: 101.615-24u/04u
Lot number: 03M

Intended use: HLA-C*07 high resolution histocompatibility testing

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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, Franzengatan 5, SE-112 51 Stockholm, Sweden.

The Authorized Representative located within the Community is: Olerup SSP AB.

Stockholm, Sweden
2012-June-11



Ann-Cathrin Jareman
Head of QA and Regulatory Affairs