

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-C*06 SSP

Product number: 101.614-12u – without Taq polymerase
Lot number: 31M
Expiry date: 2014-January-01
Number of tests: 12
Number of wells per test: 31

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2011-872-01	13	2011-872-13	25	2011-872-25
2	2011-872-02	14	2011-872-14	26	2011-872-26
3	2011-872-03	15	2011-872-15	27	2011-872-27
4	2011-872-04	16	2011-872-16	28	2011-872-28
5	2011-872-05	17	2011-872-17	29	2011-872-29
6	2011-872-06	18	2011-872-18	30	2011-872-30
7	2011-872-07	19	2011-872-19	31	2011-872-31
8	2011-872-08	20	2011-872-20		
9	2011-872-09	21	2011-872-21		
10	2011-872-10	22	2011-872-22		
11	2011-872-11	23	2011-872-23		
12	2011-872-12	24	2011-872-24		

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 7, 8, 10, 12 to 22 and 24 to 31 were available. The specificity of the primers in primer solutions 8, 10, 12, 14, 16, 19, 21, 22, 24, 27 and 30 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer. In primer solutions 13, 17, 20 and 25 it was only possible to test the 5'-primer, the 3'-primer was not possible to test. In primer solutions 7, 15, 18, 26, 28, 29 and 31 it was only possible to test the 3'-primer, the 5'-primer was not possible to test. In primer solution 3, 5, 10, 12, 16 and 21 one or two 5'-primers were not possible to test, and in primer solutions 10, 11, 19, 21 and 27 one 3'-primer was not possible to test.

Additional primers in primers solutions 5, 9 and 11 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: 2011-July-15

Approved by:



Quality Control, Supervisor

Lot No.: **31M**

Lot-specific information

www.olerup-ssp.com

Declaration of Conformity

Product name: *Olerup* SSP® HLA-C*06

Product number: 101.614-12u

Lot number: 31M

Intended use: HLA-C*06 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, Franzengatan 5, SE-112 51 Stockholm, Sweden.

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

Stockholm, Sweden
2011-July-15



Olle Olerup