CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-C*01 SSP

Product number: 101.621-12u – without *Taq* polymerase
Lot number: 09L
Expiry date: 2013-August-01
Number of tests: 12
Number of wells per test: 24

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2010-707-01	9	2010-707-09	17	2010-707-17
2	2010-707-02	10	2010-707-10	18	2011-826-18
3	2010-707-03	11	2011-826-11	19	2011-826-19
4	2011-826-04	12	2010-707-12	20	2010-707-20
5	2011-826-05	13	2010-707-13	21	2010-707-21
6	2011-826-06	14	2011-826-14	22	2011-826-22
7	2010-707-07	15	2011-826-15	23	2011-826-23
8	2010-707-08	16	2011-826-16	24	2011-826-24

The specificity of each primer solution of the HLA-C*01 primer set has been tested against 48 well characterized IHWC cell line DNAs.

No DNAs carrying the alleles to be amplified by primer solutions 2 to 12 and 14 to 24 were available. The specificity of the primers in primer solutions 2 to 5, 8 to 12, 14, 16, 18 and 22 to 24 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer. In primer solution 6, 17 and 20 it was only possible to test the 3'-primer, the 5'-primer was not possible to test. In primer solutions 7, 15, 19 and 21 it was only possible to test the 5'-primers, the 3'-primers were not possible to test. In primer solutions 11 and 24 one of the 5'-primers was not possible to test. In primer solutions 2, 4, 5, 10, 14, 16, 18 and 23 one of the 3'-primers was not possible to test.

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

Date of approval: 2011-February-25

Approved by:

Quality Control, Supervisor

Declaration of Conformity

Product name: *Olerup* SSP® HLA-C*01
Product number: 101.621-12u
Lot number: 09L

Intended use: HLA-C*01 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 Construction 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-February-25

Olle Olerup
Managing Director