CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-C*02 SSP

Product number: 101.622-12 – including *Taq* polymerase
Lot number: 01M
Expiry date: 2013-October-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	2010-719-01	13	2010-719-13	25	2011-844-25
2	2010-719-02	14	2011-844-14	26	2011-844-26
3	2010-719-03	15	2010-719-15	27	2011-844-27
4	2010-719-04	16	2010-719-16	28	2011-844-28
5	2010-719-05	17	2011-844-17	29	2011-844-29
6	2011-844-06	18	2010-719-18	30	2011-844-30
7	2010-719-07	19	2010-719-19	31	2011-844-31
8	2010-719-08	20	2010-719-20		
9	2010-719-09	21	2010-719-21		
10	2010-719-10	22	2010-719-22		
11	2010-719-11	23	2010-719-23		
12	2010-719-12	24	2010-719-24		

The specificity of each primer solution of the HLA-C*02 primer set has been tested against 48 well characterized IHWC cell line DNAs.

No DNAs carrying the alleles to be amplified by primer solutions 3 to 8, 11 to 15, 17, 19 to 23, 25 to 28, 30 and 31 were available. The specificity of the primers in primer solutions 3, 5 to 8, 11 to 15, 17, 19, 23, 25, 26 and 31 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer. In primer solutions 4, 21, 22 and 28 it was only possible to test the 3'-primer, the 5'-primer was not possible to test. In primer solutions 20, 27 and 30 it was only possible to test the 5'-primer, the 3'-primer was not possible to test. In primer solutions 3, 8, 11, 13, 15, 17, 23 and 26 one or two of the 3'-primers were not possible to test, and in primer solutions 6, 10, 12, 15 and 23 one or two 5'-primers were not possible to test.

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

Date of approval: 2011-August-26

Approved by:

A-C Ineman

Quality Control, Supervisor

Declaration of Conformity

Product name: *Olerup* SSP® HLA-C*02
Product number: 101.622-12
Lot number: 01M

Intended use: HLA-C*02 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.

Saltsjöbaden, Sweden
2011-August-26

A-C Jareman
Ann-Cathrin Jareman
Head of QA and Regulatory Affairs