CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-C*16 SSP

Product number: 101.627-12 – including *Taq* polymerase
Lot number: 18M
Expiry date: 2013-December-01
Number of tests: 12
Number of wells per test: 23

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2011-860-01	9	2010-737-09	17	2011-860-17
2	2010-737-02	10	2010-737-10	18	2011-860-18
3	2010-737-03	11	2010-737-11	19	2011-860-19
4	2010-737-04	12	2011-860-12	20	2011-860-20
5	2010-737-05	13	2010-737-13	21	2011-860-21
6	2010-737-06	14	2010-737-14	22	2011-860-22
7	2010-737-07	15	2010-737-15	23	2011-860-23
8	2010-737-08	16	2011-860-16		

The specificity of each primer solution of the HLA-C*16 primer set has been tested against 48 well characterized cell line DNAs.

No DNAs carrying the alleles to be amplified by primer solutions 6 to 15 and 19 to 23 were available. The specificity of the primers in primer solutions 6, 7, 9, 11, 14, 15 and 19 to 22 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer.
In primer solutions 10 it was only possible to test the 3'-primer, the 5'-primer was not possible to test. In primer solutions 8, 12, 13 and 23 it was only possible to test the 5'-primer, the 3'-primer was not possible to test. In primer solutions 1, 6, 7 and 20 one or two of the 5'-primers were not possible to test, and in primer solution 19 two of the 3'-primers were not possible to test.

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

Date of approval: 2011-July-13

Approved by:

Quality Control, Supervisor

Declaration of Conformity

Product name: *Olerup* SSP® HLA-C*16
Product number: 101.627-12
Lot number: 18M

Intended use: HLA-C*16 high resolution histocompatibility testing

Manufacturer: *Olerup* SSP AB
Franzengatan 5
SE-112 51 Stockholm, Sweden
Phone: +46-8-717 88 27
Fax: +46-8-717 88 18

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-13

Olle Olerup
Managing Director