CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-C*15 SSP

Product number: **101.626-12 – including *Taq* polymerase**
Lot number: **06M**
Expiry date: **2013-October-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	2010-718-01	9	2010-718-09	17	2011-848-17
2	2010-718-02	10	2010-718-10	18	2011-848-18
3	2010-718-03	11	2010-718-11	19	2011-848-19
4	2010-718-04	12	2010-718-12	20	2011-848-20
5	2010-718-05	13	2011-848-13	21	2011-848-21
6	2010-718-06	14	2010-718-14	22	2011-848-22
7	2010-718-07	15	2010-718-15	23	2011-848-23
8	2010-718-08	16	2011-848-16	24	2011-848-24

The specificity of each primer solution of the HLA-C*15 primer set has been tested against 48 well characterized cell line DNAs.

No DNAs carrying the alleles to be amplified by primer solutions 6, 8, 13, 14, 16 to 22 and 24 were available. The specificity of the primers in primer solutions 6, 8, 13, 14 and 16 to 19 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer.
In primer solution 20 it was only possible to test the 5'-primer, the 3'-primers were not possible to test. In primer solutions 21, 22 and 24 it was only possible to test the 3'-primers, the 5'-primers were not possible to test.
In primer mixes 8, 9, 14 and 19 one of the 5'-primers could not be tested, and in primer mixes 3, 7, 12, 17, 18 and 23 one or two of the 3'-primers could not be tested. Additional primers in primer solutions 9 and 23 were tested by separately adding either one 5'-primer or one 3'-primer.

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

Date of approval: 2011-May-02

Approved by:

Quality Control, Supervisor

Declaration of Conformity

Product name: *Olerup* SSP® HLA-C*15
Product number: 101.626-12
Lot number: 06M

Intended use: HLA-C*15 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, Hasselstigen 1, SE-133 33 Saltsjöbaden, Sweden.

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

Saltsjöbaden, Sweden
2011-May-02

Olle Olerup
Managing Director