CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-B*57 SSP

Product number: **101.567-12u – without *Taq* polymerase**
Lot number: **85M**
Expiry date: **2014-May-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	2009-673-01	9	2009-673-09	17	2011-835-17
2	2009-673-02	10	2009-673-10	18	2009-673-18
3	2009-673-03	11	2009-673-11	19	2009-673-19
4	2009-673-04	12	2009-673-12	20	2009-673-20
5	2009-673-05	13	2011-921-13	21	2011-921-21
6	2011-835-06	14	2009-673-14	22	2011-835-22
7	2009-673-07	15	2011-835-15	23	2011-835-23
8	2011-835-08	16	2009-673-16	24	2011-835-24

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 6, 7, 8, 11, 14 and 16 to 24 were available. The specificities of the primers in primer solutions 6, 8, 11, 14, 16, 17, 19 and 20 were tested by separately adding additional 5'-primers, respectively additional 3'-primers. In primer solutions 7 and 23 it was only possible to test the 5'-primer, the 3'-primer was not possible to test. In primer solution 18, 21, 22 and 24 it was only possible to test the 3'-primer, the 5'-primer was not possible to test.
In primer solutions 2, 6, 16, 17 and 20 one of the 3'-primers was not possible to test, and in primer solutions 8, 14 and 15 one or two of the 5'-primers were not possible to test. One additional 3'primer in primer solution 15 was tested by separately adding one 5'-primer.

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

Date of approval: 2012-January-19

Approved by:

Åsa Claesson

Production Quality Control

CE
0088

Declaration of Conformity

Product name: *Olerup* SSP® HLA-B*57
Product number: 101.567-12u
Lot number: 85M

Intended use: HLA-B*57 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 II List B, conformity assessed using Annex IV, 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.

Notified Body: Lloyd's Register Quality Assurance Limited, Hiramford, Middlemarch Office Village, Siskin Drive, Coventry CV3 4FJ, United Kingdom. (Notified Body number: 0088.)

Stockholm, Sweden
2012-January-19

Ann-Cathrin Jareman
Head of QA and Regulatory Affairs