CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-B*39 SSP

Product number: 101.566-12u/04u – without *Taq* pol.
Lot number: 47K
Expiry date: 2013-April-01
Number of tests: 12 tests – Product No. 101.566-12u
4 tests – Product No. 101.566-04u
Number of wells per test: 32

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2009-674-01	13	2010-763-13	25	2010-763-25
2	2009-674-02	14	2009-674-14	26	2009-674-26
3	2009-674-03	15	2010-763-15	27	2009-674-27
4	2010-763-04	16	2009-674-16	28	2010-763-28
5	2009-674-05	17	2009-674-17	29	2009-674-29
6	2009-674-06	18	2009-674-18	30	2009-674-30
7	2009-674-07	19	2009-674-19	31	2009-674-31
8	2010-763-08	20	2010-763-20	32	2009-674-32
9	2010-763-09	21	2009-674-21		
10	2009-674-10	22	2010-763-22		
11	2009-674-11	23	2009-674-23		
12	2009-674-12	24	2010-763-24		

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 4, 7, 10, 13, 15, 22, 25, 27, 30 and 32 were available. The specificities of the primers in primer solutions 4, 7, 10, 13, 15, 22, 25, 27, 30 and 32 were tested by separately adding one or two additional 5'-primers, respectively one or two additional 3'-primers. One or two 5'-primers in primer solutions 1, 5, 8, 13, 15, 16, 22, 25 and 32 were not possible to test. One or two 3'-primers in primer solutions 4, 9, 11, 13, 15, 22, 27, 28 and 30 were not possible to test.
Additional primers in primer solutions 3, 8, 9, 16 and 20 were tested by separately adding either 5'- or 3'-primers.
Results: No false positive or false negative amplifications were obtained.

Date of approval: 2011-March-17

Approved by:

Quality Control, Supervisor

CE
0088

For *In Vitro* Diagnostic Use.

Declaration of Conformity

Product name: *Olerup* SSP® HLA-B*39
Product number: 101.566-12u/04u
Lot number: 47K

Intended use: HLA-B*39 histocompatibility testing

Manufacturer: *Olerup* SSP AB
Hasselstigen 1
SE-133 33 Saltsjöbaden, 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 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, Hasselstigen 1, SE-133 33 Saltsjöbaden, Sweden.

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

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

Saltsjöbaden, Sweden
2011-March-17

Olle Olerup
Managing Director