CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-A low resolution

Product number: 101.401-48u/12u – without *Taq* polymerase
Lot number: 04L
Expiry date: 2013-June-01
Number of tests: 48 tests – Product No. 101.401-48u
12 tests – Product No. 101.401-12u
Number of wells per test: 23 + 1

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2010-787-01	9	2010-733-09	17	2010-787-17
2	2010-787-02	10	2010-787-10	18	2010-733-18
3	2010-733-03	11	2010-787-11	19	2010-733-19
4	2010-733-04	12	2010-733-12	20	2010-787-20
5	2010-733-05	13	2010-733-13	21	2010-733-21
6	2010-787-06	14	2010-787-14	22	2010-787-22
7	2010-733-07	15	2010-733-15	23	2010-787-23
8	2010-733-08	16	2010-787-16		

The specificity of each primer solution of the kit has been tested against 48 well characterized IHWC cell line DNAs.

Additional 5'- and 3'-primers in primer solutions 4, 5, 7, 8, 12, 14 to 17 and 20 to 23 were tested by separately adding one 3'-primer, respectively one 5'-primer. One additional 5'-primer in primer solutions 1 and 10 was tested by separately adding one 3'-primer. Additional 3'-primers in primer solutions 3, 6, 18 and 19 were tested by separately adding one 5'-primer. One of the 5'-primers in primer solutions 2, 10, 11 and 15 were not possible to test, and in primer solutions 3, 18 and 19 one 3'-primer was not possible to test.

The negative control primer pairs, **Production No. 2010-760-01**, can detect contamination with PCR products diluted 10^{-7}.

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

Date of approval: 2011-January-14

Approved by:

Åsa Olausson

Quality Control, Supervisor

Declaration of Conformity

Product name: *Olerup* SSP® HLA-A low resolution
Product number: 101.401-48u/12u
Lot number: 04L

Intended use: HLA-A low 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 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- March-30

Ann-Cathrin Jareman
Head of QA and Regulatory Affairs