CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-C low resolution SSP

Product number: 101.601-24/12 – including *Taq* pol.
Lot number: 89K
Expiry date: 2013-August-01
Number of tests: 24 tests – Product No. 101.601-24
12 tests – Product No. 101.601-12
Number of wells per test: 23 + 1

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2009-631-01	9	2009-631-09	17	2009-631-17
2	2011-811-02	10	2009-631-10	18	2011-811-18
3	2010-735-03	11	2011-811-11	19	2011-811-19
4	2011-811-04	12	2011-811-12	20	2011-811-20
5	2009-631-05	13	2011-811-13	21	2009-631-21
6	2011-811-06	14	2009-631-14	22	2009-631-22
7	2009-631-07	15	2011-811-15	23	2011-811-23
8	2009-631-08	16	2011-811-16		

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

Additional 5'-primers in primer solution 2, 6, 12 to 15, 22 and 23 were tested by separately adding one 3'-primer. Additional 3'-primers in primer solutions 2, 10, 12, 14, 15, 18, 19 and 22, were tested by separately adding one 5'-primer. In primer solutions 3, 11, 12, 14 and 18, one or two 3'-primers were not possible to test, and in primer solution 23, one 5'-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-February-16

Approved by:

Quality Control, Supervisor

Declaration of Conformity

Product name: *Olerup* SSP® HLA-C low resolution
Product number: 101.601-24/12
Lot number: 89K

Intended use: HLA-C low resolution 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 13485:2004, 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 Construction 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-February-16

Olle Olerup
Managing Director