

CERTIFICATE OF ANALYSIS

Olerup SSP® KIR Genotyping SSP

Product number: 104.101-12 – including *Taq* polymerase
 104.101-12u – without *Taq* polymerase
Lot number: 97X
Expiry date: 2017-July-01
Number of tests: 12
Number of wells per test: 23 + 1

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2013-242-01	9	2013-242-09	17	2013-242-17
2	2014-376-02	10	2013-242-10	18	2013-242-18
3	2014-482-03	11	2013-242-11	19	2013-242-19
4	2013-242-04	12	2013-242-12	20	2013-242-20
5	2013-242-05	13	2013-242-13	21	2013-242-21
6	2013-242-06	14	2013-242-14	22	2014-376-22
7	2014-482-07	15	2013-242-15	23	2013-242-23
8	2013-242-08	16	2013-242-16		

The negative control primer pairs, **Production No. 2013-242-24**, can detect contamination with PCR products diluted 10⁻⁷.

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

Date of approval: 2015-January-28

Approved by:

Karin Mattsson

Production Quality Control



Declaration of Conformity

Product name: Olerup SSP® KIR Genotyping

Product number: 104.101-12/12u

Lot number: 97X

Intended use: KIR Genotyping

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 13485:2012, 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, Franzengatan 5, SE-112 51 Stockholm, Sweden.

Stockholm, Sweden
2015-January-29



Daniel Malica
Head of QA and Regulatory Affairs