

CERTIFICATE OF ANALYSIS**Olerup SSP® KIR Genotyping SSP**

Product number: 104.101-12 – including *Taq* polymerase
 104.101-12u – without *Taq* polymerase
Lot number: 98V
Expiry date: 2016-December-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	2013-242-03	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	2014-376-07	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: 2014-July-03

Approved by:

Karin Olsson

Production Quality Control

Lot No.: **98V**

Lot-specific information

www.olerup-ssp.com

Declaration of Conformity

Product name: Olerup SSP® KIR Genotyping
Product number: 104.101-12/12u
Lot number: 98V

Intended use: KIR Genotyping

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 13485:2012, 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
2014-July-03



Daniel Malica
Head of QA and Regulatory Affairs