

CERTIFICATE OF ANALYSIS

Olerup SSP® KIR Genotyping SSP

Product number: 104.101-12 – including *Taq* polymerase
104.101-12u – without *Taq* polymerase
Lot number: 8D0
Expiry date: 2019-01-01
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	2016-664-05	13	2013-242-13	21	2013-242-21
6	2016-664-06	14	2013-242-14	22	2014-376-22
7	2016-664-07	15	2013-242-15	23	2013-242-23
8	2013-242-08	16	2016-664-16		

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: 60715

Approved by:



Production Quality Control

Declaration of Conformity

Product name: Olerup SSP® KIR Genotyping
Product number: 104.101-12/12u
Lot number: 8D0

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 EN 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
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Andrea Boman
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