

CERTIFICATE OF ANALYSIS

Olerup SSP® KIR Genotyping SSP

Product number: 104.101-12 – including *Taq* polymerase
104.101-12u – without *Taq* polymerase
Lot number: 78R
Expiry date: 2015-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	2011-939-01	9	2011-939-09	17	2011-939-17
2	2012-125-02	10	2011-939-10	18	2011-939-18
3	2011-939-03	11	2011-939-11	19	2011-939-19
4	2011-939-04	12	2011-939-12	20	2011-939-20
5	2011-939-05	13	2012-125-13	21	2011-939-21
6	2011-939-06	14	2011-939-14	22	2011-939-22
7	2011-939-07	15	2011-939-15	23	2011-939-23
8	2011-939-08	16	2011-939-16		

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

Additional primers in primer solutions 3 and 21 were tested by separately adding another 5'-primer respective another 3'-primer. In primer solutions 1, 3 and 7, one of the 5'-primers was not possible to test.

The negative control primer pairs, **Production No. 2012-051-24**, can detect contamination with PCR products diluted 10^{-7} .

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

Date of approval: 2012-January-31

Approved by:



Production Quality Control

Lot No.: **78R**

Lot-specific information

www.olerup-ssp.com

Declaration of Conformity

Product name: *Olerup* SSP® KIR Genotyping
Product number: 104.101-12/12u
Lot number: 78R

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 13485:2003, 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
2012-January-31



Ann-Cathrin Jareman
Head of QA and Regulatory Affairs