

Lot No.: **10R**

Lot-specific information

www.olerup-ssp.com

CERTIFICATE OF ANALYSIS

Olerup SSP® KIR Genotyping SSP

Product number: 104.101-12 – including *Taq* polymerase
104.101-12u – without *Taq* polymerase
Lot number: 10R
Expiry date: 2015-January-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	2011-939-02	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	2011-939-13	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-July-12

Approved by:



Production Quality Control

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Declaration of Conformity

Product name: Olerup SSP® KIR Genotyping
Product number: 104.101-12/12u
Lot number: 10R

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-July-12



Ann-Cathrin Jareman
Head of QA and Regulatory Affairs