

Lot No.: **36M**

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: 36M
Expiry date: 2013-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	2011-878-01	9	2008-538-09	17	2008-538-17
2	2011-878-02	10	2011-878-10	18	2008-538-18
3	2011-878-03	11	2008-538-11	19	2008-538-19
4	2008-538-04	12	2008-538-12	20	2008-538-20
5	2008-538-05	13	2008-538-13	21	2008-538-21
6	2008-538-06	14	2011-878-14	22	2008-538-22
7	2011-878-07	15	2011-878-15	23	2008-538-23
8	2008-538-08	16	2008-538-16		

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.

The negative control primer pairs, **Production No. 2010-760-01**, can detect contamination with PCR products diluted 10^{-7} .

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

Date of approval: 2011-July-01

Approved by:



Quality Control, Supervisor

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Declaration of Conformity

Product name: *Olerup* SSP® KIR Genotyping
Product number: 104.101-12/12u
Lot number: 36M

Intended use: KIR Genotyping

Manufacturer: *Olerup* SSP AB
Franzengatan 5
SE-112 51 Stockholm, Sweden
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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.

The Authorized Representative located within the Community is: *Olerup* SSP AB.

Stockholm, Sweden
2011-July-01



Olle Olerup
Managing Director

