

Lot No.: **07N**

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: 07N  
Expiry date: 2014-August-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. 2011-928-01**, can detect contamination with PCR products diluted  $10^{-7}$ .

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

**Date of approval:** 2012-February-28

**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:** 07N

**Intended use:** KIR Genotyping

**Manufacturer:** *Olerup* SSP AB  
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**Phone:** +46-8-717 88 27  
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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-February-28



Åsa Olausson  
Production Quality Control