

Lot No.: 9E6

Lot-specific information

www.olerup.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: 9E6  
 Expiry date: 2019-11-01  
 Number of tests: 12  
 Number of wells per test: 25 + 1

#### Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2013-242-01	11	2013-242-11	21	2013-242-21
2	2014-376-02	12	2013-242-12	22	2014-376-22
3	2017-778-03	13	2013-242-13	23	2013-242-23
4	2013-242-04	14	2013-242-14	24	2017-778-24
5	2016-664-05	15	2013-242-15	25	2017-778-27
6	2016-664-06	16	2016-664-16		
7	2016-664-07	17	2013-242-17		
8	2013-242-08	18	2013-242-18		
9	2013-242-09	19	2013-242-19		
10	2013-242-10	20	2013-242-20		

The negative control primer pairs, Production No. 2013-242-24, can detect contamination with PCR products diluted 10<sup>-7</sup>.

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

**Date of approval:** 170524

**Approved by:** *Rebecka Selmer*

#### Production Quality Control

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## Declaration of Conformity

**Product name:** Olerup SSP® KIR Genotyping  
**Product number:** 104.101-12/12u  
**Lot number:** 9E6

**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

2017-05-29



Anneli Häkkinen  
Interim Quality Assurance