

Lot No.: **3H3**

Lot-specific information

CERTIFICATE OF ANALYSIS

Olerup SSP® KIR Genotyping

Product number: 104.101-12 – including *Taq* polymerase
104.101-12u – without *Taq* polymerase
Lot number: 3H3
Expiry date: 2021-08-01
Number of tests: 12
Number of wells per test: 26 + 1

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2017-876-01	11	2017-876-11	21	2017-876-21
2	2017-876-02	12	2017-876-12	22	2017-876-22
3	2019-013-03	13	2017-876-13	23	2017-876-23
4	2017-876-04	14	2017-876-14	24	2017-876-24
5	2017-876-05	15	2017-876-15	25	2017-876-25
6	2017-876-06	16	2017-876-16	26	2017-876-26
7	2017-876-07	17	2017-876-17		
8	2017-876-08	18	2017-876-18		
9	2017-876-09	19	2017-876-19		
10	2017-876-10	20	2017-876-20		

The negative control primer pairs, **Production No. 2017-876-28**, can detect contamination with PCR products diluted 10^{-7} .

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

Date of approval: 2019-02-22

Approved by: 

Production Quality Control



Lot No.: **3H3**

Lot-specific information

Declaration of Conformity

Product name: *Olerup* SSP® KIR Genotyping
Product number: 104.101-12/12u
Lot number: 3H3

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) EN ISO 13485:2016, 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, Franzéngatan 5, SE-112 51 Stockholm, Sweden.

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

Stockholm, Sweden

Date: 20190222



Emil Jonsson
Head of Quality Assurance

