

Lot No.: 3S5

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: 3S5
Expiry date: 2027-09-01
Number of tests: 12
Number of wells per test: 29 + 1

Well specifications:

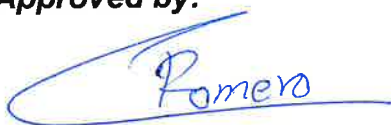
Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2023-561-01	11	2023-561-11	21	2023-561-21
2	2023-561-02	12	2023-561-12	22	2023-561-22
3	2023-561-03	13	2023-561-13	23	2023-561-23
4	2023-561-04	14	2023-561-14	24	2023-561-24
5	2023-561-05	15	2023-561-15	25	2023-561-25
6	2023-561-06	16	2023-561-16	26	2023-561-26
7	2023-561-07	17	2023-561-17	27	2023-561-27
8	2023-561-08	18	2023-561-18	28	2023-561-28
9	2023-561-09	19	2023-561-19	29	2023-561-29
10	2023-561-10	20	2023-561-20		

The negative control primer pairs, **Production No. 2023-561-30**, can detect contamination with PCR products diluted 10^{-7} .

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

Date of approval: 2023-09-13

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: 3S5

Intended use: KIR Genotyping

Manufacturer: *CareDx* AB
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SE-112 51 Stockholm, Sweden
Phone: +46-8-508 939 00
Fax: +46-8-717 88 18

We, *CareDx* 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 *CareDx* AB, Franzégatan 5, SE-112 51 Stockholm, Sweden.

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

Stockholm, Sweden
Date:

2023 09 14

Quality Assurance

