

Lot No.: 7N4

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: 7N4
Expiry date: 2026-11-01
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	2022-375-01	11	2022-375-11	21	2022-375-21
2	2022-375-02	12	2022-375-12	22	2022-375-22
3	2022-375-03	13	2022-375-13	23	2022-375-23
4	2022-375-04	14	2022-375-14	24	2022-375-24
5	2022-375-05	15	2022-375-15	25	2022-375-25
6	2022-375-06	16	2022-375-16	26	2022-375-26
7	2022-375-07	17	2022-375-17	27	2022-375-27
8	2022-375-08	18	2022-375-18	28	2022-375-28
9	2022-375-09	19	2022-375-19	29	2022-375-29
10	2022-375-10	20	2022-375-20		

The negative control primer pairs, **Production No. 2022-375-30**, can detect contamination with PCR products diluted 10^{-7} .

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

Date of approval: 2022-12-21

Approved by:



Production Quality Control



KIR Genotyping
104.101-12 – including *Taq* polymerase
104.101-12u – without *Taq* polymerase

Certificates

Page 2 of 2
Visit www.caredx.com for
“Instructions for Use” (IFU)

Lot No.: 7N4

Lot-specific information

Declaration of Conformity

Product name: *Olerup* SSP[®] KIR Genotyping
Product number: 104.101-12/12u
Lot number: 7N4

Intended use: KIR Genotyping

Manufacturer: *CareDx* AB
Franzéngatan 5
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, Franzéngatan 5, SE-112 51 Stockholm, Sweden.

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

Stockholm, Sweden

Date:

2023-01-03

Quality Assurance

