

EC Certificate No. 1434-IVDD-005/2022

EC Design-examination
Directive 98/79/EC concerning
in vitro diagnostic medical devices

Polish Centre for Testing and Certification certifies that manufactured by:

CorDx, Inc. 9540 Waples St Unit C, San Diego, CA 92121, USA

in vitro diagnostic medical devices self-testing

COVID-19 Ag Test

The list of versions of medical devices covered by this certificate is provided in the annex 1.

in terms of design documentation, comply with requirements of Annex III (Section 6) to Directive 98/79/EC (as amended) implemented into Polish law, as evidenced by the audit conducted by the PCBC Validity of the Certificate: from 14.01.2022 to 27.05.2025

The date of issue of the Certificate: 14.01.2022

The date of the first issue of the Certificate: 23.12.2021

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Issued under the Contract No. MD-137/2021 Application No: 249/2021 Certificate bears the qualified signature. Warsaw, date next to signature Module A1



President



ANNEX 1 TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

No 1434-IVDD-005/2022

List of medical devices covered by the certificate:

Br and	REF Numbers
Accu News	COV-Ag01, COV-Ag02, COV-Ag03, COV-Ag04, COV-Ag05, COV-Ag07, COV-Ag10, COV-Ag25.
Coretests	BP291-01, BP291-02, BP291-03, BP291-04, BP291-05, BP291-07, BP291-10, BP291-25.
Accufast	AF-01, AF-02, AF-03, AF-05, AF-07, AF-10, AF-25.
Axnar	1000, 1001.
BISAF	CTC19LP-1, CTC19LP-5.



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President