

COVID-19 ANTIGEN RAPID TEST(SELF-TESTING)

Hangzhou Clongene Biotech Co., Ltd

<http://en.clongene.com/>

REGULATORY STATUS

Germany BfArM

TIME TO RESULT

0.25

ASSAY TARGET

Antigen

TEST FORMAT

Lateral flow assay (strip or cassette)

TECHNOLOGY PRINCIPLE

Antibody-based detection

TARGET ANALYTE

N protein

LEVEL OF AUTOMATION

Manual

LABORATORY/POINT-OF-CARE

Near point-of-care

SELF-TESTING/SELF-COLLECTION

Intended for self-testing (version available)

VALIDATED SAMPLE TYPES

Nasal swab

CONNECTIVITY

No

IMPACT OF SARS-COV-2 VARIANT:

Alpha - No expected impact (in silico analyses)

Beta - No expected impact (in silico analyses)

Gamma - Unknown

Manufacturer performance data

SENSITIVITY

97.1%

SPECIFICITY

99.4%