Edinburgh Genetics ActivXpress+ COVID-19 Antigen Complete Testing Kit

Instructions for Use

CATALOGUE NUMBER	UDI DEVICE IDENTIFIER (UDI-DI)
EGCV0101	5060774580127
EGCV0101A	5060774580134
EGCV0101B	5060774580141
EGCV0101M	5060774580325
EGCV0101MA	5060774580332
EGCV0101MB	5060774580349

GMDN TERM
SARS-CoV-2 antigen IVD, kit, immunochromatographic test (ICT), rapid
INTENDED USE
Edinburgh Genetics ActivXpress+ COVID-19 Antigen Complete Testing Kit is intended for the qualitative detection of antigens from severe acute respiratory syndrome-associated coronavirus 2 (SARS-CoV-2) in a clinical specimen.
SUMMARY
The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, most commonly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhoea are found in a few cases. Standard recommendations to prevent infection spread include regular hand washing, covering mouth and nose when coughing and sneezing. Avoid close contact with anyone showing symptoms of respiratory illness such as coughing and sneezing.
TEST PRINCIPLE
Edinburgh Genetics ActivXpress+ COVID-19 Antigen Complete Testing Kit is a double antibody-sandwich, qualitative membrane-based immunoassay In-vitro diagnostic medical device. The kit is designed to detect nucleocapsid antigen from the SARS-CoV-2 in nasopharyngeal swab or oropharyngeal swab from patients who are suspected of being COVID-19 positive. The SARS-CoV-2 antigens present in the specimen react with anti- SARS-CoV-2 antibody-coated particles in the test cassette. The mixture then migrates upward on the membrane by capillary action and reacts with the pre-coated antibody in the test line region. If the specimen contains SARS-CoV-2 antigens, a coloured line will appear in the test line region. If the specimen does not contain SARS-CoV-2 antigens, no coloured line will appear in the test line region, indicating a negative result. To serve as a procedural control, a coloured line will always appear in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred.
STORAGE INSTRUCTIONS
- Store the kit at room temperature or refrigerated (2-30℃).
- Do not freeze.
- The kit has a shelf-life of 12 months.

INTERNAL QUALITY CONTROL
Internal controls are included in the test. A coloured line appearing in the control region (C) confirms sufficient specimen volume and correct procedural technique. Positive and negative controls, which are not included, can be used to confirm the test procedure and to verify proper test performance.

CONTENTS
EGCV0101: 1 x Test Cassette, 1 x Sterilised nasopharyngeal swab, 1 x reagent in tube with dropper
EGCV0101A: 10 x Test Cassette, 10 x Sterilised nasopharyngeal swab, 10 x reagent in tube with dropper
EGCV0101B: 20 x Test Cassette, 20 x Sterilised nasopharyngeal swab, 20 x reagent in tube with dropper
EGCV0101M: 1 x Test Cassette, 1 x Sterilised oropharyngeal swab, 1 x reagent in tube with dropper
EGCV0101MA: 10 x Test Cassette, 10 x Sterilised oropharyngeal swab, 10 x reagent in tube with dropper
EGCV0101MB: 20 x Test Cassette, 20 x Sterilised oropharyngeal swab, 20 x reagent in tube with dropper
One test cassette contains: a membrane strip coated with anti-SARS-CoV-2 monoclonal antibody on the test line and a dye pad which contains colloidal gold coupled with SARS-CoV-2 monoclonal antibody.
Materials not included but required: Gloves, Timer

PERFORMANCE CHARACTERISTICS
- When tested with 38 PCR confirmed positive and 40 confirmed negative samples, the tests show sensitivity of 94.7% (36/38) and specificity of 100% (40/s40).
- The Limit of Detection is 35 ng/mL (using recombinant SARS-CoV-2 nucleocapsid protein).
- Results show no cross-reactivity with Human coronavirus 229E, Human coronavirus OC43, Human coronavirus HKU1, Influenza A (H1N1), Influenza B (Yamagata) and the Adenovirus, MERS, NL63, 229E, OC43, HAdV-1, HAdV-3, HAdV-5, HAdV-7, HAdV-8, HAdV-11, HAdV-18, HAdV-23, HPIV-1, HPIV-2, HPIV-3, HPIV-4, HRV-1, HRV-14, HRV-42, HMPV, RSV-A, RSV-B at 1x106 pfu/mL concentration.

SAMPLE REQUIREMENTS
Specimens obtained early during symptom onset will contain the highest viral titers. Specimens obtained after 5 days of symptoms are more likely to produce negative results when compared to an RT-PCR assay. Inadequate specimen, improper specimen handling and/or transport may yield a false negative result; therefore, training in specimen collection is highly recommended due to the importance of specimen quality for generating accurate test results.

SAMPLE COLLECTION
Nasopharyngeal Swab Sample Collection
Insert mini-tip swab with a flexible shaft (wire or plastic) through the nostril parallel to the palate (not upwards) until resistance is encountered or the distance is equivalent to that from the ear to the nostril of the patient, indicating contact with the nasopharynx. Swab should reach depth equal to distance from nostrils to outer opening of the ear. Gently rub and roll the swab. Leave swab in place for several seconds to absorb secretions. Slowly remove swab while rotating it. Specimens can be collected from both sides using the same swab, but it is not necessary to collect specimens from both sides if the mini-tip is saturated with fluid from the first collection. If a deviated septum or blockage creates difficulty in obtaining the specimen from one nostril, use the same swab to obtain the specimen from the other nostril.

Oropharyngeal Swab Sample Collection
Insert swab into the posterior pharynx and tonsillar areas. Rub swab over both tonsillar pillars and posterior oropharynx and avoid touching the tongue and teeth.

SPECIMEN PREPARATION

1. Open the lid of the tube containing the buffer solution.
2. Insert the swab into the tube.
3. Rotate the swab inside the tube for one minute.
4. Close the lid of extraction tube with cap until use.

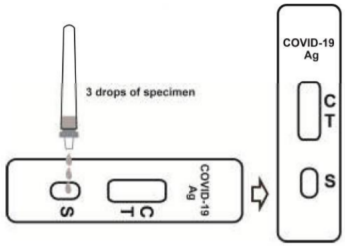
SAMPLE TRANSPORT AND STORAGE

Freshly collected specimens should be prepared as soon as possible and no later than one hour after specimen collection. Specimen already prepared may be stored at 2-8℃ for no more than 24 hours. If long-term storage is required, store at -70 ℃ and avoid repeated freeze-thaw cycles.

INSTRUCTIONS FOR USE

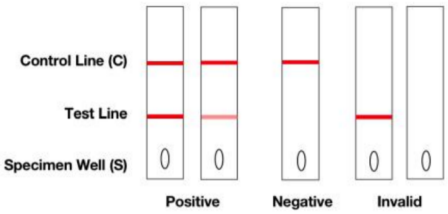
Allow the test, specimen and/or reagent to reach room temperature (18-30℃) prior to testing.

1. Remove the test cassette from the foil pouch and use within one hour.
2. Place the cassette on a clean and level surface.
3. Use dropper to transfer 3 drops (approximately 100µL) of the specimen with reagent to the specimen well (S) of the test cassette, then start the timer.
4. Wait for the coloured line(s) to appear. Read the results after 15 minutes. Do not interpret the results after 20 minutes.



RESULTS

Negative Result: One coloured line appears in the control line region (C). No line appears in the test region (T)
Positive Result: Two coloured lines appear. One coloured line appears in the control line region (C) and another line adjacent appears in the test region (T).
Invalid Result: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.



PRECAUTIONS

- For professional In-vitro diagnostic use only.
- Follow-up testing with a molecular diagnostic should be considered.
- Results from antigen testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.
- Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus.
- Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status.
- Positive results do not rule out bacterial infection or co-infection with other viruses.
- This test must be administered by a medical professional.

MANUFACTURER

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CE

REF Catalogue

LOT Lot Number

Do Not Reuse

IVD In Vitro Diagnostic Medical Device

Consult Instructions

Manufacturer

Storage Temperature Range