03/03/2022

Edinburgh Genetics ActivXpress+ COVID-19 Antigen Complete Testing Kit

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.
A positive test result needs to be further confirmed by quantitative testing, a negative result does not rule out SARS-CoV-2 infection. This kit is intended for use by a medical professional specifically instructed and trained in the techniques of in vitro diagnostic procedures.

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 the spread of infection 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 nasal 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°C).
- Do not freeze.
- The kit has a shelf-life of 18 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.

CONTENTS
EGCV0101: 1 x Test Cassette, 1 x Sterilised nasopharyngeal swab, 1 x Reagent in bottle with dropper, 1 x IFU
EGCV0101A: 10 x Test Cassette, 10 x Sterilised nasopharyngeal swab, 10 x Reagent in bottle with dropper, 1 x IFU
EGCV0101C: 15 x Test Cassette, 15 x Sterilised nasopharyngeal swab, 15 x Reagent in bottle with dropper, 1 x IFU
EGCV0101B: 20 x Test Cassette, 20 x Sterilised nasopharyngeal swab, 20 x Reagent in bottle with dropper, 1 x IFU
EGCV0101P: 1 x Test Cassette, 1 x Sterilised nasopharyngeal swab, 1 x Reagent in bottle with dropper, 1 x IFU
EGCV0101N: 1 x Test Cassette, 1 x Sterilised nasal swab, 1 x Reagent in bottle with dropper, 1 x IFU
EGCV0101NA: 10 x Test Cassette, 10 x Sterilised nasal swab, 10 x Reagent in bottle with dropper, 1 x IFU
EGCV0101NC: 15 x Test Cassette, 15 x Sterilised nasal swab, 15 x Reagent in bottle with dropper, 1 x IFU
EGCV0101NB: 20 x Test Cassette, 20 x Sterilised nasal swab, 20 x Reagent in bottle with dropper, 1 x IFU
EGCV0101NP: 1 x Test Cassette, 1 x Sterilised nasal swab, 1 x Reagent in bottle with dropper, 1 x IFU

Materials not included but required: Gloves, Timer
Note:
1. Test cassettes are sealed in an aluminium foil pouch with desiccant.

Component	Main Ingredients
Test cassette	Test strip contains SARS-CoV-2 monoclonal antibody and anti-mouse IgG polyclonal antibody
Sample diluent	0.05 M Tris-HCl

PERFORMANCE CHARACTERISTICS
Limit of Detection LoD
The Limit of Detection (LoD) of the Edinburgh Genetics ActivXpress+ COVID-19 Antigen Complete Testing Kit is $1.75x10^2 TCID_{50}$/ml.
Analytical specificity
1. **Cross reactivity**
There is no cross-reactivity with the following pathogens: Coronavirus (HKU1, OC43, NL63, 229E); MERS; Influenza A virus (2009H1N1, seasonal H1N1, H3N2, H5N1, H7N9); Influenza B virus (Yamagata, Victoria); Respiratory syncytial virus, Rhinovirus (group A, B, C); Respiratory adenovirus (type 1-5, 7, 55); Entrovirus (group A, B, C, D); Epstein-barr virus capsid antigen; Measles virus; Human cytomegalovirus; Rotavirus; Norovirus; Mumps virus; Varicella zoster virus; Parainfluenza virus; Mycoplasma pneumoniae; Chlamydia pneumoniae; Haemophilus influenza .
2. **Interfering substance**
The following common drugs will not interfere with the results of the kit: Oxymetazaoline, Dexamethasone, Flunisolide, Sulphur, Kim Anh, Benzocaine, Zanamivir, Mupirocin, Tobramycin, Kalii Dehydrographolidi Succinas, Aspirin (enteric-coated tablets), Ibruprofen (granules), Acetaminophen (slow-release tablets).
3. **Hook effect**
This kit does not have the hook effect.

CLINICAL PERFORMANCE
Edinburgh Genetics ActivXpress+ COVID-19 Antigen Complete Testing Kit Nasopharyngeal performance against PCR comparator.

Edinburgh Genetics ActivXpress+ COVID-19 Antigen Complete Testing Kit	PCR Comparator				Total
	Positive			Negative	
	Ct < 25	Ct 25- 30	Ct > 30		
Positive	96	82	0	1	179
Negative	0	2	3	263	268
Total	96	84	3	264	447
Sensitivity by Ct value	100%	97.62%	0.0%	-	-
Overall Sensitivity	97.27% (95% CI: 93.74 - 99.11%)				
Specificity	99.62% (95% CI: 97.91 - 99.99%)				
Accuracy	98.66% (95% CI: 97.10 - 99.51%)				
Kappa value	0.9721				

Edinburgh Genetics ActivXpress+ COVID-19 Antigen Complete Testing Kit Nasal performance against PCR comparator.

Edinburgh Genetics ActivXpress+ COVID-19 Antigen Complete Testing Kit	PCR Comparator				Total
	Positive			Negative	
	Ct < 25	Ct 25- 30	Ct > 30		
Positive	96	80	0	2	178
Negative	0	4	3	262	269
Total	96	84	3	264	447
Sensitivity by Ct value	100%	95.24%	0.0%	-	-
Sensitivity	96.17% (95% CI: 92.28 – 98.45%)				
Specificity	99.24% (95% CI: 97.29 – 99.91%)				
Accuracy	97.99% (95% CI: 96.21 – 99.08%)				
Kappa value	0.9582				

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
1. Tilt the patient's head back 70° to straighten the passage from the front of the nose.
2. Insert the nasopharyngeal swab with a flexible shaft through the nostril parallel to the palate.
3. **CAUTION:** Use dedicated nasopharyngeal swab for specimen collection.
4. Swab should reach depth equal to the distance from the nostrils to the outer opening of the ear and must come into contact with the nasopharynx.
5. **CAUTION:** 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.
6. Gently rub and roll the swab, 3-4 times. Leave the swab in place for several seconds to allow the swab to absorb secretions.
7. Slowly remove the swab while rotating it and insert into the reagent bottle.

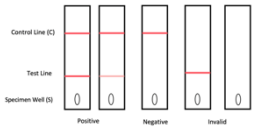
Nasal Swab Sample Collection
1. Tilt the patient's head back 70° to straighten the passage from the front of the nose.
2. **CAUTION:** Use dedicated nasal swab for specimen collection.
3. While gently rotating the swab, insert it less than one inch (about 2cm) into the nostril parallel to the palate until resistance is met at turbinates.
4. Rotate the swab 4 times against the nasal wall.
5. Remove the swab, insert it into the other nostril and repeat the process.

SPECIMEN PREPARATION
If the reagent is stored in the refrigerator, allow the reagent to return to room temperature (15-30°C)
1. Remove the seal of the bottle containing the reagent solution.
2. Insert the swab into the reagent bottle, rotate the swab in the bottle 5 times, and squeeze the swab against the tube 5 times. For a total duration of one minute.
3. Cover with the dropper cap before 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°C for no more than 8 hours. If long-term storage is required, store at -70 °C and avoid repeated freeze-thaw cycles.

INSTRUCTIONS FOR USE
Allow the test, specimen and/or reagent to reach room temperature (15-30°C) 30 minutes prior to testing.
1. Remove the test cassette from the foil pouch and use immediately.
2. Place the cassette on a clean and level surface.
3. Use dropper to transfer 3 drops (approximately 80µL) 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 since results seen after 20mins are invalid.

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.



WARNINGS
- This is a single-use in vitro diagnostic reagent, do not reuse, and do not use expired products.
- 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.
- Use fresh specimens for testing, do not use repeated freeze-thaw samples.
- Operate at room temperature (15-30°C). Test cassettes kept at a low temperature should be restored to room temperature before opening to avoid moisture absorption.
- Do not ingest desiccant
- Improper sample collection or processing may result in false-negative or false-positive results.
- If you have any questions or suggestions on the use of this kit, please contact the manufacturer.
- All specimens must be considered potentially infectious, and during collection, processing, storage, mixing of specimens and testing appropriate protective measures should be taken. Therefore, take protective measures such as wearing gloves and a mask. Dispose of all waste as potentially biohazardous.
- Failure to follow the instructions of the test procedure and interpretation of the test results may adversely affect the test performance and/or product invalid results.
- Edinburgh Genetics ActivXpress+ COVID-19 Antigen Complete Testing Kit is not intended to detect non-infectious virus during the later stages of viral shedding that may still be detected by PCR molecular tests.
- Observing results earlier than 15 minutes and later than 20 minutes may give incorrect results.
- Contamination with saliva and/or mucus may cause false positive results.
- Using an inadequate or excessive amount of reagent may lead to an incorrect result.

CATALOGUE NUMBER	UDI DEVICE IDENTIFIER (UDI-DI)
EGCV0101	5060774580127
EGCV0101A	5060774580134
EGCV0101C	5060774581766
EGCV0101B	5060774580141/5060774581605
EGCV0101P	5060774581438
EGCV0101N	5060774580837
EGCV0101NA	5060774580844
EGCV0101NC	5060774581797
EGCV0101NB	5060774580851/5060774581674
EGCV0101NP	5060774581452

REF Catalogue Number
Storage Temperature Range (2-30°C)
LOT Lot Number
Consult Instructions
Do Not Reuse
Manufacturer
IVD In Vitro Diagnostic Medical Device
EC REP EC Representative

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