

Edinburgh Genetics ActivXpress+ COVID-19 Antigen Complete Testing Kit

NAME ACCORDING TO GIMN
SARS-CoV-2 antigen IVD, kit, immunochromatographic test (ICT), rapid

INTENDED USE
The complete Edinburgh Genetics ActivXpress + COVID-19 Antigen test kit is intended for the qualitative detection of coronavirus 2-associated severe acute respiratory syndrome (SARS-CoV-2) antigens in a clinical specimen.
A positive test result should 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 healthcare professional specially trained in *in vitro* diagnostic procedures.

SUMMARY
The new coronaviruses belong to the genus β . COVID-19 is an acute respiratory infectious disease. Currently, the main source of infection is patients infected with the new coronavirus; asymptomatic infected people can also be a source of infection. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, most often 3 to 7 days. The main symptoms include fever, fatigue and dry cough. In several cases, there is a stuffy nose, runny nose, sore throat, myalgia and diarrhoea. Standard recommendations for preventing the spread of infection include regular hand washing, covering the mouth and nose with coughs and sneezing. Avoid close contact with anyone who shows signs of respiratory diseases such as coughing and sneezing.

PRINCIPLE OF THE TEST
The complete Edinburgh Genetics ActivXpress + COVID-19 Antigen test kit is a sandwich quality *in vitro* immunoassay diagnostic medical device. The kit is intended for the detection of SARS-CoV-2 nucleocapsid antigen in nasopharyngeal, oral and pharyngeal swabs and nasal swabs in patients suspected of being positive for COVID-19. The SARS-CoV-2 antigens present in the sample react with the anti-SARS-CoV-2 antibody coated particles in the test cassette. The mixture then migrates upward to the membrane by capillary action and reacts with the antibody applied in the test line area. If the sample contains SARS-CoV-2 antigens, a colored line will appear in the test area. If the sample does not contain SARS-CoV-2 antigens, no colored line will appear in the test area, indicating a negative result. To check the correctness of the procedure, a colored line always appears in the control area, which means that the correct sample volume has been added and the membrane has leaked.

STORAGE INSTRUCTIONS
• Store the kit at room temperature or refrigerated (2-30 °C).
• Do not freeze.
• The shelf life of the kit is 18 months.

INTERNAL QUALITY CONTROL
Internal controls are part of the test. The colored line in the control area (C) confirms a sufficient sample volume and the correct procedure.

- CONTENTS
- EGCV1011: 1x test cassette, 1x sterilized nasopharyngeal swab, 1x reagent in a dropper bottle
 - EGCV101A: 10x test cassettes, 10x sterilized nasopharyngeal swab, 10x reagent in a dropper bottle
 - EGCV101B: 20x test cassettes, 20x sterilized nasopharyngeal swab, 20x reagent in a dropper bottle
 - EGCV101M: 1x test cassette, 1x sterilized swab for swabbing the oral cavity and pharynx, 1x reagent in a dropper bottle
 - EGCV101MA: 10x test cassettes, 10x sterilized swab for swabbing the oral cavity and pharynx, 10x reagent in a dropper bottle
 - EGCV101MB: 20x test cassettes, 20x sterilized swab for swabbing the oral cavity and pharynx, 20x reagent in a dropper bottle
 - EGCV101N: 1x test cassette, 1x sterilized swab for nasal swab, 1x reagent in a dropper bottle
 - EGCV101NA: 10x test cassettes, 10x sterilized swab for nasal swab, 10x reagent in a dropper bottle
 - EGCV101NB: 20x test cassettes, 20x sterilized swab for nasal swab, 20x reagent in a dropper bottle

- Materials that are needed but not included: Gloves, timer
Note:
1. The test cassettes are enclosed in an aluminum foil bag with a desiccant.
2. Do not mix different batches of test cartridges and sample diluents.

Part	Main components
Test cartridge	The test strip contains 2019-nCoV monoclonal antibody and anti-mouse IgG polyclonal antibody
Sample diluent	0.05 M Tris-HCl

FUNCTIONAL PARAMETERS
Limit of Detection (LoD)
The detection limit (LoD) of the complete Edinburgh Genetics ActivXpress + COVID-19 Antigen test kit is 5 x 10² pfu / ml.
Analytical sensitivity
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 (types 1-5, 7, 95); enterovirus (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; hemophilus.
2. **Interfering substances**
The following common medicines will not interfere with the results of the kit: Oxymetazolin, dexamethasone, flunisolide, sulfur, Km Anh, benzocaine, zanamivir, mupirocin, tobramycin, potassium dihydrogenphosphate succinate, aspirin (enteric tablets), ibuprofen (granules), acetaminophen release tablets.
3. **Prozone effect (hook effect)**
This kit does not have a prozone effect.

Performance of the complete Edinburgh Genetics ActivXpress + Antigen test kit for nasopharyngeal swabs versus PCR comparator.

Complete Edinburgh test kit Genetics ActivXpress+ COVID-19 Antigen	PCR comparator				Total
	Positive		Negative		
	Ct < 25	Ct 25-30	Ct > 30	c	
Positive	96	62	6	2	179
Negative	0	2	3	1 263	266
Total	96	64	9	264	447
Sensitivity by value Ct	100%	97,62%	0,0 %		
Overall sensitivity	97,27 % (95% IS: 93,74-99,11 %)				
Specificity	99,62% (95% IS: 97,91-99,99 %)				
Accuracy	98,66% (95% IS: 97,10-99,61 %)				
Kappa value	0,9721				

Performance of the complete Edinburgh Genetics ActivXpress + Antigen test kit for oral and pharyngeal swabs versus PCR comparator.

Complete Edinburgh test kit Genetics ActivXpress+ COVID-19 Antigen	PCR comparator				Total
	Positive		Negative		
	Ct < 25	Ct 25-30	1 > 30	c	
Positive	96	79	6	2	177
Negative	0	5	6	262	270
Total	96	84	12	264	447
Sensitivity by value Ct	100%	94,0420%	33,0,0 %		
Overall sensitivity	95,63 % (95% IS: 91,57-98,09 %)				
Specificity	99,24% (95% IS: 97,29-99,91 %)				
Accuracy	97,76% (95% IS: 95,92-98,92 %)				
Kappa value	0,9535				

Performance of the complete Edinburgh Genetics ActivXpress + Antigen test kit for nasal swabs versus PCR comparator.

Complete Edinburgh test kit Genetics ActivXpress+ COVID-19 Antigen	PCR comparator				Total
	Positive		Negative		
	Ct < 25	Ct 25-30	1 > 30	c	
Positive	96	62	6	2	178
Negative	0	4	3	262	269
Total	96	66	9	264	447
Sensitivity by value Ct	100%	95,24%	0,0 %		
Sensitivity	96,17% (95% IS: 92,28-98,45 %)				
Specificity	99,24% (95% IS: 97,29-99,91 %)				
Accuracy	97,99% (95% IS: 96,21-99,08 %)				
Kappa value	0,9582				

SAMPLE REQUIREMENTS
Samples obtained early during the onset of symptoms will contain the highest viral titers. Samples obtained 5 days after the onset of symptoms are more likely to have negative results compared to the RT-PCR test. Insufficient sample, incorrect sample handling and / or transport may lead to a false negative result; therefore, sampling training is highly recommended due to the importance of sample quality for obtaining accurate test results.

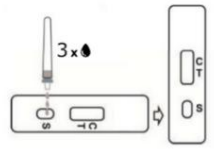
- SAMPLING
- Nasopharyngeal swab sampling**
1. Tilt the patient's head 70° to straighten the passage from the front of the nose.
 2. Insert a swab with a flexible stem for swabbing the nasopharynx through the nostril parallel to the palate.
 3. **CAUTION:** Use a nasopharyngeal swab for sampling.
 4. The tampon should reach a 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 nasal septal deflection or obstruction causes difficulty in obtaining a sample from one nostril, use the same swab to collect a sample from the other nostril.
 6. Carefully wipe the swab and turn 3-4 times. Leave the swab in place for a few seconds to absorb the secretion.
 7. Slowly pull out the swab while rotating it, then immerse it in the reagent bottle.

- Sampling with a swab for swabs from the oral cavity and pharynx**
1. Insert the tampon into the back of the pharynx and tonsils.
 2. **CAUTION:** Use a swab for oral and pharyngeal swabs for sampling.
 3. Wipe the swab over both nasal tonsils and the back of the pharynx in the mouth, but do not touch the tongue and teeth.
- Nasal swab sampling**
1. Tilt the patient's head 70° to straighten the passage from the front of the nose.
 2. **CAUTION:** Use a nasal swab for sampling.
 3. Carefully rotate the swab while inserting it no further than about 2 cm into the nostril parallel to the palate until you feel resistance from the nasal shell.
 4. Wipe the tampon against the nasal wall four times in a rotating motion.
 5. Pull out the swab, insert it into the other nostril and repeat the procedure.

SAMPLE PREPARATION
If reagent is stored in the refrigerator, allow to warm to room temperature (15-30 °C).
1. Open the cap of the tube containing the buffer solution.
2. Insert the swab into the reagent vial, invert the swab in the vial 5 times and squeeze it 5 times against the wall of the vial. Perform this procedure for one minute.
3. Close the cap of the extraction tube with the cap until use.
4. Remove the cap and cap with the dropper cap before use.

SAMPLE TRANSPORT AND STORAGE
Freshly taken samples should be prepared as soon as possible, but no later than one hour after sampling. The prepared sample can be stored at a temperature of 2-8 °C for a maximum of 8 hours. If it needs to be stored longer, store it at -70 °C and avoid re-freezing.

INSTRUCTIONS FOR USE
Allow the test, sample or reagent to reach room temperature (15-30) for 30 minutes before testing.
1. Remove the test cartridge from the foil pouch and use it immediately.
2. Place the cartridge on a clean and level surface.
3. Using a dropper, transfer 3 drops (approximately 80µl) of reagent sample to the sample well (S) of the test cassette, then start the timer.
4. Wait for the colored line (s) to appear. Read the results in 15 minutes. Do not interpret the results after 20 minutes, because the results seen after 20 minutes are invalid.



RESULTS
Negative result: One colored line (C) appears in the control area. No line appears in the test area (T).
Positive result: Two colored lines appear. One colored line appears in the control line area (C) and another adjacent line appears in the test area (T).
Invalid result: The control line does not appear. The most likely reason is insufficient sample volume or incorrect procedure. Check the procedure and repeat the test with a new test. If the problem persists, stop using the test kit immediately and contact your local distributor.



- WARNING**
- This is a single-use, *in vitro* diagnostic reagent, do not reuse, and do not use products after the expiration date.
 - Subsequent molecular diagnostic testing should be considered.
 - Antigen testing results should not be used as the sole basis for diagnosing or excluding SARS-CoV-2 infection or for informing about the status of the infection.
 - Negative results do not rule out SARS-CoV-2 infection, especially in those who have been in contact with the virus.
 - Positive results suggest the presence of viral antigens, but a clinical correlation with the patient's medical history and other diagnostic information is required to determine the status of the infection.
 - Positive results do not rule out bacterial infection or coinfection with other viruses.
 - This test must be performed by a physician.
 - Use fresh samples for testing, do not use samples that have been repeatedly frozen and thawed.
 - Work at room temperature (15-30 °C). Test cartridges stored at low temperature should be allowed to reach room temperature before opening to prevent moisture absorption.
 - Do not swallow the desiccant.
 - Improper sampling or processing can lead to false negative or false positive results.
 - If you have any questions or suggestions regarding the use of this kit, please contact the manufacturer.
 - Use the swab and reagent provided with this kit for sampling and processing and do not mix different lots of test cartridge and reagent.
 - All samples must be considered potentially infectious and appropriate protective measures must be taken during collection, processing, storage, mixing of samples and testing. Therefore, take protective measures such as wearing gloves and a mask. Dispose of all waste as potentially biohazardous.
 - Failure to follow the test procedure instructions and interpretation of test results may adversely affect test performance and / or invalid product results.
 - The Edinburgh Genetics ActivXpress + COVID-19 Antigen Complete Assay Kit is not intended to detect non-infectious virus during the later stages of virus shedding, which can still be detected by PCR molecular assays.
 - Observing results earlier than 15 minutes and later than 20 minutes can lead to incorrect results.
 - Saliva and / or mucus contamination can cause false positive results.
 - Using an insufficient or excessive amount of reagent can lead to an incorrect result.

CATALOG NUMBER	UNIQUE PRODUCT IDENTIFICATION NUMBER (UDI-DI)
EGCV1011	566074580017
EGCV101A	566074580284
EGCV101B	566074580281
EGCV101M	566074580707
EGCV101MA	566074580714
EGCV101MB	566074580721
EGCV101N	566074580281
EGCV101NA	566074580281
EGCV101NB	566074580281

REF Catalog number Storage temperature range (2-30 °C)

LOT Batch number Read the instructions

2 Do not reuse Producer

IVD *In vitro* diagnostic medical device **EC REP** EC representative

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