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Immunoassay

REF

Strip		Cassette	
REF	Size	REF	Size
RTA0101	1 test	RTA0201	1 test
RTA0102	20 tests	RTA0202	20 tests
RTA0103	50 tests	RTA0203	50 tests
RTA0104	100tests	RTA0204	100tests

Anti-SARS-CoV-2 Rapid Test

This assay is based on a colloidal gold method for the rapid, qualitative determination of Anti-SARS-CoV-2 (IgG/IgM antibodies of Severe Acute Respiratory Syndrome Coronavirus 2) in human serum, plasma or whole blood.

Key to Graphical Symbols Used

LOT	batch code		use by
	manufacturer	Σ	contains sufficient for <n> tests
IVD	*in vitro* diagnostic medical device		temperature limitation
REF	catalogue number		consult instructions for use
EC REP	authorized representative in the European Community		Do not reuse

EC REP

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CE IVD

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Contact the local dealers for all product related questions in local language

Introduction

Coronaviruses are a large family of single-stranded RNA viruses that infect mammals and birds, causing respiratory infection. Severe acute respiratory syndrome coronavirus 2 (SARS coronavirus 2 or SARS-CoV-2)[1] causes an infectious disease named COVID-19 (Coronavirus disease 2019). It may develop a fever, dry cough, fatigue and shortness of breath.[2] The results of this test may vary by apparent disease periods by time after symptom onset. It is not yet known when IgM or IgG antibodies specific to the SARS-CoV-2 virus will become detectable during an infection, or how long antibodies persist following infection. Antibodies are produced gradually by the immune response system after infection. The sensitivity of antibody detection is directly related to the time after infection when blood samples are collected.

Anti-SARS-CoV-2 Rapid Test is an immunoassay intended for the qualitative detection and differentiation of IgG and IgM from the SARS-CoV-2 in plasma from anticoagulated human blood (heparin/ EDTA/ sodium citrate) or serum from individuals with signs and symptoms of infection who are suspected of COVID-19 infection by a healthcare provider. The Anti-SARS-CoV-2 Rapid Test is an aid to be used in the diagnosis of patients with suspected SARS-CoV-2 infection in conjunction with clinical presentation and the results of other laboratory tests.

Negative results do not preclude SARS-CoV-2 virus infection and should not be used as the sole basis for patient management decisions. IgM antibodies may not be detected during the first few days of infection; the sensitivity of the Anti-SARS-CoV-2 Rapid Test early after infection is unknown. Negative results must be combined with clinical observations, patient history, and epidemiological information.

Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 coronavirus strains.

False positive results for IgM and IgG antibodies may occur due to cross-reactivity from pre-existing antibodies or other possible causes.

At this time, it is unknown for how long IgM or IgG antibodies may persist following infection.

This test is not intended for the screening of donated blood.

The Anti-SARS-CoV-2 Rapid Test is only used as a supplementary test for suspected SARS-CoV-2 infection which is detected negative nucleic acid or it was used in conjunction with nucleic acid detection in the diagnosis of suspected cases. And it cannot be used for screening in the general population.

Measurement Principle

This assay is based upon one-step capture method. This test contains a membrane, which is pre-coated with two mouse anti-human monoclonal antibodies (anti-IgG and anti-IgM) on two separated test lines. The samples with SARS-CoV-2 antibodies (IgM and/or IgG) which can specifically bind to colloidal gold labeled with recombined SARS-CoV-2 antigen, and sprayed on conjugation pads to form a red/pink line. As the complex continues to travel up in the strip, the anti-SARS-CoV-2 IgM antibodies are bound on the IgM line, and the anti-SARS-CoV-2 IgG antibodies are bound to the IgG line. The control (C) line appears when sample has flowed through the strip. The presence of anti-SARS-CoV-2 IgM and/or IgG will be indicated by a visible test line (T) in the IgM and IgG region. Both the Test Line and Control Line in result window are not visible before applying any samples. The Control Line is used for procedural control. Control line should always appear if the test procedure is performed properly and the reagents of control line are working.

Components

1. Sample Diluent

Sample diluent contains MOPS buffer.

Σ	1test	20tests	50tests	100tests
Sample Diluent	4.5mL*1	4.5mL*1	4.5mL*2	4.5mL*4

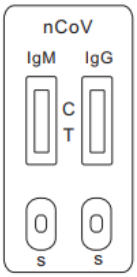
Note: The volume of the Sample Diluent indicated is the minimum dispensing volume.

2. Cassette/Strip

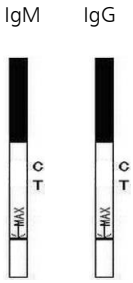
Type	Σ	1test	20tests	50tests	100tests
Cassette	SARS-CoV-2 (IgM+IgG) Cassette	1	20	50	100
Strip	SARS-CoV-2 IgM Strip	1	20	50	100
	SARS-CoV-2 IgG Strip	1	20	50	100

Cassette was individually sealed in the aluminum foiled pouch with a desiccant.
Cassette:
Each Cassette includes two test regions (SARS-CoV-2 IgM and SARS-CoV-2 IgG). (See picture 1)
Note: The cassette of SARS-CoV-2 IgM was in the left, and the cassette of SARS-CoV-2 IgG was in the right. There was no interference between the two cassettes.
Strips:
SARS-CoV-2 IgM and SARS-CoV-2 IgG strips are sealed separately in the cartridge. (See picture 2)

Picture 1



Picture 2



3. 1 copy of instruction for use

Materials Required but not Provided

1. Centrifuge
2. Sample collection container
3. Timer
4. Micropipette

Warnings and Precautions

1. For *in vitro* diagnostic use only. For professional use only. For prescription use only.
2. Follow the instruction for use carefully. Reliability of assay results cannot be guaranteed if there are any deviations from the

instructions in this package insert.
3. Handle the potentially contaminated materials safely according to local requirement.
4. Do not smoke, drink, eat or use cosmetics in the working area.
5. Use appropriate personal protective equipment when collecting and handling specimens from individuals suspected of having COVID-19. Wash hands after operations.
6. Wipe and wash the splashed sample with highly effective disinfectant. Avoid splashing and the formation of smog.
7. Use a clean sample dispensing plastic dropper or tip for every sample to avoid cross contamination.
8. Decontaminate the dispose of all samples, used kits and potentially contaminated materials as if they were infectious waste, in a biohazard container.
9. Do not mix and interchange different samples.
10. Anticoagulants such as heparin, EDTA and sodium citrate do not affect the test result.
11. Use unpacked Cassette or Strip as soon as possible to avoid being humidified. The Cassette or Strip is sensitive to humidity as well as to heat.
12. Do not use the Cassette or Strip beyond the labeled expiry date indicated on the outer container.
13. Do not use the Cassette or Strip if the pouch is damaged or the seal is broken.
14. The Cassette or Strip cannot be reused.
15. The components in different batches cannot be interchanged.

Storage

1. Store all components at 2-30 ℃. Do not freeze.
2. The Cassette or Strip was stable throughout the expiration date printed on the outer container. The Cassette or Strip should remain in the sealed aluminum foiled pouch until ready for use and not freeze. It cannot be used beyond the expiration date.
3. Store Sample Diluent at 2-30℃ after use, then it can be used until the expiration date.

Sample

1. The Anti-SARS-CoV-2 Rapid Test can be used to test serum, plasma (heparin, EDTA or sodium citrate), or venipuncture whole blood specimens. Do not use fingerstick whole blood.
2. Collect samples in accordance with correct medical practices. Specimens should be collected with appropriate infection control precautions. Proper sample collection is critical. Failure to follow the procedure may give inaccurate results.
3. Venipuncture whole blood sample could be collected in accordance with the standard practices for collecting human blood samples with anticoagulants. Validated anticoagulants include heparin, EDTA and sodium citrate. Other anticoagulants have not been tested and may give an incorrect result.
4. Collect the venipuncture whole blood into the collection tube (containing anticoagulants such as heparin, EDTA and sodium citrate) by venipuncture and then centrifuge blood to get plasma sample. Carefully withdraw the plasma into new pre-labeled tube.
5. Collect the venipuncture whole blood into the collection tube (NOT containing anticoagulants such as heparin, EDTA and sodium citrate) by venipuncture, leave to settle for 30 minutes for blood coagulation and then centrifuge blood to get serum sample of supernatant. Carefully withdraw the serum into new pre-labeled tube.
6. Sediments and suspended solids in serum or plasma samples may interfere with the test result which should be removed by centrifugation. Be sure that the samples are not decayed prior to use.
7. Insufficient processing of the sample, or disruption of the sample during transportation may cause depressed results.
8. Cap and store the serum or plasma samples at 2-8 ℃ for no more than 24 hours to be test. For longer use, freeze the serum or plasma samples at -20 ℃. Venipuncture Whole blood samples cannot be frozen and should be tested timely. Avoid multiple freeze-thaw cycles. Mix thawed samples thoroughly by low speed vortexing or by inverting 10 times. Bring samples to room temperature prior to testing for at least 30 minutes. Visually inspect the samples, if layering or stratification is observed, continue mixing until samples are visibly homogeneous.
9. If proper serum, plasma or venipuncture whole blood sample collection and preparation cannot be verified, or if samples have been disrupted due to transportation or sample handling, an additional centrifugation step is recommended. Centrifugation conditions should be sufficient to remove particulate matter.

Reagent Preparation

1. Bring all reagents, samples and Cassette or Strip to room temperature before performing the assay for approximately 30 minutes, be sure them to be completely recovered to room temperature before proceeding to the next step.
2. Remove the Cassette or Strip from the aluminum foiled pouch and place it on a clean, flat and dry surface.

Measurement Procedure

For Cassette:

1. Identify the Cassette for each sample.
2. When serum or plasma is collected, add 5 μL of the serum or plasma sample into each sample well. Then add 60 μL of the Sample Diluent. For each sample, use a separate tip and Cassette.
3. When whole blood is collected, add 10 μL of the venipuncture whole blood sample into each sample well. Then add 60 μL of the Sample Diluent. For each sample, use a separate tip and Cassette.
4. Read the test results between 15 and 20 minutes. Do not read the results after 20 minutes.

Note: both IgG and IgM Cassette must be tested.

For Strip:

1. Identify the Strip for each sample.
2. When serum or plasma is collected, add 5 μL of the serum or plasma sample into each sample well. Then add 60 μL of the Sample Diluent. For each sample, use a separate tip and Strip.
3. When whole blood is collected, add 10 μL of the venipuncture whole blood sample into each sample well. Then add 60 μL of the Sample Diluent. For each sample, use a separate tip and Strip.
4. Read the test results between 15 and 20 minutes. Do not read the results after 20 minutes.

Note: both IgG and IgM Strip must be tested.

Measurement Results

For Cassette:

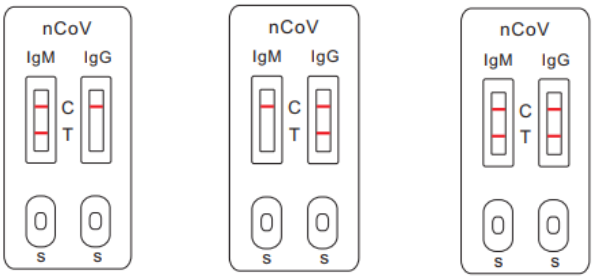
1. Positive Reactions

Observe the two colored lines, the control line in the control (C) on both the right and left sides region, and the test line in the Anti-SARS-CoV-2 IgM/IgG test (T) region of the membrane.

In addition to the presence of both control lines (C), if only the IgM test line (T) appears, the test result indicates the presence of IgM anti-SARS-CoV-2 antibodies.

In addition to the presence of both control lines (C), if only the IgG test line (T) appears, the test result indicates the presence of IgG anti-SARS-CoV-2 antibodies.

In addition to the presence of both control lines (C), if both IgM and IgG test lines (T) appear, the test result indicates the presence of IgM and IgG anti-SARS-CoV-2 antibodies.

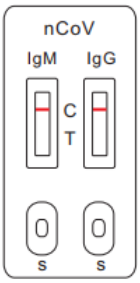


SARS-CoV-2 IgM Positive SARS-CoV-2 IgG Positive IgG and IgM Positive

Note: Any shade of color in the test line (T) region should be considered as positive, even if faint.

2. Negative Reaction

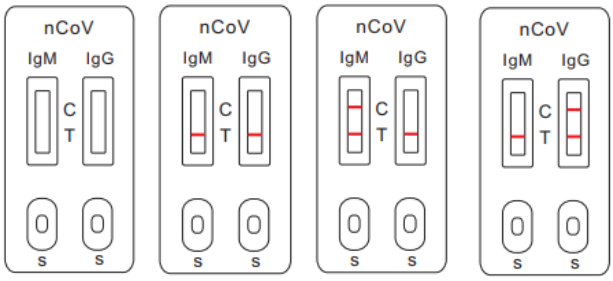
If control lines (C) are present in both result windows and no test lines appear in either IgG or IgM test line regions, the test result is negative for both analytes.



3. Invalid Reaction

If control lines (C) do not appear, the test result is invalid regardless of the appearance of the IgM or IgG test lines (T).

Some causes of invalid results are: not following the directions correctly or the test may have deteriorated beyond the expiration date. It is recommended that the sample be re-tested using a new Cassette.



For Strip:

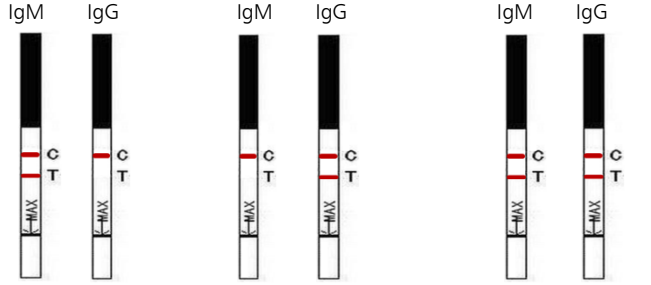
1. Positive Reactions

Observe the two colored control lines in the control (C) region, and the test line in the Anti-SARS-CoV-2 IgM/IgG test (T) region of the membrane.

In addition to the presence of both control lines (C), if only the IgM test line (T) appears, the test result indicates the presence of IgM anti-SARS-CoV-2 antibodies.

In addition to the presence of both control lines (C), if only the IgG test line (T) appears, the test result indicates the presence of IgG anti-SARS-CoV-2 antibodies.

In addition to the presence of both control lines (C), if both IgM and IgG test lines (T) appear, the test result indicates the presence of IgM and IgG anti-SARS-CoV-2 antibodies.

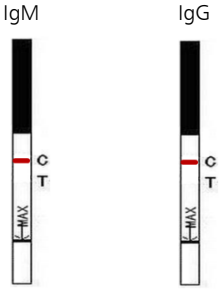


SARS-CoV-2 IgM Positive SARS-CoV-2 IgG Positive SARS-CoV-2 IgG and IgM Positive

Note: Any shade of color in the test line (T) region should be considered as positive, even if faint.

2. Negative Reaction

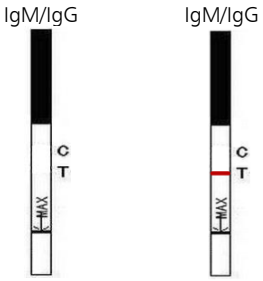
If control lines (C) are present in both result windows and no test lines appear in either IgG or IgM test line regions, the test result is negative for both analytes



3. Invalid Reaction

If control lines (C) do not appear, the test result is invalid regardless of the appearance of the IgM or IgG test lines (T).

Some causes of invalid results are: not following the directions correctly or the test may have deteriorated beyond the expiration date. It is recommended that the sample be re-tested using a new Strip.



Results interpretation

The Assay Procedure and the Interpretation of Assay Result must be followed closely when testing for the presence of SARS-CoV-2 virus specific antibodies in the serum, plasma or venipuncture whole blood specimen from individual subjects.

Laboratory test results should always be considered in the context of clinical observations and epidemiological data in making a final diagnosis and patient management decisions.

Control Procedure

An internal procedural control is included in the test. A colored line appearing in the C line is an internal procedural control. It confirms sufficient sample volume, adequate membrane wicking and correct

procedural technique.
External positive and negative controls are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.
It is recommended that each laboratory develops its suitable quality control program complying with applicable government regulations and local guidelines.

Limitations of the Procedure

1. A positive result may not indicate previous SARS-CoV-2 infection. Consider other information, including clinical history and local disease prevalence, in assessing the need for a second but different serology test to confirm an immune response.
2. If the results are inconsistent with clinical evidence, additional testing is suggested to confirm the result. A negative result does not preclude the possibility of SARS-CoV-2 infection. Any positive result should be confirmed by chest CT, NAT or other clinical diagnosis result. If symptoms persist and the result from the Anti-SARS-CoV-2 Rapid Test is negative or non-reactive, it is recommended to re-sample the patient a few days later or test with an alternative test device.
3. This kit DOES NOT produce an actual test report and the reporting laboratory MUST include this information in the test report. The results of this antibody detection kit should NOT BE SOLELY USED as the basis for diagnosis or exclusion. All testing results shall be judged in combination with epidemiological, and clinical signs, imaging, nucleic acid detection and other evidence.
4. The Anti-SARS-CoV-2 Rapid Test is limited to the qualitative detection of antibodies specific for the SARS-CoV-2 virus. The intensity of the test line does not necessarily correlate to SARS-CoV-2 antibody titer in the specimen.
5. Negative results DO NOT rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.
6. Results from antibody testing should NOT be used as the SOLE basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.
7. This test kit is for the detection of SARS-CoV-2 IgM or SARS-CoV-2 IgG in serum, plasma or venipuncture whole blood samples. Neither the quantitative value nor the rate of increase in SARS-CoV-2 IgM or SARS-CoV-2 IgG can be determined by this qualitative test.
8. Whilst every precaution has been taken to ensure the diagnostic ability and accuracy of this product, the product is used outside of the control of the Manufacturer and Distributor and the result may accordingly be affected by environmental factors and/or user error. A person who is the subject of the diagnosis should consult a doctor for further confirmation of the result.
9. The Manufacturers and Distributors of this product shall not be liable for any losses, liability, claims, costs or damages whether direct or indirect or consequential arising out of or related to an incorrect diagnosis, whether positive or negative, in the use of this product.
10. Serological assays are of importance to determine seroprevalence in a given population and define previous exposure. The results of this test may vary during different infection periods. It is not yet known and we do not yet know at what time during an infection with SARS-CoV-2 that IgM or IgG specific to the virus will become detectable or will no longer be detected. Antibodies are produced gradually by the immune response system after infection. The sensitivity of antibody detection is directly related to the time after infection when blood samples are collected.
11. False positive results for IgM and IgG antibodies may occur due to cross-reactivity from pre-existing antibodies or other possible causes.
12. All laboratories using this test must follow standard confirmatory testing and reporting guidelines according to their appropriate public health authorities.
13. Patients tested early after infection may not have detectable IgM antibody despite active infection; in addition, not all patients will develop a detectable IgM and/or IgG response to SARS-CoV-2 infection. The absolute sensitivity of the Anti-SARS-CoV-2 Rapid Test is unknown.
14. When diagnostic testing is non-reactive, the possibility of a false negative result should be considered in the context of a patient's recent exposures and the presence of clinical signs and symptoms consistent with COVID-19. This is especially important if the patient has had recent exposure to COVID-19, or clinical presentation indicates that COVID- 19 is likely and diagnostic tests for other causes of illness (e.g., other respiratory illness) are negative. Direct testing for virus (e.g., PCR testing) should always be performed in any patient suspected of COVID-19, regardless of the Anti-SARS-CoV-2 Rapid Test.

Performance Characteristics

1. Negative reference coincidence rate

Test 10 negative references, the results shall be all negative.

2. Positive reference coincidence rate

Test 6 positive references, the results shall be all positive.

3. Limit of detection

Three references of limit of detection (L1, L2, L3) were tested, L1 shall be negative and L2, L3 were all positive.

4. Precision

2 different precision references were tested with 10 replicates, the result shall be all positive.

5. Analytical specificity

Cross reaction: For the substances, Influenza A virus IgM (H1N1, H3N2), Influenza B virus (Yamagata IgM, Victoria IgM), Endemic human coronavirus IgM (OC43, 229E), CMV IgM, Rubella IgM, Toxo IgM, HSV IgM, Coxsackie virus group B IgM, Epstein-barr virus IgM, Enterovirus 71 IgM, Coxsackie virus type A16 IgM, Varicella zoster virus IgM, Mumps Virus IgM, Respiratory syncytial virus IgM, Adenovirus IgM, Chlamydia pneumoniae IgM, Mycoplasma pneumoniae IgM, Measles virus IgM, Influenza A virus IgG (H1N1, H3N2), Influenza B virus (Yamagata IgG, Victoria IgG), Endemic human coronavirus IgG (OC43, 229E), CMV IgG, Rubella IgG, Toxo IgG, HSV IgG, Coxsackie virus group B IgG, Epstein-barr virus IgG, Enterovirus 71 IgG, Coxsackie virus type A16 IgG, Varicella zoster virus IgG, Mumps Virus IgG, Respiratory syncytial virus IgG, Adenovirus IgG, Chlamydia pneumoniae IgG, Mycoplasma pneumoniae IgG, Measles virus IgG there was no cross reaction.

Interference: No interference with 8 mg/mL of haemoglobin, 0.3 mg/mL of Bilirubin, 5 mg/mL of triglycerides, HAMA, Rheumatoid factor, Antinuclear antibody (ANA), Anti-mitochondrial antibody (AMA), α -interferon, Zanamivir, Ritonavir, Tramadol, Azithromycin, Ceftriaxone, Meropenem, Levofloxacin, Oseltamivir, Mupirocin, benzocaine, Tobramycin, Peramivir, Epinephrine, Menthol, Ribavirin, Lopinavir.

6. Clinical study

The clinical performance of the Anti-SARS-CoV-2 Rapid Test was evaluated by testing a total of 717 clinical samples from individual patients. A total of 405 patients with positive PCR comparator results and 312 patients with negative PCR comparator results were tested with the Anti-SARS-CoV-2 Rapid Test. Overall study results are shown in Table 1 below. Positive serology results stratified by apparent disease period by day of symptom appearance at the time of blood collection are shown Tables 2 and 3.

Table 1. Overall Clinical Study Results for all time periods from symptom onset

Evaluation reagent			PCR Comparator*		Total
			Positive	Negative	
Anti-SARS-CoV-2 Rapid Test	Pos	IgG+/IgM+	338	0	338
		IgG-/IgM+	8	1	9
		IgG+/IgM-	11	2	13
	Neg	IgG-/IgM-	48	309	357
Total			405	312	717

*Note: Serum and plasma samples were collected from the same patients for serology testing between 1 day and > 30 days after PCR sample collection.

Results analysis:

- Positive Percent Agreement (PPA)= (IgM positive or IgG positive)/(PCR positive)
- PPA: 88.15% (357/405) (95%CI: 84.6% - 90.9%)
- Negative Percent Agreement: (NPA) = (IgM negative and IgG negative)/(PCR negative)
- NPA: 99.04% (309/312) (95%CI: 97.2% - 99.7%)

Table 2: SARS-CoV-2 IgM Positive Results by time from symptom onset

Infectious period (days)	# PCR positive at any time*	# Anti-SARS-CoV-2 Rapid Test positive	PPA	95%CI
≤7	51	19	37.25%	25.3 – 51.0%
8-14	52	38	73.08%	59.8 - 83.2%
≥15	302	289	95.70%	92.8 - 97.5%

*Note: Serum and plasma samples were collected from the same patients for serology testing between 1 day and > 30 days after PCR sample collection.

Table 3: SARS-CoV-2 IgG Positive Results by time from symptom onset

Infectious period (days)	#PCR positive at any time*	# Anti-SARS-CoV-2 Rapid Test positive	PPA	95%CI
≤7	51	16	31.37%	20.3 - 45.0%
8-14	52	34	65.38%	51.8 - 76.9%
≥15	302	299	99.01%	97.7 - 99.8%

*Note: Serum and plasma samples were collected from the same patients for serology testing between 1 day and > 30 days after PCR sample collection.

Literature References

1. "Naming the coronavirus disease (COVID-19) and the virus that causes it". World Health Organization. Archived from the original on 28 February 2020. Retrieved 28 February 2020.

2. "Coronavirus Disease 2019 (COVID-19) Symptoms". Centers for Disease Control and Prevention. United States. 10 February 2020. Archived from the original on 30 January 2020.