SCoV-2 *Detect*™ IgG Rapid Test

Instructions for Use
For *In Vitro* Diagnostic Use Only
For Prescription Use Only
For Emergency Use Authorization Only

INTENDED USE

The SCoV-2 *Detect*™ IgG Rapid Test is an *in vitro* lateral flow chromatographic immunoassay intended for the qualitative detection of IgG antibodies to SARS-CoV-2 in human serum, plasma (sodium citrate, dipotassium EDTA and sodium heparin), venous whole blood (sodium citrate, dipotassium EDTA and sodium heparin), and fingerstick whole blood. The SCoV-2 *Detect*™ IgG Rapid Test is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. The SCoV-2 *Detect*™ IgG Rapid Test should not be used to diagnose or exclude acute SARS-CoV-2 infection. At this time, it is unknown for how long antibodies persist following infection and if the presence of antibodies confers protective immunity.

Testing of serum, plasma, and venous whole blood specimens is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C 263a, that meet the requirements to perform high or moderate complexity tests. Testing of fingerstick whole blood specimens is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform high, moderate or waived complexity tests. Testing of fingerstick whole blood specimens is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

Results are for the detection of IgG SARS-CoV-2 antibodies. IgG antibodies to SARS-CoV-2 are generally detectable in blood several days after initial infection, although the duration of time antibodies are present post-infection is not well characterized. Individuals may have detectable virus present for several weeks following seroconversion.

Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.

The sensitivity of SCoV-2 *Detect*™ IgG Rapid Test early after infection is unknown. Negative results do not preclude acute SARS-CoV-2 infection. If acute infection is suspected, direct testing for SARS-CoV-2 is necessary.

False positive results for SCoV-2 *Detect*™ IgG Rapid Test may occur due to cross-reactivity from pre-existing antibodies or other possible causes. Due to the risk of false positive results, confirmation of positive results should be considered using a second, different IgG assay.

Samples should only be tested from individuals that are 15 days or more post symptom onset.

The SCoV-2 *Detect*™ IgG Rapid Test is only for use under the Food and Drug Administration's Emergency Use Authorization.

SUMMARY AND EXPLANATION OF THE TEST

The SCoV-2 *Detect*™ IgG Rapid Test is a qualitative immunoassay for the detection of IgG antibodies to SARS-CoV-2. The test can be performed using serum, plasma (sodium citrate, dipotassium EDTA and sodium heparin), venous whole blood (sodium citrate, dipotassium EDTA and sodium heparin), or fingerstick whole blood samples, and takes less than 25 minutes to obtain results.

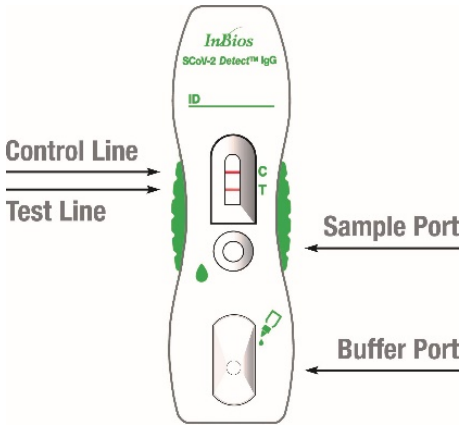
PRINCIPLE OF THE TEST

The SCoV-2 *Detect*™ IgG Rapid Test is a qualitative, membrane-based immunoassay for the detection of IgG antibodies targeting SARS-CoV-2.

This test may be used with serum, plasma, venous whole blood, or fingerstick whole blood samples. The membrane of the cassette is pre-coated with SARS-CoV-2 spike protein antigen on the test line region and utilizes a separate control line to ensure assay flow. During testing, the sample is added directly to the sample port of the cassette. After sample addition, 4 drops of Chase Buffer Type A are added to the buffer port of the cassette. The sample migrates along the membrane to react with the test and control lines. The sample will mix with anti-human IgG antibody conjugated to gold nanoparticles while migrating. If IgG antibodies against SARS-CoV-2 are present above the limit of detection of the test, a red line will appear at the IgG test line region.

A red line on the cassette's control region should always appear if the assay is performed correctly, regardless of the presence of the test line. The presence of this red control line verifies that proper flow has occurred, and catastrophic failure of the gold conjugate has not occurred. Refer to the Interpretation of Results section for additional information regarding results analysis.

The entire procedure takes approximately 20-25 minutes. The layout for the SCoV-2 *Detect*™ IgG Rapid Test is indicated below:



WARNINGS AND PRECAUTIONS

- This product has not been FDA cleared or approved but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories.
- Testing of serum, plasma, and venous whole blood specimens is limited to laboratories certified under CLIA that meet requirements to perform moderate or high complexity tests. Testing of fingerstick whole blood specimens is limited to laboratories certified under CLIA that meet the requirements to perform high, moderate, or waived complexity tests. Testing of fingerstick whole blood specimens is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.
- This product has been authorized only for detecting the presence of IgG antibodies to SARS-CoV-2, not for any other viruses or pathogens.
- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of *in vitro* diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb3(b)(1), unless the declaration is terminated or authorization is revoked sooner.
- As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
- Failure to follow the test procedure may cause erroneous results or invalidated test results.
- Do not use the test after expiration date shown on the kit box label.
- Handle all samples and kits as if they contain infectious agents. Follow the standard procedures for proper disposal of blood products and used kits.
- If using a capillary tube, control and test samples must be filled to the black line on the capillary tube.
- Wear protective clothing, eye protection, and disposable gloves while performing the assay. Wash hands thoroughly when finished.

- Chase Buffer Type A contains a preservative. Avoid all contact between hands and eyes or mucous membranes during testing.
- Do not eat, drink or smoke in the area where the blood and kits are handled.
- Avoid directly touching the tip of the Chase Buffer Type A bottle to surfaces to avoid contamination. If bottle tip touches any surface, then it is recommended to discard bottle and use a different bottle provided with the kit. Contact InBios International if additional buffer is required.
- Faint positive results may not be visible in poor lighting conditions. Read results in a well-lit area.
- This is a visually interpreted test. Operators with impaired vision may not be capable of interpreting test results. Individuals with color-impaired vision may not be able to adequately interpret test results.

STORAGE

The tests and the Chase Buffer Type A solution are designed to be stored at room temperature (15-30°C) for the duration of their shelf life. Exposure to temperatures over 30°C can impact the performance of the test and should be minimized. The tests should not be frozen. DO NOT open the foil pouch containing the test cassette until ready to test the sample.

SAMPLE TYPES

- Human serum, plasma (sodium citrate, dipotassium EDTA and sodium heparin), venous whole blood (sodium citrate, dipotassium EDTA and sodium heparin), and fingerstick whole blood can be tested with this assay. Follow the general laboratory procedures for blood collection by a trained phlebotomist.
- Testing should be performed as soon as possible after blood collection. Do not leave samples at room temperature for prolonged periods.
- **Fingerstick whole blood sample collection:** Massage patient's hand and lower part of the finger to increase blood flow. Wipe the patient's middle or ring finger with an alcohol swab and dry with gauze. Hold the finger in an upward position, press firmly on the finger, and lance the palm-side of the finger with a lancet. Apply slight pressure for blood flow. Blot the first drop of blood on a gauze pad prior to collecting the test sample with a capillary tube.
- **Venous whole blood sample collection:** Collect the blood sample in a commercially available blood collection tube containing anticoagulants including sodium citrate, dipotassium EDTA or sodium heparin. Swirl or invert the tube gently as per the manufacturer's instructions.
- **Plasma sample collection:** Collect venous whole blood into a commercially available blood collection tube containing anticoagulants including sodium citrate, dipotassium EDTA or sodium heparin. Separate the plasma by centrifugation as per the manufacturer's instructions.
- **Serum sample collection:** Collect venous whole blood into a commercially available blood collection tube that does NOT contain anticoagulants. Blood should be allowed to clot at room temperature for 30 to 60 minutes and then centrifuged according to the Clinical and Laboratory Standards Institute (CLSI Approved Guideline – Procedures for the Handling and Processing of Blood Specimens GP44 ISBN 1-56238-388-4).
- Test fingerstick whole blood immediately, without anticoagulant. Venous whole blood with anticoagulant may be stored at 2-8°C for up to 24 hours before testing. Do not freeze blood samples.
- Separated serum/plasma should remain at room temperature for no longer than one hour. If assays are not completed within one hour, serum/plasma should be refrigerated at 2-8°C up to 48 hours. If the separated serum/plasma needs to be stored beyond 48 hours, serum/plasma should be frozen at or below -20°C.
- Samples should not be frozen and thawed more than once. Frost-free freezers are not suitable for sample storage.
- Frozen serum/plasma samples should be thawed to room temperature and mixed thoroughly by gentle swirling or inversion prior to use. Always quick spin before use.
- Bring samples to room temperature (15-30°C) prior to testing.
- Do not use samples if any indication of microbial growth is observed.
- If samples are to be shipped, they should be packed in compliance with Federal Regulations covering transportation of infectious agents.

KIT CONTENTS

The kit (Catalog #COVG-RE) contains the following components:

Content	Description	Storage
Fifty (50) Test Devices	Foil pouched single use test device containing test strip inside a cassette device	15-30°C
Two (2) Chase Buffer Type A	Dropper bottle containing 6mL of Chase Buffer Type A	15-30°C
One (1) SCoV-2 *Detect*™ IgG Positive Control	Lyophilized SARS-CoV-2 reactive recombinant human IgG antibody in human serum with Tris buffer and preservative	15-30°C
One (1) Lyophilized Negative Control	Lyophilized human serum with Tris buffer and preservative.	15-30°C
One (1) SCoV-2 *Detect*™ IgG Rapid Test Instructions for Use	N/A	N/A
One (1) SCoV-2 *Detect*™ IgG Rapid Test Quick Reference Instructions	N/A	N/A

MATERIALS REQUIRED BUT NOT PROVIDED

Content	Description	Storage
Timer	N/A	N/A
Pipettor and tips, or 15µL capillary tubes*	Calibrated pipettor or capillary tubes	N/A
Lancet, alcohol swab, and gauze	For fingerstick blood collection, if applicable	N/A

*Authorized capillary tubes are available for purchase from InBios International (Part #200934) or Jiangsu Kehua Medical Instrument Co., Ltd., (Catalog #KH1106). For pipettor and tips, any manufacturer may be used. Only authorized capillary tubes may be used.

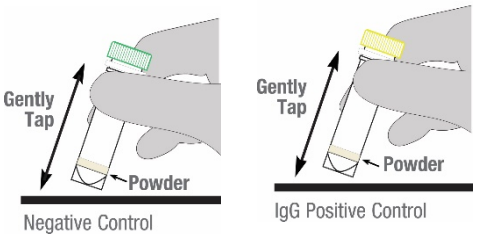
TEST PROCEDURE – Negative and Positive Control Testing

In order to establish any clinical samples results are valid and can be reported, prior to testing clinical specimens the positive and negative controls must be run:

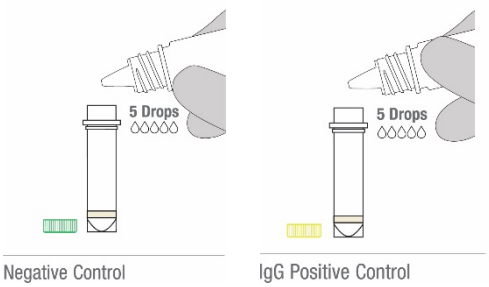
- Once for each new operator.
- Once per kit upon kit opening.
- As deemed additionally necessary by your internal quality control procedures and in accordance with Local, State, and Federal regulations or accreditation requirements.

Note: If using a capillary tube for sample addition, refer to the "Proper Use of Capillary Tube" section below before starting the procedure. Only authorized capillary tubes may be used.

1. Remove the lyophilized SCoV-2 *Detect*™ IgG negative and positive control vials from their pouches. The lyophilized pellets may have shifted during transport and may adhere to the side of the vial. Gently tap the vials until the lyophilized pellet is at the bottom of the tube.

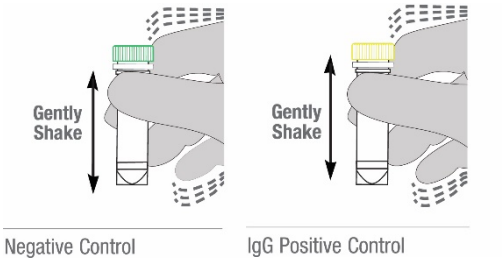


2. Reconstitute the negative and positive controls by adding 5 drops (~175µL) of Chase Buffer Type A into each control vial, being careful not to touch the vial with the dropper tip.



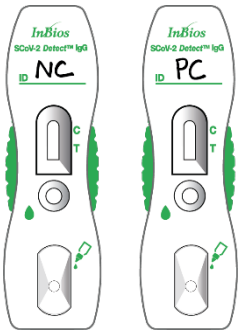
3. Dissolve the lyophilized pellets by re-capping and gently shaking the control vials several times. The lyophilized controls will be ready to use when the lyophilized pellet completely dissolves.

   Note: The solution may appear cloudy even when the pellet is completely dissolved.



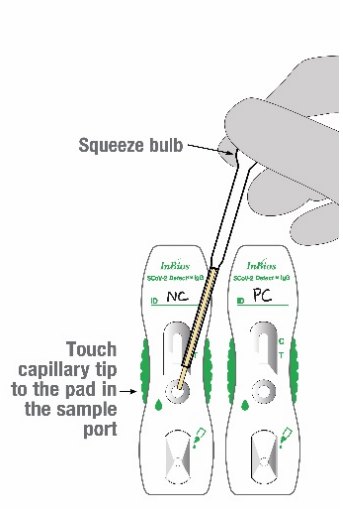
4. Remove two cassettes from each pouch and lay cassettes horizontally on a clean and flat surface. Write the control name (i.e., negative control or positive control) on the top of each cassette.

   Important: *Check to be sure the cassette is on a flat surface. Invalid results can occur if the test cassette is not on a flat surface.*

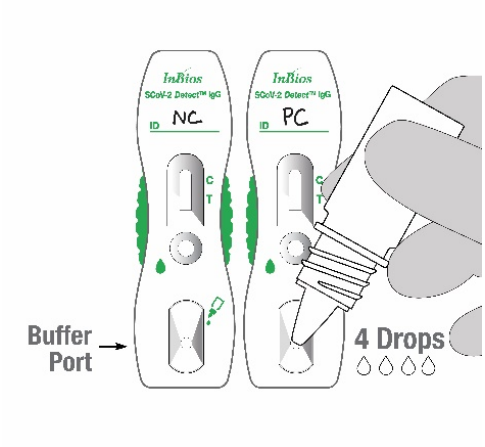


5. Using a calibrated pipettor or new authorized15µL capillary tube, add 15 µL of SCoV-2 *Detect*™ IgG negative control and positive control samples to the Sample Ports of the labelled cassettes by touching the pipette or tube tip directly to the sample pads. If using the capillary tube, refer to ***"Proper Use of Capillary Tube"*** section for directions on using the capillary tube.

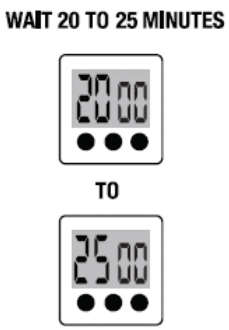
   Use a fresh pipette tip or capillary tube for addition of each sample.



6. Remove the cap of the Chase Buffer Type A bottle. Add 4 drops (~140 µL) of Chase Buffer Type A to the Buffer Ports of both cassettes. **Do not touch the tip of the bottle directly to the Buffer Port when adding the liquid.** Put the cap back on the Chase Buffer Type A bottle.



7. Allow the cassettes to remain undisturbed. Results should be interpreted between 20 and 25 minutes after starting the test. Do not interpret results after 25 minutes, as they may be inaccurate.



- Positive control should test positive and negative control should test negative. If any of the controls do not give the correct result, retest the controls on unused new cassettes, labelled properly (as PC or NC), ensuring the correct control was added to the correct cassette. If incorrect results occur twice, do not use the kit to test clinical samples and contact InBios International, Inc. (https://inbios.com/technical-support/). The controls should be used immediately after reconstitution.

TEST PROCEDURE – Specimen Testing

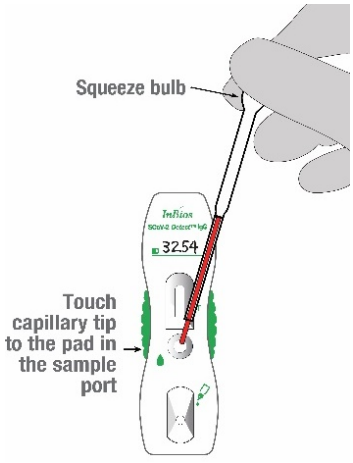
- Use serum or plasma samples that are properly collected and stored. Avoid hemolyzed or highly lipemic specimens. Use fresh (< 24 hours after collection) venous whole blood collected with anticoagulant and stored at 2-8°C. Fingerstick whole blood should be tested immediately after collection.
- Allow test samples to reach room temperature prior to testing. Failure to do so may cause improper flow of the sample in the test region.
- Prior to testing, gently mix the serum, plasma or venous whole blood sample by inverting several times.

Note: If using a capillary tube for sample addition, refer to the "Proper Use of Capillary Tube" section below before starting the procedure. Only authorized capillary tubes may be used.

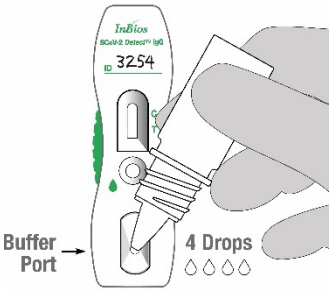
1. Remove one cassette from its pouch and write the sample identification (sample ID) on the top of the cassette.
2. Place the cassette horizontally on a clean and flat surface.

   Important: *Check to be sure the cassette is on a flat surface. Invalid results can occur if the test cassette is not on a flat surface.*

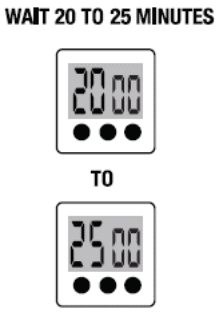
3. Using a calibrated pipettor or a new authorized 15µL capillary tube, apply 15 µL of the test sample to the Sample Port of the cassette by touching the pipette or tube tip directly to the sample pad. If using the capillary tube, refer to ***"Proper Use of Capillary Tube"*** section for directions on using the capillary tube. Ensure all the sample is added into the Sample Port and the sample is completely absorbed by the test. **Do not add the sample to the Buffer Port of the cassette.**



4. Remove the cap of the Chase Buffer Type A bottle. Add 4 drops (~140 µL) of Chase Buffer Type A to the Buffer Port of the cassette. Do not touch the tip of the bottle directly to the Buffer Port when adding the liquid. **Incorrect addition of sample or chase buffer may result in invalid results.** Put the cap back on the Chase Buffer Type A bottle.



5. Allow the cassettes to remain undisturbed. Results should be interpreted between 20 and 25 minutes after starting the test. Do not interpret results after 25 minutes, as they may be inaccurate. **For best results, perform test interpretation in a well-lit area. Performing the test under dim lighting may result in false negative results**.

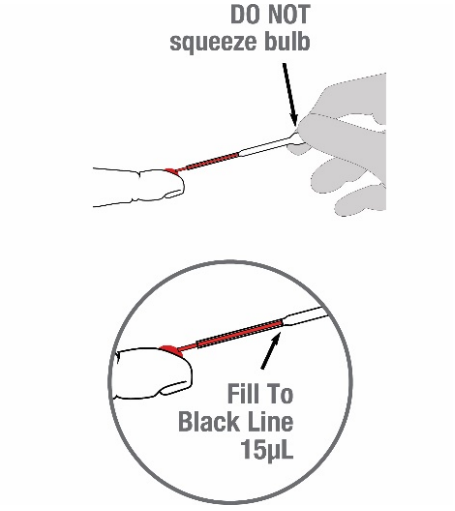


- See the Interpretation of Results section for instructions on how to interpret the SCoV-2 *Detect*™ IgG Rapid Test results.
- Dispose of cassette after test interpretation is complete. Disposal of the used cassette should be in accordance with your established laboratory bio-waste procedures.

PROPER USE OF CAPILLARY TUBE – All sample types. Only authorized capillary tubes may be used.

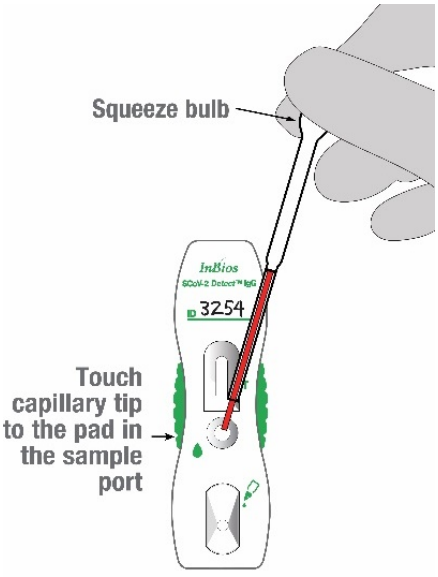
1. To draw all sample types, touch the open tip of the capillary tube to the sample. **DO NOT SQUEEZE THE BULB to draw up the sample.** The sample will immediately fill the capillary tube to the black line.
2. Wait until the volume of the sample reaches the black fill line on the capillary tube. *The capillary tube should be held horizontally for the sample to reach the black line.*
3. Keep the capillary tube in the near horizontal position until ready to apply the sample to the cassette sample port.

- *Some sample volume loss may result if the capillary tube is held in a vertical position after aspiration. In this case, re-draw the sample using a new capillary tube before sample application.*



Note: *The capillary tube may be used with the kit controls and all sample types (fingerstick whole blood, venous whole blood, plasma, and serum).*

4. Apply the sample to the sample port by **touching the tip of the capillary tube directly to the sample pad while squeezing the bulb**, until the sample is completely expelled into the sample port. Ensure all the sample is added into the Sample Port and the sample is completely absorbed by the test.



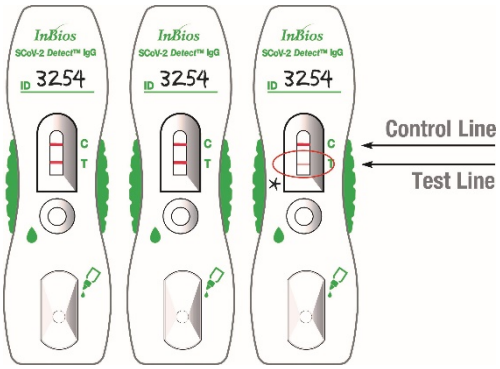
INTERPRETATION OF RESULTS

The SCoV-2 *Detect*™ IgG Rapid Test should be interpreted between 20 and 25 minutes after starting the test. Do not interpret results after 25 minutes because results interpreted after 25 minutes may be inaccurate. For best results, perform test interpretation in a well-lit area.

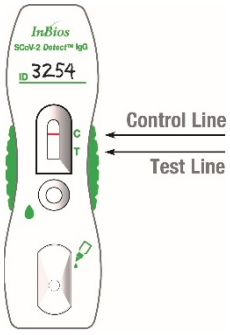
SCoV-2 Detect™ IgG Rapid Test Result			
Control Line	***Test Line***	**Reported Result**	**Interpretation**
+	+	Positive	IgG anti-SARS-CoV-2 antibodies are detected
+	-	Negative	IgG anti-SARS-CoV-2 antibodies are not detected
-	+	Invalid	Do not report invalid results. The specimen must be retested with another cassette.
-	-		

Positive Result: The test is positive for IgG antibodies to SARS-CoV-2 when a control line ("C") and a test line ("T") appear in the marked areas on the cassette membrane.

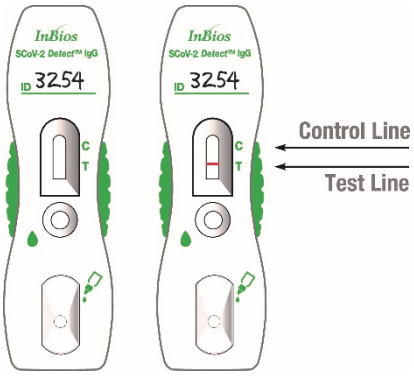
***Observe Test Line Closely!** A very faint pink test line is still considered a positive result.*



Negative Result: The test is negative when only a control line appears on the cassette. A negative result indicates that the SCoV-2 *Detect*™ IgG Rapid Test did not detect IgG antibodies to SARS-CoV-2.



Invalid Result: The test is invalid if no control line appears on the cassette, regardless of whether a test line is seen. If an invalid result is observed, re-test sample with a new cassette. If testing fingerstick whole blood a fresh sample should be collected and used.



LIMITATIONS

- For use under an Emergency Use Authorization only.
- Use of the SCoV-2 *Detect*™ IgG Rapid Test is limited to laboratory personnel who have been trained. Not for home use.
- The test is limited to the qualitative detection of anti-SARS-CoV-2 antibodies in human serum, fingerstick whole blood, venous whole blood, and plasma samples and does not indicate the quantity of the antibodies. Other specimen types have not been evaluated and should not be used with this assay. The intensity of the test line does not correlate to SARS-CoV-2 antibody titer in the specimen.
- Samples should only be tested from individuals that are 15 days or more post symptom onset.
- The test results should be interpreted between 20 and 25 minutes after starting the test. The test results should not be interpreted after 25 minutes.
- This test can only be used for the analysis of human serum, plasma (sodium citrate, sodium heparin, or dipotassium EDTA), venous whole blood (sodium citrate, sodium heparin, or dipotassium EDTA), and fingerstick whole blood samples.
- Do not use serum samples containing any glycerol, Tween, or other viscous materials. This will affect performance and decrease the sensitivity of the assay.
- Serum and plasma specimens should not be frozen more than once.
- Frozen whole blood should never be used for testing.
- This assay is not indicated for testing blood or plasma donors. This assay is also not indicated for at home testing.
- Performing the test outside the recommended temperature, 59 - 86°F (15 - 30°C), and relative humidity, 20% to 85% non-condensing, may cause erroneous results.
- Invalid results can occur if the test cassette is not on a flat surface.
- The performance of the assay has not been fully established. Assay interference from factors such as high levels of lipid, protein, HAMA, bilirubin, are yet to be established.
- This test should not be used to diagnose acute COVID-19. This test alone must not be used for any clinical treatment decision. All results must be considered with other clinical information available to the physician.
- False positive or false negative results may occur.
- Incorrect specimen volume may result in invalid or false negative results.
- Incorrect addition of sample or chase buffer may result in invalid results.
- Performing the test under dim lighting may result in false negative results.
- 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.
- Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. The sensitivity of the SCoV-2 *Detect*™ IgG Rapid Test early after infection is unknown.
- The performance of this device has not been established in individuals that have received a COVID-19 vaccine. The clinical significance of a positive or negative antibody result following COVID-19 vaccination has not been established, and the result from this assay should not be interpreted as an indication or degree of protection from infection after vaccination.
- It is not known at this time if the presence of antibodies to SARS-CoV-2 confers immunity.
- The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between April 2020 and May 2021, in the US (California, Florida, Louisiana, Nebraska, Nevada, Pennsylvania, Texas, Utah, Washington), Peru, and Columbia. The clinical performance has not been established in all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.

CONDITIONS OF AUTHORIZATION FOR LABORATORIES

The SCoV-2 *Detect*™ IgG Rapid Test Letter of Authorization*, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Patients, and other authorized labeling are available on the FDA website: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas

However, to assist clinical laboratories using the SCoV-2 *Detect*™ IgG Rapid Test ("your product" in the conditions below), the relevant Conditions of Authorization are listed below:

A. Authorized laboratories using your product must include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.
B. Authorized laboratories must use your product as outlined in the authorized labeling. Deviations from the authorized procedures, including the authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use with your product are not permitted.
C. Authorized laboratories that receive your product must notify the relevant public health authorities of their intent to run your product prior to initiating testing.
D. Authorized laboratories using your product must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
E. Authorized laboratories must collect information on the performance of your product and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and InBios International Inc. (https://inbios.com/technical-support/) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of your product of which they become aware.
F. All laboratory personnel using your product must be appropriately trained in immunoassay techniques and use appropriate laboratory and personal protective equipment when handling this kit, and use your product in accordance with the authorized labeling. All laboratory personnel using the assay must also be trained in and be familiar with the interpretation of results of your product.
G. InBios International Inc., authorized distributor(s), and authorized laboratories using your product must ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

**The letter of authorization refers to "authorized laboratories" as follows: Testing of serum, plasma (sodium citrate, dipotassium EDTA and sodium heparin), and venous whole blood (sodium citrate, dipotassium EDTA and sodium heparin) is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. 263a, that meet requirements to perform moderate or high complexity tests.*

Testing of fingerstick whole blood specimens is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42, U.S.C. §263a, that meet the requirements to perform high, moderate, or waived complexity tests. Testing of fingerstick whole blood specimens is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

PERFORMANCE CHARACTERISTICS

Clinical Evaluation with Archived Retrospective Serum/Plasma Samples: The clinical performance of the SCoV-2 *Detect*™ IgG Rapid Test was evaluated in a retrospective study by testing a total of 332 samples comprised of 68 unique serum/plasma samples collected from 68 SARS-CoV-2 RT-PCR positive individuals and 264 presumed negative serum specimens collected prior to the COVID-19 outbreak (i.e., prior to December 2019). Out of the 68 individuals, 66 had days post symptoms onset (pso) information at the time of collection.

Positive percent agreement (PPA) and 95% confidence intervals were calculated by days post symptoms onset (pso as indicated in the table below).

Days PSO	# SARS-CoV-2 RT-PCR Positive Subjects	SCoV-2 *Detect*™ IgG Results		
		# SCoV-2 *Detect*™ IgG Positive	IgG PPA	95% CI
0-7	14	13	92.9%	68.5%-98.7%
8-14	22	18	81.8%	61.5%-92.7%
≥15	30	30	100%	88.6%-100%
Total	66	N/A		

Negative percent agreement (NPA) and 95% confidence intervals were calculated as indicated in the table below.

Presumed Negative Subjects Tested	# SCoV-2 *Detect*™ IgG Negative	NPA	95% CI
264	258	97.7% (258/264)	95.1%-99%

POC Clinical Evaluation with Prospective Fingerstick Whole Blood Samples: The clinical performance of the SCoV-2 *Detect*™ IgG Rapid Test was evaluated at five POC sites in the US by 16 non-laboratorian operators representative of the intended use operator for this device at a POC setting. Capillary blood samples were prospectively collected from 65 unique subjects. 32 of the subjects were RT-PCR positive, 24 subjects were RT-PCR negative, and 9 subjects were determined to be COVID-19 negative based on a clinical assessment. All positive samples were collected ≥15 days pso. Positive and negative percent agreement calculations and 95% confidence intervals (CI) are shown in the tables below.

Positive Percent Agreement (PPA) calculation:

Prospective fingerstick whole blood samples	Days pso	# SARS-CoV-2 PCR Positive Subjects	# SCoV-2 *Detect*™ IgG Results		
			# Positive Results	PPA	95% CI
	0-7	0	0	N/A	N/A
	8-14	0	0	N/A	N/A
	≥15	32	31	96.9% (31/32)	84.3%-99.5%

Negative Percent Agreement (NPA) calculation:

Prospective fingerstick whole blood samples	# SARS-CoV-2 Negative Subjects	# SCoV-2 *Detect*™ IgG Negative	NPA	95% CI
	33	33	100% (33/33)	89.6%-100%

Independent Clinical Agreement Validation: The InBios SCoV-2 *Detect*™ IgG Rapid Test was tested at the Frederick National Laboratory for Cancer Research (FNLCR) sponsored by the National Cancer Institute (NCI). The test was validated against a panel of previously frozen samples consisting of 30 SARS-CoV-2 antibody-positive serum samples and 80 antibody-negative serum and plasma samples. Each of the 30 antibody-positive samples were confirmed with a nucleic acid amplification test (NAAT) and both IgM and IgG antibodies were confirmed to be present in all 30 samples. The presence of antibodies in the samples was confirmed by several orthogonal methods prior to testing with the InBios SCoV-2 *Detect*™ IgG Rapid Test. The presence of IgM and IgG antibodies specifically was confirmed by one or more comparator methods. Antibody-positive samples were selected at different antibody titers.

All antibody-negative samples were collected prior to 2020 and include: i) Seventy (70) samples selected without regard to clinical status, "Negatives" and ii) Ten (10) samples selected from banked serum from HIV+ patients, "HIV+". Testing was performed by one operator using one lot of the InBios SCoV-2 *Detect*™ IgG Rapid Test. Confidence intervals for sensitivity and specificity were calculated per a score method described in CLSI EP12-A2 (2008).

For evaluation of cross-reactivity with HIV+, it was evaluated whether an increased false positive rate among antibody-negative samples with HIV was statistically higher than the false positive rate among antibody-negative samples without HIV (for this, a confidence interval for the difference in false positive rates was calculated per a score method described by Altman). The results and data analysis are shown below.

Summary Results

	Comparator Method		**Collected pre-2020**		
	SARS-CoV-2 IgG Positive		**SARS-CoV-2 IgG Negative**		
SCoV-2 *Detect*™ IgG Rapid Test	**IgG+**	**IgG-**	**Negative**	**HIV+**	**Total**
IgG+	30				30
IgG-			70	10	80
Total	30		70	10	80

Summary Statistics

Measure	Estimate	Confidence Interval
IgG+ Sensitivity (PPA)	(30/30) 100%	(88.7%; 100%)
IgG- Specificity (NPA)	(80/80) 100%	(95.4%; 100%)
Positive predictive value (PPV) for prevalence = 5%	100%	(50.5%; 100%)
Negative predictive value (NPV) for prevalence = 5%	100%	(99.4%; 100%)
Cross-reactivity with HIV+	(0/10) 0% not detected	----------

Important limitations of the study:

1. Samples were not randomly selected, and sensitivity and specificity estimates may not be indicative of the real-world performance of the device.
2. These results are based on serum and plasma samples only and may not be indicative of performance with other sample types, such as whole blood, including fingerstick blood.
3. The number of samples in the panel is a minimally viable sample size that still provides reasonable estimates and confidence intervals for test performance, and the samples used may not be representative of the antibody profile observed in patient populations.

Potential Cross-Reactivity: Cross-reactivity of the SCoV-2 *Detect*™ IgG Rapid Test was evaluated by testing SARS-CoV-2 seronegative specimens from patients with antibodies to other viral infections and autoantibodies which could potentially cause false positive results. In addition, a total of 102 normal human serum (NHS) samples were collected in the US prior to the COVID-19 outbreak (i.e., known negatives) and were tested to evaluate potential cross-reactivity of the SCoV-2 Detect™ IgG Rapid Test. No false positive results were observed with the SCoV-2 *Detect*™ IgG Rapid Test when testing samples with antibodies to influenza A, influenza B, hepatitis B, respiratory syncytial viruses, *Haemophilus influenzae*, other coronaviruses, or anti-nuclear antibodies. Out of 102 NHS samples (collected in the US prior to COVID-19 outbreak), 99 tested negative while 3 tested positive. The results are presented below.

Sample description	**SCoV-2 *Detect*™ IgG Rapid Test Results**	
	Total number tested	Positive Results
Anti-HIV[a]	23	0
ANA	5	0
Anti-Influenza[b]	5	0
Anti-HBV	5	0
Anti-HCV	25	0
Anti-Respiratory syncytial virus	3	0
Anti-*Haemophilus influenzae* (IgG)	5	0
Anti-Other Coronavirus[c]	5	0
SARS-CoV-2 presumed negative serum (collected prior to COVID-19 outbreak)	102	3
Total	178	3

[a]HIV samples included HIV-1 (10) and HIV-2 (10) samples, the remaining three were unknown type.
[b]Two (2) specimens positive for antibodies to Influenza A and three (3) specimens positive for antibodies to Influenza A and Influenza B.
[c]Specimens positive for antibodies to HKU, OC43, 229E, NL63 strains of Coronavirus.

REFERENCES

1. Q. Li, *et al*. (2020). Early Transmission Dynamics in Wuhan, China, of Novel Coronavirus-Infected Pneumonia. N Engl J Med. 382:1119-1207.
2. X. Li, *et al*. (2020). Molecular immune pathogenesis and diagnosis of COVID-19. J Pharm Anal. 10(2): 102-108. https://doi.org/10.1016/j.jpha.2020.03.001.
3. CDC. Interim Guidelines for Collecting and Handling of Clinical Specimens for COVID-19 Testing. https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html.

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Insert Part Number: 900293-01
Effective Date: 08/26/2021

REF COVG-RE

EC REP

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CE

IVD

SCoV-2 *Detect*™ IgG Rapid Test

InBios

Quick Reference Instructions for Fingerstick Whole Blood

For use with the SCoV-2 *Detect*™ IgG Rapid Test. The SCoV-2 *Detect*™ IgG Rapid Test is an *in vitro* lateral flow chromatographic immunoassay intended for the qualitative detection of IgG antibodies to SARS-CoV-2 in fingerstick whole blood.

For *In Vitro* Diagnostic Use Only • For Prescription Use Only • For Use Under the Emergency Use Authorization (EUA) Only

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This is not the full Instructions for Use.

- Electronic copies of the Instructions for Use and Quick Reference Instructions can be found under the Downloads tab at www.inbios.com/scov-2-ab-detecttm-rapid-test-kit-2.
- Please contact inquiries@inbios.com if you require a printed copy of the Instructions for Use free of charge.
- This product has not been FDA cleared or approved but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories.
- This product has been authorized only for detecting the presence of IgG antibodies to SARS-CoV-2, not for any other viruses or pathogens.
- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of *in vitro* diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

Study the full Instructions for Use thoroughly before using Quick Reference Instructions. This is not a complete package insert.

CLIA Complexity: This test is only waived for fingerstick whole blood.

Testing of fingerstick whole blood specimens is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform high, moderate or waived complexity tests. Testing of fingerstick whole blood specimens is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform moderate and high complexity tests.

Kit Materials

1. Fifty (50) single use test cassettes, individually pouched (store at 15-30°C)
2. Two (2) dropper bottles of Chase Buffer Type A, 6 mL per bottle (store at 15-30°C)
3. One (1) SCoV-2 *Detect*™ IgG Positive Control (store at 15-30°C)
4. One (1) Lyophilized Negative Control (store at 15-30°C)
5. SCoV-2 *Detect*™ IgG Rapid Test Instructions for Use
6. SCoV-2 *Detect*™ IgG Rapid Test Quick Reference Instructions

Materials required but not provided:

- Timer
- Pipettor and tips, or 15 µL capillary tubes. Authorized capillary tubes are available from InBios International (Part #200934) or Jiangsu Kehua Medical Instrument Co., Ltd., (Catalog #KH1106). Only authorized capillary tubes may be used. For pipettor and tips, any manufacturer may be used.
- Lancet, gauze and alcohol swab (for fingerstick blood only)

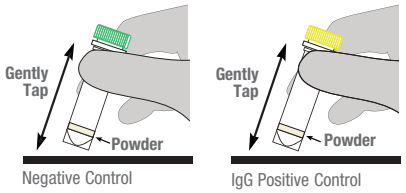
Quality Control

The positive and negative controls must be run:

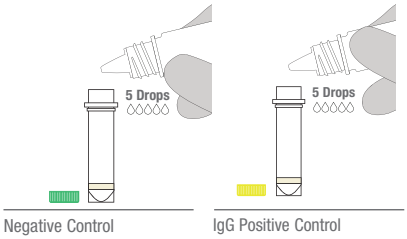
- Once for each new operator.
- Once per kit upon kit opening.
- As deemed additionally necessary by your internal quality control procedures and in accordance with Local, State and Federal regulations or accreditation requirements.

Test Procedure – Negative and Positive Control Testing

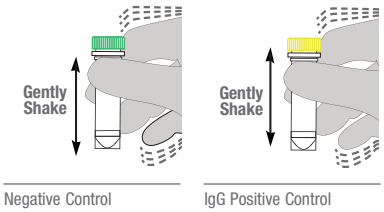
1. Remove positive and negative controls from the foil pouch. Gently tap the tubes until the powder is at the bottom of each tube.



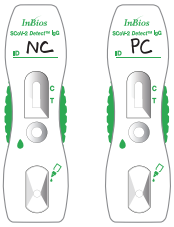
2. Remove the cap of each control. Add 5 drops of Chase Buffer Type A into each tube, *being careful not to touch the vial with the dropper tip.*



3. Dissolve the controls by re-capping and gently shaking the control tubes a few times. The controls will be ready to use when the powder in the tube completely dissolves. Liquid may be cloudy.

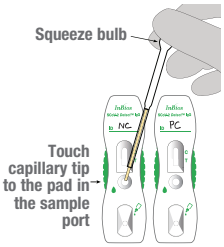


4. Remove two cassettes from each pouch and lay cassettes horizontally on a clean and flat surface. Write the control name (i.e., negative control or positive control) on the top of each cassette.

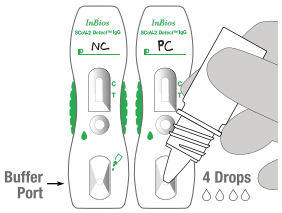


5. Use a new authorized 15µL capillary tube to add negative control and positive control to the Sample Ports of the labelled cassettes by touching the capillary tube tip directly to the sample pads. Refer to ***"Proper Use of Capillary Tube"*** section for directions on using the capillary tube.

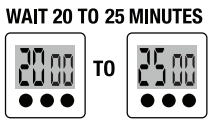
Use a fresh pipette tip or new authorized 15µL capillary tube for addition of each sample.



6. Remove the cap of the Chase Buffer Type A bottle. Add 4 drops of liquid to the Buffer Ports of both cassettes. Do not touch the tip of the bottle directly to the Buffer Port when adding the liquid. Put the cap back on the Chase Buffer Type A bottle.

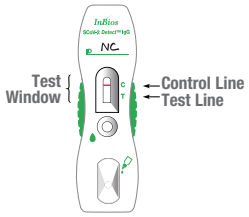


7. Read the result between 20 and 25 minutes after starting the test. Do not read results after 25 minutes.

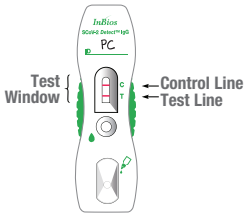


Reading the Kit Controls

The Negative Control is considered valid if only a control line appears in the test window.



The Positive Control is considered valid if control and test lines appear in the test window.



If either of the controls are invalid:

- Re-test the controls on unused new cassettes, labelled properly (as PC or NC), to ensure the correct control was added to the correct cassette.
- If incorrect results occur twice, do not use the kit to test clinical samples and contact InBios International, Inc.

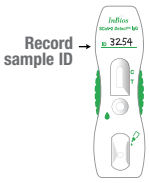
Test Procedure - Blood Samples

DO NOT open the foil pouch containing the test cassette until ready to test the sample. Place the test cassette on a clean and flat surface, such as a table top. Invalid results can occur if the test cassette is not on a flat surface.

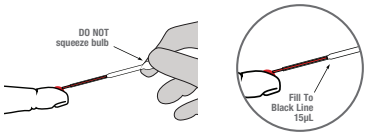
Performing the test outside the recommended temperature, 59-86ºF (15-30ºC) and relative humidity, 20% to 85% non-condensing, may cause erroneous results.

DO NOT use kits beyond their expiration date.

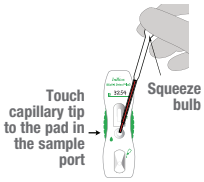
1. For each sample to be tested, remove one test cassette from the foil pouch and write the sample identification (sample ID) on the top.



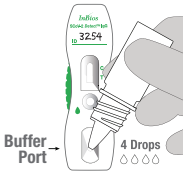
2. the sample by touching the tip of the new authorized 15µL capillary tube to the sample. The blood will immediately fill the capillary tube to the black line. Refer to ***"Proper Use of Capillary Tube"*** section for directions on using the capillary tube. DO NOT squeeze the bulb.



3. Add the sample to the Sample Port **by touching the tip of the filled capillary tube directly to the pad in the Sample Port while squeezing the bulb** and squeezing the empty part of the capillary tube. Ensure all of the blood sample is added into the Sample Port and the blood is completely absorbed by the test cassette.

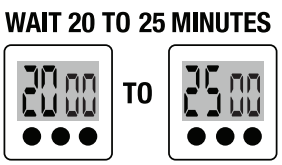


4. Remove the cap of the Chase Buffer Type A bottle. Add 4 drops of liquid to the Buffer Port. Do not touch the tip of the bottle directly to the Buffer Port when adding the liquid. Put the cap back on the Chase Buffer Type A bottle.



5. Read the result between 20 and 25 minutes after starting the test. Do not read results after 25 minutes.

For best results, perform test interpretation in a well-lit area.
Performing the test under dim lighting may result in false negative results.



Limitations

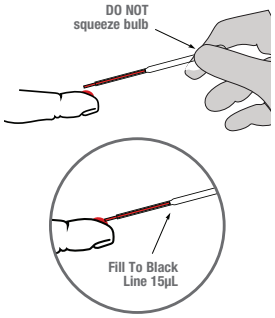
Reference the Instructions for Use for Warnings and Precautions, Specimen Collection and Handling, and Quality Control.

- Failure to follow the test procedure may cause erroneous results or invalidate the test results.
- The sample must be filled to the black line on the capillary tube.

Proper Use of Capillary Tube

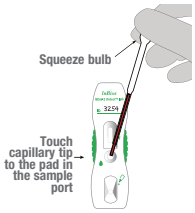
Only authorized capillary tubes may be used. To draw up the positive and negative control solution provided with kit or patient blood samples:

1. Touch the open tip of the capillary tube to the sample. DO NOT SQUEEZE THE BULB to draw up the sample.
2. The sample will immediately fill the capillary tube to the black line. The capillary tube should be held horizontally for the sample to reach the black line.
3. Wait until the volume of the sample reaches the black fill line on the capillary tube. The adjacent figure shows an example for fingerstick whole blood draw.
4. Keep the capillary tube in the near horizontal position until ready to apply the sample to the cassette sample port.
5. Some sample volume loss may occur if the capillary tube is held in a vertical position after taking up the sample. In this case, re-draw the sample using a new capillary tube before adding the sample to the test cassette.



To add the kit control samples or blood samples to the test cassette:

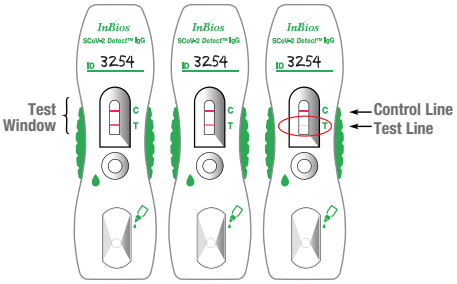
1. Touch the tip of the filled capillary tube directly to the pad in the Sample Port while squeezing the bulb.
2. Ensure all of the sample is added into the Sample Port and the sample is completed absorbed by the test cassette.



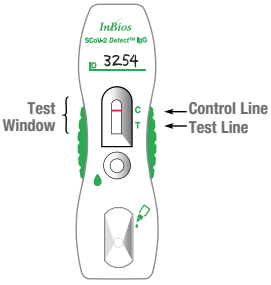
Interpretation of Results

Positive Result
The test line is positive when the control line and the test line appear in the test window.

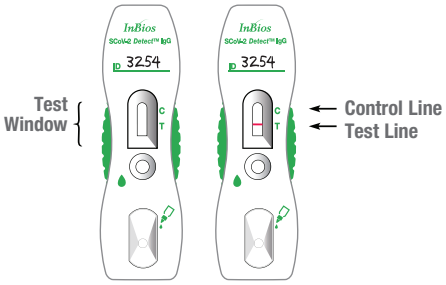
**Look closely!*
A very faint pink test line is still considered a positive result.



Negative Result
The test is negative when only the control line appears in the test window. No test line appears on the cassette.



Invalid Result
The test is considered invalid when no control line appears in the test window. The test is still considered invalid if a test line appears in the test window, but no control line appears. An invalid result should be repeated with a new cassette and a fresh fingerstick whole blood sample. If testing fingerstick whole blood, a fresh sample should be used.



Assistance

If you have any questions regarding the use of this product or if you want to report a problem with the test, please call InBios International, Inc. Technical Support at 1-866-INBIOS1 or 206-344-5821, or visit inbios.com/technical-support/ to submit your inquiry.

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Part No.: 900295-01

REF COVG-RE

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SCoV-2 *Detect*™ IgG Rapid Test Control Kit (COVC-G) Product Information Card

For Use Only with SCoV-2 *Detect*™ IgG Rapid Test
●IVD ●Rx only ●EUA only

Product Specification Sheet

Product	SCoV-2 *Detect*™ IgG Positive Control	Lyophilized Negative Control
Product Part #	500765D	500733D
Lot #	[Lot Number]	[Lot Number]
Quantity	1 vial/kit	1 vial/kit
Description	Lyophilized SARS-CoV-2 reactive recombinant human IgG antibody artificial positive control in human serum with Tris buffer and preservative	Lyophilized human serum with Tris buffer and preservative
Preservative	0.1% ProClin™	
Performance	Lyophilized controls are stable at room temperature (15 – 30º Celsius) in sealed pouch or in low humidity environment until expiration. Reconstitute lyophilized pellet using 5 drops (~175uL) of Chase Buffer Type A. Once reconstituted, controls should be used immediately.	
Storage	Room temperature (15 - 30°C), low humidity environment until ready to use or expiration.	
Date of Manufacture	[Date of Manufacture]	[Date of Manufacture]
Expiration Date	[Date of expiration]	[Date of expiration]

General Purpose Reagent. For Laboratory Use.

IMPORTANT: The Control kit is only to be used with the SCoV-2 *Detect*™ IgG Rapid Test (Catalog #COVG-RE). This sheet is not full instructions. Full instructions for use of the controls can be found in the "SCoV-2 *Detect*™ IgG Rapid Test Instructions for Use". Electronic copies for the SCoV-2 *Detect*™ IgG Rapid Test Instructions for Use and Quick Reference Instructions can be found under the Downloads tab at www.inbios.com/scov-2-ab-detecttm-rapid-test-kit-2. Please contact inquiries@inbios.com if you require a printed copy of the Instructions for Use free of charge.

- **This product has not been FDA cleared or approved but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories.**
- **This product is for use with a test authorized only for detecting the presence of IgG antibodies to SARS-CoV-2, not for any other viruses or pathogens.**
- **The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of *in vitro* diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.**