RayBiotech
Empowering your proteomics

ALLERGY SOLUTIONS

Frequently Asked Questions

- Is this a combined test for IgM and IgG?

  Yes, they are combined together into a single cassette. There is a separate window to place the blood sample for IgG and IgM that are clearly marked.

- Should I use the IgM or IgG window?

  Since the patient may not know when they are infected, it is important to test for both IgM and IgG.

- Is this test for home use?

  This is not an over-the-counter product for home use. The test must be administered by a licensed medical professional. However, it is a POC (point of care) test that does not require sending samples to a lab. Therefore, the results can be obtained on-site at a clinic.

- What is the limit-of-detection (LOD) for this assay?

  There is no known LOD of this assay. The kit is qualitative and is based on antigen-antibody interactions, and every person has different antibody affinities.

- What is the difference between the finger prick and serum/whole blood kits?

  The test cartridges and diluent provided in the finger prick and serum/whole blood kits are identical. The only difference is that the finger prick kit comes with materials necessary for capillary blood collection (lancets, alcohol swabs, bandages).

- Are these tests covered by insurance?

  The billing code for non-CDC laboratory tests for SARS-CoV-2/COVID-19 is 86328.
  The patient's insurance company should be contacted to determine coverage and pricing.

- May I see your CE certification?

  They are located at the end of this packet.

- Is this kit approved by the FDA?

  These kits are for in vitro diagnostic use and have been submitted for Emergency Use Authorization following guidance from the FDA on March 16, 2020. The tests have not been reviewed by the FDA and results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 (COVID-19) infection or to inform infection status.

- Do you have validation data to provide?

  Our IgG/IgM rapid test kit have a 84.1% sensitivity (true positive) and a 92.3% specificity (true negative) rate.

RayBiotech
Empowering your proteomics

April 11, 2020

Coronavirus (COVID-19) IgM/IgG Rapid Test

Catalog #: CG-CoV-IgM, CG-CoV-IgG

Rapid patient screening is essential to slowing the spread of COVID-19. Detect COVID-19 in whole blood, serum, and plasma using the RayBio® Coronavirus (COVID-19) IgM/IgG Test Kits.

BACKGROUND

- **SARS-CoV-2:** Virus that causes COVID-19 infection. This virus encodes for different proteins, including the nucleocapsid (N) protein that is part of a shell that encapsulates the viral RNA.
- **IgM antibody:** Produced first, reflects early infection
- **IgG antibody:** Reflects later infection and, eventually, long-term immunity

ASSAY INFORMATION

- **Antigen:** Recombinant SARS-CoV-2 full-length N protein
- **Samples types:** serum, plasma, whole blood
- **Results:** 5 - 10 minutes
- **IgM & IgG analysis:** separate kits
- **Instrument:** No instrument required (results visual by eye)
- **Sensitivity:** 84.1% (*Figure 1*)
- **Specificity:** 92.3% (*Figure 1*)

RESULTS

- **Positive results:** If a test line is present, contact your doctor (Figure 2).
- **False negatives:** If the rapid test does not properly identify a person with COVID-19, that is called a false negative. There is a 15.9% chance of this occurring (Tables 1 – 2, Figure 3).
- **False positives:** If the rapid test indicates that someone has COVID-19 when they are not infected, that is called a false positive. There is a 7.7% chance of this occurring (Tables 1 – 2, Figure 3).

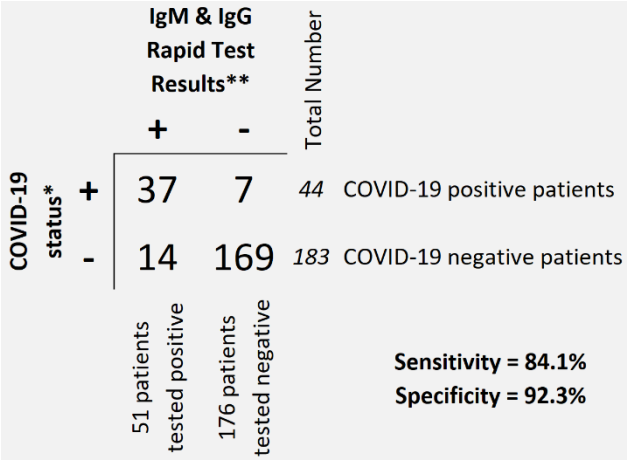

Figure 1. Sensitivity and specificity information when both IgM and IgG antibodies are measured. *The sensitivity and specificity may change as we continue to test more samples. *Confirmed through other clinical methods (e.g., RT-PCR). ** Serum samples*

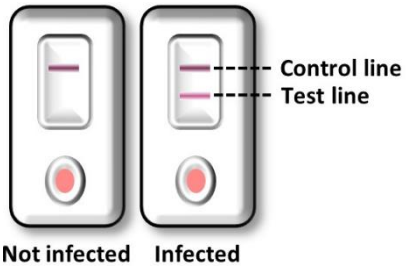

Figure 2. Schematic of possible results of the IgM/IgG rapid test. *The control line is for quality control of the device and should be present. The test line will vary in intensity based on the concentration of COVID-19 antibodies present in the sample.*

RayBiotech
Empowering your proteomics

Table 1. Clinical Interpretation of PCR and IgM/IgG rapid test results

Test Results			Clinical significance
PCR*	IgM**	IgG**	
-	-	-	Patient does not have COVID-19
-	-	+	Patient may have had COVID-19, but the virus has cleared. Patient has likely gained immunity to COVID-19.
-	+	-	Patient is in the acute phase of COVID-19 and contagious (false negative PCR results)
-	+	+	Patient has COVID-19 and is contagious (false negative PCR results) or patient is in the recovery phase of COVID-19
+	-	-	Patient has COVID-19, but antibody levels are below the detection limit (see also Table 2 and Figure 3)
+	-	+	Patient may be in late or recurrent stage of infection
+	+	-	Patient is in the acute phase of COVID-19 and contagious
+	+	+	Patient has COVID-19 and is contagious

** PCR: Throat/nasal swab sample; Detects SARS-CoV-2 viral RNA. Viral load may reflect infectivity. False negatives can occur for various reasons, including improper sample collection technique.*

*** IgM & IgG: Serum, plasma, and whole blood samples; Detects different antibody types to SARS-CoV-2 N-protein (Figure 3)*

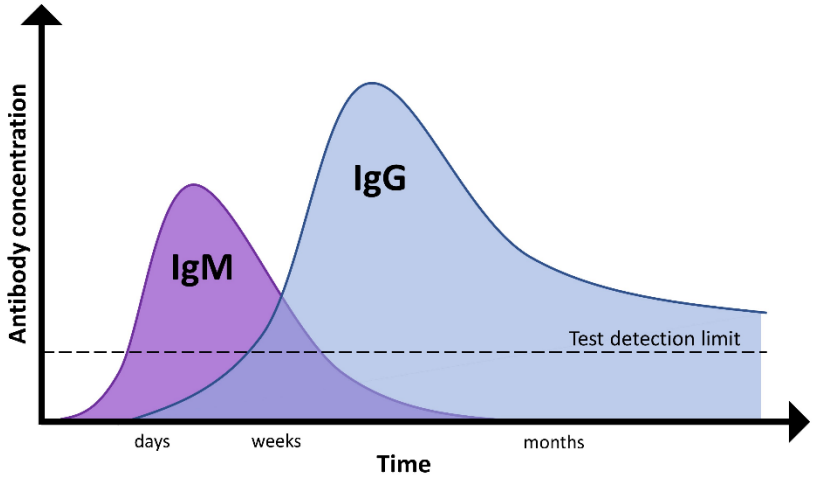

Figure 3. Schematic of IgM and IgG antibody profiles over time in response to infection. *IgM antibodies are produced first followed by the IgG antibodies. The specific antibody profiles for COVID-19 infection across time are still being ascertained. Host immune responses and antibody binding characteristics will vary. Recently, the IgG levels of a subset of recovering COVID-19 patients have been reported to drop off quickly, which may lead to negative IgG rapid test results.*

Table 2. Possible reasons for false negative or false positive results with the IgM/IgG rapid tests

Possible reason	Explanation
Assay not performed properly	Please refer to our instruction manual. Running the test differently than what is outlined in the manual can result in inaccurate data.
Antibody level below detection limit	• IgM and IgG levels change over time, and their profiles in response to COVID-19 are still being ascertained (Figure 3). For example, a false negative result with the IgM rapid test may due to the IgM phase ending (as the IgG levels increase). • Individual IgM and IgG responses will vary; we recommend that both IgM and IgG analyses are performed.
Antibodies not present (false negative)	This test detects antibodies to the wild-type Nucleocapsid Protein. • The patient may not have generated antibodies against the SARS-CoV-2 protein used in the kit. • SARS-CoV-2 virus is mutating. Patients may have antibodies to a mutated region of the N-protein
Antibody crossreactivity (false positive)	This test detects antibodies to the SARS-CoV-2 Nucleocapsid Protein, but there are regions of this protein that are the same (homologous) as other virus' nucleocapsid proteins. Antibodies targeting these homologous regions in response to a different infection will result in a false positive result. However, the possibility of this is small. • Previous infections will not have IgM antibodies and the IgG levels will be low. • We tested 36 potentially interfering specimens (5 cases of autoimmune disease related to anti-nuclear antibodies (ANA+), 6 cases of respiratory syncytial virus (RSV), 5 cases of influenza A virus, 6 cases of influenza B virus, 6 cases of hepatitis C virus (HCV) and 10 cases of hepatitis B virus (HBV) infected patients). None of them resulted in a false positive.
Unknown cause	In vitro diagnostics tests are not accurate 100% of the time. Sometimes the reasons for false results are unclear.
Test not working properly	The test is working properly if the control line is present. RayBiotech also performs quality control assessments for each test lot.

Novel Coronavirus (SARS-CoV-2) IgM Antibody Detection Kit (Colloidal Gold Method)

* This test has not been reviewed by the FDA *

For in vitro diagnostics and following FDA policy for the public health emergency

Catalog #: CG-CoV-IgM

- **PRODUCT NAME**

Generic name: Novel Coronavirus (SARS-CoV-2) IgM Antibody Detection Kit (Colloidal Gold Method).

- **PRODUCT SPECIFICATIONS**

25 tests/box

- **EXPECTED USAGE**

This kit is suitable for the qualitative detection of novel coronavirus (SARS-CoV-2) IgM antibodies in human serum and whole blood. Common signs of a person infected with a coronavirus include respiratory symptoms, fever, cough, shortness of breath, and dyspnea. In more severe cases, infection can cause pneumonia, severe acute respiratory syndrome (SARS), kidney failure, and even death. Coronavirus can be excreted through respiratory secretions or transmitted through oral fluids, sneezing, physical contact, and through air droplets.

- **DETECTION PRINCIPLES**

The detection kit uses the principle of immunochromatography: the separation of components in a mixture through a medium using capillary force and the specific and rapid binding of an antibody to its antigen. Each cassette is a dry medium that has been coated separately with novel coronavirus N protein ("T" test line) and goat anti-chicken IgY antibody ("C" control line) (Figure 1). Two free colloidal gold-labeled antibodies, mouse anti-human IgM (mIgM) and chicken IgY, are in the release pad section (S). Once diluted serum or whole blood is applied to the release pad section, the mIgM antibody will bind to coronavirus IgM antibodies if they are present, forming an IgM-IgM complex. The sample and antibodies will then move across the cassette's medium via capillary action. If coronavirus IgM antibody is present in the sample, the test line (T) will be bound by the IgM-IgM complex and develop color. If there is no coronavirus IgM antibody in the sample, free mIgM will not bind to the test line (T) and no color will develop. The free chicken IgY antibody will bind to the control line (C); this control line should be visible after the detection step as this confirms that the kit is working properly.

- **KIT COMPONENTS**

Component	Specification	Quantity	Ingredients
Detection Cassette	1 unit / bag	25 bags / kit	Test cassette, plastic pipette dropper, desiccant
Sample Diluent	245 µl / tube	25 tubes / kit	Sample diluent, liquid
Color Reference		1 card / kit	

The components of the Detection Cassette are:

1. Novel coronavirus N protein (fixed on porous capillary membrane)
2. Goat anti-chicken IgY antibody (fixed on porous capillary membrane)
3. Colloidal gold-labeled mouse anti-human IgM antibody (on the release pad)
4. Colloidal gold-labeled chicken IgY antibody (on the release pad)

Note: The components in different batches cannot be used interchangeably.

- **STORAGE AND EXPIRATION**

Keep kits in a cool and dry place at 2 – 30°C. Do not freeze the individual kits and/or box. Correctly stored kits are valid for 18 months (see the box for expiration date).

- **REQUIRED INSTRUMENTS**

None

- **SAMPLE REQUIREMENTS**

Assay is suitable for human serum or whole blood samples. Samples should be used as soon as possible after collection.

a. Whole blood collection: Any non-anticoagulated whole blood, including finger prick blood may be used, but the test must be processed immediately as per the "TESTING METHOD" section. These samples cannot be stored.
b. Serum collection: Samples should be collected via venous draw and should not be hemolyzed. Serum should be separated as soon as possible after blood collection to avoid hemolysis.
c. During sample processing disposable pipettes or pipette tips are required, and care must be taken to prevent cross-contamination.

- **SAMPLE PRESERVATION**

Non-anticoagulated samples have to be run immediately. Other samples should be run as soon as possible after collection and kept at or below 8 °C at all times. If long-term storage is required, please store at -20 °C for periods less than 3 months, or store at -80 °C for periods longer than 3 months. Avoid repeated freezing and thawing.

- **TESTING METHOD**

Read the instructions carefully before use. Bring the Detection Cassette, Sample Diluent, and sample to room temperature before testing.

a. Add 25µl of sample to the Sample Diluent and mix thoroughly. Add 2-3 drops to the release pad section (S) of the Detection Cassette.

b. The results can be interpreted is 8-10 minutes. Results measured after 20 minutes are invalid and should be discarded.

INTERPRETATION OF TEST RESULTS

a. Positive for 2019-nCoV: Both the test line (T) and the quality control line (C) are colored dark pink.
b. Negative for 2019-nCoV: The test line (T) does not develop color, or a faint gray band may be visible, but the quality control line (C) is colored.
c. Suspect: A light pink band is an inconclusive result. The sample requires an alternate testing method (such as RT-qPCR) to determine positivity.
d. Invalid: There is no colored control line (C) band. The results are invalid regardless of whether a red band appears on the test line (T); additional testing is required.

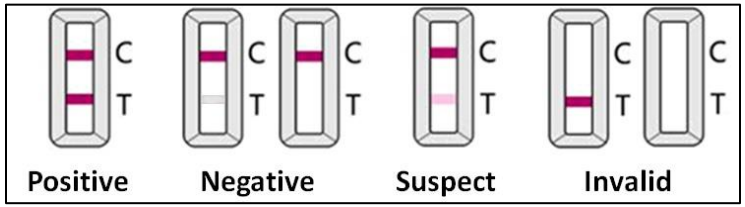

Figure 1: Representative schematic of possible lateral flow device results.
Note: If the color saturation on the test line (T) is darker than that shown for the "suspect" band, it should be judged as a positive result.

• LIMITATION OF DETECTION METHOD

a. 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.
b. 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.
c. Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.
d. Cross reactivity to other viral antibodies has not been determined (FluA, FluB, HCV, HBV, RSV, etc).
e. The product is designed only for use with human serum or whole blood samples for the qualitative detection of novel coronavirus (SARS-CoV-2).
f. Coronavirus may not be detected even though coronavirus antibodies are present in the sample, leading to a false negative. This may occur if the amount of coronavirus antibodies is below the detection level of the kit. To decrease the chance of obtaining a false negative, it is recommended that both coronavirus IgG and IgM are tested (catalog #CG-CoV-IgG, # CG-CoV-IgM).
g. If the product gets wet prior to use, or is stored improperly, it may cause incorrect results.
h. Not for the screening of donated blood.

• PRODUCT PERFORMANCE INDEX

a. Confirmation of Positive Reference samples per batch: 3 individual positive references samples were tested, and the result should identify all as positive samples. Results found 3 of 3 to be a positive and valid result.
b. Confirmation of Negative Reference samples per batch: 20 negative reference samples and products were tested, and the results should find all samples as negative. Results found 20 of 20 samples to show a negative and valid result.
c. Minimum detection limit: 3 samples at different concentrations of antibodies were tested, whereby a correct dilution (L3) and a lower dilution (L2) should be positive, while a too far diluted sample (L1), should be negative. Results confirmed L3, and L2 as positive, while L1 was negative.
d. Repeatability: 10 Detection Cassettes for the sample positive sample across 2 different lots of Detection Cassettes were probed simultaneously. All 10 showed a positive and valid result.
e. Our initial study of positive patients with China CDC found a sensitivity to positive COV2 patients of 93%, and a specificity of negative patients at 91%.

• PRECAUTIONS

a. This test has not been reviewed by the FDA.
b. This product is for in vitro diagnostic use only, both CE approved and following FDA guidance "Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency".
c. The assay should be performed as outlined in this manual, and in accordance with all instructions.
d. Do not use expired or damaged products.
e. Only use the matching diluent in the kit package. Diluents from different kit lots cannot be mixed.
f. Do not use tap water, purified water or distilled water as negative controls.
g. The test should be used within 1 hour after opening. If the ambient temperature is higher than 30 °C, or the test environment is humid, the Detection Cassette should be used immediately.
h. If there is no movement of the liquid after 30 seconds of beginning the test, 1 additional drop of sample solution should be added.
i. Take care to prevent the possibility of virus infection when collecting samples. Wear disposable gloves, masks, etc., and wash your hands afterwards.
j. This test card is designed for a single, one-time use. After use, the test card and samples should be regarded as medical waste with risk of biological infection and properly disposed of in accordance with national regulations.

Version: V7.1 **Date: 2020-APR-3**

Product Code: CG-CVO-IgM

IVD

U.S. FOOD & DRUG ADMINISTRATION

Acknowledgment Letter

3/17/2020

Jarad Wilson, Senior Business Development Manager
RAYBIOTECH Life, Inc.
3607 Parkway Lane, Suite 200
Peachtree Corners, GA 30092
UNITED STATES

Dear Jarad Wilson:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the unique document control number below. All future correspondence regarding this submission should be identified prominently with the number assigned and should be submitted to the Document Control Center at the above letterhead address. Failure to do so may result in processing delays. If you believe the information identified below is incorrect, please notify the Program Operations Staff at (301) 796-5640.

Submission Number: PEUA[redacted]
Received: 3/17/2020
Applicant: RAYBIOTECH Life, Inc.
Device: Coronavirus (SARS-CoV-2) IgM Test Kit

We will notify you when the review of this document has been completed or if any additional information is required. If you are submitting new information about a submission for which we have already made a final decision, please note that your submission will not be re-opened. For information about CDRH review regulations and policies, please refer to http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm.

Sincerely yours,

Center for Devices and Radiological Health

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

U.S. FOOD & DRUG ADMINISTRATION

Acknowledgment Letter

3/17/2020

Jarad Wilson, Senior Business Development Manager
RAYBIOTECH Life, Inc.
3607 Parkway Lane, Suite 200
Peachtree Corners, GA 30092
UNITED STATES

Dear Jarad Wilson:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the unique document control number below. All future correspondence regarding this submission should be identified prominently with the number assigned and should be submitted to the Document Control Center at the above letterhead address. Failure to do so may result in processing delays. If you believe the information identified below is incorrect, please notify the Program Operations Staff at (301) 796-5640.

Submission Number: PEUA[redacted]
Received: 3/17/2020
Applicant: RAYBIOTECH Life, Inc.
Device: Coronavirus (SARS-CoV-2) IgG Test Kit

We will notify you when the review of this document has been completed or if any additional information is required. If you are submitting new information about a submission for which we have already made a final decision, please note that your submission will not be re-opened. For information about CDRH review regulations and policies, please refer to http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm.

Sincerely yours,

Center for Devices and Radiological Health

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Title: SAFETY DATA SHEET		Effective Date: 02/20/2020
SDS Number: CG-CoV-IgG	Revision: A	Manufacturer: RayBiotech Life, Inc

1.0 PRODUCT AND COMPANY INFORMATION

1.1 Product name: Coronavirus IgG Test Kit (Colloidal Gold)

1.2 Catalog # / Part number: CG-CoV-IgG

1.3 Manufacturer / Supplier:

RayBiotech, Life
3607 Parkway Lane
Suite 200
Peachtree Corners, GA 30092
Phone: 770-729-2992 / 888-494-8555
Fax: 770-206-2393

1.4 Emergency Information:

Please call RayBiotech at 770-729-2992

EMERGENCY HEALTH INFORMATION:
800-424-8802 National Response Center

1.5 Application of the substance or mixture: Not for human use.

1.6 Other product information: This product has not been registered with CHEMTREC (USA)

2.0 HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

GHS Classification in accordance with 29 CFR 1910 (OSHA HCS)

Acute toxicity, Oral (Category 4), H302
Skin corrosion (Category 1B), H314
Serious eye damage (Category 1), H318
Skin sensitisation (Category 1), H317
Short-term (acute) aquatic hazard (Category 1), H400
Long-term (chronic) aquatic hazard (Category 1), H410
For the full text of the H-Statements mentioned in this Section, see Section 16.

2.2 GHS Label elements, including precautionary statements

Pictogram 

Signal word Danger

Hazard statement(s)

H302 Harmful if swallowed.
H314 Causes severe skin burns and eye damage.
H317 May cause an allergic skin reaction.

H318 Causes serious eye damage.
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statement(s)
P261 Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P272 Contaminated work clothing should not be allowed out of the workplace.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell. Rinse mouth.
P301 + P330 + P331 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
P304 + P340 + P310 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Immediately call a POISON CENTER/doctor.
P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/doctor.
P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.
P363 Wash contaminated clothing before reuse.
P391 Collect spillage.
P405 Store locked up.
P501 Dispose of contents/ container to an approved waste disposal plant.

2.3 Hazards not otherwise classified (HNOC) or not covered by GHS

None

3.0 COMPOSITION / INFORMATION ON INGREDIENTS

3.1 Hazardous components:

Component	Classification	Concentration
Modified Alkyl Carboxylate		
	Aquatic Chronic 4; H413	>= 0.5 - < 1.0 %
Mixture of 5-Chloro-2-methyl-4-isothiazolin-3-one and 2-Methyl-2H-isothiazol-3-one (3:1)		
CAS No. 55965-84-9 Index No. 613-167-00-5	Acute Tox. 3; Acute Tox. 2; Skin Corr. 1C; Eye Dam. 1; Skin Sens. 1A; Aquatic Acute 1; Aquatic Chronic 1; H301, H330, H310, H314, H318, H317, H400, H410 M-Factor - Aquatic Acute: 100 - Aquatic Chronic: 100	>= 0.1 - < 0.5 %

4.0 FIRST AID MEASURES

4.1 Description of first aid measures:

General advice
Consult a physician. Show this safety data sheet to the doctor in attendance. Move out of dangerous area.

Eye contact: May cause eye irritation. Flush eyes with plenty of water for at least 15 minutes. Then get immediate medical attention.

Skin contact: Take off contaminated clothing and shoes immediately. Wash off with soap and plenty of water. Consult a physician.

Inhalation: If inhaled, remove to fresh air. If breathing becomes difficult, call a physician.

Ingestion: Do NOT induce vomiting. If swallowed, drink plenty of water. Get immediate medical attention.

4.2 Most important symptoms and effects, both acute and delayed
The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11

4.3 Indication of any immediate medical attention and special treatment needed
No data available

5.0 FIRE FIGHTING MEASURES

5.1 Classification of substance or mixture: The product is non-flammable.

5.2 Suitable extinguishing media: Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

5.3 Protective equipment: Wear self-contained breathing apparatus for firefighting if necessary.

5.4 Special hazards arising from the substance or mixture
Carbon oxides, Nitrogen oxides (NOx), Sulphur oxides, Hydrogen chloride gas

6.0 ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions: Use eye protection, gloves, and apron. Implement appropriate precautions to minimize direct contact with skin or eyes and prevent inhalation of dust.

6.2 Methods for clean up: Sweep up, place in bag and hold for disposal. Ventilate area and wash site after material is picked up.

6.3 Environmental precautions: Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided.

6.4 Reference to other sections: For disposal see section 13.

7.0 HANDLING AND STORAGE

7.1 Handling: Avoid inhalation. Avoid contact with eyes, skin and clothing. Please see section 2 for precautions.

7.2 Storage: Keep tightly closed. Containers which are opened must be carefully resealed and kept upright to prevent leakage. Storage class (TRGS 510): 8A: Combustible, corrosive hazardous materials

7.3 Additional information: See product data sheet for more information on handling and storage.

8.0 EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control parameters: Contains no substances with occupational exposure limit values.

8.2 Engineering controls: Ensure adequate ventilation. Use appropriate personal protective work clothing.

8.3 Personal precautions:

Eye: Wear appropriate eye protection. Tightly fitting safety goggles. Faceshield (8-inch minimum). Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin: Wear clothing and gloves. Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

Inhalation: Respiratory equipment is not required.

9.0 CHEMICAL AND PHYSICAL PROPERTIES

9.1 Description of chemical and physical properties:

Appearance: Liquid, clear
Odor: None
pH: 7.4
Vapor pressure: Not available
Vapor density: Not available
Boiling point: Not available
Melting/freezing point: Not available
Flash point UEL/LEL: None established
Evaporation rate: Undetermined
Flammability: Non-flammable material
Solubility: Not available
Specific gravity (water = 1): Not available
Volatile %: Not available
Water content: Not available
Decomposition Temperature: Not available
Autoignition Temperature: None established
VOC content: Not available
Viscosity: Not available

10.0 STABILITY AND REACTIVITY

10.1 Stability: Stable under recommended storage conditions.

10.2 Reactivity: No data available

10.3 Materials to avoid: None determined

10.4 Hazardous decomposition: None determined

10.5 Hazardous polymerization: Does not spontaneously polymerize

11.0 TOXICOLOGICAL INFORMATION

11.1 Potential health effects:

Acute Toxicity: LD50 Oral – Rat – 862mg/kg

Eye contact: Rabbit - Corrosive to the eye.

Skin contact: Rabbit - Corrosive on skin.

Inhalation: May be harmful if inhaled. May be irritating to mucous membranes.

Ingestion: May be harmful if swallowed.

Carcinogenicity: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC, ACGIH, NTP or OSHA.

Reproductive toxicity: No Data Available

Mutagenicity: None

Sensitization: Guinea pig - May cause sensitization by skin contact.

12.0 ECOLOGICAL INFORMATION

12.1 **Ecotoxicity:** No Data Available, Undetermined

12.2 **Biodegradability:** No Data Available, Undetermined

12.3 **Mobility:** No Data Available, Undetermined

12.4 **Bioaccumulation:** No Data Available, Undetermined

13.0 DISPOSAL INFORMATION

13.1 **Disposal method:** Observe all federal, state, and local environmental regulations. Contact a licensed professional waste disposal service to dispose of this material. Contaminated packaging should be disposed of as if it were and unused product as above.

14.0 TRANSPORTATION INFORMATION

14.1 **Transport information:**

DOT Hazard class:
UN number: 3265 Class: 8 Packing group: II
Proper shipping name: Corrosive liquid, acidic, organic, n.o.s. (5-Chloro-2-methyl-2Hisothiazol-3-one)
Reportable Quantity (RQ):
Poison Inhalation Hazard: No

IATA Hazard class:
UN number: 3265 Class: 8 Packing group: II
Proper shipping name: Corrosive liquid, acidic, organic, n.o.s. (5-Chloro-2-methyl-2Hisothiazol-3-one)

IMDG Hazard class:
UN number: 3265 Class: 8 Packing group: II EMS-No: F-A, S-B
Proper shipping name: CORROSIVE LIQUID, ACIDIC, ORGANIC, N.O.S. (5-Chloro-2-methyl-2H-isothiazol-3-one)
Marine pollutant : yes

15.0 REGULATORY INFORMATION

15.1 US Federal and State Regulations:

CERCLA Sections 102a/103 Hazardous Substances (40 CFR Part 302.4): This product is not reportable under 40 CFR Part 302.4.

SARA Title III Section 302 Extremely Hazardous Substances (40 CFR Part 355): This product is not regulated under Section 302 of SARA and 40 CFR Part 355.

SARA Title III Sections 311/312 Hazardous Categorization (40 CFR Part 370): Acute Health Hazard

SARA Title III Section 313 (40 CFR Part 372): This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels for SARA Title III, Section 313.

US Inventory/TSCA (Toxic Substances Control Act): Not listed on inventory

OSHA Hazard Communication Standard: Non-hazardous

California Proposition 65: Not listed on California's listing of known or potential carcinogens.

Pennsylvania Right to Know Components

Glycols	CAS-No.
Modified alkyl carboxylate	-
Mixture of 5-Chloro-2-methyl-4-isothiazolin-3-one and 2-Methyl-2H -isothiazol-3-one (3:1)	55965-84-9

Massachusetts Right to Know Components

No components are subject to the Massachusetts Right to Know Act.

New Jersey Right to Know Components

Glycols	CAS-No.
Modified alkyl carboxylate	-
Mixture of 5-Chloro-2-methyl-4-isothiazolin-3-one and 2-Methyl-2H -isothiazol-3-one (3:1)	55965-84-9

15.2 Additional Regulations:

WHMIS Controlled Product Classification: This product has been classified in accordance with the hazard criteria of the CPR, and the MSDS contains all the information required by the CPR.

EC Inventory (EINECS/ELINCS): Not determined

Japan Inventory (MITI): Not determined

Australia Inventory (AICS): Not determined

Korea Inventory (ECL): Not determined

Canada Inventory (DSL): Not determined

Philippine Inventory (PICCS): Not determined

16.0 OTHER INFORMATION

16.1 **Disclaimer:** Not for human use.

16.2 **Note to reader:** This SDS and the information it contains is offered in good faith as accurate and complete. We have reviewed any information contained in this SDS which we received from sources outside our company. We believe that information to be correct, but cannot guarantee its accuracy or completeness. Health and safety precautions in this safety data sheet may not be adequate for all individuals and/or situations. It is the user's obligation to evaluate and use this product safely and to comply with all applicable laws and regulations. No statement made in this safety data sheet shall be construed as a permission or recommendation for the use of any product in a manner that might infringe existing patents. No warranty is made, either expressed or implied.

Title: SAFETY DATA SHEET		Effective Date: 02/20/2020
SDS Number: CG-CoV-IgM	Revision: A	Manufacturer: RayBiotech Life, Inc

1.0 PRODUCT AND COMPANY INFORMATION

1.1 Product name: Coronavirus IgM Test Kit (Colloidal Gold)

1.2 Catalog # / Part number: CG-CoV-IgM

1.3 Manufacturer / Supplier:

RayBiotech, Life
3607 Parkway Lane
Suite 200
Peachtree Corners, GA 30092
Phone: 770-729-2992 / 888-494-8555
Fax: 770-206-2393

1.4 Emergency Information:

Please call RayBiotech at 770-729-2992

EMERGENCY HEALTH INFORMATION:
800-424-8802 National Response Center

1.5 Application of the substance or mixture: Not for human use.

1.6 Other product information: This product has not been registered with CHEMTREC (USA)

2.0 HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

GHS Classification in accordance with 29 CFR 1910 (OSHA HCS)

Acute toxicity, Oral (Category 4), H302
Skin corrosion (Category 1B), H314
Serious eye damage (Category 1), H318
Skin sensitisation (Category 1), H317
Short-term (acute) aquatic hazard (Category 1), H400
Long-term (chronic) aquatic hazard (Category 1), H410
For the full text of the H-Statements mentioned in this Section, see Section 16.

2.2 GHS Label elements, including precautionary statements

Pictogram

Signal word Danger

Hazard statement(s)

H302 Harmful if swallowed.
H314 Causes severe skin burns and eye damage.
H317 May cause an allergic skin reaction.

H318 Causes serious eye damage.
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statement(s)
P261 Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P272 Contaminated work clothing should not be allowed out of the workplace.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell. Rinse mouth.
P301 + P330 + P331 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
P304 + P340 + P310 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Immediately call a POISON CENTER/doctor.
P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/doctor.
P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.
P363 Wash contaminated clothing before reuse.
P391 Collect spillage.
P405 Store locked up.
P501 Dispose of contents/ container to an approved waste disposal plant.

2.3 Hazards not otherwise classified (HNOC) or not covered by GHS

None

3.0 COMPOSITION / INFORMATION ON INGREDIENTS

3.1 Hazardous components:

Component	Classification	Concentration
Modified Alkyl Carboxylate		
	Aquatic Chronic 4; H413	>= 0.5 - < 1.0 %
Mixture of 5-Chloro-2-methyl-4-isothiazolin-3-one and 2-Methyl-2H-isothiazol-3-one (3:1)		
CAS No. 55965-84-9 Index No. 613-167-00-5	Acute Tox. 3; Acute Tox. 2; Skin Corr. 1C; Eye Dam. 1; Skin Sens. 1A; Aquatic Acute 1; Aquatic Chronic 1; H301, H330, H310, H314, H318, H317, H400, H410 M-Factor - Aquatic Acute: 100 - Aquatic Chronic: 100	>= 0.1 - < 0.5 %

4.0 FIRST AID MEASURES

4.1 Description of first aid measures:

General advice
Consult a physician. Show this safety data sheet to the doctor in attendance. Move out of dangerous area.

Eye contact: May cause eye irritation. Flush eyes with plenty of water for at least 15 minutes. Then get immediate medical attention.

Skin contact: Take off contaminated clothing and shoes immediately. Wash off with soap and plenty of water. Consult a physician.

Inhalation: If inhaled, remove to fresh air. If breathing becomes difficult, call a physician.

Ingestion: Do NOT induce vomiting. If swallowed, drink plenty of water. Get immediate medical attention.

4.2 Most important symptoms and effects, both acute and delayed
The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11

4.3 Indication of any immediate medical attention and special treatment needed
No data available

5.0 FIRE FIGHTING MEASURES

5.1 Classification of substance or mixture: The product is non-flammable.

5.2 Suitable extinguishing media: Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

5.3 Protective equipment: Wear self-contained breathing apparatus for firefighting if necessary.

5.4 Special hazards arising from the substance or mixture
Carbon oxides, Nitrogen oxides (NOx), Sulphur oxides, Hydrogen chloride gas

6.0 ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions: Use eye protection, gloves, and apron. Implement appropriate precautions to minimize direct contact with skin or eyes and prevent inhalation of dust.

6.2 Methods for clean up: Sweep up, place in bag and hold for disposal. Ventilate area and wash site after material is picked up.

6.3 Environmental precautions: Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided.

6.4 Reference to other sections: For disposal see section 13.

7.0 HANDLING AND STORAGE

7.1 Handling: Avoid inhalation. Avoid contact with eyes, skin and clothing. Please see section 2 for precautions.

7.2 Storage: Keep tightly closed. Containers which are opened must be carefully resealed and kept upright to prevent leakage. Storage class (TRGS 510): 8A: Combustible, corrosive hazardous materials

7.3 Additional information: See product data sheet for more information on handling and storage.

8.0 EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control parameters: Contains no substances with occupational exposure limit values.

8.2 Engineering controls: Ensure adequate ventilation. Use appropriate personal protective work clothing.

8.3 Personal precautions:

Eye: Wear appropriate eye protection. Tightly fitting safety goggles. Faceshield (8-inch minimum). Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin: Wear clothing and gloves. Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

Inhalation: Respiratory equipment is not required.

9.0 CHEMICAL AND PHYSICAL PROPERTIES

9.1 Description of chemical and physical properties:

Appearance: Liquid, clear
Odor: None
pH: 7.4
Vapor pressure: Not available
Vapor density: Not available
Boiling point: Not available
Melting/freezing point: Not available
Flash point UEL/LEL: None established
Evaporation rate: Undetermined
Flammability: Non-flammable material
Solubility: Not available
Specific gravity (water = 1): Not available
Volatile %: Not available
Water content: Not available
Decomposition Temperature: Not available
Autoignition Temperature: None established
VOC content: Not available
Viscosity: Not available

10.0 STABILITY AND REACTIVITY

10.1 Stability: Stable under recommended storage conditions.

10.2 Reactivity: No data available

10.3 Materials to avoid: None determined

10.4 Hazardous decomposition: None determined

10.5 Hazardous polymerization: Does not spontaneously polymerize

11.0 TOXICOLOGICAL INFORMATION

11.1 Potential health effects:

Acute Toxicity: LD50 Oral – Rat – 862mg/kg

Eye contact: Rabbit - Corrosive to the eye.

Skin contact: Rabbit - Corrosive on skin.

Inhalation: May be harmful if inhaled. May be irritating to mucous membranes.

Ingestion: May be harmful if swallowed.

Carcinogenicity: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC, ACGIH, NTP or OSHA.

Reproductive toxicity: No Data Available

Mutagenicity: None

Sensitization: Guinea pig - May cause sensitization by skin contact.

12.0 ECOLOGICAL INFORMATION

12.1 **Ecotoxicity:** No Data Available, Undetermined

12.2 **Biodegradability:** No Data Available, Undetermined

12.3 **Mobility:** No Data Available, Undetermined

12.4 **Bioaccumulation:** No Data Available, Undetermined

13.0 DISPOSAL INFORMATION

13.1 **Disposal method:** Observe all federal, state, and local environmental regulations. Contact a licensed professional waste disposal service to dispose of this material. Contaminated packaging should be disposed of as if it were and unused product as above.

14.0 TRANSPORTATION INFORMATION

14.1 **Transport information:**

DOT Hazard class:
UN number: 3265 Class: 8 Packing group: II
Proper shipping name: Corrosive liquid, acidic, organic, n.o.s. (5-Chloro-2-methyl-2Hisothiazol-3-one)
Reportable Quantity (RQ):
Poison Inhalation Hazard: No

IATA Hazard class:
UN number: 3265 Class: 8 Packing group: II
Proper shipping name: Corrosive liquid, acidic, organic, n.o.s. (5-Chloro-2-methyl-2Hisothiazol-3-one)

IMDG Hazard class:
UN number: 3265 Class: 8 Packing group: II EMS-No: F-A, S-B
Proper shipping name: CORROSIVE LIQUID, ACIDIC, ORGANIC, N.O.S. (5-Chloro-2-methyl-2H-isothiazol-3-one)
Marine pollutant : yes

15.0 REGULATORY INFORMATION

15.1 US Federal and State Regulations:

CERCLA Sections 102a/103 Hazardous Substances (40 CFR Part 302.4): This product is not reportable under 40 CFR Part 302.4.

SARA Title III Section 302 Extremely Hazardous Substances (40 CFR Part 355): This product is not regulated under Section 302 of SARA and 40 CFR Part 355.

SARA Title III Sections 311/312 Hazardous Categorization (40 CFR Part 370): Acute Health Hazard

SARA Title III Section 313 (40 CFR Part 372): This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels for SARA Title III, Section 313.

US Inventory/TSCA (Toxic Substances Control Act): Not listed on inventory

OSHA Hazard Communication Standard: Non-hazardous

California Proposition 65: Not listed on California's listing of known or potential carcinogens.

Pennsylvania Right to Know Components

Glycols	CAS-No.
Modified alkyl carboxylate	-
Mixture of 5-Chloro-2-methyl-4-isothiazolin-3-one and 2-Methyl-2H -isothiazol-3-one (3:1)	55965-84-9

Massachusetts Right to Know Components

No components are subject to the Massachusetts Right to Know Act.

New Jersey Right to Know Components

Glycols	CAS-No.
Modified alkyl carboxylate	-
Mixture of 5-Chloro-2-methyl-4-isothiazolin-3-one and 2-Methyl-2H -isothiazol-3-one (3:1)	55965-84-9

15.2 Additional Regulations:

WHMIS Controlled Product Classification: This product has been classified in accordance with the hazard criteria of the CPR, and the MSDS contains all the information required by the CPR.

EC Inventory (EINECS/ELINCS): Not determined

Japan Inventory (MITI): Not determined

Australia Inventory (AICS): Not determined

Korea Inventory (ECL): Not determined

Canada Inventory (DSL): Not determined

Philippine Inventory (PICCS): Not determined

16.0 OTHER INFORMATION

16.1 **Disclaimer:** Not for human use.

16.2 **Note to reader:** This SDS and the information it contains is offered in good faith as accurate and complete. We have reviewed any information contained in this SDS which we received from sources outside our company. We believe that information to be correct, but cannot guarantee its accuracy or completeness. Health and safety precautions in this safety data sheet may not be adequate for all individuals and/or situations. It is the user's obligation to evaluate and use this product safely and to comply with all applicable laws and regulations. No statement made in this safety data sheet shall be construed as a permission or recommendation for the use of any product in a manner that might infringe existing patents. No warranty is made, either expressed or implied.