SUMMARY AND EXPLANATION

In December 2019 a previously unknown coronavirus (CoV), ultimately named SARS-CoV-2 by the International Committee for Taxonomy of Viruses (ICTV) [1], was discovered in Wuhan City, Hubei Province, China. By March 2020 SARS-CoV-2 had been associated with an outbreak of atypical pneumonia (COVID-19) that was declared a global pandemic by the WHO. Infection by SARS-CoV-2 can be asymptomatic or can result in presentation symptoms ranging from the mild (e.g. fever, cough, fatigue and dyspnea) to the severe (e.g., acute respiratory distress, cardiac injury, organ failure and death) [2].

Like all coronaviruses, SARS-CoV-2 is an enveloped, single-stranded RNA virus with a genome that encodes 4 structural proteins: spike (S), envelope (E), membrane (M), and nucleocapsid (N) [3]. Both the S and N proteins are suitable targets for diagnostic detection as the former mediates entry into host cells and is surface-exposed [4] while the latter is abundantly expressed in early infection [5].

TEST PRINCIPLE

The RAMP® COVID-19 Antigen test is a qualitative immunochromatographic test that utilizes the RAMP® 200 instrument for the detection of SARS-CoV-2 nucleocapsid protein antigens in nasal swab specimens from individuals who are suspected of COVID-19 within the first five days of symptom onset. A swab sample is added to the buffer, which has been optimized to improve binding of the anti-SARS-CoV-2 antibodies to the protein antigens and reduce non-specific binding and fluorescent signal background. The mixed sample is then applied into the sample well of the test cartridge. The sample migrates along the strip. Fluorescent-dyed particles coated with anti-SARS-CoV-2 antibodies bind to SARS-CoV-2 protein antigens, if present in the sample. As the sample migrates along the strip, bound particles are captured at the detection zone and excess fluorescent-dyed particles are captured at the control zone.
The RAMP® 200 instrument then measures the amount of fluorescence emitted by the complexes bound at the detection zone and at the control zone. Using a ratio between the two fluorescence values (the RAMP Ratio), a qualitative reading (positive or negative) is calculated.

REAGENTS

- The RAMP® COVID-19 Antigen Test kit contains all the reagents necessary for the detection of SARS-CoV-2 antigens in nasal swab samples.
- The sample buffer contains phosphate buffer, animal protein, surfactant, detergent and ProClin® 300 / ProClin® 950 as preservatives.
- Positive control swabs contain recombinant antigen and should not contain infectious material; however standard precautions appropriate to biological reagents should be employed.

STORAGE AND STABILITY

Store at 2 to 8°C (35 to 47°F) up to stated expiry. Do not freeze.

MATERIALS PROVIDED

Each RAMP® COVID-19 Antigen Test kit contains enough materials to run either 25 (C1120-25) or 100 (C1120-100) tests, including:

Component	Quantity	
	C1120-25	C1120-100
Pouches, each containing 1 RAMP® test cartridge and 1 test tip	25	100
RAMP® Buffer Vials	25	100
Sample Collection Swabs	25	100
Positive Control Swab	1	1
Negative Control Swab	1	1
Transfer Device (75µL)	1	1
Lot Card	1	1
Instructions for Use	1	1

MATERIALS REQUIRED (BUT NOT PROVIDED)

- REF: C2100 RAMP®200 instrument control module, and
- REF: C3100 RAMP® 200 instrument test module
- REF: C2020 RAMP® COVID Antigen Control Swabs (optional)
- Optional accessories such as RAMP® printer and/or barcode scanner

Use only the listed RAMP® instruments with this test.

LOT CARD CALIBRATION

Each RAMP® test kit includes a lot card that is individually packaged in an anti-static pouch. The lot card provides information specific to the kit test cartridge lot, including lot number, expiration date, and standard curve information. For further details on loading lot-specific information, see the RAMP® instrument User Manual. No additional calibration beyond insertion of the lot card is necessary. This operation is required only once per test kit lot.

For each new lot, remove the lot card from its pouch and insert it into the lot card slot on the instrument. Once the lot card has been uploaded, return to its pouch and do not discard. Avoid touching the contacts at the end of the lot card.

WARNINGS AND PRECAUTIONS

- For use by qualified personnel per local, state, or federal regulations or accrediting agency requirements.
- Read the entire instructions for use (IFU) prior to use. Directions should be read and followed carefully, or invalid or erroneous results may occur.
- Do not interchange or mix components of different RAMP® tests, RAMP® lots or components from other manufacturers.
- Do not use the kit or any kit component beyond the stated expiry date.
- Do not use any visibly damaged components.
- Do not insert into the instrument a cartridge on which test sample, or any other fluid, is spilled.
- Disposal of all waste materials should be in accordance with local biosafety guidelines.
- Exercise standard precautions for handling all laboratory reagents and patient samples.
- The device contains material of animal origin and should be handled as a potential biohazard.
- The sample buffer provided contains ProClin®, a potential skin sensitizer. Avoid spilling or splashing reagents containing ProClin® on skin or clothing. In case of contact, thoroughly flush with water.
- The sample buffer provided contains the surfactant Triton™ X-100 which can cause skin irritation and eye damage. Avoid spilling or splashing reagents containing Triton X-100 on skin or clothing and in eyes. In case of contact, thoroughly flush with water and seek medical attention.
- If infection with SARS-CoV-2 is suspected based on current clinical and epidemiological screening criteria as recommended by public health authorities, specimens should be collected with appropriate infection control precautions and sent to state or local health departments for testing.
- The external positive and negative control swabs manufactured for this test are prepared in a simulated sample matrix, which may not mimic test specimens.

QUALITY CONTROL

Refer to the RAMP® 200 User Manual for full details on quality control operation and troubleshooting.

SYSTEM QUALITY CONTROL

The RAMP® instrument has error checking and self-diagnostic functions (Internal Quality Control (IQC)) that assure system integrity. These include algorithms and measurements used to confirm acceptable operator technique, sample handling, and test performance. Frequency of IQC may be programmed at desired intervals.

Valid results are displayed only after all performance requirements have been met.

PROCEDURAL CONTROLS

- Each RAMP® test has built-in controls. Test cartridges have a control zone that is scanned as part of the test protocol to ensure proper sample flow.
- Control limits for each lot of test cartridges are established during the manufacturing process and are incorporated in the test-specific lot parameters. If a control result does not meet specifications, the sample result is not reported, and a message is displayed.

EXTERNAL POSITIVE AND NEGATIVE CONTROL SWABS

- It is recommended that quality control materials be run with the RAMP® test in conformance with federal, state and local requirements for quality control testing.
- While the running of control materials is recommended, it is not a requirement to use, or assure, performance of the RAMP® test unless specified by local regulations or institutional requirements.
- Control swabs are used to monitor reagent reactivity. Failure of the controls to produce the expected results can mean that one of the reagents or components is no longer reactive at the time of use, the test was not performed correctly or that the reagents of samples were not added. Whenever control results fail, controls and samples should be retested. Do not perform patient tests or report patient results if the control tests do not produce expected results.
- The RAMP COVID-19 Antigen Positive Control Swab contains SARS-CoV-2 antigen is expected to display a positive result; the RAMP COVID-19 Antigen Negative Control Swab does not contain antigen and expected to display a negative result.
- To run a control swab sample, follow the instructions under the “Procedure” section in this IFU. Treat the control as a specimen swab.

RESPONSE BIOMEDICAL

INSTRUCTIONS FOR USE

RAMP® COVID-19 Antigen Test

C1120-3.0

INTENDED USE

The RAMP COVID-19 Antigen Test is an immunochromatographic test for the qualitative detection of SARS-CoV-2 nucleocapsid antigens in nasal swab specimens from individuals who are suspected of COVID-19 infection within the first five days of symptom onset.

Antigen is generally detectable in nasal swab specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definitive cause of disease.

Negative results are presumptive and do not preclude SARS-CoV-2 infection and should not be used as the sole basis for treatment or other patient management decisions, including infection control decisions. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19 and confirmed with a molecular assay, if necessary, for patient management.

The RAMP COVID-19 Antigen Test is intended for use with the RAMP 200 instrument, by trained laboratory professionals as an aid in diagnosis of SARS-CoV-2 infection. The RAMP COVID-19 Antigen Test is currently intended for laboratory use only

WARNING!

For *in vitro* diagnotic use only

Failure to follow RAMP® test procedures may result in invalid and/or erroneous results. Read the entire Instructions For Use prior to performing test.

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IVD

24-HOUR TECHNICAL SUPPORT

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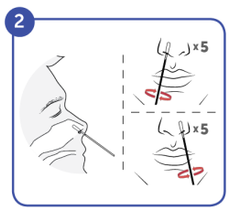
Email: techsupport@responsebio.com

RESPONSE CORPORATE OFFICE

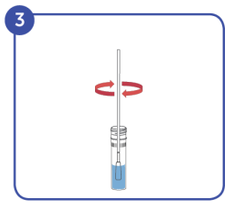
Tel: 1-888-591-5577 (toll free) Tel: 1-604-456-6010 (int'l)
Email: customersupport@responsebio.com

Running a test

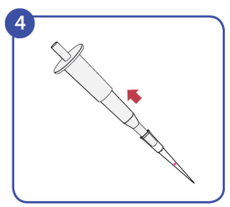
Set up RAMP200® instrument for running a patient test.



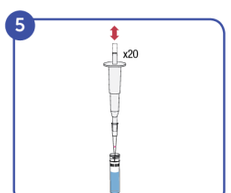
Insert swab ~1.5cm into patient nostril, rotate slowly 5x against nasal wall, repeat on other nostril.



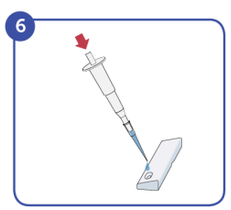
Rotate swab vigorously in the buffer for 10 sec. Press swab against the side of the tube, remove and discard.



Open foil pouch and firmly attach test tip to the transfer device.



Insert test tip into buffer and slowly depress plunger 20 times to fully mix.



Transfer 75 µL of mixed sample into test cartridge well.

Immediately insert cartridge into RAMP® instrument port. When test is finished, read result.

Discard all used components.

TEST RUN MESSAGES

When the RAMP® instrument is unable to continue a specific task, it will emit an audio alarm and display a message. Refer to the RAMP® 200 User Manual 'Troubleshooting Guide' section for a full description of all messages. If repeated tests give unexpected or inconsistent results, contact Response Biomedical Technical Support for assistance.

SAMPLE COLLECTION & PREPARATION

- Only nasal swabs provided with the RAMP COVID-19 Antigen Test should be used. Other sample types and swabs have not been evaluated and should not be used.
- Testing should be completed immediately after sample collection. However, if this is not possible, the eluted sample can be stored for up to 2 hours (at room temperature).
- Proper specimen collection, storage and transport are critical to the performance of this test. Inadequate or inappropriate specimen collection, storage and/or transport could potentially lead to false negative results. Appropriate training in specimen collection is highly recommended to ensure specimen quality. Avoid specimen samples that are visibly contaminated or excessively bloody as these may interfere with the test and cause erroneous results. If this occurs, another specimen sample should be obtained and tested.

The following specimen collection method is recommended [6].

NASAL SWAB

Collect a nasal sample by carefully inserting the entire absorbent tip of the swab into the nostril until gentle resistance is met (about 1-2cm) and firmly sample the nasal wall by rotating the swab in a circular path against the nasal wall at least 5 times. Take approximately 10 to 15 seconds to collect the sample. Slowly remove the swab from the nostril. Using the same swab, repeat in the other nostril.

PROCEDURE

1. Prepare RAMP® instrument for test cartridge. Refer to the RAMP® 200 User Manual for detailed instructions on Starting a Test.
2. Collect a nasal sample as instructed in **SAMPLE COLLECTION & PREPARATION**.
3. Uncap the buffer vial and place upright on a clean, dry level surface, or in a holder.
4. While keeping the uncapped buffer vial steady, place the swab into the sample buffer and extract by vigorously agitating for 10 seconds. Remove the swab while contacting against the side of the tube to squeeze out any excess liquid. Dispose of the swab.
5. Open a test pouch and remove the test cartridge and tip. Place the test cartridge on a clean, level surface. Firmly attach the test tip to the supplied transfer device.
6. Fully depress the transfer device plunger and insert the test tip into the buffer vial close to, but not touching, the bottom.
7. Mix sample slowly by fully pressing and releasing the plunger 20 times; while keeping the tip submerged in the buffer for optimal mixing and to minimize air bubbles.
8. Once mixing is complete, draw 75 µL of sample into the test tip by releasing the plunger one final time and immediately dispense liquid into the sample well of the test cartridge. Small droplets may remain in the tip, this is expected.
9. Immediately insert the test cartridge fully into the instrument and press until firm resistance is felt.
10. The instrument will draw the cartridge in and test development will begin.
11. The instrument will analyze the cartridge and report the result in approximately 15 minutes.
12. Remove the used test cartridge and discard all used test components according to local biohazard procedures. DO NOT reuse.

Additional Information:

- Keep the test cartridge and test tip in the sealed foil pouch until ready for use. Once opened, test cartridges and test tips must be used or discarded within 60 minutes.
- The collection swab, test cartridge, test tip, and buffer vial should be discarded after a single use. Do not reuse.

For more information on the general operation and troubleshooting of the instrument, please refer to the RAMP® 200 User Manual.

LIMITATIONS

- Factors such as technical or procedural errors or the presence of substances in specimen samples may interfere with the RAMP® test and cause erroneous results.
- Failure of the user to follow the test procedure correctly may adversely affect the test performance and/or invalidate the test result.
- A positive result does not rule out co-infections with other viruses.
- False positive results may occur with the RAMP COVID-19 Antigen Test.
- A false negative result may occur if the level of the antigen in the sample is below the detection limit of the test.
- Not validated for use in vaccinated patients.
- Tests using antibodies (i.e., immunoassays) may fail to detect, or detect with less sensitivity, SARS-CoV-2 viruses that have undergone minor amino acid changes in the target epitope region.
- All results should be considered in the context of a patient's recent exposures, medical history and the presence of clinical signs and symptoms consistent with COVID-19 and confirmed with a molecular assay if necessary for patient management.
- Potential cross-reactivity with human coronavirus HKU1 and SARS-coronavirus cannot be ruled out.
- The performance of this test was established based on the evaluation of a limited number of clinical specimens. Clinical performance has not been established with 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.

EXPECTED VALUES

The RAMP® COVID-19 Antigen Expected Values study was conducted at one site and included 127 apparently healthy, asymptomatic individuals (19 years of age and older). One (1) nasal swab sample from each individual was tested with the RAMP® COVID-19 Antigen Test and 124 samples (97.6%) were found to give results below the threshold determined during analytical qualification of the test.

PERFORMANCE CHARACTERISTICS

INTERPRETATION OF RESULTS

- **Negative result** – reported as 'COVID NEG'. **Positive result** – reported as 'COVID POS'.

REPORTING OF RESULTS

- **COVID NEG –** Report as COVID-19 antigen not detected. This result does not exclude COVID-19 infection. Presumptive; negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.
- **COVID POS –** Report as Positive for COVID-19 antigen. Result does not rule out co-infection with other pathogens.

DETECTION LIMIT

The limit of detection (LoD) of the RAMP® COVID-19 Antigen Test was determined using quantified (pfu/mL) inactivated SARS-CoV-2 virus eluted from the swab in the presence of nasal matrix. Each concentration was tested in replicates of 20. LoD was defined as the lowest concentration, at which ≥19/20 replicates tested positive.

Sample	LoD Concentration [pfu/mL]	Result
SARS-CoV-2 (inactivated)	1,500 pfu/mL	100% POS

ANALYTICAL SPECIFICITY (CROSS-REACTIVITY)

The analytical specificity of the RAMP® COVID-19 Antigen Test was evaluated by testing a panel consisting of 33 microorganisms that may be present in the nasal cavity. Bacterial and viral isolates were tested at the concentrations listed below in the presence of nasal matrix. None of the organisms tested gave a positive result in the RAMP® COVID-19 Antigen Test.

Strain/Isolate	Concentration	RAMP® COVID-19
Adenovirus, Type 1	10^5 $TCID_{50}$/mL	Negative
Adenovirus, Type 7a	10^5 $TCID_{50}$/mL	Negative
Human coronavirus, OC43	10^5 $TCID_{50}$/mL	Negative
Human coronavirus, 229E	10^5 $TCID_{50}$/mL	Negative
Human coronavirus, NL63	10^5 $TCID_{50}$/mL	Negative
Enterovirus, Type 71	10^5 $TCID_{50}$/mL	Negative
Epstein Barr Virus, B95-8	10^5 $TCID_{50}$/mL	Negative
Human parainfluenza, Type 1	10^5 $TCID_{50}$/mL	Negative
Human parainfluenza, Type 2	10^5 $TCID_{50}$/mL	Negative
Human parainfluenza, Type 3	10^5 $TCID_{50}$/mL	Negative
Human parainfluenza, Type 4	10^5 $TCID_{50}$/mL	Negative
Influenza A, Brisbane/10/07	10^5 $TCID_{50}$/mL	Negative
Influenza A, SwineNY/01/2009 H1N1	10^5 $TCID_{50}$/mL	Negative
Influenza A, Switzerland/9715293/13 H3N2	10^5 $TCID_{50}$/mL	Negative
Influenza A, Singapore/INFIMH-16-0019/16 H3N2	10^5 $TCID_{50}$/mL	Negative
Influenza B, Ohio/01/05	10^5 $TCID_{50}$/mL	Negative
Influenza B , Brisbane/60/08	10^5 $TCID_{50}$/mL	Negative
Influenza B, Wisconsin/1/10	10^5 $TCID_{50}$/mL	Negative
Human metapneumovirus, Strain G, A1 (CEID)	10^5 $TCID_{50}$/mL	Negative
RSV	10^5 $TCID_{50}$/mL	Negative
Rhinovirus, 1A	10^5 $TCID_{50}$/mL	Negative
MERS NP	1000 ng/mL	Negative
SARS NP	1000 ng/mL	Negative
H. influenza	10^6 CFU/mL	Negative
Streptococcus pneumonia	10^6 CFU/mL	Negative
Streptococcus pyogenes	10^6 CFU/mL	Negative
Candida albicans	10^6 CFU/mL	Negative
Bordella pertussis	10^6 CFU/mL	Negative
Mycoplasma pneumonia	10^6 CFU/mL	Negative
Chlamydia pneumoniee	10^6 CFU/mL	Negative
Legionella pneumophila	10^6 CFU/mL	Negative
Staphylococcus epidermidis	10^6 CFU/mL	Negative

Organisms that were not available for wet-testing were assessed for potential cross-reactivity through *in silico* analysis using the Basic Local Alignment Search Tool (BLAST) managed by the National Center for Biotechnology Information (NCBI). Protein sequence homology was used as a proxy for cross-reactivity:

- No protein sequence homology was found between the SARS-CoV-2 nucleocapsid protein and *Pneumocystis* jirovecii or *Mycobacterium tuberculosis* effectively ruling out homology-based cross-reactivity for those organisms.
- Homology between the SARS-CoV-2 nucleocapsid protein and the Human coronavirus HKU1 nucleoprotein was found to be 36.7% across 82% of sequences; while this is relatively low, cross-reactivity cannot be ruled out.

MICROBIAL INTERFERENCE

Cross-reactivity testing as described above was carried out both in the absence and presence of inactivated SARS-CoV-2 virus. None of the microorganisms tested gave a false-negative result in the RAMP® COVID-19 Antigen Test in the presence of SARS-CoV-2.

INTERFERENCE

Endogenous biomolecules, over-the-counter analgesics and medications commonly prescribed to a patient population showing symptoms of COVID-19 were tested for interference in the RAMP® COVID-19 Antigen Test. The substances were added to a simulated negative sample (RAMP® COVID-19 Antigen Test sample buffer), and a positive sample (RAMP® COVID-19 Antigen Test sample buffer containing inactivated SARS-CoV-2 virus) and tested on the RAMP® COVID-19 Antigen Test. The following substances were found to have no effect on the test results of the RAMP® COVID-19 Antigen Test when present in positive and negative simulated samples at the concentrations indicated:

Interferent	Concentration	Interferent	Concentration
Mucin	0.50 mg/mL	Phenylpropanolamine	0.05 mg/mL
Blood	5% (v/v)	Phenylephrine	1.00 mg/mL
Acetaminophen	1.00 mg/mL	Oseltamivir Phosphate	5.00 mg/mL
Acetylsalicylic Acid	1.50 mg/mL	Chloraseptic	15% (v/v)
Menthol	15.00 mg/mL	NeilMed Nasogel	5% (v/v)
Ibuprofen	1.50 mg/mL	Cromolyn	5.00 mg/mL
Benzocaine	15.00 mg/mL	Zicam	5% (v/v)
Oxymetazoline HCl	1.00 mg/mL	Alkalol	10% (v/v)
Chloropheniramine	0.50 mg/mL	Tobramycin	0.004 mg/mL
Diphenyl Hydramine	0.25 mg/mL	Mupirocin	10 mg/mL
Dextromethorphan	0.05 mg/mL	Fluticasone Propionate	0.015 mg/mL
Guaiacol Glycerol Ether	2.00 mg/mL		

PRECISION

Precision of the RAMP COVID-19 Antigen Test was evaluated by testing two samples (negative, positive) prepared in RAMP® COVID-19 Antigen Test sample buffer in 15 runs of n=5 replicates each carried out over 5 days. There was 100% agreement with the expected test results for all specimens tested.

HOOK EFFECT

No high dose hook effect was observed for the RAMP® COVID-19 Antigen Test up to the highest concentration of inactivated virus tested (1 x 10^6 pfu/mL).

CLINICAL EVALUATIONS

METHOD COMPARISON

The clinical performance of the RAMP® COVD-19 Antigen Test was established in U.S. and Canadian multi-site prospective studies in nasal swab specimens collected from individuals suspected of COVID-19 within the first 5 days of symptom onset. 113 fresh specimens were collected from symptomatic subjects (46 males and 98 females) who underwent concurrent testing using the CDC's 2019 nCoV RT-PCR Diagnostic Panel or cobas® 6800/8800 SARS-CoV-2. The RAMP® COVD-19 Antigen Test was found to have acceptable clinical sensitivity (84%) and specificity (99%) when compared to a molecular test.

		RT-PCR (CDC 2019-nCoV RT-PCR Diagnostic Panel and cobas® 6800/8800 SARS-CoV-2)	
		Positive	Negative
RAMP	Positive	63	1
	Negative	12	68
		Value	95% CI
PPA		84.00%	73.72% to 91.45%
NPA		98.55%	92.19% to 99.96%
Concordance		90.97%	85.06% to 95.11%

The clinical data analysis stratified by symptom onset is provided in the table below:

DAY 0			
RAMP	RT-PCR (CDC 2019-nCoV RT-PCR Diagnostic Panel and cobas® 6800/8800 SARS-CoV-2)		
		Positive	Negative
	Positive	6	0
	Negative	2	4
	N =	12	
	PPA	75	
	NPA	100	
	Concordance	83.33333	

DAY 1			
RAMP	RT-PCR (CDC 2019-nCoV RT-PCR Diagnostic Panel and cobas® 6800/8800 SARS-CoV-2)		
		Positive	Negative
	Positive	19	1
	Negative	7	30
	N =	57	
	PPA	73.1	
	NPA	96.77	
	Concordance	85.96491	

DAY 2			
RAMP	RT-PCR (CDC 2019-nCoV RT-PCR Diagnostic Panel and cobas® 6800/8800 SARS-CoV-2)		
		Positive	Negative
	Positive	16	0
	Negative	2	16
	N =	34	
	PPA	88.88889	
	NPA	100	
	Concordance	94.11765	

DAY 3			
RAMP	RT-PCR (CDC 2019-nCoV RT-PCR Diagnostic Panel and cobas® 6800/8800 SARS-CoV-2)		
		Positive	Negative
	Positive	7	0
	Negative	1	9
	N =	17	
	PPA	87.5	
	NPA	100	
	Concordance	94.11765	

DAY 4			
RAMP	RT-PCR (CDC 2019-nCoV RT-PCR Diagnostic Panel and cobas® 6800/8800 SARS-CoV-2)		
		Positive	Negative
	Positive	8	0
	Negative	0	5
	N =	13	
	PPA	100	
	NPA	100	
	Concordance	100	

DAY 5			
RAMP	RT-PCR (CDC 2019-nCoV RT-PCR Diagnostic Panel and cobas® 6800/8800 SARS-CoV-2)		
		Positive	Negative
	Positive	7	0
	Negative	0	4
	N =	11	
	PPA	100	
	NPA	100	
	Concordance	100	

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[6] Centers for Disease Control and Prevention. Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens for COVID-19. November 30, 2020.

GLOSSARY OF SYMBOLS

EC REP **Authorized Representative in European Community**	LOT **Batch Code**	REF **Catalogue Number**
CE **CE Mark**	 **Consult Instructions for Use**	 **Contains Sufficient for <n>Tests**
 **Do Not Reuse**	IVD **In vitro Diagnostic Medical Device**	 **Harmful, Irritant**
 **Manufacturer**	 **Temperature Limit**	 **Use-by Date**
CONTROL – **Negative Control**	CONTROL + **Positive Control**	Rx Only **Prescription Use Only (U.S. Only)**
STERILE EO **Sterilized using Ethylene Oxide**	 **Do Not Use if Package Damaged**	 **Keep Dry**

PRODUCT SUPPORT / ASSISTANCE

If you have any questions regarding the use of this product, please contact Response Biomedical Corp. Technical Support:

- Within US or Canada (+1.866.525.7267)
- Outside US or Canada (+1.604.219.6119)
- By email at **techsupport@responsebio.com**

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TRADEMARKS INFORMATION

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