Over the counter Rapid Antigen Test for detection of SARS-CoV-2 virus: Clinical Evaluation

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Protocol Number: EDP-SOP-TNC-014

Performed at:
EDP Biotech Corporation
6701 Baum Drive, Suite 110
Knoxville, TN 37919

Sponsored by:
MP Biomedicals, LLC
29525 Fountain Parkway
Solon, OH 44139

Rev. C

For Investigational Use Only.
The performance characteristics of this device have not been established

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Study Personnel and Approvals

Role	Name, Title and Contact	Approval Signature and Date
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1.0 Introduction

1.1 Device Name (working name)

Rapid SARS-CoV-2 Antigen Test (MP Biomedicals, LLC 29525 Fountain Parkway, Solon, Ohio 44139 USA).

1.2 Intended Use

The MP Biomedicals Rapid SARS-CoV-2 Antigen Test is an immunochromatography based one step in vitro test intended to detect nucleocapsid antigen from the SARS-CoV-2 virus that causes COVID-19. It is designed for over the counter (OTC) rapid qualitative determination of SARS-CoV-2 virus antigen in anterior nasal swabs from individuals within 7 days of symptom onset or without symptoms or other epidemiological reasons to suspect COVID-19 infection. This test is for non-prescription home use with self-collected anterior nasal swab specimens directly from individuals aged 14 years and older or with adult-collected anterior nasal samples directly from individuals aged 2 years or older.

1.3 Background

Coronavirus disease (COVID-19) is a disease caused by a newly discovered coronavirus, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)[1]. The SARS-CoV-2 is a ß-coronavirus, which is enveloped non-segmented positive-sense RNA virus 2[2]. It is spread by human-to-human transmission via droplets or direct contact, and infection has been estimated to have mean incubation period of 6.4 days and a basic reproduction number of 2.24–3.58. Among patients with pneumonia caused by SARS-CoV-2, fever was the most common symptom, followed by cough[3]. On 11 March 2020, the COVID-19 outbreak was characterized as a pandemic by the WHO[4]. Since then, over 70 million people worldwide have been infected with the virus with over 1.5 million deaths attributed to the virus[5]. Laboratory testing for SARS-CoV-2 is currently being performed to determine if an individual has active infection via detection of viral RNA or if an individual has an immune response to the virus from a previous infection via detection of antibodies.

Specimen collection is a crucial first step in the evaluation of an individual's SARS-CoV-2 infection status. The goal of this project is to evaluate a rapid SARS-CoV-2 antigen test for over the counter (OTC) use. Study subjects under EDP supervision, either in-person or via video conference, will collect and test anterior nasal swab samples and a Study Representative will collect and ship a second nasopharyngeal swab sample for comparator PCR testing. The Rapid SARS-CoV-2 Antigen Test

collection and testing methodology is viewed as a convenient and inexpensive method to test clinical specimens for SARS-CoV-2 and OTC access will improve the availability of COVD-19 testing.

1.4 Principles of the Device

The COVID-19 Antigen Rapid Test Device detects SARS-CoV-2 viral antigens through visual interpretation of color development. Anti-SARS-CoV-2 antibodies are immobilized on the test region of the nitrocellulose membrane. Anti-SARS-CoV-2 antibodies conjugated to colored particles are immobilized on the conjugated pad. A sample is added to the extraction buffer which is optimized to release the SARS-CoV-2 antigens from specimen. During testing, the extracted antigens bind to anti-SARS-CoV-2 antibodies conjugated to colored particles. As the specimen migrates along the strip by capillary action and interacts with reagents on the membrane, the complex will be captured by the anti-SARS-CoV-2 antibodies at the test region. Excess colored particles are captured at the internal control zone. The presence of a colored band in the test region indicates a positive result for the SARS-CoV-2 viral antigens, while its absence indicates a negative result. A colored band at the control region serves as a procedural control, indicating that the proper volume of specimen has been added and membrane wicking is working. (See Appendix 6).

2.0 Scientific Objectives

2.1 Study Rationale

Traditional specimen collection techniques used in conjunction with respiratory infectious agent identification, for examples nasopharyngeal (NP) swabbing or aspiration, are often uncomfortable for the patient. Anterior nasal (AN) swab samples have provided a more comfortable sampling alternative to NP swabs that is also less technically challenging. With ease of use and convenience for OTC home specimen collection with the Rapid SARS-CoV-2 Antigen Test, the patient experience may lead to better patient sampling for SARS-CoV-2 testing.

2.2 Study Objectives

The objective of the study is to evaluate the feasibility of using Rapid SARS-CoV-2 Antigen Test detection of SARS-CoV-2 virus in OTC home use. The presence of SARS-CoV-2 virus will be confirmed by PCR methodology. Testing will be performed with EUA PCR tests. The acceptance criteria for this study is Positive Percent Agreement (PPA) greater than or equal to eighty percent and Negative Percent Agreement (NPA) greater than or equal to ninety-eight percent).

3.0 Study Materials

EDP Biotech Corp. will obtain the Rapid SARS-CoV-2 Antigen Test kits and swab collection supplies, and Diversified Medical Health (DMH) Premier Laboratories will obtain the PCR reagents and materials to perform the testing from the respective manufacturers. EDP Biotech Corp. will maintain proper storage conditions of all reagents per the manufacturers' product package inserts.

3.1 Specimen Collection Materials/Equipment

All Rapid SARS-CoV-2 Antigen Test materials are ready for use as per Manufacturer's instructions. The materials will be used prior to expiration dating.

Table 1 Rapid SARS-CoV-2 Antigen Test Materials

Material	Manufacturer	Catalog Number	Storage
Rapid SARS-CoV-2 Antigen Test Card (sealed foil pouch)	MP Biomedicals Solon, OH USA		Ambient (15-25ºC)
Sterile swab	Zhejiang Gongdong Medical Technology Co., Ltd No. 10 Beiyuan Ave., Huangyan, 318020 Taizhou, Zhejiang, P.R.China		Ambient (15-25ºC)
Extraction tube	MP Biomedicals Solon, OH USA		Ambient (15-25ºC)
Extraction solution bottle	MP Biomedicals Solon, OH USA		Ambient (15-25ºC)
Instructions for use (IFU)	MP Biomedicals Solon, OH USA		Ambient (15-25ºC)
Tube stand	MP Biomedicals Solon, OH USA		Ambient (15-25ºC)

3.2 PCR Collection Materials

Nasopharyngeal swab specimens will be evaluated for the presence of SARS-CoV-2 RNA with the DMH Premier

CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel (CDC) at their Premier Laboratory facility in Greenville, SC (see Appendices 1 and 2).

Table 2- PCR Collection and Shipping Materials for Nasopharyngeal swab Specimens:

Material	Manufacturer/ Vendor	Catalog Number	Storage 1
Sterile Swab	Premier		Ambient (15-25ºC)
Tube Label	Premier		Ambient (15-25ºC)
Collection Tube with Universal Transport Media	Premier		Ambient (15-25ºC)
Collection Instructions	Premier		Ambient (15-25ºC)
Biohazard bag with absorbent pad	Premier		Ambient (15-25ºC)
Shipping box with cold pack	Premier		Ambient (15-25ºC)

3.3 Instrumentation

Testing of collected respiratory specimens associated with this protocol will be performed with the following equipment:

3.2.1 For nasal swab specimens at DMH Premier Laboratory:

- QuantStudio 12 K Flex Real-Time PCR System (Thermo Fisher Scientific)

3.4 Computer Hardware and Software

For this study, results will be analyzed using:

- PC Computer Platform.
- Microsoft Office Excel, version 2003 (or higher).

3.5 Collection/Storage/Transfer of Data Files

All data will be collected and stored by EDP Biotech Corp. using its established laboratory information system (LIS) upon completion of the initial testing or resolution of incomplete or disqualified runs. Results will be compiled as a specimen log as part of the clinical study documentation.

If applicable, all original instrument data printouts will be maintained as part of the study records. Additionally, records of personnel performing all assays, all instruments, reagent and control lots used for each assay run will be maintained.

Note: All required ancillary equipment and materials for the study are specified in appropriate Standard Operating Procedures (SOPs), along with the instrument

operator's manuals and reagent instructions for use (package insert), either at DMH Premier Laboratories or EDP Biotech Corp.

4.0 Study Design

This is a clinical study to evaluate the feasibility of using anterior nasal (AN) swabs on Rapid SARS-CoV-2 Antigen Test kits for OTC use in symptomatic and asymptomatic individuals following recommendations from the FDA's November 9, 2021 Template for Developers of Molecular and Antigen Diagnostic COVID-19 Tests for Home Use , Sections J 8, 9. EDP Biotech Corp. will recruit subjects for a clinical study through the internet as well as by referral throughout the United States. Rapid SARS-CoV-2 Antigen Test anterior nasal specimen collection and testing will be done under the supervision of EDP Biotech Corp. or designee in person. Standard of care (SOC) comparator NP samples will be collected at least 15 minutes prior to Ag samples with at least 15 minutes between nasal collections including collections that may occur prior to study enrollment. Comparator SOC samples will be collected first by qualified personnel at a study site or physician's office using an FDA authorized nasopharyngeal swab collection kit and SARS-CoV-2 molecular assay. An observed usability study will be conducted prior to this clinical evaluation study. Comparator SOC nasopharyngeal swab specimens will be analyzed at Premier Laboratories according to this protocol and specific assay standard operating procedure (SOP) instructions. The data collected in study may be submitted as a regulatory filing to the US FDA or other agencies. All specimens will be collected from participating consenting subjects. Additional testing of the specimens for research purposes may be performed. A single randomly generated non-repeating study ID number will be assigned to subject or subject and tester if a parent or legal guardian is testing a 2 to 13 year old and this study ID number will be applied to all informed consent and authorization forms, assent forms, tester information form, subject information form, user comprehension assessment, and any other documents associated with each valid Rapid SARS-CoV-2 Antigen test result.

4.1 Site Characteristics

All personnel involved in the study will be qualified by education and experience to conduct this study and agree to follow the study protocol.

4.2 Site Personnel

Each site in this evaluation is responsible for assignment of qualified personnel and for maintaining documented required qualifications for those personnel.

4.3 Specimen Collection

Each study volunteer who agrees to participate in the study will be asked to complete an Informed Consent Form (Appendix 7). A parent or guardian will need to consent for subjects under 18 years old. Study subjects between the ages of 7 and 13 years old will be asked to complete an age-appropriate Assent form (Appendix 8). Study subjects between ages 14 and 17 will complete the assent portion of the Informed Consent Form (Appendix 7). Minors between the ages of 2 and 13 years old will have their samples collected and tested by a parent or legal guardian. Minors between the ages of 14 and 17 will collect and test their own samples without interference from their parents or legal guardians. Specimens will be collected and tested only after the Informed Consent form is completed.

Each testing participant will be asked to complete a tester information form assessing basic demographics and socio-economic questions (Appendix 3). Each subject being tested will be asked to complete a subject information form describing any symptoms of respiratory illness and/or resent exposure to confirmed COVID-19 positive individuals within the last two weeks (Appendix 4). If the tester is self-collecting, then they skip the second half of the subject information form as indicated on the form due to redundancy of demographic and socio-economic information recorded on the tester information form. Subjects and testers will be observed by EDP Biotech Corp. personnel or designees during sample collection and testing process in person. The same unique study ID number will be associated with all forms and documents related to a single valid Rapid SARS-CoV-2 Antigen test result.

The NP swab collection will not provide participants additional training because the collection technique differs from AN collection. Participants will be reminded that the study representative is performing a different collection technique for a different test and that the participant should refer only to the instructions for use for the proper collection technique.

The Clinical Investigators or designees will observe AN swab collection and testing and ensure that the nasopharyngeal swab comparator PCR specimens from each participant are properly collected according to the protocol. NP samples will be collected according to the Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens for COVID-19 using materials approved for use with CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel (CDC) provided by DMH Premier including synthetic tip swabs with a plastic or aluminum shaft and VTM, UTM, or PBS transport media. Subjects will collect AN swab samples and perform

the Rapid SARS-CoV-2 Antigen Test using only the IFU (Appendix 7) or instructional video (link contained within the IFU) for instruction. The collection devices and storage tubes will be appropriately labeled with the study ID numbers and not the names of the participants to maintain confidentiality. The same unique study ID number will be applied to all forms and sample(s) associated with a single Rapid SARS-CoV-2 Antigen Test Card valid result.

Following Rapid SARS-CoV-2 Antigen Test, subjects will complete a questionnaire gauging user comprehension of results and consequences of performing the Rapid SARS-CoV-2 Antigen test incorrectly (Appendix 5). Replacement Rapid SARS-CoV-2 Antigen Test Cards will be provided to re-test invalid results. Repeated results will be noted.

Qualified personnel will follow instructions for collection of CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel (CDC) used by DMH Premier for comparator nasopharyngeal swab sample collection and shipment (Appendices 1 and 2).

4.4 Sample Types and Numbers

Both AN swab specimens and comparator nasopharyngeal swab specimens will be collected for detection of SARS-CoV-2. Subjects will be enrolled in an "all comers" style, including both symptomatic and asymptomatic patients. The study population will include subjects from 2 years old to greater than 65 years old. Minors must be consented by their parent or legal guardian. The parent or legal guardian should collect the samples and perform testing if the child is between 2 and 13 years old. Older children ages 14-17 should collect their samples and perform their tests without their parent or legal guardian intervening. Enrollment efforts in various zip codes will be pursued in order to represent different socioeconomic and educational backgrounds and this information will be captured in the subject and tester questionnaires (Appendix 4 & 5). High risk individuals will not be excluded. Participants who regularly use home diagnostic tests, such as glucose meters, or are trained medical or laboratory professionals will be excluded.

Study testing will continue until at least 30 PCR confirmed positives are collected, 30 PCR confirmed negatives are collected, and 25 samples are collected from minors between the ages of 2 and 13. Ideally these 30 positives should include at least 10 asymptomatic PCR positive subjects. Specimen collection may be terminated once the 30 SARS-CoV-2 RNA positive specimens and 60 total specimens have been accrued preferably including at least 10 asymptomatic

positive subjects. The FDA may require additional enrollments in order to collect at least 10 asymptomatic positive subjects.

4.5 Exclusion criteria

Subjects less than 2 years old will be excluded. Participants with prior medical or laboratory training or prior experience with self-collection or self-testing (including infectious disease home tests) will be excluded. High risk individuals will not be excluded unless they are too young or have prior training or experience that would exclude them.

4.6 Sample Handling and Management

Nasopharyngeal swab specimens after collection will be labeled and stored at 2-8°C prior to shipment on ice packs and testing.

Study specimens will be accessioned into either the DMH Premier Laboratories system (comparator nasopharyngeal swab samples) or the EDP Biotech Corp. system using assigned unique identifying number to facilitate tracking and identification during analysis. A visual inspection of the specimens will be made to ensure the specimens meet study requirements for volume content and proper appearance. Specimens may be stored refrigerated (2-8°C) prior to testing per the testing protocols for each specimen type.

Remnant samples will be maintained frozen for the duration of the study in case they are needed for repeat and/or discordant testing. Following completion of the study remnant NP samples will be labeled with the subject's unique study ID number which does not visually link to the study subject and stored in -80C freezers for as long as space permits for future research testing.

5.0 Sample Preparation and Testing Procedure

5.1 Rapid SARS-CoV-2 Antigen Test

The study participant will collect the AN swab sample and perform testing according the provided instructions for use without assistance from study personnel other than to refer the participant to the IFU for guidance.

5.2 Instrument Set-Up (Calibration and Quality Control)

All instrument quality control and calibration procedures will be performed per manufacturer's recommendations or the laboratory's QA/QC manual, as appropriate. Instrument calibration and instrument performance will be documented on each day that testing is performed. All documentation related to

the operation of the instrument will be completed, verified and recorded per the laboratory's standard procedures.

5.3 Reagent Preparation

Ag reagents will be prepared for use by EDP Biotech Corp. laboratory personnel as specified in their respective manufacturer's package insert/instruction for use documents. PCR reagents will be prepared for use by DMH Premier laboratory personnel as specified in their respective manufacturer's package insert/instruction for use documents.

5.4 Specimen Processing

Premier Laboratories or Premier Laboratories personnel will process the collected nasopharyngeal swab specimens upon receipt. EDP Biotech Corp personnel will process the collected AN swab specimen data as it is generated.

5.5 Sample Preparation

SARS-CoV-2 RNA will be extracted from the collected specimens using procedures provided by the EUA PCR kit manufacturers. The specifications for specimen integrity described in the manufacturer's instrument instructions will be followed, i.e., storage conditions prior to testing.

5.6 Sample Transport

Specimens must be packaged, shipped, and transported according to the current edition of the International Air Transport Association (IATA) Dangerous Goods Regulation. Follow shipping regulations for UN 3373 Biological Substance, Category B when sending potential 2019-nCoV specimens. Store specimens at 2-8°C and ship overnight to Premier Laboratories on ice pack. If a specimen is frozen at -70°C or lower, ship overnight to Premier Laboratories on dry ice.

5.7 Sample Storage

Remnant NP samples will be stored at -80°C in for the duration of the study in case they are needed for re-testing of discrepant results. Following completion of the study, samples will be maintained at -80°C while space permits in case they are needed for future testing. Remnant NP samples will be labeled with the unique study ID number and/or a random ID that does not visually link to the study subject.

5.8 Control/Calibrator Preparation

Assay controls will be included in each test run per manufacturers' directions.

5.9 Assay Testing

Testing of the study specimens will be performed as follows:

Nasopharyngeal swab specimen after transport will be evaluated at Premier Laboratories with the

CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel (CDC). Testing will be performed according to the specific Premier Laboratories Standard Operating Procedures associated with this test (see Appendices 1 and 2).

AN swab specimens will be evaluated at the time of collection by study subjects observed by EDP Biotech Corp. personnel or designee. Specimens will be tested per the manufacturer's product instructions (Appendix 7).

5.10 Discrepant Analysis

Discordant results will be re-tested using the CDC's Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay FDA EUA SARS-CoV-2 RT-PCR assay performed by Premier Laboratories. Results from a Discrepant analysis should not be included in the calculation of negative percent agreement (NPA) and positive percent agreement (PPA) but may be added to the performance table as a footnote.

5.11 Reporting of Results

The results obtained with the Rapid SARS-CoV-2 Antigen Test will be captured electronically in the EDP Biotech Corp. LIMS system by observers. Premier Laboratories and/or Premier Laboratories will provide the data from the nasopharyngeal swab specimen testing in an electronic format. The result of the comparator PCR test will be reported to the subject and/or their health care provider.

5.12 Adverse Events (AEs)

This is a non-significant risk device study. The study presents no potential for serious risk to the health, safety, or welfare of any human subject as it uses only commonly employed techniques for the NP and AN swab specimens. Since the study procedures are not greater than minimal risk, Serious adverse events (SAEs) are not expected. If any unanticipated problems related to the research involving risks to subjects or others happen (including SAEs) these will be reported to the IRB, Office for Human Research Protections (OHRP), and the study sponsor. AEs that are not serious but that are notable and could involve risks to subjects will be summarized in narrative or other format and submitted to the IRB, OHRP, and sponsor at the time of continuing review.

5.13 Device Malfunctions

Any invalid results of the Rapid SARS-CoV-2 Antigen Test will be repeated, and the repetition noted. Any invalid results of the nasopharyngeal swab comparator will also be repeated, if possible.

6.0 Data Management and Analysis

6.1 Sample ID Numbers and Identification

Each study site will receive a list of randomly generated non-repeating unique study ID numbers (MPB-014-###, if the study size and or duration is increased, then additional digits may be added). The same study ID number will be assigned to all documents and forms associated with a single valid Rapid SARS-CoV-2 Antigen test result including informed consent and authorization forms, assent forms, tester information form, subject information form, user comprehension assessment, and any other documents associated with each valid Rapid SARS-CoV-2 Antigen test result.

Each sample entered into the study will be tracked by the study ID number during accessioning. A data management log listing each sample number and storage information will be maintained.

6.2 Data Evaluation and Accessibility

A report tabulating and analyzing the data will be prepared by the Clinical Investigator including tables of the results and a description of any deviations from the protocol.

6.2.1 Acceptability of Data for Analysis

Valid individual specimen results generated in invalid runs are not acceptable for inclusion in final data analysis. Samples tested in invalid runs must be re-tested if the remaining specimen volume is available. Only valid results from specimens in valid runs will be included in the final data analysis.

6.2.2 Exclusion of Data from Analysis

Data from invalid runs results will be excluded. All excluded results will be documented with rationale for exclusion and a summary of these cases will be provided.

6.2.3 Data Entry and Corrections to Study Documents

All entries must be legible and made in indelible ink (preferably black); do not use pencil. Strike incorrect entries with a single line (do not obliterate or put "white-out" on the original entry). Then enter the correct information next to the original entry, initial, and date the correction.

6.2.4 Assay Run Data

Any Printouts corresponding to assay runs will be maintained and a copy placed in a study binder. A record will be maintained regarding assay reagents and calibrators by lot number and expiration date.

6.2.5 Discordant Results

If any discordant results are generated during the clinical study, further testing using a second high-sensitivity EUA PCR method, CDC's Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay performed by Premier Laboratories, will be performed with specimens yielding discordant results obtained with the initial PCR methodology. If the NP swab sample has been retained and stored properly, and there is sufficient sample available, the same sample will be run on the second PCR assay. Both the AN specimen and the nasopharyngeal swab specimen can be repeat tested if possible. The results from the discrepant analysis will be reported as a footnote in the performance table. The discordancy will not be used to alter the performance data.

6.3 Data Analysis

6.3.1 Acceptance Criteria for Method Comparison

The study sponsor or designee will ensure that all specimens are analyzed appropriately, and results are accurately transcribed to an excel spreadsheet for analysis. Qualitative results from the Antigen Test and quantitative results from the PCR Test may be evaluated for concordance between the two test methods using standard statistical methods.

7.0 Documentation

7.1 Data Reporting Forms and Tracking Log Sheets

Any required forms regarding study data or material inventory tracking (for specimens or assay reagents) will be completed in ink (black ball-point pen is preferred). Entries made with pencil are not allowed. When completing forms, do not leave blanks. If an item is missing, complete the entry with 'ND' for 'not done' or 'NA' for 'not available/applicable,' as appropriate.

All changes or corrections to any original document must be made in ink and initialed and dated by the person making the change. Incorrect data should be indicated by lining through the entry with a single line. Do not erase or use correction fluid ("White-Out" or "Liquid Paper") or eradicate the entry in any other way. The correct value should be written next to the item in question and circled. Each page with corrections must be initialed and dated by the technician performing the assay.

Assigned EDP Biotech Corp. personnel responsible for entries made to any study form will provide a signature and date on each form sheet upon completion. The Clinical Investigators (or designee) must review all study forms related to data reporting or material tracking. The Clinical Investigators are ultimately responsible for the integrity of the data recorded or submitted on the data reporting form.

7.2 Subject Questionnaire

Each subject will be asked to complete forms providing information about exhibited symptoms consistent with COVID-19 infection (Appendix 3 & 4), and forms regarding the comprehension of the test (Appendix 5).

7.3 Instrument-Generated Printouts

Any instrument-generated data printed results for each assay run (including all valid and invalid runs) must be reviewed for accuracy and signed and dated by the Principal Investigator (or designee) and then included in the study regulatory binder.

7.4 Specific Tracking Log Sheets

All test materials and controls used during the study will be recorded to indicate lot and expiration date.

8.0 IRB Requirements

8.1 Informed Consent

The study described in this protocol presents a nonsignificant risk of harm to the human subjects, as standard procedures are used for the AN swab and nasopharyngeal swab specimen collections. EDP Biotech Corp. has determined Informed Consent (IC) is appropriate from individuals to provide specimens for the research study. A proposed Informed Consent Form is presented as Appendix 8.

For this study:

a) This investigation meets the IDE exemption criteria at 21 CFR 812.2(c)(3).

b) The specimens will not be individually identifiable, i.e., the identity of the subject is not known after specimen collection based on the unique identifier and may not readily be ascertained by EDP Biotech Corp. employees or any other individuals associated with the investigation after the unique SID is assigned. In this manner, the specimens will be coded but will be individually identifiable by the clinical investigator(s) so that study participants can be given the results of the nasopharyngeal swab sample analysis for COVID-19 RNA (positive or negative).

c) The samples are provided to the laboratory staff and investigator(s) in a de-identified state, i.e., without the name of the subject, thus preventing the unintentional release or dissemination of personal information or testing results.

d) The study will be reviewed by an IRB in accordance with 21 CFR Part 56.

8.2 IRB Approval

This study will be initiated only after IRB Approval of the study has been granted. A copy of the IRB approval document will be maintained by the Clinical Investigators in a study binder.

9.0 Risk Analysis

This is a non-significant risk device study. The study presents no potential for serious risk to the health, safety, or welfare of any human subject as it uses only commonly employed techniques for the AN swab and nasopharyngeal swab specimens. There will be subject recruitment at the EDP Biotech Corp.

investigative site using public posting, e-mail correspondence, and referrals. Study results will be used to demonstrate that the Rapid SARS-CoV-2 Antigen Test technique is suitable for home use without a prescription.

10.0 Study Master File (SMF)

The Clinical Investigator (CI) or Designee(s) will collect and review copies of the required essential documents (ED) listed below in the form of a Study Master File (SMF). EDP Biotech Corp. will maintain the SMF and copies of the required EDs; the Investigator Site File (ISF) will contain original documents. MP Biomedicals is the sponsor of the study and will maintain copies of the required EDs as well.

10.1 Required Essential Documents

A binder(s), which for purposes of this clinical study will be defined as the investigator site file (ISF), will be maintained at the trial site and serves as the central source for ED maintenance at the site.

The following documents represent a complete site essential document packet and are to be maintained in the ISF:

- Clinical Investigator's (CI) Curriculum Vitae (CV) or Resume.
- CI Human Subject Protection Training documentation.
- Institutional Review Board (IRB)-Approved Protocol and Protocol Amendments.
- Protocol/Protocol Amendment(s) Signature Pages.
- IRB Compliance Documentation.
- Signed informed consent forms.
- Laboratory Certifications, e.g. CLIA.

11.0 Monitoring

The sponsor of this study shall be responsible for ensuring adequate monitoring for the study occurs. The Clinical Investigators will grant the sponsor or designee access to the testing site and all applicable study information. Access will be granted to review all study documents and all Regulatory documentation (site binders containing completed ICFs and IRB approval). Monitoring of the study will be conducted on a periodic basis throughout the evaluation. Closeout monitoring of the study will be conducted. Reports of the monitoring will be prepared. Any deficiencies observed during the monitoring will be discussed with the Clinical Investigator for remediation. Monitoring may be conducted remotely.

12.0 Investigational Study Site Compliance

12.1 Investigator Responsibility

The Clinical Investigator (CI) is expected to ensure that the methods and study design outlined in this protocol are followed. No changes to protocol methods or study design can be made without the written consent of the sponsor. It is the responsibility of the sponsor and the CIs to ensure subject confidentiality and IRB approval for the study.

12.2 Site Monitoring and Inspection

The sponsor will maintain close liaison with the study Investigators to answer any questions that may arise and to ensure that the study is being conducted according to this protocol. The study site will permit the sponsor and/or its designee to visit the site at reasonable times to audit or inspect the study records and materials. Sponsor personnel will audit the progress and compliance of the study and at the end of the study for closeout.

12.3 Record Retention

Study records will be maintained by the Clinical Investigators and Study Sponsor per EDP Biotech Corp. SOPs. Copies of all data generated from the study, all data reporting forms, and records of reagent disposition are to be maintained for a period of 5 years following the date on which the entire clinical investigation is terminated or discontinued.

13.0 Biological Safety

13.1 Toxicity and Complications

Not applicable.

13.2 Sample Handling

All volunteer specimens and materials with which the study personnel come into contact should be handled as if capable of transmitting infection, and dispensed of with precautions in accordance with Federal, State, and Local regulations.

14.0 Modifications to the Protocol

14.1 Protocol Amendments

Neither the Clinical Investigators nor study laboratory personnel will modify this protocol without contacting the Study Sponsor.

14.2 Study Termination

For any reasonable cause, the Study Sponsor may terminate the study, provided a written notice is submitted at least 30 days in advance of the intended termination. The IRB will be notified if the study is terminated.

15.0 Abbreviations

The abbreviations that are given below apply:

15.1 Abbreviations

°C	Celsius (Centigrade)
µg	Microgram
µl	Microliter
AE	Adverse Event
AMR	Analytical Measurement Range
AN	Anterior nasal (nares)
CFR	Code of Federal Regulations
dL	One-tenth of a liter
d	Day
FDA	Food and Drug Administration
hrs	Hours
IC	Informed Consent
ID	Identification or identification number
IDE	Investigational Device Exemption
IFU	Instructions for use
IRB	Institutional Review Board
IUO	Investigational use only
LIS	Laboratory information system
mL	Milliliter
N	Number
NA	Not applicable or not available
ND	Not done
Ng	Nanogram
OTC	Over the counter
PI	Principal Investigator
QC	Quality Control
RT	Room temperature (ambient)
RUO	Research Use Only
SAE	Serious Adverse Event
SOC	Standard of care
SOP	Standard Operating Procedure
wks	Weeks

16. References

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19) outbreak. J Autoimmun. 2020;109:102433. doi:https://doi.org/10.1016/j.jaut.2020.102433

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