CLINICAL PERFORMANCE STUDY PLAN

EuGeni SARS-CoV-2 Antigen Rapid Diagnostic Test

AnteoTech LTD.

Document reference number: [redacted] Version 3.0

Date: 19-Sep-2022

CONTACT INFORMATION

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CLINICAL PERFORMANCE STUDY PLAN (CPSP) SUMMARY

Version Number	3.0
Date	19-Sep-2022
Sponsor	**AnteoTech Ltd** Unit 4, 26 Brandl Street Brisbane Technology Park Eight Mile Plains QLD 4113 Australia [redacted] **EU authorized representative:** MT Promedt Consulting GmbH Altenhofstrasse 80 66386 St. Ingbert Germany [redacted] [redacted]
Clinical Performance Study Name	EuGeni SARS-CoV-2 Antigen Rapid Diagnostic Test Clinical Performance Study
Clinical Performance Study Code	[redacted]
Objectives	To determine the diagnostic accuracy in terms of specificity and sensitivity of the EuGeni SARS-CoV-2 Antigen Rapid Diagnostic Test in the diagnosis of SARS-CoV-2 in specimens prospectively collected by healthcare professionals from subjects suspected of COVID-19 disease or with unknown COVID-19 status.
Device Under Investigation	EuGeni SARS-CoV-2 Ag RDT assay and EuGeni Reader
Number of Required Specimens	A minimum estimated of 1850 prospective specimens divided as follows: Nasopharyngeal specimen collection: ○ 300 positive specimens from symptomatic subjects ○ 120 negative specimens from hospitalized patients ○ 505 negative specimens from subjects with respiratory symptoms Combined nasal mid-turbinate and throat specimen collection: ○ 300 positive specimens from symptomatic subjects ○ 120 negative specimens from hospitalized patients ○ 505 negative specimens from subjects with respiratory symptoms
Planned Number of Sites	Up to 10 sites in Europe
Study Design	This is a non-interventional, two-arm, prospective, non-randomized, open-label and multi-center Clinical Performance Study

Primary Endpoints	To assess the EuGeni SARS-CoV-2 Ag RDT diagnostic accuracy in terms of sensitivity and specificity measured as the following: • The diagnostic sensitivity will be assessed as the ability to identify the presence of a target marker associated with SARS-CoV-2, of nasopharyngeal specimens and combined nasal mid-turbinate and throat specimens, respectively, compared with gold-standard SARS-CoV-2 RT-PCR. • The diagnostic specificity will be assessed as the ability to recognise the absence of a target marker associated with SARS CoV-2, of nasopharyngeal specimens and combined nasal mid-turbinate and throat specimens, respectively, compared with gold-standard SARS-CoV-2 RT-PCR.
Secondary Endpoint	To compare the specificity and sensitivity rates of EuGeni SARS-CoV-2 Ag RDT between the two specimen collection methods.
Inclusion Criteria	1. Specimens from subjects over 12 years old agreeing to participate in the study and with a legal representative able to provide informed consent, OR; 2. Specimens from subjects over 18 years old able to provide informed consent. 3. Specimens collected with nasopharyngeal swabs, OR; 4. Combined nasal mid-turbinate and throat specimen collection.
Exclusion Criteria	1. Specimens and testing methods that are not deemed to be in line with gold-standard RT-PCR standards. 2. Specimens stored for over 2 hours at 2-8 ºC temperature between collection and testing with EuGeni SARS-CoV-2 Ag RDT 3. Specimens stored for over 5 days at -20ºC between collection and testing with RT-PCR. 4. Specimens stored for over 24h at 4ºC between collection and testing with RT-PCR. 5. Contamination and/or deterioration of the specimen which, in the opinion of the investigator, may affect its handling and/or analysis. 6. The subject is deemed unsuitable to participate in the study by the investigator.
Coordinating Investigator	[redacted]
Electronic Data Capture (EDC)	[redacted]
Data Management & Biostatistics	[redacted]
Contract Research Organization (CRO)	AKRN Scientific Consulting S.L. (Madrid, Spain)
Expected Duration of the Study	[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

Investigational Site Name

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

COMPLIANCE STATEMENT:

This clinical performance study will be conducted in accordance with this Clinical Performance Study Plan, the Declaration of Helsinki, law 14/2007 of 3 July 2007 on Biomedical Research, applicable Good Clinical Practices, ISO 20916:2019 standards and regulations: EU 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices (IVDR), repealing Directive 98/79/EC and Commission Decision 2010/227/EU, EU General Data Protection Regulation and WHO International health regulations.

The most stringent requirements, guidelines or regulations must always be followed. The conduct of the clinical performance study will be approved by the appropriate Institutional Review Board (IRB)/Ethics Committee (EC) of the respective investigational site and by the applicable regulatory authorities.

CONFIDENTIALITY STATEMENT

This document is confidential and is to be distributed for review only to investigators, potential investigators, consultants, study staff, and applicable independent Ethics Committees or Competent Authorities. The contents of this document shall not be disclosed to others without written authorization from the Sponsor unless it is necessary to obtain informed consent from potential study participants.

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1. INTRODUCTION

Rapid antigen detection (RAD) tests are used to perform rapid diagnosis of SARS-CoV-2 infection based on a qualitative approach. RAD tests detect the viral antigen by the immobilized coated SARS-CoV-2 antibody placed on the device. The results of these tests are available in a short time, reducing the workload in diagnostic hospitals and laboratories and improving the turn-around time.

EuGeni SARS-CoV-2 Antigen Rapid Diagnostic Test is an *in vitro* Diagnostic (IVD) medical device intended to be used for the qualitative detection of SARS-CoV-2 nucleocapsid antigen. The result from this IVD test identifies the presence or absence of the SARS-CoV-2 antigen as an aid for the diagnosis of COVID-19 infection.

1.1 Background and rationale

In 2019 a novel corona virus, designated as SARS-CoV-2 and associated with unusual viral pneumonia named Corona virus Disease 19 (COVID-19), sprouted in the city of Wuhan, China, and rapidly spread to create a global pandemic. Identification of people infected with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is essential for controlling its spreading and public health management.

Since the beginning of the COVID-19 outbreak, tests that can enable both mass screening and reliable detection of infected people are needed[1]. The reliance on testing underscores the importance of analytical sensitivity of virus assays, being the real-time quantitative polymerase chain reaction (RT-qPCR) from nasopharynx swab the gold-standard [2]. However, RT-PCR is expensive, time-consuming, and requires specialized laboratory personnel and instrumentation compared to rapid tests [3].

New developments in SARS-CoV-2 diagnostics have the potential to reduce cost and turnaround time [4–6]. Several diagnostic strategies are available for identifying or ruling out current infection, identifying people in need of care escalation, or testing for past infection and immune response. Point-of-care (POC) antigen and molecular tests for the detection of current SARS-CoV-2 infections are rapid antigen detection (RAD) tests, which allow earlier detection and isolation of confirmed cases compared to laboratory-based diagnostic methods.

Coronavirus RAD tests, have demonstrated good sensitivity and specificity in comparison to RT-qPCR [7–9]. Moreover, previous studies have shown that RADs can exhibit high sensitivity in detecting samples containing infectious virus, indicating a high sensitivity to detect contagious individuals [10,11]

The RAD tests, based on the immunochromatographic principle, detect SARS-CoV-2 nucleocapsid protein (N) at or near the place where a specimen is collected, providing results within few minutes[3]. In general, RAD tests consist of fixing match-paired antibodies to the surface of the cassette and coupling an anti-antigen match-paired antibodies to the detection nanoparticles. [redacted]

EuGeni SARS-CoV-2 Ag RDT is a fluorescent immunochromatographic RAD test for COVID-19 rapid detection using the [redacted] for results interpretation. The [redacted] is expected to provide positive, negative, or invalid result for the presence of SARS-CoV-2 antigen. The EuGeni device is intended to be used by healthcare professionals only.

2. IN-VITRO DIAGNOSTIC MEDICAL DEVICE OVERVIEW

2.1 IVD Medical Device under investigation

The EuGeni SARS-CoV-2 Ag RDT is a test strip based on lateral flow technology [redacted]

A [redacted] B [redacted]

[redacted]

[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

[redacted]

[redacted]

2.3 Intended User

The EuGeni SARS-CoV-2 Ag RDT is intended to be used by healthcare professionals which must be qualified and trained. This test is intended for use at the Point of Care (POC) and laboratory settings.

2.4 Mechanism of action of the Device Under Investigation

The EuGeni SARS-CoV-2 Ag RDT is a test strip based on lateral flow technology [redacted] for detection but not differentiation of SARS-CoV and SARS-CoV-2 antigen, and for internal assay control. [redacted]

The test line contains an immobilized monoclonal mouse antibody to capture SARS-CoV-2 antigen and the control line contains an immobilized control anti-mouse antibody.

[redacted]

- [redacted]
- [redacted]

[redacted] The control line must be detected by the [redacted] for the test to be valid. If the control line is not detected, the test is considered invalid and must be repeated using another test cassette.

For more precise information on the device description and the reader, please refer to the IFU.

2.5 Device Handling

All investigational products shall be stored according to the labeling and Instructions for Use (IFU) in a secure area to prevent unauthorized access or use.

[redacted]

For further device handling warnings and precautions, please see the details in the IFU.

3. CLINICAL PERFORMANCE STUDY OVERVIEW

3.1 Clinical Performance study Objective

The objective of this clinical performance study (CPS) is to determine the diagnostic accuracy (sensitivity and specificity) of the EuGeni SARS-CoV-2 Antigen Rapid Diagnostic Test in the diagnosis of SARS-CoV-2 in specimens from subjects suspected of COVID-19 disease or with unknown COVID-19 status.

4. CLINICAL PERFORMANCE STUDY DESIGN AND PROCEDURES

4.1 Clinical performance study design

This clinical performance study (CPS) is designed as a non-interventional, two-arm, prospective, non-randomized, open-label and multi-center study. The two study arms as defined depending on the specimen collection method:

1. Nasopharyngeal specimen collection for comparison with gold-standard RT-PCR
2. Combined nasal mid-turbinate and throat specimen collection for comparison with gold-standard RT-PCR

The expected minimum number of specimens for this CPS is 1850, divided as follows:

Nasopharyngeal specimen collection:

- 300 positive specimens collected from subjects at different timepoints post onset of symptoms: [redacted]
- 120 negative specimens from hospitalized patients
- 505 negative specimens from subjects with respiratory symptoms

Combined nasal mid-turbinate and throat specimen collection:

- 300 positive specimens collected from subjects at different timepoints post onset of symptoms: [redacted]
- 120 negative specimens from hospitalized patients
- 505 negative specimens from subjects with respiratory symptoms.

[redacted] The estimated numbers for each specimen type are approximate and may vary depending on the natural recruitment at the investigational sites to ensure the correct distribution of sample size requirements.

The study has been designed to involve as little pain, discomfort, fear and any other foreseeable risk as possible for the subjects, and both the risk threshold and the degree of distress are specifically defined in the clinical performance study plan (CPSP) and constantly monitored.

The CPS will be conducted in up to 10 sites in Europe. The primary and secondary endpoints will be evaluated when all specimens have been collected and analyzed. [redacted]

4.2 Clinical Performance Study Procedures

The Clinical Performance Study will occur in a single subject visit, and no clinical follow up will be required.

4.2.1 Informed Consent and Specimen collection

Before starting any study-related activity, the subject must have provided the signed informed consent form following the requirements in [Section 6.1.2]. Next, the specimen collection will be performed by professionally trained and qualified healthcare personnel.

One bilateral swab will be taken to be analyzed with the device under investigation and another bilateral swab will be taken to be analyzed with the gold-standard RT-PCR. The specimen collection method for EuGeni analysis will be performed using either a combined nasal mid-turbinate and throat swab, or a nasopharyngeal swab, which will determine the inclusion into one of the two study arms. Enrolment into the combined nasal mid-turbinate and throat arm or nasopharyngeal will not be randomized, however consecutive and parallel enrollment in both arms will take place. Regardless of the study arm, the RT-PCR specimen collection will always occur to allow result comparison between the investigational device and RT-PCR.

For further information on specimen collection, please refer to IFU [redacted]

4.2.2 Specimen analysis procedure

The specimen analysis shall be performed by professional healthcare personnel. Specimens to be analyzed by the gold-standard RT-PCR shall follow the procedures established by the standard of care. [redacted]

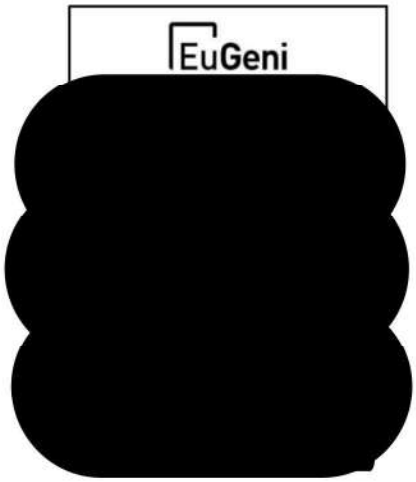
Those specimens analyzed by the EuGeni SARS-CoV-2 Antigen Rapid Diagnostic Test shall follow the procedures laid down in the IFU and protocol. [redacted]

a) Positive results indicate the presence of SARS-CoV-2-antigen and is indicative of primary SARS-CoV-2 infection. [redacted]

b) Negative results indicate the specimen does not contain SARS-CoV-2 antigen. In this case, only the [redacted] control line will be displayed. Negative results should be treated as presumptive and should not be used as the sole basis for clinical diagnosis and treatment. [redacted]

c) If a test is Invalid, a new test should be performed with a new subject specimen and a new cassette. [redacted]

For more information on the interpretation of results, please refer to the EuGeni SARS-CoV-2 Antigen Rapid Diagnostic Test IFU.



All results obtained from the investigational device should only be noted in the Case Report Form. These results will not impact or drive patient management decisions. The gold-standard RT-PCR results will provide this information to the healthcare professionals and the enrolled subjects.

4.2.2.1 Specimen handling and storage

Study site personnel shall ensure proper storage of specimens in accordance with the IFU.

The study will use fresh human specimens, potentially containing active virus and infectious materials. The handling of samples will be conducted in accordance with standard laboratory containment procedures and following local government guidance for handling SARS-CoV-2 and SARS-CoV-2 containing material.

4.3 Measures Taken to Avoid and Minimize Bias

This clinical performance study has been designed to be multicenter in order to minimize bias related to site specific standard of care patient and specimen collection method.

All participants who meet the inclusion and exclusion criteria will be eligible to join the study. Inclusion into the two study arms will not be randomized, however sites will be instructed to consecutively enroll subjects into both arms. Recruitment at each investigational site will be limited to [redacted] of the total sample size.

To avoid bias related to the collection method, all study subjects will have a bilateral swab specimen collection for investigational device analysis and for RT-PCR analysis, for direct comparison within the same subjects.

5. ENDPOINTS

5.1 Primary Endpoints

The primary endpoint of this clinical performance study is to assess the EuGeni SARS-CoV-2 Ag RDT diagnostic accuracy in terms of sensitivity and specificity measured as the following:

- The diagnostic sensitivity of EuGeni SARS-CoV-2 Ag RDT, defined as the ability to identify the presence of a target marker associated with SARS-CoV-2, of nasopharyngeal specimens and combined nasal mid-turbinate and throat specimens, respectively, compared with gold-standard SARS-CoV-2 RT-PCR.
- The diagnostic specificity of EuGeni SARS-CoV-2 Ag RDT, defined as the ability to recognise the absence of a target marker associated with SARS CoV-2, of nasopharyngeal specimens and combined nasal mid-turbinate and throat specimens, respectively, compared with gold-standard SARS-CoV-2 RT-PCR.

5.2 Secondary Endpoint

The secondary endpoint of this clinical performance study is to compare the EuGeni SARS-CoV-2 Ag RDT diagnostic accuracy (specificity and sensitivity) between the two specimen collection methods (nasopharyngeal and combined nasal mid-turbinate and throat) to assess any potential impact on diagnostic accuracy.

6. SELECTION OF SPECIMENS

6.1 Specimens and subjects providing specimens

The specimens used in this clinical performance study will be selected from any gender of subjects of the general population suspected to be infected with SARS-CoV-2 or with unknown COVID-19 status.

The Principal Investigator or designee, previously trained in this CPSP, will revise subject and specimen eligibility according to the inclusion/exclusion criteria. Those who meet all the inclusion criteria and no exclusion criteria shall be suitable to participate in the study.

6.1.1 Subject Screening

Enrolled subjects will be fully informed about the clinical performance study, following the established Informed Consent process (described in the next section). Once a duly dated and signed Informed Consent form is obtained, the clinical performance procedures may begin. Subjects under 18 years of age must be accompanied by a parent or legal representative who must also give consent for the under-age's participation in the study.

[redacted]

In case the subject does not meet all inclusion criteria or meets any of the exclusion criteria, the subject is considered a screening failure. The Principal Investigator or the delegated clinical performance study personnel will record the screening failure in the hospital records and on the screening log as required.

Subjects meeting general inclusion criteria and no exclusion criteria will be asked to sign an Informed Consent form if they wish to participate in the clinical performance study. [redacted]

Subject data will be collected following enrollment into the clinical performance study.

6.1.2 Informed Consent

The Investigator or his/her authorized designee (if applicable) will conduct the Informed Consent process, as required by applicable regulations and the center's EC. [redacted] Withdrawal from the clinical performance study will not jeopardize their future medical care or relationship with the investigator.

During the discussion, the Principal Investigator or his/her authorized designee will avoid any improper influence on the subject and will respect subject's legal rights. Financial incentives will not be given to the subject. [redacted] The subject shall have adequate time to review, ask questions, and consider participation. [redacted]

[redacted] If the subject agrees to participate, the Informed Consent form must be signed and dated by the subject and thereafter by the person obtaining the consent prior to any clinical performance study-specific procedures. [redacted]

6.1.2.1 Special Circumstances for Informed Consent

Individuals under age of 18 or under age of legal consent:

Individuals who are minors (under the age of 18 or age of legal consent, but over 12 years old) may be enrolled in this clinical performance study. Informed consent must be obtained using the IRB/EC approved informed consent in accordance with IRB/EC requirements.

In this special circumstance, the legally acceptable representative will represent the individual during the Informed Consent process, which will be performed according to the requirements in [Section 6.1.2]. The minor will also be informed about the CPS within his/her ability to understand. [redacted]

6.2 Eligibility Criteria

6.2.1 Inclusion Criteria

1. Specimens from subjects over 12 years old agreeing to participate in the study and with a legal representative able to provide informed consent, OR;
2. Specimens from subjects over 18 years old able to provide informed consent.
3. Specimens collected with nasopharyngeal swabs, OR;
4. Combined nasal mid-turbinate and throat specimens' collection.

6.2.2 Exclusion Criteria

1. Specimens and testing methods that are deemed not compatible with gold-standard RT-PCR standards.
2. Specimens stored for over 2 hours at 2-8 ºC in between collection and testing with EuGeni SARS-CoV-2 Ag RDT
3. Specimens stored for over 5 days at -20ºC between collection and testing with RT-PCR.
4. Specimens stored for over 24h at 4ºC between collection and testing with RT-PCR.
5. Contamination and/or deterioration of the specimen which, in the opinion of the investigator, may affect its handling and/or analysis.
6. The subject is deemed unsuitable to participate in the study by the investigator.

6.3 Subject Enrolment

A subject is considered enrolled in the CPS from the moment the subject provides written informed consent and has been confirmed to meet all inclusion criteria and none of the exclusion criteria.

[redacted]

6.4.1 Suspension or Early Termination of the Clinical Performance Study

While no formal statistical rule for early termination of the clinical performance study for insufficient accuracy of the device under investigation is defined, the Sponsor reserves the right to discontinue the clinical performance study at any stage with suitable written notice to the investigator. Possible reason(s) may include, but are not limited to:

- Unanticipated adverse device effect (e.g., UADE) occurs and it presents an unreasonable risk to the participating subjects.
- Further product development is cancelled.

Should the clinical performance study be discontinued by the Sponsor, subjects will be followed per routine hospital practice with device-related AEs reported to the Sponsor as per vigilance/commercial reporting requirements. [redacted]

7. ADVERSE EVENTS

The study has been designed to involve as little pain, discomfort, fear, and any other foreseeable risk as possible for subjects. [redacted]

7.1 Definition

7.1.1 Adverse Event

An adverse event (AE) is any untoward medical occurrence, unintended disease or injury, or untoward clinical signs (including abnormal laboratory findings) in subjects, users or other persons, whether or not related to the medical device under investigation.

Note 1: This definition includes events related to the medical device under investigation or the comparator.

Note 2: This definition includes events related to the procedures involved.

Note 3: For users or other persons, this definition is restricted to events related to medical devices under investigation.

7.1.2 Serious Adverse Event

If the AE meets any of the criteria below, it is regarded as a serious adverse event (SAE).

a) Led to a death,

b) Led to a serious deterioration in health of the subject, that either resulted in

   1. a life-threatening illness or injury, or
   2. a permanent impairment of a body structure or a body function, or
   3. in-patient hospitalization or prolongation of existing hospitalization, or
   4. medical or surgical intervention to prevent life threatening illness or injury or permanent impairment to a body structure or a body function.
   5. chronic disease

c) Led to fetal distress, fetal death or a congenital abnormality or birth defect.

Note: A planned hospitalization for pre-existing condition, or a procedure required by the CIP, without a serious deterioration in health, is not considered to be an SAE.

7.1.3 Device Deficiency/Device Malfunction

Device deficiency is defined as an inadequacy of a medical device related to its identity, quality, durability, reliability, safety or performance, such as malfunction, misuse or use error and inadequate labeling. This includes the failure of the device to meet its performance specifications or otherwise perform as intended. Note: Performance specifications include all claims made in the labeling of the device.

A device malfunction is the failure of a device to meet its performance specifications or otherwise perform as intended, when used in accordance with the instructions for use or CPSP.

7.2 Device Relationship

Determination of whether there is a reasonable possibility that an investigational product or device under investigation caused or contributed to an AE is to be performed by the Investigator and recorded on the appropriate CRF form. Determination should be based on assessment of temporal relationships, evidence of alternative etiology, medical/biologic plausibility, and patient condition (pre-existing condition).

7.2.1 Unanticipated (Serious Adverse) Device Effect [U(S)ADE]

Unanticipated serious adverse device effect (USADE) refers to any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.

7.3 Adverse Event and Device Deficiency/Device Malfunction Reporting

7.3.1 Adverse Event Reporting

General AE Reporting

Safety surveillance and reporting starts as soon as the patient is enrolled in the clinical performance study. [redacted] All adverse event data, [redacted] will be reported to the Sponsor on a CRF. Additional information with regard to an adverse event should be updated within the appropriate CRF.

Unchanged, chronic, non-worsening or pre-existing conditions are not AEs and should not be reported.

[redacted]

All adverse events will be collected on each subject through the study duration

SAE Reporting

The investigator should report all SAEs to the Sponsor as soon as possible but no later than outlined below.

Clinical Site	Reporting timelines
All Sites	SAEs must be reported to the Sponsor no later than 3 calendar days from the day the site personnel became aware of the event [redacted]

[redacted]

[redacted]	
[redacted]	[redacted]
[redacted]	[redacted]

7.3.2 Unanticipated Serious Adverse Device Effect Reporting to Sponsor and EC

The Sponsor requires the Investigator to report any USADE to the Sponsor within 3 calendar days of the investigator's knowledge of the event, [redacted]

7.3.3 Device Deficiency/Malfunction Reporting

All device deficiencies/malfunctions should be reported on the appropriate CRF form.

The investigator should report all device deficiencies/malfunctions to the Sponsor as soon as possible but no later than outlined below.

Clinical Sites	Reporting timelines
All Sites	Device deficiencies/malfunctions must be reported to the Sponsor no later than 3 calendar days from the day the site personnel became aware of the event [redacted]

[redacted]

8. STATISTICAL CONSIDERATIONS

[redacted]

8.1 Analysis Populations

[redacted]

- Arm 1, including specimens collected with nasopharyngeal swabs
- Arm 2, including specimens collected with combined nasal mid-turbinate and throat swabs

8.2 Statistical Analyses

8.2.1 Primary Diagnostic Accuracy Endpoint(s) Analyses

The evaluation of the accuracy of the EuGeni SARS-CoV-2 Ag RDT in the diagnosis of COVID-19 will be analyzed by means of the sensitivity and specificity capacity of this test.

- [redacted]

[redacted]

8.2.2 Secondary Endpoint Analysis

The secondary endpoint assesses any potential impact of the specimen collection method (arms 1 and 2) on EuGeni SARS-CoV-2 Ag RDT diagnostic accuracy (specificity and sensitivity rates). [redacted]

8.3 Sample Size Calculation and Assumptions

The sample size calculation is based on the objective to demonstrate an 80% sensitivity and a 98% specificity of the EuGeni SARS-CoV-2 Ag RDT for COVID-19 testing, [redacted]

[redacted]

9. QUALITY CONTROL AND QUALITY ASSURANCE

9.1 Selection of Clinical Sites and Investigators

The Sponsor or designee will select investigators qualified by education, training and experience to participate in the clinical performance study. [redacted]

9.2 Finances and Agreements

The clinical performance study will be financed by AnteoTech., Ltd. [redacted]

[redacted]

9.4 Training

9.4.1 Site Training

All Investigators and clinical performance study personnel are required to attend Sponsor training sessions, which may be conducted at an Investigator's meeting, a site initiation visit, or other appropriate training sessions. Video call or self-training may take place as required. [redacted]

9.5 Monitoring

Sponsor and/or designee will monitor the clinical performance study over its duration according to the CPSP-specific monitoring plan which will include the planned extent of source data verification. This monitoring plan will be a separate document that can be updated during the course of the study.

[redacted]

[redacted]

9.6 Deviations from CPSP

The Investigator should not deviate from the CPSP for any reason except in cases of medical emergencies when the deviation is necessary to protect the rights, safety and well-being of the subject or eliminate an apparent immediate hazard to the subject. In that event, the Investigator will notify Sponsor immediately by phone or in writing.

[redacted]

[redacted]

10.1 Protection of Personally Identifiable Information

The Sponsor respects and protects personally identifiable information collected or maintained for this clinical performance study.

[redacted]

The Sponsor requires the investigational sites to transfer into Sponsor's data management systems only pseudonymous Personal Information (key-coded) necessary to conduct the clinical performance study, such as the patient's medical condition, treatment, dates of treatment, etc. [redacted]

The Sponsor maintains a Privacy Incident procedure that complies in all respects with Applicable Law and industry best practices.

10.2 Data Management Plan

A Data Management Plan (DMP) will describe procedures used for data entry and collection. Data review and data cleaning, and issuing, resolving data discrepancies and methods for data base lock. [redacted]

[redacted]

10.4 Case Report Form Completion

Primary data collection based on source-documented hospital and/or clinic chart reviews will be performed clearly and accurately by site personnel trained on the CPSP and CRF completion. [redacted]

10.5 Record Retention

The Sponsor and Investigator/Site will archive and retain all documents pertaining to the CPS as per the applicable regulatory record retention requirements. The Investigator must obtain permission from Sponsor in writing before destroying or transferring control of any CPS records.

[redacted]

11. RISK ANALYSIS

Recruited subjects for specimen collection may have anticipated risks associated with the specimen collection procedure. A risk analysis is conducted and identified risks are similar to those well-known for standard of care collection procedures (e.g., swab collection for gold-standard RT-PCR) and are described in the IFU.

[redacted]

[redacted]

11.6 Benefit to Risk Rationale

[redacted]While there are no additional risks associated with study participation, the public health may be benefitted.

12. ETHICAL CONSIDERATION

12.1 Institutional Review Board/Ethics Committee Review and Approval

Institutional Review Board (IRB)/Ethics Committee (EC) approval for the CPSP and ICF/other written information provided to the patient will be obtained at each investigational site prior to consenting and enrolling patients in this clinical performance study. The approval letter must be received prior to the start of this clinical performance study and a copy must be provided to the Sponsor.

[redacted]

13. CLINICAL PERFORMANCE STUDY CONCLUSION

The clinical performance study will be concluded when:

- The investigational site is closed AND
- The final report has been provided to investigators or the Sponsor has provided formal documentation of clinical performance study closure.

The Sponsor shall submit the clinical performance study report (CPSR) within one year of the end of the investigation as applicable per the study.

14. PUBLICATION POLICY

The data and results from the clinical performance study are the sole property of the Sponsor. [redacted]

[redacted]

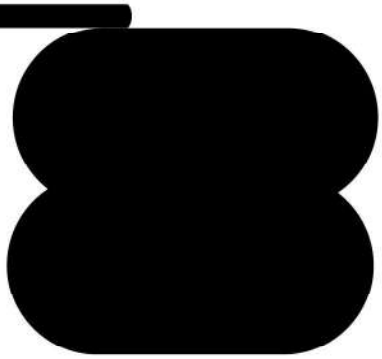
APPENDIX I: ABBREVIATIONS AND ACRONYMS

Abbreviation/Acronym	Words
AE	Adverse Event
ADE	Adverse Device Effect
CPS	Clinical Performance Study
CPSP	Clinical Performance Study Plan
CPSR	Clinical Performance Study Report
CRF	Case Report Form
CTA	Clinical Trial Agreement
DMP	Data Management Plan
EC	Ethics Committee
EDC	Electronic Data Capture
ICF	Informed Consent Form
IFU	Instructions For Use
IVD	*In vitro* Diagnostic
RT-PCR	Real-Time Polymerase Chain Reaction
PI	Principal Investigator
RAD	Rapid Antigen Detection
RDT	Rapid Diagnostic Test
SAP	Statistical Analysis Plan
SAE	Serious Adverse event

[redacted]

[redacted]

[redacted]



[redacted]

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