Statistical Analysis Plan (SAP)

EuGeni SARS-CoV-2 Antigen Rapid Diagnostic Test

AnteoTech LTD.

Document reference number: [redacted] Version 1.0

Date: 23-Nov-2022

TABLE OF CONTENTS

1. SYNOPSIS OF STUDY DESIGN

1.1 Purpose of Statistical Analysis Plan

This statistical analysis plan (SAP) is intended to provide a detailed and comprehensive description of the planned methodology and analysis to be used for the EuGeni SARS-CoV-2 Antigen Rapid Diagnostic Test Clinical Performance Study (CPS)[redacted]

1.2 Clinical Performance Study Objectives

The objective of this 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 prospectively collected by healthcare professionals from subjects suspected of COVID-19 disease or with unknown COVID-19 status.

1.3 Clinical Performance Study Design

This CPS has been designed as a non-interventional, two-arm, prospective, non-randomized, open-label and multi-center study. Specimens can be prospectively collected by two different methods, which define the two arms of the study:

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.

[redacted]

1.4 Endpoints

1.4.1 Primary endpoint

The primary endpoint of this clinical performance study is to assess the EuGeni SARS-CoV-2 Ag RDT diagnostic accuracy, 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, [redacted] compared with gold-standard SARS-CoV-2 RT-PCR.

- The diagnostic specificity of EuGeni SARS-CoV-2 Ag RDT, defined as the ability to recognize the absence of a target marker associated with SARS CoV-2, [redacted] compared with gold-standard SARS-CoV-2 RT-PCR.

1.4.2 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) [redacted]

1.5 Randomization

[redacted]

1.6 Blinding

[redacted]

2. ANALYSIS CONSIDERATIONS

2.1 Analysis Populations

2.1.1 Per-protocol (PP) population

Per-Protocol (PP) population includes all specimens that meet the study eligibility and informed consent requirements. [redacted]

2.2 Statistical Methods

[redacted]

2.2.3 Survival analyses

Survival analyses do not apply to this CPS.

2.2.4 Regression

No regression analyses are planned for this CPS.

2.3 Endpoint Analysis

2.3.1 Primary endpoint(s)

The primary endpoint of this CPS evaluates the EuGeni SARS-CoV-2 Ag RDT diagnostic accuracy, which is defined in terms of sensitivity and specificity:

- The sensitivity is the ability to detect a target marker associated with SARS-CoV-2. The sensitivity means the capacity to detect positive samples from COVID-19 patients. [redacted]

- The specificity is the ability to recognize the absence of a target marker, associated with SARS-CoV-2, which means the capacity to detect true negative samples of COVID-19. [redacted]

[redacted]

The evaluation of the primary endpoint will be performed using the PP population, analyzing the two arms of the study independently.

2.3.2 Secondary endpoint(s)

[redacted]. This analysis will be performed through the comparison of the diagnostic sensitivity and diagnostic specificity values obtained from nasopharyngeal specimens and combined nasal mid-turbinate and throat specimens.

[redacted] the differences between the specimen collection methods will be assessed by chi square statistical analysis, [redacted]

[redacted]

The evaluation of the secondary endpoint will be performed using the PP population, analyzing the two arms of the study independently.

2.4 Sample Size Calculations

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]
- [redacted]
- [redacted]

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2.7 Timing of Analysis

In addition to the interim analysis described above, the study endpoints will be assessed after all specimens are processed and analyzed by both the investigational device and the gold-standard RT-PCR technique, [redacted]

[redacted]

2.9 Subgroups of Analysis

Subgroup analyses in the context of this CPS will be performed [redacted] according to different specimen characteristics, which may include:

- The viral load, determined by the Ct value obtained in the RT-PCR analysis.
- [redacted]
- Days from symptom onset. [redacted]
- [redacted]

[redacted]

2.14 Exploratory Analysis

No exploratory analyses are considered in this CPS.

3. DESCRIPTIVE ENDPOINTS AND ADDITIONAL DATA

[redacted]

3.2 Adverse Events

All the AEs, SAEs, adverse device effects (ADEs), serious adverse device effects (SADEs), unanticipated adverse device effects (UADEs), and unanticipated serious adverse device effects (USADEs) will be summarized for all subjects who are enrolled in this CPS [redacted]

3.3 Subject Early Termination

There is no formal statistical rule defined for early termination of the CPS for insufficient performance of the tested device. [redacted]

3.4 Protocol Deviation

Protocol deviations will be summarized by major and minor categories for subjects in whom a protocol deviation was reported.

[redacted]

3.5 Number of Subject Imbalance

All efforts will be made to maintain a balanced enrollment among the participating sites.

[redacted]

[redacted]

5. ACRONYMS AND ABBREVIATIONS

Acronym or Abbreviation	Complete Phrase or Definition
AE	Adverse Event
CPS	Clinical Performance Study
CPSP	Clinical Performance Study Protocol
FN	False Negative
FP	False Positive
RAT	Rapid Antigen Test
RT-PCR	Reverse Transcription - Polymerase Chain Reaction
TN	True Negative
TP	True Positive
SAE	Serious Adverse Event
SAP	Statical Analysis Plan

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