16.1.9 Documentation of Statistical Methods

Statistical Analysis Plan version 2.0, dated 27 Jun 2025

Statistical Analysis Plan (SAP)

Protocol Title:	Phase 1 Study Evaluating Technologies for Point-of-Care Blood Collections in Support of Decentralized Outpatient Assessments in Pandemic and Clinical Trial Settings
Protocol Version No. / Date:	3.0 / 17-Jan-2025
ICON Study ID:	GHTBGD28-0D1RT5
CRF Version No. / Date:	1.0 / 03-Sep-2024
SAP Version No. / Date:	2.0 / 27-Jun-2025

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ICON Biostatistics and Programming

On behalf of:
Resilience Government Services, Inc.

1.0 Table of Contents

2.0 Purpose

The Statistical Analysis Plan (SAP) describes the statistical methods to be used during the reporting and analyses of data collected under: Resilience Government Services, Inc., Protocol: 5309/0024, Version 3.0, 17-Jan-2025.

3.0 Scope

The Statistical Analysis Plan outlines the following:

- Study Objectives
- Study Design
- Study Endpoints
- Applicable Study Definitions
- Statistical Methods

4.0 Introduction

This study is a phase 1, multicenter, observational, study to evaluate the Tasso+™ device in approximately 200 male or female adult participants in an outpatient setting who are healthy or in well-compensated health at up to 5 US sites.

The purpose of this Statistical Analysis Plan (SAP) is to ensure that the summary tables, figures, and listings (TFLs) which will be produced, and the statistical methodologies that will be used, are complete and appropriate to allow valid conclusions regarding the study objectives. Individual study results, appropriate summary statistics for study conduct (including subject disposition and demographics), and safety assessments will be presented.

The preparation of this SAP has been based on International Conference on Harmonisation (ICH) E9 and Good Clinical Practice (GCP) guidelines.

5.0 Study Objectives

Objectives	Endpoints
Primary objective	Primary endpoints
• To assess the Tasso+™ performance (sample integrity, testing accuracy, and reliability)	• Percentage of overall Tasso+™/serum separator tube (SST) samples collected that are with adequate volume and without moderate or gross hemolysis on Day 1 for each cohort and on each of Days 29 and 57 for Cohorts A and B combined • Percentage of overall Tasso+™/ ethylenediaminetetraacetic acid (EDTA) samples

	collected that are with adequate volume, without moderate or gross hemolysis, and without clotting on Day 1 for each cohort and on each of Days 29 and 57 for Cohorts A and B combined
	• Correlation of SARS-CoV-2 serology between venipuncture and Tasso+™/SST or Tasso+™/EDTA samples on Day 1 for each cohort • Correlation of each chemistry analyte between venipuncture and Tasso+™/SST samples on Day 1 for each cohort
	• Percentage of Tasso+™ device failures from Day 1 to Day 57 defined as (i) failure in activation of the lancet; (ii) lack of any blood collection within 5 minutes; (iii) incorrect attachment of the capillary collection tube to the device; (iv) damage to the device or the capillary collection tube upon handling; (v) lack of maintained seal between the device and the skin surface of the participant; or (vi) incomplete trigger of the button (not fully pressing the button once the Tasso+™ device is sealed to the skin surface)
Secondary objectives	Secondary endpoints
• To evaluate Tasso+™ user experience (safety, tolerability, and usability)	• Percentage of eligible participants who experience solicited local adverse events (AEs) including pain, tenderness, redness, swelling, or bruising within 7 days of Tasso+™ administration • Percentage of eligible participants who experience unsolicited AEs within 28 days of Tasso+™ administration • Percentage of eligible participants who experience a related Grade 3 AE, a related Grade 4 AE, a related AE leading to study discontinuation, or a related SAE within 28 days of Tasso+™ administration
	• Percentage of eligible participants who complete last Tasso+™ administration (Day 57)
	• Ease of use as assessed by the participant completing the Tasso questionnaire immediately

	following administration (on Days 1, 29, and 57) and on Day 85
• To perform surveillance for SARS-CoV-2 infection	• Percentage of eligible participants with a positive nasopharyngeal swab for SARS-CoV-2 polymerase chain reaction (PCR) on Day 1 • Percentage of eligible participants seroconverting to SARS-CoV-2 between Days 1 and 57
Exploratory objective	Exploratory endpoint
• To evaluate the impact of prior training on subsequent Tasso+™ administrations	• Descriptive analyses of proctor-supported and proctor-unsupported Tasso+™ administrations on Day 57 using each of the following endpoints: ○ Sample integrity ○ Reliability ○ Safety ○ Usability

6.0 Study Design

Each participant will be followed with a study visit in the Clinic on Day 1, and subsequent decentralized, remote study visits on Days 29, 57, and 85. The total duration of study participation is planned to be 85±3 days.

On Day 1, each participant will be randomized 2:1 to either Cohort A or Cohort B. Tasso+™ blood samples of participants randomized to Cohort A will be shipped to the Central Laboratory where they will be centrifuged and aliquoted. However, Tasso+™ blood samples of participants randomized to Cohort B will be centrifuged and aliquoted at the Site prior to shipping to the Central Laboratory, following the same approach used for venipuncture blood samples.

The decentralized visit on Day 29 (Visit 2) will be remotely supported by a prescheduled proctor during working hours to support the participant's self-administration of the Tasso+™ device. For the decentralized visit on Day 57 (Visit 3), the participant will have the option to request a prescheduled proctor session during working hours to support the participant's self-administration of the Tasso+™ device. The participant will use an electronic diary (eDiary) to report symptoms for 28 days following each Tasso+™ device administration (Symptom questionnaire) and to report on the usability of the Tasso+™ device (Tasso questionnaire) immediately following each Tasso+™ device administration (on Days 1, 29, and 57) and on Day 85. Contact information will be provided to each participant in the event they have concerns or they need help during working hours while using the Tasso+™ device.

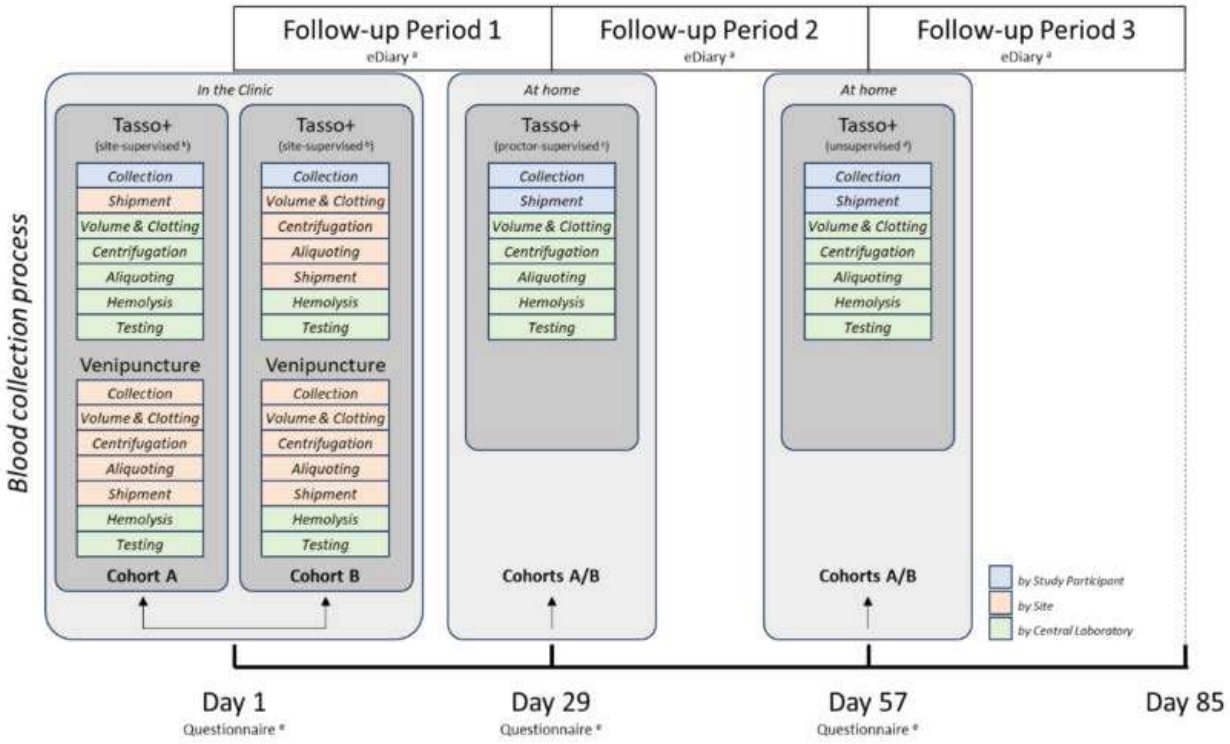
Venous blood collection (phlebotomy) will take place on Day 1; capillary blood collections using Tasso+™ device will take place on Days 1, 29, and 57; usability data will be collected after each use of Tasso+™ device and on Day 85; reliability of the device will be collected after each use of Tasso+™ device (Days 1, 29, and 57). Each Tasso+™ capillary blood collection will be followed by a 28-day follow-up period during which safety of the Tasso+™ device will be assessed using an eDiary (Symptom questionnaire).

Each self-collected Tasso+™ blood sample will be assessed for sample integrity by the Central Laboratory. Moreover, on Day 1, the self-collected capillary blood sample will be compared to a venous blood sample collected by an HCP, in order to assess device performance.

Each participant will receive nasopharyngeal swabbing on Day 1 for SARS-CoV-2 PCR testing to identify any baseline SARS-CoV-2 infections. The nasopharyngeal swab will be performed and resulted by the Site. These participants may remain on study but will be referred to their primary physician for COVID-19 management. During the study, if participants experience any COVID-19 symptoms or if they became COVID-19 positive, they are to be reported to the Investigator. SARS-CoV-2 antibody testing (Days 1 and 57) will be conducted to serologically identify intervening COVID-19 cases, or if in the absence of intervening symptoms, SARS-CoV-2 infections.

The Study Schematic and Schedule of Assessments are available in Figure 1 and Table 1 respectively.

Figure 1: Study Schematic



Footnotes:

a eDiary will be completed during each follow-up period to collect safety data (Symptom questionnaire) and user experience (Tasso questionnaire).

b Day 1 collection to be site-supervised; venipuncture samples (SST and EDTA tubes) and Cohort B Tasso+™ samples (SST and EDTA capillary collection tubes) to be centrifuged and aliquoted by the Site before shipping; venipuncture samples (SST and EDTA tubes) and Tasso+™ samples (SST and EDTA capillary collection tubes) to be shipped to Central Laboratory by the Site; Cohort A Tasso+™ samples (SST and EDTA capillary collection tubes) to be centrifuged and aliquoted by the Central Laboratory upon receipt.

c Day 29 collection to be remotely proctor-supported (during working hours); Tasso+™ samples (SST and EDTA capillary collection tubes) to be packaged and shipped to Central Laboratory by the participant.

d Day 57 collection to be remotely proctor-supported (during working hours), as requested; Tasso+™ samples (SST and EDTA capillary collection tubes) to be packaged and shipped to Central Laboratory by the participant.

e eDiary (Tasso questionnaire) will be completed immediately following each Tasso+™ administration and on Day 85 to document the user experience.

Table 1 Schedule of Assessments

Assessments	Visits[a]			
	Visit 1	Visit 2	Visit 3	Visit 4
Study Day (±visit window)	**1**	**29±3**	**57±3**	**85±3**
In-clinic	X			
Decentralized (eg, home)[b]		X	X	X
Proctor session[c]		X[c]	(X)[c]	
Training	X[c]	X[c]	(X)[c]	
Informed consent (eConsent)	X			
Demographics	X			
Medical history[d]	X			
Concomitant medication	X	X	X	X
Vital signs[e]	X			
Physical examination[f]	X			
Pregnancy urine test (females only)	X			
Eligibility check	X			
Randomization (IVRS)	X			
COVID-19 symptom screen[g]	X	X	X	X
Nasopharyngeal swab for SARS-CoV-2 PCR[h]	X			
Tasso+™ collection SST capillary collection tube (left upper arm preferred) EDTA capillary collection tube (right upper arm preferred)	 X[il] X[il]	 X[jl] X[jl]	 X[kl] X[kl]	
Venous blood collection SST tube EDTA tube	 X[im] X[im]			

Assessments	Visits[a]			
	Visit 1	Visit 2	Visit 3	Visit 4
Study Day (±visit window)	**1**	**29±3**	**57±3**	**85±3**
eDiary				
Tasso questionnaire (user experience)	X	X	X	X
Symptom questionnaire (AEs/SAEs)[n]	X	X	X	X

AE=adverse event; EDTA=ethylenediaminetetraacetic acid; IFU=instruction for use; IVRS=interactive voice response system; HCP=healthcare professional; PCR=polymerase chain reaction; SAE=serious adverse event; SST=serum-separator tube

Footnotes:

a If a participant withdraws from the study early, the assessments planned for the last follow-up/end of study Visit should be completed at the time of withdrawal.

b Defined as any remote location of convenience for the participant where the administration can be done with appropriate technique in a clean environment where samples can be packaged for shipment.

c When administering the Tasso+™ remotely, participants will receive proctor-support on Day 29 (and as requested, on Day 57), the intent being to guide the participant through the process and to help troubleshoot should any difficulties be encountered. Proctor sessions will be prescheduled by the Site to take place during working hours. Training will be performed on Day 1 (by Site) and Day 29 (by Proctor). Training on Day 57 should be performed only if requested by the participant. Training may include detailed IFU and online video training (see Section 7.4 and IFU provided separately). While assistance will be available to the participant during Day 57 Visit, it is of interest to know whether the prior trainings on Tasso+™ administration prove adequate for this subsequent administration.

d Includes COVID-19 illness/vaccine history details (if available).

e Vital signs include heart rate, systolic and diastolic blood pressure, respiratory rate, SpO2 by pulse oximetry, and body temperature (taken by ear/tympanic/temporal, oral, or forehead method). The assessment of heart rate and blood pressure will be conducted in the supine position after a minimum rest period of 5 minutes.

f Physical examination includes general appearance, skin, eyes, ears, nose, throat, head and neck, heart, chest and lungs, abdomen, extremities, lymph nodes, musculoskeletal, neurological, and other body systems, if applicable, for describing the status of the participant's health.

g The development of any COVID-19 symptoms should prompt the participant to contact the Investigator via provided Site's phone number.

h Nasopharyngeal swab for SARS-CoV-2 PCR will be performed and resulted by the Site.

i Day 1 collections: venipuncture samples by HCP (SST and EDTA tubes) and Tasso+™ samples by participant (SST and EDTA capillary collection tubes; Cohort B only) to be centrifuged and aliquoted by the Site before shipping; venipuncture samples by HCP (SST and EDTA tubes) and Tasso+™ samples by participant (SST and EDTA capillary collection tubes) and to be shipped to Central Laboratory by the Site.

j Day 29 collection remotely proctor-supported (during working hours); Tasso+™ samples (SST and EDTA capillary collection tubes) to be packaged and shipped to Central Laboratory by the participant.

k Day 57 collection remotely proctor-supported, as requested (during working hours); Tasso+™ samples (SST and EDTA capillary collection tubes) to be packaged and shipped to Central Laboratory by the participant.

L Tasso+™ samples will be tested by Central Laboratory. Assessments include (by order of priority):
- Volume measurement (SST and EDTA capillary collection tubes), hemolysis (SST and EDTA capillary collection tubes), and evidence of clotting (EDTA capillary collection tube only).
- Chemistry analytes (SST capillary collection tube): sodium, potassium, chloride, blood urea nitrogen, creatinine, glucose, phosphate, uric acid, and C-reactive protein.
- Serology (SST and EDTA capillary collection tubes); any participant who is positive for IgG Nucleocapsid assay for either capillary matrix (SST or EDTA) will be considered positive.

m Venipuncture samples will be tested by Central Laboratory. Assessments include:
- Chemistry analytes (SST tube): sodium, potassium, chloride, blood urea nitrogen, creatinine, glucose, phosphate, uric acid, and C-reactive protein.
- Serology (SST and EDTA tubes); any participant who is positive for IgG Nucleocapsid assay for either matrix (SST or EDTA) will be considered positive.

n Including training for eDiary on Visit 1. Participant can report any AE in the eDiary (Symptom questionnaire). Safety data collection will be solicited from participant for the first 7 days after Tasso+™ device administration, and unsolicited AEs will be captured for the full 28-day period after each administration.

6.1 Sample Size Considerations

Sample size was not calculated on a formal statistical basis; however, the sample size of 200 is large enough to illustrate diversity of user experience regarding the unsupported use of Tasso+™ for capillary blood collection.

6.2 Randomization

Each participant will have a unique subject screening number obtained from the interactive voice response system (IVRS). Once the participant is deemed eligible, the participant will be assigned a randomization number.

Randomization will be performed via a centralized IVRS. On Day 1, eligible participants will be assigned to either Cohort A or Cohort B in a 2:1 ratio. Thus, it is planned to randomize approximately 133 participants into Cohort A and approximately 67 participants into Cohort B.

6.3 Analysis Population Sets

Three analysis sets will be used: the Full Analysis Set (FAS), Per-Protocol Set (PPS), and Safety Analysis Set (SAS).

6.3.1 Full Analysis Set (FAS)

The FAS is defined as all participants who administered Tasso+™ either in a site-supervised, proctor-supported, or unsupported setting. This analysis set will be the primary set used for analyses/summaries of the primary endpoint, as well as for secondary endpoints of seroconversion.

6.3.2 Per-Protocol Set (PPS)

The PPS will include all participants who successfully completed at least five Tasso+™ administrations and do not have any important protocol deviations. This analysis set will be used for sensitivity analyses.

If the FAS and PPS include the same set of participants, only one set of analyses will be produced.

6.3.3 Safety Analysis Set (SAS)

The SAS is defined as all participants who administered the medical device either in a site-supervised, proctor-supported, or unsupported setting. This analysis set will be used for summaries of safety data.

7.0 Conventions and Derivations

7.1 Demographic and Baseline Characteristics

Age will be calculated as the number of years elapsed between birth date and the date of informed consent, adjusted for whether the birthday has passed as of the day of signing. (This corresponds to the typical calculation of age a person would use in conversation, namely, Age = floor ((Date of informed consent - date of birth)/365.25)).

BMI (kg/ m^2) = weight (kg) / [height (m)]^2

7.2 Derivation of Durations

Study day at visit: Date of interest – date of first clinic visit. One day is added if the difference is ≥ 0.

Duration of events: End date of event - start date of event + 1

7.3 Handling of Missing Values

Partial medication dates will be imputed for the purposes of determining prior or concomitant status. Partial medication dates will be imputed as the earliest or latest date consistent with the partial start or end date, respectively. Completely missing medication start dates will not be imputed and those records will be categorized as concomitant in TFL summaries. Completely missing medication end dates will be assigned as “Ongoing” in TFL summaries.

Otherwise, missing data in this study will not be imputed.

8.0 Interim Analyses

No formal interim analysis will be performed.

9.0 Statistical Methods

All analyses will use SAS version 9.4 or higher. Standard summary statistics will be presented for continuous and discrete variables:

- Unless otherwise noted, categorical variables will be summarized using counts and percentages. Percentages will be rounded to one decimal place, except 100% which will be displayed without any decimal places, percentages will not be displayed for zero counts.
- Continuous variables will be summarized using the number of observations (n), mean, Standard Deviation (SD), median, minimum and maximum. The minimum and maximum values will be

displayed to the same level of precision as the raw data, the mean, median, Q1, and Q3 to a further decimal place and the SD to two additional decimal places.

9.1 Subject Disposition

Subject disposition information will be summarized by cohort. The numbers and percentages of subjects enrolled/randomized, eligible and having used the medical device, terminated early, and the numbers and percentages of subjects who have completed the study and are eligible for analysis. The primary reasons for ineligibility and early withdrawal will also be tabulated.

The number and percentages of subjects in each analysis set will also be tabulated. A listing of each subject excluded from an analysis population will be listed as well as the reason why they were excluded from the population.

9.2 Demographic and Baseline Characteristics

Demographic characteristics (including age, sex, ethnicity, and race) and baseline characteristics (including height, weight, BMI, supine systolic and diastolic blood pressure, pulse, body temperature, and respiratory rate) will be summarized descriptively by Cohort for the Full analysis set.

Past medical history will be listed.

9.3 Treatments

9.3.1 Extent of Study Drug Exposure

There is no extent of study drug exposure for this study, however, counts and percentages of subjects using the TASSO+™ device with or without proctor supervision will be tabulated by cohort and visit using counts and percentages for the SAS.

9.3.2 Prior and Concomitant Medications

Prior and concomitant medications will be listed.

A medication will be defined as a prior medication if its start date is before the subject's date of first sample collection in the study.

A medication will be defined as a concomitant medication if its start date is on or after the subject's date of first sample collection in the study and prior to the date of the subject's last questionnaire response; if the subject does not have any questionnaire data, the medication start date must be prior to the subject's end of study participation date. If the medication start date comes after either of these dates, the medication will be categorized as poststudy.

9.4 Important Protocol Deviations

The study specific Protocol Deviation Guidance Document defines all important protocol deviations.

Per ICON processes, important protocol deviations data will be entered into the system of record (ICOTrial). The study team and the Sponsor will conduct on-going reviews of the deviation data from ICOTrial and the resulting set of evaluable subjects throughout the study, adjusting the deviation criteria as seems appropriate. The evaluable subjects set must be finalized at the post-freeze data review meeting (or earlier), prior to database lock.

The number of subjects excluded from the PPS and reasons for exclusion will be summarized by cohort and overall.

Numbers and percentages of subjects with protocol deviations will be summarized by category (important vs minor) and by cohort using the FAS population. Important protocol deviations leading to subject exclusions will be summarized in the final CSR.

9.5 Efficacy Analyses

9.5.1 Hypothesis Testing Strategy and Multiplicity

Hypothesis testing strategy and multiplicity are not applicable for this study.

9.5.2 Primary Endpoints

9.5.2.1 Sample Integrity

Descriptive statistics will be presented for the FAS and PPS to summarize the proportion of Tasso+™/SST and Tasso+™/EDTA samples collected on Day 1 for each cohort and on each of Days 29 and 57 for Cohorts A and B combined with the following attributes:

- Adequate volume, defined as at least 300 µL
- Without moderate or gross hemolysis, as defined by Central Laboratory SOP (see Table “Impact of Varying Degrees of Hemolysis” in Section 6.3.1 of the protocol)
- Adequate volume and without moderate or gross hemolysis (for SST samples)
- Without clotting (for EDTA samples only)
- Adequate volume, without moderate or gross hemolysis, and without clotting (for EDTA samples only)

Sample integrity data will be analyzed using the laboratory vendor data for all subjects and visits with the exception of Cohort B Day 1 records, which were collected in the electronic data capture (EDC) system.

9.5.2.2 Testing Accuracy

Pearson's correlation coefficient will be computed to quantify the strength of the direction of the linear relationship between the venipuncture collection and the Tasso+™ collection at Day 1 for each cohort for SARS-CoV-2 serology and each chemistry analyte.

Any participant who is positive for IgG Nucleocapsid assay for either matrix (SST or EDTA), will be considered SARS-CoV-2 positive.

Contingency correlation coefficient will be computed to estimate the extent of the relationship between the venipuncture collection and the Tasso+™ collection at Day 1 for each cohort for SARS-CoV-2 serology.

This analysis will be presented for both the FAS and PPS.

9.5.2.3 Reliability

For each participant, the number of failures will be calculated by summing the instances where the device or the collection process has failed as follows:

(i) failure in activation of the lancet

(ii) lack of any blood collection within 5 minutes

(iii) incorrect attachment of the capillary collection tube to the device

(iv) damage to the device or the capillary collection tube upon handling

(v) lack of maintained seal between the device and the skin surface of the participant

(vi) incomplete trigger of the button (not fully pressing the button once the Tasso+™ device is sealed to the skin surface)

The total number of device usage instances will also be recorded.

The percentage of failures will be calculated as:

$$\text{Percentage of failures} = \frac{\text{Number of Instances with Failures}}{\text{Total Number of Device Usage Instances}} \times 100\%$$

Counts and percentages will be presented for participants in the FAS and PPS.

9.5.3 Secondary Endpoints

9.5.3.1 Safety

Counts and percentages will be presented for participants in the FAS who experience:

- Solicited local AEs (including pain, tenderness, redness, swelling, bruising, and scarring)

- Unsolicited AEs
- A related Grade 3 AE
- A related Grade 4 AE
- A related AE leading to discontinuation
- A related SAE

9.5.3.2 Tolerability

The count and percentage of participants in the FAS who completed their Day 57 Tasso+™ administration will be summarized, where completion is defined as having completed at least one of Tasso+™/SST or Tasso+™/EDTA at the visit.

9.5.3.3 Usability

Descriptive statistics will be presented for participants in the FAS for each aspect of the usability questionnaire on Days 1, 29, 57 and 85.

9.5.3.4 SARS-CoV-2 Infection Surveillance

Counts and percentages will be presented for participants in the FAS for:

- Participants with a positive nasopharyngeal swab for SARS-CoV-2 PCR on Day 1
- Participants seroconverting to SARS-CoV-2 between Days 1 and 57

Any participant who is positive for IgG Nucleocapsid assay for either matrix (SST or EDTA), will be considered SARS-CoV-2 positive.

9.5.4 Exploratory Endpoints

9.5.4.1 Proctor Support

Descriptive statistics will be presented for participants who requested proctor support on the Day 57 Visit and for participants who completed the Day 57 Visit without using the proctor support in the PPS, for the following primary and secondary endpoints:

- Sample integrity
- Reliability
- Safety
- Usability

9.5.4.2 Sample Integrity

A sample integrity sub-group analysis will be conducted among only the samples collected on or after December 10th, 2024, the date at which updated sample collection instructions were implemented. The same sample integrity criteria used for the primary endpoint (volume, hemolysis, and clotting) will be summarized using frequencies and percentages by time point, collection method, and cohort.

This sub-group analysis will be conducted in the PPS.

9.5.4.3 Testing Accuracy

A stratified testing accuracy analysis will be conducted using the following two strata:

- Samples received by the central laboratory ≤ 1 day after collection (ie, received by the central laboratory either on the same day as collection or the day following collection)
- Samples received by the central laboratory > 1 day after collection

Contingency correlation coefficient will be computed to estimate the extent of the relationship between the venipuncture collection and the Tasso+™ collection at Day 1 by cohort for each biochemistry parameter.

This stratified analysis will be conducted in the PPS.

9.5.4.4 Percentage of Subjects with Complete Analyte Profile

The frequency and percentage of subjects who met the following criteria will be summarized by time point in the PPS:

- Had all of their biochemistry analytes resulted at the given time point (for SST)
- Had their SARS-CoV-2-IgG sample resulted (for SST)
- Had all of their biochemistry analytes and SARS-CoV-2-IgG sample resulted (for SST)
- Had their SARS-CoV-2-IgG sample resulted (for EDTA)

9.5.4.5 Summary of Collected Sample Volume

Boxplots will be produced to visualize the volume of sample collected for each subject by time point and collection method (SST or EDTA). The x-axis of the boxplot will be split by cohort (for Day 1 only), with two boxplots for each cohort (one for SST and one for EDTA). Day 29 and Day 57 boxplots will summarize all subjects combined, with one boxplot for SST and one boxplot for EDTA. The figure will be produced for the PPS.

9.6 Safety Analyses

The SAS will be used for the analysis of safety data.

9.6.1 Adverse Events (AE)

All AEs will be classified by primary system organ class and preferred term according to the MedDRA Version 27.0. Treatment-emergent adverse events (TEAEs) will be presented by system organ class and preferred term in frequency tables. Treatment-emergence will be defined as follows:

- If the AE has a non-missing start date and start time, then the AE will be considered treatment-emergent if it occurred on or after the date and time of first Tasso+™ administration
- If the AE has a non-missing start date but a missing start time, then the AE will be considered treatment-emergent if it occurred on or after the date of first Tasso+™ administration

Participants with multiple TEAEs will be counted only once within each preferred term and system organ class. All TEAEs will be listed.

9.6.2 Deaths and Serious Adverse Events

An SAE is any event that meets any of the following criteria:

- Results in death.
- Severe deterioration in the health of the participant by one or more of the following:
  - (i) a life-threatening illness or injury
  - (ii) a permanent impairment of a body structure or function including chronic diseases
  - (iii) in-patient or prolonged hospitalization
  - (iv) medical or surgical intervention to prevent life-threatening illness or injury, or permanent impairment to a body structure or function
  - (v) fetal distress, fetal death, congenital abnormality or birth defect including physical or mental impairment

The event will be considered an SAE when, based upon appropriate medical and scientific judgment, the event may jeopardize the participant and may require medical or surgical intervention to prevent one of the outcomes listed above. SAEs include all serious events independent of whether they have a suspected causal relationship to the device or not.

SAEs will be presented by system organ class and preferred term in frequency tables. Deaths and SAEs will be listed separately.

Device deficiency is defined as inadequacy of a medical device with respect to its identity, quality, durability, reliability, safety, or performance. Device deficiencies include malfunctions, use errors, and inadequate labelling.

Device deficiencies that did not lead to an AE but could have led to a SADE if (i) either suitable action had not been taken, (ii) intervention had not been made, or (iii) circumstances had been less fortunate; shall be reported to the Sponsor, the IRB/IEC, and the regulatory authorities. Device deficiencies will be listed.

9.6.3 Pregnancy

Urine pregnancy tests will be performed for female participants of childbearing potential on Day 1.

Pregnancy test results will be listed.

9.6.4 Laboratory Data

Laboratory data (sodium, potassium, chloride, blood urea nitrogen, creatinine, glucose, phosphate, uric acid, and C-reactive protein) will be converted to the International System of Units (SI) for reporting and processing purposes. Laboratory data outside study specific reference ranges will be highlighted within the listing.

9.6.5 Physical Examinations

Physical examinations (PEs) will be conducted at baseline. The complete physical examination will include assessments of the standard physical examination items, including, general appearance, skin, eyes, ears, nose, throat, head and neck, heart, chest and lungs, abdomen, extremities, lymph nodes, musculoskeletal, neurological, and other body systems, if applicable, to describe the status of the participant's health.

PE data will be listed.

10.0 References

Brandsma J, Chenoweth JG, Gregory MK, et al. Assessing the use of a micro-sampling device for measuring blood protein levels in healthy subjects and COVID-19 patients. pLoS One. 2022;17(8):e0272572.

Fedoruk MN. Virtual drug testing: redefining sample collection in a global pandemic. Bioanalysis. 2020;12(11):715-718.

Hendelman T, Chaudhary A, LeClair AC, et al. Self-collection of capillary blood using Tasso-SST devices for Anti-SARS-CoV-2 IgG antibody testing. PLoS One. 2021;16(9):e0255841.

11.0 Important Protocol Deviation Identification Listings

The following listings will be used to confirm any important protocol deviations and define the subjects in each analysis set at the Data Review Meeting (DRM):

- Protocol deviations identified in ICOTrial will be tracked by CTM (with the importance flag and coding completed within the system by the Medical Monitoring Associate (MMA)/ Medical Director (MD))
- List of subjects violating inclusion, exclusion or selection criteria
- List of subjects with no evidence of administering the device
- Device compliance

12.0 Glossary of Abbreviations

Glossary of Abbreviations:	
AE	Adverse event
CRF	Case Report Form
CSR	Clinical Study Report
CTM	Clinical Trial Manager
EDC	Electronic Data Capture
EDTA	Ethylenediaminetetraacetic acid
FAS	Full Analysis Set
GCP	Good Clinical Practice
HCP	Health Care Professional
ICH	International Conference on Harmonisation
IVRS	Interactive Voice Response System
MedDRA	Medical Dictionary for Regulatory Activities
PCR	polymerase chain reaction
PE	Physical Examination
PP	Per-Protocol
PT	Preferred Term
Q1	25th Percentile
Q3	75th Percentile
SAP	Statistical Analysis Plan
SAS	Safety Analysis Set
SAE	Serious Adverse Event
SD	Standard Deviation
SI	International System of Units
SOC	System Organ Class
SST	Serum Separator Tube
TEAE	Treatment Emergent Adverse Event
TFL	Tables, Figures and Listings

13.0 Approvals

Sponsor	
Sponsor Name:	Resilience Government Services, Inc.
Representative / Title:	Angie Kimbler / Director, Regulatory and Clinical Operations
Signature / Date:	Signed by: Angie Kimbler Signer Name: Angie Kimbler Signing Reason: I approve this document Signing Time: 27-Jun-2025 | 16:29:25 BST E707D2C07E31488E9E77FA9672EB72DC
ICON	
Biostatistician / Title:	Owen Jordan, MS / Biostatistician II
Signature / Date:	Signed by: Owen Jordan Signer Name: Owen Jordan Signing Reason: I approve this document Signing Time: 27-Jun-2025 | 16:18:09 BST F47685ECFCC94742A1A6F57BC4538F44

14.0 Document History

Version Date	Modified / Reviewed By	Brief Summary of Changes
0.1 / 11-Jul-2024	Kelley Qiu / Tracey Mason	Created as new
0.2 / 12-Aug-2024	Kelley Qiu / Tracey Mason	- Updated Figure 1.
0.3 / 09-Sep-2024	Kelley Qiu / Tracey Mason	- Updated section 12.6.1, MedDRA Version from 25.0 to 27.0 - Changed section 12.5.2.1 from Table 3 to Table “Impact of Varying Degrees of Hemolysis”.
1.0 / 25-Sep-2024	Kelley Qiu / Tracey Mason	- Section 8.1, added “sample size of 200 is large enough to illustrate” and removed “Investigators estimate that the sample size will be sufficient to sample the” - Section 9.1.2, removed “in the FAS and” and added “Successful completion is defined as where adequate blood was collected and sent to the lab.”
1.1 / 13-Jun-2025	Owen Jordan / Tracey Mason	- Updated by using new template - Section 9.5.2.1, sample integrity primary endpoint details updated - Section 9.3.2, prior and concomitant medication definitions added
1.2 / 25-Jun-2025	Owen Jordan / Tracey Mason	- Section 9.6.1, added TEAE definition - Section 6.3.2, updated Per-Protocol Set definition
2.0 / 27-Jun-2025	Owen Jordan / Tracey Mason	- Up-versioned to final SAP v2.0

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