



**STAT Centrifugation Validation of
Coagulation Tubes
for Clinical Laboratory Testing**

Validation for DASH Coagulation Tube Centrifugation

1. PROPOSED INTENDED USE

Coagulation Tubes, Holders, and Needles are used together as a system for the collection of venous blood. Coagulation tubes are used to collect, transport, and process blood for coagulation testing in the clinical laboratory.

2. SPECIFIC AIMS OF THE STUDY

Demonstrate the equivalent performance of Coagulation Tubes when centrifuged in a DASH Coag centrifuge at high centrifugal force (RCF or g-force) and short centrifugation times when compared to Coagulation tubes centrifuged using the centrifugation process currently in use in the hospital laboratory.

3. RATIONALE

A clinical validation is needed to demonstrate that blood samples collected in coagulation tubes centrifuged for higher RCF and less time produces test results that are substantially equivalent to coagulation tubes when spun according to manufacturer recommendations or the existing validated process in the hospital laboratory.

4. DEVICE DESCRIPTION

Vacutainer® Evacuated Blood Collection Tubes are plastic tubes with a pre-defined vacuum for exact draw volumes. They are fitted with color coded Vacutainer® Caps. The tubes, additive concentrations, volumes of liquid additives, and their permitted tolerances, as well as the blood-to-additive ratio, are in accordance to the requirements and recommendations of the international standards ISO 6710 “Single use containers for venous blood specimen collection“ and the Clinical and Laboratory Standards Institute’s Approved Standards (CLSI).

The purpose of this protocol is to validate the centrifugation of blood collection tubes in the DASH Coag centrifuge.

Validation for DASH Coagulation Tube Centrifugation

5. OBLIGATIONS OF INVESTIGATOR

- 5.1. The Investigators are responsible for following this protocol and all guidelines regulating this clinical validation.
- 5.2. The Investigators are responsible for ensuring that participating staff members are adequately trained for the tasks performed.
- 5.3. The Investigators are responsible for informing and obtaining consent from all patients.
- 5.4. The Investigators are responsible for the accuracy and completeness of all study records and report forms.
- 5.5. The following persons and site will act as the Investigators for this study at each site:

Site 1: **[Site Name]**

[Address]

Principal Investigator: **[Name]**
[Title]
[Phone]
[Email]

Site 2: **[Site Name]**

[Address]

Principal Investigator: **[Name]**
[Title]
[Phone]
[Email]

Site 3: **[Site Name]**

[Address]

Principal Investigator: **[Name]**
[Title]
[Phone]
[Email]

Validation for DASH Coagulation Tube Centrifugation

6. ELIGIBILITY CRITERIA

6.1. Inclusion Criteria

- 6.1.1. Donors must be at least 18 years old, capable of giving Informed Consent, and meet the site's requirements for blood donation.
- 6.1.2. Blood donations must include the number of tubes designated in the Study Test Plan.

6.2. Exclusion Criteria

- 6.2.1. Sufficient blood could not be collected to adequately fill the number of tubes designated in the Study Test Plan.
- 6.2.2. Blood is severely hemolyzed in the tube following collection and processing. Other factors such as fibrin, turbidity, etc. may be cause for exclusion as well.

7. STUDY DESIGN – METHOD COMPARISON

7.1. Study Design for alternate centrifugation settings (Adjust to your needs)

The purpose of the method comparison study is to demonstrate the equivalent performance of coagulation tubes when centrifuged in a DASH Coag centrifuge when compared to this same tube when centrifuged according to tube manufacturer IFU or the existing laboratory process.

Two sodium citrate coagulation tubes, e.g. 1 Validation Tube and 1 Current Process Tube will be drawn from each of 20 participants. (Adjust to your needs)

After blood collection, the tubes will be centrifuged in a Drucker DASH centrifuge as indicated in the table below. The time between blood collection and centrifugation must not exceed 2 hours.

Table 1

Tube	Centrifugation RCF	Centrifugation Time
Current Lab Process (A)	TBD xg	TBD min
Evaluation (B)	4400 xg	3 min

After centrifugation, all tubes will be analyzed using Coagulation and Hematology assays as indicated in Table 2 below.

Validation for DASH Coagulation Tube Centrifugation

Table 2: Method Comparison Assays

Analyte	Assay	Assay Reference Range	Assay Measuring Range
ProThrombin Time (PT)			
Thrombin Time (TT)			
Activated Partial ThromboPlastin Time (aPTT)			
Plasma Platelet Count (Plt) (<10 is ideal)			

The above assays were selected as representative of typical tests frequently ordered in the coagulation laboratory. Platelet counts are included to give an indication of the cleanliness of the sample and the affect that the cleanliness may have on the coagulation analyzer. Samples will be representative of a normal population and focus only on the impact of centrifugation.

Validation for DASH Coagulation Tube Centrifugation

7.2. Test Plan

- 7.2.1. Collect blood in a randomized tube sequence from 20 donors.
 - 7.2.1.1. Blood will be drawn from each donor into 2 evaluation tubes.
 - 7.2.1.2. Blood should be collected from a typical adult population.
- 7.2.2. Mix tubes according to the Instructions for use immediately following collection.
- 7.2.3. Designate each of the 2 Tubes as Tube A, B. Each donor should have a unique identifying number in addition to the Evaluation Tube designation.
- 7.2.4. Centrifuge (1) tube within 2 hours of collection using the current hospital process to separate plasma from cells.
- 7.2.5. Centrifuge (1) Evaluation tubes in a DASH Coag centrifuge as indicated in Table 1 to separate plasma from cells.
- 7.2.6. Note any pre-analytic issues that could impact analysis, including but not limited to short fill, hemolysis and fibrin, noting the sample identification used for evaluation purposes. Adversely affected samples should be documented and potentially eliminated from the study.
- 7.2.7. Perform analyte testing in duplicate from designated Tubes, on a single instrument to eliminate differences attributed to the specific analyzer.
 - 7.2.7.1. Instrument maintenance and calibration should be up to date and the appropriate controls and sufficient reagent loaded to complete required testing.
 - 7.2.7.2. Order of tube analysis should be randomized.
 - 7.2.7.3. Perform testing as soon as possible following blood collection and sample processing (within 4 hours is preferable). Document the time elapsed. Samples and QC material will be analyzed according to the manufacturer's Instructions-for-Use information. Only results with valid QC results will be used in the study.
- 7.2.8. Repeat the test procedure using a second instrument platform if available and sample volume permits.
- 7.2.9. Provide the following documents to the Laboratory Manager or Drucker Diagnostics for analysis and review and keep on file for reference.
 - 7.2.9.1. Copies of all instrument printouts with appropriate sample identification,
 - 7.2.9.2. All data recorded in Excel spreadsheets for ease of manipulation (record all results in US units),
 - 7.2.9.3. Copies of package inserts for all assays and controls used in the study,
 - 7.2.9.4. Other documentation, as needed.

Validation for DASH Coagulation Tube Centrifugation

7.3. Data Analysis

- 7.3.1. All tubes will be visually inspected after centrifugation and before starting analysis.
- 7.3.1.1. Any abnormalities must be documented.
- 7.3.1.2. Tubes should be appropriately filled, and sample volume must be adequate for testing required.
- 7.3.1.3. Hemolysis should be evaluated by instrument automated methodology.
- 7.3.2. For the quantitative assays:
- 7.3.2.1. Comparison between Tubes will be performed for each analyte assessed by Linear Regression.
- 7.3.2.2. Slope, intercept, their corresponding 95% Confidence Intervals, and the correlation coefficient will be presented.
- 7.3.2.3. Bias will be calculated at the medically relevant levels for each analyte.
- 7.3.2.4. Acceptance Criteria:
- Slope = 1.0 ± 0.15 :
 - Intercept: The 95% Confidence Interval includes 0.00 or is not clinically significant (if the assay's measuring range is narrow)
 - Bias: At the medically relevant levels, the bias is either within the expected precision of the assay or not clinically significant.

8. GENERAL INFORMATION

- 8.1. The Investigator and staff will supply the tubes, assay reagents, calibrators, controls reagents and other consumables as required. Lot numbers of tubes, controls and reagents will be recorded.
- 8.2. If possible, all tests should be run in duplicate for improved statistical rigor.
- 8.3. Sample handling precautions and sample limitations should be adhered to as outlined in each assay manufacturer's package insert. Caution should be used to avoid remixing platelets after centrifugation.
- 8.4. The Investigator will record any factors that may impact analysis results.
- 8.5. Samples must be optimally filled. Gently invert each tube 5-10 times, or as recommended in the Instructions-for-Use, immediately following collection. Do not shake. Vigorous mixing or delayed mixing in plasma tubes may result in clotting and incorrect test results.

Validation for DASH Coagulation Tube Centrifugation

- 8.6. Controls for the performed tests will be included with each test run and used in accordance with reagent and instrument manufacturers' recommended procedures. The manufacturer's guidelines will be followed for operation and maintenance of the instrument.
- 8.7. Daily, weekly and monthly maintenance must be up to date as per manufacturer's instructions and laboratory procedures.
- 8.8. The testing site must complete all data collection and documentation as soon as possible following the completion of the test plan procedures.

9. ACCOUNTABILITY OF INVESTIGATIONAL PRODUCT

Upon completion of the trial, all investigational products must be disposed of according to OSHA, state, and laboratory policies and procedures.

10. STATISTICAL CONSIDERATIONS

The results of all tests will be analyzed as defined in the Data Analysis sections of this protocol to determine the equivalence of centrifugation methods recommended by the tube manufacturer with high-speed and rapid centrifugation methods.

11. FINAL REPORT BY INVESTIGATOR

The Investigator will prepare a report summarizing the results of the trial. A manuscript based on the results of this study may be prepared subsequently and submitted for publication. The authorship of any publications resulting from this study will be the subject of prior agreement between the Investigator and Drucker Diagnostics subject to the provisions of Section 17 below.

12. ADVERSE DEVICE REPORTING

No adverse events (AE) and/or adverse device effects (ADE) are anticipated to be associated with the use of these products. If any are found, they will be documented and reported, per the site's standard procedure.

Validation for DASH Coagulation Tube Centrifugation

13. INFORMED CONSENT

The site's Institutional Review Board approval of the Informed Consent is required for donor participation. The Informed Consent will be obtained per the site's IRB policy using the IRB-approved Informed Consent form as necessary.

14. CONFIDENTIALITY

The site's employees must not share this protocol, tools, data, or any information on the study design with outside parties without approval from Drucker Diagnostics.

15. PUBLICATION POLICY

The data generated may be used by Drucker Diagnostics for future product development, publication, white papers, brochures, etc.

16. FINANCIAL DISCLOSURE OF THE INVESTIGATOR

I certify that I have no significant equity in Drucker Diagnostics or proprietary interest in the financial acquisition of the products being evaluated, other than the receipt of equipment for the performance of the clinical validation, which was agreed upon prior to the commencement of the validation. I also certify that any compensation I receive is not dependent on the outcome of the trial.

17. STATEMENT OF INVESTIGATOR

I have reviewed this protocol and agree with its contents. I will conduct the trial in an efficient manner and will ensure all participants are adequately trained with the tasks assigned. I also will account that the data are accurately reported. I will notify the sponsor of any problems incurred during the performance of this trial. Any changes or problems will be documented.

Signature

Date

Investigator (Name and Address)

Validation for DASH Coagulation Tube Centrifugation

Addendum A: Test Results Sheet

Specimen ID #		
Analyte	Sample Result A	Sample Result B
ProThrombin Time (PT)		
Total Protein (TP)		
Thrombin Time (TT)		
Plasma Platelet Count (Plt) (<10 is ideal)		
Specimen ID #		
Analyte	Sample Result A	Sample Result B
ProThrombin Time (PT)		
Total Protein (TP)		
Thrombin Time (TT)		
Plasma Platelet Count (Plt) (<10 is ideal)		
Specimen ID #		
Analyte	Sample Result A	Sample Result B
ProThrombin Time (PT)		
Total Protein (TP)		
Thrombin Time (TT)		
Plasma Platelet Count (Plt) (<10 is ideal)		
Specimen ID #		
Analyte	Sample Result A	Sample Result B
ProThrombin Time (PT)		
Total Protein (TP)		
Thrombin Time (TT)		
Plasma Platelet Count (Plt) (<10 is ideal)		