Evaluation of VACUETTE® 9NC Coagulation Sodium Citrate 3.2% Tubes

Background:

Greiner Bio-One offers VACUETTE® 9NC Coagulation Sodium Citrate 3.2% and VACUETTE® 9NC Coagulation Sodium Citrate 3.8% blood collection tubes.

Various manufacturers of blood collection tubes offer plastic collection tubes or even double wall plastic collection tubes for coagulation tests to reduce the risk of sharp injury and biohazardous exposure due to broken glass during handling or centrifugation [1].

VACUETTE® 9NC Coagulation tubes are plastic, evacuated, sterile tubes with a pre-defined nominal volume for achieving correct additive concentrations. The VACUETTE® 9NC Coagulation tube contains either a buffered 3.2% (0.109 mol/l) or a 3.8% (0.129 mol/l) tri-sodium citrate dehydrate/citric acid monohydrate solution in accordance with the requirements of the international standards for evacuated blood collection systems such as ISO 6710 [2], CLSI H01-A6 [3]. The mixing ratio is 1 part citrate solution to 9 parts blood. The mark on the tube label indicates the nominal fill volume ± 10%, reflecting the tolerance range for ensuring the correct fill volume and avoiding errors associated with inadequate filling of the tube that may artifactually prolong APTT and PT results [4].

VACUETTE® 9NC Coagulation Sodium Citrate blood collection tubes are available with double-wall technology (sandwich tubes – plastic within plastic) for reliable analytical results. The outer tube is made of polyethylene terephthalate preserving the vacuum and ensuring a long shelf-life, while the inner tube is made of polypropylene preventing the citrate solution from evaporating. Polypropylene is ideal for sensitive coagulation parameters, due to its nonreactive characteristics [5].

Citrate anticoagulated venous blood is the most commonly obtained sample for coagulation determinations. Coagulation tests measure the blood's ability to clot, and how long it takes to clot in order to determine the patient's risk of excessive bleeding or developing thrombosis somewhere in the blood vessels. The additive in the tube functions as an anticoagulant by chelating calcium. Calcium is added back to the sample to investigate coagulation parameters under controlled conditions in the laboratory.

The VACUETTE® 9NC Coagulation Tube is intended for collection of citrate anticoagulated whole blood samples for hemostasis testing [6].

Study Objective:

A clinical evaluation was carried out with 21 healthy donors to compare the performance of the VACUETTE® 9NC Coagulation Sodium Citrate 3.2% tube in comparison to the VACUTAINER® Sodium Citrate 3.2% tube.

Study design:

The following tube types were used in this study:

Sample ID	Description
A	VACUETTE® 9NC Coagulation Sodium Citrate (3.2%) 3 ml, (item No.: 454325)
B	VACUTAINER® Buffered Sodium Citrate (3.2%) 2.7 ml (item No.: 363048)

The study was approved by Ethics Commission and informed consent was given by all participants.

All samples were drawn using an SBC Set (# 450085) with a discard tube prior collection of the coagulation tubes. Directly after venous blood collection, all tubes A and B were carefully inverted 4 times. The tubes were then spun in a temperature controlled centrifuge (20-22°C, swing-out bucket, Hettich Rotanta 460R) for 10 min at 2000g. Analysis was performed on an ACL Top® 700 CTS with the instrument's accompanying reagents.

Determined parameters:

- Prothrombin time (PT)
- Activated partial thromboplastin time (aPTT)
- Fibrinogen
- Antithrombin III (AT III)

The hematocrit of all donors was within the defined range of 20%-55% to ensure the correct mixing ratio [7].

Results

Table 1 Normal range, acceptance criteria and highest single deviation of each parameter

Parameter	Normal range	Acceptance criteria	Highest single deviation Comparison sample A to B initial values
aPTT	25.1 - 36.5 sec	15% (CLIA)	6.9%
AT III	83 - 128%	8.3% (BV)	11.49%
Fibrinogen	238 - 498 mg/dl	20% (CLIA)	10.55%
PT	70 - 130 %	15% (CLIA)	8.99%

CLIA: Clinical Laboratory Improvement Amendments [8],
BV: 2004 update of the Spanish Society of Clinical Chemistry and Molecular Pathology (SEQC) table of Desirable Quality Specifications based on Biological Variation [8]

Table 2 Summary of initial values

Parameter	N	Sample	Mean	STD	Correlation Coefficient	Intercept (Conf. Int 95%)	Slope (Conf. Int. 95%)
aPTT [sec]	21	A	28.97	2.08	0.97343	1.16	0.99
	21	B	28.10	2.05		(-1.99; 4.31)	(0.88; 1.1)
ATIII [%]	21	A	95.48	8.71	0.88853	9.52	0.89
	21	B	96.14	8.66		(-11.87; 30.92)	(0.67; 1.12)
Fibrinogen [mg/dl]	21	A	291.76	38.07	0.94622	9.98	0.97
	21	B	289.67	37.02		(-36.64; 56.6)	(0.81; 1.13)
PT [%]	21	A	98.67	16.75	0.98263	1.81	1.02
	21	B	95.10	16.16		(-7.09; 10.71)	(0.93; 1.11)

Two deviations for ATIII were found that slightly exceeded the acceptance criteria of 8.3%. As these deviations were not systematic when comparing the two tubes and within the normal range, they were not considered to be clinically significant. Antithrombin is the most important physiological inhibitor of all serine proteinase in the coagulation cascade having high affinity to thrombin and factor Xa. Slight changes result in an imbalance with higher coagulability and the risk of thromboembolism. Apart from familiar parameters such as prothrombin time, activated partial thromboplastin time, coagulation factor analysis and platelet function analysis, a careful patient history remains the prerequisite for the evaluation of bleeding tendencies [9].

Conclusion:

No clinically significant deviations occurred in the comparison between VACUETTE® 9NC Coagulation Sodium Citrate 3.2% Sandwich tubes and BD Vacutainer® Sodium Citrate 3.2% tubes. The correlation coefficient was high for each parameter (see table 2 above). In the study described above, equivalent performance was demonstrated between VACUETTE® 9NC Coagulation Sodium Citrate 3.2% tubes and BD Vacutainer® Sodium Citrate 3.2% tubes.

References:

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