

Original Article

ASSESSMENT OF BREAKAGE RESISTANCE OF IMPROVACUTER® VENOUS BLOOD COLLECTION TUBES UNDER STANDARDISED DROP TESTING CONDITIONS

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ABSTRACT

Blood collection tubes are integral to diagnostic workflows but are routinely exposed to mechanical stress during handling, transportation, and routine laboratory processing. Structural failure of these tubes may result in specimen loss and pose potential biohazard risks to healthcare personnel. This standards-based verification study evaluated the breakage resistance of six categories of IMPROVACUTER® venous blood collection tubes. A total of 108 tubes from three independent manufacturing lots were filled to their nominal draw volumes and subjected to a standardised 1 m drop test, with three consecutive drops per tube onto a concrete surface. Following testing, tubes were inspected for visible cracks, leakage, breakage, or cap dislodgement. Evaluation criteria were based on ISO 6710:2017 and ISO 2859-1 (AQL 1.5), with a predefined practical acceptance criterion of at least 90% passing per tube category. The overall pass rate was 94.4% (102/108; 95% CI, 88.3%–97.9%). Citrate tubes achieved a 100% pass rate, while Gel & Clot Activator, EDTA K2, Heparin, and Glucose tubes each demonstrated a 94.4% pass rate. Clot Activator tubes showed a pass rate of 88.9%. These findings indicate high breakage resistance under the standardised drop-test conditions evaluated; other performance characteristics were not assessed.

KEYWORDS: blood collection tubes, breakage resistance, mechanical stress, IMPROVACUTER®

INTRODUCTION

Venous blood collection tubes are fundamental to modern clinical diagnostics, providing a controlled and standardised environment for specimen collection, transport, and subsequent laboratory analysis. Their proper function is essential for reliable and reproducible test results across diverse diagnostic disciplines, including haematology, clinical chemistry, and coagulation testing (1,2). Commonly used tube types in routine practice include Gel & Clot Activator tubes for serum separation, dipotassium ethylenediaminetetraacetate (EDTA K2) tubes for whole blood haematology analysis, and Citrate tubes for coagulation studies, each incorporating specific additives and material properties to preserve sample integrity and analytical accuracy (2,3).

Despite strict manufacturing and quality control standards, blood collection tubes are routinely exposed to mechanical stresses during daily laboratory workflows. These stresses can occur during phlebotomy, specimen transport, automated handling, centrifugation, or routine bench processing (3). Accidental drops, particularly from bench height or during sample transfer, are common in high-throughput laboratories. Structural failure under such conditions can pose occupational hazards and may lead to loss or contamination of diagnostic specimens, potentially compromising test reliability and patient care (4). Recent recommendations on venous blood sampling emphasise standardisation of collection and pre-analytical handling to support specimen quality and safety (10). In addition, multicentre verification during blood collection tube shortages has highlighted the importance of independently verifying alternative tube products before routine implementation (6).

Mechanical failure of blood collection tubes may arise from multiple factors, including material composition, tube geometry, wall thickness, and cap design. Even minor defects, such as hairline cracks or cap dislodgement, can result in vacuum loss, leakage, or altered sample-to-additive ratios, adversely affecting analytical accuracy (5). The transition from traditional glass tubes to plastic alternatives, particularly polyethylene terephthalate (PET), has improved impact resistance and laboratory safety. However, variability in tube design and manufacturing processes still necessitates independent performance verification (6,7).

Evaluating the mechanical integrity of blood collection tubes is critical for ensuring product reliability, laboratory safety, and compliance with international standards. International Organization for Standardization (ISO) 6710:2017 specifies essential safety and mechanical performance criteria for single-use venous blood collection containers, including resistance to breakage under defined testing conditions (3). Adherence to these standards is a key aspect of medical device quality assurance and regulatory oversight.

In this context, the present study evaluates the breakage resistance of the IMPROVACUTER® range of venous blood collection tubes under standardised drop-test conditions. The study was designed as a standards-based local product performance verification rather than a comparative study of superiority against other commercially available brands.

MATERIALS AND METHODS

Tube Types, Specifications, and Materials

Six categories of IMPROVACUTER® tubes were evaluated. Tube volumes ranged from 0.5 mL to 6.0 mL with dimensions of either 13 × 75 mm or 13 × 100 mm. Most variants were constructed from PET, with citrate tubes utilising a PET/polypropylene (PP) composite. The EDTA concentration of 1.8 mg/mL (1.8

g/L) of blood corresponds to the standard anticoagulant concentration recommended for haematological specimen collection to preserve cellular morphology and prevent clot formation (2).

Study Design and Sample Size

This experimental evaluation was conducted using a standardised drop-test protocol as an attribute-based, standards-based product performance verification of IMPROVACUTER® venous blood collection tubes; it was not designed as a comparative study against other brands. The study was conducted at the Special Protein Unit, Institute for Medical Research, Kuala Lumpur, Malaysia on April 2025. A total of 108 tubes were evaluated across six tube categories and three independent manufacturing lots. Six tubes were tested from each lot for each tube category, giving a total of 6 tube categories × 3 lots × 6 tubes per lot = 108 tubes, or 18 tubes per category. Three independent lots were included to assess lot-to-lot consistency and to avoid drawing conclusions from a single manufacturing batch. Each tube was classified as pass or fail based on the predefined failure criteria. ISO 2859-1 with an Acceptance Quality Limit (AQL) of 1.5 was used as the basis for the sampling and acceptance approach (3,9).

Drop Test Procedure

Each tube was filled with rose syrup as a blood substitute according to its intended nominal draw volume, allowing the tube to draw the liquid based on its designed vacuum capacity. Tubes were released from a height of 1 m onto a concrete surface. Tube orientation at impact was not deliberately controlled, to reflect accidental drop conditions in which the position of the tube at impact is unpredictable. Each tube was dropped three consecutive times. Testing was conducted under ambient laboratory conditions in an air-conditioned laboratory with the air-conditioning set at 24°C; relative humidity was not recorded during the testing session. All drop tests were performed by the same trained operator using the same protocol to ensure consistency. After testing, tubes were visually inspected for visible cracking, leakage, breakage, or cap dislodgement.

Acceptance Criteria

Individual tubes were classified as failed if any visible crack, leakage, breakage, or cap dislodgement was observed. A tube category was considered acceptable if at least 90% of tested units met the pass criteria. The ≥90% pass rate was the predefined practical acceptance criterion for this verification, while ISO 2859-1 with AQL 1.5 provided the basis for the sampling and acceptance approach.

Statistical Analysis

This was an attribute-based verification study using predefined pass/fail criteria. Because the objective was to determine whether each tube category met the predefined acceptance criterion rather than to compare groups or test a superiority hypothesis, inferential group-comparison testing was not performed. Pass rates were summarised descriptively with exact binomial 95% confidence intervals calculated using the Clopper–Pearson method.

RESULTS

The breakage resistance evaluation of 108 IMPROVACUTER® venous blood collection tubes demonstrated an overall pass rate of 94.4% under the standardised drop-test conditions. Table 1 summarised the number tested, passed, failed, and the acceptance percentage for each tube category. Five of the six tube categories met the predefined ≥90% practical acceptance criterion; the Clot Activator category had a pass rate of 88.9%.

Acceptance rates varied slightly between tube types. Citrate tubes demonstrated a 100.0% pass rate (95% CI, 81.5%–100.0%). Gel & Clot Activator, EDTA.K2, Heparin, and Glucose (NaF/EDTA) tubes each achieved a 94.4% pass rate (95% CI, 72.7%–99.9%). Clot Activator tubes showed the lowest pass rate at 88.9% (95% CI, 65.3%–98.6%). The overall pass rate was 94.4% (95% CI, 88.3%–97.9%), as shown in Table 2. Of the 108 tubes tested, 102 (94.4%) passed without any visible crack, leakage, breakage, or cap dislodgement, while 6 tubes (5.6%) failed. Failure modes were categorised descriptively as hairline crack, hazy appearance, leakage, cap dislodgement, or complete breakage/shattering. No gross leakage or complete tube shattering was observed. The frequency of each observed failure mode is summarised in Table 3.

Table 1. Breakage resistance of IMPROVACUTER® venous blood collection tubes under standardised drop testing.

Tube Type	Additive	Material	Tested (n)	Pass (n)	Fail (n)	Acceptance (%)
Gel & Clot Activator	Gel + Clot Activator	PET	18	17	1	94.4
Clot Activator	Clot Activator	PET	18	16	2	88.9
EDTA.K2	EDTA.K2	PET	18	17	1	94.4
Citrate	Sodium citrate	PET / PET-PP	18	18	0	100.0
Heparin	Lithium heparin	PET	18	17	1	94.4
Glucose (NaF/EDTA)	NaF + EDTA	PET	18	17	1	94.4
Total	-	-	108	102	6	94.4

EDTA K2: dipotassium ethylenediaminetetraacetic acid; NaF: sodium fluoride. PET: Polyethylene terephthalate, PP: Polypropylene.

Table 2. Pass rates and exact binomial 95% confidence intervals for IMPROVACUTER® venous blood collection tubes.

Tube Type	Pass / Tested	Pass Rate (%)	95% CI for Pass Rate (%) ^a
Gel & Clot Activator	17 / 18	94.4	72.7% – 99.9
Clot Activator	16 / 18	88.9	65.3% – 98.6
EDTA.K2	17 / 18	94.4	72.7% – 99.9
Citrate	18 / 18	100.0	81.5% – 100.0
Heparin	17 / 18	94.4	72.7% – 99.9
Glucose (NaF/EDTA)	17 / 18	94.4	72.7% – 99.9
Overall	102 / 108	94.4	88.3% – 97.9

^aExact binomial 95% confidence intervals were calculated using the Clopper–Pearson method.

Table 3. Descriptive breakdown of observed failure modes among failed tubes.

Failure mode	Number of tubes (n)	Percentage of failed tubes (%)
Hazy appearance at the bottom	6/108	5.5
Hairline crack	0	0
Leakage	0	0
Cap dislodgement	0	0
Complete breakage / shattering	0	0

DISCUSSION

The findings of this study provide a standards-based characterisation of breakage resistance for IMPROVACUTER® venous blood collection tubes under the standardised drop-test conditions evaluated. This was a product performance verification study and not a comparative study against other brands. Citrate tubes achieved a 100.0% pass rate, whereas Clot Activator tubes had the lowest pass rate at 88.9%. However, the observed differences between tube categories should not be attributed solely to material or design because individual tube weights were not measured and the total filled mass may have differed according to tube size, wall thickness, cap design, additive composition, material, and nominal draw volume. These differences could influence impact energy during a drop.

The failure pattern observed in this study was relatively minor. Only 6 of the 108 tubes tested, showing hazy appearance at the bottom, while no leakage, hairline cracks, cap dislodgement, or complete breakage/shattering was observed following the standardized drop test. This finding indicates that the majority of tubes maintained their overall structural integrity despite repeated mechanical impact. Importantly, none of the observed defects resulted in gross tube failure or loss of tube contents, suggesting good resistance to more severe forms of mechanical damage (3,5).

Most evaluated tubes were constructed from PET, a material commonly used in clinical diagnostics because of its impact resistance and reduced fracture risk compared with traditional glass tubes. Previous work has supported the use of plastic tubes as alternatives to glass for selected laboratory applications (7). Nevertheless, the present study was not designed to isolate the independent effect of PET or PET/PP construction on breakage resistance, and causal attribution to tube material cannot be made from these data.

Automated pre-analytical systems and pneumatic tube transport can expose collection tubes to mechanical stresses that differ from a controlled vertical drop. These conditions were not evaluated in the present study. Therefore, the observed 94.4% overall pass rate should be interpreted only in relation to the standardised drop-test protocol and should not be taken as evidence of performance during pneumatic tube transport, centrifugation, or automated handling. These settings should be evaluated separately in future studies.

The need for local verification is particularly relevant when alternative blood collection tube brands are introduced during supply disruptions (1). Recent multicentre verification during a global tube shortage demonstrated the importance of verifying alternative collection tubes to support diagnostic continuity (6). By evaluating three independent manufacturing lots and applying a standardised attribute-based pass/fail approach, the present study provides local evidence on breakage resistance under the specific controlled conditions tested; it does not establish superiority over other products or performance across all laboratory workflows.

The practical contribution of this study is the documentation of breakage resistance under a defined one-meter drop-test condition. The results may inform product verification and quality assurance for the specific mechanical property assessed. However, vacuum retention, specimen integrity, centrifugation tolerance, pneumatic tube transport, automated handling, and analytical performance were outside the scope of this study and cannot be inferred from the present findings.

This study has several limitations. First, no comparator tube from another commercially available brand was included; therefore, the findings should be interpreted as a standards-based product performance verification and not as a comparative or superiority assessment. Second, individual tube weights were not measured. Differences in total filled tube mass due to tube size, wall thickness, cap design, additive composition, material, and nominal draw volume may have influenced impact energy and the observed breakage resistance between tube categories. Third, relative humidity was not recorded during testing. Finally, durability was assessed only using a controlled standardised drop test. Additional mechanical stresses encountered in routine practice, including centrifugation, pneumatic tube transport, and automated handling, were not evaluated. Further studies incorporating comparator products and simulated routine laboratory workflows are needed for a more comprehensive assessment of tube performance.

CONCLUSION

This study demonstrated that IMPROVACUTER® venous blood collection tubes showed high breakage resistance under standardised one-meter drop-test conditions. The overall pass rate was 94.4%, with five of the six tube categories meeting the predefined $\geq 90\%$ practical acceptance criterion. These findings should be interpreted as a standards-based product performance verification under the conditions tested, rather than as evidence of superiority over other brands. Other performance characteristics, including vacuum retention, specimen integrity, centrifugation, pneumatic tube

transport, automated handling, and analytical performance, were not evaluated and should be assessed in future studies.

Supplementary Materials: Not applicable.

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Institutional Review Board Statement: The study was registered with the National Medical Research Register (NMRR) under registration number NMRR ID-25-01347-AEU. Ethical review and approval were not required in accordance with the guidelines of the Malaysian Medical Research and Ethics Committee (MREC), as this study involved only observational analysis and did not involve human participants, patient samples, or identifiable personal data. Therefore, the study was considered outside the scope of research requiring ethical review under applicable MREC regulatory requirements.

Informed Consent Statement: *Not applicable.*

Data Availability: Not applicable.

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Conflicts of Interest: FS and SNISN are employees of Alfa Diagnostik Sdn Bhd, the distributor of the evaluated IMPROVACUTER® tubes.

CITATION

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REFERENCES

1. Bowen RA, Remaley AT. Interferences from blood collection tube components on clinical chemistry assays. Biochem Med (Zagreb). 2014;24(1):31-44
2. Clinical and Laboratory Standards Institute. Collection of Diagnostic Venous Blood Specimens. GP41-Ed7. Wayne, PA: CLSI; 2017.
3. International Organization for Standardization. ISO 6710:2017: Single-use containers for human venous blood specimen collection. Geneva: ISO; 2017.

4. Lippi G, Chance JJ, Church S, et al. Preanalytical quality improvement: from dream to reality. *Clin Chem Lab Med*. 2011;49(7):1113–26.
5. McCall RE, Tankersley CM. *Phlebotomy Essentials*. 7th ed. Burlington, MA: Jones & Bartlett Learning; 2020.
6. Nell EM, Bailly J, Oelofse D, Linström M, Opie J, Chapanduka ZC, Vreede H, Korf M. Multicentre verification of haematology laboratory blood collection tubes during a global blood collection tube shortage. *Int J Lab Hematol*. 2023;45(5):707-716.
7. Kratz A, Stanganelli N, Van Cott EM. A comparison of glass and plastic blood collection tubes for routine and specialized coagulation assays: a comprehensive study. *Arch Pathol Lab Med*. 2006;130(1):39-44
8. World Health Organization. *WHO Guidelines on Drawing Blood: Best Practices in Phlebotomy*. Geneva: WHO; 2010.
9. International Organization for Standardization. *ISO 2859-1:2026. Sampling procedures for inspection by attributes — Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection*. Geneva: ISO; 2026
10. Simundic AM, et al. Joint EFLM-COLABIOCLI Recommendation for venous blood sampling. *Clin Chem Lab Med*. 2018;56(12):2015–2038.