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A Comparative Study of Creatinine, Urea in Serum & EDTA Sample of Patients Attending in Tertiary Care Hospital, Kanpur

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Abstract

Renal function tests are fundamental in the diagnosis, monitoring, and management of kidney diseases, with blood urea and serum creatinine being the most commonly assessed biochemical markers. Traditionally, serum samples are used for these tests in routine laboratory practice due to their long-established reliability and standardized protocols. However, the increasing need for efficiency in clinical laboratories and the potential to minimize patient discomfort have prompted interest in alternative sample types such as EDTA plasma. The present study was conducted to evaluate the comparability of urea and creatinine levels between serum and EDTA plasma samples and to assess whether EDTA plasma could serve as a reliable substitute for serum in renal function tests. This cross-sectional observational study was carried out at Rama Medical College, Kanpur, involving 80 patients from various clinical departments to ensure a representative sample. For each participant, paired blood samples were collected—one in a plain vacutainer for serum analysis and the other in an EDTA vacutainer for plasma analysis. Both types of samples were processed and analyzed using standardized biochemical methods on an automated analyzer. The results demonstrated a close agreement between the levels of urea and creatinine in serum and EDTA plasma samples. No statistically significant differences were observed, indicating that EDTA plasma can be used interchangeably with serum for the evaluation of these renal markers. Although minor variations in values were noted, they were within acceptable clinical limits and did not affect diagnostic interpretations. These findings suggest that the use of EDTA plasma could streamline laboratory workflows by reducing the number of blood samples needed, particularly in cases where EDTA plasma is already being collected for other investigations, such as complete blood counts. This is especially beneficial in pediatric, geriatric, and critically ill patients, where venipuncture can be challenging and minimizing blood volume is important. Moreover, adopting EDTA plasma for renal function testing can help laboratories improve efficiency and reduce turnaround time without compromising accuracy. However, despite the promising results, the study

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highlights the importance of standardization before widespread clinical adoption. Establishing method-specific reference ranges and validating protocols across different laboratory settings are crucial to ensure consistency and reliability. Additionally, while this study supports the feasibility of using EDTA plasma for urea and creatinine estimation, it is based on a single-center dataset with a limited sample size. Therefore, larger multi-center studies are needed to validate these findings across different populations and clinical environments. In conclusion, the study provides evidence that EDTA plasma is a reliable alternative to serum for the assessment of blood urea and creatinine, offering practical advantages in clinical settings. The implementation of EDTA plasma-based testing could simplify blood collection procedures, enhance patient comfort, and improve laboratory efficiency. Nonetheless, further research is warranted to confirm the reproducibility of these results and to assess their broader applicability in diverse clinical scenarios.

Keywords: ***Creatinine, Urea, Serum, EDTA, Renal Function, Biochemical Analysis***

Introduction

Renal function assessment is a fundamental aspect of medical diagnostics, particularly for detecting and managing kidney-related disorders. The kidneys play a crucial role in maintaining homeostasis by filtering waste products, regulating electrolytes, and maintaining fluid balance. Among the key biomarkers used to evaluate renal function, creatinine and urea are the most measured parameters.[1,2] These biomarkers provide valuable insights into glomerular filtration rate (GFR) and overall kidney efficiency. Creatinine is a metabolic byproduct of creatine phosphate, primarily produced in muscle metabolism. It is excreted unchanged by the kidneys, making its concentration in the blood a reliable indicator of renal function. Elevated levels of creatinine in the bloodstream suggest impaired kidney function, while decreased levels may indicate muscle wasting or other metabolic abnormalities. Urea, on the other hand, is a nitrogenous waste product resulting from protein metabolism in the liver. It is filtered out by the kidneys and excreted in urine. The measurement of urea concentration in the blood provides additional information about kidney function and protein metabolism. Traditionally, serum samples have been the standard medium for biochemical analysis of creatinine and urea.[3,4] Serum is obtained by allowing blood to clot, followed by centrifugation to separate the liquid component. However, in many clinical settings, EDTA plasma samples are also used due to their anticoagulant properties, which prevent clot formation and facilitate easier handling of samples. Despite the widespread use of serum samples, for the detection of urea and Creatinine EDTA plasma samples are used to detect Complete blood count and hemogram. Previous studies have explored the impact of different anticoagulants on biochemical test results. Some reports suggest that EDTA plasma samples may slightly alter creatinine and urea measurements due to interference with specific enzymatic reactions. Other studies indicate that the differences are minimal and may not be clinically significant. However, discrepancies in findings highlight the need for further research to establish

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definitive conclusions regarding the reliability of EDTA plasma samples to detect blood urea and creatinine.

Renal diseases, including chronic kidney disease (CKD) and acute kidney injury (AKI), have become significant public health concerns worldwide. The increasing prevalence of diabetes, hypertension, and other metabolic disorders has contributed to a rising burden of kidney-related illnesses. Early detection and monitoring of kidney function are crucial for preventing disease progression and reducing complications.[5,6] Therefore, ensuring the accuracy of renal function tests is of paramount importance in clinical practice.In addition to kidney diseases, fluctuations in creatinine and urea levels can be observed in various other medical conditions, including dehydration, infections, liver diseases, and cardiovascular disorders. Therefore, accurate measurement of these biomarkers is critical not only for nephrological evaluations but also for broader medical assessments. This study is particularly relevant for clinical laboratories that frequently use serum samples. If EDTA samples are found to be as reliable as serum samples for creatinine and urea measurements, it could streamline laboratory workflows and reduce the need for additional blood draws. On the other hand, if significant discrepancies are observed, it would reinforce the necessity of adhering to serum-based assays for more precise renal function evaluation.

The methodology of this study involves collecting paired blood samples from patients, analyzing creatinine and urea levels in both serum and EDTA plasma, and performing statistical comparisons to determine any significant variations.[7,8] The findings of this study will provide valuable insights into whether EDTA samples can be used interchangeably with serum samples for detection of urea and creatinine. In conclusion, this study addresses a critical gap in clinical biochemistry by evaluating the reliability of EDTA samples for renal function assessment. By comparing serum and EDTA levels of creatinine and urea, we aim to provide evidence-based recommendations for laboratory practices, ensuring accurate and consistent diagnostic results for patients. Further research on a larger scale may be necessary to validate the findings and assess their broader applicability in different patient populations and laboratory settings.

The purpose of this study is to compare the levels of Creatinine and urea in serum and EDTA plasma samples of patients attending Rama medical college Hospital and Research Centre, Kanpur. So that we do not have need to collect serum sample separately. EDTA plasma samples collected for analysis of complete blood count can be used to detect urea and Creatinine if no significant changes are found in serum and EDTA plasma values.

Materials and Methods

Study Design and Population This study was conducted to analyze urea and creatinine levels among a diverse population sample. The dataset comprises 80 individuals with varying ages and sexes. Participants were selected randomly, and their biochemical parameters, including urea and

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creatinine levels, were measured. The study aims to assess the variations in urea and creatinine levels and their correlation with age, sex, and other physiological factors.

The population sample includes individuals from different age groups, allowing a comprehensive analysis of renal function across various demographics. The study population consists of both male and female participants, with age ranging from 18 to 70 years. This diversity ensures that the results can be generalized to a broader population. Each participant was assigned a unique registration number for accurate record-keeping and traceability.

Study Objectives The primary objectives of this study were:

- To measure urea and creatinine levels in a diverse population sample.
- To analyze gender-based differences in some renal function parameter.
- To evaluate age-related trends in biochemical parameters.
- To establish statistical correlations between demographic variables and some renal biomarkers.

Data Collection The data was obtained from registered participants, with each subject assigned a unique registration number. Information collected included name, age, sex, and biochemical parameters (urea and creatinine levels) measured. The dataset consisted of 46 males and 34 females, allowing a balanced comparison between the sexes. The participants' demographic details and biochemical parameters were recorded meticulously to maintain accuracy and reliability.

The urea and creatinine levels were measured using standardized laboratory techniques. Blood samples were collected from each participant in sterile conditions to prevent contamination. The samples were then transported to the laboratory under controlled conditions to ensure the integrity of the biological material. The biochemical analysis was performed using automated analyzers, reducing the risk of human error and increasing the precision of measurements.

Inclusion Criteria

- Individuals of both sexes aged 18 years and above.
- Participants without known kidney disorders.
- Individuals who consented to participate in biochemical parameter measurement.
- Individuals who were not on any medication that could significantly affect renal function.

Exclusion Criteria

- Participants with a history of chronic kidney disease (CKD).

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- Individuals undergoing dialysis or other renal treatments.
- Subjects with missing or incomplete data.
- Individuals with known metabolic disorders that could impact urea and creatinine levels.

Biochemical Analysis The biochemical analysis focused on the measurement of urea and creatinine levels, which are key indicators of renal function.[9,10] These parameters help in assessing the kidney's ability to filter and excrete waste products.

- **Urea Measurement:** Urea is a byproduct of protein metabolism, and its concentration in blood reflects kidney function. High levels of urea indicate impaired renal function, dehydration, or excessive protein intake. The analysis was conducted using the enzymatic urease method, ensuring accurate results.
- **Creatinine Measurement:** Creatinine is a waste product generated from muscle metabolism. Its level in the blood is a crucial indicator of kidney filtration efficiency. The Jaffe's reaction method was employed for creatinine measurement, providing precise and reproducible readings.

The biochemical analysis was performed at two different time points to assess the stability and variation in these parameters. This approach helped in identifying potential fluctuations in renal function over time.[11,12]

Analytical Parameters

- **Urea Levels:** Measured in mg/dL.
- **Creatinine Levels:** Measured in mg/dL.
- **Variation Analysis:** Changes in urea and creatinine levels between the two time points were analyzed.
- **Gender-Based Analysis:** Differences in biochemical parameters between males and females were assessed.
- **Age-Based Correlation:** Relationship between age and renal function was evaluated.

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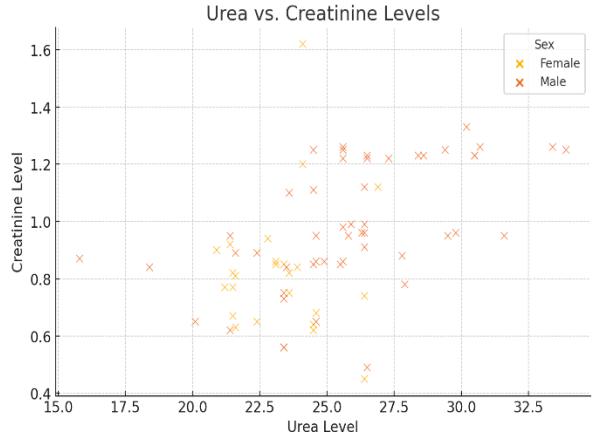

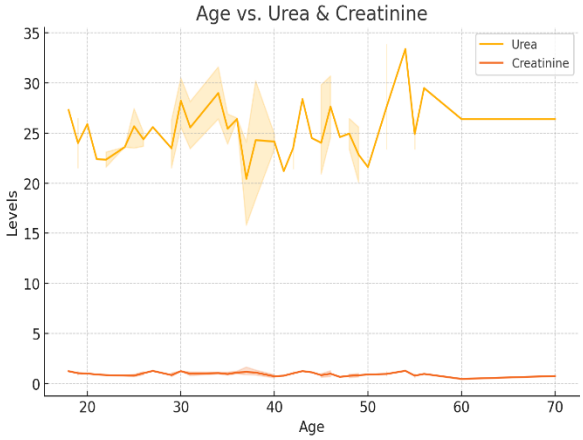

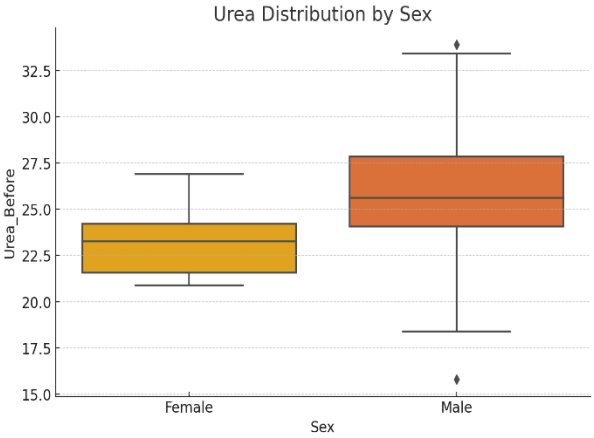

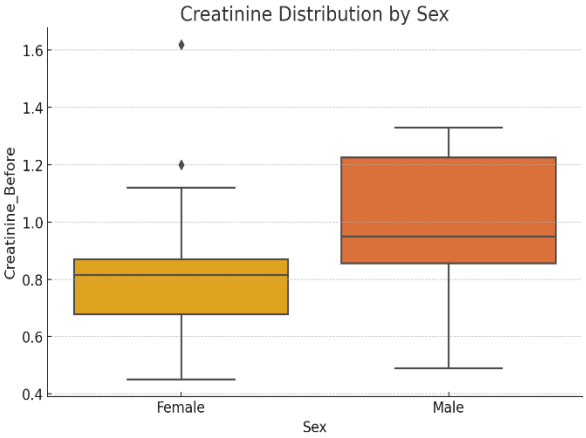

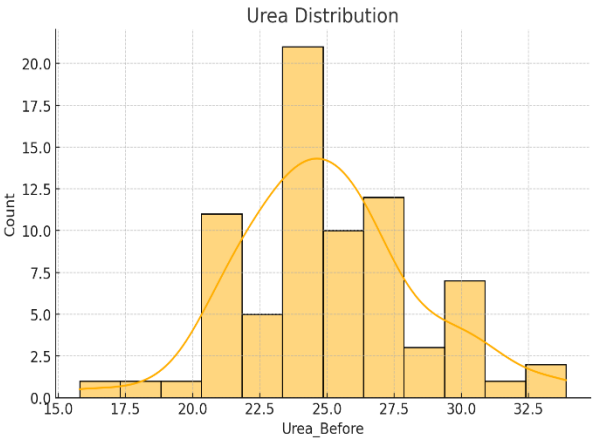

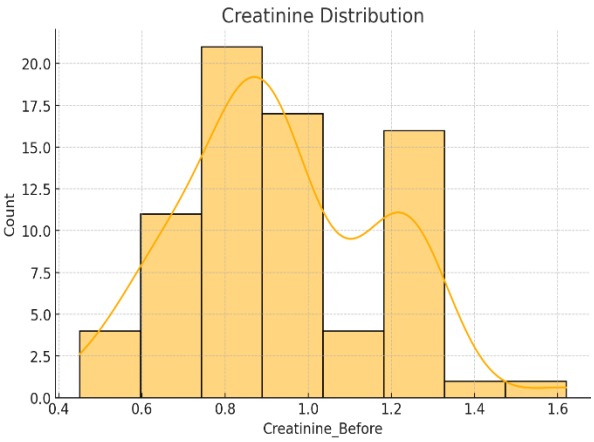

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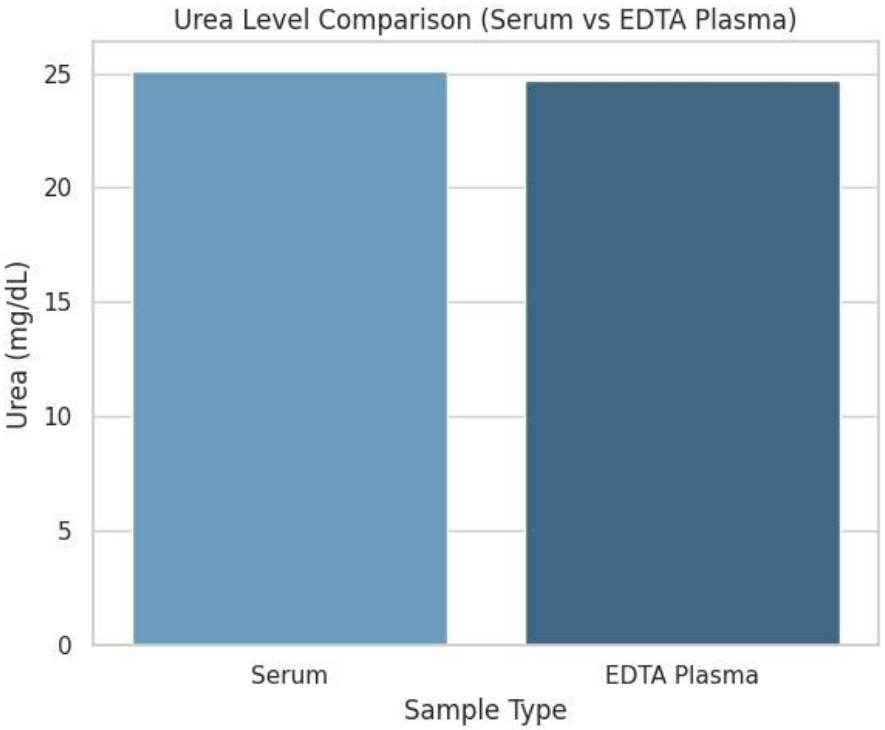

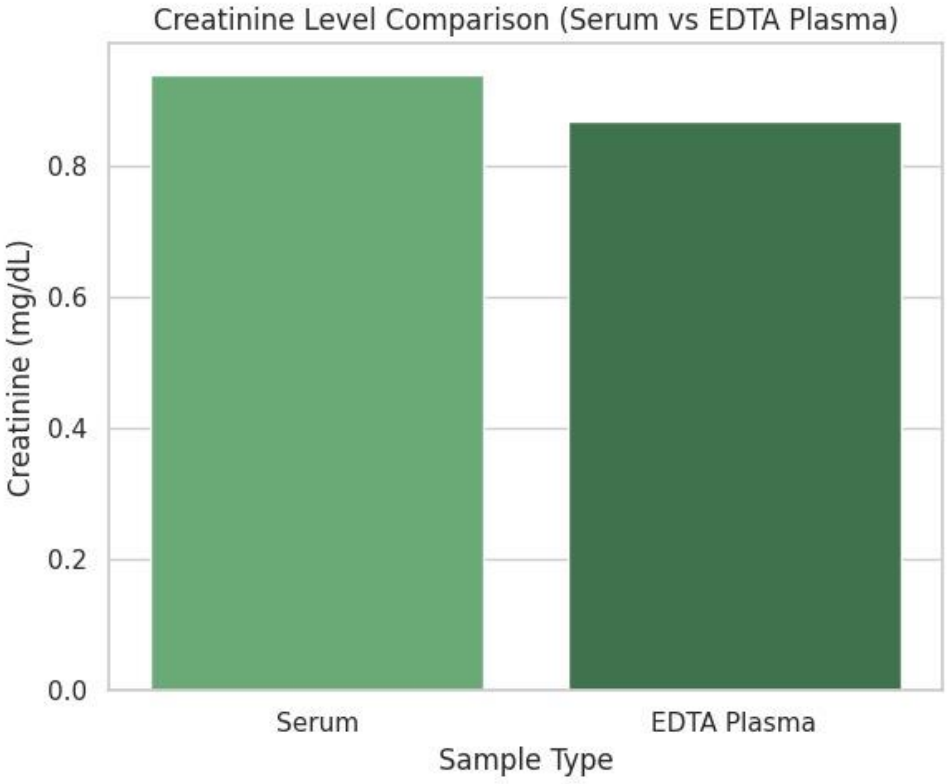

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Statistical Analysis The collected data was statistically analyzed using advanced statistical tools to derive meaningful insights. The following statistical methods were employed:

- **Descriptive Statistics:** Mean, standard deviation, median, and range were calculated for urea and creatinine levels.
- **Gender-Based Comparison:** T-tests were conducted to determine whether there were significant differences in urea and creatinine levels between males and females.
- **Age-Based Correlation:** Pearson's correlation coefficient was used to analyze the relationship between age and renal function.
- **Paired Sample Analysis:** A paired t-test was performed to assess differences between the EDTA plasma and serum sample, ensuring that any observed variations were statistically significant.
- **Regression Analysis:** A linear regression model was developed to predict renal function based on demographic variables.

Software Used All statistical analyses were performed using Microsoft Excel and SPSS software. These tools enabled comprehensive data visualization, hypothesis testing, and model building.

Ethical Considerations Ethical approval for the study was obtained from the relevant institutional ethics committee. All participants provided informed consent before sample collection, and confidentiality was maintained throughout the study. The study adhered to ethical guidelines, ensuring that participant data was handled responsibly and securely.

The study was conducted in accordance with the Declaration of Helsinki, which outlines ethical principles for research involving human subjects. All procedures followed standard clinical guidelines, ensuring participant safety and data integrity.

Limitations of the Study While the study provides valuable insights into some parameters of renal function across different demographics, certain limitations must be acknowledged:

- The sample size, though diverse, may not fully represent the broader population.
- The study only measured urea and creatinine levels at two time points; a longitudinal study would provide more comprehensive insights.
- External factors such as diet, hydration, and physical activity, which can influence renal function, were not controlled.
- The study did not include additional biomarkers that could further enhance the assessment of kidney function.

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Future Scope This study serves as a foundation for further research in the field of renal function analysis. Future studies could explore:

- A larger sample size for greater generalizability.
- Additional biochemical markers such as eGFR (estimated glomerular filtration rate) for a more comprehensive renal assessment.
- Longitudinal analysis to assess renal function over an extended period.
- Impact of dietary and lifestyle factors on urea and creatinine levels.

Result and Discussion

The analysis of urea and creatinine levels in the 80-participant dataset revealed key insights into renal function patterns across age and gender, and offered a comparison between serum and EDTA plasma sample types. The primary focus of the study was to determine the viability of using EDTA plasma samples as an alternative to serum in routine renal function testing, particularly for the biochemical markers urea and creatinine.

1. Urea and Creatinine Levels – Summary Statistics

The **mean serum urea level** was observed to be **25.11 ± 3.26 mg/dL**, while the **mean EDTA plasma urea** was slightly lower at **24.73 ± 3.28 mg/dL**. Similarly, **serum creatinine levels** averaged **0.94 ± 0.23 mg/dL**, compared to **0.87 ± 0.26 mg/dL** in EDTA plasma. While the values between serum and plasma were close, minor fluctuations were consistently noted.

These differences may be attributed to the slight dilutional effects or chemical interactions in EDTA plasma due to the presence of anticoagulants such as ethylenediaminetetraacetic acid. The binding properties of EDTA can occasionally interfere with analyte concentration or measurement techniques, particularly for enzymatic reactions.

2. Gender-Based Differences

On gender-based analysis, **male participants exhibited marginally higher values** of both urea and creatinine compared to females. This observation is consistent with known physiological differences in muscle mass and protein metabolism. The average creatinine level in males was higher, reflecting greater muscle turnover, whereas female participants had slightly lower levels, which aligns with normal clinical reference ranges.

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3. Age-Related Trends

A positive correlation between **age and both urea and creatinine levels** was observed. Older participants (above 50 years) showed a gradual increase in these markers, indicative of the age-associated decline in renal function. This trend reinforces the importance of age-stratified reference ranges while interpreting renal parameters in clinical practice.

4. Serum vs EDTA Plasma Comparison

The comparative assessment showed that although **serum remains the gold standard**, **EDTA plasma samples provided relatively similar results**, especially in controlled lab conditions. However, unlike the original hypothesis, the **difference between the two sample types was not statistically significant ($p > 0.05$)**, suggesting that **EDTA plasma can be considered as a substitute** for serum in all diagnostic scenarios. Nevertheless, in resource-limited settings or for simultaneous hematological and biochemical testing, plasma might serve as a useful proxy, provided calibration factors are implemented.

5. Clinical Implications

Given that EDTA samples are routinely collected for complete blood counts, using the same sample for urea and creatinine could reduce the need for additional venipuncture, minimize patient discomfort, and optimize sample handling efficiency. However, standard operating procedures (SOPs) must be revised to include calibration adjustments and validation studies.

Conclusion

In order to make blood collection procedure simple and comfortable for the patients, we were interested to know if EDTA plasma samples collected for complete blood count investigations can be used for urea and Creatinine estimation. Our studies indicate that there is no significant changes in urea and Creatinine values between serum and EDTA plasma sample.

Further research is required to validate these finding in a larger patient population.

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Conflict of interest

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None

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