

Creatinine Assay Market – Global Industry Size, Share, Trends, Opportunity, and Forecast, 2018-2028F Segmented By Test Type (Jaffe Kinetic Method, Enzymatic Method), By Product (Reagents, Kits), By Sample (Blood/Serum, Urine), By End User (Hospitals, Diagnostic Laboratories), By Region, Competition

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Abstracts

The Global Creatinine Assay Market was valued at USD 360.12 million in 2022 and is expected to exhibit robust growth in the forecast period, with a CAGR of 6.6% through 2028. The measurement of creatinine is a vital test conducted to evaluate renal function in the human body. Creatinine, a chemical compound produced after muscle energy production, remains in the body. Assessing creatinine levels in blood and urine samples enables the determination of kidney status as the kidneys filter out creatinine. In adults, the normal range for creatinine measurement is 0.5 to 1.2 milligrams per deciliter of blood. Elevated creatinine levels indicate unhealthy kidney conditions. The increasing prevalence of kidney diseases, particularly in developing countries due to unfavorable living conditions, has resulted in a growing demand for creatinine measurement tests. Moreover, the market growth is driven by the cost-effectiveness and widespread availability of test kits and reagents.

Key Market Drivers

Growing Incidence of Kidney-Related Health Problems

Kidney disorders, including chronic kidney disease (CKD), contribute significantly to global mortality rates. Early diagnosis and appropriate treatment play a crucial role in preventing complications. Creatinine testing methods are utilized to evaluate renal



functionality. Market players prioritize the production of high-quality products to meet the rising demand. Furthermore, increased research activities in this field contribute to the expansion of the global market. The growing number of individuals diagnosed with kidney-related diseases has led to a higher demand for creatinine testing to assess kidney function and monitor disease progression. Regular monitoring of kidney function, including creatinine levels, is necessary for patients with kidney diseases. This continuous monitoring drives the need for frequent creatinine testing. Creatinine assays are routinely performed in hospitals, clinics, and healthcare facilities to evaluate kidney function in patients admitted with kidney-related issues or undergoing treatments that may impact kidney function. The adoption of point-of-care creatinine testing has increased in critical care settings due to the need for rapid results and immediate clinical decision-making, which enables timely patient management. In the pharmaceutical industry, creatinine assays are used in pre-clinical and clinical research to assess the impact of new drugs on kidney function and potential nephrotoxicity. The growing awareness about kidney health has led to an increase in routine health checkups that include creatinine testing to detect early signs of kidney dysfunction, thereby boosting the global creatinine assay market.

The growing demand for rapid diagnostic techniques and procedures to measure creatinine levels in blood and urine is a key driver of market growth. The prevalence of diabetes, which has a negative impact on kidney health, along with the increasing incidence of chronic kidney disorders among the aging population and the rising number of patients with kidney cancer, glomerulonephritis, and renal failures, among others, are fueling the need for rapid diagnostic procedures to measure creatinine levels. Creatinine, an endogenous waste product formed during the breakdown of creatine found in muscles, is used by clinical laboratories to assess health and kidney function by testing glomerular filtration rate (GFR) and blood urea nitrogen (BUN).

Technological advancements in creatinine detection have led to the development of a biosensor construction based on a single-mode fiber-multicore fiber-multimode fiber-single-mode fiber (SMFMCF-MMF-SMF) configuration. This construction is characterized by simplicity, portability, and high sensitivity. To enhance the generation of strong evanescent waves, the diameter of the sensing probe has been reduced to 90m using chemical etching. The sensor probe is functionalized with graphene oxide (GO), gold nanoparticles (AuNPs), molybdenum disulfide nanoparticles (MoS2-NPs), and the creatininase (CA) enzyme. Fiber optic localized surface plasmon resonance (LSPR) is employed to assess the concentration of creatinine. Two-dimensional (2D) materials, such as GO and MoS2-NPs, are used to enhance biocompatibility, while CA increases the probe's specificity. The use of evanescent waves (EWs) enhances the



impact of AuNPs on LSPR.

Moreover, high-resolution transmission electron microscopy (HR-TEM) and UV-visible spectroscopy are utilized to analyze and evaluate the shape and absorption spectra of nanoparticles (NPs). Scanning electron microscopy (SEM) is used to characterize NPs adsorbed on the surface of the fiber probe. The performance of the sensor probe is evaluated in terms of reusability, repeatability, stability, selectivity, and pH tests. The suggested sensor exhibits a sensitivity of 0.0025 nm/M, a standard deviation of 0.107, and a detection limit of 128.4m within a linear detection range of 0 - 2000m. Based on these findings, significant market growth is anticipated in the forecast period.

Increasing Geriatric Population

The increasing geriatric population and the subsequent rise in age-related health conditions significantly drive the demand for creatinine assay. With advancing age, the risk of kidney-related diseases and impairments in kidney function tends to escalate. The assessment of kidney function and monitoring renal health in the elderly population heavily relies on the crucial role of the creatinine assay. Age-related changes naturally occur in the kidneys, leading to reduced kidney function and a decline in the glomerular filtration rate (GFR). Detecting kidney dysfunction in older adults is vital, and the creatinine assay serves as a fundamental tool in this process. Elderly individuals often require multiple medications to manage chronic conditions, emphasizing the importance of kidney function in clearing drugs from the body. By facilitating appropriate drug dosage adjustments, creatinine assays help healthcare providers prevent potential toxicity and adverse effects in older patients. Regular creatinine testing enables early detection of kidney disease in older adults, allowing for timely interventions and management to prevent disease progression and complications. As the geriatric population continues to grow, the demand for creatinine assay is expected to remain high. Ensuring kidney health and early detection of kidney diseases will be paramount in managing the health and well-being of the elderly population, making creatinine testing an indispensable tool in geriatric care and medicine.

Key Market Challenges

Limited awareness of creatinine testing methods:

Many patients may lack awareness of the importance of creatinine testing in evaluating kidney function and its impact on overall health. Different healthcare settings may employ various methods for creatinine testing, leading to confusion among patients and



healthcare providers regarding the accuracy and reliability of results. In some cases, healthcare providers may prioritize other health parameters over creatinine testing, potentially missing early signs of kidney dysfunction. Public health initiatives and awareness campaigns may not adequately address the significance of kidney health and creatinine testing in promoting overall well-being.

Underutilization of creatinine assay kits in in vitro diagnostics (IVD):

Limited availability or usage of creatinine assay kits in IVD can result in restricted access to these diagnostic tests for healthcare providers and patients. This could potentially lead to underdiagnosis or delayed diagnosis of kidney-related conditions. Limited usage of creatinine assay kits may also contribute to a lack of standardization in creatinine testing across different healthcare settings. Standardization is crucial for ensuring consistent and reliable results, and the absence of widely used assay kits can hinder this process. Healthcare providers may explore alternative diagnostic methods for assessing kidney function, such as point-of-care tests or other biomarkers, potentially diverting demand away from traditional creatinine assays. Manufacturers of creatinine assay kits might experience reduced demand for their products, affecting their revenue and profitability. This, in turn, could impact their ability to invest in research and development or improvements to their assay kits.

Key Market Trends

Point-of-Care Testing:

POCT can be conducted at the patient's bedside, in outpatient clinics, or even in remote or resource-limited areas. It eliminates the need for patients to visit a centralized laboratory for creatinine testing, thereby enhancing accessibility to diagnostic services. For patients with chronic kidney disease (CKD) or those undergoing treatments that may affect kidney function, POCT allows for frequent and convenient monitoring of creatinine levels, enabling timely adjustments to treatment plans. In telemedicine or remote healthcare settings, POCT of creatinine enables remote monitoring of kidney function, promoting continuity of care and personalized treatment plans. Furthermore, POCT can lead to cost savings by reducing the need for multiple visits or sample transportation to centralized laboratories.

Growing Demand in Emerging Markets:

As access to healthcare improves in emerging markets, the demand for cost-effective



and user-friendly creatinine kits is expected to increase. Manufacturers are likely to focus on developing affordable and reliable solutions for these markets. The improvement of healthcare infrastructure and expanded access to medical services in emerging markets mean that more individuals can undergo regular health check-ups, including assessments of kidney function. Growing awareness about the importance of preventive healthcare is encouraging individuals to seek regular screenings, including creatinine testing, to detect early signs of kidney dysfunction. Government initiatives to enhance healthcare access and quality, along with efforts to address noncommunicable diseases (NCDs), can further drive the demand for creatinine assays.

Segmental Insights

Insights on Test Types:

Based on the test types, Jaffe's Kinetic method emerged as the dominant segment in the market. This is primarily due to its status as the oldest and most traditional method for measuring creatinine, resulting in the largest market share. The Jaffe method utilizes a simple colorimetric assay, where creatinine reacts with picric acid under alkaline conditions, forming a red-orange chromophore. The intensity of the color change is directly proportional to the concentration of creatinine, making it a convenient measurement method. The Jaffe method is widely accepted and standardized in clinical laboratories, making it a reference method for creatinine testing. Its credibility is further established by its extensive use in clinical trials and research studies. Other contributing factors to the significant share of this segment include the wide availability and cost-effectiveness of Jaffe's Kinetic Test Kits.

Insights on Sample:

Among the sample, blood samples dominate the Creatinine Assay Kits Market. This segment holds the largest market share due to the accessibility of blood samples. Blood is commonly used for creatinine testing because creatinine, a waste product of muscle metabolism, is released into the bloodstream and subsequently filtered by the kidneys. The concentration of creatinine in blood remains relatively stable and serves as an indicator of kidney function, specifically the glomerular filtration rate (GFR). However, the urine sample segment is experiencing rapid growth, driven by the increasing use of urine samples for creatinine measurements, particularly in the assessment of kidney function. Urine creatinine is often used to calculate creatinine clearance, an additional method for estimating GFR. However, it is important to note that urine creatinine assays are typically used in conjunction with blood creatinine measurements, further



establishing the dominance of blood samples in the sample segment.

Regional Insights:

The North America market is projected to hold a significant revenue share during the forecast period. This can be attributed to the increasing prevalence of renal failure and chronic kidney diseases, as well as advancements in creatinine testing methods and improved healthcare infrastructure in the region. Furthermore, favorable reimbursement policies are expected to further drive market growth. In 2022, the Asia Pacific market witnessed a rapid growth rate, fueled by major players implementing various strategies to expand their revenue opportunities and geographic presence. The market in the Asia Pacific region is experiencing rapid revenue growth due to factors such as growing awareness about creatinine testing methods, a rising geriatric population with chronic diseases like diabetes and kidney disorders, and increased research and development activities in the healthcare sector.

Key Market Players

Abbott Laboratories

Thermo Fisher Scientific

Merck KGaA

Quidel Corporation

Cell Biolabs, Inc.

Genway Biotech

Randox Laboratories Ltd.

ACON Laboratories

Nova Biomedical

Sysmex India Pvt. Ltd.



Report Scope:

In this report, the Global Creatinine Assay Market has been segmented into the following categories, in addition to the industry trends which have also been detailed below:

Creatinine Assay Market, By Test Type: Jaffe Kinetic Method **Enzymatic Method** Creatinine Assay Market, By Product: Reagents Kits Creatinine Assay Market, By Sample: Blood/Serum Urine Creatinine Assay Market, By End User: Hospitals Diagnostic Laboratories Creatinine Assay Market, By Region: North America **United States**

Canada

Mexico



| Europe | |
|----------------------|----------------|
| I | France |
| Į | United Kingdom |
| I | Italy |
| (| Germany |
| ; | Spain |
| Asia-Pacific | |
| (| China |
| 1 | India |
| , | Japan |
| , | Australia |
| ; | South Korea |
| South America | |
| I | Brazil |
| , | Argentina |
| (| Colombia |
| Middle East & Africa | |
| ; | South Africa |
| ; | Saudi Arabia |



UAE

Competitive Landscape

Company Profiles: Detailed analysis of the major companies present in the Global Creatinine Assay Market.

Available Customizations:

Global Creatinine Assay market report with the given market data, Tech Sci Research offers customizations according to a company's specific needs. The following customization options are available for the report:

Company Information

Detailed analysis and profiling of additional market players (up to five).



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