

U.S. Renal Biomarkers Market Size, Share & Trend Analysis Report By Biomarkers (Functional Biomarkers, Upregulated Proteins), By Diagnostic Technique (ELISA, Immunoassays, Clinical Chemistry Assays), By End-use (Hospitals & Clinics, Diagnostic Laboratories), And Segment Forecasts, 2025 - 2033

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Abstracts

The U.S. renal biomarkers market size was estimated at USD 592.95 million in 2024 and is projected to reach USD 1,207.75 million by 2033, growing at a CAGR of 8.4% from 2025 to 2033. The rising prevalence of kidney disease, particularly chronic kidney disease (CKD) and acute kidney injury (AKI) along with the urgent clinical need for earlier and more nuanced detection beyond conventional measures. CKD often remains asymptomatic until advanced stages, and biomarkers that can reveal subclinical pathology or early injury are of growing interest. In the U.S., an estimated 35.5 million adults have chronic kidney disease (CKD), and a significant number are unaware of their condition. Globally, CKD affects around 850 million people, which is approximately 9% of the adult population. A 2024 study projects that by 2032, nearly 125 million people across eight major countries will have advanced CKD, a 25% increase since 2022.

Approximately one-third of people 65 and older have chronic kidney disease (CKD), compared to about 12% of people 45 to 64 and only 6% of adults 18 to 44, according to data released by the CDC in 2024. The prevalence is slightly higher in women (14%), than in men (12%). Significant racial and ethnic disparities also exist: the highest prevalence is found among non-Hispanic Black adults (20%), followed by non-Hispanic Asian and Hispanic adults (14% each), and non-Hispanic White adults (12%). The data highlights the critical need for enhanced screening programs and early intervention

strategies.

The U.S. renal biomarkers market is growing due to the rising prevalence of CKD and increasing number of the laboratory automation, clear FDA pathways, and insurer willingness to reimburse novel tests that meet evidentiary thresholds. Test ordering frequency has increased, and protocols have been updated as a result of Medicare's Merit-based Incentive Payment System, which ties nephrology practice scores to annual albuminuria rates. The market is expanding as a result of the active development and commercialization of renal biomarker assays by major players such as Abbott Laboratories and bioMérieux SA. Recently, in August 2025, BioPorto and Roche Diagnostics collaboration: The ProNephro AKI test (based on NGAL biomarker) has become commercially available to U.S. labs via Roche's cobas c 501 analyzers. NGAL is a protein that indicates kidney cell damage and can detect injury earlier than standard tests such as serum creatinine. The test is cleared for pediatric use (ages 3 months to 21 years), helps identify moderate-to-severe acute kidney injury (AKI) within 48-72 hours, enabling earlier interventions.

Moreover, as per CDC data published in May 2024, CDC estimating that more than 1 in 7 adults-around 35.5 million people, or 14% of the adult population are affected in U.S. Alarmingly, CKD often goes undiagnosed: as many as 9 in 10 adults with CKD are unaware of their condition, and even among those with severe CKD, approximately one in three remain undiagnosed.

U.S. Renal Biomarkers Market Report Segmentation

This report forecasts revenue growth and provides an analysis of the latest trends in each of the sub-segments from 2021 to 2033. For this study, Grand View Research has segmented the U.S. Renal Biomarkers market based on biomarker, diagnostic technique/platform, and end-use:

Biomarkers Outlook (Revenue, USD Million, 2021 - 2033)

Functional Biomarkers

Serum Creatinine

Blood Urea Nitrogen (BUN)

Estimated Glomerular Filtration Rate (eGFR)

Upregulated Proteins

Kidney Injury Molecule-1 (KIM-1)

Neutrophil Gelatinase-Associated Lipocalin (NGAL)

Cystatin C

Interleukin-18 (IL-18)

Others

Other Novel Biomarkers

microRNA biomarkers

Proteomic/metabolomic markers

Diagnostic technique /Platform Outlook (Revenue, USD Million, 2021 - 2033)

Enzyme-Linked Immunosorbent Assay (ELISA)

Immunoassays

Clinical Chemistry Assays

Point-of-Care Testing (POCT) Devices

Molecular Diagnostics

Other Emerging Platforms

End-use Outlook (Revenue, USD Million, 2021 - 2033)

Hospitals & Clinics

Diagnostic Laboratories

Academic & Research Institutes

Pharmaceutical & Biotechnology Companies

Others

This report can be delivered to the clients within 2 Business Days

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