

U.S. CLIA Endocrine Testing Market Size, Share & Trends Analysis Report By Product (Kits & Reagents, Instruments), By Testing Type, By Clinical Setting (OBGYN Office, Fertility / IVF Clinics), And Segment Forecasts, 2026 - 2033

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Abstracts

U.S. CLIA Endocrine Testing Market Summary

The U.S. CLIA endocrine testing market size was estimated at USD 14.06 billion in 2025 and is projected to reach USD 34.38 billion by 2033, growing at a CAGR of 11.94% from 2026 to 2033. Market growth is supported by the increasing prevalence of chronic and hormonal disorders and the need for high sensitivity and analytical accuracy in hormone detection.

Advancements in automated CLIA platforms are enhancing diagnostic efficiency. Furthermore, regulatory compliance under the Clinical Laboratory Improvement Amendments ensures standardized testing quality, supporting consistent adoption of endocrine testing services in the U.S.

The rising burden of chronic and hormonal disorders is significantly increasing the demand for endocrine testing in the U.S. Conditions such as diabetes, thyroid dysfunction, and polycystic ovary syndrome (PCOS) are becoming more prevalent due to aging populations, sedentary lifestyles, obesity, and environmental factors. According to the report published by the World Health Organization in January 2026, PCOS affects approximately 10-13% of reproductive-age women globally, with nearly 70% of cases remaining undiagnosed, indicating a substantial gap in diagnostic testing. Moreover, the National Center for Biotechnology Information reports that at least 5% of adults in the U.S. are affected by endocrine disorders, including hypothyroidism, osteopenia, and

vitamin D deficiency. This growing clinical burden is driving consistent demand for advanced, high-sensitivity endocrine testing across CLIA-certified laboratories in the U.S.

Advancements in automated chemiluminescence immunoassay (CLIA) platforms are significantly improving the efficiency, scalability, and precision of endocrine testing in the U.S. Modern CLIA analyzers are designed for high-throughput processing, minimal manual intervention, and rapid turnaround times, enabling laboratories to handle large test volumes while reducing operational errors. These systems support automated sample handling, calibration, and result interpretation, which enhances reproducibility and consistency in hormone analysis. For instance, in March 2026, F. Hoffmann-La Roche Ltd. received a CLIA moderate-complexity classification from the U.S. Food and Drug Administration for its Ionify steroid assays integrated with the cobas Mass Spec solution, enabling routine clinical laboratories to perform highly accurate steroid hormone testing through automated, standardized workflows. These advancements are accelerating the adoption of high-throughput, automated endocrine testing solutions across U.S. CLIA-certified laboratories, supporting improved diagnostic efficiency and scalability.

Regulatory compliance under the Clinical Laboratory Improvement Amendments is supporting the growth of the U.S. CLIA endocrine testing industry by ensuring standardized testing quality, accuracy, and reliability across laboratories. These regulations mandate strict quality control, proficiency testing, and personnel standards, reducing diagnostic errors and improving clinical confidence in hormone test results. The classification of tests based on complexity also enables laboratories to expand service offerings while maintaining compliance. This structured framework encourages the adoption of advanced automated testing platforms. It promotes consistency in diagnostic practices, ultimately increasing test volumes and supporting the sustained expansion of endocrine testing services across the U.S.

The growth of large reference laboratories, combined with favorable reimbursement and insurance coverage, is supporting the expansion of the U.S. CLIA endocrine testing market. Major diagnostic laboratories are increasing capacity and adopting automation, enabling centralized testing models with higher throughput and faster turnaround times. This enhances operational efficiency and supports large-scale endocrine testing. In parallel, reimbursement policies in the U.S. encourage the use of diagnostic services by improving affordability and access. Although pricing pressures persist, consistent insurance coverage continues to sustain testing demand, contributing to steady market growth.

U.S. CLIA Endocrine Testing 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. CLIA endocrine testing market report based on product, testing type, and clinical setting:

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

Kits & Reagents

Instruments

Testing Type Outlook (Volume, Number of Tests; Revenue, USD Million, 2021 - 2033)

Thyroid Testing

TSH

Free T4 (fT4)

T4 (Total)

Free T3 (FT3)

T3 (Total)

Anti-TPO

Anti-Tg

Thyroglobulin (Tg)

T3 Resin Uptake

Hormone Testing

FSH

hCG

Testosterone

Progesterone

Prolactin

Estradiol E2

Luteinizing Hormone (LH)

Sex Hormone-Binding Globulin (SHBG)

DHEA-S (dehydroepiandrosterone sulfate)

Human growth hormone (HGH)

Anti-Müllerian Hormone (AMH)

Bone Health

Vitamin D

Parathyroid hormone (PTH)

Serum CTX (Carboxy-terminal collagen crosslinks)

NTx (N-telopeptide)

Osteocalcin

Alkaline phosphatase (ALP)

Clinical Setting Outlook (Volume, Number of Tests; Revenue, USD Million, 2021 - 2033)

OBGYN office

Fertility / IVF Clinics

Physician office labs (POLs)

Hospital Labs Small (500 beds)

Others

This report can be delivered to the clients within 3 Business Days

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