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Steroid Hormones, Nuclear Receptors And Coregulators

SAT015

Improving The Quality Of Disease Biomarker Measurements In Patient Care And Research-CDC's Clinical Standardization Programs

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High-quality disease biomarker tests are critical for the correct diagnosis and treatment of patients, accurate interpretation of research data, and effective use of research findings in health care. CDC's Clinical Standardization Programs (CDC CSP) assist researchers and laboratories with assessing and improving the analytical performance of biomarker tests performed in patient care, public health, and research. CDC CSP develops and applies reference methods, materials, and protocols to consistently calibrate biomarker tests across instruments and laboratories and to assess and improve other analytical performance characteristics, such as analytical specificity. CDC CSP works with test manufacturers and laboratories operating in-house developed tests to correctly calibrate tests. Additional programs help clinical and research laboratories monitor the accuracy and reliability of tests over time. Furthermore, CDC CSP collaborates with researchers on the development of reference intervals and on using new and emerging biomarkers in patient care and public health. CDC CSP provides comprehensive programs for traditional blood lipids, testosterone, estradiol, vitamin D, and free thyroxine. Programs for free testosterone, parathyroid hormones, apolipoproteins, and angiotensin peptides will be available soon. CDC CSP collaborated with members of the Partnership for the Accurate Testing of Hormones (PATH) and established reference intervals for testosterone in men. CDC CSP is currently working to develop reference intervals for testosterone in women and for estradiol in postmenopausal women. A CDC CSP interlaboratory study on free thyroxine measurements showed high variability in calibration accuracy among free thyroxine assays. CDC CSP is using its reference methods and materials to minimize this variability. It is anticipated that assay recalibration may change measurement values for some tests by up to 50%. CDC CSP is working with PATH and the International Federation for Clinical Chemistry and Laboratory Medicine (IFCC) to educate stakeholders about the upcoming change in free thyroxine measurements.

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