

PATH Fact Sheet: The Importance of Accurate Hormone Tests

WHAT ARE HORMONE ASSAYS?

Hormone assays are tests that doctors rely on when they need to measure patients' hormone levels to diagnose and treat a broad range of serious health conditions. These include: diabetes, pituitary disease, osteoporosis (weak bones), polycystic ovarian syndrome, menopause, infertility, diseases affecting growth, development and reproduction, and adrenal and thyroid disorders.

WHY IS STANDARDIZATION OF HORMONE ASSAYS IMPORTANT?

Though hormone assays are widely used by physicians, some current hormone tests are not sufficiently accurate or reliable, which makes diagnosis and management difficult.

Two laboratories using different tests to measure the same hormone level could get significantly different results for the same patient using the same sample. Inaccurate test results can lead to misdiagnoses or incorrect treatment. Different or wrong results can cause delayed diagnoses and treatment, and increased expense. Consequently, patients can suffer unnecessary and avoidable repeated tests and potential disease complications, fail to be treated appropriately, or undergo unnecessary treatment. Accurate hormone assays will lead to fewer medical errors, eliminate the need for costly repeat testing, and reduce unnecessary healthcare costs.

Inaccurate tests used in medical research make research findings uncertain and not repeatable. This makes it impossible for clinical practitioners to use research findings to make evidence-based clinical decisions. A result of non-standardized hormone assays is that criteria used to diagnose patients differ depending on which test is being used, leading to inconsistent patient care.

In addition, there is a general lack of awareness among physicians and other health care professionals of the poor quality of some hormone assays and its consequences. Insurance companies, health groups, and public payers (like Medicare) are unknowingly paying for inaccurate results.

WHY AREN'T ALL HORMONE ASSAYS STANDARDIZED NOW?

For tests approved by the FDA, programs exist which aim to demonstrate that tests done in laboratories are performing as expected. For most tests, these programs are based on how well different laboratories that run the same assay compare with each other; they do not, however, evaluate the accuracy of the test result. Going beyond traditional proficiency testing, the Centers for Disease Control and Prevention (CDC) has successfully standardized the tests for cholesterol and selected hormones such as testosterone,



estradiol, and vitamin D with the aim of ensuring that certified laboratories produce test results that are accurate and consistent. However, the CDC does not have the resources to increase its standardization activities to include other high priority hormones such as thyroid hormones, to help promote accuracy-based tests.

WHAT TO DO?

A focused effort aimed at laboratories, assay manufacturers, physicians, researchers, insurers, and patients is needed to:

1. Help standardize hormone tests for testosterone, estradiol, thyroid hormones, thyroid stimulating hormone, vitamin D, parathyroid hormone, aldosterone and insulin-like growth factor-1 (IGF-1).
2. Increase awareness of the public health benefits when standardized tests are utilized.

These goals can be achieved by:

- Ensuring that the CDC has the means to standardize high-priority hormone assays.
- Creating awareness and providing information to laboratories, physicians, researchers, payers, and patients to ensure standardized, accurate tests are being used.
 - Physicians should utilize standardized tests where available.
 - Insurers should support coverage of those tests that are standardized and should provide incentives to non-standardized tests to become standardized.
 - Clinical trials should require use of standardized tests only.
 - The public and patients should be aware of the importance of accurate hormone tests.
- Creating reference intervals and treatment goals based on standardized tests.
- Making use of accurate, standardized hormone tests a key health care quality measure.

WHO IS PATH?

The **Partnership for the Accurate Testing of Hormones** (PATH) was established in 2010 to address the need for better hormone tests for use in healthcare and research to enable better patient care. PATH currently comprises 20 clinical, medical and public health organizations. It provides technical and scientific support to the CDC Steroid Hormone Standardization Program including identifying high priority hormones in need for standardization. It conducts educational activities on hormone measurements for physicians and other health care providers, and advocates for the universal use of standardized hormone tests.