

CDC's Clinical Standardization Programs to improve accuracy and reliability of hormone tests

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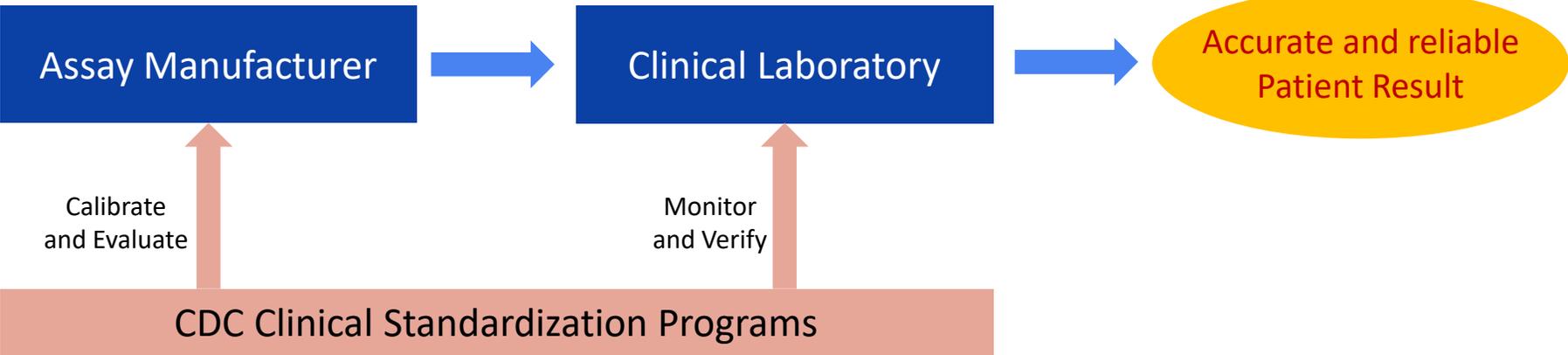
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Agency for Toxic Substances and Disease Registry
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CDC's Clinical Standardization Programs help laboratories and manufacturers to improve and maintain the accuracy and reliability of laboratory tests



CDC improves patient care and public health by ensuring laboratory measurements are accurate and reliable

Goal

Improve diagnosis, treatment, and prevention of selected diseases by standardizing clinical laboratory measurements

Objective

Create measurement results that are traceable to one accuracy basis and thus are comparable across methods, location, and over time

Standardization is a process in which the accuracy, and other relevant analytical performance parameters of an assay are improved and maintained to meet certain clinical needs

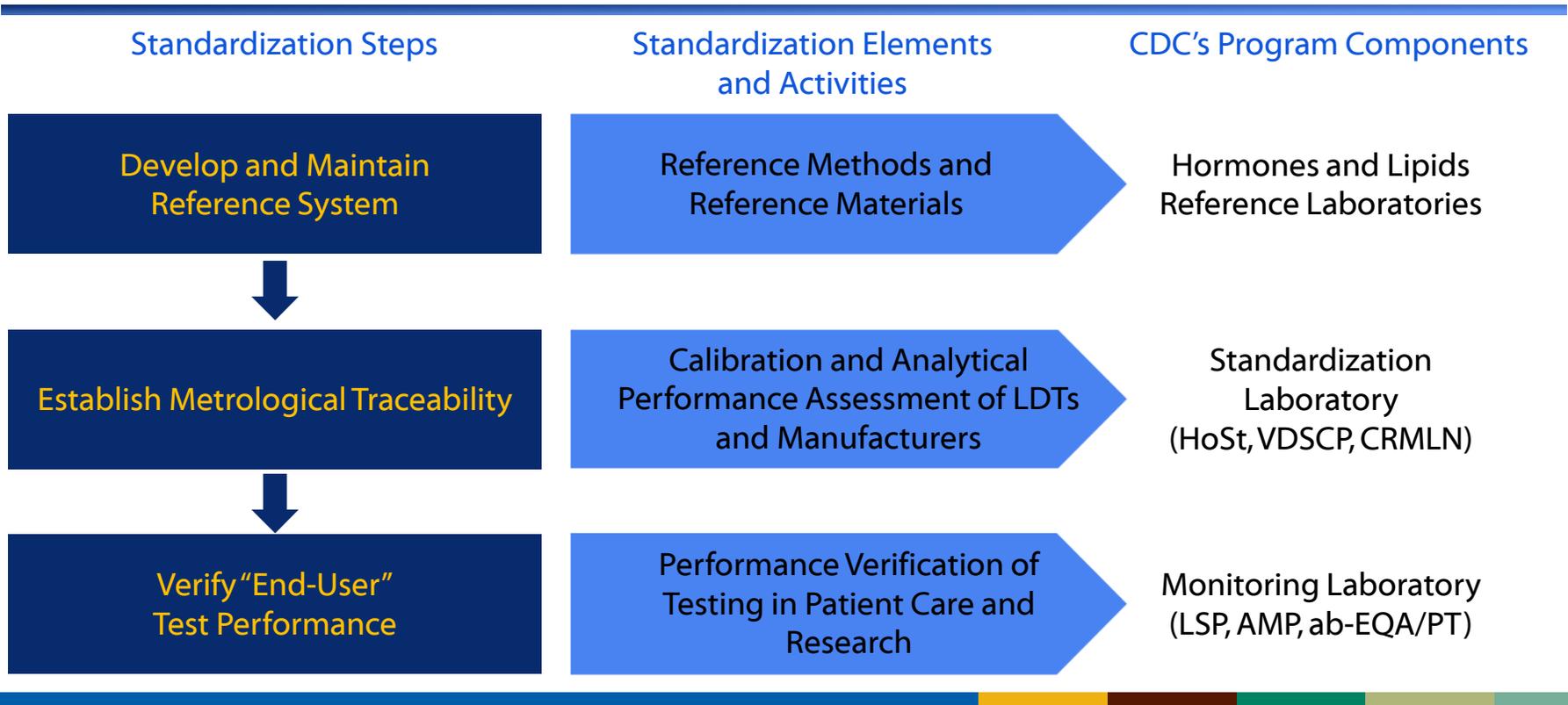
A standardized laboratory test has demonstrated through a thorough, independent assessment that its analytical performance meets relevant analytical performance goals



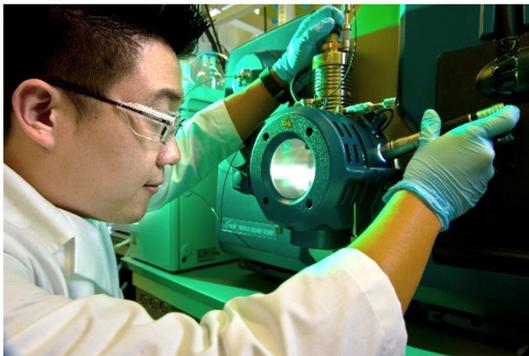
CDC's Clinical Standardization Programs improve and maintain accurate and reliable disease biomarker measurements for new and established assays

Program Name	Biomarker	Program Focus	Main Participants
Cholesterol Reference Method Laboratory Network (CRMLN)	Total Cholesterol, Total Glycerides, HDL-Cholesterol, LDL-Cholesterol	Improve and Maintain Accuracy and Reliability	Assay Manufacturers and Laboratories with LDTs
Hormones Standardization Program (HoSt)	Testosterone Estradiol Thyroxine (2019) Triiodothyronine (2019)		
Vitamin D Standardization Certification Program (VDSCP)	Total 25-hydroxyvitamin D		
Lipids Standardization Program (LSP)	Total Cholesterol, Total Glycerides, HDL-Cholesterol, Apo Lipoprotein A-I, Apo Lipoprotein B	Monitor Accuracy and Reliability During Routine Testing	Clinical and Research Laboratories
Accuracy-based Monitoring Program (AMP)	Testosterone Estradiol Total 25-hydroxyvitamin D		

CDC's Clinical Standardization Programs provide unique services at every step in the standardization process



CDC operates reference methods for key disease biomarkers



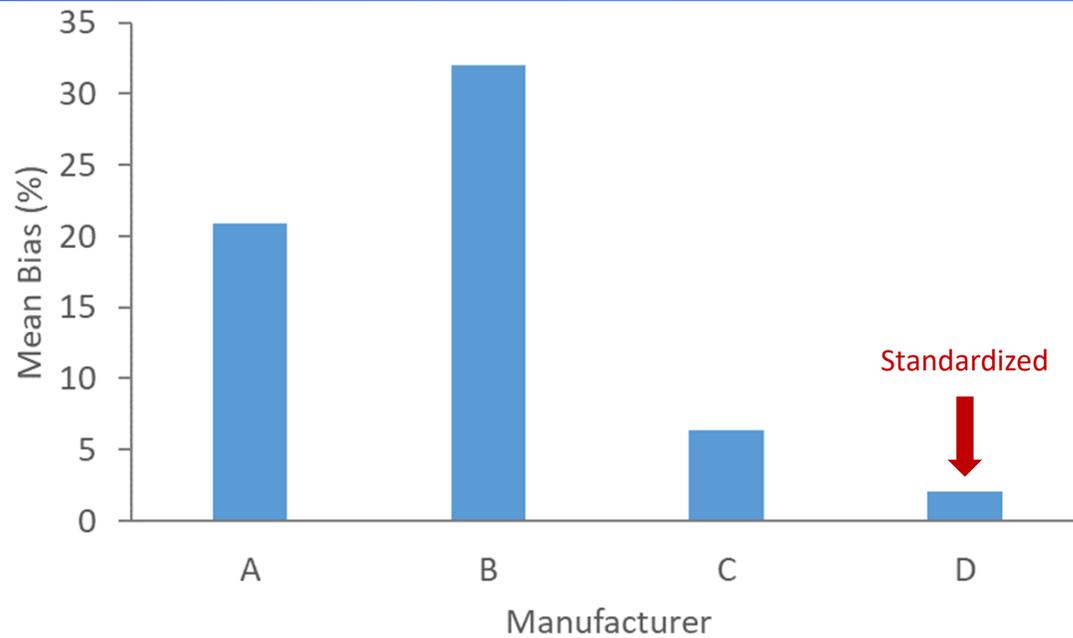
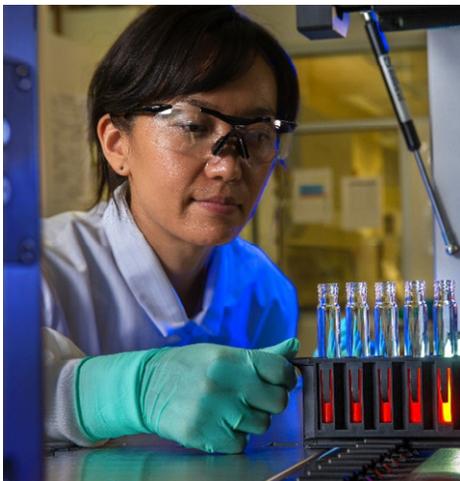
	Accuracy	Precision
Total Cholesterol	$\pm 1.0\%$	$\leq 1\%$
LDL-Cholesterol	$\leq 2\%$	$\leq 1.5\%$
HDL-Cholesterol	≤ 1.0 mg/dL	≤ 1 SD
Triglycerides	$\leq 2.5\%$	$\leq 2.5\%$
Total 25-Hydroxyvitamin D	$\pm 1.7\%$	$\leq 5.0\%$
Testosterone	$\pm 2.1\%$	$\leq 2.7\%$
Estradiol	$\pm 2.8\%$	$\leq 5.7\%$

CDC is developing new reference methods and harmonization programs

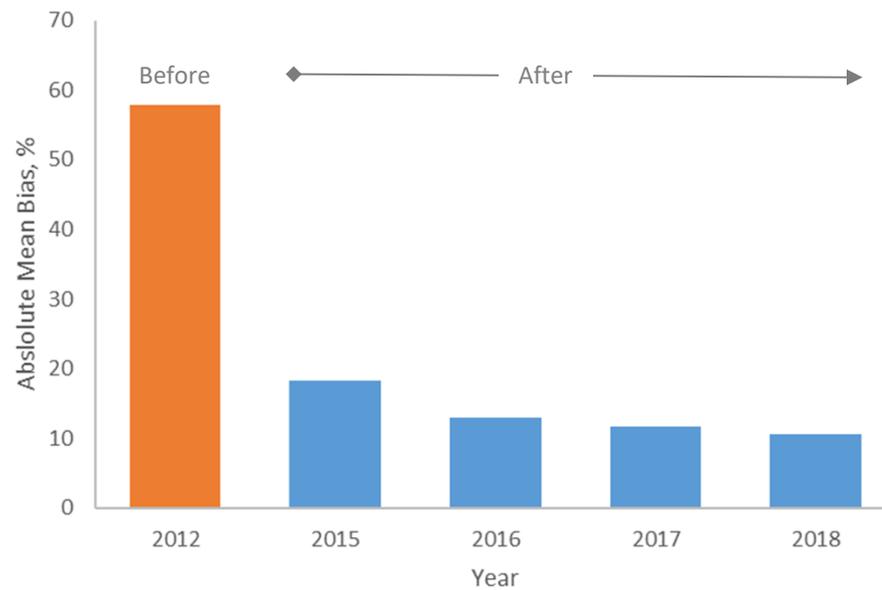
- Thyroid stimulating hormone
- Thyroid hormones
- Parathyroid hormones



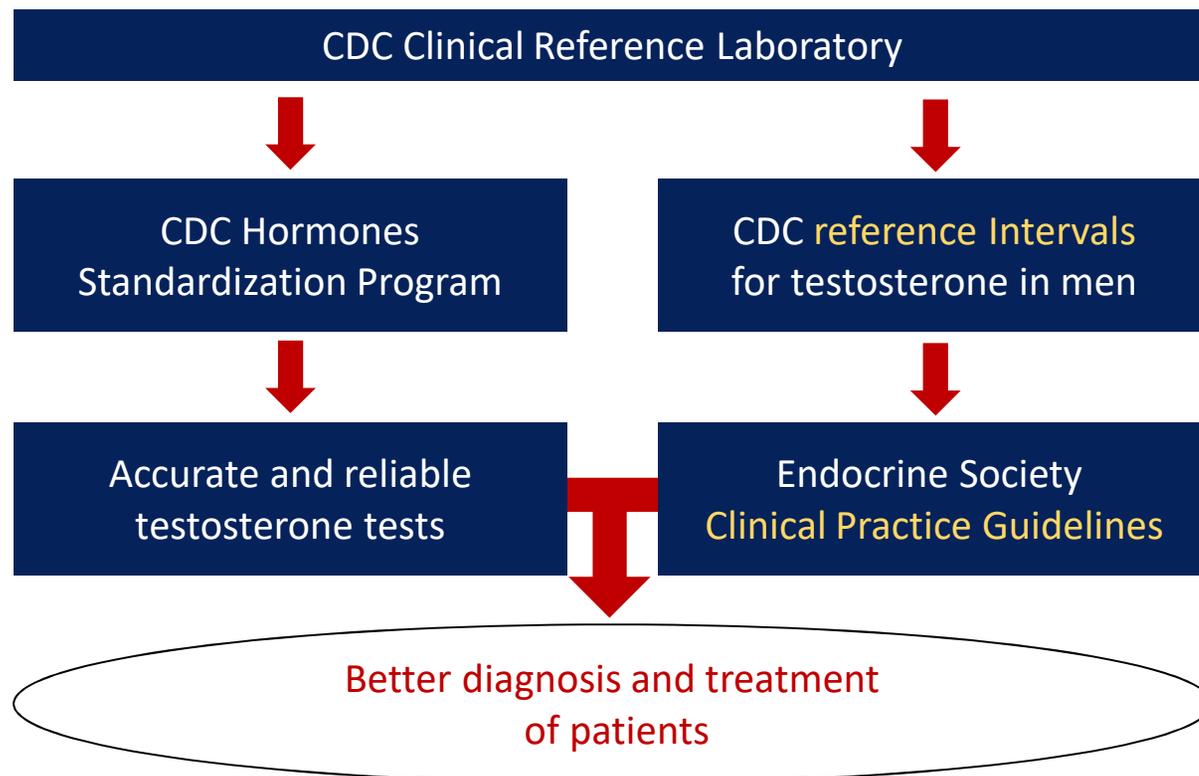
Testosterone tests standardized by CDC showed better accuracy than non-standardized tests in 2018



Estradiol measurements of participants in the CDC Hormones Standardization Program improve over time

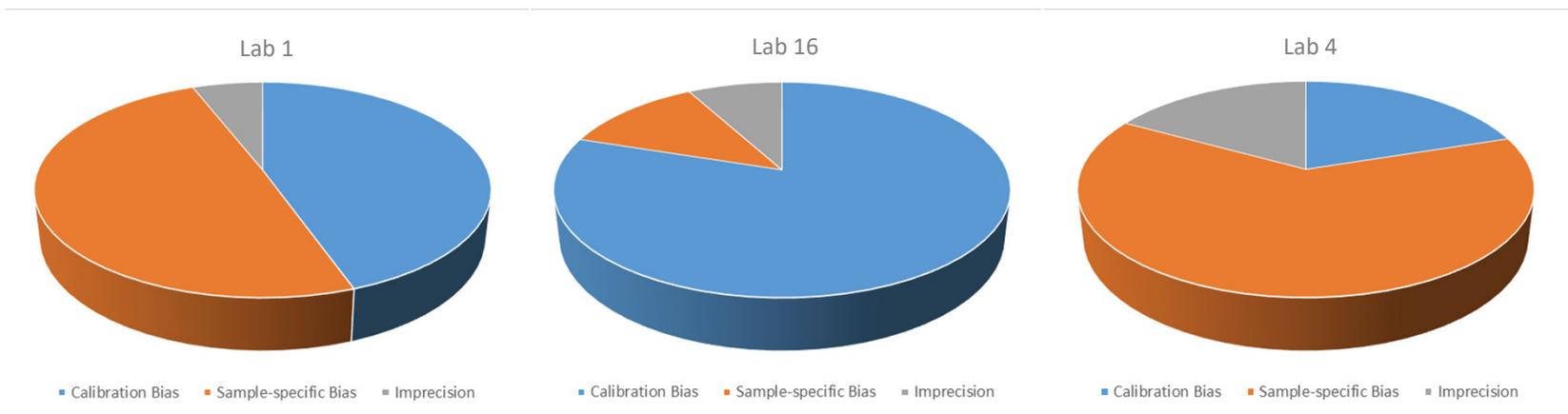


CDC Hormones Standardization Program for testosterone improved patient care through **standardization of tests** and development **standardized reference intervals**

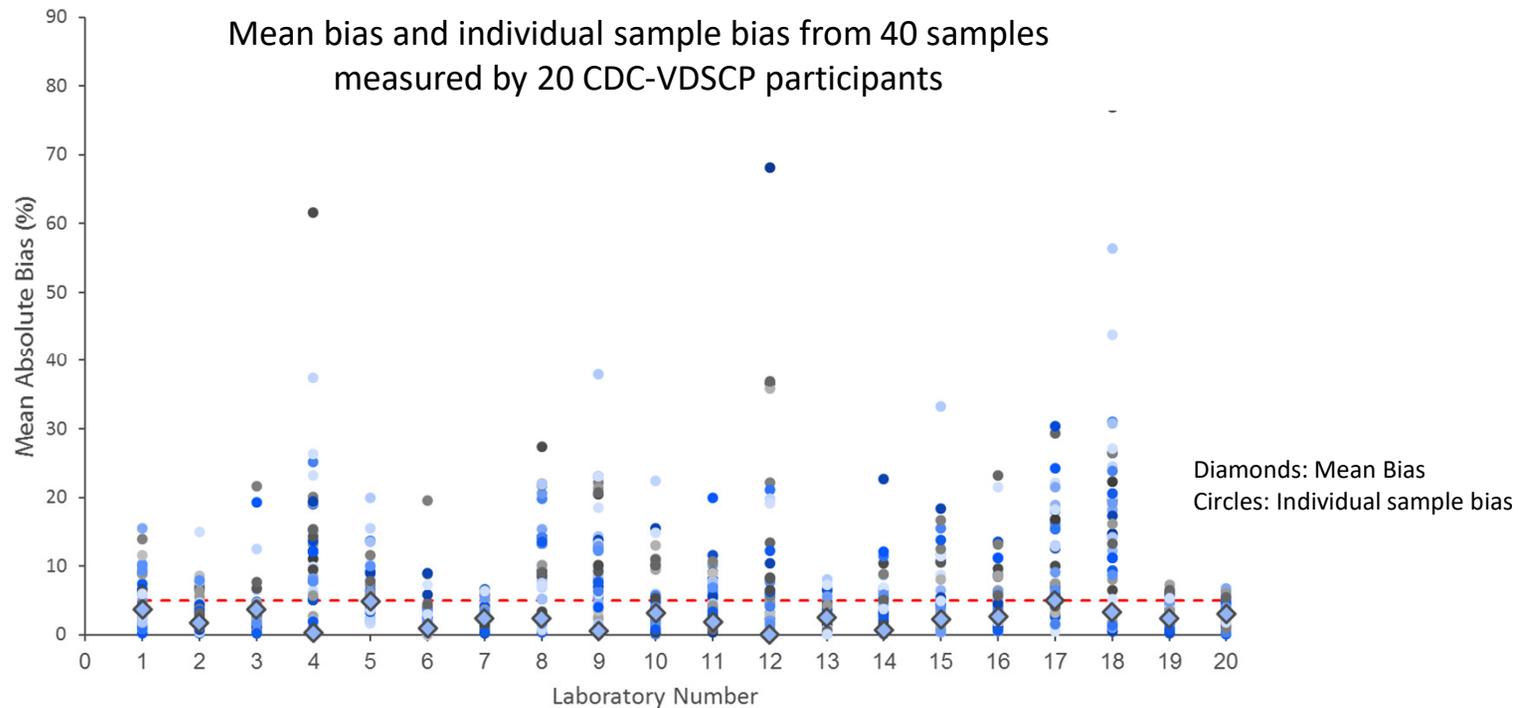


Mean bias (calibration bias) is not always a major contributor to measurement inaccuracy

Proportion of calibration bias, sample-specific effects, and imprecision contributing to inaccurate estradiol measurements in 3 participants of an interlaboratory comparison study

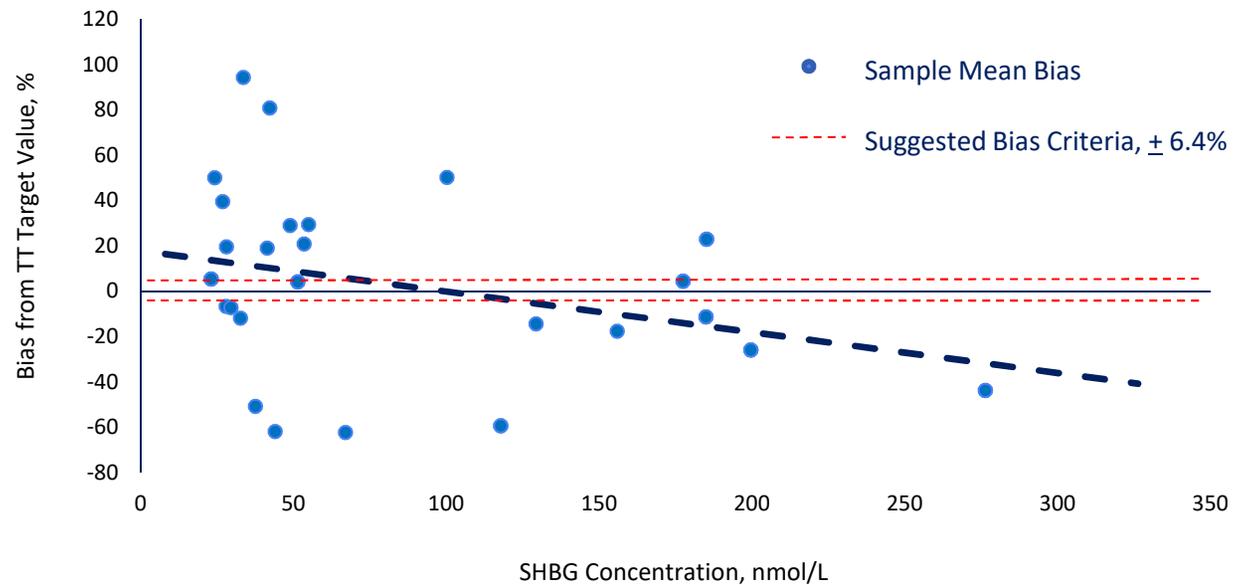


CDC's Clinical Standardization Programs use individual donor samples to better detect and address measurement bias caused by sample-specific factors



The bias of some testosterone assays appears to be associated with SHBG concentrations in the sample

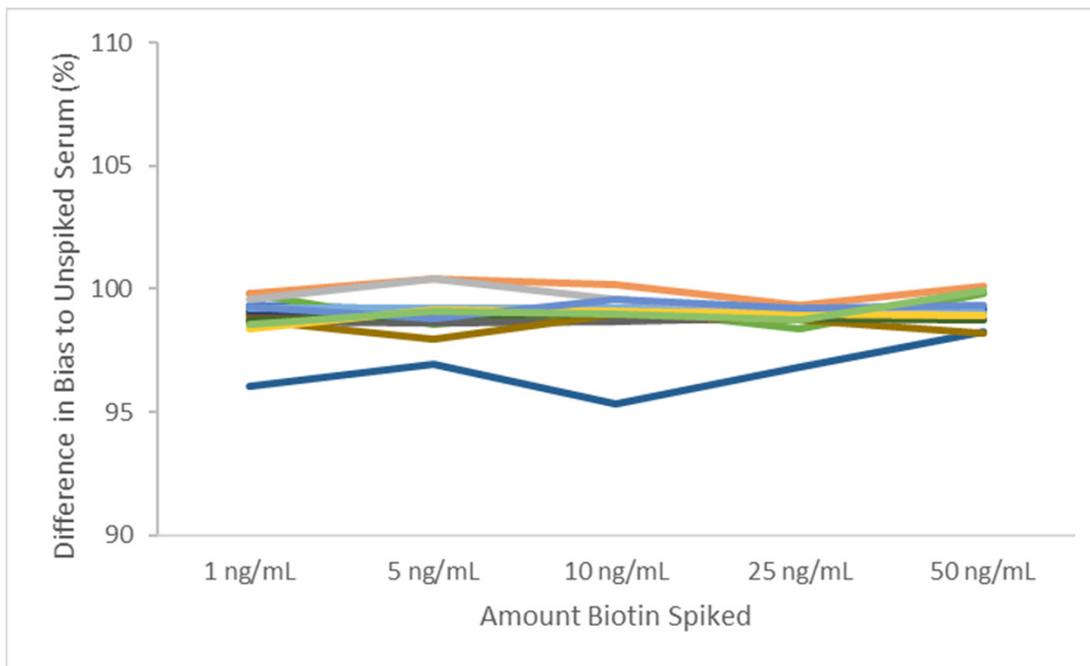
Individual sample mean bias by SHBG concentration observed with one participant



➤ CDC Hormone Standardization Program is screening all sera for SHBG

Initial study suggests that some assays have no association between moderately increased biotin levels and measurement bias

Percent difference in measurement bias between unspiked and biotin-spiked sera determined in 20 participants



➤ CDC Clinical Standardization Program is screening all sera for biotin

Sera used in CDC's Clinical Standardization Programs have biotin concentrations of < 1 ng/mL

**CDC is continuously addressing needs and requests from its stakeholders
by expanding its standardization program activities**

Reference methods and materials development	<ul style="list-style-type: none">• PTH• Free and total T4• Glucose• Creatinine
Standardization and harmonization programs in development	<ul style="list-style-type: none">• PTH• Thyroid function tests (Free and total T4 and TSH)• Free testosterone• Binding proteins
Accuracy-based Monitoring Program (AMP) for clinical and research laboratories	Available for vitamin D and testosterone



Partnership for the Accurate Testing of Hormones (PATH) supports and promotes standardized hormone tests for better healthcare and research

PATH is a stakeholder organization

- Consists of clinical, medical and public health organizations
- Promotes accurate tests and appropriate use of hormone tests through
 - Education
 - Advocacy
 - Technical Support

www.hormoneassays.org

PATH Members

American Association for Clinical Chemistry
American Society for Bone and Mineral Research
American Thyroid Association
American Urological Association
Androgen Excess/PCOS Society
Association of Public Health Laboratories
Centers for Disease Control and Prevention
College of American Pathologists
Endocrine Society
International Andrology Society
Laboratory Corporation of America
National Institute of Health/NICHD
North American Menopause Society
Pediatric Endocrine Society
Quest Diagnostics
Siemens Healthineers



Summary

CDC's Clinical Standardization Programs improve the accuracy and reliability of clinical tests and enables correct and consistent diagnosis, treatment and prevention of key chronic diseases

- show measurable improvements in accuracy with tests used in research and patient care
 - address calibration accuracy and sample-specific bias
 - provide new accuracy-based monitoring programs designed for clinical and research laboratories
 - expand to include new high priority analytes
- 

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CDC Standardization Team

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Organizations

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CDC Division of Cancer Prevention and Control
Partnership for the Accurate Testing of Hormones
American Association of Clinical Chemistry
The Endocrine Society
CDC Foundation

Thank you!

For further information, please contact
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