



NATIONAL ASSOCIATION OF
CHRONIC DISEASE DIRECTORS

Promoting Health. Preventing Disease.

CLINICAL STANDARDIZATION



Improving the diagnosis, detection, and treatment
of cardiovascular diseases through standardization

What is standardization?

ACCURATE, RELIABLE, AND PRECISE LABORATORY TESTING OVER TIME AND ACROSS METHODS

Standardization makes clinical tests accurate and comparable over time and across methodologies and laboratories. Laboratory tests are performed to assess patient health status or address a public health research question. Standardization can offer accurate and reliable laboratory testing for use in clinical diagnosis, treatment, and public health decisions.

Standardization minimizes variability in patient testing and clinical trial outcomes. The results from standardized tests are compared with established reference ranges and clinical decision points. Without standardization, the accuracy of test results for clinical care and clinical trials can be compromised.

Clinical standardization programs improve the diagnosis, treatment, and prevention of cardiovascular diseases through standardized laboratory testing.

Laboratory standardization programs assure the accuracy and reliability of the following tests for cardiovascular biomarkers such as:

- **Total cholesterol (TC)**
- **High-density lipoprotein cholesterol (HDL-C)**
- **Low-density lipoprotein cholesterol (LDL-C)**
- **Triglycerides (TG)**
- **Apolipoprotein B**

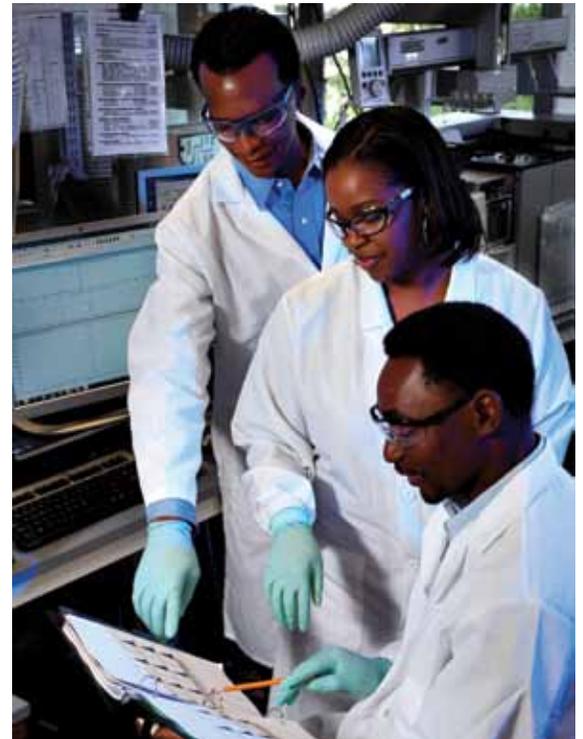


IMAGE CREDIT: CDC

STANDARDIZATION

COMPARABLE RESULTS

IMPROVED OUTCOMES



Standardization connects patient results, population data, and research findings, thus improving the diagnosis, treatment, and prevention of disease.

Standardized laboratory tests are needed to:

- Accurately diagnose patients and provide better patient care.
- Reliably monitor population health and assess effectiveness of public health activities.
- Inform clinical and public health decision-makers with data on accuracy of testing.

Who benefits from laboratory standardization?

DOCTORS, PUBLIC HEALTH OFFICIALS, RESEARCHERS, AND PATIENTS

Doctors

Doctors can diagnose and treat patients more effectively with accurate tests that allow the use of evidence-based clinical guidelines.

Researchers

Researchers can compile and compare testing data across laboratories and studies to formulate evidence-based patient guidelines and public health policies.

Public Health Officials

Public health officials can evaluate public health impact with reliable monitoring of biomarkers in populations over many years even if testing methods and equipment change.

Patients

Patients can be assured of the accuracy of their clinical tests, thus giving them confidence in disease prevention and treatment recommendations.

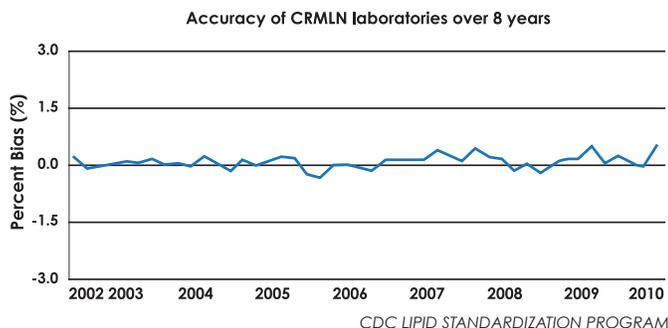


STANDARDIZED
MEASUREMENTS

Laboratory standardization creates and maintains accurate research, patient, and public health data that can be comparable. This allows for the rapid transfer of research findings to clinical and public health practice and facilitates the interpretation of public health data.

Standardization activities for tests used in patient care are performed by national and international organizations. As an example, standardization efforts by the Centers for Disease Control and Prevention (CDC) for cardiovascular biomarkers impact doctors, public health officials, researchers, and patients.

For Doctors



CDC's Cholesterol Reference Method Laboratory Network (CRMLN) assures accurate testing of an estimated 300 million cholesterol tests performed in patient care annually in the U.S. and enables doctors to better diagnose patients at risk of cardiovascular disease.

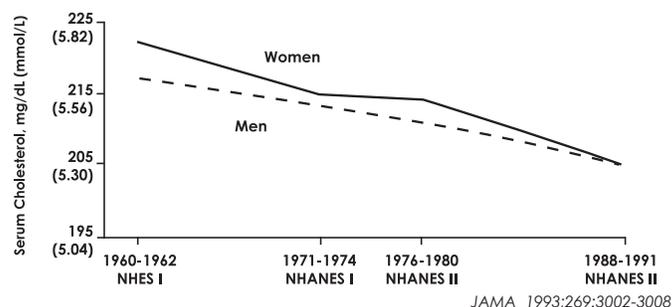
For Researchers

Classification	Cholesterol Levels in Blood
Desirable	<200 mg/dL / <5.17 mmol/L
Borderline High	200-239 mg/dL / 5.17-6.18 mmol/L
High	≥240 mg/dL / ≥6.20 mmol/L

JAMA 2001;285:2486-2497

Standardized clinical and epidemiology studies enable researchers to develop and implement evidence-based clinical guidelines. The National Institute of Health's National Cholesterol Education Program developed guidelines for identifying individuals with high blood cholesterol levels using studies from CDC's Lipid Standardization Program.

For Public Health Officials



Standardization programs continue to provide information to public health officials that support education programs and interventions focused on preventing heart disease. CDC's Lipid Standardization Programs enabled the monitoring of the continuous decline in total cholesterol levels in the U.S., demonstrating the success of these public health activities.

For Patients



Prev Chronic Dis 2011;8(6):A136

Reliable testing and treatments help increase screening rates and public awareness. An economic analysis of CDC's Lipid Standardization Program (LSP) and Cholesterol Reference Method Laboratory Network (CRMLN) found that LSP and CRMLN have prevented more than 340 thousand deaths since their inception and resulted in annual estimated health care savings of \$1.53 billion and about 13,500 life-years gained annually.

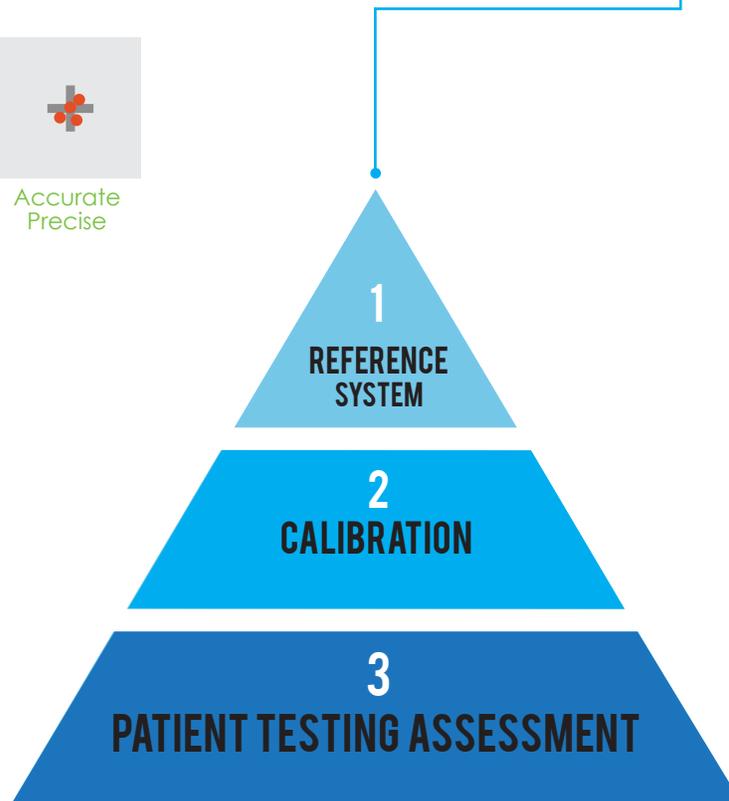
For more information on CDC's clinical standardization programs: www.cdc.gov/labstandards

How does standardization work?

THE THREE STEPS FOR RELIABLE STANDARDIZATION

The two most important characteristics of a good clinical chemistry test are **accuracy** and **precision**.

Both are achieved by making patient measurements **traceable** to one common reference system.



THE THREE STEP STANDARDIZATION PROCESS

CDC uses a three step standardization process. CDC's standardization program for cardiovascular biomarkers provides one example of how this process works.

1

REFERENCE SYSTEM

In the first standardization step, a system consisting of reference methods and reference materials is established.



CDC's Cholesterol Reference Laboratory produces highly accurate and precise reference methods for TC, HDL-C, LDL-C and TG. These methods are traceable to the standards created by the National Institute of Standards and Technology. CDC also maintains a Cholesterol Reference Method Laboratory Network, which is an international network of reference laboratories that are calibrated and monitored by CDC.

CDC and CRMLN laboratories use these reference methods to assign concentrations to blood samples used for calibration and verification.

2

CALIBRATION

In the second standardization step, clinical tests are calibrated using the blood samples evaluated in the first standardization step.



CRMLN laboratories calibrate test manufacturers and clinical laboratories. They also assist manufacturers and laboratories in improving test performance, so that clinical tests meet the accuracy and precision needed in patient care and public health.

Participants that meet performance goals are certified as standardized.

3

PATIENT TESTING ASSESSMENT

In the third standardization step, the accuracy and precision of patient testing is monitored to assess the calibration activities performed in step two.



CDC monitors testing performed in patients enrolled in epidemiological studies and clinical trials through their Lipid Standardization Programs. By collaborating with organizations such as the College of American Pathologists and other proficiency testing programs, CDC can monitor testing performed in patient care.

Services

TO LABORATORIES, TEST MANUFACTURERS, RESEARCHERS, AND DOCTORS

Standardization programs, such as the CDC program for cardiovascular biomarkers, provide services to laboratories, test manufacturers, researchers, and doctors in all three steps of the standardization process.

1

REFERENCE SYSTEM

- Assign target values to serum-based materials for use as calibrators and controls.
- Aid laboratories and test manufacturers in achieving accurate and precise measurements.
- Perform research to identify and improve problems in clinical testing measurements.

2

CALIBRATION

- Assure the accuracy and precision of clinical tests.
- Provide materials and technical assistance with test calibration.
- Certify tests that meet performance goals needed for optimal patient care.

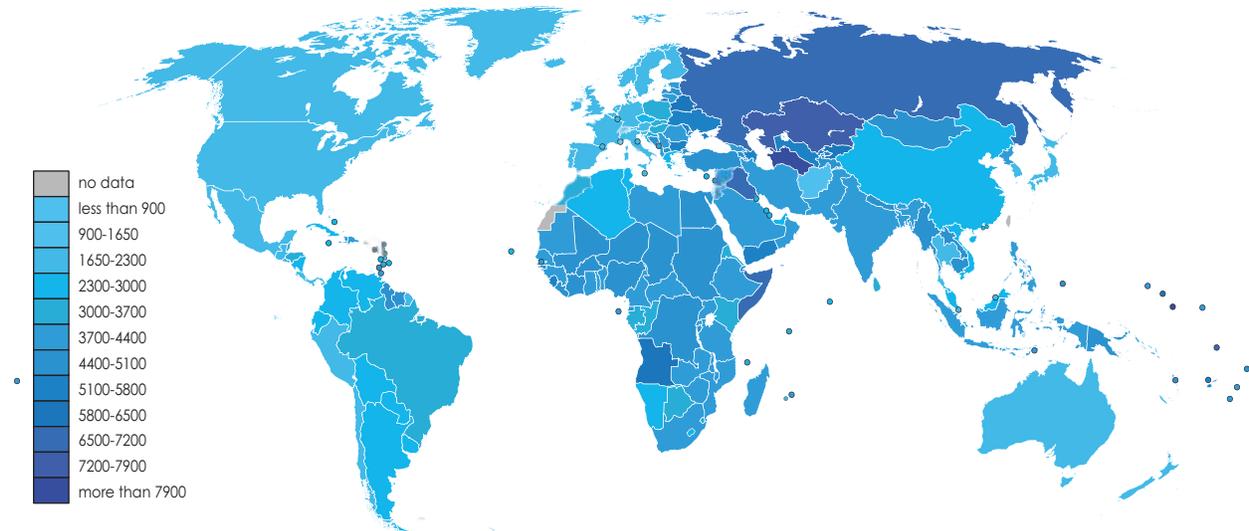
3

PATIENT TESTING ASSESSMENT

- Provide accuracy-based control blood samples to research laboratories, monitor and certify the accuracy and precision of measurements performed in clinical trials and other research studies.
- Assign target values to proficiency testing and external quality assurance programs, enabling clinical laboratories the ability to assess their measurement accuracy.
- Conduct focused studies to assess test performance and evaluate serum materials for their suitability as calibrator and control.

Cardiovascular diseases are a global problem. Clinical standardization is important for patient care around the world and involves collaboration with national and international partners to help improve the diagnosis, treatment, and prevention of cardiovascular diseases. Lipid Standardization Program partners include the National Institute for Standards and Technology (NIST), the World Health Organization (WHO), the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC), the Joint Committee for Traceability in Laboratory Medicine (JCTLM), the American Association of Clinical Chemistry (AACC), and other professional organizations.

Global disease burden due to cardiovascular disease



Age-standardized disability-adjusted life year (DALY) rates from cardiovascular diseases by country (per 100,000 inhabitants). The disability-adjusted life year (DALY) is a measure of overall disease burden and one DALY represents the loss of one year of healthy life.

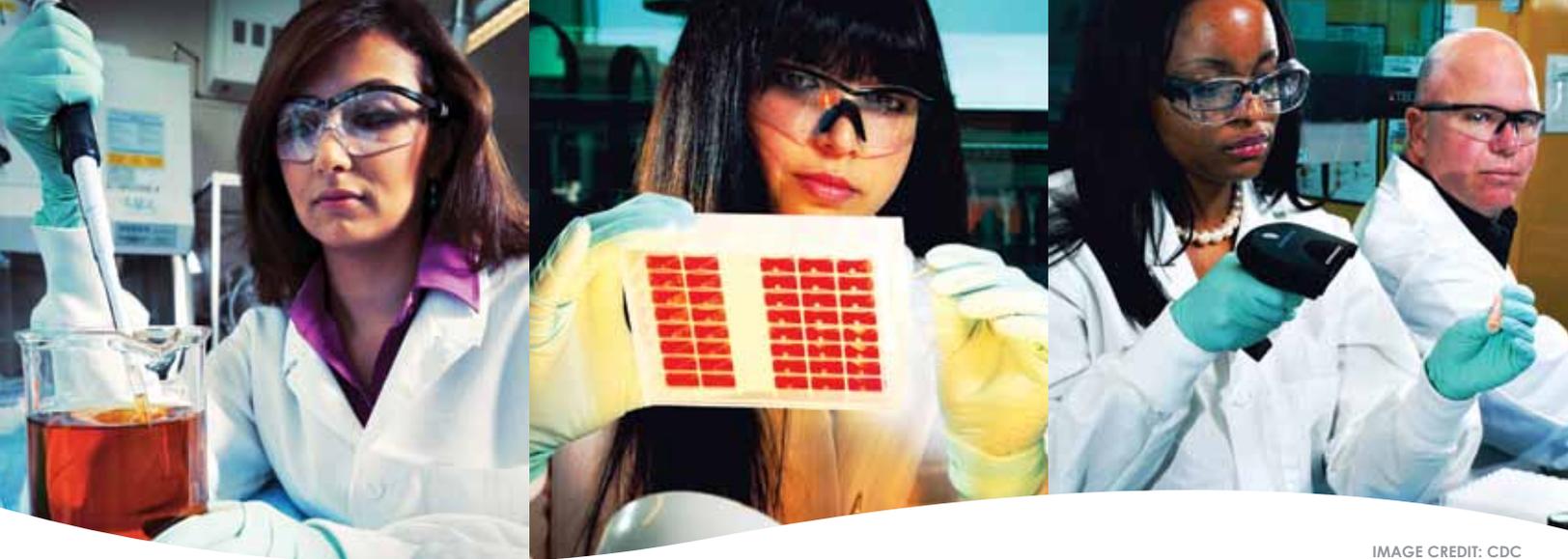


IMAGE CREDIT: CDC

ADDITIONAL RESOURCES:

The American Association of Clinical Chemistry (AACC)

www.aacc.org

Centers for Disease Control and Prevention (CDC)

www.cdc.gov

The International Federation of Clinical Chemistry and Laboratory Medicine (IFCC)

www.ifcc.org

The Joint Committee for Traceability in Laboratory Medicine (JCTLM)

www.bipm.org/en/committees/jc/jctlm/

National Institute for Standards and Technology (NIST)

www.nist.gov

The World Health Organization (WHO)

www.who.int



ABOUT NACDD

The National Association of Chronic Disease Directors (NACDD), is a non-profit public health organization committed to serving the chronic disease program directors of each state and U.S. jurisdiction. Since its founding in 1988, NACDD has been a national leader in mobilizing efforts to reduce chronic diseases and the associated risk factors through state and community-based prevention strategies.

NACDD supports the standardization efforts of CDC's Clinical Chemistry Branch, Division of Laboratory Sciences. Without standardization of cardiovascular and other chronic disease biomarkers, our partner state public health agencies could not be assured of the accuracy of the epidemiological and clinical data they rely on to plan and implement state-based chronic disease prevention and control programs and policies.

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For more information on NACDD's role in support of clinical standardization:
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