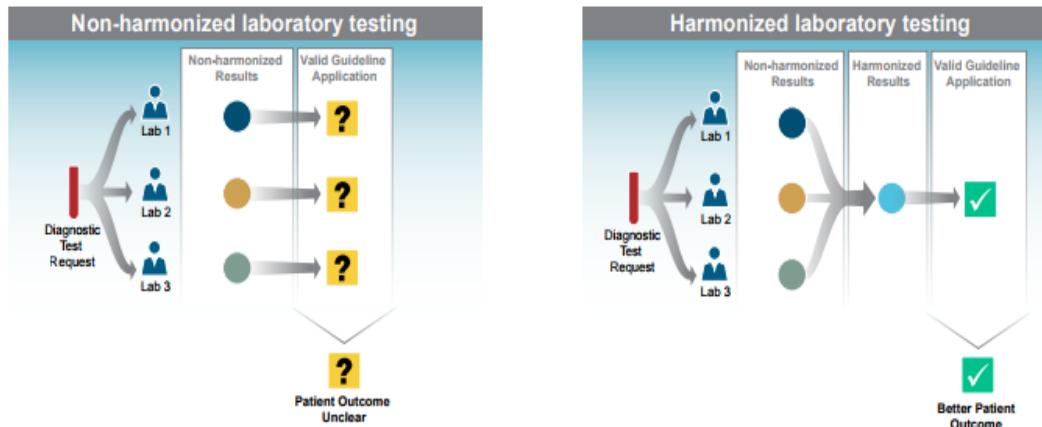


The Need to Harmonize Clinical Laboratory Test Results

Laboratory test results are a critical component of patient care. These values help physicians diagnose disease and are critical to developing clinical guidelines that direct treatment options and are instrumental in ongoing efforts to improve and measure the quality of patient care. Most tests report a numeric value for healthcare providers to interpret and the range of numbers reported for a test for a certain condition may vary depending on the method used.

Different test methods, however, may report different numeric values for the same condition. Although these test results may be accurate within the context of its own method, this variation can create confusion for physicians and patients. Clinical laboratory test results need to be harmonized so that healthcare providers and the public receive the same numeric result regardless of the method or instrument used or the setting where it was performed.



Harmonized test results ensure that clinical guidelines based on the results of laboratory tests assure more reliable diagnoses and prevent treatment errors. In addition, harmonized clinical laboratory test results may prevent unnecessary — and expensive — follow-up diagnostic procedures and treatments that could arise due to misinterpretation of results.

AACC and its partners call on Congress to provide \$9.2 million for harmonization activities directed by the Environmental Health Laboratory in fiscal year (FY) 2021.

Congress has demonstrated its support for this effort by providing CDC with \$2 million annually for harmonizing test results since 2018. This funding has given the agency needed resources to advance harmonization for select hormone tests that will improve diagnosis and treatment for diseases such as hypothyroidism, chronic kidney disease, and osteoporosis.

The Trump Administration is recommending \$7 million for CDC's harmonization efforts in the Department of Health and Human Services Budget in the FY 2021 budget, \$5 million above FY 2020 enacted levels, which will permit CDC to continue “*delivering the unique diagnostic methods, profiles of measurements, and measurement quality needed for public health decisions.*”

HARMONIZATION PARTNERS

- American Association for Clinical Chemistry
- American Clinical Laboratory Association
- American Medical Technologists
- American Society for Clinical Laboratory Science
- American Society for Clinical Pathology
- American Urological Association
- ARUP Laboratories
- Association of Public Health Laboratories
- Clinical Laboratory Management Association
- COLA
- College of American Pathologists
- Endocrine Society
- Laboratory Corporation of America Holdings
- Mayo Medical Laboratories
- PCOS Challenge: The National Polycystic Ovary Syndrome Association
- Pediatric Endocrine Society
- Quest Diagnostics
- Roche Diagnostics
- Siemens Healthineers
- Thermo Fisher Scientific