

White Paper Summary

Harmonizing Clinical Laboratory Test Results

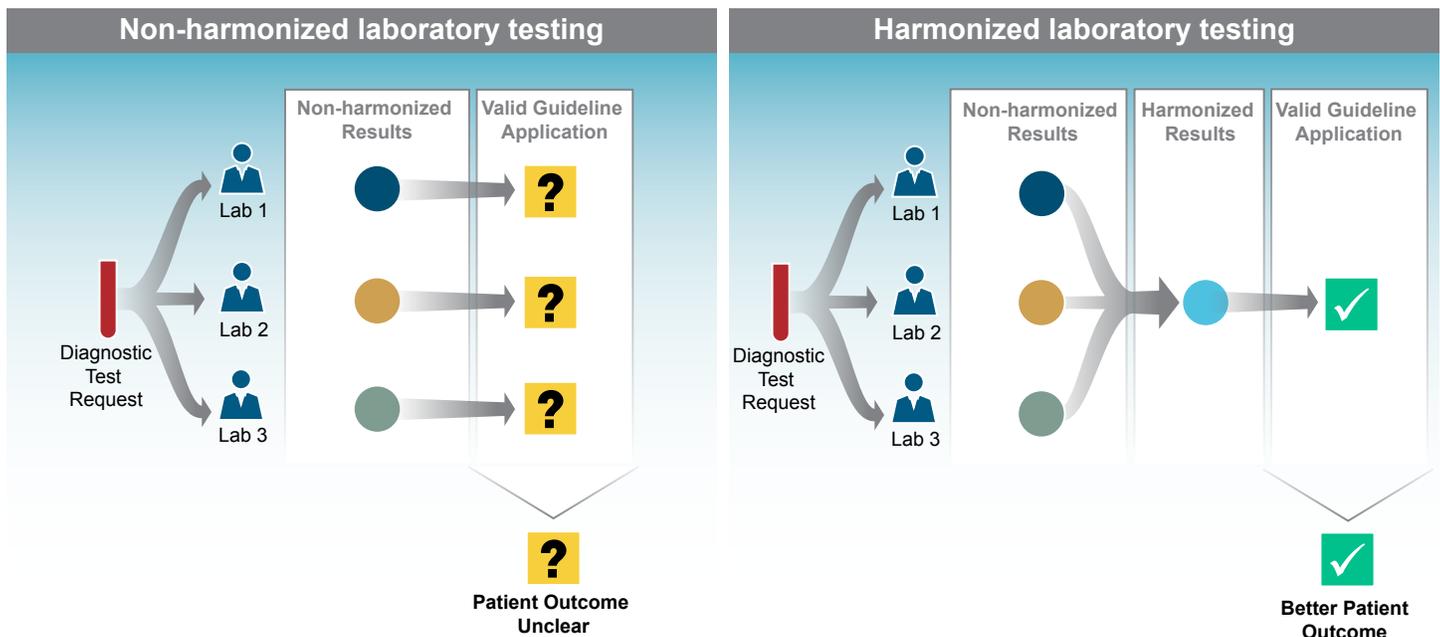
To read the full report go to: https://www.aacc.org/~media/files/harmonization_white_paper_july2015.pdf

The Problem: Some Lab Tests Lack a Gold Standard, and Results Vary from Lab to Lab

AACC urges Congress to appropriate funding for CDC in fiscal year 2017, and in subsequent years, to initiate and complete the studies needed to harmonize clinical laboratory tests results.

When a patient enters an emergency room, visits the doctor's office, or spends time in a hospital, nurses and doctors depend on lab tests to provide patient care. Whether it is an emergency like a heart attack, an infectious disease such as HIV, or cancer, accurate laboratory tests give healthcare professionals vital insights, so patients get the care they need.

While most laboratory tests are very reliable, there is not yet a gold standard that physicians, scientists, and clinical laboratory experts can agree upon for many tests. Unfortunately, this means that a test result at one hospital may have a significantly different answer compared to another hospital or reference lab—even in the same city. Experts call this a lack of harmonization. A test that is harmonized provides the same results regardless of the test manufacturer or lab.



How Patients and Providers Are Affected

When laboratory tests are not harmonized, the entire continuum of patient care can be affected in profound—but not always obvious—ways. For example, as medicine moves toward evidence-based guidelines as a way to ensure the best care for the population, often these guidelines are anchored in lab test results. However, if the test used in a guideline is not harmonized, test results can mislead physicians and defeat the purpose of following the guideline. Other critical benefits of harmonized tests include:

- **Fewer medical errors:** Harmonized laboratory tests allow more accurate decision making by physicians, reducing diagnostic and treatment errors that result from too much variation in test results.
- **Lower healthcare costs:** False-positive or false-negative results from non-harmonized clinical laboratory tests can lead to unnecessary follow-up diagnostic procedures and treatments, adding unnecessary costs to patient care. During treatment, variations in lab results from non-harmonized tests can lead to unnecessary or even harmful changes in treatment regimens.

What Laboratory Experts Are Doing

The laboratory community has already teamed up with the public health and medical communities to harmonize some critical tests, like cholesterol for heart disease and hemoglobin A1c for diabetes. AACC recommends that similar efforts be undertaken to harmonize other lab tests as well.

What Congress Recommends

On December 14, 2014, the House and Senate passed, and the President signed into law, the Consolidated and Furthering Continuing Appropriations Act of 2015. In the accompanying report language, the two chambers identified harmonizing of clinical laboratory test results as a key priority, stating:

“Laboratory professionals use a variety of test methods to obtain accurate and informative results to diagnose and treat patients, which may result in the reporting of different numeric values for the same test. CDC is urged to partner with the private sector in “harmonizing” clinical laboratory test results.”

The Next Step

AACC has formed a consortium of domestic and international partners to identify those clinical laboratory tests that are most appropriate for harmonization. CDC has a long history of developing uniform clinical laboratory test results and the reference materials used by medical device manufacturers to calibrate their devices to report uniform results. AACC urges Congress to appropriate funding for CDC in fiscal year 2017, and in subsequent years, to initiate and complete the studies needed to harmonize clinical laboratory tests results.