OVERSIGHT OF LABORATORY-DEVELOPED TESTS

What are the principles of the CAP’s policy on laboratory-developed tests (LDTs)?
The CAP’s longstanding principles for LDT oversight are:
• Ensure quality laboratory testing for patients.
• Allow for innovation in laboratory testing.
• Prevent undue administrative or regulatory burdens on laboratories.

What LDT oversight elements should Congress move forward?
The CAP’s policy on LDT oversight includes a tiered risk-based approach that allows for
evaluation of patient risk based on a laboratory’s claims for the test and potential harm of
an incorrect or misinterpreted test. Legislation also should include a grandfather
 provision and encourage coordination between federal agencies to avoid duplicative and
unduly burdensome requirements on laboratories.

How are LDTs currently regulated?
Current oversight requirements governing LDTs are the laboratory requirements
prescribed in CLIA. The FDA claims jurisdiction for the oversight of LDTs and exercises
an enforcement discretion policy at this time. The FDA has not finalized a plan to regulate
LDTs but defers to Congress to draft legislation to address this issue.

How should Congress legislate on the oversight of LDTs?
A legislative plan for LDTs must focus on protecting patients and providing access to
safe diagnostic tests with an oversight framework that is the least burdensome for
laboratories. Extraneous provisions included in legislation interfere with goals of ensuring
quality tests for patients.

What was the CAP’s position on the Diagnostic Accuracy and Innovation Act
(DAIA)?
The CAP opposed the DAIA legislation because it included provisions irrelevant to LDT
oversight and it utilized a regulatory structure that was overly complex. DAIA sought to
open CLIA and subject laboratories to regulations and scrutiny that would stifle
innovation of tests, including those at the lowest level of risk. For smaller and rural
laboratories, DAIA sought to create another layer of regulatory complexity and burden for
laboratories that still need to operate under current CLIA requirements.

What is the CAP’s position on the Verifying Accurate Leading-edge IVCT
Development Act (VALID Act)?
Compared to the DAIA bill, the draft VALID Act omits extraneous provisions to reopen
CLIA and focuses on the oversight of LDTs. Excluding extraneous CLIA provisions from
the VALID Act is a positive step forward. Although the VALID Act takes a focused and material approach to LDTs, the CAP is still concerned with certain aspects of the bill and provided its comments to the bill’s sponsors in February 2019. The CAP seeks to engage with the legislative sponsors to discuss these provisions and address concerns.

**What specific concerns does the CAP have with the VALID Act?**
The CAP is seeking clarification on certain aspects of the VALID Act. For example, the CAP is concerned with quality system requirements, which appear to be duplicative, costly, and burdensome because laboratories would need to implement new processes and procedures as well as hire additional staff. The CAP also questions application of a precertification program that is narrowly focused on low-risk tests and would be applicable to a relatively small number of tests. By broadening precertification, the program would be applicable to a larger number of tests and would further reduce regulatory burden.

**What are the positive aspects of the VALID Act?**
The VALID Act provides a better foundation for any future legislative proposal since its focus remains on LDT oversight rather than extraneous CLIA modifications. The VALID Act leverages existing processes, which may help mitigate cost and reduce burdens for laboratories when implementing an oversight framework. The CAP also appreciates that the VALID Act will not attempt to regulate the practice of medicine.

**Will the FDA attempt to regulate LDTs without congressional action?**
No. The FDA has deferred to Congress. In January 2017, the FDA issued a [discussion paper](https://www.fda.gov/downloads/Drugs/ScienceResearch/ucm559462.pdf) on LDTs to advance the public discussion and spur further dialogue on oversight of LDTs.

**Should the FDA have oversight of LDTs?**
During the Obama and Trump administrations, FDA jurisdiction regarding regulation of LDTs has been clearly outlined in the FDA oversight proposals and communications – including in draft LDT guidance (2014) and a discussion paper (2017). With the current administration deferring to Congress, the CAP advocates for the government to minimize burden on laboratories. This can be achieved through coordination between the FDA and the CMS to eliminate duplicative requirements.

**Should oversight of LDTs go through the rulemaking process?**
With our field evolving quickly, the CAP supports an exception to the Administrative Procedures Act so regulatory guidance can be utilized for an LDT oversight framework instead of the traditional rulemaking process. We believe use of the rulemaking process will stifle innovation and lead to rigid regulatory constraints in a time of rapid technology development and evidence generation.