

# CAPITOL STREET

February 28, 2024

## Diagnostics Update

Downclassification, LDT Final Rules, MoIDX Oversees Proteomic Tests

Relevant Companies



### »» Our Take & Next Up

**FDA is scheduled to release the final laboratory developed test (LDT) regulations in April as FDA&CMS double down on the pathway, and down classify up to 50% of high risk (class III) to moderate risk (class II).** The FDA may be delayed with the pending April final LDT rule timeline, and partial/potential government shutdown does not help matters. We view the down-classification as a FDA resource issue, but labs should be aware of the still-onerous 510(k) de novo pathway (versus PMA) potentially taking years & millions of dollars (lack of a predicate device). *Capitol Street participated in a Gilmartin IR webinar event yesterday ([here](#)) and our policy thoughts can be found below.*

### »» Key Points

**As a reminder, in January 2024, FDA & CMS doubled down on the need for LDT regulation.** Leaders of both agencies issued a statement dismissing CLIA as the right approach and re-committed to a proposal to have a 4-year phase of LDT under the medical device pathway. Our analysis is [here](#). We expect litigation over the LDT pathway by industry groups following any finalized guidance, which will only further slow implementation, and provide the potential for the pathway to come right back to Congress again.

**The FDA is preparing for the LDT workload and staffing shortcomings through declassifying certain high risk in-vitro diagnostic tests.** Tests that will be reclassified include companion diagnostics (oncology), infectious disease tests and pharmacogenomic tests. These tests will go from class III (high risk) into class II (moderate risk) and will no longer be required to go through the premarket approval (PMA) pathway, the most stringent type of FDA medical device review. However, the regulatory burden remains for tests as laboratories will still need to use the 510(k) de novo pathway given the lack of a predicate device. A CDRH leader at a Friends Of Cancer Research meeting publicly estimated that 50% of high-risk tests will be reclassified as moderate risk.

**FDA's proposed 4-year phase of LDT in pathway is due in April (delay would not be surprising).** In September 2023, FDA released proposed guidance on how they plan to end general enforcement discretion for laboratory developed tests (LDTs) [here](#).

- The general enforcement discretion approach plans to be phased-out during a 4-year period for all LDTs and instead be replaced with regulatory oversight under the agency's medical device authorities.
- FDA plans to regulate low-risk tests (class I devices), tests currently on the market, and tests for rare diseases under the same framework.
- Blood donor screening tests, tests intended for "emergencies," and direct-to-consumer (DTC) tests are exempt.

**Proteomic testing will now be regulated by MolDx, presenting a pathway to prove utility and provide more consistent coverage.** On January 31, MolDX (administered by Palmetto) released [changes](#) to their proteomics testing coverage. Proteomic testing under specific CPT codes (RA, ovarian & prostate cancer, liver disease, lung cancer, cardiovascular disease, chronic kidney disease, among others) will now have to undergo MolDX requirements, including receiving a Z code and undergoing tech assessments. Proteomic testing commercial coverage may also improve as UNH is expected to incorporate Z codes into their coverage requirements starting April 1.

**In commercial markets, payers are focused on diagnostic utility in determining coverage and are building internal resources to review diagnostics.** Historically, diagnostics have found reimbursement difficult to access due to lack of clinical utility data at launch. While the FDA is focused on the scientific validity of a test, payers are also concerned with timeliness of test results and the impact on clinical decision making and costs. Regardless of FDA approval status, diagnostics will not interest payers if it does not solve a clinical or cost issue for them.

---

**Ipsita Smolinski**  
**Managing Director | Capitol Street**  
ipsita@capitol-street.com

202.250.3741 | www.capitol-street.com

900 19th St NW 6th Fl  
Washington, D.C. 20006

**CAPITOL STREET**

---

**Copyright 2024 Capitol Street.**

*This communication, including this broadcast and any attachments hereto, is intended solely for the original recipient(s) and may not be redistributed without the written consent of Capitol Street. This communication is for informational purposes only and is not intended as an offer or solicitation for the purchase or sale of any financial instruments, nor is it intended as advice to purchase or sell such instruments*