CAPITOL STREET

February 28, 2024

Diagnostics Update

Downclassification, LDT Final Rules, MolDX 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...

Want to keep reading or learn more?

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