Put It on the Board

Oncomine Dx Target approved as CDx to aid in therapy selection for patients with *RET* mutations/fusions in thyroid cancers

October 2022—The Food and Drug Administration has granted approval to Thermo Fisher Scientific's Oncomine Dx Target Test as a companion diagnostic to aid in selecting patients with *RET*-fusion-positive locally advanced or metastatic non-small cell lung cancer, *RET*-fusion-positive advanced or metastatic thyroid cancer, and *RET*-mutation-positive advanced or metastatic medullary thyroid cancer who may be eligible for treatment with Lilly's Retevmo (selpercatinib).

This is the first approval for the Oncomine Dx Target Test as a companion diagnostic for a therapy targeting *RET*-positive thyroid cancer and the second approval associated with *RET*-positive NSCLC.

Initially approved in 2020, Retevmo is a selective *RET* kinase inhibitor and was the first therapy approved for patients with advanced *RET*-driven lung and thyroid cancers. *RET* alterations are found in about two percent of patients with NSCLC, 60 percent of patients with medullary thyroid cancer, and 20 percent in other thyroid cancers.

Oncomine Dx Target is a next-generation-sequencing–based test that can detect multiple alterations at once from a small sample.

FDA clears Cobas Pure system for low- to mid-volume laboratories

Roche received 510(k) clearance from the Food and Drug Administration for its Cobas Pure Integrated Solutions. The compact and modular solution combines three technologies—clinical chemistry, immunoassay, and ion-selective electrode diagnostic testing—on a single platform.

Cobas Pure Integrated Solutions has a footprint of about 21 square feet. It is able to perform up to 870 tests per hour with access to Roche's full clinical chemistry and immunochemistry assay menu. Within the first year after launch, the menu will include more than 186 diagnostic tests across a wide range of disease areas. Roche says the system operates seamlessly with its Cobas Pro Integrated Solutions for mid- to high-volume laboratories.

BD launches software for flow cytometry research

BD launched BD Research Cloud, a cloud-based software solution designed to streamline the flow cytometry workflow for higher-quality experiments and faster time to insight for scientists working across immunology, virology, oncology, and infectious disease monitoring.

BD says its Research Cloud bridges and integrates all of the flow cytometry workflow steps, enabling scientists to more easily design reagent panels, connect instruments with data analysis software, store experimental data and procedures, and manage collaboration.

More than 120 medical associations to Congress: stop the cuts

The CAP and the AMA were two of 124 medical associations to share, in a letter to congressional leaders, their alarm about the "mounting financial instability of the Medicare physician payment system."

The instability, they wrote in their Sept. 22 letter, stems from "statutory payment cuts, perennial lack of inflationary updates, significant administrative barriers, and the cumulative impact of the pandemic." The payment system "remains on an unsustainable path threatening beneficiaries' access to physicians."

The associations outlined how the proposed 2023 Medicare physician fee schedule would cut the Medicare conversion factor by about 4.5 percent, which doesn't account for inflation.

They urged Congress to do the following:

- Provide relief from the scheduled -4.42 percent budget neutrality cut in Medicare physician fee schedule payments.
- End the statutory annual pay freeze and provide a Medicare economic index update for the coming year.
- Extend the five percent Advanced Alternative Payment Model participation incentive and halt the “impossible-to-meet” revenue threshold increase for five years to encourage more physicians to transition from fee-for-service to alternative payment models.
- Waive the four percent pay-as-you-go, or PAYGO, sequester triggered by passage of the American Rescue Plan Act.