Put It on the Board

AMP reports findings on pandemic's impact, molecular test interpretation

April 2021—In an Association for Molecular Pathology survey focused on molecular testing in oncology during the pandemic, 70 percent of 163 respondents reported having decreased or stopped the development and validation of new tests in their laboratories.

Forty-eight percent said the turnaround time for test results increased, and 42 percent stopped or canceled plans to upgrade or buy new equipment.

Those are some of the findings of the responses to a question about the effects of the pandemic on the laboratory's operations and its ability to perform molecular testing in oncology.

The survey was conducted between Sept. 29 and Oct. 14, 2020. Its purpose was to document how the pandemic has affected national and international labs that provide such testing. The top five countries contributing to the survey were the U.S. (59 percent), Canada (12 percent), India (six percent), Italy (three percent), and Spain (three percent).

Other immediate effects on operations, as reported by respondents who were able to select all that applied, were an inability to fill open staff positions with qualified candidates (31 percent), having taken on fewer trainees or interns (27 percent), having started to send out some tests rather than perform them in-house (25 percent), and having reduced lab staff (22 percent), among others.

The survey also aimed to understand if and how molecular testing performed for clinical trials was affected. About half of the respondents were performing molecular testing for cancer in clinical trials. Sixty-four percent of respondents that perform such testing report that the testing had been affected by the pandemic—23 percent reported a significant effect and 41 percent a slight effect.

The top two effects were a decrease in or halting of newly enrolled patients and patients being unable or reluctant to travel outside the home.

About 40 percent of respondents said the pandemic negatively affected the turnaround time for any of the molecular cancer tests their lab offers, and staffing shortages were the top reason for longer TATs.

The full AMP report is at www.amp.org/advocacy/sars-cov-2-survey.

In a separate AMP analysis released in March, on the work effort in molecular test interpretation, 103 molecular professionals from the AMP and American College of Medical Genetics and Genomics reported that their efforts spent on data analysis, interpretation, and reporting for molecular diagnostic tests were not reimbursed sufficiently. The respondents strongly agreed that access, data, and decision-making would improve with better reimbursement.

Whole genome sequencing and whole exome sequencing in human genetics were reported as the most time-consuming (seven to nine hours) for data analysis, interpretation, and reporting, along with next-generation sequencing for oncology panels of more than 50 genes (six hours).

Technical difficulty, additional research requirements, and placing test results into clinical context were rated as the greatest drivers of time burdens related to analysis and reporting.

The full results, including recommendations and next steps, are at www.amp.org/MDx_Survey_Report.

Ventana ALK (D5F3) OK'd as CDx for Lorbrena

The Food and Drug Administration approved the Ventana ALK (D5F3) CDx Assay as a companion diagnostic to identify ALK-positive non-small cell lung cancer patients eligible for treatment with Pfizer's drug Lorbrena (lorlatinib). It is the only immunohistochemistry test approved by the FDA as a companion diagnostic for Lorbrena.

The assay is intended for the qualitative detection of the ALK protein in formalin-fixed, paraffin-embedded NSCLC tissue stained with a BenchMark Ultra or BenchMark XT automated staining instrument. It is indicated as an aid in identifying patients eligible for treatment with Xalkori (crizotinib), Zykadia (ceritinib), Alecensa (alectinib), or Lorbrena in the United States.

EUA requested for T-Spot.COVID test

Oxford Immunotec Global PLC released the T-Spot.COVID test, a CE-marked ELISpot-based test intended for qualitative detection of a cell-mediated (T cell) immune response to SARS-CoV-2 in human whole blood. The company said in early March it had filed an EUA request to the FDA.

In a clinical study using samples collected in the U.S., the T-Spot.COVID test detected a SARS-CoV-2 T-cell-mediated immune response in PCR-positive individuals, even with negative serology test results, according to the company. The test therefore complements results obtained by antibody serology to give a more comprehensive view of an individual's adaptive immune response to SARS-CoV-2 infection, the company says. The test could also be used, for example, alongside serology tests to support clinical assessment of those who present with suspected COVID-19 but are PCR negative.

In the study, the T-Spot.COVID test had a positive agreement with PCR results of 96.6 percent (84/87) in SARS-CoV-2-infected individuals less than 60 days after a first PCR-positive result. At greater than 60 days (with the furthest time point after first positive PCR test result being more than 240 days), positive agreement remained high, at 83.3 percent (40/48). The T-Spot.COVID test detected substantially more people with previous positive PCR results than serology in the cohort, whose positivity rate was lower and declined faster over time.

In an endemic cohort of U.S. individuals selected to be at a relative lower risk of SARS-CoV-2 infection (based on the absence of self-reported symptoms, negative serology results, and no prior history of a positive PCR test result for SARS-CoV-2), the T-Spot.COVID test had a negative agreement of 98 percent (96/98). "We cannot exclude the possibility that a proportion of this group had, or still have, an asymptomatic infection, seronegative at the time of testing, but in whom the T-Spot.COVID test was able to detect a T cell response," the company said in its March 4 release.

In other news, PerkinElmer on March 9 announced it had completed its previously announced acquisition of Oxford Immunotec. PerkinElmer announced on Jan. 7 its intent to acquire the company.

Agilent to acquire Resolution Bioscience

Agilent Technologies entered into a definitive agreement to acquire Resolution Bioscience. Under the terms of the agreement, Agilent will pay $550 million in cash at closing and up to an additional $145 million based on future performance milestones.

Resolution Bioscience's noninvasive liquid biopsy assay platform supports the biopharma services market and the clinical oncology diagnostic testing market. The platform was designed for a centralized CLIA test service and a distributable kit format. The company's homologous recombination deficiency assay received breakthrough device designation from the FDA.

Latest on COVID-19

Editor's note: See captodayonline.com for news on SARS-CoV-2 tests (Coronavirus News). A list of FDA EUAs for COVID-19 can be found at https://j.mp/covid-19-EUA.