

# Put It on the Board

## AMP issues genetic variant data sharing recommendations

August 2021—The Association for Molecular Pathology on July 29 called on all relevant individuals and organizations to support and facilitate the sharing of molecular genetic variant data and offered recommendations.

Participation in data sharing among clinical laboratories continues to remain low, the AMP says in its position statement, despite the availability of public databases, multiple recommendations, and calls to action, as well as incentives to contribute to them. The NIH's ClinGen resource reports that as of January 2020 only 15 clinical labs within the U.S. met their minimum requirements for data sharing to be recognized in the program, according to the AMP.

"Thus, information that is vital to the advancement of molecular pathology and improvement of patient care continues to be siloed," the AMP says.

In its position statement, the AMP provides recommendations for organizations, institutions, and companies; for operators of public databases; and for clinical laboratories. Two of its four recommendations for clinical labs are as follows: They should assign dedicated personnel to interface between shared sequence databases and diagnostic genetic test result platforms, and they should gain a better understanding of the clinical relevance of variants in different populations.

The full position statement is at <https://bit.ly/AMP-var-data>.

## FDA clears MSI analysis system

The FDA has cleared Promega's OncoMate MSI Dx Analysis System for determining microsatellite instability status in colorectal cancer tumors.

OncoMate is a fluorescent, multiplex PCR-based fragment sizing test that the company says can be performed using a portion of a single formalin-fixed, paraffin-embedded section. It targets five mononucleotide repeat markers, and results are available in about 10 hours.

## FDA authorizes imported blue-top tubes

The FDA on July 22 issued an emergency use authorization to import and increase the supply of blue-top test tubes.

The EUA was issued to Becton, Dickinson, and Company for its BD Vacutainer Plus Citrate Plasma Tubes manufactured in the United Kingdom.

The CAP on June 15 issued recommendations ([https://bit.ly/CAP\\_bluetop](https://bit.ly/CAP_bluetop)) to guide laboratories in reducing the clinical impact of the shortage of 3.2 percent sodium citrate blue-top tubes, which is expected to persist until the end of this year.

## MET exon 14 skipping CDx approved

Foundation Medicine received FDA approval for FoundationOne Liquid CDx to be used as a companion diagnostic to aid in identifying patients with *MET* exon 14 skipping in metastatic non-small cell lung cancer for whom capmatinib may be appropriate.

Capmatinib (Tabrecta) is the first therapy the FDA approved for adult patients with metastatic NSCLC whose tumors have an alteration that leads to *MET* exon 14 skipping.