Put It on the Board

Caveats on use of SARS-CoV-2 PCR Ct values in clinical practice

May 2021—In an April 21 blog post, the Association for Molecular Pathology advised against routine use of SARS-CoV-2 PCR cycle threshold values to inform clinical decisions.

Blake W. Buchan, PhD, D(ABMM), author of the post and associate professor in the Department of Pathology, Medical College of Wisconsin, explains the key considerations related to the derivations, reliability, and reporting of Ct values. He is a member of the AMP Clinical Practice Committee and was the AMP's representative for its work with the Infectious Diseases Society of America on a joint statement on the use of SARS-CoV-2 PCR Ct values for clinical decisions (http://bit.ly/AMP-IDSA-statement).

Dr. Buchan writes in his post that the use of different specimen collection devices, specimen types, nucleic acid extraction methods, genomic targets, and RT-PCR chemistries all contribute to variability in the final reported Ct value.

He says reporting Ct values for public health or epidemiologic studies may be important to the research and understanding of SARS-CoV-2 infection and transmission, but he urges caution in reporting Ct values in the medical record. If such values are reported routinely or sporadically, he writes, "consideration should be given to inclusion of an interpretive comment that specifically states the test used and the lack of verification for use in individual patient care."

The full post is at: http://bit.ly/AMP-IDSA-Ct.

FDA OKs CDx to identify endometrial cancer patients for immunotherapy

The Food and Drug Administration approved the Ventana MMR RxDx Panel for advanced or recurrent endometrial cancer patients. Testing can identify patients eligible for treatment with Jemperli (dostarlimab-gxly) monotherapy, an anti-PD1 immunotherapy from GlaxoSmithKline that was approved by the FDA on April 22.

The Ventana MMR RxDx Panel, a label expansion of Roche's current on-market Ventana MMR IHC Panel, is a qualitative immunohistochemistry test intended for use in assessing mismatch repair proteins (MLH1, PMS2, MSH2, MSH6) in formalin-fixed, paraffin-embedded endometrial carcinoma tissue by light microscopy.

Illumina partners for TP53 companion diagnostic

Illumina and Kartos Therapeutics announced a partnership to co-develop a TP53 companion diagnostic based on the content of Illumina's TruSight Oncology 500. This companion diagnostic for multiple hematologic indications will be the first to use the TSO 500 genomic profiling assay with peripheral whole blood as a diagnostic sample type.

Illumina says the initial focus of the collaboration will be the co-development of multiple companion diagnostic claims in blood cancers for Kartos' KRT-232, an oral MDM2 inhibitor that activates p53 to drive tumor cell death in TP53 wild-type cancers.

Philips, Ibex team up for AI-powered digital pathology

Royal Philips and artificial intelligence company Ibex Medical Analytics announced a collaboration to promote their digital pathology and AI solutions to hospitals, health networks, and pathology labs worldwide.

Ibex's Galen AI-powered cancer diagnostics platform is currently in clinical use in Europe and the Middle East. Ibex uses AI to develop clinical-grade solutions that help pathologists detect and grade cancer in biopsies. The companies say the combination of Philips' digital pathology solutions and Ibex's Galen platform has improved

reporting efficiency, productivity, and accuracy.

Hologic to buy Mobidiag

Hologic has signed a definitive agreement to acquire Mobidiag Oy, a privately held, commercial-stage Finnish-French developer of innovative molecular diagnostic tests and instrumentation, for an enterprise value of about $795 million.

“Acquiring Mobidiag will further strengthen our international and diagnostics businesses by enabling us to expand into the large, fast-growing acute care adjacency with a near-patient testing solution that offers ease of use, multiplex capability, and rapid turnaround time,” Jan Verstreken, Hologic group president, international, said in an April 8 statement.

Mobidiag develops and markets PCR-based tests for acute care conditions such as gastrointestinal and respiratory infections, antimicrobial resistance management, and health-care–associated infections. The Amplidiag and Novodiag platforms are automated instruments with turnaround times ranging from 50 minutes to two hours.

The acquisition is expected to close early in the fourth quarter of fiscal 2021.

DiaSorin to buy Luminex

DiaSorin SpA has agreed to acquire Luminex for about $1.8 billion.

DiaSorin will gain access to Luminex’s molecular diagnostics multiplexing technology and a portfolio that will strengthen its existing offering while expanding its presence in the United States. The transaction is expected to close in the third quarter of this year.

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.