From the President’s Desk

written by CAP TODAY
January 17, 2024

January 2024—I was planning to write about a much more pleasant topic this month, but instead I’ll use this column to address something that’s gnawing at all of us now: the prospect of FDA regulation of laboratory-developed tests.

Clinical pathology selected abstracts

written by CAP TODAY
January 17, 2024

January 2024—People respond differently to SARS-CoV-2 infection, with some having a very severe clinical course and sequelae while others recover quickly. Several research studies have used laboratory data to identify patient populations most at risk for severe outcome from COVID-19. However, many of these studies were conducted in China and did not represent the demographics of the U.S. population. Among the drawbacks of these studies were that most analyzed variance between two patient groups, yet statistical differences don’t always correlate with clinically useful predictions. Furthermore, these studies used data from throughout patients’ disease course, and clinicians would like to identify patients at risk during their initial interaction.

Anatomic pathology selected abstracts

written by CAP TODAY
January 17, 2024

January 2024—Diffuse parenchymal lung disease is a well-recognized complication of systemic connective tissue disease but rarely arises in patients with psoriasis or psoriatic arthritis, which are poorly understood. Therefore, the authors conducted a study to characterize diffuse parenchymal lung disease (DPLD) associated with psoriasis or psoriatic arthritis, with or without prior immunomodulation. Their pathology consultation files were searched for patients having psoriasis or psoriatic arthritis and DPLD. After excluding cases with active infection or smoking-related DPLD only, 44 patients (22 of whom were women; median age, 60 years; range, 23–81 years) were enrolled in the study. Clinical history and pathology slides were reviewed.

Molecular pathology selected abstracts

written by CAP TODAY
January 17, 2024

January 2024—*DDX41* is involved in multiple cellular processes, including RNA metabolism and splicing. Inherited variants have been linked to an increased risk of the blood neoplasms myelodysplastic syndrome (MDS) and acute myeloid leukemia (AML).

Q&A column

written by CAP TODAY
January 17, 2024

January 2024
Q. Can a person who has a bachelor of science degree in health care administration sign off on competency assessments? Read answer.

Q. Our laboratory uses a total protein assay from Beckman Coulter that has an analytical measurement range of 3–12 g/dL for serum determinations. The assay sensitivity states 1 g/dL of total protein. Can we loop sensitivity into our AMR and make our reporting range 1–12 g/dL? Will this make our assay a laboratory-developed test? Quite often our clinicians need assays reported to 1 g/dL, since they need to calculate the ratio of total protein serum to body fluid as per Light's criteria. If we report to 1 g/dL, we have to loop sensitivity into our AMR. Read answer.

Newsbytes

written by CAP TODAY
January 17, 2024

January 2024—When the medical microbiology laboratory at Yale-New Haven Hospital makes operational changes, it uses data analytics to monitor their impact. Yet the process of implementing laboratory analytics can be challenging.

Put It on the Board

written by CAP TODAY
January 17, 2024

January 2024—The Association for Molecular Pathology on Dec. 14 published a joint report on what to consider for a slice testing strategy for diagnostics, including gene selection, analytic performance, coverage, quality, and interpretation. Slice testing is the practice of bioinformatically selecting a subset of genes from exome or genome sequencing assays.

CLSI releases jointly developed 2023 breakpoint implementation toolkit

written by CAP TODAY
January 17, 2024

January 2024—The Clinical and Laboratory Standards Institute, Association of Public Health Laboratories, American Society for Microbiology, the CAP, and Centers for Disease Control and Prevention have jointly developed a breakpoint implementation toolkit (BIT) to assist clinical laboratories in updating minimal inhibitory concentration breakpoints. The toolkit includes links to other resources that explain the rationale behind breakpoint updates, regulatory requirements for updating breakpoints, and detailed instructions for performing an AST breakpoint validation or verification. Manufacturers of AST systems can provide guidance on breakpoints used and clearance status with their systems.

FDA clears BD MiniDraw capillary blood collection system

written by CAP TODAY
January 17, 2024

January 2024—BD announced it has received FDA 510(k) clearances for its BD MiniDraw, a novel blood collection device that obtains blood samples from a fingerstick. The clearances include low-volume blood collection for a lipid panel, selected chemistry tests, and hemoglobin and hematocrit testing.

Biocare Medical unveils IntelliPath+ staining instrument

written by CAP TODAY
January 17, 2024

January 2024—Biocare Medical has introduced the IntelliPath+ advanced staining instrument, intended for in vitro diagnostic use and redesigned with input from users and the latest technological advancements. It is an open system that accommodates continuous random access with immediate stat capabilities and can process 50 slides per run.