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FDA clears Epoc NXS Host mobile computer, 01/21:66

Roche launches PIK3CA test with CE mark, 01/21:66

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Biocare unveils Oncore Pro for IHC and ISH, 02/21:78

Thermo Fisher to acquire Mesa Biotech, 02/21:78

Roche launches CE-IVD digital pathology IA algorithms, 02/21:78

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Ventana ALK (D5F3) OK'd as CDx for Lorbrina, 04/21:77

EUA requested for T-Spot.COVID test, 04/21:77

Agilent to acquire Resolution Bioscience, 04/21:77

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Caveats on use of SARS-CoV-2 PCR Ct values in clinical practice, 05/21:70

FDA OKs CDx to identify endometrial cancer patients for immunotherapy, 05/21:70

Illumina partners for TP53 companion diagnostic, 05/21:70

Philips, Ibex team up for AI-powered digital pathology, 05/21:70

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FDA allows for first POC chlamydia, gonorrhea test, 06/21:82

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PerkinElmer to acquire Immunodiagnostic Systems, 06/21:82

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FDA approves Rybrevant and Lumakras for NSCLC, 07/21:90

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Q&A

If an instrument is moved a short distance, is it necessary to conduct revalidation? (Darden), 01/21:62

At what level or time is aPTT considered incorrect? Is an aPTT of less than 22 seconds an acceptable result? (Chen, Ravindran), 01/21:62

Can toxicology testing be performed on a person who has been deceased for two years? (Jones, Graham), 02/21:71

Is there a standardized procedure for performing platelet estimates that incorporates the dilution effect for low hemoglobin in anemic patients? (Kovach, Skelton), 02/21:71

For many years, breast cancers were tested routinely for HER2 and estrogen and progesterone receptors in an attempt to find actionable

treatments. Then it was discovered that over- and underfixation with formalin could give erroneous results. Have standards been developed to address this issue with the latest actionable IHC markers, such as PD-L1? Shouldn't this be addressed for all actionable IHC markers? (Rimm, Bellizzi), 03/21:56

In our hospital, respiratory therapy runs most of the blood gas tests on instruments in centralized locations. Staff are able to enter into the blood gas instrument, which is connected to the LIS, to whom they gave critical results. However, staff do not have a way to document that a result was read back. The majority of these critical results happen in the neonatal intensive care and intensive care units, where respiratory therapy is a part of the care team, so results are given in person. Is documenting a read-back necessary when critical results are communicated verbally? How does the CAP checklist COM.30100 relate to point-of-care testing? (Jacobs), 03/21:56

What is the correct nomenclature for HbA1c in printed test reports? (Faix), 3/21:57

What is the recommended procedure for analyzing cerebrospinal fluid from patients suspected of having Creutzfeldt-Jakob disease? In addition to sending the specimen to the National Prion Disease Pathology Surveillance Center for 14-3-3 testing, should the laboratory perform a cell count and/or meningitis panel? (Harris), 04/21:72

Is light protection needed for folate samples? Most major reference laboratories do not require folate samples to be protected from light, and I could not find any studies on the topic. (Chambliss), 04/21:72

Many times a platelet count on an automated hematology system indicates some degree of thrombocytopenia or the analyzer reports a high mean platelet volume or platelet large cell ratio, while a blood smear shows large platelets and/or giant platelets. Is it OK to include a comment in the report that the platelets are adequate or that the count could be due to large platelets, especially with values that indicate marked thrombocytopenia?

(Pozdnyakova), 04/21:72

I am part of a two-pathologist practice in a rural community hospital of 110 beds. We have been asked more frequently lately to evaluate liver and kidney biopsies for organ transplantation. We are hesitant to evaluate these biopsies for transplantation purposes due to frozen section artifacts and because we

send all of our kidney biopsies performed by local nephrologists to a reference laboratory and do not evaluate kidney biopsies. It seems that regardless of what we say about the biopsies, the surgeons transplant the organs. We believe it is out of our scope of practice to evaluate liver and kidney biopsies for organ transplantation. What do you think? (Adeyi, Sopha), 05/21:64

What is the minimum and maximum formalin fixation time for cytology specimens for optimal immunohistochemical and nucleic-acid-based molecular testing? (Sundling, Ambaye, Roy-Chowdhuri), 05/21:64

If an exfoliative cytology specimen (for example, pleural fluid) is received fresh, how long can it stay refrigerated before it needs to be placed in formalin fixative for cell block preparation? That is, what is the recommended cold ischemic time? (Sundling, Ambaye, Roy-Chowdhuri), 06/21:75

Are two levels of a control required for a manual reticulocyte count? 06/21:75 (Rose), 06/21:76

What are the requirements for obtaining emergency use authorization versus 510(k) clearance? (Rogers), 06/21:76

Are the PCR assays for SARS-CoV-2 from most manufacturers quantitative? (Rogers), 06/21:76

Is there a best specimen type to use for SARS-CoV-2 molecular testing? (Rogers), 06/21:76

What is the primary test type used to detect SARS-CoV-2? (Rogers), 06/21:76

I know that a molecular test detects nucleic acid and an antigen test detects viral protein, but how do they compare for clinical use and which is better? (Rogers), 06/21:76

Our lab does not have reference ranges established for body fluid manual differentials. Is it acceptable to use ranges from a reference material and include a disclaimer citing the source of the ranges? (Kovach), 07/21:83

In our lab, we perform semen analysis and make slides to send out for sperm morphology using Kruger's strict criteria. We get quite a few results back as swollen sperm head for probable contamination. The reference lab insisted that liquefying agent was added, but when we reviewed the results, the sample was normal, so liquefying agent wasn't used. What can

cause a sperm head to swell, other than liquefying agent? (Behnke), 07/21:84

Is it necessary for a lab to report a corrected sodium level when the glucose level is really high? Studies show pseudohyponatremia can occur due to hyperglycemia. How common is this, and how do we decide which correction factor to use? Is it possible that this is easily overlooked by providers due to comorbidities in patients? (Faix), 08/21:63

Payers are limiting reimbursement for PCR respiratory panels to a small subset of tested pathogens and only with certain indications. Many panels available from manufacturers test for more pathogens than can be reimbursed. What is the best approach to deal with this issue? Should large respiratory panels no longer be offered? If a large panel is performed, should only a limited number of pathogen results be reported, even though the entire panel was performed? Should the entire panel be reported but only a limited number of pathogens billed for? (Edwards), 08/21:63

The number of kit-based tests has increased in recent years, and it's becoming more difficult and costly to keep up with competency assessment. Are we allowed to group different kit-based tests into the same test system for competency assessment? For rarely performed tests, do we need to evaluate all six elements of competency if previously tested specimens are not available? (Eubanks, Wielgos), 08/21:64

What is the ideal collection tube for measuring the level of ammonia in blood? Is a tube containing EDTA suitable? (Devaraj, Poventud-Fuentes), 09/21:80

Is there a requirement to notify nursing personnel or doctors about each critical value obtained for a patient after the initial occurrence of the critical result? (Darden), 09/21:80

After naloxone is administered, are opiates still detectable in the body? If so, for how long and in what quantities? (Jones), 10/21:78

Why do proficiency testing specimen results for common immunoassay analytes sometimes vary greatly with different instrument manufacturers and their reagents? Does that mean the patient's results for the same specimen could vary greatly based on the instrument used? (Tebo), 10/21:79

Can staff who have proof of licensure (such as from the American Registry of Radiologic Technologists) but do not have a copy of their diploma be authorized to use POC testing equipment? (Martire), 11/21:84

Is 10 percent allowable error acceptable for reagent lot-to-lot verification for all parameters? (Suh-Lailam, Schmotzer), 11/21:84

We use the CAP Competency Assessment Program to create quizzes to satisfy the problem-solving element of the CAP's competency assessment requirements. Is there a requirement to create a new quiz each year or can the same quiz be given every year? Is it OK to use the same quiz for the initial competency and the annual competency? (Netols), 12/21:62

Are there red blood cell parameters, such as RBC count or mean corpuscular volume, that can affect a platelet estimate? When determining a platelet estimate, should we always look at the same area of the slide regardless of the patient's RBC, hematocrit and hemoglobin levels, and indices results? (Xu), 12/21:62

Quality assurance/quality control/quality improvement

Accuracy-Based Programs for 'bigger dividends,' better care, 07/21:01

Quality management systems

Latest checklist takes quality management to next level, 11/21:03

Race/ethnicity

Parsing the role of racism in Alzheimer's biomarkers, 10/21:01

EGFR equation no longer Black and white, 12/21:01

Rare diseases

Higher stakes in systemic mastocytosis, 06/21:01

Puzzling out platelet function disorders, 06/21:01

Reference intervals

New data on reference ranges for transgender men, 02/21:05

Renal pathology/renal disease

A transparent lens on estimated GFR, 05/21:01

Residency/residents

Surgical Pathology Review: easing the transition, 02/21:60

How Geisinger medical school updated informatics training, 07/21:84

Salivary gland/saliva testing

Reflections on use of Milan System, edition 1, 08/21:50

Screening tests (see also Prenatal screening, Diagnostic assays/markers/tests/test kits)

Problems, solutions at core of UTI, *C. diff* modules. 04/21:61

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Coag issues occupy COVID's central stage, 07/21:01

A few years in, a new picture for liquid biopsy, 07/21:05

Testing for platelet function using platelet-rich plasma, 07/21:38

CSF biomarkers in 'a new era' for Alzheimer's, 08/21:01

Testing for platelet function using whole blood, 08/21:05

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Sex hormones

New data on reference ranges for transgender men, 02/21:05

SHIELD project

New hope for lab data interoperability, 11/21:01

Social media

New website streamlines lab product searches, 01/21:18

A new 'safety zone' for practice problem-solving, 01/21:20

Specimen collection and handling

A preanalytics push in accreditation checklists, 09/21:20

Specimen integrity

A preanalytics push in accreditation checklists, 09/21:20

Staffing

One year later, life in labs remains a juggling act, 03/21:20

'Gaps loom large': labor shortage hitting hard, 06/21:22

Lab leaders on growth, labor, and cybersecurity, 07/21:24

Lab staff shortage calls for speed, money, and more, 08/21:01

Salaries, schools, students—all eyes on workforce, 09/21:32

'Scary situation'—lab leaders on staffing and COVID-19, 10/21:30

Panel weighs in on practices, pressures in heme labs, 10/21:56

Compass Group members on test pre-approvals, staff search and strategies, 11/21:01

Security in the cloud leads off in LIS exchange, 11/21:54

Tight and terrible: lab leaders on budgets and staffing, 12/21:01

Efficiency, utility, and the 'movement in the field', 12/21:38

Standard of care

A preanalytics push in accreditation checklists, 09/21:20

Surgical pathology

Surgical Pathology Review: easing the transition, 02/21:60

Under one cover: grossing, staging, and reporting, 07/21:76

Tacrolimus

PGx in transplant medicine: tacrolimus as foundation, 08/21:30

Telecytology

Telecytology for rapid on-side evaluation, 01/21:50

Test development/management

Putting labs front, center in pandemic plans, 01/21:01

Analytics reframes decisions from bench to C-suite, 07/21:01

Test ordering

Primary HPV screen only? Experts warn of risk, 01/21:01

For POC molecular, pauses, plans, and testing precautions, 01/21:01

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CSF biomarkers in 'a new era' for Alzheimer's, 08/21:01

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In coag collections, every detail counts, 09/21:01

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Test standardization

From manual to staging system—AJCC's new path, 04/21:36

ED, lab views on point-of-care cardiac troponin, 06/21:41

Transplant viral monitoring struggles and solutions, 06/21:59

Test utilization (see also Screening tests)

No letup in pandemic struggle for supplies, staff, 01/21:05

Variants, vaccines, predictions: Compass on COVID, 02/21:20

Problems, solutions at core of UTI, *C. diff* modules. 04/21:61

Testing supplies

No letup in pandemic struggle for supplies, staff, 01/21:05

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Thrombocytopenia

Coag issues occupy COVID's central stage, 07/21:01

Thyroid disease/testing

Under one cover: grossing, staging, and reporting, 07/21:76

Toxicology testing/consults

Tox testing challenges in adolescents, young adults, 03/21:36

Transgender medical care

New data on reference ranges for transgender men, 02/21:05

Transplantation/transplant services

In transplantation, detecting CMV antiviral resistance, 02/21:01

Transplant viral monitoring struggles and solutions, 06/21:59

PGx in transplant medicine: tacrolimus as foundation, 08/21:30

Troponin

ED, lab views on point-of-care cardiac troponin, 06/21:41

Tumor grading

A sizable shift in CNS tumor classification, 11/21:01

Tumor mutational burden

MMR, MSI testing guidelines near finish line, 12/21:01

21st Century Cures Act

Results release: new steps under new rules?, 10/21:01

Urinalysis/urinary tract infections/urinary cytology

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Efficiency, utility, and the 'movement in the field', 12/21:38

Vasculitis

Vascular changes in lung—a piece of the puzzle, 03/21:21

Vendor news

New website streamlines lab product searches, 01/21:18

Next moves for core labs — panel takes stock, 06/21:62

Virtual education

Virtual education in cytology: pandemic silver lining, 01/21:50

Virtual, blended inspections a sign of the times, 06/21:05

Viruses/viral outbreaks/virology

Transplant viral monitoring struggles and solutions, 06/21:59

Visualization software/Dashboards

Analytics reframes decisions from bench to C-suite, 07/21:01

Whole genome sequencing

DELFI approach as 'pretest' in early cancer detection, 12/21:05

Whole slide imaging

Telecytology for rapid on-side evaluation, 01/21:50

Workload limits

World Health Organization

A sizable shift in CNS tumor classification, 11/21:01

World Wide Web/websites

New website streamlines lab product searches, 01/21:18

A new 'safety zone' for practice problem-solving, 01/21:20