

[Put It on the Board](#)

written by CAP TODAY
February 15, 2023

February 2023—The CAP and three other organizations told the FDA in a Jan. 6 letter they are increasingly concerned that it is not recognizing updated antimicrobial susceptibility interpretive criteria, or breakpoints, in a sufficiently timely manner.



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[AscencioDx COVID-19 test, molecular detector get EUA](#)

written by CAP TODAY
February 15, 2023

Feb. 14, 2023—Anavasi Diagnostics announced FDA emergency use authorization for its AscencioDx COVID-19 test and AscencioDx molecular detector for use in point-of-care settings operating under a CLIA certificate of waiver, certificate of compliance, or certificate of accreditation.



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BioFire SpotFire system and panel get 510(k) clearance

written by CAP TODAY
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Feb. 8, 2023—BioMérieux has received FDA 510(k) clearance and a CLIA waiver for its BioFire SpotFire system and respiratory panel.



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Sysmex Inostics' Plasma-Safe-SeqS NGS Technology



Sysmex Inostics' Plasma-Safe-SeqS (PSS) technology offers highly sensitive mutation detection across the most clinically relevant gene targets. [Learn more.](#)



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[Stemline's Orserdu approved for patients with ESR1 mutations](#)

written by CAP TODAY
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Jan. 31, 2023—The U.S. Food and Drug Administration has approved Stemline Therapeutics' Orserdu (elacestrant) for the treatment of postmenopausal women or adult men with ER+, HER2-, ESR1-mutated advanced or metastatic breast cancer with disease progression following at least one line of endocrine therapy.



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[Congress nixes national patient identifier—again](#)

written by CAP TODAY
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Jan. 30, 2023—Congress once more failed to embrace movement towards a national patient identification system, leaving in place a ban on using federal funds to promote or adopt NPI standards in the omnibus fiscal year 2023 spending bill.



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An oncologist contacted the laboratory to ask if our standard estradiol immunoassay was appropriate to monitor her breast cancer patients who are on an aromatase inhibitor. What should I say?

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January 2023—Mass-spectrometry-based assays are preferred for measuring estradiol (E2) in populations where low concentrations are expected, such as in males, postmenopausal females, prepubertal children, and those receiving estrogen-suppressing medications or therapies. Comparing the E2 reference interval for postmenopausal females (approximately <10 pg/mL) to that of premenopausal females (15–350 pg/mL, depending on the phase of the menstrual cycle) illustrates what concentrations could be considered low.



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I am updating our procedure for blood draw volume limits and using So You're Going to Collect a Blood Specimen: An Introduction to Phlebotomy, 15th edition, by Frederick L. Kiechle, MD, PhD, as a guide.

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February 2023—The chart in the manual lists volume limits for a single blood draw at 2 cc/kg. Other charts online list 2.5 cc/kg and a maximum milliliters per 30-day period that is twice the single blood

draw (5 cc/kg). I am going to use 2 cc/kg and add a column for maximum milliliters in a 30-day period at 4 cc/kg. The phlebotomists are confused about whether a single blood draw means every day of the patient's admission or if you would take the single blood draw and only allow the remainder of the 30-day limit. You could essentially draw the single blood draw volume limit on day one and the remainder on day two. Please clarify.



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[Qiagen launches EZ2 Connect MDx for](#)

diagnostic use

written by CAP TODAY

February 15, 2023

Jan. 19, 2023—Qiagen has launched its EZ2 Connect MDx for use in diagnostic laboratories.



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