HemoSonics gets expanded clearance for Quantra system

written by CAP TODAY
December 11, 2025

December 2025—HemoSonics has received FDA 510(k) clearance for expanded use of its Quantra hemostasis system with QStat cartridges in peripartum obstetric procedures. It is the first FDA-cleared viscoelastic testing platform for obstetric bleeding, according to a company press release. The system uses SEER (sonic estimation of elasticity via resonance) sonorheometry to measure the coagulation properties of a whole blood sample. It provides results in about 15 minutes.

FDA clears Simplexa COVID-19, flu A/B, RSV Direct kit

written by CAP TODAY
December 11, 2025

December 2025—Diasorin has received FDA 510(k) clearance for the Simplexa COVID-19/Flu A/B and RSV Direct kit, a sample-to-answer test for the detection of SARS-CoV-2, influenza A and B virus, and respiratory syncytial virus directly from nasopharyngeal and nasal swab specimens. The kit runs on the Liaison MDX system and provides differential detection in about 45 minutes.

ARUP study validates AI for parasite detection

written by CAP TODAY
December 11, 2025

December 2025—The *Journal of Clinical Microbiology* has published an article describing ARUP Laboratories' validation of a deep convolutional neural network to detect parasites in concentrated wet mounts of stool.

Smart In Media releases v3.2 of PathoZoom-SL

written by CAP TODAY
December 11, 2025

December 2025—Smart In Media has released version 3.2 of its PathoZoom Scan and LiveView. The new version includes enhancements to workflow, image transmission, and LIS integration.

Qiagen to acquire Parse Biosciences

written by CAP TODAY
December 11, 2025

December 2025—Qiagen has entered into a definitive agreement to fully acquire Parse Biosciences, a provider of scalable, instrument-free solutions for single-cell research, for $225 million. The acquisition will expand Qiagen's Sample technologies portfolio into the single-cell sequencing market with highly scalable chemistry designed to power research involving millions of billions of cells, according to a press release from Qiagen. Parse's scalable chemistry is also expected to accelerate growth in Qiagen's digital insights bioinformatics business.

FDA approves Ortho Vision, MTS DAT card

written by CAP TODAY
December 11, 2025

December 2025—The FDA has approved QuidelOrtho Corp.'s Micro Typing Systems DAT card, a gel-based solution for direct antiglobulin testing, and the Ortho Vision platform, an automated blood testing system.

FecalSwab cleared for use on QIAstat-Dx GI panels

written by CAP TODAY
December 11, 2025

December 2025—The Food and Drug Administration has granted expanded clearance for use of the

FecalSwab sample type across all Qiagen QIAstat-Dx gastrointestinal panels, enabling full pathogen detection, including of Shiga toxin–producing *E. coli* and enteropathogenic *E. coli*. STEC and EPEC can now be reported when testing by FecalSwab collected from stool samples with the QIAstat-Dx Gastrointestinal Panel 2, including detection of clinically relevant STEC subtypes such as stx2f. STEC can now also be reported for the QIAstat-Dx GI Panel 2 Mini B and QIAstat-Dx GI Panel 2 Mini B&V.

Proscia adds virtual staining to Concentriq software

written by CAP TODAY
December 11, 2025

December 2025—Proscia is introducing virtual staining, powered by Pictor Labs, to its Concentriq software platform to help laboratories reduce the costs associated with traditional chemical methods and drive efficiency in high-throughput workflows. Virtual staining uses AI models to replicate the effects of stains on tissue images. These models can generate a whole slide virtually stained image from label-free inputs in a few minutes. The company will integrate a menu of H&E, immunohistochemical, and special stains into Concentriq.

GSI Group acquires GenesisBPS

written by CAP TODAY
December 11, 2025

December 2025—GSI Group Holdings has acquired GenesisBPS, a designer and manufacturer of specialized benchtop blood processing equipment and laboratory consumables. GSI Group provides a wide range of laboratory single-use products, benchtop instruments, and related accessories and has locations across the U.S., Europe, and Asia. GenesisBPS joins GSI Group brands Globe Scientific, AmScope, Euromex, and Physix, among others.

FDA qualifies AIM-MASH AI Assist for MASH clinical trials

written by CAP TODAY
December 11, 2025

Dec. 11, 2025—PathAI announced that the Food and Drug Administration has qualified AIM-MASH AI Assist through the drug development tool (DDT) biomarker qualification program for use within a context of use in metabolic dysfunction–associated steatohepatitis (MASH) clinical trials.