

## [Randox type 1 diabetes risk test gets CE mark](#)

written by CAP TODAY  
December 8, 2025

Dec. 8, 2025—Randox's type 1 diabetes risk test has received CE marking.



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## [Roche gets clearance, CLIA waiver for POC \*Bordetella\* test](#)

written by CAP TODAY  
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Dec. 2, 2025—Roche's Cobas Liat *Bordetella* test for the detection of *Bordetella* infections, including pertussis, has been granted FDA 510(k) clearance and a CLIA waiver.



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## [CMS finalizes pricing determination for OncoReveal CDx](#)

written by CAP TODAY  
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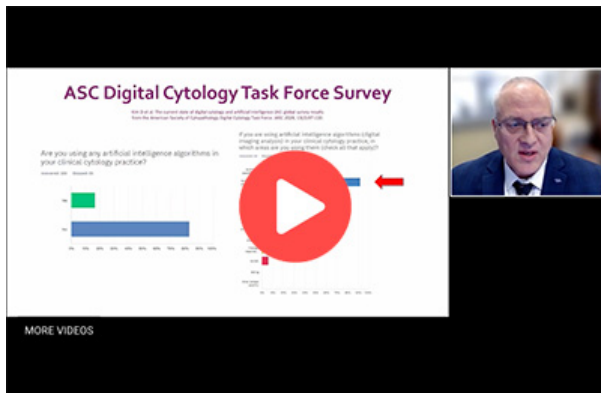
Dec. 1, 2025—The Centers for Medicare and Medicaid Services has finalized its pricing determination for Pillar Biosciences' OncoReveal CDx.



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## [Pathologist Perspectives: Experience Leveraging the Genius® Digital Diagnostics System for Digital Cytology-October 29, 2025](#)

written by CAP TODAY  
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Webinar presenters **Liron Pantanowitz, MD, PhD, MHA**, Chair and Maud Menten Professor of Pathology, UPMC/University of Pittsburgh UPMC Shadyside Hospital, and **Richard Lozano, MD**, President, P&C Labs, LLC. and Vice President, Chippis, Caffrey, Dubilier, and PSC, discuss their experience with the Genius Digital Diagnostics System and data leveraging digital cytology for cervical cancer screening.



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## **Streck adds Accellix platform to CD-Chex Plus RUO control**

written by CAP TODAY  
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November 2025—Streck added the Accellix automated cell phenotyping platform to its CD-Chex Plus (RUO) control.



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## **Bio-Rad launches specialty immunoassay controls in Europe**

written by CAP TODAY  
December 8, 2025

November 2025—Bio-Rad Laboratories launched Specialty Immunoassay Plus in Europe, a comprehensive immunoassay quality control product for specialty immunoassay testing procedures.



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# [Ifinatamab deruxtecan gets breakthrough therapy designation](#)

written by CAP TODAY  
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November 2025—The FDA granted breakthrough therapy designation to Ifinatamab deruxtecan for treating extensive-stage small cell lung cancer after platinum-based chemotherapy.



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# [Qiagen launches QIAstat-Dx Rise](#)

written by CAP TODAY  
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November 2025—Qiagen launched QIAstat Dx Rise, an FDA-cleared automated syndromic testing system for hospitals and laboratories.



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# [Quest launches advanced PGx test service](#)

written by CAP TODAY  
December 8, 2025

November 2025—Quest Diagnostics launched a pharmacogenomic laboratory test service to help providers understand a patient’s genetic response to drug therapies.



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## [Quickvue Influenza + SARS test available for professional use](#)

written by CAP TODAY  
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November 2025—QuidelOrtho’s Quickvue Influenza + SARS test, a CLIA-waived immunoassay, is now available for professional use.



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