

FDA approves new indications for Roche HER2 tests

written by CAP TODAY
December 16, 2025

Dec. 16, 2025—The Food and Drug Administration has approved additional indications for Roche's Pathway anti-HER2/neu (4B5) Rabbit Monoclonal Primary Antibody and Ventana HER2 Dual ISH DNA Probe Cocktail tests.



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Werfen applauds call to address undetected hemolysis

written by CAP TODAY
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Dec. 15, 2025—Werfen announced its commendation of the publication of a special report underscoring the urgent need to address the risks of undetected in vitro hemolysis (Wu AHB, et al. *J Appl Lab Med*. 2025;10[5]:1347-1361).



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[Natera acquires Foresight Dx](#)

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Dec. 12, 2025—Natera has completed a transaction to acquire cancer diagnostics company Foresight Diagnostics.



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[Randox launches a nitazenes array](#)

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December 2025—Randox Toxicology has launched its Nitazenes Array, an immunoassay designed to detect a broad spectrum of nitazene analogs from a single sample. The array was developed using Randox's proprietary biochip array technology and offers a rapid turnaround time. It is available on the company's Evidence MultiStat platform.



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[BD enteric bacterial panels get clearance, CE-](#)

[IVDR certification](#)

written by CAP TODAY
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December 2025—BD has received FDA 510(k) clearance and CE marking for its Enteric Bacterial Panel and Enteric Bacterial Panel Plus for the BD Cor system. BD EBP offers a range of targets for enteric bacterial pathogens, including *Salmonella* spp., *Campylobacter* spp. (*C. jejuni*, *C. coli*), *Shigella* spp./enteroinvasive *Escherichia coli*, and Shiga toxin-producing *E. coli*. BD EBP Plus detects enterotoxigenic *E. coli* and heat-labile and heat-stable enterotoxin genes. The panel also identifies *Plesiomonas shigelloides*, *Vibrio* spp. (*V. vulnificus*, *V. parahaemolyticus*, *V. cholerae*), and *Yersinia enterocolitica*.



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[Siemens introduces drug testing analyzer](#)

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December 2025—Siemens Healthineers has introduced the Atellica DT 250 benchtop analyzer, to help identify substance use, monitor therapeutic and immunosuppressant drugs, and perform serum toxicology testing. It also offers automated specimen validity testing to detect substitution, adulteration, and dilution of urine samples. The analyzer can process 225 test results per hour and provide first results in as few as eight minutes. It features a menu of more than 65 immunoassays for use with urine, serum, and plasma samples and 10 open channels for customizable, user-defined testing.



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Primerdesign launches Exsig Mag RapidBead Pro Extraction kit

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December 2025—Primerdesign launched its Exsig Mag RapidBead Pro Extraction kit, a next-generation magnetic bead-based kit used to extract high-quality DNA and RNA from diverse sample types. The workflow reduces hands-on time compared to traditional methods and extracts DNA and RNA in less than 20 minutes.



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Bruker gets expanded clearance for MALDI Biotyper CA system

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December 2025—Bruker announced that its MALDI Biotyper CA system received expanded clearance from the FDA. The clearance includes the MBT Compass HT CA software and MBT Fast Shuttle US IVD as well as an expansion of the FDA-cleared reference library.



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Clear Labs collaborates with Labcorp, Pillar Biosciences

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December 2025—Clear Labs announced at the Association for Molecular Pathology annual meeting (Boston, Nov. 11-15) its collaboration with Labcorp to automate PGDx kitted oncology NGS assays on the Clear Dx platform. Clear Labs says the collaboration aims to develop streamlined, end-to-end workflows that help laboratories improve efficiency, consistency, and throughput while laying the groundwork for future adoption across a range of genomic applications. This new workflow will expand Clear Labs' infectious disease applications into oncology testing.



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IDT, Beckman Coulter partner to automate NGS workflows

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December 2025—Integrated DNA Technologies and Beckman Coulter Life Sciences are forming a strategic partnership to automate IDT's customizable next-generation-sequencing assay solutions on Beckman Coulter's newly launched Biomek i3 benchtop liquid handler. Through this partnership, the companies will work to automate IDT's Archer FusionPlex and VariantPlex targeted sequencing assays and xGen Hybrid Capture workflows on the Biomek i3 system.



