
# The Evolving Landscape of Diagnostics—Prospects in Healthcare

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**ABSTRACT**

Modern healthcare relies heavily on diagnostic technologies and techniques because they offer vital information for disease detection, management, and individualized therapy. These tools support early disease detection, inform treatment choices, and track patient results. There are several platforms in the diagnostics industry, and developments are making tests faster, easier to obtain, and more accurate, especially in companion and point-of-care (POC) diagnostics.

Near-patient testing is made possible by POC, which eliminates the need for central labs and provides rapid and useful results. In environments with inadequate healthcare infrastructure and the treatment of long-term illnesses such as diabetes, this technology is becoming more and more significant. POC devices are already widely used for cardiovascular evaluations, infectious disease screening, and blood glucose monitoring. Remote treatment, patient involvement, and real-time health monitoring are all being improved by the increasing incorporation of wearable technology and mobile health apps into POC testing. Companion diagnostics (CDx) focuses on personalized medicine by identifying the best treatments for specific patients based on their biological traits or genetic composition. Oncology is a predominant area in healthcare that has seen the most advancements in CDx. The development of advanced molecular testing and next-generation sequencing has broadened the use of CDx, allowing for more accurate patient classification and better therapy results.

Healthcare diagnostics will continue to develop in the future thanks to advancements in big data analytics, machine learning, and artificial intelligence. By improving diagnostic precision and prediction power, these technologies will enable earlier disease detection, individualized treatment regimens, and improved population health management. It is anticipated that the combination of telemedicine and diagnostics, gadget miniaturization, and a growing emphasis on at-home testing would further democratize healthcare by enhancing patient-centered and accessible diagnostics.

**Keywords:** Point-of-care diagnostics, Companion diagnostics, Wearable technology, Molecular diagnostics, Artificial intelligence in healthcare

## Key Concepts and Areas in Diagnostics

An age-old adage is "*prevention is better than cure*." Nevertheless, since humans continue to be plagued by maladies for generations, cure is the "holy grail" of survival. Giant leaps and advances in modern medicine have accomplished much of this feat. With longer life expectancy, and changes in lifestyle, and consumption, however, diseases have evolved, which have spurred a research race to be ahead of the curve in diagnosing and/or early detection for better management. Diagnostics are essential to contemporary healthcare because they make it possible to identify, track, and treat illnesses. They include state-of-the-art point-of-care (POC) technology and conventional laboratory-based diagnostic techniques (laboratory-developed tests [LDTs], which are now classified as "in vitro diagnostics" [IVD]). Clinical decision-making is guided by diagnostics, which enable early condition detection, evaluation of therapy effectiveness, and assessment of disease progression. Diagnostics are essential for adjusting treatment to meet the needs of each patient as customized medicine becomes more and more of a focus in healthcare.[1]

Over the next 5 years, the diagnostics market, which includes POC testing and IVD, is expected to rise significantly.[2] The rising incidence of infectious and chronic diseases, technological developments, and growing healthcare spending, especially in emerging nations, are important factors. With a cumulative annual growth rate (CAGR) of 6.9%, the global IVD market is expected to increase from roughly $98.3 billion in 2023 to $119.4 billion by 2029. The increasing prevalence of ailments such as infectious diseases, diabetes, and cardiovascular disorders, especially in North America and Asia Pacific, is a major factor driving demand. Improved healthcare infrastructure and rising healthcare spending are predicted to drive strong development in emerging nations such as China, India, and Brazil. The POC diagnostics business, focusing on fast testing outside traditional lab conditions, is also increasing significantly. This market is predicted to increase from $24.8 billion in 2021 to $43.5 billion by 2026, achieving a CAGR of 11.9%. The expansion is motivated by the increasing need for speedier diagnosis and the convenience of decentralized testing, especially in low-resource and rural locations.[3]

One of the industries most affected is **medical diagnostics**, which is transforming patient care, treatment planning, and disease detection. Early detection and patient outcomes have significantly improved, thanks to developments in imaging technology, molecular diagnostics, and POC testing (POCT).

**Imaging:** Noninvasive diagnosis of diseases including cancer, heart disease, and neurological disorders is now possible because of technologies such as MRI, CT scans, and ultrasound.[4]

**Molecular diagnostics** identify certain disease-related genetics, RNA, or protein markers. These methods, which provide accurate, individualized diagnosis, have completely changed the field.

A popular method for amplifying DNA to find genetic material from infections or mutations in human DNA is polymerase chain reaction (PCR). PCR is frequently

used to diagnose cancer and infectious disorders such as COVID-19 and HIV. PCR was foundational in SARS-CoV-2 detection during the COVID-19 pandemic. Comprehensive genomic study is made possible by next-generation sequencing (NGS), which finds mutations connected to inherited genetic diseases or malignancies. NGS is pivotal for cancer genomics, aiding in personalized therapy selection.[5] Emerging tools for rapid, highly sensitive detection of genetic material, such as CRISPR-Cas9 for viral detection. CRISPR diagnostics have been applied for rapid COVID-19 testing.[6,7]

**POC Diagnostics:** Especially in places with limited resources, tools such as portable blood analyzers, pregnancy tests, and glucometers have made it possible to obtain rapid diagnostic results outside of clinical settings.[8]

**Environmental diagnostics:** Monitoring the quality of the air, water, and soil has been made possible by environmental diagnostics instruments and sensors. Risks to ecosystems and public health are reduced when pollutants and dangerous compounds are detected early.

Water Quality Monitoring: Water bodies are now better monitored thanks to sensors that can identify chemical pollutants in the water, such as pesticides and heavy metals. Water contamination has also been evaluated using remote sensing methods.[9]

Air Quality: To monitor particle matter (PM), NOx, $CO_2$, and other air pollutants, diagnostic instruments such as gas sensors have been installed in cities across the globe. Addressing problems like respiratory illnesses and climate warming needs this.[10]

**Agricultural diagnostics:** Crop management, soil health evaluation, and livestock disease monitoring have all advanced as a result of agricultural diagnostics. Farmers may manage illnesses and maximize harvests with the use of tools like biosensors, genomics, and remote sensing.[11]

Soil Health: Farmers can make well-informed decisions on crop rotation, fertilizer use, and irrigation management by using diagnostics of the soil microbiota and nutrient levels.

The integrity and safety of systems and structures are guaranteed by the use of diagnostics in engineering and manufacturing for quality control, maintenance, and predictive analytics.

**Veterinary diagnostics:** Food security and animal health have increased because of veterinary diagnostics. To stop the spread of zoonotic infections, methods including PCR, immunoassays, and imaging are used to diagnose illnesses in pets and cattle.

Livestock Health: To prevent epidemics and guarantee the safety of meat and dairy products, diagnostics for illnesses including bovine tuberculosis, avian flu, and foot-and-mouth disease are crucial.[12]

## Current Diagnostics Platforms in Healthcare

**Laboratory-based Diagnostics**: These have historically constituted the backbone of healthcare diagnostics, employing sophisticated technology and highly trained workers. Common examples include:

- Biochemical assays: Blood testing for glucose, cholesterol, and electrolytes.
- Microbial cultures: These are used to cultivate pathogens in a lab setting, such as bacteria from a throat swab, to identify diseases.
- Histopathology: Examining tissue samples to identify diseases such as cancer.

**Immunoassays:** Immunoassays are essential for the diagnosis of autoimmune diseases, viral diseases, and hormone imbalances because they may identify particular antigens or antibodies in bodily fluids.

- Enzyme-Linked Immunosorbent Assay (ELISA): A popular test for identifying proteins in a sample, such as antibodies or antigens. It is used to measure hormone levels (such as insulin and thyroid hormones), screen for HIV, and check for hepatitis B.
- Flow Cytometry: Often employed in hematology to distinguish various cell types, such as in the diagnosis of leukemia, this technique is used for immunophenotyping. Flow cytometry has been indispensable in cancer diagnostics and immune cell profiling.[13]

## Wearables and Remote Monitoring Devices

Wearable technology and devices for remote monitoring wearable sensors are now crucial for ongoing patient monitoring outside of medical facilities because of the development of telemedicine.

- Continuous Glucose Monitors (CGMs): These are devices that diabetics use to continuously measure their blood sugar levels.
- Wearable ECG monitors: Devices that track heart rhythms and notify users of abnormal cardiac activity, such as smartwatches.[14]

For this review, the focus will be on POC and companion diagnostics (CDx) with an emphasis on the healthcare sector (Figure 1).

**POC diagnostics** refer to medical testing performed at or near the site of patient care, providing immediate results that can directly inform clinical decisions. Unlike traditional diagnostics conducted in centralized laboratories, POC devices allow for rapid diagnosis, often within minutes, enabling timely treatment, improved patient outcomes, and potentially lowering healthcare costs. POC diagnostics are used in various clinical settings, such as hospitals, clinics, and even in home-care environments.[15]

## Current Technological Formats for POC Diagnostics

1. **Lateral Flow Assays (LFAs):** With their ease of use, affordability, and adaptability, LFAs are arguably the most popular proof-of-concept


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**Fig 1 | Key platforms in point-of-care and companion diagnostics in healthcare**

technology. Rapid COVID-19 antigen tests and at-home pregnancy tests are typical examples. LFAs transfer a liquid sample via capillary action down a test strip, which is sometimes shown as a colored line, where specific target analytes are bound by detecting antibodies or other agents.[16]

2. **Microfluidics:** Lab-on-a-chip (LOC) is a miniaturized device that integrates multiple laboratory functions onto a small chip, often just a few centimeters in size. It uses microchannels and sensors to process tiny amounts of biological or chemical samples, such as blood or saliva, for tasks such as mixing, separating, and analyzing. LOC devices are portable, fast, and cost-effective, making them ideal for diagnostics and testing in remote or low-resource settings. "LOC" technologies, also known as microfluidic systems, have become advanced platforms that can carry out several laboratory tasks on a single chip. These tools integrate multiple diagnostic processes (e.g., mixing, detection, and analysis) and can manage small sample volumes. They can be used for everything from the identification of cancer biomarkers to the diagnosis of infectious diseases.[17]
3. **Electrochemical Sensors:** The electrical signal produced when target molecules attach to recognition elements on the sensor's surface is measured by electrochemical biosensors. These sensors have been used in glucose meters and are currently being developed for POC detection of cardiac biomarkers, infectious pathogens, and other analytes.
4. **Paper-based Platforms:** Paper-based diagnostics provide a low-cost, environmentally friendly alternative to traditional diagnostic tests. These devices leverage the capillary action of paper to perform biochemical assays. Advances in paper-based microfluidics have enabled these devices to detect a range of analytes with reasonable sensitivity, making them attractive for use in resource-limited settings. **Optical Biosensors:** An inexpensive and sustainable substitute for conventional diagnostic testing is paper-based diagnostics. These instruments use paper's capillary activity to carry out biochemical tests. These devices can now detect a variety of analytes with a fair level of sensitivity because of advancements in paper-based microfluidics, which makes them appealing for application in environments with minimal resources.[18,19]
5. **Smartphone-based POC Diagnostics:** Because of their sensitivity and specificity, optical techniques are being used more and more in POC diagnostics. Detection frequently relies on colorimetric or fluorescent changes that occur when the analyte binds. Surface plasmon resonance-based sensors and fluorescent-based lateral flow tests are two examples.[20] Table 1 summarizes the currently available POC diagnostic platforms.

**Table 1 | POC diagnostics in the market**

| POC diagnostic | Condition/use | Relevant research/studies |
|---|---|---|
| Abbott ID NOW | COVID-19, influenza, RSV, Strep A | Research supports its rapid molecular diagnostic capabilities for respiratory infections |
| BinaxNOW (Abbott) | COVID-19 | Widely used for COVID-19 antigen testing |
| Cepheid GeneXpert | COVID-19, TB, MRSA, HIV | PCR-based system offering rapid testing for multiple conditions |
| Quidel QuickVue | COVID-19, influenza, RSV, Strep A | FDA-approved for COVID-19 antigen detection |
| i-STAT (Abbott) | Blood gas, electrolytes, cardiac markers | Widely used in emergency settings for blood analysis; studies in *Critical Care Medicine* validate its accuracy for cardiac and metabolic markers |
| Roche Cobas Liat | Respiratory pathogens, COVID-19 | Rapid, high-sensitivity PCR platform for detecting pathogens; validated by several studies, particularly for influenza and COVID-19 diagnostics |
| Alere Afinion | Diabetes (HbA1c), Lipid profile | Commonly used for managing diabetes and cardiovascular risk; multiple studies confirm its efficacy in ***Diabetes Care*** for HbA1c measurement |
| HemoCue Hb 201+ | Anemia (hemoglobin levels) | Popular for assessing hemoglobin levels; validated by research in *Clinical Chemistry and Laboratory Medicine* for anemia diagnosis |
| DPP HIV-Syphilis Assay (Chembio Diagnostics) | HIV and syphilis co-infection | Dual rapid test for HIV and syphilis; validated by studies in *PLOS ONE* and recommended for high-risk populations |
| StatStrip Glucose (Nova Biomedical) | Diabetes (blood glucose monitoring) | Gold standard for glucose monitoring in hospitals and intensive care units, with validation studies in *Journal of Diabetes Science and Technology* |
| Biosynex AMPLIQUICK® | Zika, Dengue, Chikungunya | Multiplex rapid diagnostic test for tropical diseases, validated by *American Journal of Tropical Medicine and Hygiene* for simultaneous detection of arboviruses |

## Challenges in Developing and Bringing POC Diagnostics to Market

1. **Technical Limitations**
   Sensitivity and Specificity: Sensitivity and simplicity are frequently traded off in POC devices. Although extremely sensitive techniques are used in traditional lab-based tests, it might be difficult to simplify them for quick proof-of-concept use without compromising performance.

   The integration of all diagnostic capabilities into a small, affordable, and user-friendly device is still a major technical challenge, despite the potential of microfluidics and other downsized platforms.

   Multiplexing: Much work needs to be done to enable the simultaneous testing of many analytes in a single POC device without cross-reactivity or signal interference.
2. **Regulatory Challenges:** POC diagnostics have a complicated regulatory process, especially for self-testing devices. To guarantee that devices function dependably in non-laboratory situations, regulatory agencies such as the European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA) want thorough validation. The development process becomes more complicated and expensive due to the requirement to demonstrate analytical performance, user safety, and ease of use.
3. **Manufacturing and Scalability:** There are several obstacles to overcome when bringing POC diagnostic devices from prototype to mass manufacturing, particularly when preserving accuracy and functionality in high quantities. In high-throughput production settings, ensuring reproducibility and upholding quality standards may result in longer development times and higher costs.
4. **Affordability and Accessibility:** The cost of creating high-performance POC devices may restrict their availability, despite the fact that POC diagnostics hold promise for expanding access to healthcare, especially in settings with limited resources. It takes creative technical and commercial strategies to strike a balance between affordability and the addition of cutting-edge features such as networking and real-time data exchange.
5. **Integration with Healthcare Systems:** Integrating POC diagnostics with the current healthcare system is one of the biggest obstacles to its implementation. Traditional lab-based workflows and centralized data repositories are essential components of many healthcare systems. To reach their full potential, POC diagnostics must be seamlessly integrated with telemedicine platforms and electronic health records.

## Companion Diagnostics

In vitro diagnostic tools or tests known as CDx offer crucial data for the secure and efficient use of related medicines. The first predictive biomarker associated with drug development was the HER2 protein, which resulted in the approval of trastuzumab (Herceptin) and HER2 immunohistochemical (IHC) assay, HercepTest (Dako).[21] These diagnostics support the precision medicine approach by identifying patient populations who are most likely to benefit from a particular drug, anticipating possible side effects, or tracking the therapeutic response. CDx makes sure that medications are more successful by customizing them to each patient's


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unique traits. This reduces unneeded therapy and its related toxicities.

### Areas of Application

CDx is essential in several therapeutic domains, chief among these being:

**Oncology:** Because of the variety of cancers and the growing number of targeted treatments, oncology has accounted for the majority of CDx development. Treatments including EGFR inhibitors for lung cancer, BRAF inhibitors for melanoma, and HER2 inhibitors for breast cancer are all guided by CDx.

**Cardiology:** CDx is becoming more popular in cardiology, especially with antiplatelet treatments, as CYP2C19 genotyping and other testing can predict how well clopidogrel medication will work.

**Infectious diseases:** Despite being less prevalent, CDx is being used to customize antiviral treatments, especially for illnesses caused by the hepatitis C virus and HIV.

**Immunology:** CDx is being investigated to predict responses to biologics in autoimmune illnesses and inflammatory disorders, particularly in psoriasis and rheumatoid arthritis.

**Neurology:** Biomarkers including tau protein and amyloid beta are being studied as possible CDx for future treatments in Alzheimer's disease and multiple sclerosis, two major expanding fields. The regulatory approval of CDx involves rigorous pathways to ensure their safety, efficacy, and reliability. CDx must demonstrate that they are analytically and clinically validated for their intended use, typically in identifying patients who are most likely to benefit from a specific therapy. Regulatory agencies such as the U.S. FDA, the EMA, and others follow distinct yet overlapping frameworks. In the United States, CDx devices are generally classified as Class III medical devices, requiring a premarket approval application that includes evidence from clinical trials conducted alongside the corresponding therapeutic product. The approval process often involves collaboration between the device manufacturer and the pharmaceutical company, ensuring that both the diagnostic and its associated therapy are co-developed and approved in parallel.

Internationally, standards such as the In Vitro Diagnostic Regulation in the EU impose additional requirements for performance evaluation and post-market surveillance. Given the critical role of CDx in personalized medicine, regulators prioritize transparency and alignment with therapeutic development timelines to ensure rapid and reliable patient access to these technologies.

### Technological Platforms in CDx

Technological platform advancements have been essential to the creation and application of CDx. At the moment, several platforms are used:

PCR: PCR's excellent sensitivity and specificity make it one of the most used platforms, especially for identifying gene mutations or amplifications.[22]

NGS: NGS is quickly becoming a popular CDx platform since it allows for the simultaneous identification of several genomic changes. Large gene panels or even whole-genome sequencing may be necessary in oncology, where it is especially helpful.[23]

A well-established technique in CDx, IHC is especially useful for protein expression indicators. For example, immunotherapies for a variety of malignancies are guided by PD-L1 IHC testing.[24]

Chromosome rearrangements, amplifications, and translocations can be found using fluorescence in situ hybridization, which is especially useful in oncology. For example, it can identify ALK rearrangements in lung cancer.

With its high throughput and precision, mass spectrometry is being investigated more and more for proteome and metabolomic profiling, particularly for the identification and validation of biomarkers.[25] Table 2 summarizes the currently available CDx platforms in the market.

### Challenges in Bringing CDx to Market

Despite significant advancements, the development and commercialization of CDx face several challenges:[26–30]

**Regulatory Obstacles:** Since both a CDx and a treatment need concurrent clinical validation, co-development is challenging. Approval delays may

**Table 2 | CDx platforms in the market**

| Companion diagnostic | Condition | Relevant research/studies |
|---|---|---|
| FoundationOne CDx (Foundation Medicine) | Various cancers (lung, breast, colorectal, etc.) | Validated by multiple studies, including analyses of over 300 genes involved in tumor growth (Foundation Medicine's NGS-based assay) |
| Oncomine Dx Target Test (Thermo Fisher) | Non-small cell lung cancer (NSCLC) | FDA-approved for detecting mutations in EGFR, ALK, ROS1 genes |
| PD-L1 IHC 22C3 pharmDx (Agilent Technologies) | NSCLC, bladder cancer | Assesses PD-L1 expression, crucial for immunotherapy decisions (e.g., Keytruda treatment); backed by clinical trials on checkpoint inhibitors |
| BRACAnalysis CDx (Myriad Genetics) | Breast and ovarian cancers | Detects BRCA1/2 mutations for PARP inhibitor eligibility; approved for use with Lynparza |
| Therascreen EGFR RGQ PCR Kit (Qiagen) | NSCLC | Approved for identifying EGFR mutations to guide treatment with tyrosine kinase inhibitors (TKIs), validated through clinical trials |
| Vysis ALK Break Apart FISH Probe Kit (Abbott) | ALK-positive NSCLC | Validated by studies showing improved outcomes for patients treated with ALK inhibitors, such as crizotinib |
| Guardant360 CDx (Guardant Health) | Solid tumors | Liquid biopsy approved for comprehensive genomic profiling; various studies confirm its utility in noninvasive cancer monitoring |

result from different regulatory procedures, particularly for international markets.

**Clinical value and Validation**: To demonstrate the clinical value of CDx, it is necessary to show both the analytical validity of the CDx and the improvement in patient outcomes that result from its use. Large-scale, frequently costly clinical trials are necessary for this.

**Cost and Reimbursement:** Developing CDx might be prohibitively expensive, particularly if NGS or sophisticated biomarker discovery platforms are needed. Furthermore, getting healthcare systems to approve reimbursement is still a major obstacle, especially in regions outside of the United States and Europe.

**Data Integration and Interpretation:** The difficulty of integrating and understanding big information in a way that is therapeutically useful increases with the prevalence of multi-omics techniques and complicated data from platforms such as mass spectrometry and NGS. To guarantee that the data are actionable, bioinformaticians, physicians, and regulatory bodies must work together.

**Market Penetration and Adoption:** After receiving approval, CDx may take some time to become a standard part of clinical practice. This could be the result of doctors' resistance to altering long-standing treatment paradigms, a lack of awareness, or a perception of the complexity of testing procedures.

Table 4 provides a comparison summary of POC and CDx platform attributes.

Implementing POC and CDx in low-income and low-resource settings requires innovative frameworks that address financial, logistical, and infrastructural barriers while ensuring high-quality and reliable healthcare delivery. Below are some novel frameworks and approaches tailored for such contexts:

1. **Frugal Innovation Framework**
   This framework emphasizes cost-effective solutions without compromising quality. It focuses on leveraging local resources, low-cost materials, and simplified designs. For POC and CDx, this could mean:
   - Development of paper-based microfluidic devices.
   - Use of mobile phones as diagnostic interfaces, utilizing built-in cameras and computational power.
   - Low-power or solar-powered diagnostic tools to address energy constraints.

   **Case Example:** A paper-based LFA for infectious diseases such as malaria or HIV.
2. **Decentralized Diagnostic Networks**
   This framework establishes a hub-and-spoke model where central facilities support peripheral centers with training, quality control, and data management.
   - **Implementation:**
     - Portable POC devices deployed in community clinics.
     - Regular telemedicine consultations with experts from central hubs.
   - **Advantages:** Reduces the need for sophisticated infrastructure at every site.

   **Case Example:** A regional laboratory oversees POC HIV testing and antiretroviral therapy management at village clinics.
3. **Integration of Diagnostics into Community Health Programs**
   Integrating POC diagnostics into existing community health worker (CHW) programs can maximize reach and minimize operational costs.
   - Equip CHWs with portable diagnostic kits.
   - Provide training on CDx linked to treatment protocols (e.g., TB drug susceptibility testing).

   **Case Example:** Community workers use GeneXpert MTB/RIF for TB detection in rural areas.
4. **Digital Health and Artificial Intelligence Frameworks**
   The use of digital tools and artificial intelligence (AI) algorithms to augment diagnostic capabilities in low-resource settings includes:
   - Mobile apps for data interpretation.
   - AI-powered platforms to analyze test results, reducing the reliance on highly trained personnel.
   - Cloud-based systems for remote access to test results.

   **Case Example:** Smartphone apps combined with POC devices to monitor chronic conditions such diabetes or hypertension.
5. **Public–Private Partnership (PPP) Framework**
   Establishing collaborations between governments, private companies, and NGOs can help fund and scale POC and CDx.
   - Private companies provide technology and training.
   - Governments ensure regulatory approvals and infrastructure support.
   - NGOs focus on community outreach and implementation.

   **Case Example:** PPPs delivering malaria diagnostics and treatments under the Affordable Medicines Facility-malaria initiative.
6. **Open-Source Diagnostic Platforms**
   Developing open-source tools and platforms for diagnostics can reduce costs and promote adaptability.
   - Shared blueprints for diagnostic devices.
   - Collaborative platforms for knowledge sharing among researchers and healthcare workers.

   **Case Example:** Open-source CRISPR-based diagnostic tools for emerging diseases.
7. **Crowdsourcing and Local Manufacturing Framework**
   Crowdsourcing designs and locally manufacturing diagnostic devices can lower costs and increase accessibility.


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- Engage local engineers and innovators to create culturally and contextually appropriate diagnostics.
- Establish small-scale production units for rapid deployment.

**Case Example:** Local production of rapid antigen tests for COVID-19 using 3D-printed components.

8. **Ecosystem-Based Approaches**
   This framework integrates diagnostics with broader health and economic ecosystems.
   - Partner with microfinance institutions to fund community diagnostic centers.
   - Link diagnostics to pharmaceutical supply chains to ensure treatment availability post-diagnosis.

   **Case Example:** An ecosystem model for cervical cancer screening with immediate linkage to treatment in rural clinics.

**Key Enablers for Success:**

1. **Capacity Building**: Continuous training of healthcare providers and community workers.
2. **Policy Support**: Streamlined regulatory pathways for diagnostic approval.
3. **Sustainability Models**: Implement pay-per-use systems or social enterprise models to ensure financial viability.
4. **Community Engagement**: Build trust and awareness around new diagnostic tools.

These frameworks combine innovative technology with sustainable practices, addressing the unique challenges of low-resource settings while ensuring equity in healthcare access.

## Current Developments in POC and CDx

The Cancer Center at Illinois has created two novel biomarker detection tools that could revolutionize POC diagnostics. Photonic Resonator Absorption Microscopy (PRAM), developed in collaboration with scientists at Stanford, Huntsman Cancer Institute, and the Mayo Clinic can rapidly detect a variety of cancer biomarkers using a novel gold nanoparticle (AuNP) tagging method. The PRAM technique uses a photonic crystal as a microscope surface instead of a standard glass slide. To identify and count individual AuNPs, the photonic crystal offers extremely high contrast. Researchers can see and quantify individual molecules (proteins, nucleic acids, antibodies, circulating tumor DNA (ctDNA)) in a sample thanks to AuNPs, which are tags placed on molecules for biosensing.[25]

Digital diagnostic methods that use deep learning and AI-based verification for LFAs can improve sensitivity and shorten assay times. When compared to human analysis, this method produced diagnostic times as low as 2 min with greater accuracy for both infectious and noninfectious disorders. It greatly improves POCT, enabling both non-experts and medical professionals to make quick and precise decisions.[31] Selected currently available POC and CDx-marketed platforms are listed in Tables 1–3.

Regulatory agencies and healthcare industries are developing significant initiatives after the COVID-19 pandemic, which saw monumental development in bringing to market POC tests to enhance digital diagnostics.[32,33]

## Future Prospects of POC and CDx

With several technical developments and strategic efforts aimed at transforming diagnostic processes, the

**Table 3 | List of cleared or approved companion diagnostic devices (*In Vitro* and Imaging Tools) — FDA**

| Diagnostic name (manufacturer) | Indication—Sample type | Drug trade name (generic) NDA/BLA | Biomarker(s) | Biomarker(s) (details) | PMA/510(k)/513(f)(2)/HDE (approval/clearance/grant date) |
|---|---|---|---|---|---|
| AAV5 DetectCDx (ARUP Laboratories) | Hemophilia A patients—Plasma | ROCTAVIAN (valoctocogene roxaparvovec-rvox) BLA 125720 | Anti-AAV5 Antibodies | Antibodies to the adeno-associated virus serotype 5 (AAV5) viral vector | P190033 (06/29/2023) |
| Abbott RealTime IDH1 (Abbott Molecular, Inc.) | Acute myeloid leukemia—Peripheral blood or bone marrow | Tibsovo (ivosidenib) NDA 211192 | IDH1 | R132 mutations (R132C, R132H, R132G, R132S, and R132L) | P170041 (07/20/2018) |
| Abbott RealTime IDH1 (Abbott Molecular, Inc.) | Myelodysplastic syndromes (MDS)—Peripheral blood or bone marrow | Tibsovo (ivosidenib) NDA 211192 | IDH1 | R132 mutations (R132C, R132H, R132G, R132S, and R132L) | P170041/S007 (10/24/2023) |
| Abbott RealTime IDH1 (Abbott Molecular, Inc.) | Acute myeloid leukemia—Peripheral blood or bone marrow | Rezlidhia (olutasidenib) NDA 215814 | IDH1 | R132 mutations (R132C, R132H, R132G, R132S, and R132L) | P170041/S006 (12/01/2022) |
| Abbott RealTime IDH2 (Abbott Molecular, Inc.) | Acute myeloid leukemia—Peripheral blood or bone marrow | Idhifa (enasidenib) NDA 209606 | IDH2 | R140Q, R140L, R140G, R140W, R172K, R172M, R172G, R172S, and R172W | P170005 (08/01/2017) |
| Agilent Resolution ctDx FIRST assay (Resolution Bioscience, Inc.) | Non-small cell lung cancer (NSCLC)—Plasma | Krazati (adagrasib) NDA 216340 | KRAS | KRAS G12C | P210040 (12/12/2022) |
| Bond Oracle HER2 IHC System (Leica Biosystems) | Breast cancer—Tissue | Herceptin (trastuzumab) BLA 103792 | ERBB2 (HER2) | HER-2 protein overexpression | P090015 (04/18/2012) |

*Continued*

**Table 3 | Continued**

| Diagnostic name (manufacturer) | Indication—Sample type | Drug trade name (generic) NDA/BLA | Biomarker(s) | Biomarker(s) (details) | PMA/510(k)/513(f)(2)/HDE (approval/clearance/grant date) |
|---|---|---|---|---|---|
| BRACAnalysis CDx (Myriad Genetic Laboratories, Inc.) | Ovarian cancer—Whole blood | Lynparza (olaparib) NDA 208558 | BRCA1 and BRCA2 | Mutations | P140020 (12/19/2014) |
| BRACAnalysis CDx (Myriad Genetic Laboratories, Inc.) | Breast cancer—Whole blood | Lynparza (olaparib) NDA 208558 | BRCA1 and BRCA2 | Mutations | P140020/S012 (01/12/2018) |
| BRACAnalysis CDx (Myriad Genetic Laboratories, Inc.) | Breast cancer—Whole blood | Talzenna (talazoparib) NDA 211651 | BRCA1 and BRCA2 | Mutations | P140020/S015 (10/16/2018) |
| BRACAnalysis CDx (Myriad Genetic Laboratories, Inc.) | Ovarian cancer—Whole blood | Rubraca (rucaparib) NDA 209115 | BRCA1 and BRCA2 | Mutations | P140020/S016 (10/16/2018) |
| BRACAnalysis CDx (Myriad Genetic Laboratories, Inc.) | Pancreatic cancer—Whole blood | Lynparza (olaparib) NDA 208558 | BRCA1 and BRCA2 | Mutations | P140020/S019 (12/27/2019) |
| BRACAnalysis CDx (Myriad Genetic Laboratories, Inc.) | Metastatic castrate-resistant prostate cancer (mCRPC)—Whole blood | Lynparza (olaparib) NDA 208558 | BRCA1 and BRCA2 | Mutations | P140020/S020 (05/19/2020) |
| cobas 4800 BRAF V600 Mutation Test (Roche Molecular Systems, Inc.) | Melanoma—Tissue | Zelboraf (vemurafenib) NDA 202429 | BRAF | V600E | P110020 (08/17/2011) |
| cobas 4800 BRAF V600 Mutation Test (Roche Molecular Systems, Inc.) | Melanoma—Tissue | Cotellic (cobimetinib) NDA 206192 in combination with Zelboraf (vemurafenib) NDA 202429 | BRAF | V600E or V600K | P110020/S016 (11/07/2016) |
| Cobas EGFR Mutation Test v1 (Roche Molecular Systems, Inc.) | Non-small cell lung cancer (NSCLC)—Tissue | Tarceva (erlotinib) NDA 021743 | EGFR (HER1) | Exon 19 deletion or exon 21 L858R substitution mutation | P120019 (07/15/2013) |
| Cobas EGFR Mutation Test v2 (Roche Molecular Systems, Inc.) | Non-small cell lung cancer (NSCLC)—Tissue | Tagrisso (osimertinib) NDA 208065 | EGFR (HER1) | T790M | P120019/S007 (11/13/2015) |
| Cobas EGFR Mutation Test v2 (Roche Molecular Systems, Inc.) | Non-small cell lung cancer (NSCLC)—Tissue | Tagrisso (osimertinib) NDA 208065 | EGFR (HER1) | Exon 19 deletion or exon 21 L858R substitution mutation | P120019/S016 (04/18/2018) |
| Cobas EGFR Mutation Test v2 (Roche Molecular Systems, Inc.) | Non-small cell lung cancer (NSCLC)—Plasma | Tagrisso (osimertinib) NDA 208065 | EGFR (HER1) | Exon 19 deletion or exon 21 L858R substitution mutation | P120019/S018 (04/18/2018) |
| Cobas EGFR Mutation Test v2 (Roche Molecular Systems, Inc.) | Non-small cell lung cancer (NSCLC)—Tissue or plasma | Iressa (gefitinib) NDA 206995 | EGFR (HER1) | Exon 19 deletion or exon 21 L858R substitution mutation | P120019/S019 (08/22/0218) |
| Cobas EGFR Mutation Test v2 (Roche Molecular Systems, Inc.) | Non-small cell lung cancer (NSCLC)—Tissue or plasma | Iressa (gefitinib) NDA 206995 | EGFR (HER1) | Exon 19 deletion or exon 21 L858R substitution mutation | P120019/S031 (10/27/2020) Group Labeling, see table below |
| Cobas EGFR Mutation Test v2 (Roche Molecular Systems, Inc.) | Non-small cell lung cancer (NSCLC)—Tissue or plasma | Tarceva (erlotinib) NDA 021743 | EGFR (HER1) | Exon 19 deletion or exon 21 L858R substitution mutation | P120019/S031 (10/27/2020) Group Labeling, see table below |
| Cobas EGFR Mutation Test v2 (Roche Molecular Systems, Inc.) | Non-small cell lung cancer (NSCLC)—Tissue or plasma | Gilotrif (afatinib) NDA 201292 | EGFR (HER1) | Exon 19 deletion or exon 21 L858R substitution mutation | P120019/S031 (10/27/2020) Group Labeling, see table below |
| Cobas EGFR Mutation Test v2 (Roche Molecular Systems, Inc.) | Non-small cell lung cancer (NSCLC)—Tissue or plasma | Tagrisso (osimertinib) NDA 208065 | EGFR (HER1) | Exon 19 deletion or exon 21 L858R substitution mutation | P120019/S031 (10/27/2020) Group Labeling, see table below |
| Cobas EGFR Mutation Test v2 (Roche Molecular Systems, Inc.) | Non-small cell lung cancer (NSCLC)—Plasma | Tagrisso (osimertinib) NDA 208065 | EGFR (HER1) | T790M | P150044 (09/28/2016) |
| Cobas EGFR Mutation Test v2 (Roche Molecular Systems, Inc.) | Non-small cell lung cancer (NSCLC)—Plasma | Tarceva (erlotinib) NDA 021743 | EGFR (HER1) | Exon 19 deletion or exon 21 L858R substitution mutation | P150047 (06/01/2016) |
| Cobas EZH2 Mutation Test (Roche Molecular Systems, Inc.) | Follicular lymphoma tumor—Tissue | Tazverik (tazemetostat) NDA 213400 | EZH2 | Y646N, Y646F or Y646X (Y646H, Y646S, or Y646C), A682G, and A692V of the EZH2 gene | P200014 (06/18/2020) |
| Cobas KRAS Mutation Test (Roche Molecular Systems, Inc.) | Colorectal cancer—Tissue | Erbitux (cetuximab) BLA 125084 | KRAS | Mutations in codons 12 and 13 of KRAS gene | P140023 (05/07/2015) |

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Table 3 | Continued

| Diagnostic name (manufacturer) | Indication—Sample type | Drug trade name (generic) NDA/BLA | Biomarker(s) | Biomarker(s) (details) | PMA/510(k)/513(f)(2)/HDE (approval/clearance/grant date) |
|---|---|---|---|---|---|
| Cobas KRAS Mutation Test (Roche Molecular Systems, Inc.) | Colorectal cancer—Tissue | Vectibix (panitumumab) BLA 125147 | KRAS | Mutations in codons 12 and 13 of KRAS gene | P140023 (05/07/2015) |
| CRCDx RAS Mutation Detection Assay Kit (EntroGen, Inc.) | Colorectal cancer (CRC)—Tissue | Vectibix (panitumumab) BLA 125147 | KRAS and NRAS | KRAS wild-type biomarkers (the absence of mutations in exons 2, 3, or 4) and NRAS wild-type biomarkers (the absence of mutations in exons 2, 3, or 4) | P220005 (09/29/2023) |
| Dako EGFR pharmDx Kit (Dako North America, Inc.) | Colorectal cancer—Tissue | Erbitux (cetuximab) BLA 125084 | EGFR (HER1) | EGFR (HER1) protein expression | P030044 (02/12/2004) |
| Dako EGFR pharmDx Kit (Dako North America, Inc.) | Colorectal cancer—Tissue | Vectibix (panitumumab) BLA 125147 | EGFR (HER1) | EGFR (HER1) protein expression | P030044/S002 (09/27/2006) |
| FerriScan (Resonance Health Analysis Services Pty Ltd) | Non-transfusion-dependent thalassemia—Tissue | Exjade (deferasirox) NDA 021882 | Liver iron concentration imaging | Liver iron concentration based on the proton transverse relaxation rate of MRI images | DEN130012/K124065 (01/23/2013) |
| FoundationFocus CDxBRCA Assay (Foundation Medicine, Inc.) | Ovarian cancer—Tissue | Rubraca (rucaparib) NDA 209115 | BRCA1 and BRCA2 | BRCA1 and BRCA2 alterations | P160018 (12/19/2016) |
| FoundationOne CDx (Foundation Medicine, Inc.) | Non-small cell lung cancer (NSCLC)—Tissue | Gilotrif (afatinib) NDA 201292 | EGFR (HER1) | Exon 19 deletion or exon 21 L858R substitution mutation | P170019 (11/30/2017) |
| FoundationOne CDx (Foundation Medicine, Inc.) | Non-small cell lung cancer (NSCLC)—Tissue | Iressa (gefitinib) NDA 206995 | EGFR (HER1) | Exon 19 deletion or exon 21 L858R substitution mutation | P170019 (11/30/2017) |
| FoundationOne CDx (Foundation Medicine, Inc.) | Non-small cell lung cancer (NSCLC)—Tissue | Tarceva (erlotinib) NDA 021743 | EGFR (HER1) | Exon 19 deletion or exon 21 L858R substitution mutation | P170019 (11/30/2017) |
| FoundationOne CDx (Foundation Medicine, Inc.) | Non-small cell lung cancer (NSCLC)—Tissue | Tagrisso (osimertinib) NDA 208065 | EGFR (HER1) | T790M | P170019 (11/30/2017) |
| FoundationOne CDx (Foundation Medicine, Inc.) | Non-small cell lung cancer (NSCLC)—Tissue | Alecensa (alectinib) NDA 208434 | ALK | ALK rearrangements | P170019 (11/30/2017) |
| FoundationOne CDx (Foundation Medicine, Inc.) | Non-small cell lung cancer (NSCLC)—Tissue | Xalkori (crizotinib) NDA 202570 | ALK | ALK rearrangements | P170019 (11/30/2017) |
| FoundationOne CDx (Foundation Medicine, Inc.) | Non-small cell lung cancer (NSCLC)—Tissue | Zykadia (ceritinib) NDA 211225 | ALK | ALK rearrangements | P170019 (11/30/2017) |
| FoundationOne CDx (Foundation Medicine, Inc.) | Non-small cell lung cancer (NSCLC)—Tissue | Tafinlar (dabrafenib) NDA 202806 in combination with Mekinist (trametinib) NDA 204114 | BRAF | V600E | P170019 (11/30/2017) |
| FoundationOne CDx (Foundation Medicine, Inc.) | Breast cancer—Tissue | Herceptin (trastuzumab) BLA 103792 | ERBB2 (HER2) | ERBB2 (HER2) amplification | P170019 (11/30/2017) |
| FoundationOne CDx (Foundation Medicine, Inc.) | Breast cancer—Tissue | Perjeta (pertuzumab) BLA 125409 | ERBB2 (HER2) | ERBB2 (HER2) amplification | P170019 (11/30/2017) |
| FoundationOne CDx (Foundation Medicine, Inc.) | Breast cancer—Tissue | Kadcyla (ado-trastuzumab emtansine) BLA 125427 | ERBB2 (HER2) | ERBB2 (HER2) amplification | P170019 (11/30/2017) |
| FoundationOne CDx (Foundation Medicine, Inc.) | Colorectal cancer—Tissue | Erbitux (cetuximab) BLA 125084 | KRAS | KRAS wild-type (absence of mutations in codons 12 and 13) | P170019 (11/30/2017) |
| FoundationOne CDx (Foundation Medicine, Inc.) | Colorectal cancer—Tissue | Vectibix (panitumumab) BLA 125147 | KRAS and NRAS | KRAS wild-type (absence of mutations in exons 2, 3, and 4) and NRAS wild-type (absence of mutations in exons 2, 3, and 4) | P170019 (11/30/2017) |
| FoundationOne CDx (Foundation Medicine, Inc.) | Melanoma—Tissue | Mekinist (trametinib) NDA 204114 | BRAF | V600E and V600K | P170019 (11/30/2017) Group Labeling, See table below |
| FoundationOne CDx (Foundation Medicine, Inc.) | Ovarian cancer—Tissue | Lynparza (olaparib) NDA 208558 | BRCA1 and BRCA2 | BRCA1 and BRCA2 alterations | P170019/S004 (07/01/2019) |

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Table 3 | Continued

| Diagnostic name (manufacturer) | Indication—Sample type | Drug trade name (generic) NDA/BLA | Biomarker(s) | Biomarker(s) (details) | PMA/510(k)/513(f)(2)/HDE (approval/clearance/grant date) |
|---|---|---|---|---|---|
| FoundationOne CDx (Foundation Medicine, Inc.) | Breast cancer—Tissue | Piqray (alpelisib) NDA 212526 | PIK3CA | C420R, E542K, E545A, E545D [1635G>T only], E545G, E545K, Q546E, Q546R, H1047L, H1047R, and H1047Y | P170019/S006 (12/03/2019) |
| FoundationOne CDx (Foundation Medicine, Inc.) | Non-small cell lung cancer (NSCLC)—Tissue | Tagrisso (osimertinib) NDA 208065 | EGFR (HER1) | Exon 19 deletion or exon 21 L858R substitution mutation | P170019/S008 (07/01/2019) Group Labeling, See table below |
| FoundationOne CDx (Foundation Medicine, Inc.) | Non-small cell lung cancer (NSCLC)—Tissue | Tabrecta (capmatinib) NDA 213591 | MET | MET single-nucleotide variants and indels that lead to MET exon 14 skipping | P170019/S011 (05/06/2020) |
| FoundationOne CDx (Foundation Medicine, Inc.) | Cholangiocarcinoma—Tissue | Pemazyre (pemigatinib) NDA 213736 | FGFR2 | FGFR2 fusions and select rearrangements | P170019/S013 (04/17/2020) |
| FoundationOne CDx (Foundation Medicine, Inc.) | Metastatic castrate-resistant prostate cancer (mCRPC)—Tissue | Lynparza (olaparib) NDA 208558 | Homologous recombination repair (HRR) genes | BRCA1, BRCA2, ATM, BARD1, BRIP1, CDK12, CHEK1, CHEK2, FANCL, PALB2, RAD51B, RAD51C, RAD51D, and RAD54L alterations | P170019/S015 (05/19/2020) |
| FoundationOne CDx (Foundation Medicine, Inc.) | Solid tumors—Tissue | Keytruda (pembrolizumab) BLA 125514 | TMB | TMB ≥ 10 mutations per megabase | P170019/S016 (06/16/2020) |
| FoundationOne CDx (Foundation Medicine, Inc.) | Solid tumors—Tissue | Vitrakvi (larotrectinib) NDA 210861 | NTRK1, NTRK2 and NTRK3 | NTRK1, NTRK2, and NTRK3 fusions | P170019/S017 (10/23/2020) |
| FoundationOne CDx (Foundation Medicine, Inc.) | Solid tumors—Tissue | Keytruda (pembrolizumab) BLA 125514 | MSI-High | Microsatellite instability-High (MSI-H) | P170019/S029 (02/18/2022) |
| FoundationOne CDx (Foundation Medicine, Inc.) | Melanoma—Tissue | Tecentriq (atezolizumab) BLA 761034 in combination with Cotellic (cobimetinib) NDA 206192 and Zelboraf (vemurafenib) NDA 202429 | BRAF | BRAF V600 mutations | P170019/S030 (01/19/2022) |
| FoundationOne CDx (Foundation Medicine, Inc.) | Non-small cell lung cancer (NSCLC)—Tissue | BRAFTOVI (encorafenib) NDA210496 in combination with Mektovi (binimetinib) NDA210498 | BRAF | V600E | P170019/S039 (10/11/2023) |
| FoundationOne CDx (Foundation Medicine, Inc.) | Solid tumors—Tissue | RETEVMO (selpercatinib) NDA214246 | RET | RET fusions | P170019/S043 (10/06/2023) |
| FoundationOne CDx (Foundation Medicine, Inc.) | Breast cancer—Tissue | TRUQAP (capivasertib) NDA218197 in combination with FASLODEX (fulvestrant) NDA021344 | PIK3CA | AKT1/PTEN alterations | P170019/S048 (11/16/2023) |
| FoundationOne CDx (Foundation Medicine, Inc.) | Solid tumors—Tissue | Rozlytrek (entrectinib) NDA 212725 | NTRK1, NTRK2 and NTRK3 | NTRK1, NTRK2, and NTRK3 fusions | P170019/S014 (06/07/2022) |
| FoundationOne CDx (Foundation Medicine, Inc.) | Non-small cell lung cancer (NSCLC)—Tissue | Rozlytrek (entrectinib) NDA 212725 | ROS1 | ROS1 fusions | P170019/S014 (06/07/2022) |
| FoundationOne CDx (Foundation Medicine, Inc.) | Prostate cancer—Tissue | AKEEGA (niraparib + abiraterone acetate) NDA 216793 | BRCA1 and BRCA2 | BRCA1 and BRCA2 alterations | P170019/S042 (08/11/2023) |
| FoundationOne Liquid CDx (Foundation Medicine, Inc.) | Non-small cell lung cancer (NSCLC)—Plasma | Iressa (gefitinib) NDA 206995 | EGFR (HER1) | Exon 19 deletion or exon 21 L858R substitution mutation | P190032 (08/26/2020) P190032/S008 (12/19/2022) Group Labeling, See table below |
| FoundationOne Liquid CDx (Foundation Medicine, Inc.) | Non-small cell lung cancer (NSCLC)—Plasma | Tagrisso (osimertinib) NDA 208065 | EGFR (HER1) | Exon 19 deletion or exon 21 L858R substitution mutation | P190032 (08/26/2020) P190032/S008 (12/19/2022) Group Labeling, See table below |
| FoundationOne Liquid CDx (Foundation Medicine, Inc.) | Non-small cell lung cancer (NSCLC)—Plasma | Tarceva (erlotinib) NDA 021743 | EGFR (HER1) | Exon 19 deletion or exon 21 L858R substitution mutation | P190032 (08/26/2020) P190032/S008 (12/19/2022) Group Labeling, See table below |

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Table 3 | Continued

| Diagnostic name (manufacturer) | Indication—Sample type | Drug trade name (generic) NDA/BLA | Biomarker(s) | Biomarker(s) (details) | PMA/510(k)/513(f)(2)/HDE (approval/clearance/grant date) |
|---|---|---|---|---|---|
| FoundationOne Liquid CDx (Foundation Medicine, Inc.) | Non-small cell lung cancer (NSCLC)—Plasma | BRAFTOVI (encorafenib) NDA210496 in combination with Mektovi (binimetinib) NDA210498 | BRAF | V600E | P190032/S011 (10/11/2023) |
| FoundationOne Liquid CDx (Foundation Medicine, Inc.) | Metastatic castrate-resistant prostate cancer (mCRPC)—Plasma | Rubraca (rucaparib) NDA 209115 | BRCA1 and BRCA2 | BRCA1 and BRCA2 alterations | P190032 (08/26/2020) |
| FoundationOne Liquid CDx (Foundation Medicine, Inc.) | Non-small cell lung cancer (NSCLC)—Plasma | Tabrecta (capmatinib) NDA 213591 | MET | MET single-nucleotide variants and indels that lead to MET exon 14 skipping | P190032/S001 (07/15/2021) |
| FoundationOne Liquid CDx (Foundation Medicine, Inc.) | Non-small cell lung cancer (NSCLC)—Plasma | Rozlytrek (entrectinib) NDA 212725 | ROS1 | ROS1 fusions | P190032/S004 (12/22/2022) |
| FoundationOne Liquid CDx (Foundation Medicine, Inc.) | Solid tumors—Plasma | Rozlytrek (entrectinib) NDA 212725 | NTRK1, NTRK2, and NTRK3 fusions | NTRK1/2/3 fusions | P190032/S004 (12/22/2022) |
| FoundationOne Liquid CDx (Foundation Medicine, Inc.) | Non-small cell lung cancer (NSCLC)—Plasma | Alecensa (alectinib) NDA 208434 | ALK | ALK rearrangements | P200006 (10/26/2020) |
| FoundationOne Liquid CDx (Foundation Medicine, Inc.) | Breast cancer—Plasma | Piqray (alpelisib) NDA 212526 | PIK3CA | C420R, E542K, E545A, E545D [1635G>T only], E545G, E545K, Q546E, Q546R, H1047L, H1047R, and H1047Y | P200006 (10/26/2020) |
| FoundationOne Liquid CDx (Foundation Medicine, Inc.) | Metastatic castrate-resistant prostate cancer (mCRPC)—Plasma | Lynparza (olaparib) NDA 208558 | BRCA1, BRCA2 and ATM | BRCA1, BRCA2, and ATM alterations | P200006 (10/26/2020) |
| FoundationOne Liquid CDx (Foundation Medicine, Inc.) | Metastatic colorectal cancer (mCRC)—Plasma | BRAFTOVI (encorafenib) NDA 210496 in combination with cetuximab BLA 125084 | BRAF | BRAF V600E alteration | P190032/S010 (06/08/2023) |
| FoundationOne Liquid CDx (Foundation Medicine, Inc.) | Metastatic castrate-resistant prostate cancer (mCRPC)—plasma | AKEEGA (niraparib +abiraterone acetate) NDA 216793 | BRCA1 and BRCA2 | BRCA1 and BRCA2 alterations | P190032/S014 (06/28/ 2024) |
| Guardant360 CDx (Guardant Health, Inc.) | Non-small cell lung cancer (NSCLC)—Plasma | Tagrisso (osimertinib) NDA 208065 | EGFR (HER1) | EGFR exon 19 deletions, EGFR exon 21 L858R, and T790M | P200010 (08/07/2020) |
| Guardant360 CDx (Guardant Health, Inc.) | Non-small cell lung cancer (NSCLC)—Plasma | Rybrevant (amivantamb) BLA 761210 | EGFR (HER1) | EGFR exon 20 insertions | P200010/S001 (05/21/2021) |
| Guardant360 CDx (Guardant Health, Inc.) | Non-small cell lung cancer (NSCLC)—Plasma | Lumakras (sotorasib) NDA 214665 | KRAS | G12C | P200010/S002 (05/28/2021) |
| Guardant360 CDx (Guardant Health, Inc.) | Non-small cell lung cancer (NSCLC)—Plasma | ENHERTU (fam-trastuzumab deruxtecan-nxki) BLA 761139 | ERBB2 | ERBB2 activating mutations (SNVs and exon 20 insertions) | P200010/S008 (08/11/2022) |
| Guardant360 CDx (Guardant Health, Inc.) | Breast cancer—Plasma | Orserdu (elacestrant) NDA 217639 | ESR1 | ESR1 missense mutations between codons 310 and 547 | P200010/S010 (01/27/2023) |
| HER2 CISH pharmDx Kit (Dako Denmark A/S) | Breast cancer—Tissue | Herceptin (trastuzumab) BLA 103792 | ERBB2 (HER2) | HER-2/neu (ERBB2) gene amplification | P100024 (11/30/2011) |
| HER2 FISH pharmDx Kit (Dako Denmark A/S) | Breast cancer—Tissue | Herceptin (trastuzumab) BLA 103792 | ERBB2 (HER2) | HER-2/neu (ERBB2) gene amplification | P040005 (05/03/2005) |
| HER2 FISH pharmDx Kit (Dako Denmark A/S) | Gastric and gastroesophageal cancer—Tissue | Herceptin (trastuzumab) BLA 103792 | ERBB2 (HER2) | HER-2/neu (ERBB2) gene amplification | P040005/S005 (10/20/2010) |
| HER2 FISH pharmDx Kit (Dako Denmark A/S) | Breast cancer—Tissue | Perjeta (pertuzumab) BLA 125409 | ERBB2 (HER2) | HER-2/neu (ERBB2) gene amplification | P040005/S006 (06/08/2012) |
| HER2 FISH pharmDx Kit (Dako Denmark A/S) | Breast cancer—Tissue | Kadcyla (ado-trastuzumab emtansine) BLA 125427 | ERBB2 (HER2) | HER-2/neu (ERBB2) gene amplification | P040005/S009 (02/22/2013) |
| HercepTest (Dako Denmark A/S) | Breast cancer—Tissue | Herceptin (trastuzumab) BLA 103792 | ERBB2 (HER2) | HER-2 protein overexpression | P980018 (09/25/1998) |
| HercepTest (Dako Denmark A/S) | Gastric and gastroesophageal cancer—Tissue | Herceptin (trastuzumab) BLA 103792 | ERBB2 (HER2) | HER-2 protein overexpression | P980018/S010 (10/20/2010) |

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**Table 3 | Continued**

| Diagnostic name (manufacturer) | Indication—Sample type | Drug trade name (generic) NDA/BLA | Biomarker(s) | Biomarker(s) (details) | PMA/510(k)/513(f)(2)/HDE (approval/clearance/grant date) |
|---|---|---|---|---|---|
| HercepTest (Dako Denmark A/S) | Breast cancer—Tissue | Perjeta (pertuzumab) BLA 125409 | ERBB2 (HER2) | HER-2 protein overexpression | P980018/S015 (06/08/2012) |
| HercepTest (Dako Denmark A/S) | Breast cancer—Tissue | Kadcyla (ado-trastuzumab emtansine) BLA 125427 | ERBB2 (HER2) | HER-2 protein overexpression | P980018/S016 (02/22/2013) |
| INFORM HER-2/neu (Ventana Medical Systems, Inc.) | Breast cancer—Tissue | Herceptin (trastuzumab) BLA 103792 | ERBB2 (HER2) | HER-2/neu (ERBB2) gene amplification | P940004 (12/30/1997) |
| InSite Her-2/neu (CB11) Monoclonal Antibody (Biogenex Laboratories, Inc.) | Breast cancer—Tissue | Herceptin (trastuzumab) BLA 103792 | ERBB2 (HER2) | HER2 protein overexpression | P040030 (12/22/2004) |
| KIT D816V Assay (ARUP Laboratories, Inc.) | Aggressive systemic mastocytosis—Bone marrow | Gleevec (imatinib mesylate) NDA 021588 | KIT | D816V | H140006 (12/18/2015) |
| LeukoStrat CDx FLT3 Mutation Assay (Invivoscribe Technologies, Inc.) | Acute myelogenous leukemia—Peripheral blood or bone marrow | Rydapt (midostaurin) NDA 207997 | FLT3 (ITD/TDK) | ITD mutations and TKD mutations D835 and I836 | P160040 (04/28/2017) |
| LeukoStrat CDx FLT3 Mutation Assay (Invivoscribe Technologies, Inc.) | Acute myelogenous leukemia—Peripheral blood or bone marrow | Xospata (gilterinib) NDA 211349 | FLT3 (ITD/TDK) | ITD mutations and TKD mutations D835 and I836 | P160040/S002 (11/28/2018) |
| LeukoStrat CDx FLT3 Mutation Assay (Invivoscribe Technologies, Inc.) | Acute myelogenous leukemia (AML)—Peripheral blood or bone marrow | VANFLYTA (quizartinib) NDA 216993 | FLT3 (ITD/TDK) | IDT mutations and TKD mutations D835 and I836 | P160040/S011 (07/20/2023) |
| MAGE-A4 IHC 1F9 pharmDx (Agilent Technologies, Inc.) | Synovial sarcoma—Tissue | Tecelra (afamitresgene autoleucel)—BLA 125789 | Melanoma-associated antigen 4 (MAGE-A4) | MAGE-A4 protein overexpression | P230016 (08/01/2024) |
| MRDx BCR-ABL Test (MolecularMD Corporation) | Chronic myeloid leukemia—Peripheral blood | Tasigna (nilotinib) NDA 022068 | t(9;21) Philadelphia chromosome | BCR-ABL fusion | K173492 (12/22/2017) |
| Myriad myChoice CDx (Myriad Genetic Laboratories, Inc.) | Ovarian cancer—Tissue | Lynparza (olaparib) NDA 208558 | Myriad HRD | Deleterious or suspected deleterious mutations in BRCA1 and BRCA2 genes and/or positive Genomic Instability Score) | P190014/S003 (05/08/2020) |
| nAbCyte Anti-AAVRh74var HB-FE Assay (Labcorp Drug Development) | Moderate to severe hemophilia B patients—Serum | BEQVEZ (fidanacogene elaparvovec) BLA 125786 | AAVRh74var capsid neutralizing antibodies | Neutralizing antibodies to the adeno-associated virus serotype Rh74var (AAVRh74var) capsid | H230005 (04/25/2024) |
| ONCO/Reveal Dx Lung & Colon Cancer Assay (O/RDx-LCCA) (Pillar Biosciences, Inc.) | Colorectal cancer—Tissue | Erbitux (cetuximab) BLA 125084 | KRAS | KRAS wild-type (absence of mutations in codons 12 and 13) | P200011 (07/30/2021) |
| ONCO/Reveal Dx Lung & Colon Cancer Assay (O/RDx-LCCA) (Pillar Biosciences, Inc.) | Colorectal cancer—Tissue | Vectibix (panitumumab) BLA 125147 | KRAS | KRAS wild-type (absence of mutations in codons 12 and 13) | P200011 (07/30/2021) |
| ONCO/Reveal Dx Lung & Colon Cancer Assay (O/RDx-LCCA) (Pillar Biosciences, Inc.) | Non-small cell lung cancer (NSCLC)—Tissue | A tyrosine kinase inhibitor approved by FDA for that indication | EGFR (HER1) | Exon 19 deletion or exon 21 L858R substitution mutation | P200011 (07/30/2021) Group Labeling, See table below |
| Oncomine Dx Target Test (Life Technologies Corporation) | Non-small cell lung cancer (NSCLC)—Tissue | Tafinlar (dabrafenib) NDA 202806 in combination with Mekinist (trametinib) NDA 204114 | BRAF | V600E | P160045 (06/22/2017) |
| Oncomine Dx Target Test (Life Technologies Corporation) | Non-small cell lung cancer (NSCLC)—Tissue | Xalkori (crizotinib) NDA 202570 | ROS1 | ROS1 fusions | P160045 (06/22/2017) |
| Oncomine Dx Target Test (Life Technologies Corporation) | Non-small cell lung cancer (NSCLC)—Tissue | Iressa (gefitinib) NDA 206995 | EGFR (HER1) | Exon 19 deletion or exon 21 L858R substitution mutation | P160045 (06/22/2017) |

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**Table 3 | Continued**

| Diagnostic name (manufacturer) | Indication—Sample type | Drug trade name (generic) NDA/BLA | Biomarker(s) | Biomarker(s) (details) | PMA/510(k)/513(f)(2)/HDE (approval/clearance/grant date) |
|---|---|---|---|---|---|
| Oncomine Dx Target Test (Life Technologies Corporation) | Non-small cell lung cancer (NSCLC)—Tissue | Gavreto (pralsetinib) NDA 213721 | RET | RET fusions | P160045/S019 (09/04/2020) |
| Oncomine Dx Target Test (Life Technologies Corporation) | Non-small cell lung cancer (NSCLC)—Tissue | Rybrevant (amivantamb) BLA 761210 | EGFR (HER1) | Exon 20 insertion mutations | P160045/S027 (12/01/2021) |
| Oncomine Dx Target Test (Life Technologies Corporation) | Cholangiocarcinoma—Tissue | Tibsovo (ivosidenib) NDA 211192 | IDH1 | Single-nucleotide variants | P160045/S028 (08/25/2021) |
| Oncomine Dx Target Test (Life Technologies Corporation) | Non-small cell lung cancer (NSCLC)—Tissue | ENHERTU (fam-trastuzumab deruxtecan-nxki) BLA 761139 | ERBB2 | ERBB2 Activating Mutations (SNVs And Exon 20 Insertions) | P160045/S035 (08/11/2022) |
| Oncomine Dx Target Test (Life Technologies Corporation) | Non-small cell lung cancer (NSCLC)—Tissue | Retevmo (selpercatinib) NDA 213246 | RET | RET fusions | P160045/S031 (09/21/2022) |
| Oncomine Dx Target Test (Life Technologies Corporation) | Medullary thyroid cancer (MTC)—Tissue | Retevmo (selpercatinib) NDA 213246 | RET | RET mutations (SNVs, MNVs, and deletions) | P160045/S031 (09/21/2022) |
| Oncomine Dx Target Test (Life Technologies Corporation) | Thyroid cancer (TC)—Tissue | Retevmo (selpercatinib) NDA 213246 | RET | RET fusions | P160045/S031 (09/21/2022) |
| Oncomine Dx Target Test (Life Technologies Corporation) | Anaplastic thyroid cancer (ATC)—Tissue | Tafinlar (dabrafenib) NDA 202806 in combination with Mekinist (trametinib) NDA 204114 | BRAF | BRAF V600E mutations | P160045/S025 (09/29/2023) |
| PathVysion HER-2 DNA Probe Kit (Abbott Molecular Inc.) | Breast cancer—Tissue | Herceptin (trastuzumab) BLA 103792 | ERBB2 (HER2) | HER-2/neu (ERBB2) gene amplification | P980024 (12/11/1998) |
| PATHWAY anti-Her2/neu (4B5) Rabbit Monoclonal Primary Antibody (Ventana Medical Systems, Inc.) | Breast cancer—Tissue | Herceptin (trastuzumab) BLA 103792 | ERBB2 (HER2) | HER-2 protein overexpression | P990081 (11/28/2000) |
| PATHWAY anti-Her2/neu (4B5) Rabbit Monoclonal Primary Antibody (Ventana Medical Systems, Inc.) | Breast cancer—Tissue | Kadcyla (ado-trastuzumab emtansine) BLA 125427 | ERBB2 (HER2) | HER-2 protein overexpression | P990081/S039 (05/03/2019) |
| PATHWAY anti-Her2/neu (4B5) Rabbit Monoclonal Primary Antibody (Ventana Medical Systems, Inc.) | Breast cancer—Tissue | Enhertu (fam-trastuzumab deruxtecan-nxki) BLA 761139 | ERBB2 (HER2) | HER-2 protein overexpression | P990081/S047 (09/30/2022) |
| PD-L1 IHC 22C3 pharmDx (Dako North America, Inc.) | Non-small cell lung cancer (NSCLC)—Tissue | Keytruda (pembrolizumab) BLA 125514 | PD-L1 | PD-L1 protein expression | P150013 (10/02/2015) |
| PD-L1 IHC 22C3 pharmDx (Dako North America, Inc.) | Cervical —Tissue | Keytruda (pembrolizumab) BLA 125514 | PD-L1 | PD-L1 protein expression | P150013/S009 (06/12/2018) |
| PD-L1 IHC 22C3 pharmDx (Dako North America, Inc.) | Head and neck squamous cell carcinoma (HNSCC)—Tissue | Keytruda (pembrolizumab) BLA 125514 | PD-L1 | PD-L1 protein expression | P150013/S014 (06/10/2019) |
| PD-L1 IHC 22C3 pharmDx (Dako North America, Inc.) | esophageal squamous cell carcinoma (ESCC)—Tissue | Keytruda (pembrolizumab) BLA 125514 | PD-L1 | PD-L1 protein expression | P150013/S016 (07/30/2019) |
| PD-L1 IHC 22C3 pharmDx (Dako North America, Inc.) | Triple-negative breast cancer (TNBC)—Tissue | Keytruda (pembrolizumab) BLA 125514 | PD-L1 | PD-L1 protein expression | P150013/S020 (11/13/2020) |
| PD-L1 IHC 22C3 pharmDx (Dako North America, Inc.) | Non-small cell lung cancer (NSCLC)—Tissue | Libtayo (cemiplimab-rwlc) BLA 761097 | PD-L1 | PD-L1 protein expression [Tumor Proportion Score (TPS) ≥ 50%] | P150013/S021 (02/22/2021) |
| PD-L1 IHC 22C3 pharmDx (Dako North America, Inc.) | Gastric or gastroesophageal junction (GEJ) Adenocarcinoma—tissue | Keytruda (pembrolizumab) BLA 125514 | PD-L1 | PD-L1 protein expression | P150013/S027 (11/07/2023) |

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**Table 3 | Continued**

| Diagnostic name (manufacturer) | Indication—Sample type | Drug trade name (generic) NDA/BLA | Biomarker(s) | Biomarker(s) (details) | PMA/510(k)/513(f)(2)/HDE (approval/clearance/grant date) |
|---|---|---|---|---|---|
| PD-L1 IHC 28-8 pharmDx (Dako North America, Inc.) | Non-small cell lung cancer (NSCLC)—Tissue | Opdivo (nivolumab) BLA 125554 in combination with Yervoy (ipilimumab) BLA 125377 | PD-L1 | PD-L1 protein expression (tumor cell staining ≥1%) | P150025/S013 (05/15/2020) |
| PDGFRB FISH Assay (ARUP Laboratories, Inc.) | Myelodysplastic syndrome/ myeloproliferative disease—Bone marrow | Gleevec (imatinib mesylate) NDA 021588 | PDGFRB | PDGFRB gene rearrangement at 5q31~33 | H140005 (12/18/2015) |
| POMC/PCSK1/LEPR CDx Panel (PreventionGenetics, LLC) | Obesity—Blood or saliva | Imcivree (setmelanotide acetate) NDA 213793 | POMC, PCSK1 and LEPR | Variants (pathogenic/likely pathogenic) and variants of uncertain significance | DEN200059 (01/21/2022) |
| SeCore CDx HLA Sequencing System (One Lambda Inc.) | Uveal melanoma—Whole blood | Kimmtrak (tebentafusp-tebn) BLA 761228 | HLA | HLA-A*02:01 | BR220737 (11/28/2022) |
| SeCore CDx HLA Sequencing System (One Lambda, Inc.) | Synovial sarcoma—Whole blood | Tecelra (afamitresgene autoleucel) BLA 125789 | HLA | Eligible alleles: HLA-A*02:01, HLA-A*02:02, HLA-A*02:03, or HLA-A*02:06 and their P-group alleles. Exclusion alleles: HLA-A*02:05 and its P-group alleles | BK241074 (08/01/2024) |
| SPOT-LIGHT HER2 CISH Kit (Life Technologies Corporation) | Breast cancer—Tissue | Herceptin (trastuzumab) BLA 103792 | ERBB2 (HER2) | HER-2/neu (ERBB2) gene amplification | P050040 (07/01/2008) |
| therascreen BRAF V600E RGQ PCR Kit (QIAGEN GmbH) | Colorectal cancer—Tissue | Braftovi (encorafenib) NDA 210496 in combination with Erbitux (cetuximab) BLA 125084 | BRAF | V600E | P190026 (04/15/2020) |
| therascreen EGFR RGQ PCR Kit (Qiagen Manchester, Ltd.) | Non-small cell lung cancer (NSCLC)—Tissue | Gilotrif (afatinib) NDA 201292 | EGFR (HER1) | Exon 19 deletion or exon 21 L858R substitution mutation | P120022 (07/12/2013) |
| therascreen EGFR RGQ PCR Kit (Qiagen Manchester, Ltd.) | Non-small cell lung cancer (NSCLC)—Tissue | Iressa (gefitinib) NDA 206995 | EGFR (HER1) | Exon 19 deletion or exon 21 L858R substitution mutation | P120022/S001 (07/10/2015) |
| therascreen EGFR RGQ PCR Kit (Qiagen Manchester, Ltd.) | Non-small cell lung cancer (NSCLC)—Tissue | Gilotrif (afatinib) NDA 201292 | EGFR (HER1) | L861Q, G719X, and S7681 | P120022/S016 (01/12/2016) |
| therascreen EGFR RGQ PCR Kit (Qiagen Manchester, Ltd.) | Non-small cell lung cancer (NSCLC)—Tissue | Vizimpro (dacomitinib) NDA 211288 | EGFR (HER1) | Exon 19 deletion or exon 21 L858R substitution mutation | P120022/S018 (09/27/2018) |
| therascreen FGFR RGQ RT-PCR Kit (QIAGEN Manchester Ltd.) | Urothelial cancer—Tissue | Balversa (erdafitinib) NDA 212018 | FGFR3 | Exon 7: R248C (c.742C>T), S249C (c.746C>G); exon 10: G370C (c.1108G>T) and Y373C (c.1118A>G); and fusions (FGFR3-TACC3v1 and FGFR3-TACC3v3) | P180043 (04/12/2019) |
| therascreen KRAS RGQ PCR Kit (Qiagen Manchester, Ltd.) | Colorectal cancer—Tissue | Vectibix (panitumumab) BLA 125147 | KRAS | G12A, G12D, G12R, G12C, G12S, G12V, G13D | P110027 (05/23/2014) |
| therascreen KRAS RGQ PCR Kit (Qiagen Manchester, Ltd.) | Non-small cell lung cancer (NSCLC)—Tissue | Lumakras (sotorasib) NDA 214665 | KRAS | G12C | P110027/S012 (05/28/2021) |
| therascreen KRAS RGQ PCR Kit (Qiagen Manchester, Ltd.) | Colorectal cancer—Tissue | Erbitux (cetuximab) BLA 125084 | KRAS | G12A, G12D, G12R, G12C, G12S, G12V, G13D | P110030 (07/06/2012) |
| therascreen KRAS RGQ PCR Kit (Qiagen Manchester, Ltd.) | Colorectal cancer—Tissue | Erbitux (cetuximab) BLA 125084 | KRAS | KRAS wild-type (absence of mutations in codons 12 and 13) | P110027/S013 (12/02/2022) |
| therascreen KRAS RGQ PCR Kit (Qiagen Manchester, Ltd.) | Non-small cell lung cancer (NSCLC)—Tissue | Krazati (adagrasib) NDA 216340 | KRAS | KRAS G12C | P110027/S013 (12/02/2022) |
| therascreen PDGFRA RGQ PCR Kit (QIAGEN GmbH) | Gastrointestinal stromal tumors (GIST)—Tissue | AYVAKIT (Avapritinib) NDA 212608 | PDGFRA | D842V mutation | P210002 (06/29/2023) |
| therascreen PIK3CA RGQ PCR Kit (QIAGEN GmbH) | Breast cancer—Tissue or plasma | Piqray (alpelisib) NDA 212526 | PIK3CA | C420R, E542K, E545A, E545D [1635G>T only], E545G, E545K, Q546E, Q546R, H1047L, H1047R, and H1047Y | P190001 (05/24/2019) P190004 (05/24/2019) |
| THXID BRAF Kit (bioMérieux Inc.) | Melanoma—Tissue | Mekinist (trametinib) NDA 204114 | BRAF | V600E or V600K | P120014 (05/29/2013) |

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**Table 3 | Continued**

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|---|---|---|---|---|---|
| THXID BRAF Kit (bioMérieux Inc.) | Melanoma—Tissue | Tafinlar (dabrafenib) NDA 202806 | BRAF | V600E | P120014 (05/29/2013) |
| THXID BRAF Kit (bioMérieux Inc.) | Melanoma—Tissue | Braftovi (encorafenib) NDA 210496 in combination with Mektovi (binimetinib) NDA 210498 | BRAF | V600E or V600K | P120014/S008 (06/27/2018) |
| TruSight Oncology Comprehensive (Illumina, Inc.) | Non-small cell lung cancer (NSCLC)—Tissue | Retevmo (selpercatinib) NDA 213246 | RET | RET fusions | P230011 (08/21/2024) |
| TruSight Oncology Comprehensive (Illumina, Inc.) | Solid tumors—Tissue | Vitrakvi (larotrectinib) NDA 210861 | NTRK1, NTRK2, and NTRK3 fusions | NTRK1/2/3 fusions | P230011 (08/21/2024) |
| Ventana ALK (D5F3) CDx Assay (Ventana Medical Systems, Inc.) | Non-small cell lung cancer (NSCLC)—Tissue | Xalkori (crizotinib) NDA 202570 | ALK | ALK protein expression | P140025 (06/12/2015) |
| Ventana ALK (D5F3) CDx Assay (Ventana Medical Systems, Inc.) | Non-small cell lung cancer (NSCLC)—Tissue | Zykadia (ceritinib) NDA 211225 | ALK | ALK protein expression | P140025/S005 (05/26/2017) |
| Ventana ALK (D5F3) CDx Assay (Ventana Medical Systems, Inc.) | Non-small cell lung cancer (NSCLC)—Tissue | Alecensa (alectinib) NDA 208434 | ALK | ALK protein expression | P140025/S006 (11/06/2017) |
| Ventana ALK (D5F3) CDx Assay (Ventana Medical Systems, Inc.) | Non-small cell lung cancer (NSCLC)—Tissue | Lorbrena (lorlatinib) NDA 210868 | ALK | ALK protein expression | P140025/S014 (03/03/2021) |
| Ventana FOLR1 (FOLR-2.1) RxDx Assay (Ventana Medical Systems, Inc.) | Epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer—Tissue | Elahere (mirvetuximab soravtansine-gynx) BLA 761310 | FOLR1 | FOLR1 protein expression | P220006 (11/14/2022) |
| Ventana HER2 Dual ISH DNA Probe Cocktail (Ventana Medical Systems, Inc.) | Breast cancer—Tissue | Herceptin (trastuzumab) BLA 103792 | ERBB2 (HER2) | HER-2/neu (ERBB2) gene amplification | P190031 (07/28/2020) |
| Ventana MMR RxDx Panel (Ventana Medical Systems, Inc.) | Endometrial carcinoma (EC)—Tissue | Jemperli (dostarlimag-gxly) NDA 761174 | Deficient mismatch repair (dMMR) proteins | MLH1, PMS2, MSH2, and MSH6 | P200019 (04/22/2021) |
| Ventana MMR RxDx Panel (Ventana Medical Systems, Inc.) | Solid tumors | Jemperli (dostarlimag-gxly) NDA 761174 | Deficient mismatch repair (dMMR) proteins | MLH1, PMS2, MSH2, and MSH6 | P210001 (08/17/2021) |
| Ventana MMR RxDx Panel (Ventana Medical Systems, Inc.) | Solid tumors | Keytruda (pembrolizumab) BLA 125514 | Deficient mismatch repair (dMMR) proteins | MLH1, PMS2, MSH2, and MSH6 | P210001/S001 (03/21/2022) |
| Ventana MMR RxDx Panel (Ventana Medical Systems, Inc.) | Endometrial carcinoma (EC)—Tissue | Keytruda (pembrolizumab) BLA 125514 in combination with Lenvima (lenvatinib) NDA 206947 | Proficient mismatch repair (pMMR) proteins | MLH1, PMS2, MSH2, and MSH6 | P210001/S002 (06/16/2022) |
| Ventana PD-L1 (SP142) Assay (Ventana Medical Systems, Inc.) | Urothelial carcinoma—Tissue | Tecentriq (atezolizumab) BLA 761034 | PD-L1 | PD-L1 protein expression (PD-L1 stained tumor-infiltrating immune cells [IC] covering ≥ 5% of the tumor area) | P160002 (05/18/2016) |
| Ventana PD-L1 (SP142) Assay (Ventana Medical Systems, Inc.) | Non-small cell lung cancer (NSCLC)—Tissue | Tecentriq (atezolizumab) BLA 761034 | PD-L1 | PD-L1 protein expression (PD-L1 stained ≥ 50% of tumor cells [TC ≥ 50%] or PD-L1 stained tumor-infiltrating immune cells [IC] covering ≥ 10% of the tumor area [IC ≥ 10%]) | P160002/S006 (07/02/2018) |
| Ventana PD-LI (SP263) Assay (Ventana Medical Systems, Inc) | Non-small cell lung cancer (NSCLC)—Tissue | Tecentriq (atezolizumab) BLA 761034 | PD-L1 | PD-L1 protein expression | P160046/S010 (10/15/2021) |
| Vysis ALK Break Apart FISH Probe Kit (Abbott Molecular Inc.) | Non-small cell lung cancer (NSCLC)—Tissue | Xalkori (crizotinib) NDA 202570 | ALK | ALK gene rearrangements | P110012 (08/26/2011) |

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Table 3 | Continued

| Diagnostic name (manufacturer) | Indication—Sample type | Drug trade name (generic) NDA/BLA | Biomarker(s) | Biomarker(s) (details) | PMA/510(k)/513(f)(2)/HDE (approval/clearance/grant date) |
|---|---|---|---|---|---|
| Vysis ALK Break Apart FISH Probe Kit (Abbott Molecular Inc.) | Non-small cell lung cancer (NSCLC)—Tissue | Alunbrig (brigatinib) NDA 208772 | ALK | ALK gene rearrangements | P110012/S020 (05/22/2020) |
| Vysis CLL FISH Probe Kit (Abbott Molecular, Inc.) | B-cell chronic lymphocytic leukemia—Peripheral blood | Venclexta (venetoclax) NDA 208573 | TP53 | Deletion chromosome 17p (17p-) | P150041 (04/11/2016) |
| xT CDx (Tempus Labs, Inc.) | Colorectal cancer (CRC)—Tissue (matching blood/saliva) | Erbitux (cetuximab) BLA 125084 | KRAS | KRAS wild-type (absence of mutations in codons 12 or 13) | P210011 (04/28/2023) |
| xT CDx (Tempus Labs, Inc.) | Colorectal cancer (CRC)—Tissue (matching blood/saliva) | Vectibix (panitumumab) BLA 125147 | KRAS and NRAS | KRAS wild-type (absence of mutations in exons 2, 3, or 4) and NRAS wild-type (absence of mutations in exons 2, 3, or 4) | P210011 (04/28/2023) |

future of POC diagnostics in healthcare is quite bright. The following are the main opportunities for POC diagnostics in the future, backed by pertinent research and professional evaluations.[14, 23, 28, 30, 34–42]

1. Combining Machine Learning and AI
   AI is being included in POC devices to improve predictive analytics, data interpretation, and diagnostic accuracy. Large amounts of health data from POC testing can be processed by AI to find trends that could help with early disease detection and improved decision-making.
2. Implantable and Wearable Sensors for Ongoing Surveillance
   One important trend for the future is the creation of wearable and implanted sensors for real-time health monitoring. These tools eliminate the need for sporadic lab-based testing by enabling continuous assessment of biomarkers and vital signs. For individualized treatment and real-time health monitoring, the gathered data can be sent to healthcare practitioners.
3. Molecular and Genomic POC Diagnostics
   Future POC devices will allow real-time molecular diagnostics, particularly for genetic disorders, cancer, and infectious diseases, thanks to advancements in genomics and NGS. By examining patients' DNA profiles at the time of service, these gadgets will provide individualized therapy alternatives.
4. Growth in the Control of Infectious Diseases
   POC diagnostics will become even more important in the management of infectious diseases, especially in the context of pandemic preparedness. To contain epidemics and provide prompt public health interventions, portable devices that can identify infections such as influenza, TB, and COVID-19 will be essential.
5. Home-Based Testing and Decentralized Healthcare
   Decentralized healthcare is becoming more and more popular, with diagnostic equipment moving from labs and hospitals to households. This will lessen the strain on healthcare systems by enabling consumers to self-test for a variety of illnesses, including diabetes, kidney function, and even cancer.
6. Multiplexed POC Test Development
   A single POC device may test for several conditions simultaneously thanks to multiplexing, which provides a whole health profile all at once. More multiplexed features will be added to future POC diagnostics, which will make them useful for screening for a variety of illnesses, including cancer, autoimmune disorders, and respiratory infections.
7. Growing Utilization of Integration in Telemedicine
   POC diagnostics in conjunction with telemedicine will enable home consultations and real-time health monitoring. By enabling remote access to diagnostic results and prompt interventions, this integration expands the reach of medical practitioners, boosting emergency response and chronic disease management.
8. LOC and Miniaturization Technologies
   Diagnostic tools are increasingly being reduced in size to become small, easily navigable gadgets. With the use of LOC technologies, sophisticated tests can be carried out quickly at the point of care using small sample volumes because whole diagnostic procedures can be carried out on a microchip.
9. Eco-Friendly Diagnostics
   Future POC diagnostics will probably concentrate on lowering waste, energy usage, and the environmental impact of disposable diagnostic kits as sustainability gains more emphasis.


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The creation of recyclable and biodegradable materials for test cartridges and biosensors may fall under this category.

10. Worldwide Health and Illness Monitoring
POC diagnostics will be essential to global health, especially in the areas of epidemic control and disease surveillance. International efforts to monitor and control infectious diseases, particularly in low-resource settings, will be aided by portable POC tests that can identify new pathogens.
11. Complementing Liquid Biopsies
CDx is increasingly integrating with liquid biopsy technology, which uses blood samples to find ctDNA or other biomarkers. This makes it possible to track the course of the disease and the effectiveness of treatment without intrusive methods, especially in malignancies where tissue biopsies are difficult to obtain.
12. Multi-Omic CDx Advances
Multi-omic techniques (genomics, proteomics, metabolomics, etc.) will probably be used in CDx to provide a thorough understanding of a patient's biology. This multifaceted data can improve patient outcomes for a wider spectrum of diseases by increasing the accuracy of diagnosis and medication choices.

## Conclusions

To sum up, healthcare diagnostics—especially POC and CDx—are developing quickly, influencing customized treatment in the future and enhancing patient outcomes. By facilitating quicker, easier, and decentralized testing and providing patients and physicians with timely information, POC diagnostics have already shown their transformational potential. In the meantime, CDx are becoming increasingly important in precision medicine, assisting in customized patient treatments according to their molecular and genetic profiles.

Future developments in these fields will be accelerated by the incorporation of cutting-edge technology such as NGS, machine learning, and AI. While NGS will continue to transform molecular diagnostics by offering deeper insights into the genetic foundations of diseases, AI and ML algorithms are anticipated to improve diagnostic test accuracy by finding patterns in massive datasets. Furthermore, the advancement of implantable and wearable biosensors will provide continuous, real-time monitoring of medical issues, enabling preventative measures.

The adoption of these new technologies will accelerate the transition to a more data-driven, preventative, and individualized healthcare system. To reach their full potential, issues with data privacy, regulatory frameworks, and the incorporation of diagnostics into clinical practice need to be resolved. Healthcare diagnostics will develop further with sustained innovation and cross-sector cooperation, which will eventually result in better patient care, illness management, and a more effective healthcare system. Sustainable and eco-friendly POC and CDx can play a critical role in reducing health disparities and addressing global health challenges by making healthcare more accessible and equitable. These technologies often rely on renewable materials, energy-efficient processes, and low-waste designs, which reduce costs and environmental impact, making them more feasible for low-resource settings. By providing rapid and accurate diagnostics at the community level, they minimize the need for expensive centralized laboratories and long patient travel distances. This accessibility is particularly valuable for underserved populations in rural or remote areas, where traditional healthcare infrastructure is limited. Furthermore, eco-friendly diagnostics align with global efforts to mitigate climate change, which disproportionately affects vulnerable populations. By reducing both the financial and environmental burdens of healthcare, sustainable diagnostics enhance the global health system's resilience and ensure that lifesaving technologies reach those most in need.

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