REAGAN-UDALL FOUNDATION FOR THE FDA

Over-the-Counter Diagnostics: Advancing Home as a Health Care Hub

Public Meeting Summary

Issued July 2026

REAGAN-UDALL FOUNDATION FOR THE FDA

About the Reagan-Udall Foundation for the FDA

The Reagan-Udall Foundation for the FDA is an independent non-profit created by Congress to advance regulatory science to help the U.S. Food and Drug Administration accomplish its mission. The Foundation manages a suite of programs that assist the FDA in engaging with external stakeholders and that facilitate evidence generation, improve public understanding of the FDA, and deliver more accessible health information to the public.

Apple, Checkable, Consumer Healthcare Products Association, Hims & Hers, and National Association of Chain Drug Stores provided funding for this meeting

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Background

Consumer use of at-home diagnostic tests has become an established element of the health care system, reshaping how and where people access information about their health. The COVID-19 pandemic demonstrated that advances in at-home diagnostic technology can empower patients, allowing them to find answers more quickly and conveniently, expediting the diagnostic and treatment process. However, uncertainty in pathways to market access and payment can slow innovation and adoption, underscoring the importance of clear regulatory processes and meaningful engagement with consumers and health care professionals.

The Reagan-Udall Foundation for the FDA convened this public meeting on March 25, 2026 to explore opportunities and barriers in the development, review, deployment, and integration of over-the-counter (OTC) diagnostic devices, with a focus on improving access to timely, actionable health information.[1] The meeting featured discussions among health professionals, researchers, diagnostics developers and manufacturers, and others with expertise about the development and delivery of consumer health products. This document presents key learnings from the meeting. This summary does not represent the views of the U.S. Food and Drug Administration (FDA), sponsors of the event, or any other organization.

1 See Appendix A for the public meeting agenda.

Landscape of OTC Diagnostics

The U.S. health care system is shifting toward a more home-centered and patient-driven model of care.[2] Increasingly, patients are able to initiate and manage their care more independently with the expansion of telehealth, at-home testing, and connected health devices. Many activities that once required clinical settings are now commonly performed at home, such as diagnostic testing and routine monitoring. More than half of American adults reported using telehealth at some point in 2024.[3] This shift reflects a broader change in how individuals engage with care and how services are delivered across the health care system.

OTC diagnostics enable individuals to collect samples, run tests, and interpret results without direct clinical involvement, supporting greater autonomy and more immediate access to health information. Although OTC diagnostics are often viewed as a recent development, they have been used by consumers for decades. At-home pregnancy tests, first introduced in the 1970s using lateral flow technology, remain one of the most recognizable examples. Today, the OTC diagnostic market is dominated by a few categories: blood glucose monitoring, pregnancy and ovulation tests, infectious disease tests, and cardiovascular monitors. Of those, blood glucose monitors are a longstanding and widely adopted category, particularly among individuals managing diabetes, and they continue to represent a substantial share of the market's commercial value. Advances in digital connectivity allow for continuous glucose monitors and smartphone-enabled tracking tools that support routine disease management outside traditional clinical settings. OTC diagnostics have also become increasingly available for cardiovascular-related conditions, including at-home blood pressure monitors, pulse oximeters, and other wearables and sensors capable of tracking heart rate and detecting irregular cardiac rhythms.

How do OTC diagnostics detect health conditions?

In Vitro

Tests done on samples such as blood or tissue from the human body (e.g., saliva, blood, urine).

Sensor-Based

Continuous or episodic measurements of physiological data from wearables and biosensors.

Imaging

Portable imaging devices and software used to capture and analyze visual clinical data (e.g., smartphone cameras).

2 Richardson E. Over-the-Counter Diagnostics: Advancing Home as a Health Care Hub, March 25, 2026. https://reaganudall.org/news-and-events/events/over-counter-diagnostics-advancing-home-health-care-hub

3 Knowles M, Krasniansky A, Kaganoff S. Screenagers to Silver Surfers: How each generation clicks with care. Rock Health. Published March 17, 2026. Accessed May 12, 2026. https://rockhealth.com/insights/screenagers-to-silver-surfers-how-each-generation-clicks-with-care/

Figure 1. At-Home and Closer-to-Home Testing Paradigms[4]

	OTC *In Vitro* Diagnostic	At-Home Collection Test	Direct to Consumer Testing	Point of Care / CLIA Waived
Sample Collection	Self-collection; instructions/ platform designed for a lay user. *Typically self-pay.*	At home via test kit (stool, urine, oral fluid, fingerstick) and mailed to a partner lab. *Typically Rx and reimbursed by insurance.*	At home via kit or at a blood draw site. *Consumer orders directly. Typically self-pay.*	Collected by/under supervision of trained staff at a CLIA-waived facility, *Typically reimbursed by insurance.*
Analysis	At home	CLIA-Certified Lab	CLIA-Certified Lab	At the site of care (pharmacy, mobile unit, school, etc.)
Follow-up	*Within minutes*	*Days–weeks*	*Days–weeks*	*Within minutes*
Results Delivery	Consumer receives results directly and determines next steps.	Results to consumer and/or ordering clinician. Clinician follows up as needed.	Results returned digitally; some offer optional clinician follow-up.	Results delivered onsite. Follow-up typically available in the same visit.

Note: *Payment and reimbursement models vary by test type, payer policies, and jurisdiction.*
CLIA is an abbreviation for "Clinical Laboratory Improvement Amendments." CLIA is a set of federal regulations that establishes quality standards for all laboratory testing to ensure the accuracy, reliability, and timeliness of patient test results.

> *"Care is increasingly something that happens or at least is initiated outside of a clinic or a lab… the home has become a genuine site of health care.*
>
> — ELIZABETH RICHARDSON, MSC · CANAL ROW ADVISORS

4 Richardson E. Over-the-Counter Diagnostics: Advancing Home as a Health Care Hub, March 25, 2026. https://reaganudall.org/news-and-events/events/over-counter-diagnostics-advancing-home-health-care-hub

More recently, the COVID-19 pandemic was a major inflection point for adoption of OTC diagnostics, rapidly expanding and normalizing consumer use of self-administered infectious disease testing. The widespread deployment of at-home COVID-19 tests increased public familiarity with at-home diagnostics and demonstrated their value within broader public health infrastructure. The pandemic accelerated consumer trust, market growth, and regulatory learning related to OTC diagnostics, while simultaneously exposing important gaps in reporting infrastructure and policy frameworks. Survey data indicate that 72% of Americans have used an at-home test at some point, although most of that use was concentrated in COVID-19 testing.[5] At the same time, more than half of Americans now report owning at least one wearable or connected health device.[6] Despite the growth in availability and use of OTC diagnostics, the market remains concentrated in a limited number of established categories. This concentration underscores a persistent gap between emerging innovations, such as artificial intelligence (AI)-enabled diagnostics and smartphone-based tools, and their widespread adoption in routine care.

Equitable adoption of OTC diagnostics depends on a range of structural and access-related factors. Distribution channels shape whether tests are readily available through community pharmacies, online platforms, or community-based programs, while affordability remains a key determinant of use. Evidence from the pandemic demonstrated that when tests are provided at no cost, uptake increases substantially, whereas out-of-pocket costs can limit access and contribute to disparities. Digital access is another critical factor, as many newer diagnostics and companion tools rely on smartphones, broadband connectivity, and app-based interfaces. Beyond access, several systemic challenges continue to limit integration in care delivery.

5 Knowles M, Krasniansky A, Nagappan A. The new era of consumer engagement: Insights from Rock Health's ninth annual Consumer Adoption Survey. Rock Health. Published March 18, 2024. Accessed May 12, 2026. https://rockhealth.com/insights/the-new-era-of-consumer-engagement-insights-from-rock-healths-ninth-annual-consumer-adoption-survey/

6 Knowles M, Krasniansky A, Kaganoff S. Screenagers to Silver Surfers: How each generation clicks with care. Rock Health. Published March 17, 2026. Accessed May 12, 2026. https://rockhealth.com/insights/screenagers-to-silver-surfers-how-each-generation-clicks-with-care/

Current Environment for OTC Diagnostics

During the public meeting, speakers described the current regulatory framework and considerations for real-world data collection and performance evaluation of OTC diagnostics. Discussion explored how these products are developed, regulated, and ultimately delivered to consumers for use. Presenters highlighted the potential for OTC diagnostics to support earlier detection, timely intervention, improved disease management, and expanded public health surveillance. At-home testing can also generate valuable patient-generated health data that is often not captured within traditional health care systems. However, realizing the clinical and public health value of these technologies depends on whether results can be trusted, understood, and acted on appropriately by consumers, clinicians, and public health systems.

Regulation and Development

Dr. Courtney Lias from FDA's Center for Devices and Radiological Health (CDRH) noted that diagnostics are not a new category of health care technology, but rather an expanding and evolving component of home-based care. Building on decades of experience with products such as pregnancy tests and glucose monitors, FDA has authorized hundreds of OTC diagnostics and is now seeing rapid growth in newer categories, including multiplex respiratory panels, sexually transmitted infection (STI) screening, and genetic testing. CDRH's "Home as a Healthcare Hub" initiative underscores a broader strategic emphasis on advancing health care delivery within the home, supported in part by expanding access to over-the-counter drugs and diagnostic tools.

> *"Validation is not just about the chemistry; it is about the person. What kind of information shows me that somebody can pick up this test, use it according to the instructions, and get the right answer without a professional over their shoulder?*
>
> — COURTNEY LIAS, PHD · U.S. FOOD AND DRUG ADMINISTRATION

Figure 2. Key Considerations for OTC Diagnostics Design[7]

Successful translation of laboratory-based tests into safe and effective home-use products requires consideration for iterative design, validation, and regulatory planning needs. Key considerations for the design of OTC diagnostics are listed in Figure 2. Dr. Lias emphasized that OTC diagnostics must be designed for lay users with varying levels of health literacy and technical ability, including clear labeling, intuitive workflows, and safeguards against misuse or inaccurate results. Human factors and usability studies are critical components of regulatory review for OTC products.

7 Lias C. Over-the-Counter Diagnostics: Advancing Home as a Health Care Hub, March 25, 2026. https://reaganudall.org/news-and-events/events/over-counter-diagnostics-advancing-home-health-care-hub

FDA evaluates OTC diagnostics within the context of intended use, acceptable risk, and anticipated public health benefit, recognizing that performance expectations may differ depending on the condition being tested and the consequences of false results. In some contexts, broader access and increased testing uptake may justify tradeoffs in analytical performance if overall public health benefits are substantial. Dr. Lias highlighted the ways FDA has sought to support innovation through guidance documents, submission templates, collaborative validation programs, and early engagement pathways for developers.[8]

Speakers noted that regulatory considerations often influence product development well before a product reaches submission or review. Dr. Anita Nosratieh from Abbott underscored that regulatory strategy shapes product development from the earliest stages. Decisions related to intended use, target population, risk profile, usability, and the expected degree of clinical oversight can shape both study design and validation approaches early in development. Participants also emphasized that performance expectations should be considered in the context of the test's intended application, weighing the potential benefits and limitations alongside the clinical or public health need the product is meant to serve. Manufacturers must account for the full context in which consumers will use and act on a test, including the test's intended use, risk profile, target population, and expected level of clinical oversight.

Real-World Performance

Dr. Ramy Arnaout from Beth Israel Deaconess Medical Center noted that OTC diagnostic results remain largely disconnected from health care and public health data infrastructure. Although consumers frequently use and act on at-home test results, most data are not routinely integrated into electronic health records (EHRs) or surveillance systems, limiting their value for clinical decision-making, epidemiology, and health care quality improvement. Existing reporting approaches, including provider documentation, patient portal entry, and image or barcode-based tools, often require additional effort from patients or clinicians and can be operationally burdensome or inconsistent. The lack of standardized reporting, interoperability, and data sharing mechanisms was identified as a major barrier to understanding real-world test performance.

8 See Appendix B for a list of FDA resources related to home use tests.

Dr. Arnaout highlighted emerging opportunities to improve data integration and performance monitoring through AI, smartphone-enabled tools, and synthetic data methods. Potential future models could allow consumers to capture and share results directly from smartphones while maintaining greater control over how their data are used and shared. AI-enabled local processing and the use of de-identified or synthetic datasets were also discussed as potential tools to enable secondary uses of data for epidemiologic monitoring, product performance evaluation, and regulatory assessment.

Consumer Access

Dr. Stacey Swartz of Neighborhood Pharmacy of Del Ray provided additional perspective on how OTC diagnostics are selected, distributed, and used in real-world community settings. Stocking decisions are heavily influenced by cost, insurance coverage, consumer demand, product simplicity, and practical workflow considerations, particularly for small, independent pharmacies with limited shelf space. Counseling frequently focuses less on how to perform the test and more on how consumers interpret and respond to results, including decisions about treatment, isolation, follow-up care, and when to seek medical attention. Panelists observed that consumers do not always interpret results as intended, particularly when dealing with faint or ambiguous results, underscoring the importance of clear labeling, consumer education, and intuitive design.

Julie Barnes from Maverick Health noted that health insurance coverage for OTC diagnostics remains limited and highly dependent on demonstrated clinical utility and cost-effectiveness. Health plans generally prioritize products that prevent more costly downstream care, support chronic disease management, or replace more expensive diagnostic procedures. While prescribed devices such as glucose monitors are commonly reimbursed, most OTC diagnostics are not routinely covered unless they are directly tied to medical necessity or proven treatment pathways. Payers are reluctant to pay for products that generate duplicative testing or represent uncertain clinical value. However, presenters noted that evolving reimbursement models, interoperability initiatives, and pilot programs involving connected monitoring technologies may gradually expand payer interest in home-based diagnostics and real-world data collection.

> *For us to have real progress in this space we need to have continued collaboration across regulators, health care providers, consumers, payers, and developers, with a shared focus on safety, access, and trust.*

— ANITA NOSRATIEH, PHD · ABBOTT

Speakers emphasized that broader adoption of OTC diagnostics will require continued collaboration among regulators, developers, clinicians, researchers, pharmacists, payers, and consumers. Future progress in the OTC diagnostics ecosystem will depend on balancing safety, access, usability, trust, privacy, and data integration while ensuring that these technologies deliver meaningful clinical and public health value.

Integrating OTC Diagnostics into Care Delivery

OTC diagnostics play an important role in expanding health access and advancing the home as a health care hub. A panel of experts in pharmacy, medicine, telehealth, and considerations for older adults explored the facilitators and barriers to integrating these tools into routine care delivery and health information systems.

Turning Results into Action

A recurring theme was that integration alone is insufficient without clearly defined care pathways for acting on results. Pharmacists were highlighted as accessible and trusted first points of contact for OTC testing, with nearly 90% of Americans living within five miles of a pharmacy.[9] Pharmacists can support appropriate test selection, provide instructions for correct use, interpret results in context, and refer patients to primary care, telehealth, or urgent care when needed. Deborah Autor from Hims & Hers discussed telehealth as a critical enabler of hybrid care models, supporting clinician-supported interpretation and treatment initiation without requiring in-person visits. In addition to OTC diagnostics where consumers receive immediate results, availability of laboratory tests that can use specimens collected at home is expanding. Collectively, these models point toward more distributed diagnostic ecosystems spanning home, pharmacy, and virtual care.

> *"It needs to be usable. It needs to be something that patients get clear action, how to use the test, the results, and then how do we take that information and get it to the right provider.*
>
> — MICHAEL UMBLEBY, RPH · WALGREENS

9 Berenbrok LA, Tang S, Gabriel N, et al. Access to community pharmacies: A nationwide geographic information systems cross-sectional analysis. J Am Pharm Assoc (2003). 2022;62(6):1816-1822.e2. doi:10.1016/j.japh.2022.07.003

TEST-TO-TREAT MODELS

"Test-to-treat" models represent a key opportunity to increase the clinical value of OTC diagnostics by more directly linking testing to timely treatment decisions. In these programs, a positive result can trigger rapid clinical evaluation and, when appropriate, immediate prescribing at the point of care, reducing delays between diagnosis and treatment initiation. During COVID-19, there were many pharmacy-based test-to-treat programs that helped patients who tested positive in community or home settings gain faster access to antiviral medications. This approach reduced reliance on multiple separate health care visits during a time-sensitive treatment window, when early antiviral initiation was critical for effectiveness.

Making Results Visible to Clinicians

Although consumer use of OTC diagnostics continues to grow, integration into clinical workflows and EHRs remains limited, constraining their impact on both individual care and population health. In practice, OTC diagnostics are often used outside the visibility of the health care system. Individuals test, interpret results, and determine next steps without direct clinical involvement. While this autonomy supports convenience and access, it also introduces variability in interpretation and follow-up. Dr. John Whyte of the American Medical Association noted that results from OTC diagnostics are rarely captured in structured EHR fields (e.g., laboratory sections), meaning they are effectively invisible to clinicians. When results are captured at all, they typically rely on workarounds, such as manual patient portal entry or faxed results, that are used inconsistently and add burden to patients, caregivers, and clinicians. These approaches also introduce variability in data quality, as patient recall and attestation are often unreliable mechanisms for clinical data transfer. Broader barriers further limit integration, including the absence of standardized reporting formats, limited interoperability across platforms, and a lack of incentives to ensure reliable and systematic data transmission into clinical systems.

THE ROLE OF THE CAREGIVER IN OTC TESTING

Caregivers are essential, often underrecognized partners in the use of OTC diagnostics, particularly when individuals are older adults, children, or people with complex health needs. James Appleby, BSPharm, MPH, Gerontological Society of America, emphasized that caregivers frequently serve as the bridge between testing at home and appropriate clinical follow-up, especially for older adults. Dr. Tanya Altmann of Calabasas Pediatrics in California shared how she helps families use OTC diagnostics to make decisions about whether to keep children home from school or daycare as well as whether to seek care through an office visit, urgent care, or emergency department. Caregivers help with test administration, interpret results, and make decisions about next steps in care as well as shoulder the practical and emotional burden of acting on uncertain or ambiguous results. In many cases, the effectiveness of OTC diagnostics depends on how well caregivers are supported, informed, and integrated into care pathways.

Speakers discussed the potential for digital tools and connected technologies to enable scalable integration of OTC diagnostics. Smartphone-based applications, QR code and barcode scanning, image capture of test results, and emerging device integrations were presented as practical mechanisms to reduce friction in data reporting and improve consistency of structured data capture in clinical and public health systems. More advanced approaches include AI systems capable of supporting result interpretation, automating data extraction from images, and integrating multiple streams of patient-generated health data into clinical summaries.

Data Privacy and Consumer Trust

Full integration of OTC diagnostics faces additional challenges related to data privacy, data quality, and the appropriate use of patient-generated health information. Speakers raised concerns about the interpretation of OTC and wearable-derived data, particularly when patients assume that results are equivalent in precision and clinical authority to laboratory-grade diagnostics without understanding variability, sensitivity, or specificity. Dr. Whyte emphasized the importance of maintaining rigorous standards for diagnostic validity, particularly when results inform clinical decision-making, prescribing, or escalation of care. From a regulatory and systems perspective, there is tension between ensuring access to high-quality, clinically reliable data and expanding access to convenient, home-based testing that may not always meet traditional laboratory thresholds but still provides meaningful health insights.

Patient-controlled data-sharing models were presented as one approach to address both engagement and trust concerns. Rather than relying solely on automated system-level data transmission, speakers proposed frameworks in which consumers authorize sharing of results with clinicians, caregivers, or public health systems, potentially on a persistent or semi-automated basis. Such models could reduce repeated consent burden while preserving patient autonomy and control over sensitive health information. However, the effectiveness of these approaches depends on the development of interoperable standards, secure data infrastructure, and transparent governance mechanisms that define how data are used across clinical care, research, and surveillance contexts.

Finally, participants distinguished between the integration needs of individual clinical care and those of public health surveillance, noting that each domain has different requirements for data completeness, timeliness, and granularity. In clinical care, the priority is actionable, patient-specific information that can be reliably interpreted within the context of an individual's health status and used to guide diagnosis and treatment. In contrast, public health systems are more focused on aggregate trends, population-level signals, and early detection of outbreaks or disparities. OTC diagnostics offer significant potential for both domains, but only if data can be standardized, aggregated appropriately, and linked in ways that preserve both utility and privacy.

Next Generation OTC Diagnostics

The final session of the meeting focused on the next generation of OTC diagnostics and the broader shift toward home-centered, technology-enabled models of care. Speakers emphasized that emerging technologies, including AI-enabled diagnostics, smartphone-based testing platforms, connected devices, and wearable sensors, are rapidly expanding the scope of what consumers can monitor and manage outside traditional clinical settings. Several speakers emphasized that access remains a central driver of innovation in OTC diagnostics. Paul Wardle of Klick USA Inc. reiterated that effective health care requires access not only to diagnostics, but also to the interventions that follow them. Diagnostics and treatment should be viewed as part of a continuous care loop, particularly for chronic conditions such as diabetes, hypertension, asthma, and hyperlipidemia, where measurement over time informs treatment decisions and disease management. Many unmet health care needs stem not from the absence of effective therapies, but from barriers that prevent people from obtaining timely testing, evaluation, and treatment. Dr. Marcia Howard from the Consumer Healthcare Products Association highlighted the role of OTC diagnostics in reducing barriers to care caused by provider shortages, transportation challenges, the time and cost burden of clinic visits, and other financial limitations, especially for people in rural or underserved communities.

ADDITIONAL CONDITION FOR NONPRESCRIPTION USE (ACNU)

Additional Condition for Nonprescription Use (ACNU)[10] is a regulatory approach that allows certain prescription-level products to be used safely without a prescription, if specific conditions are met to ensure appropriate self-selection, correct use, and reliable interpretation of results. In the context of OTC diagnostics, effective health care depends on both access to testing and clear pathways for acting on results. ACNU serves as a mechanism for unlocking access to prescription treatments in the home setting by enabling safe, structured nonprescription use while preserving appropriate safeguards for safety and clinical integrity.

10 U.S. Food and Drug Administration. Nonprescription Drug Product with an Additional Condition for Nonprescription Use. Updated January 2, 2025. Accessed May 12, 2026. https://www.fda.gov/drugs/over-counter-otc-nonprescription-drugs/nonprescription-drug-product-additional-condition-nonprescription-use

Participants also discussed opportunities to expand existing diagnostic technologies to additional diseases and conditions in the home setting. Patty Post from Checkable highlighted how existing lateral flow technology is being adapted and tested for a potential at-home streptococcal diagnostic. She noted that expanding familiar testing technologies into the home could reduce unnecessary clinic visits, improve convenience and access for families, and extend the reach of physicians and pharmacists through telehealth and community-based follow-up care.

Emerging OTC technologies were presented as tools capable of reducing these barriers by embedding health monitoring more directly into consumers' daily routines. Smartphone-connected diagnostics, digital self-assessment platforms, and wearable devices were described as mechanisms that can support more continuous engagement with health data outside traditional health care environments. Sam Surette of Apple described "opportunistic detection" models in which wearable devices passively collect and analyze sensor data to identify possible signs of chronic conditions such as sleep apnea, atrial fibrillation, or hypertension. Rather than requiring users to actively seek testing, these systems can generate notifications that prompt individuals to seek follow-up care when concerning patterns are detected. Participants described these approaches as particularly important for conditions that are frequently underdiagnosed or ignored until symptoms become severe.

Speakers also emphasized that consumers increasingly expect health technologies to function within familiar digital ecosystems. Connected diagnostics integrated into smartphones, wearable devices, and consumer applications may reduce stigma, simplify testing workflows, and increase willingness to engage in proactive health monitoring. Several participants noted that wearables and passive monitoring tools blur traditional distinctions between wellness products[11] and clinical diagnostics, creating opportunities for earlier intervention while also introducing new regulatory and evidentiary challenges. Dr. Michael Mina of HTR Advisors highlighted the growing role of continuous data streams and consumer-facing technologies in helping individuals better understand their own health behaviors and physiological responses, particularly as AI tools become more integrated into health decision-making. Participants suggested that these technologies may support a broader shift toward preventive and proactive care models that allow individuals to identify potential health concerns earlier and seek intervention sooner.

11 U.S. Food and Drug Administration. General Wellness: Policy for Low Risk Devices. Published January 2026. Accessed May 12, 2026. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/general-wellness-policy-low-risk-devices

Regulatory frameworks were described as both safeguards and enablers of innovation; however, innovation is advancing more quickly than existing regulatory frameworks, health insurance coverage, and health data infrastructure. Multiple speakers described the current environment as an "ecosystem shift" in which health care delivery, diagnostics, software, and consumer technologies are converging faster than traditional systems are able to adapt. Participants noted that existing health care and regulatory models were largely designed around clinician-mediated testing and episodic care, whereas emerging technologies increasingly support decentralized, continuous, and patient-directed health management. Kathryn Capanna from FDA's Center for Devices and Radiological Health emphasized that regulation requires balancing timely access with appropriate standards for safety, effectiveness, and usability. Several speakers noted that the rapid evolution of technology for diagnostics may require regulatory models that are more adaptive and responsive than traditional device pathways. The discussion also highlighted growing interest in regulatory approaches that better account for public health value and access considerations.

> *"Health care is a team sport, regulation is a team sport, innovation is a team sport. And when we're in a paradigm shift like we are in this space, it really takes a coordinated effort.*
>
> **— KATHRYNN CAPANNA, MBA · U.S. FOOD AND DRUG ADMINISTRATION**

Current frameworks place most technologies into either prescription or OTC categories without fully accounting for broader public health benefits associated with accessibility and timely availability. Speakers suggested that future regulatory discussions may need to consider pathways specifically designed for public health-oriented technologies that prioritize early awareness, accessibility, and prevention rather than solely individual clinical diagnosis.

Trust emerged as another central theme throughout the discussion. Participants emphasized that broader adoption of next-generation OTC diagnostics will depend on consumer confidence in the accuracy, safety, and oversight of these technologies, as well as confidence in how personal health data are collected, stored, and shared. Speakers repeatedly stressed the importance of privacy-preserving systems that allow individuals to retain control over their health information. Device manufacturers and regulators alike emphasized that consumers must trust both the technology itself and the standards governing its development and regulation.

Finally, participants emphasized that realizing the full potential of next-generation OTC diagnostics will require coordinated action across the health care ecosystem. Several speakers highlighted the importance of developing shared innovation roadmaps that align technological capabilities with patient readiness, usability considerations, and evolving regulatory standards. Across the discussion, there was broad agreement that the future of OTC diagnostics will increasingly involve distributed, technology-enabled care models in which testing, monitoring, interpretation, and treatment occur across home, pharmacy, virtual, and clinical settings.

Conclusion

OTC diagnostics are reshaping health care by enabling more care to begin in the home and giving individuals faster access to health information. Throughout the meeting, speakers noted that this shift is already well underway, but its impact depends on how well these tools are integrated into broader clinical and public health systems. Continued progress will require coordinated action across product development, regulatory science, health insurance coverage, clinical workflow integration, data governance, and consumer education. With the right infrastructure and safeguards, OTC diagnostics have the potential to support more timely, accessible, and patient-centered care.

APPENDIX A

Public Meeting Agenda

March 25, 2026 · 1:00–4:30 pm ET · Hybrid Public Meeting

MEETING PURPOSE

Consumer use of at-home diagnostic tests has become an established element of the health care system, reshaping how and where people access information about their health. The COVID-19 pandemic demonstrated that advances in at-home diagnostic technology can empower patients, allowing them to find answers more quickly and conveniently, expediting the diagnostic and treatment process. However, uncertainty in pathways to market access and payment can slow innovation and adoption, underscoring the importance of clear regulatory processes and meaningful engagement with consumers and health care professionals. With the growing public appreciation of accessible health care solutions, this public meeting will foster collaboration, explore critical gaps, and illuminate pathways for the development, review, and deployment of at-home diagnostic devices to improve health care access, and advance the home as a hub of health care.

AGENDA

1:00 pm — **Welcome**

Moderator — Susan C. Winckler, RPh, Esq, Reagan-Udall Foundation for the FDA

1:05 pm — **Snapshot of OTC Diagnostics**

This presentation will explore how the landscape of diagnostics testing, health care delivery, and consumer behavior has evolved in recent years.

Presenter — Elizabeth Richardson, MSc, Canal Row Advisors

1:20 pm — **Current Environment for OTC Diagnostics**

This session will begin with presentations outlining the current regulatory framework and considerations for real-world data collection and performance evaluation of OTC diagnostics. The panel discussion will examine how these products are developed, regulated, and ultimately delivered to consumers for use.

Presenters & Reactor Panel — Courtney Lias, PhD, U.S. Food and Drug Administration; Ramy Arnaout, MD, DPhil, Beth Israel Deaconess Medical Center; Julie Barnes, JD, Maverick Health Policy; Anita Nosratieh, PhD, Abbott; Stacey Swartz, PharmD, Neighborhood Pharmacy of Del Ray

2:30 pm

Panel Discussion: Integrating OTC Diagnostics into Care Delivery

This panel discussion will explore how OTC diagnostics are supporting expanded health access and advancing home as a healthcare hub. Panelists will discuss the role of OTC diagnostics in improving individual clinical care as well as broader public health.

Panel & User Perspective — James Appleby, BSPharm, MPH, Gerontological Society of America; Deborah Autor, Esq, Hims & Hers; Michael Umbleby, RPh, Walgreens; John Whyte, MD, MPH, American Medical Association; Tanya Altmann, MD, FAAP, Calabasas Pediatrics

3:30 pm

Next Generation OTC Diagnostics

This session will begin with brief case study presentations from diagnostic developers and manufacturers highlighting innovations in the pipeline. A panel discussion will explore opportunities to expand consumer benefit with OTC diagnostics.

Case Study Presentations & Reactor Panel — Paul Wardle, MA, MMath, Klick USA Inc.; Patty Post, BA, Checkable; Sam Surette, BS, Apple; Kathryn Capanna, MBA, U.S. Food and Drug Administration; Marcia Howard, PhD, CAE, Consumer Healthcare Products Association; Michael Mina, MD, PhD, HTR Advisors

4:30 pm

Adjourn

FDA Resources about Home Use Tests

WEBSITES

- Over-the-Counter (OTC) Medical Devices: Considerations for Device Manufacturers | FDA
- Home Use Tests | FDA
- OTC — Over The Counter database for IVD Home Use Lab Tests (Over The Counter) Tests

GUIDANCE DOCUMENTS

- Design Considerations for Devices Intended for Home Use
- Applying Human Factors and Usability Engineering to Medical Devices
- Labeling Requirements — Over-The-Counter (Non-Prescription) Medical Devices
- Guidance on Medical Device Patient Labeling

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