



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

March 25, 2026 | 1-4:30pm 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

1pm

Welcome

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

1:05pm

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

1:20pm

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:

- Courtney Lias, PhD, U.S. Food and Drug Administration
- Ramy Arnaout, MD, DPhil, Beth Israel Deaconess Medical Center

Reactor panel:

- Julie Barnes, JD, Maverick Health Policy
- Anita Nosratieh, PhD, Abbott
- Stacey Swartz, PharmD, Neighborhood Pharmacy of Del Ray

2:30pm **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:

- James Appleby, BSP Pharm, MPH, Gerontological Society of America
- Deborah Autor, Esq, Hims & Hers
- Michael Umbleby, RPh, Walgreens
- John Whyte, MD, MPH, American Medical Association

3:25pm **User Perspective**
Speaker: Tanya Altmann, MD, FAAP, Calabasas Pediatrics

3:30pm **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:

- Paul Wardle, MA, MMath, Klick USA Inc.
- Patty Post, BA, Checkable
- Sam Surette, BS, Apple

Reactor panel:

- Kathryn Capanna, MBA, U.S. Food and Drug Administration
- Marcia Howard, PhD, CAE, Consumer Healthcare Products Association
- Michael Mina, MD, PhD, HTR Advisors

4:30pm **Adjourn**

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