

CHEAT SHEET

Disruptive therapeutics and diagnostics series | Volume 1 of 6

At-Home Diagnostics

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Key takeaways

- Home tests – also called self-tests or home-use tests – are typically sold over the counter and allow users to test self-collected specimens and interpret the results on their own without the help of trained health professionals.
- Most recently, the Covid-19 pandemic has increased the demand for, patient familiarity with, and investment in home testing technologies.
- At home diagnostic tests are disrupting two elements of healthcare: care delivery, and cost and payment models.



DISRUPTIVE THERAPEUTICS AND DIAGNOSTICS SERIES

VOLUME 1 [This volume](#)

At-Home Diagnostics

Home tests – also called self-tests or home-use tests – are typically sold over the counter and allow users to test self-collected specimens and interpret the results on their own without the help of trained health professionals.

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Biomarker Testing

Biomarker testing (also known as mutation, genomic, or molecular testing) uses laboratory tests to help the health care team gather as much information as possible about a patient’s disease state.

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Ultra High-Cost Drugs

Ultra high-cost drugs (UHCDs) are expensive, potentially durable, or curative therapies currently approved to treat conditions that are orphan and rare disease.

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What is it?

Home tests – also called self-tests or home-use tests – are typically sold over the counter and allow users to test self-collected specimens and interpret the results on their own without the help of trained health professionals. There are also types of at home-collection tests that require patients to collect samples at home, mail them to a laboratory or clinic for analysis and obtain the results later.

Most recently, market growth for at-home testing has been spurred by the global Covid-19 pandemic. However, FDA-approved home tests have existed in the US for the detection, diagnosis, or management of various health conditions for several years.

Home tests have many applications. According to the FDA, some examples include:

- Detecting possible health conditions when you have no symptoms, so that you can get early treatment and lower your chance of developing later complications such as Covid-19, cholesterol testing, and hepatitis testing.
- Detecting specific conditions when there are no signs so that you can take immediate action and seek care such as pregnancy testing.
- Monitoring conditions to allow frequent changes in treatment such as glucose testing to monitor blood sugar levels in diabetes.

1. Inpatient care management relies more heavily on RNs and social workers to staff their programs.

Source: Advisory Board interviews and analysis.
"Home Use Tests," U.S. Food and Drug Administration, April 2019,
<https://www.fda.gov/medical-devices/in-vitro-diagnostics/home-use-tests>

Why does it matter?

During the Covid-19 pandemic, with millions of workers furloughed and laid off, many individuals lost income and health insurance, making them less likely to seek traditional care, which has influenced people's demand for at-home health care.

There are several trends that aided in accelerating at-home diagnostic adoption:

- **Advancements in home testing technology** that limit the potential for error when patients collect their own samples. Lab vendors are exploring different technologies such as biometric patch sensors in lieu of at-home blood draws. Research will need to rigorously evaluate the quality and safety of these technologies to inform practice and policy.
- **Provider involvement in home testing.** Technology and patient preference shifts motivated some health systems to create a home testing business that lends credibility to at-home options. In addition, at-home diagnostics can help hospital capacity and alleviate provider burnout by allowing clinical staff to work more top of license.
- **Increased accessibility and affordability of "lite" lab tests** that can easily be administered at home, paid for out-of-pocket, and serve as an addition (rather than a substitution) to regular testing.
- **Increased public health awareness:** At-home testing holds many public health benefits, for infectious diseases like Covid-19. Self-testing at home can substantially reduce or eliminate the risk of people spreading the virus, as well as being more convenient than traditional diagnostics.

What makes it disruptive?

Areas of disruption

Care delivery

Although health systems have embraced at-home diagnostics by embedding testing results into provider workflows and care pathways, they see home testing for labs as a potential liability, fearing low quality and high costs. Similarly, lab directors are often concerned about proper protocols for follow-up care and patient education. Often primary care providers are more willing to use home testing to screen patients before clinic visits, but they still feel it is necessary to confirm the tests in-office for those with positive or concerning results to advance appropriate use and reduce anxiety.

Cost/payment models

At-home diagnostics may have implications on downstream care, as well as reducing avoidable costs for patients and providers such as delayed treatment and recurring readmissions.

Prior to Covid-19, payment models typically involved patients paying out-of-pocket for at-home diagnostics. However, during the pandemic, we quickly transitioned to a model where the government and other insurers moved to cover these. How payment models evolve will have implications for general uptake and use by consumers.

A note on health equity

If at-home diagnostics are administered at home, paid for out-of-pocket, and serve as an addition (rather than a substitution) to regular testing this could lead to increased accessibility and affordability of lab tests and alleviate costs for underserved groups. However, the technological demands of some diagnostic tests could create barriers to adoption and widen digital inequities.

Conversations you should be having

Sector	Conversations
Payers	<ul style="list-style-type: none"> • How is my organization conveying efficiency in our value proposition to health systems and patients? • How can we encourage the equitable adoption of at-home diagnostics? • How do we make at-home diagnostics accessible to the targeted populations by collaborating on risk-mitigating contracts with manufacturers?
Health systems	<ul style="list-style-type: none"> • How can we educate internal and external stakeholders on where and how at-home testing fits into their care pathways? • How does at-home testing fit into my system's long-term strategy?
Labs	<ul style="list-style-type: none"> • How does my organization compare when it comes to helping health systems manage the logistics of home-collection tests?

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