

Thesis Synopsis

Title: Global Self Testing Diagnostic Device Market

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Date of Submission: June 2025

1. Introduction

The rise of self-testing diagnostic devices marks a transformative phase in global healthcare, where individuals are empowered to detect and manage health conditions from the comfort of their homes. These devices include glucose monitors, pregnancy kits, and COVID-19 antigen tests, reflecting a shift toward decentralized, patient-centered care. Driven by chronic disease prevalence, aging populations, and digital health integration, the market for self-diagnostic tools is growing rapidly. This study investigates the trends, adoption drivers, and strategic implications of this growing sector globally.

2. Need for the Study

Despite their widespread adoption and market penetration, there remains limited holistic academic research examining self-testing devices across economic, regulatory, and technological dimensions on a global scale. As healthcare systems continue to promote patient autonomy and cost-effectiveness, understanding the self-diagnostics landscape is vital for industry players, investors, and policymakers. This study aims to bridge that gap by providing a structured analysis of market trends, adoption behavior, challenges, and opportunities in the self-testing segment.

3. Objectives

- To analyze the global market size and growth trajectory of self-testing diagnostic devices.
- To evaluate demand patterns and regional adoption rates.
- To examine adoption variations across care settings—home, hospital, and ambulatory.
- To review regulatory, reimbursement, and procurement frameworks.
- To identify top manufacturers, emerging startups, and technological innovations shaping the market.

4. Research Questions

- What is the current market size and projected growth of self-testing diagnostic devices globally?
- What are the regional and demographic trends influencing adoption?
- How do regulatory and reimbursement frameworks impact market expansion?
- Which companies and technologies are leading innovation in the self-testing space?
- What challenges limit the scalability and reliability of self-testing diagnostics?

1. Methodology

Approach:

Descriptive and analytical research using both primary and secondary data sources.

Data Sources:

- *Primary*: Expert interviews and qualitative surveys of industry professionals.
- *Secondary*: Reports from WHO, FDA, McKinsey, IQVIA, IBEF, Statista, Grand View Research, and academic journals.

Sampling Technique:

Purposive sampling to gather insights from stakeholders including device manufacturers, regulatory authorities, and healthcare providers.

Analysis Tools:

- Descriptive statistics
- Graphical analysis (charts, tables)
- Thematic analysis for qualitative data

6. Scope of the Study

The study focuses on self-testing diagnostic devices used for infectious diseases (e.g., COVID-19, HIV), chronic illnesses (e.g., diabetes, hypertension), fertility monitoring, and digital diagnostics. While the research adopts a global perspective, emphasis is placed on high-growth markets such as the U.S., EU, India, China, and Latin America.

7. Limitations

- Limited primary data collection in some emerging regions.
- Constant technological evolution may outdate certain projections.
- Access to proprietary business data from key players was restricted.

9. Expected Contribution

- Provide a strategic overview of global trends in self-testing diagnostics.
- Help manufacturers, investors, and policymakers make informed decisions.
- Highlight opportunities for digital innovation, patient empowerment, and market expansion.
- Support academic and industrial discourse on the decentralization of diagnostics and healthcare access.

10. References

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4. IBEF. (2023). Indian Medical Devices Industry Report.
5. Cue Health, Everlywell, Abbott, Roche, HealthCube – Company Portfolios and Market Data.
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