ABSTRACT

1. Background and Public Health Context

Among women of reproductive age, hormonal abnormalities such polycystic ovarian syndrome (PCOS), polycystic ovarian disease (PCOD), thyroid dysfunction, and associated subfertility problems pose a rapidly expanding public health concern.

Studies conducted in Tamil Nadu show that the prevalence of PCOS among young women and adolescents is notably high. In one community-based study of adolescents and young women in Tamil Nadu, approximately 18% were found to have PCOS by the Rotterdam criteria. This underscores the local burden of hormonal disorders in the state and highlights the need for accessible early screening solutions.

The prevalence of PCOS has risen dramatically in India over the last ten years, according to epidemiological research; estimates vary from 12% to over 25% in some groups.

In the world, about 70% of women with PCOS do not have a diagnosis. Infertility, metabolic syndrome, cardiovascular disease, type 2 diabetes, and endometrial cancer are among the long-term issues and treatment delays caused by this diagnostic gap.

2. Limitations of Current Diagnostic Pathways

Hormonal diagnostic routes are nevertheless more expensive, intrusive, and centralized in spite of the growing load. Clinical interpretation, skilled specialists, laboratory-based immunoassay systems, and venous blood collection are all necessary for standard testing procedures. Comprehensive hormonal panels in India usually cost between INR 5,000 and 6,000, which prevents a significant portion of the population from affording routine screening. Timely access to testing is further hindered by the lack of laboratory facilities in Tier 2, Tier 3, and rural areas. Early examination is further discouraged by the social shame associated with menstruation and reproductive health as well as insufficient awareness. Because of this, most women don’t seek medical help until their symptoms worsen or they start having problems getting pregnant.

3. Research Gap and Innovation Opportunity

A significant research and healthcare gap is the lack of a decentralized, reasonably priced, and non-invasive multi-hormone screening tool made especially for routine monitoring outside of laboratory settings and early identification. Even though Lateral Flow Assay (LFA) technology has been effectively used for pregnancy detection and testing for infectious diseases, its application for multi-analyte reproductive hormone detection, specifically, utilizing menstrual blood as a diagnostic matrix, remains understudied and difficult from a scientific standpoint. The complex biological matrix that is menstrual fluid, which includes blood, endometrial tissue, mucus, and cellular debris, might affect the stability of biomarkers and the detection of signals. There are a scientific opportunity and an innovative pathway to overcome these technological obstacles.

4. Proposed Solution and Technological Approach

Developing and clinically validating a novel in-vitro diagnostic (IVD) tool for early hormonal screening based on LFA technology is the goal of the proposed study. The idea focuses on using menstrual blood as a regular, non-invasive sample source, with the option to add venous blood if necessary. Key reproductive hormone indicators associated with PCOS, irregular menstruation, and subfertility disorders may be detected and interpreted by the device.

5. Structured Research and Validation Framework

Through an organized and quantifiable development framework, the research will advance:

- Assay Optimization and Prototype Engineering: To improve analytical performance, a multi-analyte LFA strip with standardized biomarker extraction from menstrual fluid, optimal antigen–antibody interactions, and matrix stabilization procedures was developed. The goal will be to achieve excellent sensitivity and specificity in the realm of low hormone concentrations.
- Analytical Validation: Under a range of environmental circumstances, laboratory-based validation studies will evaluate performance criteria such as sensitivity, specificity, repeatability, reproducibility, and stability. Before testing on humans, this step guarantees scientific soundness.

- Clinical Validation: Under the consent of the Institutional Ethics Committee (IEC), multi-centre clinical trials will assess the device's performance in comparison to recognized laboratory gold-standard diagnostic techniques. Equivalency and diagnostic reliability will be established by statistical analysis.
- Regulatory and Quality Compliance: In line with the Medical Devices Rules of 2017, a Quality Management System aligned with ISO 13485 was implemented and submitted for regulatory certification under the Central Drugs Standard Control Organization (CDSCO). Regulatory preparedness would be further strengthened by cooperation with recognized labs and adherence to Indian Council of Medical Research (ICMR) validation standards.

6. Affordability, Accessibility, and Deployment Potential

The suggested approach aims for infrastructure independence, usability, and price (less than INR 1,000 per test). High-volume production is made possible by its paper-based design, which also lessens the environmental impact and industrial complexity. The invention might change women's healthcare from reactive, symptom-driven intervention to proactive, preventative monitoring by decentralizing hormone screening.

Systemic disparities in healthcare access are addressed by the solution, which goes beyond clinical advantages. It is especially well-suited to be implemented through community outreach initiatives, pharmacies, and primary health centres, expanding the diagnostic reach to underprivileged groups. By reducing illness risk, modifying lifestyle, and enabling prompt medical consultation, early detection of hormonal imbalance can eventually save long-term healthcare costs.

7. Expected Impact and Conclusion

This initiative, in short, fills a well-defined and empirically substantiated public health gap. By conforming to regulatory and quality requirements, creating organized validation procedures, and adapting LFA technology to a unique biological matrix, it has significant innovation potential. With methodical investigation, analytical verification, and clinical assessment, the suggested solution is ready to go from idea to scalable deployment, making a significant contribution to women's healthcare prevention.