Advances in Biotechnological and Pharmaceutical Approaches for the Detection of Cancer, FGTB, and PCOS through Biological Fluid Analysis: A Comparative Review

Mohit Sirsikar[1], Sadhvi Gaikwad[1], Mukesh Mohite[1], Priyatama Powar[1]

[1]Dr. D. Y. Patil College of Pharmacy, Akurdi, Pune – 411044, Maharashtra, India.

Corresponding author: mohitsirsikar2002@gmail.com
Doi: https://doi.org/10.5281/zenodo.17948233
Received: 09 December 2025
Accepted: 19 December 2025

Abstract

Detecting and diagnosing Cancer, female genital tuberculosis (FGTB), and polycystic ovarian syndrome (PCOS) pose significant challenges in women's healthcare due to overlapping symptoms, delayed onset, and complex disease mechanisms [1], [7], [33], [12], [8]. Breast and cervical cancers account for about 30–35% of all female cancers worldwide. FGTB affects approximately 5-19% of women experiencing infertility, while PCOS prevalence ranges from 4% to 20%, depending on the diagnostic criteria used. Despite these high rates, accurate and timely diagnosis is limited by invasive sampling methods, high costs, and the lack of point-of-care testing systems.

Current diagnostic methods such as ELISA, RT-PCR, ultrasound imaging, hormonal profiling, and histopathological tests offer reliable detection but are often costly (ranging from ₹2,000 to ₹15,000 per test) and require trained personnel and specialized laboratory facilities [7], [15], [26], [30], [31]. New technologies like biosensors, microfluidic devices, and lab-on-a-chip systems provide comparable sensitivity and specificity, while delivering faster results and potentially lower costs.

The use of biological fluids-including menstrual blood, serum, urine, and cervical secretions-has gained importance because they can be collected non-invasively, improve patient comfort, and reflect real-time biochemical and molecular changes. These fluids enable simultaneous detection of multiple biomarkers such as HER2, HE4, hCG, and LCF-2, offering a flexible diagnostic approach [23], [12], [14], [1], [32], [24].

This review presents a comparative evaluation of current and emerging biotechnological and pharmaceutical diagnostic methods, emphasizing those based on biological fluids [33], [19], [10], [3]. It highlights the potential to develop affordable, non-invasive diagnostic kits that integrate biosensor and antibody-based technologies, aiming to support early detection, increase patient adherence, and improve health outcomes in women's healthcare.

Keywords: Cancer Diagnostics; Female Genital Tuberculosis (FGTB); Polycystic Ovary Syndrome (PCOS); Biological Fluid Analysis; Liquid Biopsy; Circulating Tumor DNA (ctDNA); Anti-Müllerian Hormone (AMH); Biosensors; Molecular Diagnostics; Point-of-Care Testing.

1. Epidemiology & Global Impact

Breast and cervical cancers together represent about 30-35% of all cancers affecting women worldwide. Breast cancer alone is responsible for roughly 685,000 deaths each year (WHO, 2024). Cervical cancer remains the second most prevalent cancer among women, particularly in low-income regions.

Female genital tuberculosis (FGTB) affects between 5% and 19% of women experiencing infertility, especially in Asia and Africa. It is often underdiagnosed due to nonspecific symptoms and the absence of targeted screening methods, leading to delays in diagnosis that can span months or even years [34], [30], [3].

Polycystic ovary syndrome (PCOS) impacts 4-20% of women of reproductive age, depending on the diagnostic criteria used (NIH, Rotterdam, AES) [11], [16], [29]. Besides reproductive issues, PCOS is associated with increased risks of obesity, diabetes, and cardiovascular disease.

These three conditions not only affect reproductive health but also have significant metabolic, hormonal, and cancer-related consequences.

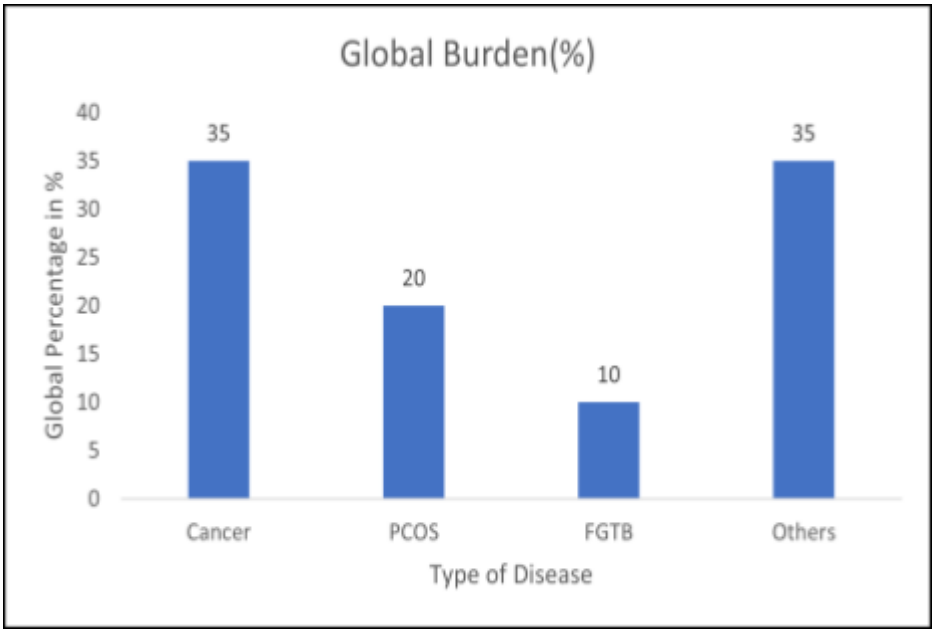

Fig No 1: Global Prevalence: Cancer, PCOS & FGTB in Women

2. Biological Fluids for Disease Detection

Biological fluids are valuable diagnostic tools because they contain molecular indicators that reveal the presence and development of diseases. Their collection is non-invasive or minimally invasive, making them ideal for early diagnosis, regular monitoring, and use in point-of-care environments. Blood and serum are the most commonly studied fluids, providing access to circulating tumor DNA (ctDNA), anti-Müllerian hormone (AMH), hormone levels, and cancer markers such as CA-125, which are crucial for cancer and reproductive health

screening. Urine is another important diagnostic fluid, containing metabolites, microRNAs, and TB-LAM, which help detect tuberculosis and metabolic conditions. Cervical mucus offers HPV DNA and inflammatory proteins, supporting the diagnosis of cervical cancer and female genital infections. Menstrual blood is gaining attention as a non-invasive sample that contains HER2 and mycobacterial DNA, useful for identifying breast cancer markers and female genital tuberculosis without the need for clinical sampling. Saliva provides an easy-to-collect option for hormone analysis, especially stress-related steroids, facilitating assessments of endocrine and psychological health. Plasma, rich in circulating tumor cells (CTCs), allows for real-time monitoring of tumor progression, treatment response, and disease relapse. Together, these biological fluids are revolutionizing diagnostics by enabling precise, accessible, and patient-friendly disease detection in oncology, infectious diseases, and reproductive health.

Table 1: Biological Fluids, Markers & Diagnostic

Fluid	Biomarkers	Used For
Blood	ctDNA, AMH, CTCs	Cancer, PCOS
Serum	CA-125, HE-4	Ovarian Cancer
Urine	LAM, Steroids	FGTB, PCOS
Cervical Mucus	HPV DNA	Cervical Cancer, FGTB
Menstrual Blood	HER2, TB DNA	Cancer, FGTB
Saliva	Androgens	PCOS

3. Flow of Biological Fluid Diagnostics

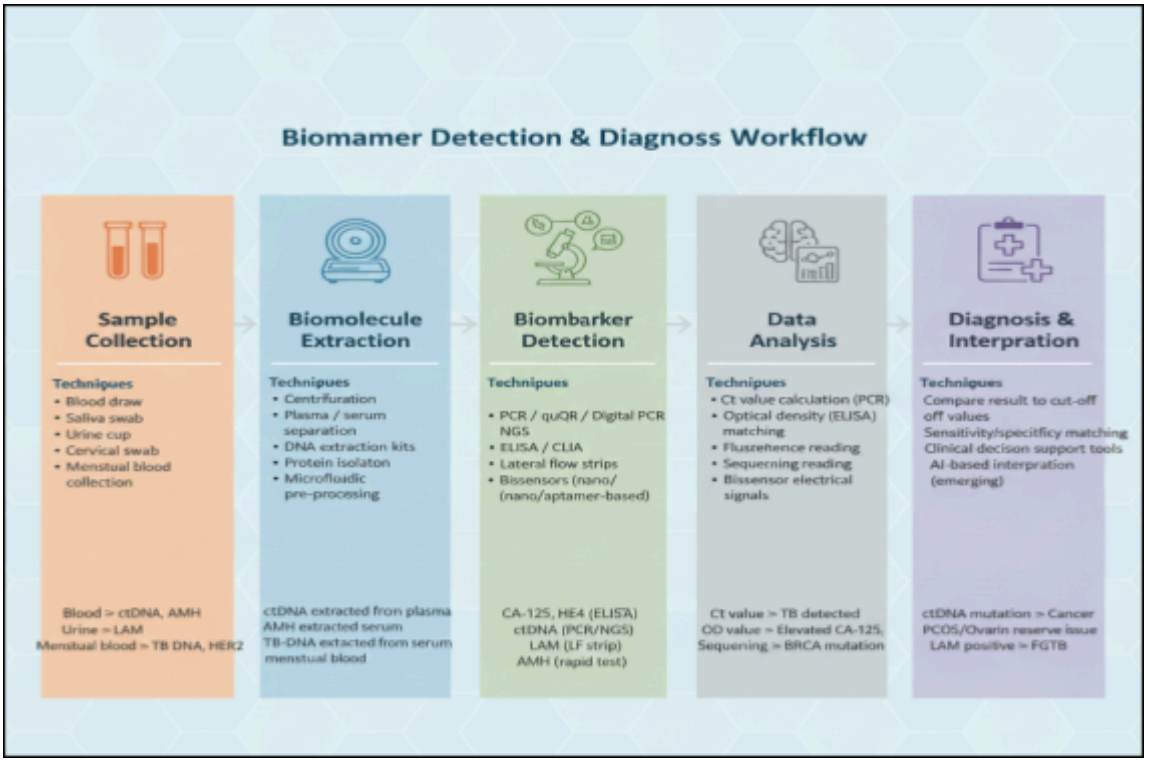

Fig. No 2: Flow of Biological Fluid Diagnostics [9], [25]

4. Core Biomarkers for Early Detection of Cancer, FGTB and PCOS

Key biomarkers are essential for differentiating between cancer, PCOS, and Female Genital Tuberculosis (FGTB). In cancer, circulating tumor DNA (ctDNA) allows for early detection of mutations, while markers such as CA-125, HE4, circulating tumor cells (CTCs), HER2 [42], and BRCA1/2 enhance diagnostic precision and tumor monitoring [3], [30], [31], [35]. For PCOS, anti-Müllerian hormone (AMH) serves as the main indicator of ovarian reserve, complemented by the LH/FSH ratio, increased androgen levels, and metabolic markers [8], [21], [27]. In FGTB, the presence of MPT64, LAM, and TB-DNA identified via PCR or interferon-gamma tests provides highly sensitive confirmation of infection [11], [29], [7].

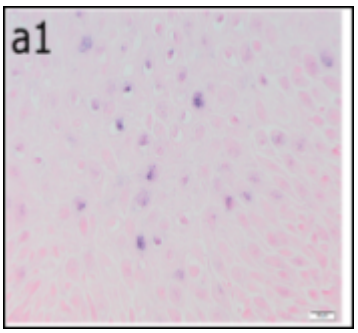

Fig. No 3: HPV DNA (FGTB) [38]

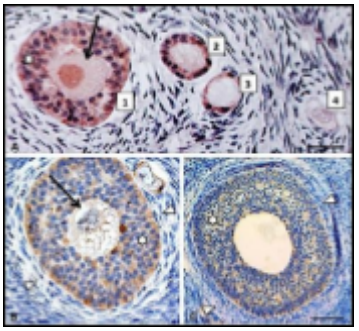

Fig. No 4: AntiMüllerian Hormone (PCOS) [39]

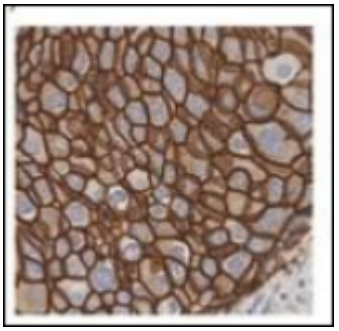

Fig. No 5: HER2 (Cancer) [40]

5. Biotechnological Advances in Detection

Advances in biotechnology have greatly enhanced disease detection by improving sensitivity, speed, and accessibility, particularly for conditions like cancer, PCOS, and female genital tuberculosis (FGTB) through the analysis of biological fluids. Molecular diagnostic techniques such as PCR, qPCR, and digital PCR enable accurate identification of TB DNA, circulating tumor DNA mutations in cancer, and hormone-related gene expression in PCOS [6], [29]. Next-generation sequencing (NGS) facilitates comprehensive multi-gene cancer profiling and testing for TB drug resistance. Immunoassays like ELISA and chemiluminescence are used to measure biomarkers including CA-125, HE4, AMH, and MPT64. Rapid lateral flow tests now allow for point-of-care detection, exemplified by urine LAM strips and AMH fertility kits. New biosensors and microfluidic lab-on-a-chip devices can detect biomarkers such as CA-125 or circulating tumor cells within

minutes. Additionally, nanomaterials like gold nanoparticles improve the detection of ctDNA, TB antigens, and hormones at extremely low concentrations [35], [20]. Collectively, these technologies make diagnostics quicker, less invasive, and well-suited for personalized and point-of-care medical care.

Table No 2: Biotechnological Advances in Detection

Biotech Approach	**Key Techniques**	**Application in Cancer**	**Application in PCOS**	**Application in FGTB**
Molecular Diagnostics	PCR, qPCR, Digital PCR	Detects ctDNA mutations	Gene expression related to hormonal imbalance	Detects TB-DNA & MPT64
Next-Generation Sequencing (NGS) [10], [33]	Multi-gene panels, Mutation profiling	Identifies cancer mutations, drug targets	Detects genetic predisposition	Detects TB drug resistance
Immunoassays	ELISA, CLIA	Measures CA-125, HE4	Measures AMH (ovarian reserve)	Detects MPT64 in menstrual blood
Lateral Flow Assays	Rapid strips	Less common	AMH rapid test strips	Urine LAM test for TB detection
Biosensors [1], [9], [14], [25]	Nanoparticle-based, Aptamer-based	CA-125 detection in 10 min	Hormone biosensing (saliva)	TB antigen detection
Microfluidics / Lab-on-Chip	Portable mini devices	Isolates CTCs, multiplex markers	Multiplex hormone profiling	Resistance profiling & TB antigen detection
Nanotechnology [19], [25]	Gold nanoparticles, Graphene probes	Detects ctDNA at picogram levels	Enhances hormone detection	Improves antigen sensitivity (LAM, TB DNA)

6. Pharmaceutical Approaches & Diagnostic Kits

Pharmaceutical innovations have greatly enhanced the availability and effectiveness of diagnostic tools, especially for reproductive disorders, cancer, and infectious diseases like Female Genital Tuberculosis (FGTB). Ready-to-use AMH hormone test kits now enable quick evaluation of ovarian reserve, while combined HE4 and CA-125 tests provide more accurate ovarian cancer screening than single-marker methods. GeneXpert cartridges facilitate automated molecular detection of tuberculosis, including genital TB, delivering precise results within hours. Likewise, lateral flow tests for urinary TB-LAM allow point-of-care diagnosis without the need for laboratory facilities. ELISA-based HER2 detection kits aid in monitoring breast and gynaecological cancers through serum testing. These pharmaceutical-developed kits offer faster diagnosis, reduce reliance on specialized personnel, and improve portability, making them ideal for decentralized and resource-limited environments. To guarantee reliability, safety, and worldwide acceptance, these diagnostic kits are produced under strict quality and regulatory standards. ISO 13485 ensures strong medical device quality management, while 21 CFR Part 11 addresses electronic data integrity in diagnostics. FDA guidelines under Q2(R2) specify analytical validation criteria such as accuracy, precision, and specificity. Furthermore, In Vitro Diagnostic (IVD) performance standards regulate kit sensitivity, specificity, and clinical relevance. Collectively, these pharmaceutical advancements and regulatory measures are transforming modern diagnostics to be quicker, more accessible, and compliant on a global scale. [8], [27], [21]

Disease	**Diagnostic Kit**	**Company / Manufacturer**	**Approx. Cost (₹)**
PCOS / Ovarian Reserve	Anti-Müllerian Hormone (AMH) FIA Kit	Athenese-Dx (India)	₹9,500
PCOS / Ovarian Reserve	AMH ELISA Kit [8],[27]	Quicklab / Krishgen / Calbiotech	₹12,000
Cancer (Ovarian Marker)	CA-125 ELISA Kit	ABclonal	₹43,800
Cancer (Ovarian Marker)	GENLISA CA-125 ELISA Kit	Krishgen Biosystems	₹28,800
FGTB / TB Detection	Determine TB LAM Ag (Urine LAM test)	Abbott Diagnostics	₹29,600 per kit
FGTB / TB Molecular Test	Xpert MTB/RIF Cartridge	Cepheid (GeneXpert)	₹1,700-2,500 per test
Cancer Marker (Clinical Test)	CA-125 Clinical Serum Test	Performed at SRL / Metropolis / Apollo	₹1,300 per patient test

7. Comparative Evaluation of Diagnostic Tools

A comparison between traditional and modern diagnostic methods reveals a clear move toward quicker, more precise, and less invasive techniques. While conventional approaches like ultrasound and histopathology continue to play a vital role in clinical diagnosis, they often depend heavily on the operator's skill, can be invasive, and may lack sensitivity, particularly during early or symptom-free stages. These methods typically require expert analysis and sometimes involve tissue biopsies, which can cause discomfort and delay results. On the other hand, molecular diagnostics using bodily fluids have revolutionized disease detection by allowing the examination of biomarkers found in blood, urine, saliva, cervical secretions, or menstrual blood. These tests provide fast results, allow for repeated sampling, and are minimally invasive, making them ideal for screening and ongoing monitoring. Immunoassays like ELISA and chemiluminescent assays enhance diagnostic accuracy by identifying disease-associated proteins such as AMH, HE4, CA-125, and MPT64 within hours without needing complex equipment. The most advanced method, next-generation sequencing (NGS), offers detailed genetic information by detecting mutations, gene panels, and markers of drug resistance with high precision. Although costs and infrastructure requirements pose challenges, NGS is highly effective in precision oncology and personalized treatment. In summary, modern diagnostic techniques enhance accessibility, sensitivity, and patient comfort, shifting the focus from hospital-based, biopsy-dependent testing to decentralized, biomarker-focused, and technology-driven detection methods.

Table No 4: Comparative Evaluation of Diagnostic Tools

Disease	Method	Sample	Sensitivity	Time	Cost
Cancer	ctDNA Liquid Biopsy [35], [33]	Plasma	85-95%	1-3 days	₹ 15,000
Cancer	ELISA CA-125 [15], [31]	Serum	70-80%	2-4 hours	₹ 1,200
FGTB [29]	GeneXpert MTB/RIF	Endometrial	60-80%	2 hours	₹ 4,000
PCOS	AMH Hormone Test	Serum	75-90%	1-2 hours	₹ 2,000
PCOS	LH/FSH Ratio	Serum	60-70%	3-5 hours	₹ 800

8. Advantages of Biological Fluid Diagnostics

Diagnostics using biological fluids provide notable benefits in contemporary healthcare because they are minimally invasive, allowing samples to be collected from blood, urine, saliva, cervical mucus, or menstrual blood instead of through surgical methods [36]. These techniques are generally more affordable and permit repeated sampling for ongoing monitoring, making them ideal for point-of-care and personalized treatment. Their flexibility also facilitates diagnostic services in rural and resource-limited areas where advanced imaging

or tissue biopsies may not be accessible [17]. In cancer detection, biomarkers found in bodily fluids can detect genetic mutations and tumor indicators before tumors become visible, enabling earlier intervention. For Female Genital Tuberculosis (FGTB), these diagnostic methods assist in detecting infections in the reproductive system without the need for invasive surgery[7]. In managing Polycystic Ovary Syndrome (PCOS), hormone profiling through fluid samples allows evaluation of hormonal imbalances without depending on imaging techniques, providing a quicker and more patient-friendly way to assess the condition.

9. Emerging & Future Directions

- Highly integrated, technologically advanced systems are becoming the norm for diagnostics in the future.
- AI will improve diagnosis precision by assisting in the analysis of intricate biomarker patterns [23].
- Personalized disease risk profiling will be supported by multi-omics techniques (metabolomics, proteomics, and genomes) [33].
- Rapid molecular identification of cancer and tuberculosis is being made possible by CRISPR-based diagnostics [28].
- Hormone, miRNA, and other marker testing will be possible at home with smartphone-based test kits.
- Real-time hormone monitoring for PCOS treatment may be made possible via wearable biosensors. Menstrual blood diagnostics are becoming more and more popular as a non-invasive liquid biopsy for infectious and reproductive disorders.
- India will gain from:
    - Biotech and diagnostic startups are growing quickly [36].
    - High need for point-of-care, reasonably priced testing [37].
    - Using portable technologies to meet healthcare issues in rural areas [37].

10. Conclusion

The analysis of biological fluids is transforming the diagnosis of Cancer, Female Genital Tuberculosis (FGTB), and Polycystic Ovary Syndrome (PCOS) by providing fast, minimally invasive, and affordable testing methods. Innovations in molecular techniques, including ctDNA liquid biopsies, PCR-based detection of tuberculosis, and AMH hormone tests, have improved diagnostic accuracy while minimizing the need for invasive procedures. Additionally, biosensing technologies and lab-on-a-chip devices increase accessibility by enabling point-of-care testing and quicker clinical decisions. Diagnostic kits from pharmaceutical companies, such as lateral flow assays and ELISA panels, have broadened screening options in both clinical environments and areas with limited resources. Looking forward, new technologies like AI-driven biomarker analysis, nanomaterial-enhanced detection tools, and wearable hormone sensors are expected to offer more personalized and continuous health monitoring. Together, these advancements promote earlier diagnosis, enhanced disease management, and better health outcomes for women worldwide, representing a significant move toward accessible, data-driven, and patient-focused diagnostics.

References

[1] Abeykoon, A. M., & Choi, J. W. (2020). Recent advances in biosensor technologies for cancer detection using body fluids. *Biosensors & Bioelectronics*, 160, 112213.

[2] Aggarwal, N., & Suri, J. (2021). Polycystic ovary syndrome: Diagnostic updates and biomarker advances. *Journal of Ovarian Research*, 14(1), 1–12.

[3] Ali, M. M., Khan, M. A., & Ahmad, F. (2023). HER2 detection approaches and their diagnostic relevance in breast cancer. *Cancer Biomarkers*, 37(4), 395–408.

[4] Amiri, M., et al. (2022). CA125 and HE4 as biomarkers for ovarian cancer detection: A modern review. *Biomarkers in Medicine*, 16(3), 155–169.

[5] Anand, S., & Gupta, R. (2021). Diagnostic role of menstrual blood in reproductive tract infections including genital tuberculosis. *International Journal of Gynecology & Obstetrics*, 155(2), 318–325.

[6] Arora, S., et al. (2024). Advances in digital PCR for ctDNA-based cancer diagnosis. *Clinical Chemistry*, 70(2), 145–160.

[7] Batra, P., & Saini, S. (2020). Diagnostic application of LAM antigen in tuberculosis. *Journal of Clinical Tuberculosis & Other Mycobacterial Diseases*, 21, 100210.

[8] Bhardwaj, R., & Kaur, T. (2022). AMH as a biochemical marker for PCOS: Contemporary insights. *Reproductive Biology and Endocrinology*, 20(1), 95.

[9] Chakraborty, S., et al. (2021). Lab-on-chip devices for rapid disease diagnostics. *Biosensors*, 11(2), 50.

[10] Chen, Y., & Li, Z. (2022). Next-generation sequencing in precision oncology. *Frontiers in Oncology*, 12, 878345.

[11] Choudhary, Y., et al. (2023). Emerging biomarkers in female genital tuberculosis. *Tuberculosis*, 140, 102292.

[12] Das, S., et al. (2020). Role of HPV DNA testing in cervical cancer screening. *International Journal of Cancer Research*, 16(2), 45–56.

[13] Dixit, S., & Shukla, V. (2023). Biological fluids as diagnostic tools in oncology. *Biomedical Research & Therapy*, 10(6), 2208–2220.

[14] Fatima, S., & Pathak, R. (2024). Microfluidic biosensors in reproductive health diagnostics. *Analytical & Bioanalytical Chemistry*, 416(4), 765–779.

[15] Garg, R., et al. (2022). ELISA-based detection methods for cancer biomarkers: A review. *Analytical Biochemistry*, 650, 114745.

[16] Gupta, S., & Yadav, R. (2021). Diagnostic challenges in female genital tuberculosis: A clinical review. *International Journal of Infectious Diseases*, 105, 345–352.

[17] Haque, M. E., et al. (2020). Saliva-based hormone profiling in reproductive disorders. *Journal of Endocrinology*, 245(3), 253–262.

[18] Hassan, S., & Ahmed, A. (2022). Urine-based biomarkers for tuberculosis detection. *BMC Infectious Diseases*, 22, 738.

[19] Heidari, M., & Rahman, H. (2023). Nanotechnology-enabled diagnostic tools for early cancer detection. *Journal of Nanobiotechnology*, 21(1), 66.

[20] Jain, R., et al. (2021). Clinical utility of circulating tumor cells (CTCs) in cancer diagnostics. *Cancer Letters*, 522, 33–45.

[21] Kaur, S., & Singh, P. (2022). Diagnostic relevance of androgen levels in PCOS. *Journal of Clinical Endocrinology & Metabolism*, 107(3), 555–568.

[22] Khan, M., et al. (2023). HER2 detection in serum for cancer management: Advances and challenges. *Molecular Diagnosis & Therapy*, 27, 455–470.

[23] Kim, J., & Park, H. (2024). AI-assisted biomarker identification for oncology diagnostics. *Nature Biomedical Engineering*, 8(2), 122–138.

[24] Kumar, A., & Maheshwari, V. (2020). Role of menstrual blood diagnostics in TB and endometrial disorders. *Clinical Microbiology Reviews*, 33(4), e00012-20.

[25] Li, F., et al. (2021). Nanomaterial-based biosensors for rapid biomarker detection. *Sensors and Actuators B: Chemical*, 331, 129422.

[26] Mittal, A., & Sharma, P. (2022). Point-of-care diagnostic kits for reproductive disorders. *Diagnostics*, 12(10), 2356.

[27] Nanda, R., & Kalyani, H. (2020). AMH and LH/FSH ratio as diagnostic markers for PCOS. *Gynecological Endocrinology*, 36(7), 592–598.

[28] Patel, N., et al. (2024). CRISPR-based diagnostics for rapid detection of infectious diseases. *Trends in Biotechnology*, 42(1), 34–46.

[29] Roy, S., & Dey, K. (2021). Molecular diagnostic tools for tuberculosis. *Expert Review of Molecular Diagnostics*, 21(5), 427–441.

[30] Singh, R., & Pandey, P. (2023). Tumor markers in gynecologic cancers: An updated review. *Gynecologic Oncology Reports*, 47, 101064.

[31] Sinha, A., et al. (2022). High-sensitivity biosensors for CA-125 detection. *Analytical Chemistry*, 94(3), 1448–1460.

[32] Thomas, P., & Radhakrishnan, R. (2021). Menstrual blood as a non-invasive diagnostic fluid: Opportunities and challenges. *Bioanalysis*, 13(18), 1455–1470.

[33] Tripathi, S., et al. (2024). Multi-omics integration for cancer diagnostics. *Frontiers in Molecular Biosciences*, 11, 1287654.

[34] WHO. (2024). Global cancer statistics report. *World Health Organization*.

[35] Zhang, X., et al. (2020). Circulating tumor DNA as a biomarker in cancer diagnosis. *Nature Reviews Clinical Oncology*, 17(6), 338–351.

[36] Gubala, V., Harris, L. F., Ricco, A. J., Tan, M. X., & Williams, D. E. (2012). Point of care diagnostics: status and future. *Analytical chemistry*, *84*(2), 487-515.

[37] Kurtzman, G. (2005). A business model for diagnostic startups-a business model for a new generation of diagnostics companies. *Biotechnology Healthcare*, *2*(5), 50.

[38] St John, A., & Price, C. P. (2013). Economic evidence and point-of-care testing. *The Clinical Biochemist Reviews*, *34*(2), 61.

[39] Barjis, J., Kolfschoten, G., & Maritz, J. (2013). A sustainable and affordable support system for rural healthcare delivery. *Decision Support Systems*, *56*, 223-233.

[40] Przybylski, M., Millert-Kalińska, S., de Mezer, M., Krzyżaniak, M., Kurzawa, P., Żurawski, J., ... & Pruski, D. (2024). Evaluation of automatic signal detection of in situ hybridization for detecting HPV DNA in cervical tissue derived from patients with cervical intraepithelial neoplasia. *Cancers*, *16*(20), 3485.

[41] Almeida, F. R., Costermans, N. G., Soede, N. M., Bunschoten, A., Keijer, J., Kemp, B., & Teerds, K. J. (2018). Presence of anti-Müllerian hormone (AMH) during follicular development in the porcine ovary. *PLoS One*, *13*(7), e0197894.

[42] Che, Y., Ren, F., Zhang, X., Cui, L., Wu, H., & Zhao, Z. (2023). Immunohistochemical HER2 recognition and analysis of breast cancer based on deep learning. *Diagnostics*, *13*(2), 263.