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Review Article

Diagnostic Biomarkers in Cervical, Breast, and Prostate Cancers: A Review

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Abstract

Laboratory-based biomarkers are becoming more and more important in the diagnosis of cancer, supporting therapy selection, risk assessment, and early detection. Prostate, breast, and cervical cancers account for a significant amount of cancer-related morbidity and mortality worldwide, especially in Africa, where access to sophisticated testing and delayed diagnosis continue to be significant obstacles. With a focus on their applicability to laboratory medicine practice, this narrative review investigates both established and developing diagnostic biomarkers for these three cancers. Emerging liquid biopsy techniques like circulating tumor DNA (ctDNA), exosomal RNA, and circulating microRNAs are reviewed alongside validated tissue and molecular biomarkers, such as high-risk human papillomavirus (HPV) testing and p16/Ki-67 dual immunostaining for cervical cancer; oestrogen receptor (ER), progesterone receptor (PR), HER2, and multigene assays for breast cancer; and prostate-specific antigen (PSA) and urine-based molecular tests for prostate cancer. Important operational, analytical, and equity-related issues that impact implementation in environments with limited resources are highlighted. The research emphasizes how crucial diagnostic labs are to converting biomarker advancements into clinically and publicly significant cancer control plans throughout Africa.

Keywords: Diagnostic biomarkers; cervical cancer; breast cancer; prostate cancer; laboratory medicine; liquid biopsy; HPV; ER/PR; HER2; PSA

Introduction

Prostate, breast, and cervical cancers are the main causes of cancer-related death in Africa and are among the most frequently diagnosed cancers globally. Even while early detection and efficient screening have greatly decreased mortality in high-income settings, many African nations still struggle with late presentation, inadequate diagnostic capabilities, and unequal access to necessary laboratory services [1-4].

Modern oncological practice relies heavily on diagnostic biomarkers for screening, diagnosis, prognostication, and therapeutic decision-making. These biomarkers include assays based on nucleic acids, multigene expression profiles, protein-based immunohistochemistry markers, and circulating tumor-derived analytes that can be found in blood or urine. It is crucial for laboratory professionals to comprehend the clinical value, performance characteristics, and implementation needs of these biomarkers [5-8].

This review summarizes the most recent research on diagnostic biomarkers for prostate, breast, and cervical cancers, with an emphasis on analytical validity, laboratory workflows, and applicability in African health systems.

Table 1: Summary of Established and Emerging Biomarkers by Cancer Type

Cancer	Established Biomarkers	Emerging Liquid Biopsy Biomarkers	Clinical Use	Limitations / Africa Context
Cervical	HPV DNA/mRNA, p16^INK4a/Ki 67	cfHPV DNA, circulating miRNAs	Screening, triage, recurrence monitoring	Limited follow-up systems; cost and lab infrastructure barriers
Breast	ER/PR, HER2	ctDNA, CTCs, exosomes	Subtyping, treatment selection, therapy monitoring	Limited access to molecular assays; liquid biopsy still research-stage
Prostate	PSA (total, velocity)	PCA3, ctDNA, CTCs	Screening, biopsy decision, prognosis	Low specificity of PSA; advanced molecular tests scarce in many regions

A comparative table with rows for each cancer (cervical, breast, prostate) and columns for biomarker categories.
(Adapted from the web)

Methods

Diagnostic biomarkers pertinent to laboratory medicine in prostate, breast, and cervical malignancies were the subject of a narrative literature review. In addition to important oncology and pathology publications, worldwide recommendations, and current systematic reviews published up to 2025, electronic searches were conducted using PubMed and PubMed Central. Combinations of "diagnostic biomarkers," "molecular testing," "immunohistochemistry," "liquid biopsy," and "cancer type" were among the search phrases. Guidelines-endorsed biomarkers, research with obvious laboratory implications, and literature on implementation in low- and middle-income settings were prioritized.

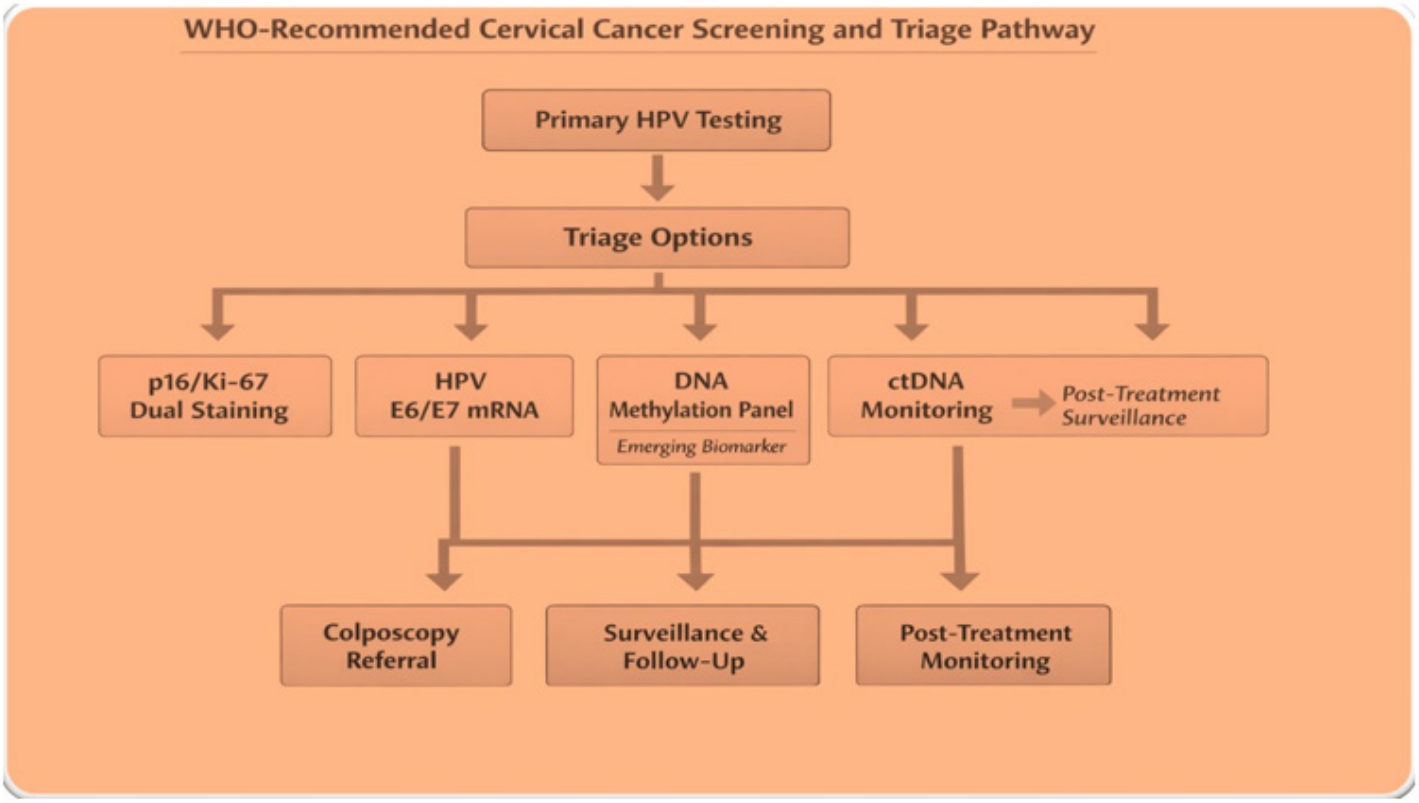
Cervical Cancer

Established laboratory biomarkers

The World Health Organization (WHO) recommends high-risk HPV testing as the preferred main screening approach, and it is the cornerstone of modern cervical cancer screening. Cervical intraepithelial neoplasia grade 2 or worse (CIN2+) can be detected with great sensitivity using combined HPV DNA and mRNA assays, which surpass cytology alone. Longer screening intervals are made possible by primary HPV testing, which is compatible with high-throughput laboratory operations [9-12].

Dual immunostaining with p16^INK4a^/Ki-67 has become an established triage strategy for HPV-positive women, improving specificity for clinically significant cervical lesions by identifying HPV-induced cell cycle deregulation and active proliferation.13-15 This approach significantly reduces unnecessary colposcopy referrals, an important advantage in resource-limited health systems.16,17 HPV E6/E7 mRNA assays, by detecting transcriptionally active infections, offer higher specificity than HPV DNA testing and are increasingly incorporated into laboratory-based triage algorithms [19-20].

Cervical Cancer Screening and Triage Algorithm Flowchart (Adapted from the internet)



Emerging biomarkers

The detection of circulating HPV DNA through liquid biopsy methods such as droplet digital PCR is being investigated as a tool for post-treatment surveillance and disease monitoring in invasive cervical cancer [21,22]. Furthermore, DNA methylation panels targeting viral and host gene sequences have shown potential as laboratory-based triage tools for diagnosing CIN2+ lesions [23–25]. Although many of these assays are still largely in the research stage, they may eventually serve as scalable alternatives to traditional cytology [26].

Conventional tumor markers, including squamous cell carcinoma antigen, are mostly utilized for disease surveillance and have limited diagnostic usefulness. Despite being outside of standard screening paradigms, immune biomarkers, such as PD-L1 expression, are becoming more and more important for directing treatment in advanced disease [27-32].

Laboratory implementation considerations

In many African laboratories, issues with reagent availability, infrastructure limitations, quality assurance, and follow-up systems still exist despite the compelling evidence in favor of HPV-based screening [33-35]. Careful laboratory and public health coordination is necessary for the selection of suitable triage techniques and integration with immunization programs [36,37].

Breast Cancer

Core tissue biomarkers

The primary biomarkers for classifying breast cancer and choosing a course of treatment are still the estrogen receptor (ER), progesterone receptor (PR), and HER2. Decisions about endocrine therapy and HER2-targeted medications are made using immunohistochemistry (IHC) for ER/PR and IHC/ISH for HER2 [38]. In certain situations, chemotherapy decisions may be influenced by the Ki-67 proliferation index, which also provides information on prognosis [38]. Standardized testing and reporting are advised by guidelines [38,39].

Genomic assays and multigene signatures

In ER-positive, HER2-negative early breast cancer, Oncotype DX, MammaPrint, Prosigna, EndoPredict, and other tools offer prognostic data and can forecast the value of adjuvant chemotherapy [38,39], these tools are increasingly used in guideline-directed decision-making. To prevent overtreatment, ASCO guidelines encourage the selective use of these assays [39].

Liquid biopsy and circulating markers

For early detection, monitoring of minimal residual disease (MRD), and identification of actionable mutations (e.g., PIK3CA, ESR1) in metastatic illness, circulating tumor DNA (ctDNA) and circulating tumor cells (CTCs) are being intensively studied 40. In multi-cancer early detection investigations, ctDNA methylation panels have demonstrated a high sensitivity for cancer detection; they are currently being evaluated specifically for MRD detection and breast cancer screening 41. The metastatic scenario is where clinical adoption of response monitoring and mutation testing is expanding the fastest [40,41].

Clinical application and limitations

Standardized Ki-67 scoring, interpretation of HER2-low status, analytic sensitivity of ctDNA for early disease, and cost/access difficulties for multigene tests continue to be challenges despite the validation and endorsement of ER/PR/HER2 testing and genomic assays [38,39,42]. An ongoing research objective is the incorporation of liquid biomarkers into routine early detection [40-42].

Prostate Cancer
PSA and derivatives

The most popular biomarker for identifying and tracking prostate cancer remains prostate specific antigen (PSA). PSA testing in many screening programs has contributed to earlier detection and lower prostate cancer mortality; however, it has well established limitations, including low specificity, risk of overdiagnosis, and risks related to biopsy procedures. PSA derivatives such as PSA velocity, PSA density, and percentage of free/total PSA, along with multivariable risk calculators, offer modest improvements in discriminatory performance compared with PSA alone [42].

Urine and tissue molecular tests

Urinary molecular tests, including urinary mRNA panels such as MyProstateScore (MiPS), SelectMDx, and ExoDx Prostate Intelliscore, use combinations of biomarkers (e.g., TMPRSS2 ERG fusion transcripts and PCA3) to improve specificity for clinically significant disease and help guide decisions about repeat biopsies. Tissue based genetic assay panels such as Prolaris, Decipher, and Oncotype DX Prostate provide prognostic information that informs treatment decision making between definitive therapy and active surveillance [42-45].

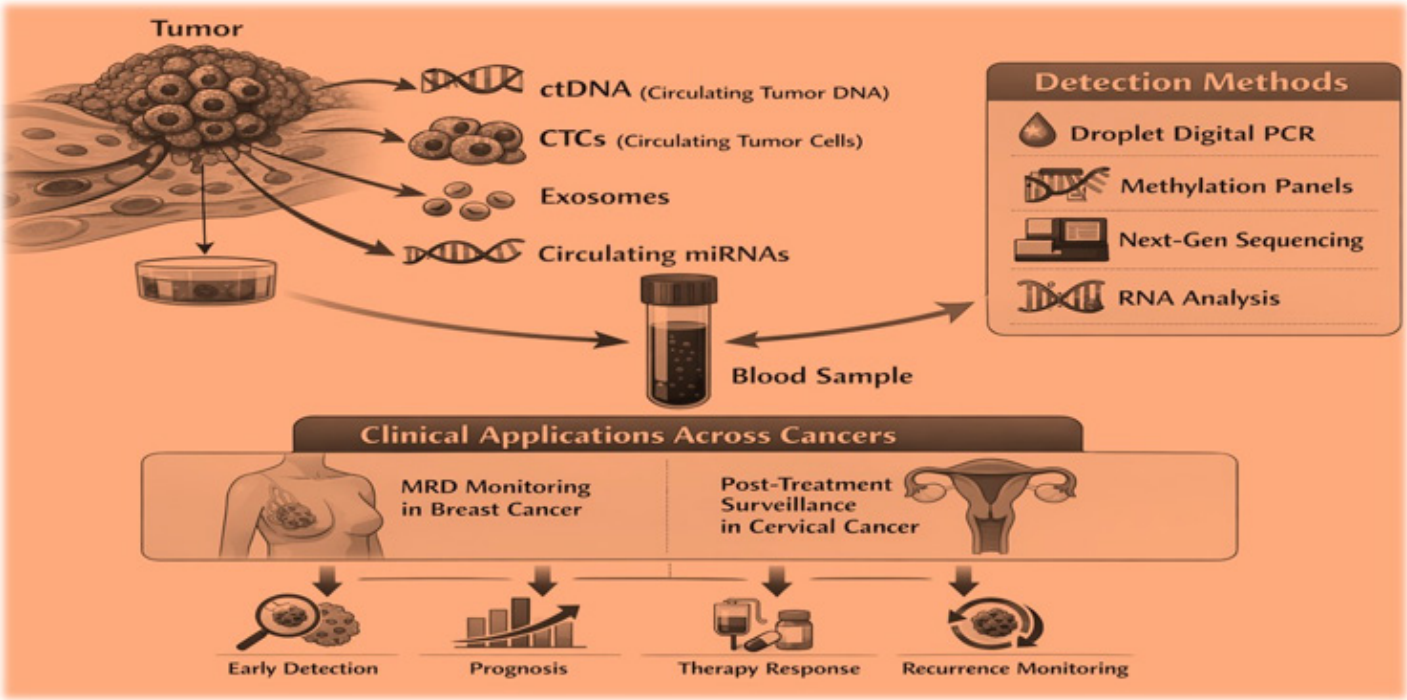
Composite and commercial risk scores

Serum based composite scores such as the Prostate Health Index (PHI) and the 4Kscore combine PSA and kallikrein markers (including total PSA, free PSA, intact PSA, and human kallikrein 2) to stratify risk and reduce unnecessary biopsies by improving differentiation between benign disease and clinically significant prostate cancer. These tests have been validated in multiple cohorts and are increasingly available in clinical practice [42-44].

Liquid biopsy and emerging biomarkers

Liquid biopsy techniques, including analysis of circulating tumor DNA (ctDNA) methylation, extracellular vesicle RNA, and microRNA (miRNA) signatures in urine and blood, are emerging as noninvasive methods to detect clinically important disease and monitor disease course. While promising, many candidates remain under clinical validation, and integration of.

Components of Liquid Biopsy Techniques



- A schematic diagram illustrating key elements (e.g., ctDNA, CTCs, exosomes, circulating miRNAs) with icons or labeled arrows showing their origins from tumors, detection methods (e.g., droplet digital PCR, methylation panels), and applications across cancers (e.g., MRD monitoring in breast, post-treatment surveillance in cervical).

Analytical and clinical validity

The analytical variability of assays (preanalytic variables, assay platforms, thresholds) is a major obstacle to translation [50]. Cost-effectiveness evaluations, prospective clinical validation, and thorough analytical validation are necessary for high-impact adoption [51,52]. There is an urgent need for harmonized reporting, assay performance measures, and standardized sample management [52].

Equity, access, and guideline alignment

The availability of high-value biomarkers (HPV testing, ER/PR/HER2, PSA) varies by area [53]. In order to lessen global inequities, WHO guidelines recommend scalable cervical screening programs (HPV primary testing when possible, alternatives where necessary) [54]. The equitable application of modern biomarkers and genetic testing is influenced by factors such as cost, laboratory infrastructure, and physician training [55].

Future Directions and Research Priorities

1. Extensive prospective cohort studies to verify multi-analyte liquid tests and ctDNA methylation for early detection and MRD in these malignancies.
2. Standardization programs (international consortia) for test preanalytics and reporting
3. Research on the cost-effectiveness and execution of HPV testing scale-up and p16/Ki-67 triage techniques in low- and middle-income countries.
4. Combining AI with multi-omics (genomics, methylomics, proteomics) to increase diagnostic precision while maintaining clinical interpretability and regulatory supervision.

Conclusions

Prostate, breast, and cervical cancer detection and treatment have been revolutionized by diagnostic biomarkers. Current clinical practice and guidelines are supported by established tissue and molecular indicators (HPV testing and p16/Ki-67 for cervical cancer; ER/PR/HER2 and multigene assays for breast cancer; PSA and composite urine/blood panels for prostate cancer). The quick development of liquid biopsy technologies, especially ctDNA and methylation panels, has great potential for early detection and customized monitoring; however, before widespread routine adoption, issues with analytic standardization, prospective validation, cost-effectiveness, and equitable access must be resolved. To turn promising biomarkers into population benefits, more cooperative research and practical implementation studies will be necessary.

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