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Aptasensors and External Quality Management for Cardiovascular Disease: Opportunities and Challenges

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ABSTRACT

Keywords: Cardiovascular Disease (CVD); Acute Myocardial Infarction (AMI); Heart Failure; Atherosclerotic Cardiovascular Disorders; Aptasensors

Abbreviations: CVD: Cardiovascular Disease; AMI: Acute Myocardial Infarction; EQM: External Quality Management; SELEX: Systematic Evolution of Ligands by Exponential Enrichment; CTNI: Cardiac Troponin I; CTNT: Cardiac Troponin T; BNP: B-Type Natriuretic Peptide; NT-proBNP: NTerminal Pro-B-Type Natriuretic Peptide; CRP: C-Reactive Protein; CK-MB: Creatine Kinase-Mb; POC: Point-of-Care; EQA: External Quality Assessment

Introduction

Cardiovascular disease (CVD) remains the leading cause of morbidity and mortality worldwide, accounting for millions of deaths annually. Early diagnosis and accurate monitoring of cardiovascular biomarkers are essential for improving patient outcomes, particularly in acute myocardial infarction (AMI), heart failure, and atherosclerotic cardiovascular disorders. Conventional laboratory methods, including immunoassays and chemiluminescent platforms, have significantly improved cardiovascular diagnostics; however, they often require centralized laboratory infrastructure, trained personnel, and relatively long turnaround times. Recent advances in biosensor technologies, particularly aptamer-based biosensors (aptasensors), offer promising alternatives for rapid, sensitive, and point-of-care detection of cardiovascular biomarkers. Simultaneously, the integration of these novel technologies into clinical practice necessitates robust external quality management (EQM) frameworks to ensure analytical reliability, comparability, and clinical validity.

Aptasensors: Principles and Advantages

Aptamers are short single-stranded DNA or RNA oligonucleotides selected through the Systematic Evolution of Ligands by EXponential enrichment (SELEX) process. These molecules exhibit high affinity and specificity toward target analytes, including proteins, peptides, small molecules, and cells. When incorporated into sensing platforms, aptamers serve as recognition elements analogous to antibodies, creating devices known as aptasensors [1]. Compared with conventional antibody-based immunosensors, aptasensors offer several advantages. Aptamers demonstrate superior thermal stability, resistance to denaturation, ease of chemical modification, lower production costs, and batch-to-batch consistency. Furthermore, aptamers can be synthesized chemically without requiring biological systems, reducing variability associated with antibody production. These characteristics make aptasensors particularly attractive for point-of-care diagnostics and resource-limited settings [1,2]. Electrochemical aptasensors have emerged as the most extensively

investigated platform for cardiovascular biomarker detection. Their compatibility with miniaturized devices, low power requirements, and rapid signal generation facilitate the development of portable diagnostic systems capable of near-patient testing. Recent innovations involving nanomaterials, microfluidics, and signal amplification strategies have further enhanced analytical performance [2].

Cardiovascular Biomarkers Targeted by Aptasensors

Cardiac troponins remain the gold-standard biomarkers for diagnosing myocardial infarction. Numerous studies have demonstrated highly sensitive aptasensors capable of detecting cardiac troponin I (cTnI) and cardiac troponin T (cTnT) at femtomolar and even attomolar concentrations. Such sensitivity may facilitate earlier diagnosis than conventional laboratory assays and potentially improve emergency department triage [2,3]. In addition to troponins, aptasensors have been developed for detecting other clinically relevant cardiovascular biomarkers, including:

- B-type natriuretic peptide (BNP)
- N-terminal pro-B-type natriuretic peptide (NT-proBNP)
- C-reactive protein (CRP)
- Myoglobin
- Creatine kinase-MB (CK-MB)
- D-dimer

Interleukins and inflammatory mediators associated with vascular disease These biomarkers support diagnosis, prognosis, and therapeutic monitoring in heart failure, acute coronary syndromes, and inflammatory cardiovascular conditions. Recent multiplexed aptasensor platforms have demonstrated the simultaneous measurement of several biomarkers within a single assay, offering comprehensive cardiovascular risk assessment.

Point-of-Care Testing and Clinical Potential

The emergence of point-of-care (POC) diagnostics represents one of the most important applications of aptasensor technology. Traditional laboratory testing frequently involves sample transportation and centralized processing, leading to delays in clinical decision-making. Aptasensors can provide rapid results directly at the bedside, in ambulances, emergency departments, outpatient clinics, and even home-care environments [3]. The clinical significance of rapid cardiovascular biomarker testing is particularly evident in acute myocardial infarction. Early detection of troponin elevations enables prompt initiation of reperfusion therapy and risk stratification. Recent reviews have highlighted the potential of portable aptasensor systems to shorten diagnostic timelines while maintaining high analytical sensitivity and specificity. Moreover, integration with smartphone-based platforms, wireless communication systems, and cloud-based health infrastructures may facilitate remote monitoring of patients with chronic cardiovascular diseases. Such approaches align with the growing emphasis on personalized medicine and digital healthcare ecosystems.

The Need for External Quality Management

Despite remarkable technological progress, widespread clinical adoption of aptasensors requires rigorous quality assurance mechanisms. External quality management encompasses all activities designed to evaluate and improve the performance of diagnostic assays beyond the individual laboratory. These activities include external quality assessment (EQA), proficiency testing, interlaboratory comparisons, standardization programs, and post-market surveillance [3]. Historically, conventional laboratory assays for cardiac biomarkers have benefited from extensive quality management frameworks developed by international organizations and professional societies. Such frameworks ensure that test results generated across different laboratories remain comparable and clinically meaningful. Novel aptasensor platforms must achieve similar levels of standardization before they can be routinely incorporated into diagnostic pathways. Several analytical variables may influence aptasensor performance, including aptamer sequence integrity, immobilization chemistry, electrode fabrication, nanomaterial characteristics, signal transduction mechanisms, environmental conditions, and sample matrix effects. Without adequate quality control procedures, these factors may introduce significant analytical variability.

External Quality Assessment for Aptasensor-Based Testing

External quality assessment programs involve the distribution of standardized specimens to participating laboratories, followed by comparison of reported results against consensus or reference values. EQA schemes have played a central role in improving the quality of cardiac troponin and natriuretic peptide measurements worldwide [3,4]. For aptasensor-based cardiovascular testing, EQA implementation presents unique challenges. First, there are currently limited certified reference materials specifically designed for aptamer-based detection systems. Second, the diversity of sensing platforms—including electrochemical, optical, fluorescence, colorimetric, and microfluidic approaches—complicates direct method comparison. Third, many aptasensors remain in the developmental or early commercialization stages, limiting opportunities for large-scale proficiency testing [4]. To address these issues, future EQA programs should incorporate matrix-appropriate cardiovascular biomarker specimens, commutable reference materials, and performance criteria linked to clinical decision limits. International collaboration among academic institutions, diagnostic manufacturers, regulatory agencies, and professional organizations will be essential for establishing harmonized evaluation protocols.

Standardization and Regulatory Considerations

Analytical standardization remains a major challenge in cardiovascular diagnostics. Even among established laboratory assays, differences in calibration, antibody specificity, and assay design may generate clinically significant discrepancies. Similar concerns apply to aptasensors [5]. Regulatory agencies increasingly emphasize analytical validation parameters such as sensitivity, specificity, accuracy, precision, reproducibility, robustness, and clinical utility. For aptasensor technologies, standardized validation frameworks should include:

1. Limit of detection and quantification.
2. Inter- and intra-assay precision.
3. Matrix interference studies.
4. Stability testing.
5. Lot-to-lot reproducibility.
6. Cross-reactivity assessment.
7. Clinical concordance with reference laboratory methods.

The development of internationally recognized reference measurement procedures and certified reference materials for cardiovascular biomarkers will facilitate harmonization among different aptasensor platforms.

Future Perspectives

The future of cardiovascular diagnostics is likely to involve increasingly decentralized testing strategies supported by advanced biosensor technologies. Aptasensors are well positioned to contribute to this transformation due to their sensitivity, specificity, scalability, and compatibility with portable diagnostic devices. Emerging trends include multiplexed biomarker detection, wearable biosensors, artificial intelligence-assisted signal interpretation, and integration with telemedicine platforms [6]. However, technological innovation alone is insufficient. Sustainable clinical implementation requires comprehensive quality management systems capable of ensuring analytical reliability and patient safety. Future research should prioritize multicenter validation studies, development of certified reference materials, establishment of external quality assessment programs, and harmonization of regulatory standards. These efforts will help bridge the gap between laboratory innovation and routine clinical application [7].

Conclusion

Aptasensors represent one of the most promising innovations in cardiovascular biomarker detection, offering exceptional sensitivity, rapid analysis, portability, and potential for point-of-care deployment. Advances in electrochemical sensing, nanotechnology, and multiplexed platforms have significantly expanded their diagnostic capabilities for biomarkers such as cardiac troponins, natriuretic peptides, CRP, and CK-MB. Nevertheless, the successful translation of aptasensor technologies into routine clinical practice depends on the establishment of rigorous external quality management systems. External quality assessment, assay standardization, reference material development, and regulatory harmonization will be crucial for ensuring reliable and clinically actionable results. As these challenges are addressed, aptasensors may become integral components of future cardiovascular diagnostic pathways, supporting earlier diagnosis, personalized treatment, and improved patient outcomes [8].

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