OPINION

Serum Oncoprotein Detection Challenges: Implications for Breast Cancer Diagnosis

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Breast cancer is a common disease that has a better prognosis when detected early. Current screening and monitoring technologies have increased survival rates, but their limits have prompted researchers to look into biomarker assessment to better early diagnosis and therapy monitoring. The enzyme-linked immunosorbent assay (ELISA) is a specific and robust technique for measuring protein biomarkers in blood or its components. To maintain the clinical relevance of this assay format, various technological obstacles must be overcome, such as the ultrasensitive detection of trace biomarkers and the avoidance of possible assay interference owing to the increasing usage of monoclonal antibody (mAb) therapies. There have been several approaches to improving the sensitivity of ELISA, including using more sensitive substrates, integrating ELISA with polymerase chain reaction (PCR), and adding nanoparticles as shuttles for detecting antibodies and enzymes. These changes have led in significant improvements in the detection of extremely low amounts of protein biomarkers, with some systems successfully detecting antigen at sub-femtomolar quantities. The widespread use of mAb treatments in cancer has created a new modern challenge for ELISA, especially when both therapeutic and test antibodies target the same protein antigen. To address difficulties such as epitope overlap and steric hindrance, diagnostic antibodies must be designed rationally, using contemporary antibody production pipelines, epitope binning techniques, and computational tools to selectively target biomarker epitopes. This study examines the technological techniques in ELISA that have been adopted to far, as well as their viability in addressing existing sensitivity restrictions and interference issues in the clinical situation. The impact of these recent advances will be determined by their transformation from research laboratory protocols into simple, dependable detection systems that can ideally be replicated in point-of-care devices to maximise utilisation and transform both the diagnostic and therapeutic monitoring landscapes.

Breast cancer is the second most common kind of cancer in women, after only skin cancers. According to the American Cancer Society, 268,000 women were diagnosed with invasive breast cancer in the United States in 2019, with 3.8 million survivors having previously been diagnosed. While prognoses differ amongst breast cancer subtypes, it is generally documented that early detection improves patient outcomes substantially. Current 5-year survival rates for localised and regional breast cancer are 99 percent and 86 percent, respectively, at the time of diagnosis, but decrease dramatically to 28 percent when a patient is found late-stage with distant metastases. Screening approaches such as mammography and ultrasonography have improved early identification of breast cancer, but their limitations have prompted research to find biomarkers that might be used for early-stage diagnosis as well as therapy efficacy evaluation. Measuring essential molecular properties of biofluids, notably blood and its components, is the most preferred way for diagnosing and monitoring therapy success. An enzyme-linked immunosorbent assay (ELISA) immunoassay of protein biomarkers in biological samples is excellent for this purpose. ELISA is a highly specific, minimally intrusive, and cost-effective tool for determining a patient's pathological and biological condition. The gold standard immunoassay for quantifying proteins in biofluid has long been ELISA, and the ever-expanding list of clinically relevant biomarkers for disease diagnosis and treatment management drives the need for next-generation assays that are specific and sensitive enough to quantify trace amounts of protein. While ELISA is a selective, sensitive, and dependable test approach, it has faced major technological obstacles in its current clinical use.

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Many variants of the conventional ELISA have been created, considerably improving the assay's sensitivity while maintaining clinical relevance. Because protein targets, unlike nucleic acids, cannot be amplified to strengthen their signal, alternative signal-based amplification procedures have been devised to improve ELISA sensitivity. Using more sensitive nanoparticle-based substrates, integrating ELISA with polymerase chain reaction (PCR), and using nanoparticles as shuttles for detecting antibodies and enzymes are some approaches. These changes have led in significant improvements in the detection of extremely low amounts of protein biomarkers, with some systems successfully detecting antigen at sub-femtomolar quantities.

ELISA has been widely utilised in both clinical and scientific applications to assay for proteins of interest, and enhancements to the standard ELISA platform will be required to retain clinical relevance. The sensitivity of immunoassays is essentially determined by the properties of the assay antibodies, and new techniques for producing epitope-targeted antibodies and their constituent fragments give a path to developing very sensitive tests devoid of any interfering components. Furthermore, when new disease-related biomarkers are identified to be clinically meaningful in the sub-Nanomolar range, ultrasensitive amplification approaches like the ones discussed here will be required.

Amplification procedures should ideally be simple and adaptable to point-of-care (POC) devices such as lateral-flow assays (LFA) or microfluidics platforms. Indeed, gold plasmonics and magnetic nanoparticles are already used in commercial LFA devices as steady and sensitive ways of signal amplification. 157 These gadgets have the potential to be especially revolutionary in underserved parts of the globe, where the World Health Organization estimates that only 35% of low-income nations have access to pathology services for diagnosis. 158 Targeted therapies for breast cancer is based on biomarker analysis, which is generally conducted on tumour specimens by pathologists. Qualification for targeted mAb treatments trastuzumab and pertuzumab, for example, is based on HER2 overexpression shown by IHC or fluorescent in situ hybridization (FISH), assays that are frequently unavailable in resource-constrained settings. While tissue HER2 analysis is the gold standard for diagnosing HER2-positive breast cancer, soluble HER2 ECD quantification could effectively bring underserved patients off the sidelines by diagnosing those with an elevated serum HER2 ECD level at the time of presentation and providing access to targeted therapies with proven outcome benefits.