



Enzyme Immunoassays: From Concept to Product Development

S.S. Deshpande

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Since the classical work of Rosalyn Yalow and Solomon Berson on the radioimmunoassay of insulin in the late 1950s, which so brilliantly opened new domains in the diagnostics sector, immunoassays have been well received as a diagnostic and research tool in several disciplines of life sciences. The economics, rapidity, sensitivity, specificity, and the easy-to-use approach of immunodiagnostic tests are widely recognized, and have had a tremendous impact on clinical, agricultural, food, veterinary, and environmental diagnostics. At present, in the clinical diagnostic sector alone, immunoassay products command an annual worldwide market value in excess of U. S. \$10 billion, which is expanding by about 10% per annum. The recent trend toward increasing demand for automation of immunoassays and stable reagents clearly shows a definitive shift to nonisotopic immunoassay systems on a large scale. Historically, enzyme immunoassays have been in a prime position for in-house applications, primarily because of the easy access to inexpensive measuring equipment as well as to a vast body of literature on labeling techniques and applications. The recent popularity with the general public of several over-the-counter immunoassay products based on this technology, such as glucose level kits for diabetics, cholesterol screening tests, and pregnancy detection test kits, is quite evident.

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