



Genomic Biomarkers for Pharmaceutical Development: Chapter 5. microRNA Biomarkers as Potential Diagnostic Markers for Cancer (Japan Annual Reviews in Electronics, Computers and Telecommunications)

Elizabeth Mambo, Anna E. Szafranska-Schwarzbach, Gary Latham, Alex Adai, Annette Schlageter, Bernard Andruss

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The focus of this chapter is on the development of miRNA diagnostics and the process for miRNA biomarker development. We discuss pancreatic cancer as a model for the application of miRNA-based tests in different clinical biopsy specimen types. Asuragen's miRInform® Pancreas test illustrates the development of a laboratory developed test (LDT) that was validated in compliance with Clinical Laboratory Improvement Amendments (CLIA) and College of American Pathologists (CAP) regulations. We provide an overview of work on miRNA-based signatures which is focused on resolving clinical dilemmas in solid and cystic pancreatic lesions. We also review some of the promising miRNA candidates identified in biofluids from other cancer types. These studies highlight the emergence of miRNA-based diagnostic tools which have the potential to impact the clinical management of cancer by guiding early diagnosis, aiding in the assessment of patients' prognosis, and enabling the identification of novel, more effective therapeutic targets.

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