

CYTOPATHOLOGY – THE LEADING EDGE TO THERANOSTICS AND PERSONALIZED MEDICINE

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The objective of the study is to describe the companion diagnostics that are necessary to differentiate specific cancers; describe the therapeutic modalities or personalized drugs that are coupled with the companion diagnostic; Understand the relationship between cytopathologic diagnosis of cancer from multiple organ sites and its relationship to theranostics; describe the FDA approved drugs that are used to treat leukemias and lymphomas, carcinomas and sarcomas and also to describe the tumor suppressor genes and their subsequent mutations that are associated with triaging patients with specific personalized therapies. The field of cytopathology has evolved from basic Pap staining of tumors followed by H&E tissue diagnosis of disease to the use of immunocytochemistry and complementary ancillary molecular diagnostics to aid in specifying the disease. However, due to the sequencing of the human genome and the subsequent genomic revolution, the field of theranostics has evolved. Theranostics is the coupling of companion diagnostic tools (in

particular, molecular profiling) with specific therapeutic drugs. This personalized approach to diagnosis allows the clinician to provide therapy based on specific genetic mutations of the tumors from their patients. The FDA has dramatically increased the number of cleared/approved *in vitro* assays for patients with genetic mutations that respond to drugs that prevent the expression of the mutations, such as tyrosine kinase inhibitors. These alternative forms of therapy have dramatically increased the survival rate in patients with stage four and metastatic cancer. It is imperative that pathologists and laboratory professionals determine which companion diagnostic assay should be chosen and recommend the clinically actionable drugs tailored to their genetic mutation to the clinician. This change in the scope of practice creates unprecedented opportunities to more accurately diagnose patients and guide the selection of personalized therapies.

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