Abstract

Circulating tumor cells (CTCs) are rare cancer cells that can be detected in the blood of patients with solid malignancies. The Veridex CellSearch Assay was analytically and clinically validated, and has received U.S. Food and Drug Administration (FDA) clearance for the enumeration of CTCs in breast, colorectal, and prostate cancer. A number of alternative assays, with potential advantages, are currently undergoing clinical and/or analytic validation before their routine use can be established. In prostate cancer, high pretreatment CTC counts have been associated with worse survival, and changes in CTC counts in response to treatment have been established as indicators of response to treatment. Additional analyses are ongoing to establish the value of CTC counts as a surrogate of survival in prospective, phase III trials, which could influence the process of drug development and regulatory approval.

Additionally, CTCs have a potential role in the molecular characterization of prostate cancer, serving as "liquid biopsies" to determine the molecular characteristics of the disease. The study of androgen receptor (AR) mutations or amplification, chromosomal rearrangements, or the determination of DNA repair biomarkers has been evaluated in clinical trials. CTCs have a wide range of potential applications, from their prognostic use in stratification of patients in clinical trials or the assessment of response to treatment, to the pharmacodynamic evaluation of novel agents, or the discovery and use of predictive biomarkers that can aid in the development of personalized medicine.