Identification, validation, and clinical implementation of tumor-associated biomarkers to improve therapy concepts, survival, and quality of life of cancer patients: tasks of the Receptor and Biomarker Group of the European Organization for Research and Treatment of Cancer (RBG-EORTC) advises on methodologies, test kits and test reagents utilized for tumor biomarker determination. Tumor-associated biomarkers are important and clinically useful tools which can aid the early diagnosis of cancer, determine prognosis, predict therapy response, and monitor disease. With regard to clinical use of tumor-associated biomarkers, quality assessment and quality assurance programs of the RBG-EORTC are crucially important issues. Test reagents, assays, and procedures for tumor sample collection and handling should be standardized. Furthermore, standard operating procedures (SOPs) should be developed for each type of tumor specimen. Assay formats and the quality of the tumor biomarker assay results have to be monitored by continuous within- and inter-laboratory proficiency testing. With this approach, a major step forward in the knowledge and
understanding of the biological role and the clinical utility of tumor-associated biomarkers would be anticipated.