Pharmacogenomic Testing in Current Clinical Practice

Implementation in the Clinical Laboratory
Preface

The “personalization” of therapeutics promises to deliver a more efficacious and cost-effective approach towards treating patients with chronic diseases. For many medications, the pharmaceutical industry’s objective of “one drug fits all individuals” has proven to be incorrect. Pharmacogenomics is an emerging discipline that will be essential for implementing personalized medicine. While there have been dozens of contemporary review articles on the science and specific application of pharmacogenomics to particular drugs, this book, “Pharmacogenomic Testing in Current Clinical Practice: Implementation in the Clinical Laboratory” is the first compilation of the tests currently in routine clinical use. In this rapidly changing field, we recognize that a text of this type will be quickly outdated. Nevertheless, we have assembled chapters from the key authorities and investigators who have conducted the essential clinical trials necessary to justify pharmacogenomic testing today.

This book is designed as a reference to clinical laboratory directors who are contemplating or assigned the task of establishing a pharmacogenomics laboratory, and pharmacologists and clinicians who must interpret results of testing. Each author has given a pharmacologic background on the target drug, the need for pharmacogenomic testing, and how results can be translated into clinical decisions. Where appropriate, case studies are given to illustrate typical clinical scenarios. An extensive bibliography is cited so that the reader can refer to the original studies.

In planning for this book, we made a distinction between pharmacogenomic tests for genes that alter drug metabolism, transport, and excretion from “companion diagnostic tests” that are performed on tumor tissues. Pharmacogenomic tests are conducted to determine germ line mutations using DNA extracted from blood or buccal swabs. Companion diagnostics are conducted to determine somatic mutations using DNA and RNA from tissue biopsies. The US Food and Drug Administration’s Center for Drug Evaluation and Research have made a similar distinction. The CDER have made recommendations on the use of pharmacogenomic tests in conjunction with specific therapeutics such as warfarin or clopidogrel. For many companion tests, the FDA has coapproved a drug (e.g., trastuzumab) requiring a positive test result (Her2/neu) for its labeled
therapeutic use. We have determined that companion diagnostic tests are outside of the scope of this book.

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