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""Appendix B: Gene Expression Based Tests Developed at Duke University and Used in Clinical Trials""""Appendix C: Introduction to Biomarkers""; ""Appendix D: Reporting Guidelines""; ""Appendix E: Committee Member and Staff Biographies""; ""Appendix F: Information Gathering Sessionsand Speakers""; ""Acronyms and Abbreviations""; ""Glossary""

Sommario/riassunto

Technologies collectively called omics enable simultaneous measurement of an enormous number of biomolecules; for example, genomics investigates thousands of DNA sequences, and proteomics examines large numbers of proteins. Scientists are using these technologies to develop innovative tests to detect disease and to predict a patient's likelihood of responding to specific drugs. Following a recent case involving premature use of omics-based tests in cancer clinical trials at Duke University, the NCI requested that the IOM establish a committee to recommend ways to strengthen omics-based test development and evaluation. This report identifies best practices to enhance development, evaluation, and translation of omics-based tests while simultaneously reinforcing steps to ensure that these tests are appropriately assessed for scientific validity before they are used to guide patient treatment in clinical trials.