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Titolo	Policy issues in the development and adoption of biomarkers for molecularly targeted cancer therapies : workshop summary // Sharyl J. Nass, Jonathan Phillips, and Margie Patlak, rapporteurs ; National Cancer Policy Forum, Board on Health Care Services, Institute of Medicine of the National Academies
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Nota di bibliografia	Includes bibliographical references.
Nota di contenuto	Front Matter; Reviewers; Acknowledgments; Contents; Boxes, Figures, and Tables; Acronyms; Workshop Summary; INTRODUCTION; MOLECULAR BIOLOGY REVOLUTION IN CANCER DIAGNOSIS AND TREATMENT; Lessons Learned from Single Analyte Tests; Next-Generation Sequencing; RNA Sequencing Tests; Tests for Circulating Tumor DNA; Business Climate for Developing Diagnostic Tests; CHALLENGES IN BIOMARKER TEST DEVELOPMENT; Setting Standards; Assessing Analytical Validity, Clinical Validity, and Clinical Utility; Sharing Data; REGULATORY OVERSIGHT CHALLENGES; Evolving Regulation of Laboratory-Developed Tests Companion Diagnostics CLINICAL IMPLEMENTATION CHALLENGES; Insufficient or Inadequate Specimens; Tsunami of Information; Choosing the Best Test; Time Delays; Lack of Resources; Reporting Test Results; Incidental Findings; REIMBURSEMENT CHALLENGES; Lack of Evidence; Investigational and Off-Label Uses; Incidental Findings; Greater Expense, But Not Necessarily Greater Value; GATHERING THE

EVIDENCE: INNOVATIVE CLINICAL TRIALS; Basket Trials; Lung-MAP
Umbrella Trial; Challenges with Basket and Umbrella Trials; GATHERING
THE EVIDENCE: COVERAGE DECISIONS; Coverage with Evidence
Development
The MolDx Approach to Test ReimbursementGreen Park Collaborative
Recommendations; GATHERING THE EVIDENCE: DATABASES AND
REGISTRIES; My Cancer Genome; ClinGen; Targeted Agent and
Molecular Profiling Utilization Registry; Challenges in Using Databases;
EDUCATION AND CLINICAL DECISION SUPPORT NEEDS; Guidelines;
Treatment Pathways; RESEARCH NEEDS; CLOSING REMARKS;
REFERENCES; Appendix: Workshop Statement of Task and Agenda;
POLICY ISSUES IN THE DEVELOPMENT AND ADOPTION OF
MOLECULARLY TARGETED THERAPIES FOR CANCER
