

The World Market for Cancer Diagnostics, 5th Edition: Precision and Personalized Testing Arrives

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Abstracts

Cancer testing is maturing from personalized medicine to precision medicine, where protein and molecular biomarkers are essential for precise diagnosis, therapy selection, therapy monitoring and early detection of cancer recurrence. The market for cancer testing are comprehensively covered in Kalorama Information's Worldwide Market for Cancer Diagnostics, 5th. Edition. This report, authored by Kalorama Diagnostic Analyst Shara Rosen, contains detailed market data on the following IVD segments for their use in cancer diagnostics:

Histology/Cytology

Immunoassays

Flow Cytometry

Rapid Tests

Molecular Assays

Tissue Arrays

Circulating Tumor Cells

Pharmacodiagnostics, Molecular

Cancer Testing: Constant Innovation

Given the unfortunate statistics of cancer in the developed world, innovation is a must. Growth rates in cancer testing tends to be higher than in other IVD fields. Diagnostic tests for effective cancer screening are obviously needed more than ever. As this report goes to print a number of significant developments are taking place in cancer follow up.

New imaging modalities and digital analysis of x-ray mammograms are looking to improve the accuracy of breast cancer screening. These same imaging techniques are being used to screen patients for the metastasis of cancer from the primary site.

Lab testing for new cancer biomarkers - hormone, receptor and protein assays - improve the detection of cancer in patients that present with symptoms. These are now available in multiplexed tests that make better use of tissue samples.

With developments in the analysis of circulating cancer cells and cell free DNA in peripheral blood they are poised to help in the screening of high risk individuals.

Improved immunohistochemical stains and in situ hybridization make detection of cancer cells in biopsied tissue more effective. The use next generation analysis of individual tumor cells including sequencing, mass spectrometry and PCR further enhance cancer testing in tissues.

Bioinformatic analysis of gene and protein patterns detected in tumor cells and peripheral blood is proving to be a big breakthrough in cancer diagnosis. The technology has pinpointed gene and protein targets that will make up the next generation of cancer tumor marker panels.

The next big advances are related to tests based on the detection of circulating nucleic acid molecules and RNA and DNA methylation patterns.

Complete Market and Trend Analysis

Kalorama Information reports are always based on primary research of the market with particular attention to important market trends that are more important to understand than today's numbers. Shara Rosen not only defines the marketplace and provides market numbers, but her report also examines trends that are driving cancer testing

now and determining where it will go in the future. Some of the trends examined in this report include:

Commercializing Next Generation Cancer Tests

Clinical Molecular Test Reimbursement Coding In The U.S.

Regulatory Requirements of Cancer Tests

Gene Patents and Test Commercialization

The Physician's Role in Test Acceptance

Biomarkers: Issues in Research to Clinic

Miniaturization and Multiplexed Assays

The Emergence Of Non-Invasive Tools

Bioinformatics – Data To Information

Digital PCR, Mass Spectrometry, Next-Generation Sequencing

Sample Preparation and System Automation

The Role of In Vivo Cellular and Molecular Imaging

and Analyst Conclusions, Strategy Implications and Unmet Market Needs

Based on an analysis of these trends, the report includes a 'Technology Forecast' to 2025 that takes each particular technology used now in solid tumor testing and predicts its future role.

Personalized Cancer Testing and Advances In Precision

The phenomenon of test personalization comes under many guises – pharmacogenomic, pharmacogenetic, companion tests, and represents one of the fastest growing segments of the market for cancer tests. It has emerged fully from

research into clinical practice. Instrumentation now automates many of the sample preparation and assay steps that were formerly labor intensive. New tests are being launched all the time. Some personalized cancer tests are CE Marked and FDA-cleared and many more are in development. More and more laboratories offer complex panels of tests that help physicians evaluate disease risk and make therapeutic decisions. Government and private healthcare payers have recognized the value of new molecular tools and are agreeing to pay for them.

This report covers those trends and has tables describing the following:

Most Common Cancer Drug/Gene Mutation Combinations

Selected Pharmacodiagnostic Histology Tests

Chemotherapy Resistance Tests

Innovations in Personalized Molecular Tests for Cancer

Therapeutic Drug Monitoring Immunoassays

Major Protein And Molecular Markers Used In Tissue Staining

Unparalleled Review of Cancer Testing Competitors: Top Tier IVD Companies And Specialist Companies

This report is written from the point of view of diagnostic modalities for the detection and management of cancer and in particular solid tumors. The technology to detect cancers of the blood - lymphomas, myelomas and leukemias - is mature and well established. The routine complete blood count screens for blood cell abnormalities and is followed by bone marrow analysis and flow cytometric studies of the blood cell surface markers. These to arrive at a more specific diagnosis. As such this report does not discuss area of hematological cancer diagnosis in great detail.

Market analysis in this report covers world markets for in vitro cancer diagnostics, however the reader will find a bias toward the developed areas of the globe -- N. America, Japan and Western Europe. However cancer is a growing global problem and where possible the report covers cancer testing in the more industrialized developing countries of Latin America and Asia Pacific.

The emphasis is on in vitro diagnostic tests, however a discussion of the role of diagnostics in cancer management, must include in vitro and in vivo tests. The two are inextricably linked. The same cell markers used in flow cytometry and antibodies used for immunoassays to detect elements of the immunity process are used as vectors for imaging agents to detect tumors and to monitor the extent of cancer metastasis.

In addition to extensive reviews of products on the market and in development in each segment, the report provides detailed company profiles in several sections. Companies profiled include the following:

Abbott Diagnostics

Beckman Coulter Inc./Danaher

Becton, Dickinson and Company

bioMérieux Inc.

Bio-Rad Laboratories Inc.

Danaher Corporation

AB Sciex

Leica

GE Healthcare

Gen-Probe Inc.

Hologic, Inc.

IRIS International, Inc.

Novartis Diagnostics

Ortho Clinical Diagnostics

PerkinElmer, Inc.

QIAGEN N.V.

Roche Diagnostics

Siemens Healthcare Diagnostics

Sysmex Corporation

Abnova

ApoCell, Inc.

Biocept, Inc.

Clearbridge BioMedics

Cynvenio Biosystems, Inc.

Epic Sciences Inc.

Fluxion Biosciences, Inc.

Ikonisys, Inc.

NaturalNano, Inc.

On-Q-ity

ProKyma Technologies

RareCyte, Inc.

ScreenCell

Sony DADC Biosciences

Veridex, LLC

WaveSense LLC

Advanced Cell Diagnostics

Amoy Diagnostics Co. Ltd.

Applied Spectral Imaging

Biocare Medical, LLC

Biodis Biotechnology

BioMarker Strategies

Biomoda Inc.

BioView Ltd.

Bruker Corporation

CCC Diagnostics, Inc.

Caliper Life Sciences

Celerus Diagnostics

Cernostics, Inc.

ChipDX, LLC

Circadian Technologies Limited

Cymogen Dx, LLC

Dako A/S

Diagnostic Biosystems (DBS)

DVS Sciences Inc.

DxTerity Diagnostics Inc.

Halo Healthcare Inc. (formerly NeoMatrix, LLC)

HistoRx, Inc.

Horizon Discovery Ltd

iKaryos Diagnostics

IncellDx, Inc.

Leica Biosystems

Metamark Genetics, Inc.

Nodality, Inc.

Norchip

Oxford Cancer Biomarkers

Philips Handheld Diagnostics

QuantuMDx

Theranostics Health Inc.

Ventana Medical Systems Inc.

Arbor Vita Corporation

Axela Biosensors, Inc.

Binding Site (The)

BioCurex, Inc.

Biomerica Inc.

Cellmid Ltd.

Eutropics Pharmaceuticals

Fujirebio Diagnostics, Inc.

GeneTex

Gold Standard Diagnostics:

HealthLinx Limited

Immunomedics

MabCure Inc.

Matrix-Bio

Nano Discovery Inc.

Oncimmune USA LLC

OncoCyte Corp.

OncoHealth Corp.

OPKO Health, Inc.

Polymedco Cancer Diagnostic Products, LLC

Proteomika S.L.

Radiant Pharmaceuticals Corporation

Saladax Biomedical, Inc.

ScheBo-Biotech AG

Wako Diagnostics

Abcodia

Adaptive Biotechnologies Corporation

Affymetrix, Inc.

Agilent Technologies Inc.

ArcticDx Inc.

Arrayit Diagnostics Inc.

Asuragen, Inc.

Autogenomics Inc.

Biocartis

Biodesix, Inc.

Cepheid

DiagnoCure

Diagnoplex SA

Enzo Biochem Inc.

Epigenomics AG

Falcon Genomics, Inc.

GeneCentric Diagnostics, Inc.

GeneNews Limited

Genetic Technologies Limited

Genomica S.A.U.

Illumina Inc.

Inform Genomics, Inc.

Ipsogen SA

Life Technologies

TrovaGene, Inc.

VolitionRx Limited

And Many More Companies..

Contents

CHAPTER ONE: EXECUTIVE SUMMARY

Introduction
Scope and Methodology
Size and Growth of the Market
Test Segments
Geographic Distribution
Market Trends

CHAPTER TWO: INTRODUCTION

Background
Cancer - Diagnosis And Therapy Management
Point of View

CHAPTER THREE: MARKET ISSUES IN THE COMMERCIALIZATION OF CANCER DIAGNOSTICS

Background
Demographics of cancer, A Global Phenomenon
Cancer World Market Estimate
Cancer in the World - Screening and Government Supported Programs
United States
Canada
Europe
China
India
Africa
Commercializing Next Generation Cancer Tests
Clinical Molecular Test Reimbursement Coding In The U.S.
Test Services – Route For Cancer Innovation
Regulatory Requirements of Cancer Tests
Gene Patents and Test Commercialization
Impact of Companion Test Development
The Physician's Role in Test Acceptance

CHAPTER FOUR: TECHNOLOGICAL TRENDS THAT ENABLE THE FUTURE OF

CANCER DIAGNOSTICS

Background
Biomarkers: Issues in Research to Clinic
Miniaturization and Multiplexed Assays
The Emergence Of Non-Invasive Tools
Bioinformatics – Data To Information
New Technologies Applied To Cancer Diagnostics
Overview
Digital PCR
Mass Spectrometry
Chromosome Analysis
Next-Generation Sequencing
Sample Preparation and System Automation
The Role of In Vivo Cellular and Molecular Imaging

CHAPTER FIVE: MARKET ANALYSIS – CANCER TESTING

The Market for Cancer Diagnostics
Major Vendors and Companies to Watch
Acquisitions, Alliances and Collaborations
Screening – The Debate Continues
Prospects for Decentralized Cancer Testing
Cancer Specific Tests
Breast Cancer
Colon Cancer
Lung Cancer
Ovarian Cancer
Pancreatic Cancer

CHAPTER SIX: CANCER TESTS IN CLINICAL CHEMISTRY

Selected Tissue Function Clinical Chemistry Tests
Major Players In Chemistry Analyzers and Reagents

CHAPTER SEVEN: IMMUNOASSAY CANCER TESTS

Role Of Immunoassays In Cancer Management
Selected Widely Used Tumor Markers

Lab-Based Assays
POC – rapid tests
Colon Cancer
Prostate Cancer
Bladder Cancer

CHAPTER EIGHT: TISSUE- AND CELL-BASED CANCER TESTS

Background
Market Overview
Pap Smear & HPV Testing
Tissue Microarrays
Cell Signaling Pathway Testing

CHAPTER NINE: MARKET ANALYSIS – CANCER TESTS IN FLOW CYTOMETRY

Market Size
Selected Flow Cytometry Innovations For Cancer Testing

CHAPTER TEN: MARKET ANALYSIS - CIRCULATING TUMOR CELLS IN CANCER DIAGNOSTICS

Market Size
Selected CTC Capture And Analysis Systems

CHAPTER ELEVEN: - CANCER MOLECULAR ASSAYS

Background
RNA - Ribonucleic Acid
Methylated Gene (meDNA) Patterns
Circulating Plasma DNA
Minimal Residual Disease

CHAPTER TWELVE: PERSONALIZED CANCER TESTING ADVANCES IN PRECISION

Background
Pharmacodiagnostic Histology
Therapeutic Drug Monitoring Immunoassays

CHAPTER THIRTEEN: CONCLUSIONS AND STRATEGIC IMPLICATIONS

Conclusions and Strategic Implications

Unmet Market Needs

CHAPTER FOURTEEN: COMPANY PROFILES: MAJOR IVD COMPANY CANCER TESTING

Abbott Diagnostics

Molecular Histology

Companion Tests

Molecular Diagnostics

Core Lab

Hematology

Alere

NMP22

Beckman Coulter Inc./Danaher

Core Lab

Immunoassays

Histology

Flow Cytometry

Becton, Dickinson and Company (BD)

Histology

Molecular

Flow Cytometry

bioMérieux Inc.

Bio-Rad Laboratories Inc.

Danaher Corporation

AB Sciex

Leica

GE Healthcare

Cell Imaging

Sequencing

Gen-Probe Inc.

HPV

Hologic, Inc.

IRIS International, Inc.

Novartis Diagnostics

Ortho Clinical Diagnostics
PerkinElmer, Inc.
CLIA Lab
QIAGEN N.V.
Histology
Roche Diagnostics
PCR
Companion Tests
Hematological Cancers
Core Lab
Siemens Healthcare Diagnostics
Histology
Sysmex Corporation

CHAPTER FIFTEEN: COMPANY PROFILES: CIRCULATING TUMOR CELLS SPECIALISTS

Abnova
ApoCell, Inc.
Biocept, Inc.
Clearbridge BioMedics
Cynvenio Biosystems, Inc.
Epic Sciences Inc.
Fluxion Biosciences, Inc.
Ikonisys, Inc.
NaturalNano, Inc.
On-Q-ity
ProKyma Technologies
RareCyte, Inc.
ScreenCell
Sony DADC Biosciences
Veridex, LLC
WaveSense LLC

CHAPTER SIXTEEN: COMPANY PROFILES: TISSUE AND CELL TEST SPECIALISTS

Advanced Cell Diagnostics
Amoy Diagnostics Co. Ltd.

Applied Spectral Imaging
Biocare Medical, LLC
Biodis Biotechnology
BioMarker Strategies
Biomoda Inc.
BioView Ltd.
Bruker Corporation
CCC Diagnostics, Inc.
Caliper Life Sciences
Celerus Diagnostics
Cernostics, Inc.
ChipDX, LLC
Circadian Technologies Limited
Cymogen Dx, LLC
Dako A/S
Immunohistochemistry
Companion Diagnostics
Diagnostic Biosystems (DBS)
DVS Sciences Inc.
DxTerity Diagnostics Inc.
Halo Healthcare Inc. (formerly NeoMatrix, LLC)
HistoRx, Inc.
Horizon Discovery Ltd
iKaryos Diagnostics
IncellDx, Inc.
Leica Biosystems
Metamark Genetics, Inc.
Nodality, Inc.
Norchip
Oxford Cancer Biomarkers
Philips Handheld Diagnostics
QuantuMDx
Theranostics Health Inc.
Ventana Medical Systems Inc.

CHAPTER SEVENTEEN: COMPANY PROFILES: CANCER PROTEIN MARKER SPECIALISTS

Arbor Vita Corporation

Axela Biosensors, Inc.
Binding Site (The)
BioCurex, Inc.
Biomerica Inc.
Cellmid Ltd.
Eutropics Pharmaceuticals
Fujirebio Diagnostics, Inc.
GeneTex
Gold Standard Diagnostics:
HealthLinx Limited
Immunomedics
MabCure Inc.
Matrix-Bio
Nano Discovery Inc.
Oncimmune USA LLC
OncoCyte Corp.
OncoHealth Corp
OPKO Health, Inc.
Polymedco Cancer Diagnostic Products, LLC
Proteomika S.L.
Radiant Pharmaceuticals Corporation
Saladax Biomedical, Inc.
ScheBo-Biotech AG
Wako Diagnostics

CHAPTER EIGHTEEN: COMPANY PROFILES: MOLECULAR TEST SPECIALISTS

Abcodia
Adaptive Biotechnologies Corporation
Affymetrix, Inc.
Agilent Technologies Inc.
ArcticDx Inc.
Arrayit Diagnostics Inc.
Asuragen, Inc.
Autogenomics Inc.
Biocartis
Biodesix, Inc.
Cepheid
DiagnoCure

Diagnoplex SA
Enzo Biochem Inc.
Epigenomics AG
Falcon Genomics, Inc.
GeneCentric Diagnostics, Inc.
GeneNews Limited
Genetic Technologies Limited
Genomica S.A.U.
Illumina Inc.
Inform Genomics, Inc.
Ipsogen SA
Life Technologies
Med BioGene, Inc. (MBI)
MicroActive Project
MolecularMD Corporation
NanoString Technologies Inc.
Onconome, Inc
Orion Genomics
Oxford Gene Technology
Randox Laboratories Ltd.
RainDance Technologies, Inc.
Sequenom
Skyline Diagnostics B.V.
Soricimed Biopharma Inc. (formerly BioProspecting NB Inc.)
Transgenomic, Inc.
TrimGen Genetic Technology
TrovaGene, Inc.
VolitionRx Limited

CHAPTER NINETEEN: COMPANY PROFILES: CANCER TEST SERVICE PROVIDERS

20/20 GeneSystems, Inc.
Acupath Laboratories, Inc.
Advanced Laboratory Services Inc.
Aetna Innovation Labs
Agendia BV
Market Expansion
Product News

AltheaDx Diagnostics, Inc.
ARUP Laboratories
Atossa Genetics, Inc.
BC Cancer Agency
Beijing Genome Institute (BGI)
Bio-Reference Laboratories, Inc. (BRLI)
bioTheranostics
Bostwick Laboratories
Cancer Genetics, Inc.
Caris Life Sciences
Castle Biosciences Inc.
CBLPath
Chronix Biomedical
Clariant Inc.
CombiMatrix Molecular Diagnostics, Inc.
Complete Genomics
deCode genetics ehf
DiaTech Oncology
Everist Genomics Inc. (EGI)
Exact Sciences Corp.
Exosome Diagnostics
Foundation Medicine Inc.
GenoID Ltd.
Genomic Health, Inc.
Genoptix Medical Laboratory
Inostics GmbH
Insight Genetics
InterGenetics Inc.
Lab21 Limited
Laboratory Corporation of America Holdings (LabCorp)
Mayo Medical Laboratories
MDxHealth SA (formerly Oncomethylome Sciences)
Metabolistics Inc.
Mira Dx
MolecularMD Corp.
Myriad Genetics, Inc.
NeoGenomics, Inc.
Nuvera Biosciences, Inc.
NewGene

OncoPlex Diagnostics (formerly Expression Pathology Inc.)

OvaGene Oncology Inc.

Pacific Edge Diagnostics

Pathwork Diagnostics

Phenomenome Discoveries Inc.

Precision Therapeutics

Predictive Biosciences

Quest Diagnostics

Response Genetics, Inc.

RiboMed Biotechnologies, Inc.

Rosetta Genomics Ltd.

Sequentia, Inc. (formerly MLC Dx, Inc.)

Signal Genetics

Signature Diagnostics AG

Veracyte, Inc.

Vermillion Inc.

LIST OF EXHIBITS

CHAPTER ONE: EXECUTIVE SUMMARY

Table 1-1: Exchange Rate Fluctuations, 2009-2012

Table 1-2: Worldwide Market for Cancer In Vitro Diagnostics, 2012-2017

Figure 1-1: Growth In Cancer In Vitro Diagnostics Market, 2012-2017

Table 1-3: Worldwide Market for Histology/Cytology Cancer IVD, 2012-2017

Table 1-4: Worldwide Market for Immunoassays Cancer IVD, 2012-2017

Table 1-5: Worldwide Market for Flow Cytometry Cancer IVD, 2012-2017

Table 1-6: Worldwide Market for Rapid Tests Cancer IV, 2012-2017

Table 1-7: Worldwide Market for Molecular Assays Cancer IVD, 2012-2017

Table 1-8: Worldwide Market for Tissue Arrays Cancer IVD, 2012-2017

Table 1-9: Worldwide Market for Circulating Tumor Cells Cancer IVD, 2012-2017

Table 1-10: Worldwide Market for Molecular Pharmacodiagnosics Cancer IVD,
2012-2017

CHAPTER TWO: INTRODUCTION

Table 2-1: Selected Test Gene Panel Targets (ALK, BRAF, C-Kit, EGFR, KRAS, P53, PIK3CA)

CHAPTER THREE: MARKET ISSUES IN THE COMMERCIALIZATION OF CANCER

DIAGNOSTICS

Table 3-1: Cancer Incidence, Worldwide, By Cancer Type In 2008

Figure 3-1: World Cancer Test Sales, Percentage by Region (N. America, EU, Japan, ROW)

Table 3-2: World Cancer Test Market by Region (N. America, EU, Japan, ROW), 2007-2012

Table 3-3: Cancer Death Rates, by Region (Africa, Americas, Europe, Southeast Asia, Western Pacific, China, East Mediterranean, India), 2008

Table 3-4: Selected Cancer Company Lab Service Expansions

Table 3-5: Revenues For A Selection Of Molecular Test Service Labs, Worldwide, 2012, \$ Million (Estimated)

Table 3-6: Selected Hospital Cancer Test Services

Table 3-7: Selected IVD and Pharmaceutical Company Collaborations

CHAPTER FOUR: TECHNOLOGICAL TRENDS THAT ENABLE THE FUTURE OF CANCER DIAGNOSTICS

Table 4-1: Selected Multiplexed Cancer Test And Service Innovations

Table 4-2: Selected Non-Invasive Cancer Test Innovations

Table 4-3: Selected Information Technology Innovations In Molecular Testing

Table 4-4: Selected App Products

Table 4-5: Selected Cancer Tests using Mass Spectrometry

Table 4-6: Selected Companies Involved In Chromosomal Analysis Of Cancer Cells

Table 4-7: Selected Chromosome-Based Cancer Tests And Services

Table 4-8: Sequencing Platforms Available

Table 4-9: Selected Sequencing-Based Tests And Test Services

Table 4-10: Selected Sample Preparation Systems for Sequencing Tests

Table 4-11: Selected Nucleic Acid Sample Preparation Products

MARKET OVERVIEW – MARKET ANALYSIS

Table 5-1: Worldwide Market for Selected Cancer In Vitro Diagnostics

(Histology/Cytology, Immunoassays, Flow Cytometry, Rapid Tests, Molecular Assays, Tissue Arrays, CTCs, Pharmacodiagnostics, Circulating Plasma DNA), 2012-2017

Table 5-2: Revenues of Selected Cancer Testing Companies

Table 5-3: Cancer Diagnostics and the Top Tier of IVD Companies

Table 5-4: Selected Acquisitions, Mergers And New Cancer Test Investments

Table 5-5: Selected Cancer Test Collaborations

Table 5-6: Selected Cancer Test Distribution Agreements

Table 5-7: Selected Cancer Test Licensing Agreements

Table 5-8: Selected POL-appropriate Cancer Test Systems

CHAPTER SIX: CANCER TESTS IN CLINICAL CHEMISTRY

Table 6-1: Selected Tissue Function Clinical Chemistry Tests

Table 6-2: Major Players For Clinical Chemistry Analyzers And Reagents

CHAPTER SEVEN: IMMUNOASSAY CANCER TESTS

Table 7-1: Selected Widely Used Tumor Markers

Table 7-2: Selected Cancer Immunoassay Technology Innovations

Table 7-4: Cancer Immunoassay Sales, Lab-based (PSA, CEA, CA 125, AFP, Others), 2012-2017

Table 7-5: Rapid Cancer Test Sales by Test Category (FOB, PSA, NMP22, Other) Worldwide 2012-2017

CHAPTER EIGHT: TISSUE- AND CELL-BASED CANCER TESTS

Table 8-1: Selected Histology Test Services

Table 8-2: Selected Innovations In Tissue-Based Cancer Tests

Table 8-3: Worldwide Histology/Cytology Sales (Pap, in situ hybridization, immunohistochemistry, HPV, Tissue Microarrays), 2012-2017

Table 8-4: Revenues of the Major Histology Companies, 2009-2012

Table 8-5: Selected Major Protein And Molecular Markers

Table 8-6: Selected Technology Innovations In Cancer Testing

Table 8-8: Selected HPV Test Innovations

Table 8-9: Selected Tissue Microarray Products

Table 8-10: Selected Live Cell Cancer Tests

Table 8-11: Selected New Cancer Tests and Technologies

CHAPTER NINE: CANCER TESTS IN FLOW CYTOMETRY

Table 9-1: Selected flow cytometry innovations for cancer testing

CHAPTER TEN: CIRCULATING TUMOR CELLS IN CANCER DIAGNOSTICS

Table 10-1: Selected CTC Capture And Analysis Systems

CHAPTER ELEVEN: CANCER MOLECULAR ASSAYS

Table 11-1: Selected Commercial Molecular Cancer Tests

Table 11-2: Selected Molecular Instrumentation Innovations

Table 11-3: Selected RNA-Based Cancer Tests

Table 11-4: Selected Methylated DNA tests

CHAPTER TWELVE: PERSONALIZED CANCER TESTING ADVANCES IN PRECISION

Table 12-1: Most Common Cancer Drug/Gene Mutation Combinations

Table 12-2: Major Protein And Molecular Markers Used In Tissue Staining

Table 12-3: Selected Pharmacodiagnostic Histology Tests

Table 12-4: Selected Chemotherapy Resistance Tests

About

2012 marked the 20th anniversary of PCR-based diagnostic tests. Roche Diagnostics launched the Amplicor CT – Chlamydia test in 1992. Since then polymerase chain reaction amplification (PCR) has remained the dominant molecular test technology.

Roche has maintained the dominance of PCR with an out-licensing program for its PCR-based intellectual property portfolio. This has contributed to the development of variations on PCR that make sure the technique will remain vibrant even in face of next generation sequencing, especially since whole genome sequencing is not always necessary when targeted amplification and quantification is enough.

More than 15 years ago, qPCR (quantitative PCR) set the gold standard for sensitive DNA quantification and has been used extensively in areas such as disease research, diagnosis and preventative medicine.

Now, several companies have brought PCR technology one-step further. DigitalPCR (dPCR), was first presented in the early 1990s and is a refinement of quantitativePCR. The key difference between dPCR and qPCR lies in the method by which nucleic acids are quantified. Digital PCR transforms exponential and analog PCR into a linear, digital signal. Single molecules are isolated by dilution and individually amplified by PCR; each product is then analyzed separately for the presence of mutations by various labels.

Digital PCR developers contend that this new technology provides even more precise measurements than even qPCR methods especially for the detection of target molecules at extremely low levels. This is expected to improve early diagnosis of cancer and the development of more precise personalization when the DNA level are particularly low, essentially at the earliest stages of a disease.

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