









MEDICAL DEVICES

PHARMACEUTICALS

CHEMICALS

FOOD & BEVERAGE

ELECTRONICS

# Table of Contents and List of Tables

Copyright 2012 VENTURE PLANNING GROUP This material is confidential for use by our clients only and may not be reprinted or reproduced.

VPG Publications, Consulting, Clients www.VPGcorp.com

VPG Market Research Reports www.VPGMarketResearch.com

VPG Partner Reports www.Research-Store.com/VPG

VENTURE PLANNING GROUP 545 Eighth Avenue, Suite 401 New York, NY 10018 Phone + 1 212 564 2838 Fax + 1 212 564 8133 *info@vpgcorp.com* 

## <u>Table of Contents</u>

### <u>Introduction</u>

Worldwide Market And Technology Overview

- A. DNA Sequencing
  - 1. Introduction
  - 2. Sequencing Methods
  - 3. Autoradiography
  - 4. The Human Genome Project
  - 5. Sequencing Automation
  - 6. Image Scanners
  - 7. Fluorescent Detection
  - 8. Gene Profiling
  - 9. Gene Expression
  - 10. Polymorphism Screening
  - 11. Protein Interaction Networks
- B. DNA And RNA Probe Technology
  - 1. Basic Principles
  - 2. Probe Preparation
  - 3. The DNA Probe Test
    - a. Sample Preparation
    - b. Hybridization
    - c. Separation
    - d. Detection/Measurement
  - 4. Test Formats
    - a. Filter Hybridization
    - b. Southern Blot
    - c. Northern Blot
    - d. In Situ Hybridization
    - e. Others
  - 5. Labeling Techniques
    - 6. Amplification Methods
      - Polymerase Chain Reaction
        - Temperature Cyclers

- PCR Variations
  - \* Immuno-PCR
  - \* QC-PCR
  - \* DAP-PCR
- Strand Displacement Activation
- o **TMA**
- Ligase Chain Reaction
- Branched DNA
  - Hybridization Protection Assay
- Nucleic-Acid Sequence-Based Amplification
- Self-Sustained Sequence Replicase
- Others
  - Ampliprobe
  - CAR
  - CAS
  - CPT
  - Dendritic Polymer Technology
  - ISO-CR
  - LAT
  - Probe Networks
  - RAMP
  - Repair Chain Reaction
  - Rolling Circles
  - Sequence Independent Gene Amplification
  - Sequence Initiation Reaction
  - SISPA
  - Solid Phase Amplification
- C. Detection Technologies
  - 1. Radioactive Methods
    - a. Overview
    - b. Major Isotopes
    - P-32
    - ∘ **S-35**
    - ∘ **H−**3
    - ∘ I**-125**
  - 2. Non-Isotopic Methods
    - a. Enzymatic Labels
    - b. Chemical Labeling
      - Indirect Chemical Labeling
      - Direct Chemical Labeling

- c. Fluorescence
- d. Chemiluminescence
- e. Electrical Conductivity
- D. Instrumentation Review
  - 1. Abbott LCx
  - 2. Beckman Coulter/Biomek FK
  - 3. Becton Dickinson SDA
  - 4. Bio-Rad GeneScope
  - 5. Gen-Probe Tigris
  - 6. Roche Cobas Amplicor
  - 7. Tecan LS Series
- E. Biochips: Genosensors, Microarrays, and
  - Labs-on-the-Chip
  - Liquid Transportation and Mixing
  - Separation
  - Reaction
  - Detection
- F. Pharmacogenomics
- G. Major Applications
  - 1. Microbiology/Infectious Diseases
    - a. Overview
    - b. Major Infectious Diseases
    - \* AIDS
      - Structure and Composition
      - Classification
      - AIDS Origins
      - Animal Lentivirus Systems
      - Virus Receptors
      - HIV Infections in Humans
        - Pathogenesis and Pathology
      - CD4T Lymphocytes and Memory Cells
      - Monocytes and Macrophages
      - Lymphoid Organs
      - Neural Cells
      - Viral Coinfections
        - Clinical Findings
      - Plasma Viral Load

- Pediatric AIDS
  - Neurologic Disease
  - Opportunistic Infections
  - Cancer
- Immunity
  - Virus Isolation
  - Serology
  - Viral Nucleic Acid/Antigen Detection
- Epidemiology
  - Worldwide Spread of AIDS
  - United States
  - Routes of Transmission
- DNA Probes
  - Overview
  - Quantitative PCR
  - In Situ PCR
  - Needed Improvements
- Viral Load/Drug Resistance Testing
- Genotype and Phenotype Testing
- Blood Banking Considerations
- \* Adenovirus
  - Background
  - Diagnostic Tests
  - Vaccines and Drugs
  - Adeno-Associated Viruses (AAV)
- \* Anthrax/Bacillus Anthracis
  - Background
  - Diagnostic Tests
  - Vaccines and Drugs
- \* Babesiosis
  - Background
- \* BEA and Other Bartonella Diseases
  - Background
  - Diagnostic Tests
  - Vaccines and Drugs
- \* Chagas Disease
  - Background

- \* Campylobacter
  - Background
  - Diagnostic Tests
    - Culture Identification
  - Vaccines and Drugs
- \* Chlamydia
  - Background
    - Chlamydia psittaci
    - Chlmaydia pneumoniae
    - Chlamydia trachomatis
  - Diagnostic Tests
  - Vaccines and Drugs
- \* Creutzfeldt-Jakob's Disease
  - Background
  - Blood Transmission
  - Diagnostic Tests
  - Major Commercial and Academic Players
    - Bayer
    - Disease Sciences/Bio Tec Global
    - Imperial College School of Medicine
    - Ortho-Clinical Diagnostics
    - Pall
    - ProMetic Life Sciences
    - Proteome Sciences/Idexx
    - Q-One Biotech
    - Serono
    - U.S. Agricultural Research Service
  - Drugs
  - Vaccines
- \* Cytomegalovirus
  - Background
    - Chorioretinitis
      - Gastrointestinal
      - Central Nervous System Disease
  - Diagnostic Tests
  - Vaccines and Drugs
- \* Ebola Virus
  - Background
    - Epidemiology
    - Clinical Syndromes

- Diagnostic Tests
- Vaccines and Drugs
- \* EchoVirus
  - Background
    - Acute Aseptic Meningitisis
    - Encephalitis
    - Exanthems
    - Respiratory Disease
    - Myopericarditis
    - Neonatal Infections
  - Diagnostic Tests
  - Vaccines and Drugs
- \* Encephalitis
  - Background
  - Diagnostic Tests
  - Vaccines and Drugs
- \* Enteroviruses
  - Background
  - Diagnostic Tests
    - Viral Isolation and Identification
    - Antibody Tests
  - Vaccines and Drugs
- \* Epstein-Barr Virus
  - Background
  - Diagnostic Tests
  - Vaccines and Drugs
- \* Gonorrhea
  - Background
  - Diagnostic Tests
  - Vaccines and Drugs
- \* Hepatitis
  - Hepatitis A
  - Hepatitis B
    - Structure and Composition
    - Replication
  - Hepatitis C
  - Hepatitis D (Delta)
  - Hepatitis E
  - Hepatitis G
  - Hepatitis Infections Pathology
  - Clinical Findings
  - Laboratory Tests

- Hepatitis A
- Hepatitis B
- Hepatitis C
- Hepatitis D
- Hepatitis E
- Virus-Host Immune Reactions
- Epidemiology
  - Hepatitis A
  - Hepatitis B
  - Hepatitis C
  - Hepatitis D (Delta)
- Vaccines and Drugs
- \* Herpes Simplex Virus
  - Background
  - Diagnostic Tests
  - Vaccines and Drugs
- \* Legionella
  - Background
  - Diagnostic Tests
  - Vaccines and Drugs
- \* Lyme Disease
  - Background
    - Clinical Description
    - Clinical Case Definition
    - Laboratory Criteria for Diagnosis
    - Case Classification
  - Diagnostic Tests
  - Vaccines and Drugs
- \* Malaria
- \* Mycoplasma
  - Background
    - Ureaplasma Urealyticum & Mycoplasma Hominis
  - Diagnostic Tests
  - Veggines and Drug
  - Vaccines and Drugs
- \* Papillomaviruses/HPV
  - Background
    - HPV in Cancer
    - Cervical Neoplasm
  - Diagnostic Tests
  - Vaccines and Drugs

- Prevention
- \* Parvovirus B19
  - Background
    - Microbiology
    - Epidemiology
    - Clinical Syndromes
    - Erythema Infectiosum (Slapped Cheek)
    - Adult Polyarthropathy
    - Transient Aplastic Crisis
    - Transient Pancytopenia
    - Red Cell Aplasia in Immunocompromised
    - Perinatal Infections
  - Diagnostic Test
  - Vaccines and Drugs
- \* Pneumonia
  - Background
  - Diagnostic Tests
  - Vaccines and Drugs
- \* Polyomaviruses
  - Background
  - Diagnostic Tests
  - Vaccines and Drugs
- \* Salmonellosis
  - Background
  - Diagnostic Tests
  - Vaccines and Drugs
- \* Shigellosis
  - Background
  - Diagnostic Tests
  - Vaccines and Drugs
- \* Streptococci
  - Background
  - Diagnostic Tests
  - Vaccines and Drugs
    - Group A Streptococci
    - Group B Streptococci
- \* Toxoplasmosis
  - Background
  - Diagnostic Tests
  - Vaccines and Drugs

- \* Tuberculosis
  - Background
  - Diagnostic Tests
    - Microscopic Characteristics
    - Cultural Characteristics
    - Skin Tests
    - MDRTB
  - Vaccines and Drugs
- \* West Nile Virus
  - Background
    - Clinical Syndromes
  - Diagnostic Tests
  - Vaccines and Drugs
- \* Yersinia
  - Background
  - Diagnostic Tests
  - Vaccines and Drugs
- c. Antibiotic Susceptibility
- 2. Cancer Testing
  - a. Overview
  - b. Major Cancer Types
    - \* Prostate
    - \* Lung
    - \* Colon and Rectum
    - \* Breast
    - \* Skin
    - \* Uterine
    - \* Leukemia
    - \* Oral
  - c. Oncogenes
    - Abl/abl-bcr
    - o AIB1
    - BCL-2
    - o BRCA1
    - CD44
    - C-fos
    - ∘ C-myb
    - C-myc
    - *° C*YP17
    - Erb-B
    - HPC1

### <u>Table of Contents</u> (continued)

- N-myc
- o **P40**
- 。 **P51**
- 。 **P53**
- PIK3CA
- **PTI-1**
- o Ras
- 。Reg
- Sis
- Src
- 3. Genetic Diseases
  - a. Overview
  - b. Nucleic Acid Amplification
  - c. Chromosome Imaging
  - d. Genomics Technologies
  - e. Proteomics Technologies
  - f. Current Pharmacogenomic Tests
  - g. Future Pharmacogenomic Testing
  - h. Major Diseases
    - \* Achondroplasia
    - \* Autosomal Dominant Polycystic Kidney Disease
    - \* Cancer
    - \* Cosmetogenomics
    - \* Cystic Fibrosis
    - \* Down's Syndrome
    - \* Duchenne and Becker Muscular Dystrophy
      - \* Factor V (Leiden)
      - \* Factor IX Deficiency
      - \* Fragile X Syndrome
      - \* Heart Disease
      - \* Hemochomatosis
      - \* Hemophilia
      - \* Huntington's Disease
      - \* Maternal-Fetal Incompatibility
      - \* Multiple Endocrine Neoplasia
      - \* Phenylketonuria (PKU)
      - \* Polycystic Kidney Disease (PKD)
      - \* Prenatal Screening
      - \* Retinitis Pigmentosa
      - \* Retinoblastoma
      - \* Sickle Cell Anemia

- \* Spinal Muscular Atrophy
- \* Vitamin B12 Metabolism
- i. Social Issues and Concerns
- 4. Forensic Testing
  - a. Overview
  - b. Multilocus and Single Locus Probes
    - \* Multilocus Probes
    - \* Single Locus Probes
    - \* PCR and RFLP
  - c. The FBI
  - d. DNA Profile Data Banks
    - \* U.S.A.
    - \* U.K.
  - e. Judicial Implementation
  - f. Major Crime Categories
  - g. Factors Contributing to the DNA Probe Market Expansion
    - \* Technology Availability
    - \* Use of Hair as Evidence
  - h. Wildlife Forensics
- 5. Paternity Testing/HLA Typing
- 6. Other Applications
  - a. Disease Susceptibility Testing
  - b. Cardiovascular Diseases
  - c. Diabetes
  - d. Alzheimer's Disease
  - e. Periodontal Disease
  - f. Plasma Purification
  - g. Organ Transplantation
  - h. Water Contamination
  - i. Other
- H. Competing/complementing Technologies
  - 1. Monoclonal Antibodies/Immunoassays
  - 2. RNA Probes
  - 3. Two-Dimensional Electrophoresis
  - 4. Flow Cytometry
- I. Worldwide Market Overview
  - 1. Business Environment
  - 2. Market Structure
  - 3. Market Size and Growth

### <u>UK</u>

- A. Executive Summary
- B. Business Environment
- C. Market Structure
- D. Market Size, Growth And Major Suppliers' Sales And Market Shares

#### Major Product Development Opportunities

- A. Instrumentation
- B. Reagent Kits and Test Systems/panels
- C. Computers, Software and Automation
- D. Auxiliary Products

### Design Criteria For Decentralized Testing Products

#### Alternative Market Penetration Strategies

- A. Internal Development
- B. Collaborative Arrangements
- C. University Contracts
- D. Distribution Strategies For Decentralized Testing Markets
  - 1. Marketing Approaches
  - 2. Product Complexity
  - 3. Customer Preference
  - 4. Established Suppliers
  - 5. Emerging Suppliers
  - 6. Major Types Of Distributors
  - 7. Market Segmentation

### Potential Market Entry Barriers And Risks

- A. Market Maturity
- B. Cost Containment
- C. Competition
- D. Technological Edge And Limitations
- E. Patent Protection
- F. Regulatory Constraints
- G. Decentralized Testing Market Challenges

#### Competitive Profiles

- Abbott
- Affymetrix
- Agilent
- Applied Gene Technologies
- Arca
- Beckman Coulter/Danaher
- Becton Dickinson
- Biokit
- BioMerieux
- Bio-Rad
- Biotest
- Caliper
- Cepheid
- Decode
- Diadexus
- Eiken
- Enzo
- Exact Sciences
- Fujirebio
- Gen-Probe
- Hologic
- Illumina
- Innogenetics/Solvay
- Kreatech
- Li-Cor Biosciences
- Life Technologies
- Monogram Biosciences
- Myriad Genetics
- Nanogen/Elitech
- Novartis
- Orchid CellMark
- Ortho-Clinical Diagnostics
- Proteome Sciences
- Qiagen
- Roche
- Scienion
- Sequenom
- Shimadzu
- Siemens
- Sierra Molecular
- Takara Bio
- Tecan Group

## <u>Table of Contents</u> (continued)

### <u>Appendixes</u>

Appendix I:	Major Universities and Research Centers Developing NAT Technology
Appendix II:	Glossary of Terms
Appendix III:	Currency Exchange Rates

#### <u>List of Tables</u>

Major Companies Developing or Marketing AIDS NAT And Other Direct Identification Tests

Major Companies Developing or Marketing Adenovirus NAT And Other Direct Identification Tests

Major Companies Developing or Marketing Campylobacter NAT And Other Direct Identification Tests

Major Companies Developing or Marketing Chlamydia NAT And Other Direct Identification Tests

Major Companies Developing or Marketing CMV Molecular Diagnostic And Other Direct Identification Tests

Major Companies Developing or Marketing EBV Molecular Diagnostic And Other Direct Identification Tests

Major Companies Developing or Marketing Gonorrhea NAT And Other Direct Identification Tests

Major Companies Developing or Marketing Hepatitis NAT And Other Direct Identification Tests

Major Companies Developing or Marketing Herpes NAT And Other Direct Identification Tests

Major Companies Developing or Marketing Legionella NAT And Other Direct Identification Tests

#### <u>List of Tables</u> (continued)

Major Companies Developing or Marketing Lyme Disease NAT And Other Direct Identification Tests

Major Companies Developing or Marketing Mycoplasma NAT And Other Direct Identification Tests

Major Companies Developing or Marketing Papilloma Virus NAT And Other Direct Identification Tests

Major Companies Developing or Marketing Pneumonia NAT And Other Direct Identification Tests

Major Companies Developing or Marketing Salmonella NAT And Other Direct Identification Tests

Major Companies Developing or Marketing Shigella NAT And Other Direct Identification Tests

Major Companies Developing or Marketing Streptococci NAT And Other Direct Identification Tests

Major Companies Developing or Marketing Toxoplasmosis NAT And Other Direct Identification Tests

Major Companies Developing or Marketing Tuberculosis NAT And Other Direct Identification Tests

Oncogenes Potential Application in Cancer Diagnosis

Major Companies Developing or Marketing Cancer NAT Tests

#### <u>List of Tables</u> (continued)

Major Companies Developing or Marketing NAT Assays For Genetic Diseases

Summary Table U.K., NAT Test Volume And Sales Forecast by Major Application

U.K., Laboratories Performing DNA Sequencing by Market Segment

U.K., NAT Market Potential Laboratory Universe by Market Segment

U.K., NAT Test Volume Forecast By Major Application

U.K., Major Infectious Disease Molecular Diagnostics Test Volume Forecast

U.K., Infectious Disease Screening NAT Volume Forecast

U.K., NAT Market Forecast By Major Application

U.K., Infectious Disease Screening NAT Reagent Market Forecast by Test

U.K., NAT Market by Major Supplier