

# 2015-2019 New Frontiers in the US Point-of-Care/POC Diagnostic Testing: Business Challenges, Emerging Technologies, Competitive Landscape

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## **Abstracts**

2015-2019 New Frontiers in the US Point-of-Care/POC Diagnostic Testing: Business Challenges, Emerging Technologies, Competitive Land scape is VPGMarketResearch's new report, which provides comprehensive analysis of theten POC market segments, including their dynamics, size, growth, regulatory requirements, technological trends, competitive land scape, and emerging opportunities for instrument and consumable suppliers.

#### Rationale

The growing economic pressures on hospitals, coupled with advances in diagnostic technologies, intensifying competition among suppliers and physicians, and changing consumer demand s are shifting diagnostic testing from hospitals and commercial laboratories closer to the patient.

## Market Segmentation

Review of theten POC market segments, including their dynamics, trends, structure, size, growth and major suppliers.

Five-year test volume and reagent sales forecasts for over 300 chemistry, immunodiagnostic, microbiology, hematology and coagulation procedures by market segment:

Home/Personal Testing



# Physician Offices/Group Practices

Emergency Rooms	
Operating/Recovery Suites	
ICUs/CCUs	
Cancer Clinics	
Ambulatory Care Centers	
Surgery Centers	
Nursing Homes	
Birth Centers and by test category:	
Routine and Special Chemistry	
Microbiology/Infectious Diseases	
Hematology	
Flow Cytometry	
Coagulation	
Immunoproteins	
Drugs of Abuse	
TDM	
Endocrine Function	
Tumor Markers	



## Sales and Market Share Analysis

Sales and market shares ofmajor reagent and instrument suppliers.

## Current and Emerging Tests and Instrumentation

Analysis of over 130 diagnostic procedures.

Review of leading chemistry, immunoassay, hematology and coagulation analyzers market by

Abaxis, Abbott, Alfa Wasserman, Awareness Technologies, Beckman Coulter/Danaher, Becton Dickinson, Behnk Elektronik, Biocode, Bio/Data, bioMerieux, Cardiovascular Diagnostics, Carolina Chemistries, Diagnostica Stago, Diesse Ves Matic, Drew-Scientific, Helena Laboratories, Horiba, Instrumentation Laboratory, Inverness, ITC Hemochron, Medica, Menarini, Nihon Kohden, Nova Biomedical, Ortho-Clinical Diagnostics, Polymedco, Rand ox, Roche, Siemens, Sysmex, Teco Medical Instruments, Trinity Biotech, and other suppliers.

## Routine Clinical Chemistry Tests

Albumin, Alkaline Phosphatase, ALT/SGPT, Ammonia, Amylase, AST/SGOT, Bilirubin, Blood Gases, BUN (Blood Urea Nitrogen), Calcium, Cholesterol, Cholinesterase, Creatinine, CK-MB, Electrolytes (Carbon Dioxide/Bicarbonate, Chloride, Potassium, Sodium), Ferritin, Follate/Folic Acid, Fructosamine, GGT, Glucose, HDL, Iron, LDH, Magnesium, Phosphorus, Potassium, Protein, Sodium, Triglycerides, Troponin, Uric Acid, Urinalysis, Vitamin B12.

#### Infectious Disease Tests

AIDS/HIV, Adenovirus, Aeromonads, Bartonella, Blastocystis Hominis, Campylobacter, Cand ida, Chancroid, Chlamydia, Clostridium, Coronavirus, Coxsackievirus, Cryptosporidium, Cyclospora, CMV, E. Coli, Echovirus, Encephalitis, Enterovirus, EBV, Giardia, Gonorrhea, Granuloma Inguinale, Hantavirus, H. Pylori, Hepatitis (A, B, C, D, E), Herpes Simplex Virus, Human Herpes Virus-6 (HHV-6), Influenza, Legionella, Lyme disease, Pymphogranuloma, Malaria, Measles, Meningitis, Mononucleosis, Microsporidium, Mononucleosis, Mumps, Mycoplasma, Polyomaviruses, Parvovirus



B19, Pneumonia, Polyomaviruses, Pseudomonas, Rabies, RSV, Rhinovirus, Rheumatoid Arthritis, Rotavirus, Rubella, Salmonellosis, Septicemia, Shigella, Staphylococci, Streptococci, Syphilis, Toxoplasmosis, Trichomonas, Tuberculois, Vibrio, West Nile, Yersenia.

#### **Tumor Markers**

ACTH, AFP, Beta-2 Microglobulin, CA 15-3/27.29, CA 19-9, CA 125, Calcitonin, Cathepsin, CEA, Chromogranin, Colon-Specific Antigen, Cytokeratins, Estrogen Receptor, Ferritin, Gastrin, HCG, Insulin, Interferons, Interleukins, Lymphocyte Subtyping, Neuron-Specific Enolase, Nucleolar, Occult Blood, Oncogenes, Pancreatic Oncofetal Antigen, Pap Smear, Parathyroid Hormone, Progesterone Receptor, Prostatic Acid Phosphatase, Prostatic Specific Antigen, S-100 Protein, Serotonin, Sialic Acid, Squamous Cell Carcinoma Ag, TDT, Thymidine Kinase, Thyroglobulin, Tissue Polypeptide Antigen, and others.

## Routine and Special Hematology Tests

CBC + 5-Part Differential, Manual Differential/Review, Hematocrit (Automated, Manual), Hemoglobin (Automated, Manual), Sedimentation Rate, Reticulocytes, WBC (Automated, Manual), Platelets (Automated, Manual), Bone Marrow Analysis, RBC, Eosinophils and others.

## Flow Cytometry Tests

Cell Surface Markers (CD4/CD8/T&B Lymphocytes, CD34, Others), Chemotherapy Monitoring (Leukemia/Lymphoma, Others), HLA Typing, Sperm Analysis, Cell Cycle Kinetics, Cell Function Testing, Chromosomal Abnormalities, Fetal Cell Analysis, Granulocyte Function, Receptor DNA/RNA Analysis, Cell Culturing.

#### **Endocrine Function Tests**

Cortisol, Estradiol, FSH, HCG, Gastrin, LH, Progesterone, PTH/IO PTH, Prolactin, T3, T3 Uptake, Free T3, T4, Free T4, TBG, Testosterone, TSH.

Therapeutic Drug Monitoring (TDM) Tests

Amikacin, Carbamazepine, Digoxin, Gentamicin, Lidocaine, Lithium, Methotrexate, Phenobarbital, Phenytoin/Dilatin, NAPA/Procainamide, Quinidine, Theophylline,



Tobramycin, Valproic Acid, Vancomycin.

## Coagulation Tests

Activated Clotting Time (ACT) (1), Activated Protein C Resistance, Activated PTT (APTT), Alpha 2-Antiplasmin, Antithrombin III, Bleeding Time, D-Dimer, Factor II, Factor V, Factor V Leiden, Factor VII, Factor VIII, Factor IX, Factor Ixa, Factor X (Stuart Factor), Factor Xa, Factor XI, Factor XII, Factor XIII, Fibrin Degradation Products, Fibrinogen, Fletcher Factor/Pre-Kallikrein Factor Activation, Heparin/Anti-Factor Xa, Heparin-Induced Thrombocytopenia, Plasmin, Plasminogen, Plasminogen Activator Inhib., Platelet Function/Aggregation, Protein C, Protein S, Prothrombin Mutation, Prothrombin Time (PT), Reptilase Time, Thrombin Time, Von Willebrand 's Factor Fav/Ag, and others.

Immunoprotein Tests

C3, C4, CRP, IgA, IgE Specific, IgE Total, IgG, Immunoglobulins, Protein Electrophoresis, and others.

Drugs of Abuse

Amphetamines, Barbiturates, Benzodiazepines, Cannabinoids/Marijuana, Cocaine, LSD, Methadone, Methaqualone, Opiates, Phencyclidine, Propoxyphene, and others.

Technology Review

Emerging technologies and their applications for POC testing.

Comprehensive listings of companies developing or marketing POC diagnostic technologies and products, by test.

#### Strategic Recommendations

Specific opportunities for new POC instruments and reagent systems with potentially significant market appeal during the next five years.

Design criteria for POC testing products.



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Potential market entry barriers and risks.

# Competitive Assessments

Assessments of major suppliers and emerging market entrants, including their sales, product portfolios, marketing tactics, joint ventures, and new products in R&D.

The companies analyzed in the report include:

Abbott
ADI/American Diagnostica
Agilent Technologies
Alere/Biosite/Inverness
Axis-Shield
Beckman Coulter/Danaher
Becton Dickinson
Bio/Data
Biomerieux

Bio-Rad

Cepheid

Chrono-Log

Corgenix



Decode Genetics
Diadexus
Diagnocure
Diagnostica Stago/Trinity Biotech
Diamedix/Erba
Diasorin
Eiken Chemical
EKF Diagnostics
Fujirebio
Grifols
Helena Laboratories
Hologic/Gen-Probe
Horiba
Instrumentation Laboratory
International Technidyne/Nexus DX
Kreatech/Leica
Kyowa Medex
Lonza
Mackay Life Sciences



Matritech	
Nihon Kohden	
Ortho-Clinical Diagnostics	
Polartechnics	
Polymedco	
Qiagen	
Roche	
SDIX	
Sequenom	
Siemens	
Sienco	
Sysmex	
Takara Bio	
ThermoFisher	
Tosoh	
Wako	
Zycare/Alere	

# Methodology

This report is based on a combination of primary and secondary sources of information, including review of recent technical and business publications, manufacturer product



literature, industry analyst reports, and VPGMarketResearch's proprietary data files.

Contains 1,172 pages and 256 tables



## **Contents**

#### INTRODUCTION

#### **EXECUTIVE SUMMARY**

## RATIONALE FOR TESTING DECENTRALIZATION

- 1. Overview
- 2. Regulatory Trends
- 3. Economic Trends
- 4. Demographic Trends
- 5. Technological Trends
- 6. Social Trends
- 7. Quality of Care
- 8. Defensive Medicine
- 9. Quality Control Issues

## **WORLDWIDE MARKET AND TECHNOLOGY OVERVIEW**

- A. Major Routine Chemistry Tests
  - 1. Albumin
  - 2. Alkaline Phosphatase
  - 3. ALT/SGPT
  - 4. Ammonia
  - 5. Amylase
  - 6. AST/SGOT
  - 7. Bilirubin
  - 8. Blood Gases
  - 9. Blood Urea Nitrogen (BUN)
  - 10. Calcium
  - 11. Cholesterol
  - 12. Cholinesterase
  - 13. Creatinine
  - 14. Electrolytes
  - a. Carbon Dioxide/Bicarbonate
  - b. Chloride
  - c. Potassium
  - d. Sodium



- 15. Ferritin
- 16. Follate/Folic Acid
- 17. Fructosamine
- 18. Gamma-Glutamyl Transpeptidase (GGT)
- 19. Glucose
- 20. High Density Lipoprotein (HDL)
- 21. Iron
- 22. Lactate Dehydrogenase (LDH)
- 23. Magnesium
- 24. Phosphorus
- 25. Protein
- 26. Triglycerides
- 27. Troponin
- 28. Uric Acid
- 29. Urinalysis
- 30. Vitamin B12

## **INFECTIOUS DISEASE TESTS**

- 1. AIDS
- 2. Adenovirus
- 3. Campylobacter
- 4. Candida
- 5. Chlamydia
- 6. Clostridium Difficile
- 7. Cytomegalovirus
- 8. Enteroviruses
- 9. Epstein-Barr Virus
- 10. Gonorrhea
- 11. Helicobacter Pylori
- 12. Hepatitis
  - a. Hepatitis A
  - b. Hepatitis B
  - c. Hepatitis C
  - d. Hepatitis D
- 13. Herpes Simplex Virus
- 14. Human Herpes Virus-6 (HHV-6)
- 15. Influenza Viruses
- 16. Legionella



- 17. Lyme Disease
- 18. Measles (Rubeola)
- 19. Meningitis
- 20. Mononucleosis
- 21. Mumps
- 22. Mycoplasma
- 23. Papillomaviruses
- 24. Pneumonia
- 25. Respiratory Syncytial Virus (RSV)
- 26. Rheumatoid Arthritis
- 27. Rotavirus (Reovirus)
- 28. Rubella (German Measles)
- 29. Salmonellosis
- 30. Shigellosis
- 31. Staphylococcus Aureus
- 32. Streptococci
- 33. Syphilis

## **TUMOR MARKERS**

- 1. Alpha-Fetoprotein (AFP)
- 2. Carcinoembrionic Antigen (CEA)
- 3. Occult Blood
- 4. Prostatic Acid Phosphatase (PAP)
- 5. Prostate-Specific Antigen (PSA)

## MAJOR ROUTINE AND SPECIAL HEMATOLOGY TESTS

- 1. CBC Analysis
  - a. Hemoglobin Concentration
  - b. Hematocrit Determination
  - c. Red Blood Cell Count
  - d. Platelets

## **ENDOCRINE FUNCTION TESTS**

- 1. Cortisol
- 2. Follicle-Stimulating Hormone (FSH)
- 3. Gastrin



- 4. Human Chorionic Gonadotropin (HCG)
- 5. LH
- 6. Prolactin
- 7. T3
- 8. T3 Uptake
- 9. Free T3
- 10. Thyroxine (T4)
- 11. Free T4
- 12. TBG
- 13. TSH

## THERAPEUTIC DRUG MONITORING (TDM)

- 1. Overview
- 2. Carbamazepine
- 3. Digoxin
- 4. Gentamicin
- 5. Lidocaine
- 6. Lithium
- 7. Phenytoin/Dilantin
- 8. Procainamide
- 9. Quinidine
- 10. Theophylline
- 11. Valproic Acid

## **COAGULATION TESTS**

- 1. Introduction
- 2. Activated Partial Thromboplastin Time (APTT)
- 3. Alpha-2 Antiplasmin
- 4. Antithrombin III
- 5. Bleeding Time
- 6. D-Dimer
- 7. Factor VIII
- 8. Fibrin Degradation Products
- 9. Fibrinogen
- 10. Heparin
- 11. Proteins C and S
- 12. Prothrombin Time (PT)



## 13. Thrombin Time

#### **IMMUNOPROTEIN TESTS**

- 1. CRP
- 2. Immunoglobulins

## **DRUGS OF ABUSE**

- 1. Overview
- 2. Test Methodologies
- 3. Amphetamines
- 4. Barbiturates
- 5. Benzodiazepines
- 6. Cannabinoids/Marijuana
- 7. Cocaine
- 8. Lysergic Acid Diethylamide (LSD)
- 9. Methadone
- 10. Methaqualone
- 11. Opiates
- 12. Phencyclidine

## **INSTRUMENTATION**

1. Chemistry Analyzers Manufactured by:

Abaxis

Abbott

Alfa Wassermann

Awareness Technologies

Beckman Coulter/Danaher

bioMeriuex

Carolina Chemistries

Horiba

Inverness

Medica

**Nova Biomedical** 

**Ortho-Clinical Diagnostics** 

Polimedco

Randox



#### Roche

2. Hematology Analyzers Manufactured by:

Abbott

**Becton Dickinson** 

Beckman Coulter/Danaher

Biocode

**Drew-Scientific** 

Diesse Ves Matic

Horiba

Menarini

Nihon Kohden

Polymedco

Sysmex

3. Coagulation Analyzers Manufactured by:

Behnk Elektronik

Bio/Data

Cardiovascular Diagnostics

Diagnostica Stago

Helena Laboratories

Instrumentation Laboratory

**ITC** Hemochron

Roche

Siemens

Sysmex

**Teco Medical Instruments** 

Trinity Biotech

## **CURRENT AND EMERGING TECHNOLOGIES**

- 1. Monoclonal Antibodies
- 2. Immunoassays
  - a. Technological Principle
  - b. Enzyme Immunoassays (EIA)

Overview

**ELISA** 

**Dot Immunobinding Assays** 

Capillary Immunoassays

Particle-Membrane Capture Immunoassay

**Enzyme Amplification** 



c. Fluorescent Immunoassays

Fluorescent Polarization

Time-Resolved Pulse Fluorescence

d. Luminescence

Chemiluminescence

Bioluminescence

- e. Latex Agglutination
- f. Immunoprecipitation
- 3. Dry Chemistry
- 4. Biosensors
- 5. IT and Automation
- 6. Molecular Diagnostics
  - a. Technology Overview
  - b. Amplification Methods

Polymerase Chain Reaction

Ligase Chain Reaction

**Branched DNA** 

Q-Beta Replicase

Strand Displacement Activation

Self-Sustained Sequence Replicase

#### **CURRENT AND EMERGING TECHNOLOGIES**

#### U.S.A.

- A. Market Overview
  - 1. Business Environment
  - a. Health Care Expenditures
  - b. Cost Consciousness
  - c. Reimbursement
  - d. Industry Consolidation
  - e. Managed Care

PPO

**HMO** 

- f. Hospitals
- g. Admissions
- h. Length of Stay
- i. Industry Diversification
- j. Physician Demographics



- k. Aging Population
  - More Chronic Illness
  - Disease Incidence
  - Susceptibility to latrogenesis
  - Multiple Illnesses Cases
- I. Laboratory Regulations
- 2. Market Structure
  - a. Hospitals
  - b. Commercial/Private Laboratories
- B. Personal Testing
  - 1. Glucose Monitoring

Market and Technology Overview

**Invasive Testing** 

Non-Invasive Testing

Genetic Testing

- 2. Pregnancy Tests
- 3. Occult Blood Tests
- 4. Market Size and Growth
- C. Physician Offices/Group Practices
  - 1. Market Summary
  - 2. Market Structure
  - 3. Test Volume and Sales Forecasts
- D. Ancillary Hospital Locations
  - 1. Introduction
    - a. Emergency Departments
    - b. Operating Suites
    - c. Intensive Care Units
  - 2. Emergency Departments
    - a. Market Summary
    - b. Test volume and Sales Forecasts
  - 3. Operating and Recovery Suites
    - a. Market Summary
    - b. Test Volume and Sales Forecasts
  - 4. ICUs/CCUs
    - a. Market Summary
    - b. Test Volume and Sales Forecasts
- E. Cancer Clinics
  - 1. Introduction
  - 2. Market Summary



- 3. Test Volume and Sales Forecasts
- F. Ambulatory Care Centers
  - 1. Introduction
  - 2. Market Summary
  - 3. Market Structure
  - 4. Test Volume and Sales Forecasts
- G. Surgery Centers
  - 1. Introduction
  - 2. Market Summary
  - 3. Market Structure
  - 4. Test Volume and Sales Forecasts
- H. Nursing Homes
  - 1. Introduction
  - 2. Market Summary
  - 3. Market Structure
  - 4. Test Volume and Sales Forecasts
- I. Birth Centers
  - 1. Introduction
  - 2. Market Summary
  - 3. Market Structure
  - 4. Test Volume and Sales Forecasts
- J. Major Suppliers' Instrument Placements, Installed Base, Consumables Sales and Market Shares

#### MAJOR PRODUCT DEVELOPMENT OPPORTUNITIES

- A. Routine and Special Chemistry
- B. Microbiology/Infectious Diseases
- C. Hematology and Flow Cytometry
- D. Coagulation

## **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

## **COMPANY PROFILE**

Abbott

ADI/America Diagnostica

Agilent Technologies

Axis-Shield

Beckman Coulter/Danaher

**Becton Dickinson** 

Bio/Data

Biomerieux

Bio-Rad

Biosite/Inverness/Alere

Cepheid

Chrono-Log

Corgenix

Decode

Diadexus

Diagnocure



Diagnostica Stago/Trinity Biotech

Diamedix

Diasorin

Eiken Chemical

**EKF Diagnostics** 

Fujirebio/Innogenetics

Grifols

Helena Laboratories

Hologic/Gen-Probe

Horiba

Instrumentation Laboratory

International Technidyne/Nexus DX

Kreatech

Kyowa Medex

Lonza

Mackay Life Sciences

Matritech

Nihon Kohden

**Ortho-Clinical Diagnostics** 

**Polartechnics** 

Polymedco

Qiagen

Roche

**SDIX** 

Sequenom

Siemens

Sienco

Sysmex

Takara Bio

ThermoFisher/Life Technologies

Tosoh

Wako

Zycare/Alere



## **List Of Tables**

## **LIST OF TABLES**

Executive Summary Table I: All Decentralized Testing Markets, Diagnostics Sales

Forecasts by Market Segment

Executive Summary Table II: All Decentralized Testing Markets, Reagent Sales

Forecasts by Market Segment

Executive Summary Table III: All Decentralized Testing Markets, Instrument Sales

Forecasts by Market Segment

Major Companies Developing or Marketing Albumin Tests

Major Companies Developing or Marketing Alkaline Phosphatase Tests

Major Companies Developing or Marketing ALT/SGPT Tests

Major Companies Developing or Marketing Amylase Tests

Major Companies Developing or Marketing AST/SGOT Tests

Major Companies Developing or Marketing Bilirubin Tests

Major Companies Developing or Marketing Blood Gas Analyzers

Major Companies Developing or Marketing BUN Tests

Major Companies Developing or Marketing Calcium Tests

Major Companies Developing or Marketing Cholesterol Tests

Major Companies Developing or Marketing Creatinine Tests

Major Companies Developing or Marketing Electrolyte Tests

Major Companies Developing or Marketing Ferritin Tests

Major Companies Developing or Marketing GGT Tests

Major Companies Developing or Marketing Glucose Tests

Major Companies Developing or Marketing HDL Tests

Major Companies Developing or Marketing Iron Tests

Major Companies Developing or Marketing LDH Tests

Major Companies Developing or Marketing Magnesium Tests

Major Companies Developing or Marketing Phosphorus Tests

Major Companies Developing or Marketing Protein Tests

Major Companies Developing or Marketing Triglycerides Tests

Major Companies Developing or Marketing Uric Acid Tests

Major Companies Developing or Marketing Vitamin B-12/Folate Tests

Major Companies Developing or Marketing AIDS Tests

Major Companies Developing or Marketing Adenovirus Tests

Major Companies Developing or Marketing Campylobacter Tests

Major Companies Developing or Marketing Candida Tests

Major Companies Developing or Marketing CMV Tests



Major Companies Developing or Marketing EBV Tests

Major Companies Developing or Marketing Gonorrhea Tests

Major Companies Developing or Marketing Helicobacter Pylori Tests

Major Companies Developing or Marketing Hepatitis Tests

Major Companies Developing or Marketing Herpes Tests

Major Companies Developing or Marketing Influenza Tests

Major Companies Developing or Marketing Legionella Tests

Major Companies Developing or Marketing Lyme Disease Tests

Major Companies Developing or Marketing Measles Tests

Major Companies Developing or Marketing Meningitis Tests

Major Companies Developing or Marketing Mononucleosis Tests

Major Companies Developing or Marketing Mumps Tests

Major Companies Developing or Marketing Mycoplasma Tests

Major Companies Developing or Marketing Pneumonia Tests

Major Companies Developing or Marketing RSV Tests

Major Companies Developing or Marketing Rotavirus Tests

Major Companies Developing or Marketing Rubella Tests

Major Companies Developing or Marketing Salmonella Tests

Major Companies Developing or Marketing Shigella Tests

Major Companies Developing or Marketing Streptococci Tests

Major Companies Developing or Marketing Syphilis Tests

Major Companies Developing or Marketing AFP Tests

Major Companies Developing or Marketing CEA Tests

Major Companies Developing or Marketing Occult Blood Tests

Major Companies Developing or Marketing Prostatic Acid Phosphatase Tests

Major Companies Developing or Marketing PSA Tests

Major Companies Developing or Marketing FSH Tests

Major Companies Developing or Marketing HCG Tests

Major Companies Developing or Marketing LH Tests

Major Companies Developing or Marketing Prolactin Tests

Major Companies Developing or Marketing T3 Tests

Major Companies Developing or Marketing T4 Tests

Major Companies Developing or Marketing TSH Tests

Major Companies Developing or Marketing TDM Tests

Major Companies Developing or Marketing Digoxin Tests

Major Companies Developing or Marketing Lithium Tests

Major Companies Developing or Marketing Phenytoin/Dilantin Tests

Major Companies Developing or Marketing Theophylline Tests

Major Companies Developing or Marketing Valproic Acid Tests



Major Companies Developing or Marketing APTT Tests

Major Companies Developing or Marketing Alpha-2 Antiplasmin Tests

Major Companies Developing or Marketing Antithrombin III Tests

Major Companies Developing or Marketing Bleeding Time Tests

Major Companies Developing or Marketing D-Dimer Tests

Major Companies Developing or Marketing Factor Assays Tests

Major Companies Developing or Marketing Fibrin Degradation Product Tests

Major Companies Developing or Marketing Fibrinogen Tests

Major Companies Developing or Marketing Heparin Tests

Major Companies Developing or Marketing Protein C Tests

Major Companies Developing or Marketing Protein S Tests

Major Companies Developing or Marketing PT Tests

Major Companies Developing or Marketing Thrombin Time Tests

Major Companies Developing or Marketing CRP Tests

Major Companies Developing or Marketing DRUGS OF ABUSE Tests

U.S.A., Personal Testing Total Diagnostic Market Forecast

U.S.A., Physician Offices/Group Practices Total Diagnostic Sales Forecast by Market Segment

U.S.A., Physician Offices/Group Practices Reagent Sales Forecast by Market Segment

U.S.A., Physician Offices/Group Practices Instrument Sales Forecast by Market Segment

U.S.A., Office-Based Physicians Forecast by Practice Type

U.S.A., Physician Offices/Group Practices Forecast by Type

U.S.A., Physician Office/Group Practice Laboratories Forecast by Practice Size

U.S.A., Physician Offices/Group Practices Routine and Special Chemistry Test Volume Forecast

U.S.A., Physician Offices Laboratories Major Infectious Disease Test Volume Forecast

U.S.A., Physician Offices/Group Practice Microbiology Test Volume Forecast by Market Segment

U.S.A., Physician Offices/Group Practices Routine Hematology Test Volume Forecast

U.S.A., Physician Offices Laboratories Flow Cytometry and Special Hematology Test Volume Forecast

U.S.A., Physician Offices/Group Practices Coagulation Test Volume Forecast

U.S.A., Physician Offices/Group Practices TDM Test Volume Forecast

U.S.A., Physician Offices/Group Practices Endocrine Function Test Volume Forecast

U.S.A., Physician Offices/Group Practices Major Tumor Marker Test Volume Forecast

U.S.A., Physician Offices/Group Practices Immunoprotien Test Volume Forecast

U.S.A., Physician Offices/Group Practices drugs of abuse Test Volume Forecast

U.S.A., Physician Offices/Group Practices Routine and Special Chemistry Test Volume



## Forecast by Practice Type

- U.S.A., Physician Offices/Group Practices Microbiology/Infectious Disease Test Volume Forecast by Practice Type
- U.S.A., Physician Offices/Group Practices Hematology and Flow Cytometry Test Volume Forecast by Practice Type
- U.S.A., Physician Offices/Group Practices TDM Test Volume Forecast by Practice Type U.S.A., Physician Offices/Group Practices Endocrine Function Test Volume Forecast by Practice Type
- U.S.A., Physician Offices/Group Practices tumor markers Test Volume Forecast by Practice Type
- U.S.A., Physician Offices/Group Practices Immunoprotein Test Volume Forecast by Practice Type
- U.S.A., Physician Offices/Group Practices Drugs of Abuse Test Volume Forecast by Practice Type
- U.S.A., Physician Offices/Group Practices Routine and Special Chemistry Reagent Market Forecast by Test
- U.S.A., Physician Offices Laboratories Major Infectious Disease Reagent Market Forecast by Test
- U.S.A., Physician Offices/Group Practices Microbiology Reagent Market Forecast by Market Segment
- U.S.A., Physician Offices/Group Practices Hematology and Flow Cytometry Consumables Market Forecast
- U.S.A., Physician Offices/Group Practices TDM Reagent Market Forecast by Test
- U.S.A., Physician Offices/Group Practices Endocrine Function Reagent Market Forecast by Test
- U.S.A., Physician Offices/Group Practices Major Tumor Marker Reagent Market Forecast by Test
- U.S.A., Physician Offices/Group Practices Coagulation Reagent Market Forecast
- U.S.A., Physician Offices/Group Practices Immunoprotein Reagent Market Forecast by Test
- U.S.A., Physician Offices/Group Practices drugs of abuse Reagent Market Forecast by Test
- U.S.A., AncillaryHospital Locations Estimated Number
- U.S.A., AncillaryHospital Locations Annual Utilization
- U.S.A., Hospital Emergency Departments Total Diagnostics Sales Forecast by Market Segment
- U.S.A., Hospital Emergency Departments Reagent Sales Forecast by Market Segment
- U.S.A., Hospital Emergency Departments Instrument Sales Forecast by Market Segment



- U.S.A., Hospital Emergency Departments Routine and Special Chemistry Test Volume Forecast
- U.S.A., Hospital Emergency Departments Profiles, Panels and Individual Tests
- U.S.A., Hospital Emergency Departments DRUGS OF ABUSE Test Volume Forecast
- U.S.A., Hospital Emergency Departments Routine Hematology Test Volume Forecast
- U.S.A., Hospital Emergency Departments Coagulation Test Volume Forecast
- U.S.A., Hospital Emergency Departments Selected Infectious Disease Test Volume Forecast
- U.S.A., Hospital Emergency Departments Routine and Special Chemistry Reagent Market Forecast by Test
- U.S.A., Hospital Emergency Departments DRUGS OF ABUSE Reagent Market Forecast by Test
- U.S.A., Hospital Emergency Departments Hematology Reagent Market Forecast
- U.S.A., Hospital Emergency Departments Coagulation Reagent Market Forecast
- U.S.A., Hospital Emergency Departments Selected Infectious Disease Reagent Market Forecast by Test
- U.S.A., Hospital Operating and Recovery Suites Total Diagnostics Sales Forecast by Market Segment
- U.S.A., Hospital Operating and Recovery Suites Reagent Sales Forecast by Market Segment
- U.S.A., Hospital Operating and Recovery Suites Instrument Sales Forecast By Market Segment
- U.S.A., Hospital Operating and Recovery Suites Routine and Special Chemistry Reagent Test Volume Forecast
- U.S.A., Hospital Operating and Recovery Suites Routine Hematology Test Volume Forecast
- U.S.A., Hospital Operating and Recovery Suites Coagulation Test Volume Forecast
- U.S.A., Hospital Operating and Recovery Suites Routine and Special Chemistry Reagent Market Forecast by Test
- U.S.A., Hospital Operating and Recovery Suites Hematology Reagent Market Forecast
- U.S.A., Hospital Operating and Recovery Suites Coagulation Reagent Market Forecast
- U.S.A., Hospital ICUs/CCUs Total Diagnostics Sales Forecast by Market Segment
- U.S.A., Hospital ICUs/CCUs Reagent Sales Forecast by Market Segment
- U.S.A., Hospital ICUs/CCUs Instrument Sales Forecast by Market Segment
- U.S.A., Hospital ICUs/CCUs Routine and Special Chemistry Test Volume Forecast
- U.S.A., Hospital ICUs/CCUs Routine Hematology Test Volume Forecast
- U.S.A., Hospital ICUs/CCUs Coagulation Test Volume Forecast
- U.S.A., Hospital ICUs/CCUs Routine and Special Chemistry Reagent Market Forecast by Test



- U.S.A., Hospital ICUs/CCUs Hematology Reagent Market Forecast
- U.S.A., Hospital ICUs/CCUs Coagulation Reagent Market Forecast
- U.S.A., Cancer Clinics Total Diagnostics Sales Forecast by Market Segment
- U.S.A., Cancer Clinics Reagent Sales Forecast by Market Segment
- U.S.A., Cancer Clinics Instrument Sales Forecast by Market Segment
- U.S.A., Cancer Clinics Major Tumor Markers Test Volume Forecast
- U.S.A., Cancer Clinics Routine and Special Chemistry Test Volume Forecast
- U.S.A., Cancer Clinics Routine Hematology/Flow Cytometry Test Volume Forecast
- U.S.A., Cancer Clinics Endocrine Function Test Volume Forecast
- U.S.A., Cancer Clinics Coagulation Test Volume Forecast
- U.S.A., Cancer Clinics Major Tumor Marker Sales Forecast by Test
- U.S.A., Cancer Clinics Routine and Special Chemistry Reagent Market Forecast by Test
- U.S.A., Cancer Clinics Hematology and Flow Cytometry Reagent Market Forecast
- U.S.A., Cancer Clinics Endocrine Function Reagent Market Forecast
- U.S.A., Cancer Clinics Coagulation Reagent Market Forecast
- U.S.A., Ambulatory Care Centers Total Diagnostics Sales Forecast by Market Segment
- U.S.A., Ambulatory Care Centers Reagent Sales Forecast by Market Segment
- U.S.A., Ambulatory Care Centers Instrument Sales Forecast by Market Segment
- U.S.A., Ambulatory Care Centers Estimated Number of Facilities and Patient Visits
- U.S.A., Ambulatory Care Centers Most Frequent Diagnoses
- U.S.A., Ambulatory Care Centers Routine and Special Chemistry Test Volume Forecast
- U.S.A., Ambulatory Care Centers Routine Hematology Test Volume Forecast
- U.S.A., Ambulatory Care Centers Microbiology and Serology Test Volume Forecast
- U.S.A., Ambulatory Care Centers Drugs of Abuse Test Volume Forecast
- U.S.A., Ambulatory Care Centers Coagulation Test Volume Forecast
- U.S.A., Ambulatory Care Centers Routine and Special Chemistry Reagent Market Forecast by Test
- U.S.A., Ambulatory Care Centers Drugs of Abuse Reagent Market Forecast by Test
- U.S.A., Ambulatory Care Centers Hematology Reagent Market Forecast
- U.S.A., Ambulatory Care Centers Microbiology and Serology Reagent Market Forecast by Test
- U.S.A., Ambulatory Care Centers Coagulation Reagent Market Forecast
- U.S.A., Surgery Centers Total Diagnostics Sales Forecast by Market Segment
- U.S.A., Surgery Centers Reagent Sales Forecast by Market Segment
- U.S.A., Surgery Centers Instrument Sales Forecast by Market Segment
- U.S.A., Surgery Centers Most Frequently Performed Procedures
- U.S.A., Surgery Centers Routine and Special Chemistry Test Volume Forecast
- U.S.A., Surgery Centers Routine Hematology Test Volume Forecast



- U.S.A., Surgery Centers Coagulation Test Volume Forecast
- U.S.A., Surgery Centers Microbiology and Serology Test Volume Forecast
- U.S.A., Surgery Centers Routine and Special Chemistry Reagent Market Forecast by Test
- U.S.A., Surgery Centers Hematology Consumable Market Forecast
- U.S.A., Surgery Centers Coagulation Reagent Market Forecast
- U.S.A., Nursing Homes Total Diagnostics Sales Forecast by Market Segment
- U.S.A., Nursing Homes Reagent Sales Forecast by Market Segment
- U.S.A., Nursing Homes Instrument Sales Forecast by Market Segment
- U.S.A., Nursing Homes Estimated Number of Facilities, Beds and Occupancy Rate
- U.S.A., Nursing Homes Routine and Special Chemistry Test Volume Forecast
- U.S.A., Nursing Homes Coagulation Test Volume Forecast
- U.S.A., Nursing Homes Routine Hematology Test Volume Forecast
- U.S.A., Nursing Homes Routine and Special Chemistry Reagent Market Forecast by Test
- U.S.A., Nursing Homes Coagulation Reagent Market Forecast
- U.S.A., Nursing Homes Hematology Reagent Market Forecast
- U.S.A., Birth Centers Total Diagnostics Sales Forecast by Market Segment
- U.S.A., Birth Centers Reagent Sales Forecast by Market Segment
- U.S.A., Birth Centers Instrument Sales Forecast by Market Segment
- U.S.A., Birth Centers Facilities, Patient Visits, and Births
- U.S.A., Birth Centers Routine and Special Chemistry Test Volume Forecast
- U.S.A., Birth Centers Profiles, Panels and Individual Tests
- U.S.A., Birth Centers Microbiology and Serology Test Volume Forecast
- U.S.A., Birth Centers Coagulation Test Volume Forecast
- U.S.A., Birth Centers Routine Hematology Test Volume Forecast
- U.S.A., Birth Centers Routine and Special Chemistry Reagent Market Forecast by Test
- U.S.A., Birth Centers Microbiology and Serology Testing Market Forecast
- U.S.A., Birth Centers Hematology Reagent Market Forecast
- U.S.A., Birth Centers Coagulation Reagent Market Forecast
- U.S.A., Major Suppliers of Clinical Chemistry Diagnostics Products, Estimated Sales and Market Shares
- U.S.A., Major Suppliers of Clinical Chemistry Reagents, Estimated Market Shares
- U.S.A., Major Suppliers of Clinical Chemistry Analyzers, Estimated Market Shares
- U.S.A., Major Suppliers of Immunodiagnostic Products, Estimated Market Shares
- U.S.A., Major Suppliers of Immunoassay Reagents, Estimated Market Shares
- U.S.A., Major Suppliers of Immunoassay Analyzers, Estimated Market Shares
- U.S.A., AIDS Testing Market Estimated Market Shares of Major Suppliers
- U.S.A., Chlamydia Testing Market Estimated Market Shares of Major Suppliers



- U.S.A., CMV Testing Market Estimated Market Shares of Major Suppliers
- U.S.A., Gonorrhea Testing Market Estimated Market Shares of Major Suppliers
- U.S.A., Helicobacter Pylori Testing Market Estimated Market Shares of Major Suppliers
- U.S.A., Hepatitis Testing Market Estimated Market Shares of Major Suppliers
- U.S.A., Herpes Testing Market Estimated Market Shares of Major Suppliers
- U.S.A., Influenza Testing Market Estimated Market Shares of Major Suppliers
- U.S.A., Lyme Disease Testing Market Estimated Market Shares of Major Suppliers
- U.S.A., Mononucleosis Testing Market Estimated Market Shares of Major Suppliers
- U.S.A., Rubella Testing Market Estimated Market Shares of Major Suppliers
- U.S.A., Streptococci Testing Market Estimated Market Shares of Major Suppliers
- U.S.A., Syphilis Testing Market Estimated Market Shares of Major Suppliers
- U.S.A., AFP Testing Market by Major Suppliers
- U.S.A., CA 15-3/27-29 Testing Market by Major Suppliers
- U.S.A., CA 19-9 Testing Market by Major Suppliers
- U.S.A., CEA Testing Market by Major Suppliers
- U.S.A., PAP Testing Market by Major Suppliers
- U.S.A., PSA Testing Market by Major Suppliers
- U.S.A., Hematology Analyzers Estimated Placements and Installed Base
- U.S.A., Flow Cytometers Estimated Placements and Installed Base
- U.S.A., Hematology Diagnostics Market Estimated Market Shares of Major Suppliers
- U.S.A., Hematology Instrument Market Estimated Market Shares of Major Suppliers
- U.S.A., Hematology Consumable Market Estimated Market Shares of Major Suppliers
- U.S.A., Flow Cytometry Diagnostics Market Estimated Market Shares of Major Suppliers
- U.S.A., Flow Cytometry Consumable Market Estimated Market Shares of Major Suppliers
- U.S.A., Flow Cytometry Instruments Market Estimated Market Shares of Major Suppliers
- U.S.A., Major Suppliers of Coagulation Diagnostic Products Estimated Market Shares of Major Suppliers



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