

# **U.S. Medical Device Testing Services Market Size, Share & Trends Analysis Report By Service (Biocompatibility Tests, Chemistry Test, Microbiology & Sterility Testing, Package Validation), By Phase (Preclinical, Clinical), And Segment Forecasts, 2025 - 2033**

<https://marketpublishers.com/r/UADC9DDE97E4EN.html>

Date: September 2025

Pages: 120

Price: US\$ 5,950.00 (Single User License)

ID: UADC9DDE97E4EN

## **Abstracts**

### **U.S. Medical Device Testing Services Market Summary**

The U.S. medical device testing services market size was estimated at USD 2.23 billion in 2024 and is projected to reach USD 5.09 billion, growing at a CAGR of 9.66% from 2025 to 2033. The market is driven by a strong regulatory framework, rapid technological innovations, and the increasing complexity of devices entering the market.

Other factors contributing to market growth are an aging population, a rise in chronic diseases, and a robust innovation pipeline. Manufacturers are increasingly outsourcing testing functions to reduce compliance costs, navigate regulatory complexities, and accelerate product launches. Besides, the stringent safety and performance standards set by the U.S. Food and Drug Administration (FDA) and international compliance requirements such as ISO and IEC standards fuel demand for specialized third-party testing services. These services are essential for ensuring regulatory compliance, mitigating risks, and accelerating the time-to-market for manufacturers, particularly in high-growth sectors like minimally invasive surgical tools, implantable devices, diagnostic imaging systems, and wearable technologies.

In addition, the rising complexity in device design due to advanced materials, miniaturization, and the integration of artificial intelligence (AI), Internet of Things (IoT),

and wireless technologies has expanded testing requirements to encompass cybersecurity validation, software performance testing, usability engineering, and interoperability assessments. Besides, the surge in clinical trials for both novel and next-generation devices has increased the demand for capabilities in electrical safety, electromagnetic compatibility (EMC), mechanical durability, microbiological safety, and biocompatibility evaluation. Also, the current testing processes cover multiple stages, including feasibility studies, performance verification, and post-market surveillance, ensuring product efficacy and patient safety.

## U.S. Medical Device Testing Services Market Report Segmentation

This report forecasts revenue growth at the country level and provides an analysis of the latest industry trends in each of the sub-segments from 2021 to 2033. For this study, Grand View Research has segmented the U.S. medical device testing services market report based on service and phase:

Service Outlook (Revenue, USD Million, 2021 - 2033)

Biocompatibility Tests

Cardiovascular Device's Biocompatibility Tests

Orthopedic Device's Biocompatibility Tests

Dental Implant Devices' Biocompatibility Tests

Dermal Filler's Biocompatibility Tests

General Surgery Implantation Devices Biocompatibility Tests

Neurosurgical Implantation Devices Biocompatibility Tests

Ophthalmic Implantation Device's Biocompatibility Tests

Others

Chemistry Test

Chemical characterization (E&L)

- Analytical method development and validation
- Toxicological Risk Assessment and consulting
- Microbiology & Sterility Test
- Bioburden Determination
- Pyrogen & Endotoxin Testing
- Sterility Test & Validation
- Antimicrobial Testing
- Others
- Package Validation
- Phase Outlook (Revenue, USD Million, 2021 - 2033)
- Preclinical
  - Large animal research
    - Biocompatibility Tests
    - Chemistry Test
    - Microbiology & Sterility Test
  - Small animal research
    - Biocompatibility Tests
    - Chemistry Test
    - Microbiology & Sterility Test

## Clinical

**This report can be delivered to the clients within 2 Business Days**

## Contents

### **CHAPTER 1. RESEARCH METHODOLOGY AND SCOPE**

- 1.1. Market Segmentation & Scope
- 1.2. Segment Definitions
  - 1.2.1. Service
  - 1.2.2. Phase
- 1.3. Research Methodology
- 1.4. Information Procurement
  - 1.4.1. Purchased Database
  - 1.4.2. GVR's Internal Database
  - 1.4.3. Secondary Sources
  - 1.4.4. Primary Research
- 1.5. Information Or Data Analysis
  - 1.5.1. Data Analysis Models
- 1.6. Market Formulation & Validation
- 1.7. Model Details
  - 1.7.1. Commodity Flow Analysis
  - 1.7.2. Parent Market Analysis
- 1.8. List Of Secondary Sources
- 1.9. List Of Abbreviations
- 1.10. Objectives

### **CHAPTER 2. EXECUTIVE SUMMARY**

- 2.1. Market Outlook
- 2.2. Segment Outlook
- 2.3. Competitive Insights

### **CHAPTER 3. U.S. MEDICAL DEVICE TESTING SERVICES MARKET VARIABLES, TRENDS & SCOPE**

- 3.1. Market Lineage Outlook
  - 3.1.1. Parent Market Outlook
  - 3.1.2. Related/Ancillary Market Outlook
- 3.2. Market Dynamics
  - 3.2.1. Market Driver Analysis
    - 3.2.1.1. Complexity in Product Design Of Medical Device Testing Services

- 3.2.1.2. Intense Competition in Medical Device Industry
- 3.2.1.3. Increasing number of smaller Players lacking in-house testing capabilities
- 3.2.1.4. Strict Approval Norms
- 3.2.2. Market Restraint Analysis
  - 3.2.2.1. Legal and Regulatory Issues
  - 3.2.2.2. Delays in contractual obligations
- 3.2.3. Market Challenges
- 3.2.4. Market Opportunities
- 3.3. Technology Landscape
- 3.4. Pricing Model Analysis
- 3.5. Tariff Impact Analysis
- 3.6. Value Chain Analysis
  - 3.6.1. Supply Trends
  - 3.6.2. Demand Trends
- 3.7. Market Analysis Tools
  - 3.7.1. Porter's Five Force Analysis
  - 3.7.2. PESTEL by SWOT Analysis
  - 3.7.3. COVID-19 Impact Analysis

## **CHAPTER 4. U.S. MEDICAL DEVICE TESTING SERVICES MARKET: SERVICE ESTIMATES & TREND ANALYSIS**

- 4.1. U.S. Medical Device Testing Services Market, By Service: Segment Dashboard
- 4.2. U.S. Medical Device Testing Services Market, By Service: Movement Analysis
- 4.3. U.S. Medical Device Testing Services Market Estimates & Forecasts, By Service, 2021 - 2033
- 4.4. Biocompatibility Tests
  - 4.4.1. Biocompatibility Tests Market Estimates and Forecasts, 2021 - 2033 (USD Million)
  - 4.4.2. Cardiovascular Device's Biocompatibility Tests
    - 4.4.2.1. Cardiovascular Device's Biocompatibility Tests Market Estimates and Forecasts, 2021 - 2033 (USD Million)
  - 4.4.3. Orthopedic Device's Biocompatibility Tests
    - 4.4.3.1. Orthopedic Device's Biocompatibility Tests Market Estimates and Forecasts, 2021 - 2033 (USD Million)
  - 4.4.4. Dental Implant Devices' Biocompatibility Tests
    - 4.4.4.1. Dental Implant Devices' Biocompatibility Tests Market Estimates and Forecasts, 2021 - 2033 (USD Million)
  - 4.4.5. Dermal Filler's Biocompatibility Tests

4.4.5.1. Dermal Filler's Biocompatibility Tests Market Estimates and Forecasts, 2021 - 2033 (USD Million)

4.4.6. General Surgery Implantation Devices Biocompatibility Tests

4.4.6.1. General Surgery Implantation Devices Biocompatibility Tests Market Estimates and Forecasts, 2021 - 2033 (USD Million)

4.4.7. Neurosurgical Implantation Devices Biocompatibility Tests

4.4.7.1. Neurosurgical Implantation Devices Biocompatibility Tests Market Estimates and Forecasts, 2021 - 2033 (USD Million)

4.4.8. Ophthalmic Implantation Device's Biocompatibility Tests

4.4.8.1. Ophthalmic Implantation Device's Biocompatibility Tests Market Estimates and Forecasts, 2021 - 2033 (USD Million)

4.4.9. Others

4.4.9.1. Others Market Estimates and Forecasts, 2021 - 2033 (USD Million)

4.5. Chemistry Test

4.5.1. Chemistry Test Market Estimates and Forecasts, 2021 - 2033 (USD Million)

4.5.2. Chemical characterization (E&L)

4.5.2.1. Chemical Characterization (E&L) Market Estimates and Forecasts, 2021 - 2033 (USD Million)

4.5.3. Analytical method development and validation

4.5.3.1. Analytical Method Development and Validation Market Estimates and Forecasts, 2021 - 2033 (USD Million)

4.5.4. Toxicological Risk Assessment and consulting

4.5.4.1. Toxicological Risk Assessment and Consulting Market Estimates and Forecasts, 2021 - 2033 (USD Million)

4.6. Microbiology & Sterility Testing

4.6.1. Microbiology & Sterility Testing Market Estimates and Forecasts, 2021 - 2033 (USD Million)

4.6.2. Bioburden Determination

4.6.2.1. Bioburden Determination Market Estimates and Forecasts, 2021 - 2033 (USD Million)

4.6.3. Pyrogen & Endotoxin Testing

4.6.3.1. Pyrogen & Endotoxin Testing Market Estimates and Forecasts, 2021 - 2033 (USD Million)

4.6.4. Sterility Test & Validation

4.6.4.1. Sterility Test & Validation Market Estimates and Forecasts, 2021 - 2033 (USD Million)

4.6.5. Antimicrobial Testing

4.6.5.1. Antimicrobial Testing Market Estimates and Forecasts, 2021 - 2033 (USD Million)

#### 4.6.6. Others

4.6.6.1. Others Market Estimates and Forecasts, 2021 - 2033 (USD Million)

#### 4.7. Package Validation

4.7.1. Package Validation Market Estimates and Forecasts, 2021 - 2033 (USD Million)

### **CHAPTER 5. U.S. MEDICAL DEVICE TESTING SERVICES MARKET: PHASE ESTIMATES & TREND ANALYSIS**

5.1. U.S. Medical Device Testing Services Market, By Phase: Segment Dashboard

5.2. U.S. Medical Device Testing Services Market, By Phase: Movement Analysis

5.3. U.S. Medical Device Testing Services Market Estimates & Forecasts, By Phase, 2021 - 2033

#### 5.4. Preclinical

5.4.1. Preclinical Market Estimates and Forecasts, 2021 - 2033 (USD Million)

##### 5.4.2. Small Animals

5.4.2.1. Small Animals Market Estimates and Forecasts, 2021 - 2033 (USD Million)

##### 5.4.2.2. Biocompatibility Tests

5.4.2.2.1. Biocompatibility Tests Market Estimates and Forecasts, 2021 - 2033 (USD Million)

##### 5.4.2.3. Chemistry Tests

5.4.2.3.1. Chemistry Tests Market Estimates and Forecasts, 2021 - 2033 (USD Million)

##### 5.4.2.4. Microbiology & Sterility Tests

5.4.2.4.1. Microbiology & Sterility Tests Market Estimates and Forecasts, 2021 - 2033 (USD Million)

##### 5.4.3. Large Animals

5.4.3.1. Large Animals Market Estimates and Forecasts, 2021 - 2033 (USD Million)

##### 5.4.3.2. Biocompatibility Tests

5.4.3.2.1. Biocompatibility Tests Market Estimates and Forecasts, 2021 - 2033 (USD Million)

##### 5.4.3.3. Chemistry Tests

5.4.3.3.1. Chemistry Tests Market Estimates and Forecasts, 2021 - 2033 (USD Million)

##### 5.4.3.4. Microbiology & Sterility Tests

5.4.3.4.1. Microbiology & Sterility Tests Market Estimates and Forecasts, 2021 - 2033 (USD Million)

##### 5.4.4. Others

5.4.4.1. Others Market Estimates and Forecasts, 2021 - 2033 (USD Million)

#### 5.5. Clinical

### 5.5.1. Clinical Market Estimates and Forecasts, 2021 - 2033 (USD Million)

## **CHAPTER 6. COMPETITIVE LANDSCAPE**

### 6.1. Participant Categorization

### 6.2. Market Position Analysis, 2024 (Heat Map Analysis)

### 6.3. Company Profiles

#### 6.3.1. SGS SA

##### 6.3.1.1. Company Overview

##### 6.3.1.2. Financial Performance

##### 6.3.1.3. Service Benchmarking

##### 6.3.1.4. Strategic Initiatives

#### 6.3.2. Laboratory Corporation of America Holdings

##### 6.3.2.1. Company Overview

##### 6.3.2.2. Financial Performance

##### 6.3.2.3. Service Benchmarking

##### 6.3.2.4. Strategic Initiatives

#### 6.3.3. Nelson Laboratories, LLC

##### 6.3.3.1. Company Overview

##### 6.3.3.2. Financial Performance

##### 6.3.3.3. Service Benchmarking

##### 6.3.3.4. Strategic Initiatives

#### 6.3.4. T?V S?D

##### 6.3.4.1. Company Overview

##### 6.3.4.2. Financial Performance

##### 6.3.4.3. Service Benchmarking

##### 6.3.4.4. Strategic Initiatives

#### 6.3.5. Charles River Laboratories

##### 6.3.5.1. Company Overview

##### 6.3.5.2. Financial Performance

##### 6.3.5.3. Service Benchmarking

##### 6.3.5.4. Strategic Initiatives

#### 6.3.6. Element Minnetonka

##### 6.3.6.1. Company Overview

##### 6.3.6.2. Financial Performance

##### 6.3.6.3. Service Benchmarking

##### 6.3.6.4. Strategic Initiatives

#### 6.3.7. Eurofins Scientific

##### 6.3.7.1. Company Overview

- 6.3.7.2. Financial Performance
- 6.3.7.3. Service Benchmarking
- 6.3.7.4. Strategic Initiatives
- 6.3.8. Pace Analytical Services LLC
  - 6.3.8.1. Company Overview
  - 6.3.8.2. Financial Performance
  - 6.3.8.3. Service Benchmarking
  - 6.3.8.4. Strategic Initiatives
- 6.3.9. Intertek Group Plc
  - 6.3.9.1. Company Overview
  - 6.3.9.2. Financial Performance
  - 6.3.9.3. Service Benchmarking
  - 6.3.9.4. Strategic Initiatives
- 6.3.10. North America Science Associates Inc. (NAMSA)
  - 6.3.10.1. Company Overview
  - 6.3.10.2. Financial Performance
  - 6.3.10.3. Service Benchmarking
  - 6.3.10.4. Strategic Initiatives

## List Of Tables

### LIST OF TABLES

Table 1 List of Secondary Sources

Table 2 List of Abbreviations

Table 3 U.S. Medical Device Testing Services Market Estimates and Forecasts, by Service, 2021 - 2033 (USD Million)

Table 4 U.S. Medical Device Testing Services Market Estimates and Forecasts, by Phase, 2021 - 2033 (USD Million)

## List Of Figures

### LIST OF FIGURES

- Fig. 1 Market research process
- Fig. 2 Information procurement
- Fig. 3 Primary research pattern
- Fig. 4 Market research approaches
- Fig. 5 Market formulation & validation
- Fig. 6 Commodity flow analysis
- Fig. 7 Value-chain-based sizing & forecasting
- Fig. 8 QFD model sizing & forecasting
- Fig. 9 Bottom-up approach
- Fig. 10 Market snapshot
- Fig. 11 Segment snapshot 1
- Fig. 12 Segment snapshot 2
- Fig. 13 Competitive landscape snapshot
- Fig. 14 Parent market outlook, 2024 (USD Billion)
- Fig. 15 Ancillary market outlook, 2024 (USD Billion)
- Fig. 16 U.S. Medical Device Testing Services Market Dynamics
- Fig. 17 Porter's five forces analysis
- Fig. 18 PESTEL analysis
- Fig. 19 U.S. Medical Device Testing Services Market: Service Outlook and Key Takeaways
- Fig. 20 U.S. Medical Device Testing Services Market: Service Movement Analysis
- Fig. 21 Biocompatibility Tests Market Estimates and Forecasts, 2021 - 2033 (USD Million)
- Fig. 22 Cardiovascular Device's Biocompatibility Tests Market Estimates and Forecasts, 2021 - 2033 (USD Million)
- Fig. 23 Orthopedic Device's Biocompatibility Tests Market Estimates and Forecasts, 2021 - 2033 (USD Million)
- Fig. 24 Dental Implant Devices' Biocompatibility Tests Market Estimates and Forecasts, 2021 - 2033 (USD Million)
- Fig. 25 Dermal Filler's Biocompatibility Tests Market Estimates and Forecasts, 2021 - 2033 (USD Million)
- Fig. 26 General Surgery Implantation Devices Biocompatibility Tests Market Estimates and Forecasts, 2021 - 2033 (USD Million)
- Fig. 27 Neurosurgical Implantation Devices Biocompatibility Tests Market Estimates and Forecasts, 2021 - 2033 (USD Million)

Fig. 28 Ophthalmic Implantation Device's Biocompatibility Tests Market Estimates and Forecasts, 2021 - 2033 (USD Million)

Fig. 29 Others Market Estimates and Forecasts, 2021 - 2033 (USD Million) Market Estimates and Forecasts, 2021 - 2033 (USD Million)

Fig. 30 Chemistry Test Market Estimates and Forecasts, 2021 - 2033 (USD Million) Market Estimates and Forecasts, 2021 - 2033 (USD Million)

Fig. 31 Chemical Characterization (E&L) Market Estimates and Forecasts, 2021 - 2033 (USD Million)

Fig. 32 Analytical Method Development and Validation Market Estimates and Forecasts, 2021 - 2033 (USD Million)

Fig. 33 Toxicological Risk Assessment and Consulting Market Estimates and Forecasts, 2021 - 2033 (USD Million)

Fig. 34 Microbiology & Sterility Test Market Estimates and Forecasts, 2021 - 2033 (USD Million)

Fig. 35 Bioburden Determination Market Estimates and Forecasts, 2021 - 2033 (USD Million)

Fig. 36 Pyrogen & Endotoxin Testing Market Estimates and Forecasts, 2021 - 2033 (USD Million)

Fig. 37 Sterility Test & Validation Market Estimates and Forecasts, 2021 - 2033 (USD Million)

Fig. 38 Antimicrobial Testing Market Estimates and Forecasts, 2021 - 2033 (USD Million)

Fig. 39 Others Market Estimates and Forecasts, 2021 - 2033 (USD Million)

Fig. 40 Package Validation Market Estimates and Forecasts, 2021 - 2033 (USD Million)

Fig. 41 U.S. Medical Device Testing Services Market: Phase Outlook and Key Takeaways

Fig. 42 U.S. Medical Device Testing Services Market: Phase Movement Analysis

Fig. 43 Preclinical Market Estimates and Forecasts, 2021 - 2033 (USD Million)

Fig. 44 Large Animal Research Market Estimates and Forecasts, 2021 - 2033 (USD Million)

Fig. 45 Biocompatibility Tests Market Estimates and Forecasts, 2021 - 2033 (USD Million)

Fig. 46 Chemistry Test Market Estimates and Forecasts, 2021 - 2033 (USD Million)

Fig. 47 Microbiology & Sterility Test Market Estimates and Forecasts, 2021 - 2033 (USD Million)

Fig. 48 Small Animal Research Market Estimates and Forecasts, 2021 - 2033 (USD Million)

Fig. 49 Biocompatibility Tests Market Estimates and Forecasts, 2021 - 2033 (USD Million)

Fig. 50 Chemistry Test Market Estimates and Forecasts, 2021 - 2033 (USD Million)

Fig. 51 Microbiology & Sterility Test Market Estimates and Forecasts, 2021 - 2033 (USD Million)

Fig. 52 Clinical Market Estimates and Forecasts, 2021 - 2033 (USD Million)

Fig. 53 Key company categorization

Fig. 54 Service heat map analysis

Fig. 55 Strategic framework

## I would like to order

Product name: U.S. Medical Device Testing Services Market Size, Share & Trends Analysis Report By Service (Biocompatibility Tests, Chemistry Test, Microbiology & Sterility Testing, Package Validation), By Phase (Preclinical, Clinical), And Segment Forecasts, 2025 - 2033

Product link: <https://marketpublishers.com/r/UADC9DDE97E4EN.html>

Price: US\$ 5,950.00 (Single User License / Electronic Delivery)

If you want to order Corporate License or Hard Copy, please, contact our Customer Service:

[info@marketpublishers.com](mailto:info@marketpublishers.com)

## Payment

To pay by Credit Card (Visa, MasterCard, American Express, PayPal), please, click button on product page <https://marketpublishers.com/r/UADC9DDE97E4EN.html>