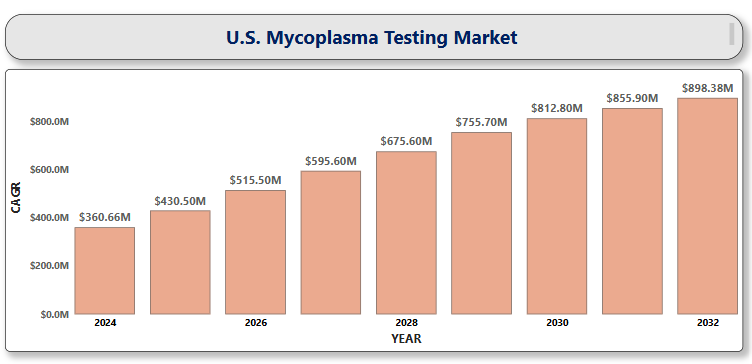
A close-up of hands holding a tablet and a pen

Description automatically generated**U.S. Mycoplasma Testing Market**

According to Intelli, the U.S. Mycoplasma Testing Market size was valued at USD 360.66 Million in 2024 and is projected to reach USD 898.38 Million by 2032, growing at a compound annual growth rate (CAGR) of 12.58%, during the forecast period of 2024 to 2032.



Mycoplasma testing is a critical quality control measure in the biotechnology, pharmaceutical, and cell therapy industries, aimed at detecting contamination by *Mycoplasma* species, among the smallest and most pervasive prokaryotes lacking a cell wall. Unlike most bacteria, *Mycoplasma* can pass through standard filtration processes and evade detection due to their small size (0.1–0.3 µm) and resistance to antibiotics that target cell wall synthesis. These contaminants pose a serious threat to cell cultures, biopharmaceutical production, and research validity by altering host cell metabolism, growth rates, and gene expression without overt signs of infection. Because of their elusive characteristics, *Mycoplasma* contamination can severely impact biomanufacturing processes by compromising entire production batches, distorting experimental outcomes, and causing significant delays in product development. As a result, early detection and effective prevention strategies are critical. To safeguard product quality and ensure patient safety, regulatory bodies such as the FDA, EMA, and USP have established rigorous guidelines mandating *Mycoplasma* testing in biologics and cell-based products. A variety of testing methodologies are employed to detect *Mycoplasma*, including conventional culture-based assays, DNA fluorochrome staining, polymerase chain reaction (PCR), and more sophisticated nucleic acid amplification techniques. Each approach is evaluated based on its sensitivity, specificity, time-to-result, and alignment with regulatory standards. As the demand for biologics, gene therapies, and personalized medicine accelerates, robust mycoplasma detection methods have become indispensable tools in safeguarding the integrity of biologics manufacturing and ensuring compliance with global quality standards.

**U.S. Mycoplasma Testing Market Definition**

The U.S. Mycoplasma Testing Market refers to the sector within the American biotechnology and pharmaceutical industries that focuses on the development, distribution, and application of diagnostic tools and technologies used to detect A close-up of hands holding a tablet and a pen

Description automatically generated*Mycoplasma* contamination in biological products. This market plays a vital role in maintaining the integrity, safety, and efficacy of biopharmaceuticals, vaccines, gene therapies, and cell-based treatments. It encompasses a wide range of testing methodologies including PCR, ELISA, nucleic acid amplification, and culture-based assays, designed to meet stringent regulatory requirements set forth by agencies like the FDA and USP.

**U.S. Mycoplasma Testing Market Overview**

The U.S. Mycoplasma Testing Market is experiencing steady growth, driven by several critical factors. The expanding biopharmaceutical and biologics sectors have increased the demand for stringent quality control measures, including routine mycoplasma testing. Rising adoption of cell and gene therapies, which require contamination-free environments, further accelerates the need for rapid and reliable detection methods. Regulatory mandates set forth by prominent agencies such as the FDA and the USP are key forces shaping the U.S. Mycoplasma Testing Market, requiring biomanufacturers to adhere to strict quality control standards. These regulations necessitate comprehensive screening of biologics, vaccines, and cell-based therapies for Mycoplasma contamination before products can advance to market or clinical use. In response, manufacturers are increasingly adopting advanced testing technologies to ensure compliance and maintain product integrity. Cutting-edge innovations—particularly in polymerase chain reaction (PCR)-based assays and next-generation nucleic acid amplification techniques—are revolutionizing the testing landscape by offering high sensitivity, greater specificity, faster turnaround times, and scalability for high-throughput environments. These technologies reduce the risk of undetected contamination and minimize delays in production pipelines. Moreover, the growing frequency of Mycoplasma-related contamination incidents has underscored the potentially devastating impact on manufacturing operations, including costly batch discards, production halts, regulatory setbacks, and damage to brand reputation. These high stakes have pushed biopharmaceutical companies to invest heavily in proactive testing strategies as a risk mitigation measure. As such, mycoplasma testing is no longer seen as a regulatory burden but as a strategic necessity for maintaining product quality, regulatory compliance, and market competitiveness. Collectively, these dynamics underscore the vital role of the mycoplasma testing market in safeguarding the A close-up of hands holding a tablet and a pen

Description automatically generatedreliability of the U.S. biomanufacturing ecosystem and supporting the advancement of innovative therapies.

**U.S. Mycoplasma Testing Market Segmentation**

The U.S. Mycoplasma Testing Market is strategically segmented by product type, technology, and end user, enabling targeted solutions that address the diverse quality control needs of biopharmaceutical manufacturers, research institutions, and contract service providers across the life sciences landscape.

**U.S. Mycoplasma Testing Market, By Product Type**

* **Instruments**
* **Kits & Reagents**
* **Services**

The U.S. Mycoplasma Testing Market by Product Type is primarily driven by the kits and reagents segment, which holds the largest market share due to their essential role in routine testing and compatibility with a wide range of detection technologies. Meanwhile, the instruments segment continues to grow steadily, fueled by increasing adoption of automated systems and advanced PCR machines, particularly in large-scale biomanufacturing facilities seeking to reduce human error and improve throughput. The services segment is also expanding rapidly, driven by the outsourcing trend among pharmaceutical and biotech firms aiming to streamline operations, reduce in-house testing burdens, and ensure compliance with stringent FDA and USP guidelines.

**U.S. Mycoplasma Testing Market, By Technology**

* **PCR (Polymerase Chain Reaction)**
* **ELISA (Enzyme-Linked Immunosorbent Assay)**
* **Culture-based Testing**
* **Nucleic Acid Amplification Techniques (NAATs)**
* **Direct Assay/Enzymatic Methods**

The U.S. Mycoplasma Testing Market by Technology is dominated by PCR (Polymerase Chain Reaction), which holds the largest market share due to its unmatched sensitivity, A close-up of hands holding a tablet and a pen

Description automatically generatedrapid turnaround time, and broad adoption in both R&D and commercial bioproduction settings. While culture-based testing remains the regulatory gold standard, it is increasingly being supplemented or replaced by faster, more automated techniques like nucleic acid amplification technologies (NAATs), which are gaining popularity for their high-throughput capabilities and superior accuracy. ELISA assays continue to be a reliable, cost-effective solution for initial screenings, particularly in smaller laboratory settings. At the same time, direct assays and enzymatic methods are establishing themselves as key tools for real-time contamination monitoring. Collectively, these technologies create a dynamic testing ecosystem designed to meet the growing demands for speed, precision, and regulatory adherence within the U.S. biotechnology and pharmaceutical industries.

**U.S. Mycoplasma Testing Market,** **By End User**

* **Pharmaceutical and Biotechnology Companies**
* **Contract Research Organizations (CROs)**
* **Cell Banks and Biomanufacturers**
* **Academic & Research Institutes**

The U.S. Mycoplasma Testing Market by End User is primarily driven by pharmaceutical and biotechnology companies, which account for the largest share due to their critical need for contamination-free products in drug development, biologics manufacturing, and cell-based therapies. Contract Research Organizations (CROs) play a key role as well, offering outsourced testing services to multiple clients, thus driving market growth through high-volume, cost-effective solutions. Cell banks and biomanufacturers are another significant segment, requiring rigorous testing to ensure the purity and viability of their cell lines used in production. Additionally, academic and research institutes continue to be essential users of mycoplasma testing, particularly for basic research and experiments involving cell cultures, where contamination can lead to skewed results and unreliable data.

**Key Players**

The “U.S. Mycoplasma Testing Market" study report will provide valuable insight emphasizing the U.S. market. The major players in the market Thermo Fisher Scientific, Lonza Group, Charles River Laboratories, Roche Diagnostics, Merck KGaA, BioMérieux, A close-up of hands holding a tablet and a pen

Description automatically generatedFujifilm Wako Chemicals, QIAGEN, Applied Biological Materials, ViroStat, Hologic, Biotest AG, GenScript, Bio-Rad Laboratories, Agilent Technologies, Becton Dickinson and Company, Molecular Devices, Abbott Laboratories, Karius, Inc., PreScience Technologies, Inc., Aviva Systems Biology among others. Our market analysis also entails a section solely dedicated to such major players wherein our analysts provide an insight into the financial statements of all the major players, along with product benchmarking and SWOT analysis.

**Key Development**

* In 2024, Danaher Corporation achieved a significant milestone with FDA clearance for its Xpert Xpress GBS, a next-generation dual-target molecular diagnostic test designed for the rapid detection of Group B Streptococcus.

**Market Attractiveness**

The image of market attractiveness provided further helps to get information about the region leading in the U.S. Mycoplasma Testing Market. We cover the major impacting factors driving the industry growth in the given region.

**Porter’s Five Forces**

The image provided would further help to get information about Porter's five forces framework providing a blueprint for understanding the behavior of competitors and a player's strategic positioning in the respective industry. Porter's five forces model can be used to assess the competitive landscape U.S. Mycoplasma Testing Market, gauge the attractiveness of a particular sector, and assess investment possibilities.

A close-up of hands holding a tablet and a pen

Description automatically generatedTABLE OF CONTENT

1 **INTRODUCTION OF** **U.S. MYCOPLASMA TESTING MARKET**

* 1. Overview of the market
  2. Scope of report
  3. Assumptions

1. **EXECUTIVE SUMMARY**
2. **RESEARCH METHODOLOGY**
   1. Data Mining
   2. Validation
   3. Primary Interviews
   4. List of Data sources
3. **U.S. MYCOPLASMA TESTING MARKET OUTLOOK**
   1. Overview
   2. Market Dynamics
      1. Drivers
      2. Restrains
      3. Opportunities
      4. Trends
   3. Portes Five FORCE Model
   4. Value Chain Analysis

**5 U.S. MYCOPLASMA TESTING MARKET, BY PRODUCT TYPE**

5.1 Overview

A close-up of hands holding a tablet and a pen

Description automatically generated5.2 Instruments

5.3 Kits & Reagents

5.4 Services

**6 U.S. MYCOPLASMA TESTING MARKET, BY TECHNOLOGY**

6.1 Overview

6.2 PCR (Polymerase Chain Reaction)

6.3 ELISA (Enzyme-Linked Immunosorbent Assay)

6.4 Culture-based Testing

6.5 Nucleic Acid Amplification Techniques (NAATs)

6.6 Direct Assay/Enzymatic Methods

**7** **U.S. MYCOPLASMA TESTING MARKET, BY END USER**

7.1 Overview

7.2 Pharmaceutical and Biotechnology Companies

7.3 Contract Research Organizations (CROs)

7.4 Cell Banks and Biomanufacturers

7.5 Academic & Research Institutes

1. **U.S. MYCOPLASMA TESTING MARKET COMPETITIVE LANDSCAPE**
   1. Overview
   2. Company Market Ranking
   3. A close-up of hands holding a tablet and a pen

      Description automatically generated Key Developments Strategies
2. **COMPANY PROFILES**

**9.1 Thermo Fisher Scientific**

* + 1. Overview
    2. Financial Performance
    3. Product Outlook
    4. Key developments
  1. **Lonza Group**
     1. Overview
     2. Financial Performance
     3. Product Outlook
     4. Key developments
  2. **Charles River Laboratories**
     1. Overview
     2. Financial Performance
     3. Product Outlook
     4. Key developments
  3. **Roche Diagnostics**
     1. Overview
     2. Financial Performance
     3. Product Outlook
     4. Key developments
  4. **Merck KGaA**
     1. Overview
     2. Financial Performance
     3. A close-up of hands holding a tablet and a pen

        Description automatically generatedProduct Outlook
     4. Key developments
  5. **BioMérieux**
     1. Overview
     2. Financial Performance
     3. Product Outlook
     4. Key developments
  6. **Fujifilm Wako Chemicals**
     1. Overview
     2. Financial Performance
     3. Product Outlook
     4. Key developments
  7. **QIAGEN**
     1. Overview
     2. Financial Performance
     3. Product Outlook
     4. Key developments

* 1. **Applied Biological Materials**
     1. Overview
     2. Financial Performance
     3. Product Outlook
     4. Key developments
  2. **ViroStat**
     1. Overview
     2. Financial Performance
     3. A close-up of hands holding a tablet and a pen

        Description automatically generatedProduct Outlook
     4. Key developments
  3. **Hologic**
     1. Overview
     2. Financial Performance
     3. Product Outlook
     4. Key developments
  4. **Biotest AG**
     1. Overview
     2. Financial Performance
     3. Product Outlook
     4. Key developments
  5. **GenScript**
     1. Overview
     2. Financial Performance
     3. Product Outlook
     4. Key developments
  6. **Bio-Rad Laboratories**
     1. Overview
     2. Financial Performance
     3. Product Outlook
     4. Key developments
  7. **Agilent Technologies**
     1. Overview
     2. Financial Performance
     3. Product Outlook
     4. A close-up of hands holding a tablet and a pen

        Description automatically generatedKey developments
  8. **Becton Dickinson and Company**
     1. Overview
     2. Financial Performance
     3. Product Outlook
     4. Key developments
  9. **Molecular Devices**
     1. Overview
     2. Financial Performance
     3. Product Outlook
     4. Key developments
  10. **Abbott Laboratories**
      1. Overview
      2. Financial Performance
      3. Product Outlook
      4. Key developments
  11. **Karius, Inc.**
      1. Overview
      2. Financial Performance
      3. Product Outlook
      4. Key developments
  12. **PreScience Technologies, Inc.**
      1. Overview
      2. Financial Performance
      3. Product Outlook
      4. Key developments
  13. A close-up of hands holding a tablet and a pen

      Description automatically generated**Aviva Systems Biology**
      1. Overview
      2. Financial Performance
      3. Product Outlook
      4. Key developments

1. **KEY DEVELOPMENTS**
   1. Product Launches/Developments
   2. Merges and Acquisitions
   3. Business Expansions
   4. Partnerships and Collaborations
2. **Appendix**

11.1 Related Research