

# **IVD Contract Manufacturing Market Forecasts To 2032 – Global Analysis By Service Type (Assembly & Production (CMO), Fill & Finish, Packaging & Labeling, Sterilization, Analytical Testing & QC, Regulatory & Compliance Support, Reagent Formulation & Development, Logistics & Cold Chain, And Kitting & Warehousing), Product Type, Technology, Contract Type, Capacity, End User And By Geography**

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## **Abstracts**

According to Statistics MRC, the Global IVD Contract Manufacturing Market is accounted for \$23.71 billion in 2025 and is expected to reach \$53.75 billion by 2032 growing at a CAGR of 12.4% during the forecast period. IVD contract manufacturing involves delegating the creation of in vitro diagnostic instruments, reagents, and test kits to expert external manufacturers. These firms support every stage of production, including design, engineering, testing, mass manufacturing, and adherence to regulatory standards. This approach helps IVD companies lower expenses, improve efficiency, and speed product launches, allowing them to concentrate on research and market strategies while maintaining consistent quality and regulatory compliance.

According to the International Trade Agency (ITA), the medical device market in Canada accounted for USD 6.5 billion in 2022, which is expected to grow at a rate of 2.1 % by 2026.

Market Dynamics:

### Driver:

#### High cost of in-house IVD manufacturing

Companies face heavy capital requirements for specialized equipment, cleanroom infrastructure, and skilled labor. Ongoing costs related to quality assurance, compliance, and validation further increase operational burdens. Smaller firms and startups often struggle to sustain these investments, limiting their ability to scale production. Contract manufacturers provide a cost-effective alternative by spreading infrastructure and expertise across multiple clients. As a result, outsourcing is increasingly viewed as a strategic solution to reduce overhead and accelerate market entry.

### Restraint:

#### Complex and evolving global regulatory landscape

Compliance with standards such as FDA, CE-IVD, and ISO 13485 requires extensive documentation and continuous monitoring. Manufacturers must adapt quickly to evolving rules, which vary across regions and product categories. This complexity often delays product launches and increases the cost of certification. Smaller players may find it difficult to navigate these requirements without external expertise. Consequently, regulatory challenges act as a restraint, slowing adoption and limiting the pace of innovation.

### Opportunity:

#### Adoption of advanced technologies

Technologies such as AI-driven analytics, robotics, and cloud-based platforms are streamlining production workflows. These innovations improve accuracy, reduce turnaround times, and enhance scalability for diverse diagnostic applications. Contract manufacturers are increasingly investing in smart manufacturing systems to attract global clients. Integration of advanced materials and microfluidics is enabling next-generation diagnostic kits. As healthcare systems embrace digital transformation, adoption of these technologies is expected to drive significant growth in outsourced IVD production.

### Threat:

## Cybersecurity and data interoperability gaps

Sensitive patient data and proprietary research are vulnerable to breaches if systems are not adequately protected. Interoperability challenges between different software and data standards further complicate secure collaboration. Contract manufacturers must invest heavily in cybersecurity infrastructure to maintain trust with clients. Failure to address these risks could result in reputational damage and regulatory penalties. As digital integration expands, cybersecurity and interoperability gaps remain a critical threat to the industry.

## Covid-19 Impact:

The COVID-19 pandemic disrupted global supply chains and created shortages in raw materials and reagents. However, it also highlighted the importance of rapid diagnostic solutions, boosting demand for IVD products. Contract manufacturers played a vital role in scaling up production to meet urgent testing needs. Remote collaboration tools and digital platforms became essential for maintaining continuity in manufacturing. Post-pandemic strategies now emphasize resilience, distributed production, and digital agility across the IVD ecosystem.

The reagents & kits segment is expected to be the largest during the forecast period

The reagents & kits segment is expected to account for the largest market share during the forecast period, due to these products are essential for routine diagnostic testing across hospitals, laboratories, and point-of-care settings. High demand for consumables ensures recurring revenue streams for manufacturers. Outsourcing production of reagents and kits allows companies to meet global demand efficiently. Contract manufacturers provide scalability and quality assurance, making them preferred partners for this segment.

The research institutes / academic labs segment is expected to have the highest CAGR during the forecast period

Over the forecast period, the research institutes / academic labs segment is predicted to witness the highest growth rate, due to increasing focus on translational research and personalized medicine is driving demand for specialized diagnostic solutions. These institutions often lack large-scale manufacturing capabilities, making outsourcing a practical choice. Contract manufacturers support rapid prototyping and small-batch production for experimental diagnostics. Collaborations between academia and industry

are fostering innovation and accelerating commercialization.

Region with largest share:

During the forecast period, the North America region is expected to hold the largest market share, due to the region benefits from advanced healthcare infrastructure and strong demand for diagnostic testing. Regulatory frameworks such as FDA approvals provide credibility and global market access. Leading contract manufacturers are headquartered in the U.S., offering extensive expertise and capacity. High adoption of innovative diagnostic technologies further strengthens regional dominance.

Region with highest CAGR:

Over the forecast period, the Asia Pacific region is anticipated to exhibit the highest CAGR, owing to expanding healthcare infrastructure and rising awareness of diagnostics are fueling demand across the region. Countries such as China, India, and South Korea are investing heavily in local manufacturing capabilities. Government initiatives and public-private partnerships are encouraging outsourcing and technology transfer. The region's cost advantages and growing patient population make it attractive for global manufacturers.

Key players in the market

Some of the key players in IVD Contract Manufacturing Market include Thermo Fi, Fujirebio, Merck KGa, Meridian B, Bio-Techno, KMC Systeme, Argonaut, Cone Biop, Invetech, Kimball EI, Randox La, Phillips-M, TE Connec, Viant Med, and Celestica.

Key Developments:

In November 2025, Thermo Fisher Scientific Inc. announced the grand opening of its East Coast flagship Advanced Therapies Collaboration Center (ATxCC) in Philadelphia, marking the company's second ATxCC in the United States following the opening of its Carlsbad, California, site. Together, these centers expand the company's nationwide network supporting cell and gene therapy (CGT) innovation, providing critical resources to biotech, biopharma and translational researchers developing next-generation cell-based immunotherapies.

In June 2025, Fujirebio Holdings, Inc. announced that Fujirebio Diagnostics, Inc., a subsidiary of Fujirebio, has acquired all shares of Plasma Services Group, Inc.

(hereinafter “Plasma Services Group”). The transaction value has not been disclosed. The company is particularly well positioned in the field of rare diseases. From its state-of-the-art FDA registered, ISO certified facility in Moorestown, NJ, USA, Plasma Services Group provides sera and other samples for materials of control reagents and calibrators for a wide range of diseases and offers sample collection services globally.

#### Service Types Covered:

Assembly & Production (CMO)

Fill & Finish

Packaging & Labeling

Sterilization

Analytical Testing & QC

Regulatory & Compliance Support

Reagent Formulation & Development

Logistics & Cold Chain

Kitting & Warehousing

#### Product Types Covered:

Reagents & Kits

Consumables

Instruments & Components

Point-Of-Care / Rapid Tests

Molecular Diagnostics

Immunoassays

Clinical Chemistry Products

Hematology Products

Microbiology Panels

Technologies Covered:

PCR / Qpcr

Isothermal Amplification

NGS Workflows

Immunoassay Platforms

Lateral Flow / Rapid Tests

Biosensors & Electrochemical

Microarray / Hybridization

Contract Types Covered:

End-To-End

Project / Batch Manufacturing

Toll Manufacturing

Co-Development / Co-Manufacturing

White-Label / Private-Label

**Capacities Covered:**

Pilot / Small-Scale

Commercial-Scale

High-Throughput / Mass-Market

**End Users Covered:**

IVD Oems / Diagnostic Firms

Biotech &amp; Pharma Companies

Hospitals &amp; Clinical Labs

POC Manufacturers

Research Institutes / Academic Labs

Veterinary Diagnostics

Direct-To-Consumer Testing Firms

**Regions Covered:**

North America

US

Canada

Mexico

Europe

Germany

UK

Italy

France

Spain

Rest of Europe

Asia Pacific

Japan

China

India

Australia

New Zealand

South Korea

Rest of Asia Pacific

South America

Argentina

Brazil

Chile

Rest of South America

Middle East & Africa

Saudi Arabia

UAE

Qatar

South Africa

Rest of Middle East & Africa

What our report offers:

- Market share assessments for the regional and country-level segments
- Strategic recommendations for the new entrants
- Covers Market data for the years 2024, 2025, 2026, 2028, and 2032
- Market Trends (Drivers, Constraints, Opportunities, Threats, Challenges, Investment Opportunities, and recommendations)
- Strategic recommendations in key business segments based on the market estimations
- Competitive landscaping mapping the key common trends
- Company profiling with detailed strategies, financials, and recent developments
- Supply chain trends mapping the latest technological advancements

Free Customization Offerings:

All the customers of this report will be entitled to receive one of the following free customization options:

#### Company Profiling

Comprehensive profiling of additional market players (up to 3)

SWOT Analysis of key players (up to 3)

#### Regional Segmentation

Market estimations, Forecasts and CAGR of any prominent country as per the client's interest (Note: Depends on feasibility check)

## Competitive Benchmarking

Benchmarking of key players based on product portfolio, geographical presence, and strategic alliances

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