

Japan IVD Centralized Diagnostics Market (By Segment: Clinical Chemistry, Immunoassay, Coagulation, Urinalysis, Hematology, Flow Cytometry, Immunohematology, Microbiology), Key Company Profiles, Market Dynamics and Recent Developments – Forecast to 2030

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Abstracts

The Japan IVD Centralized Diagnostics market is projected to grow from US\$ 1,950 Million in 2025, to over US\$ 2,205 Million by 2030. Japan's IVD Centralized Diagnostics market represents one of the most mature and technologically advanced diagnostic ecosystems globally, underpinned by universal healthcare coverage, a rapidly ageing population, and a strong emphasis on early disease detection. Unlike decentralized and point-of-care testing, centralized diagnostics continue to account for the majority of in-vitro diagnostic testing volumes across large hospitals, commercial laboratories, and reference laboratories due to their ability to deliver high-throughput, standardized, and cost-efficient testing. As healthcare providers continue to prioritize early disease detection and precision medicine, centralized diagnostic laboratories remain the backbone of Japan's clinical testing infrastructure, handling a significant share of high-volume and complex diagnostic assays.

Immunoassay and Clinical Chemistry remain the backbone of Japan's IVD Centralized Diagnostics market, collectively accounting for approx. 70% share of the market in 2025. Clinical chemistry analyzers are extensively utilized for routine health check-ups, metabolic disorder monitoring, liver and kidney function assessment, and chronic disease management, while immunoassay platforms are experiencing robust growth owing to rising demand for oncology biomarkers, infectious disease diagnostics, endocrine testing, and cardiac biomarkers. The country's preventive healthcare culture,

characterized by regular health screenings and annual medical examinations, continues to generate significant demand for automated high-throughput laboratory systems capable of processing thousands of samples daily with high precision.

The competitive landscape remains highly consolidated, with global companies such as Roche, Abbott, Siemens, Beckman Coulter (Danaher), and Sysmex competing alongside strong domestic players including Fujifilm, HORIBA, and Eiken Chemical. These companies continue to invest in automation, menu expansion, and digital laboratory solutions to strengthen their market position. Looking ahead, the Japan IVD centralized diagnostics market is expected to maintain stable long-term growth, supported by increasing diagnostic demand from an ageing population, expanding chronic disease burden, greater adoption of advanced biomarker testing, and continued modernization of clinical laboratory infrastructure across hospitals and independent diagnostic laboratories.

Recent Developments

In February 2026, Fujirebio and Sysmex entered into a strategic sales collaboration for dementia diagnostics, under which Sysmex became the exclusive distributor of Fujirebio's fully automated LUMIPULSE immunoassay systems and dementia-related assay reagents across agreed markets. The partnership enhances the commercialization of automated neurodegenerative disease testing by combining Fujirebio's biomarker expertise with Sysmex's extensive sales and service network. It also reinforces the growing industry shift toward fully automated, high-throughput immunoassay platforms for blood-based dementia biomarkers, improving laboratory accessibility, workflow efficiency, and adoption of centralized in vitro diagnostics.

In December 2025, Roche announced that it has secured CE Mark approval for its mass spectrometry reagent pack for antibiotics drug monitoring. This establishes Roche's in-vitro diagnostics (IVD) menu as the broadest available for any automated mass spectrometry platform, including already 39 of the most frequently tested targets. The cobas Mass Spec solution Ionify reagent portfolio includes tests for therapeutic drug monitoring for immunosuppressants and antibiotics, along with steroid hormones and vitamin D metabolites. These tests will enable laboratories to transition from labor-intensive and manual operation to a fully automated, standardized, easy to use solution. The cobas Mass Spec solution is currently available in selected markets accepting the CE mark, as well as other markets including the United Kingdom, Canada and Japan.

Sysmex Corporation announced its 2025–2028 Mid-Term Management Plan, outlining a strategy to strengthen its leadership in hematology, hemostasis, immunochemistry, and laboratory automation while accelerating investments in digital transformation (DX) and AI-enabled diagnostics. The plan emphasizes expanding integrated diagnostic solutions by combining advanced analyzers, automation platforms, and digital technologies to improve laboratory productivity, workflow efficiency, and clinical decision-making. This strategic direction reinforces the growing demand for high-throughput, data-driven centralized in vitro diagnostics, positioning Sysmex to capitalize on increasing laboratory automation and AI adoption across Japan's healthcare system.

By Segment: Japan IVD Centralized Diagnostics Market – Key Takeaways

Immunoassay is the largest segment of the Japan IVD Centralized Diagnostics market, driven by the increasing demand for oncology biomarkers, cardiac biomarkers, infectious disease diagnostics, and autoimmune disease testing. The widespread adoption of high-throughput chemiluminescence immunoassay (CLIA) systems and fully automated laboratory platforms has significantly enhanced testing sensitivity, accuracy, and laboratory efficiency. Furthermore, Japan's ageing population, growing burden of chronic diseases, and expanding precision medicine initiatives are accelerating the adoption of advanced immunoassay solutions, reinforcing the segment's dominant position and supporting sustained market growth over the forecast period.

The Japan IVD Centralized Diagnostics Immunoassay market is led by Abbott, Fujirebio, and Roche, which maintain strong positions through their comprehensive immunoassay portfolios and advanced automated laboratory platforms. Abbott has a significant presence with its ARCHITECT and Alinity immunoassay systems, while Fujirebio leverages its expertise in high-value biomarkers, particularly in neurodegenerative diseases and infectious diseases. Roche remains a key market leader with its cobas immunoassay platforms, offering an extensive test menu spanning oncology, cardiology, endocrinology, and infectious diseases.

Clinical Chemistry is the second-largest segment of the Japan IVD Centralized Diagnostics market, supported by its critical role in routine health screening, preventive care, and chronic disease management. The rising prevalence of

diabetes, cardiovascular diseases, kidney disorders, and liver diseases continues to drive consistently high testing volumes across hospitals and reference laboratories. The Japan IVD Centralized Diagnostics Clinical Chemistry market is led by Roche, FUJIFILM Wako, Minaris Medical, Sekisui Medical, and ARKRAY, which have established strong positions through comprehensive clinical chemistry analyzer portfolios and reagent offerings.

The Hematology segment is an important component of the Japan IVD Centralized Diagnostics market, driven by the growing demand for complete blood count (CBC) testing, anemia diagnosis, infection monitoring and hematological malignancy detection. The increasing prevalence of chronic diseases, an ageing population, and routine health screening programmes continue to support stable testing volumes across hospitals and diagnostic laboratories.

Sysmex dominates the Japan hematology market with its comprehensive portfolio of automated hematology analyzers and reagents, followed by Beckman Coulter (Danaher), and Siemens Healthineers, all of which have a strong presence across hospital laboratories and centralized diagnostic facilities.

Microbiology remains a strategically important segment of the Japan IVD Centralized Diagnostics market, supported by the increasing focus on rapid pathogen identification, antimicrobial resistance (AMR) surveillance, and effective infection control in hospitals. bioMérieux is the leading player in Japan's microbiology diagnostics market, driven by its comprehensive portfolio of blood culture systems, microbial identification platforms, and antimicrobial susceptibility testing (AST) solutions. Becton Dickinson (BD) is another major participant, offering advanced automated blood culture and microbiology workflow systems that enhance laboratory efficiency and support rapid infectious disease diagnosis. Beckman Coulter (Danaher) also maintains a notable presence through its laboratory automation solutions and integrated diagnostic platforms, strengthening microbiology laboratory workflows and improving diagnostic turnaround times across hospitals and centralized laboratories.

The Coagulation segment is witnessing steady growth in the Japan IVD Centralized Diagnostics market, driven by the country's ageing population and the rising prevalence of cardiovascular diseases, stroke, venous thromboembolism, and other bleeding and thrombotic disorders. Sysmex and Sekisui Medical dominate the Japan coagulation diagnostics market, supported

by their comprehensive portfolios of coagulation analyzers, reagents, and quality control solutions. Their strong domestic presence, continuous product innovation, and extensive installed base across hospitals and centralized laboratories have enabled them to maintain market leadership.

iGATE RESEARCH report titled “Japan IVD Centralized Diagnostics Market (By Segment: Clinical Chemistry, Immunoassay, Coagulation, Urinalysis, Hematology, Flow Cytometry, Immunohematology, Microbiology), Key Company Profiles, Market Dynamics and Recent Developments – Forecast to 2030” provides a comprehensive analysis of the Japan IVD Centralized Diagnostics Market.

This report has been analyzed from 14 View Points:

- 1) Japan – IVD Centralized Diagnostics Market & Forecast (2021 - 2030)
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By Segment: Japan IVD Centralized Diagnostics Market & Forecast

1. Clinical Chemistry

Clinical Chemistry Instruments

CC Instruments

CCIA Combo systems

CC Reagents

CC Routine

CC Drugs of Abuse

CC TDM

CC HbA1c

CC Specific Proteins

2. Immunoassay

Immunoassay Instruments

Immunoassay Blood Screening

Immunoassay Reagents

Immunoassay Thyroid

Immunoassay Anemia

Immunoassay Hormones

Immunoassay Oncology

Immunoassay Infectious Diseases

Immunoassay Fertility/Pregnancy

Immunoassay Cardiac

Troponin

BNP

Pro-BNP

Other IA Cardiac

Immunoassay Critical Care

CRP

PCT

Other IA Critical Care

Immunoassay Bone Health

Immunoassay Autoimmune

Immunoassay Sars-Cov2

Immunoassay Allergy

Immunoassay Immunosuppressants

Immunoassay Neurology

3. Coagulation

Instruments & service revenue

Traditional tests

Other tests

4. Urinalysis

Instruments & service revenue

Qualitative

Sedimentation

5. POC Hematology

Instruments & service revenue

Blood cell count (CBC)

Cell imaging analysis

6. Flow Cytometry

7. Immunochemistry

Blood Grouping & Typing

Antibody Screening and Identification

Antigen Typing

8. Microbiology

Automated ID/ AST

Automated Blood Culture

Manual ID/ AST + Culture

Japan IVD Centralized Diagnostics Market – Key Company Profiles

Japan IVD Centralized Diagnostics Market (By Segment: Clinical Chemistry, Immunoassay, Coagulation, Urinalysis...

1. Roche
2. Abbott
3. Sysmex
4. Fujirebio
5. Siemens
6. Sekisui
7. Ortho Clinical Diagnostics
8. Denka
9. Arkray
10. bioMérieux
11. Danaher - Beckman Coulter
12. Tosoh
13. Fujifilm - Wako
14. Fujifilm
15. EIKEN CHEMICAL
16. Minaris
17. Shino-Test
18. LSI Medience
19. Canon - Canon
20. JEOL
21. Hitachi
22. Bio-Rad
23. Kanto
24. Nittobo
25. Kainos
26. Nipro
27. Kyokuto
28. Thermo Fisher Scientific
29. Thermo Fisher Scientific (Phadia)
30. Thermo Fisher Scientific - Oxoid
31. MBL
32. Werfen
33. Sanwa
34. Horiba ABX - Horiba
35. Nihon Kohden
36. Becton Dickinson
37. Grifols
38. Immucor

39. Nissui

Data Source

iGATE RESEARCH employs rigorous primary and secondary research techniques in developing distinctive data sets and research material for business reports. This report is built by using data and information sourced from Proprietary Information Database, Primary and Secondary Research Methodologies, and In house analysis by iGATE Research dedicated team of qualified professionals with deep industry experience and expertise.

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Japan IVD Centralized Diagnostics Market (By Segment: Clinical Chemistry, Immunoassay, Coagulation, Urinalysis...

PROFILES, CENTRALIZED DIAGNOSTICS REVENUE

- 13.1 Roche
- 13.2 Abbott
- 13.3 Sysmex
- 13.4 Fujirebio
- 13.5 Siemens
- 13.6 Sekisui
- 13.7 Ortho Clinical Diagnostics
- 13.8 Denka
- 13.9 Arkray
- 13.10 bioMérieux
- 13.11 Danaher - Beckman Coulter
- 13.12 Tosoh
- 13.13 Fujifilm - Wako
- 13.14 Fujifilm
- 13.15 EIKEN CHEMICAL
- 13.16 Minaris
- 13.17 Shino-Test
- 13.18 LSI Medience
- 13.19 Canon - Canon
- 13.20 JEOL
- 13.21 Hitachi
- 13.22 Bio-Rad
- 13.23 Kanto
- 13.24 Nittobo
- 13.25 Kainos
- 13.26 Nipro
- 13.27 Kyokuto
- 13.28 Thermo Fisher Scientific
- 13.29 Thermo Fisher Scientific (Phadia)
- 13.30 Thermo Fisher Scientific - Oxoid
- 13.31 MBL
- 13.32 Werfen
- 13.33 Sanwa
- 13.34 Horiba ABX - Horiba
- 13.35 Nihon Kohden
- 13.36 Becton Dickinson
- 13.37 Grifols

13.38 Immucor

13.39 Nissui

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