

# THE FLUORESCENCE IMMUNOASSAY (FIA) MARKET IN INDIA

*Prepared by Sanstrat Research Team, June 2025*

## 1. Executive Summary

The Indian IVD market size is about 1.9 – 2.4 billion USD (INR 16,000 – 20,000 Cr) in 2024 growing at about 14-16 percent CAGR. The IVD industry caters mainly to the Pathology Labs (stand-alone labs and hospital-based labs), and to some extent to the doctor's office.

The Indian Fluorescence Immunoassay (FIA) market represents a dynamic and robust segment of the nation's in-vitro diagnostics (IVD) industry, with a current valuation of **₹435 crores (USD 51 Million)**. The market structure is heavily skewed towards recurring revenue, with reagent sales constituting 90% of the total market value, while instrument sales account for the remaining 10%. The market is projected to grow at a strong Compound Annual Growth Rate (CAGR) of **12-15%**.

Covid 19 has given quite a lot of impetus to FIA products due to its ability to perform tests such as Covid Ag, CRP and D-Dimer.

Competition is consolidated among a handful of key international players, with **Boditech (33%), Wondfo (23%), and SD Biosensor (21%)** commanding a collective market share of 77%. The primary customer base is composed of hospital Labs (50%) and private laboratories (30%), with a smaller but significant segment in doctors' offices (20%).

A critical market trend is the definitive shift from semi-automated to fully automated systems. The presence of advanced, fully automated point-of-care (POC) solutions from major players like Boditech and the introduction of such systems by competitors like Wondfo and Getein indicate that automation is now a key competitive differentiator. At the same time, heightened competition and Chinese players have pulled down the price points. Strategic local investments, such as Boditech's manufacturing facility in Haryana, further underscore the long-term growth potential of the Indian market.

## **2. Indian FIA Market Analysis**

### **2.1. Market Size & Financial Structure**

- **Total Market Valuation:** ₹435 Crores
- **Reagent Sales Revenue:** ₹390 Crores (90%)
- **Instrument Sales Revenue:** ₹45 Crores (10%)

The financial model of the market is based on initial instrument placement followed by a continuous stream of high-margin reagent sales. Annually, approximately **5,000 new instruments** are sold, each supporting a test menu of **15-40 parameters**, ensuring sustained reagent consumption. There are approx. over 32000 FIA POC analysers installed in India by all companies put together.

### **2.2. Key Diagnostic Parameters**

A small number of high-volume tests are the primary revenue drivers. The following six parameters account for an estimated **80% of total reagent sales**:

1. **HbA1c** (Diabetes)
2. **Troponin I (Trop I)** (Cardiac)
3. **TSH** (Thyroid/Hormone)
4. **C-reactive protein (CRP)** (Inflammation)
5. **Procalcitonin (PCT)** (Infection/Sepsis)
6. **D-dimer** (Coagulation)

### **2.3. End-User Segmentation**

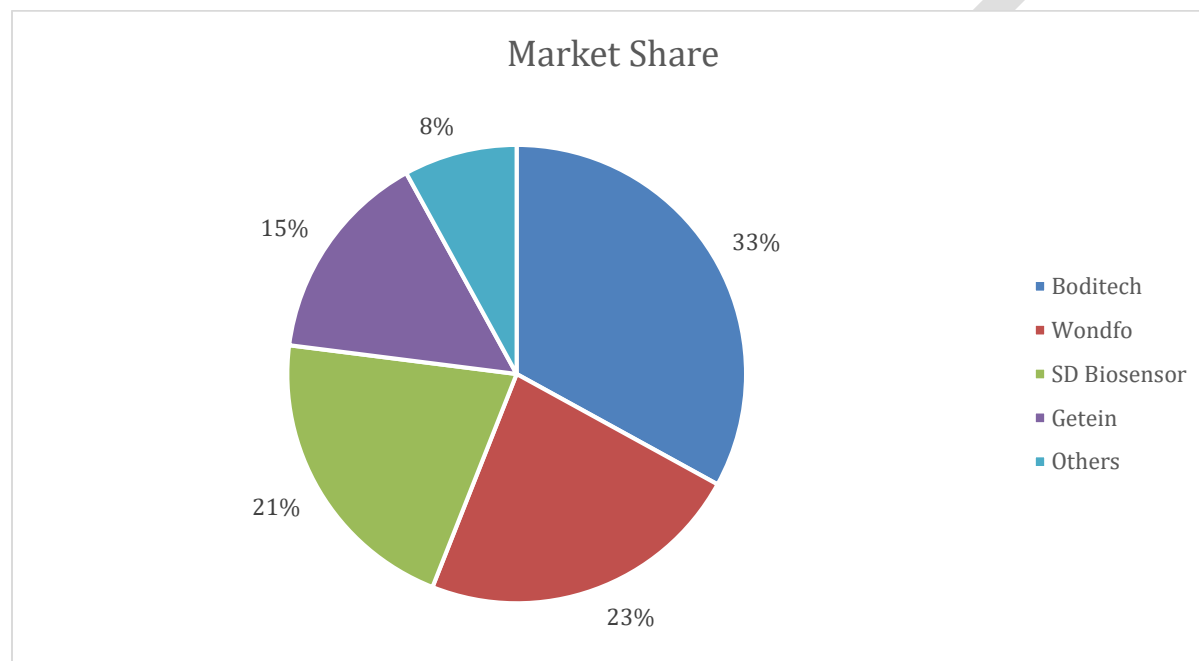
The market demand is segmented across three primary healthcare settings:

- **Hospitals (50%):** The largest segment, driven by demand from emergency rooms, Intensive Care Units (ICUs), and central labs for rapid diagnostics.
- **Laboratories (30%):** Private diagnostic labs utilize FIA for both routine and specialized testing.
- **Doctors' Offices (20%):** A growing segment, particularly for diabetologists, endocrinologists, and cardiologists who require immediate results at the point-of-care.
- **Government Sector:** Currently has a negligible share, indicating a significant untapped opportunity for market expansion through public health initiatives and tenders. Many of the parameters in the FIA are not part of the Essential List of Diagnostic Tests at PHC /CHC level.

### 3. Competitive Landscape & Key Player Profiles

The Indian FIA market is dominated by foreign-based companies, primarily from South Korea and China, who operate through a network of local distributors and, in some cases, wholly-owned subsidiaries.

#### 3.1. Market Share Data



#### 3.2. Detailed Company Profiles

##### 1. Boditech

- **Headquarters:** Gangwon-do, South Korea
- **Indian Presence:** Boditech Med India Pvt Ltd (Mumbai HQ, est. 2021); manufacturing facility in Reliance MET City, Jhajjar (inaugurated April 2025).
- **Last Year Revenue:** ₹142 Crores
- AFIAS range – Rs 9.5 Cr, I Chroma – Rs 92.50 Cr, Instacheck II (OEM by Diasys) – Rs 40 Crores,
- **Strategic Positioning:** Market leader with a strong focus on both high-end automated POC systems and broad-reach compact readers. The local manufacturing plant provides a significant strategic advantage in the supply chain and scalability.
- **Major OEM Partner:** Diasys (for the Instacheck II platform)
- **Distribution Network:**
  - CPC Diagnostics: 38%

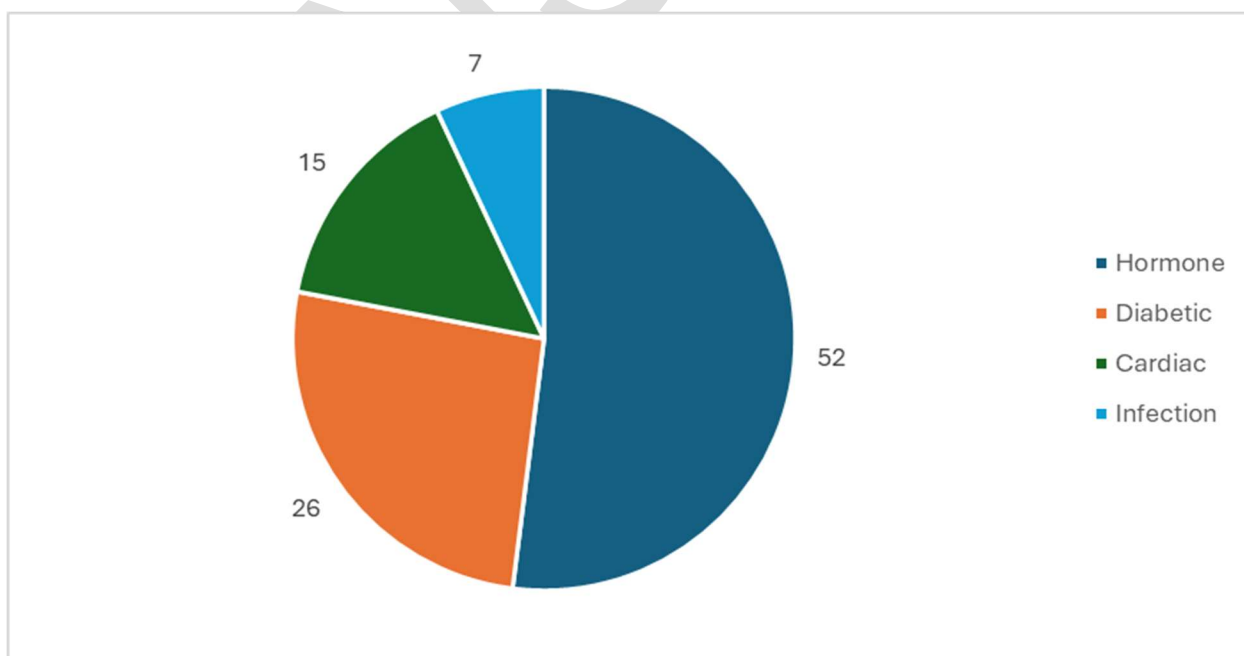
- Kin Diagnostics: 33%
- Diasys Diagnostics: 28% (Model Instacheck II is OEM from Boditech)

- **Top 5 Selling Parameters:** CRP, Vitamin D, TnI, HbA1c, TSH.

#### Product Portfolio in India:

- **AFIAS Series (AFIAS-1, AFIAS-6, etc.):**
  - **Technology:** Fully automated immunoassay analyser. A true POC system with integrated pipetting, mixing, and incubation, eliminating manual errors.
  - **Features:** Extremely compact (3.5 kg, size of a landline phone), multiple variants based on channel count (1 to 6 tests at a time).
  - **Target Market:** Doctors' clinics, emergency departments.
  - **Market Penetration:** 290 installations, generating ₹1.00 crore/month in sales.
  - **Price:** ₹1.5 lac (base model) to ₹6.5 lac (6-channel variant).
- **ichroma™ Series (I, II, III, M2, M3):**
  - **Technology:** Compact, single-cartridge semi-automated readers.
  - **Workflow:** Requires manual steps (sample mixing with buffer, incubation, pipetting). Ichroma-I has a built-in incubator.
  - **Market Penetration:** Over 8,000 installations across India.
  - **Target Market:** Broad deployment in labs and hospitals.

#### Profile-wise Business Distribution:



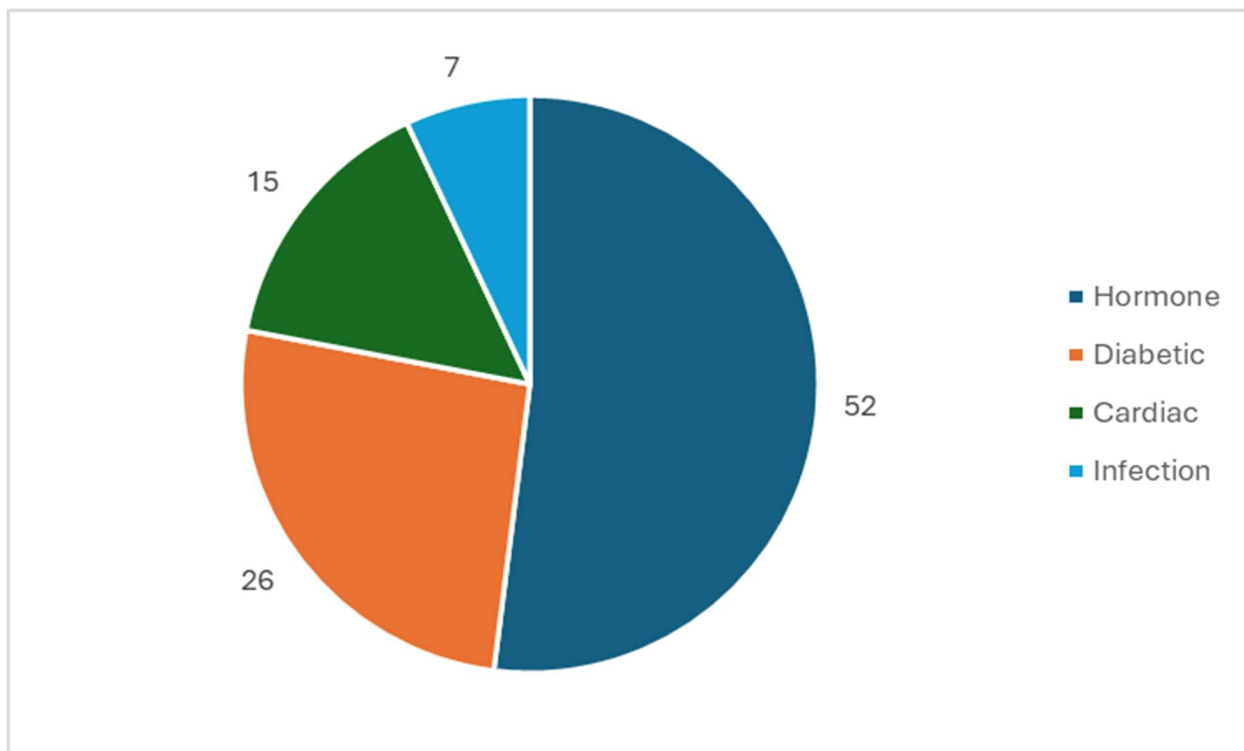
## 2. Wondfo

- **Headquarters:** Guangzhou, China
- **Last Year Revenue:** ₹102 Crores
- **FIA Device Brand name** - Finecare
- **Strategic Positioning:** An early market entrant that built its share through aggressive pricing, with reagents **25-30% cheaper** than competitors (e.g., T3+T4+TSH at ₹80 each vs. ₹110-120).
- **Key Success Factors:** Price competitiveness; successful placement of ~250 instruments in Karnataka PHCs via local purchase budgets; focus on labs (70% of business).
- **Distribution Network:**
  - Matrix Labs: 54%
  - Avantor: 23%
  - Rapid Diagnostic: 12%
  - Star Biomed: 11%
- **Top 5 Selling Parameters:** CRP, T4, T3, HbA1c, TSH.

### Product Portfolio in India:

- **Finecare™ FIA Meter Plus (FS-113):**
  - **Type:** Portable semi-automatic analyser.
  - **Features:** 8" LED touch screen, LIS/HIS connectivity, built-in thermal printer.
  - **Price:** ₹54,000 - ₹75,000.
- **Finecare™ FIA Meter III Plus (FS-205):**
  - **Type:** Semi-automatic analyser with higher throughput.
  - **Features:** 20 channels, 10" LCD touch screen, LIS/HIS connectivity.
  - **Price:** ₹230,000 - ₹250,000.

### Profile-wise Business Distribution:



### 3. SD Biosensor

- Head Quarters: Gyeonggi-do, South Korea
- Last Year Revenue: Rs 93 Crores
- A major player with 21% market share. Operates local manufacturing in Gurugram, Haryana. Strategically focuses more on **Diabetologists, Cardiologists, and Small Nursing Homes** than other competitors. The key product is the **STANDARD F200 Analyzer**. They also have **STANDARD F400** model with continuous loading of samples.
- They have over 10000 installation base and sell about 1000 devices annually
- **Distribution:** Direct by the company through local distributors.

### 4. Getein

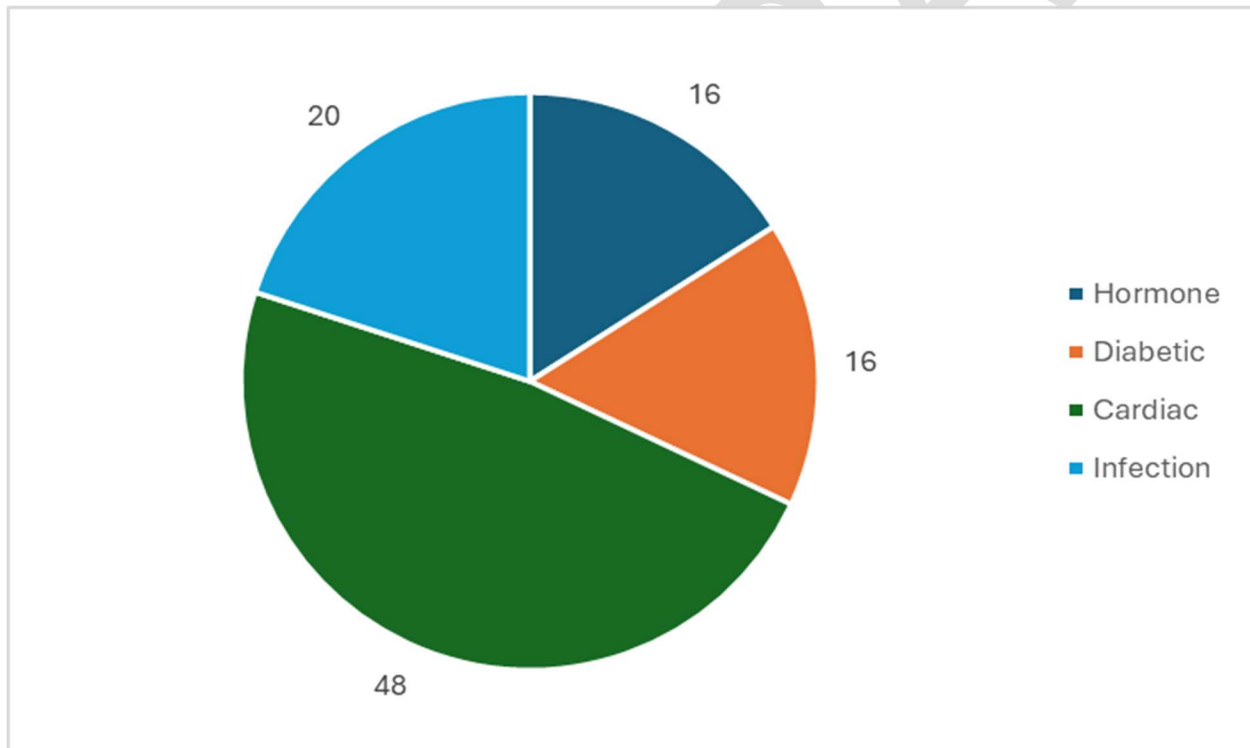
- **Headquarters:** Nanjing, China
- **Last Year Revenue:** ₹65 Crores
- **Strategic Positioning:** Competes across different price points with a diverse portfolio, including a model (FIA 8600) directly comparable to the highly automated AFIAS.
- **OEM Partners:** Cipla (Cipoint), Agappe Diagnostics (Mispa Revo).
- **Distribution Network:**

- Cipla: 28%
- Sogar: 16%
- Peerless Biotech: 16%
- Others (Reckon).
- **Top 5 Parameters:** PCT, NT-proBNP, TnI, TSH, HbA1c.

#### Product Portfolio in India:

- **FIA 8000:** Portable analyser. Price: ~₹65,000.
- **FIA 8600:** Portable analyser, automated features comparable to AFIAS. Price: ~₹18,000.
- **FIA 1100:** Portable analyser. Price: ~₹125,000.
  - **Common Features:** One-step testing, auto-recognition of test items, 7-inch touch screen, USB/LAN ports.

#### Profile-wise Business Distribution:



#### 5. Lansion Bio

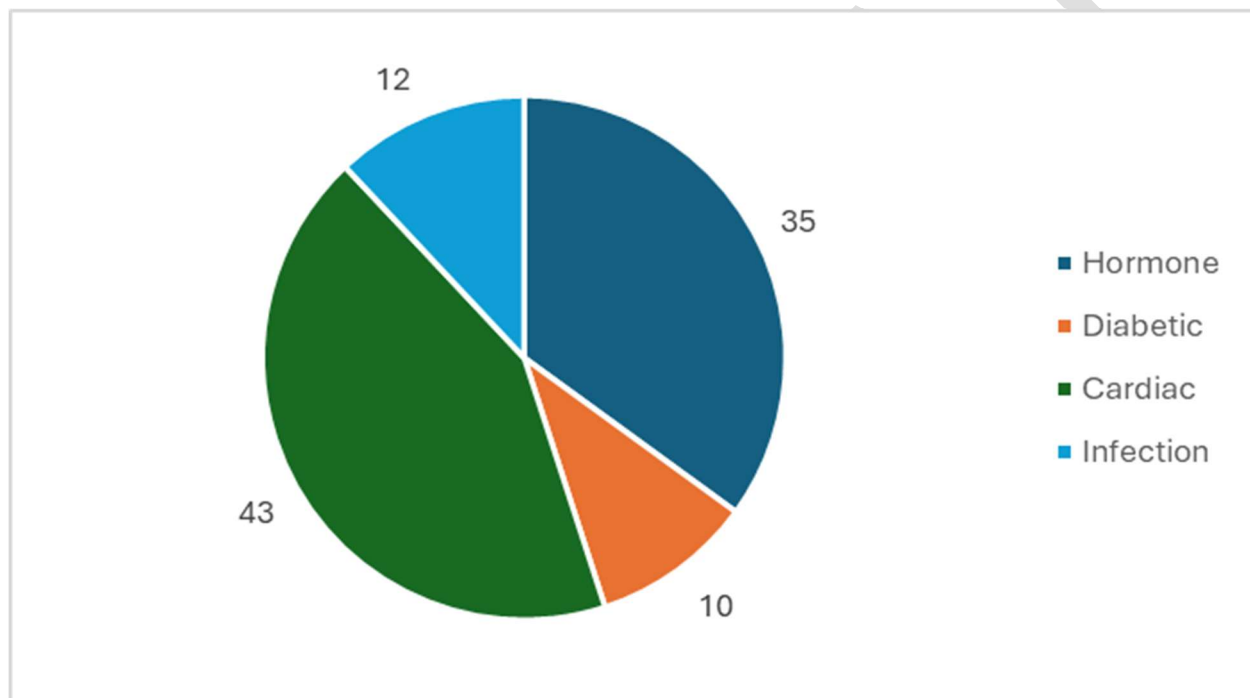
- **Headquarters:** Nanjing, China
- **Technology Focus:** Time-Resolved Fluorescence Immunoassay (TRFIA).
- **Last Year Revenue:** ₹4.7 Crores
- **OEM Partners:** Tulip (FIA Check).

- **Distribution Network:**
  - Agappe Diagnostics: 95%
  - Tulip Diagnostics: 5%
- **Top 5 Selling Parameters:** NT-proBNP, T4, T3, TSH, Tnl.

#### Product Portfolio:

- **LS-1100:** Portable TRFIA analyser with 7" touch screen and built-in battery.
- **LS-2100:** High-throughput TRFIA analyser for high-volume settings.
- **LS-4000:** Handheld TRFIA analyser for field/emergency use.

#### Profile-wise Business Distribution:



## 6. Zybio

- **Headquarters:** Chongqing, China
- **Last Year Revenue:** ₹2.1 Crores
- **Distribution Network:** Dominated by a single importer, Biodx Healthcare (98%).
- **Top 5 Selling Parameters:** Vitamin D, HbA1c, T4, T3, TSH.

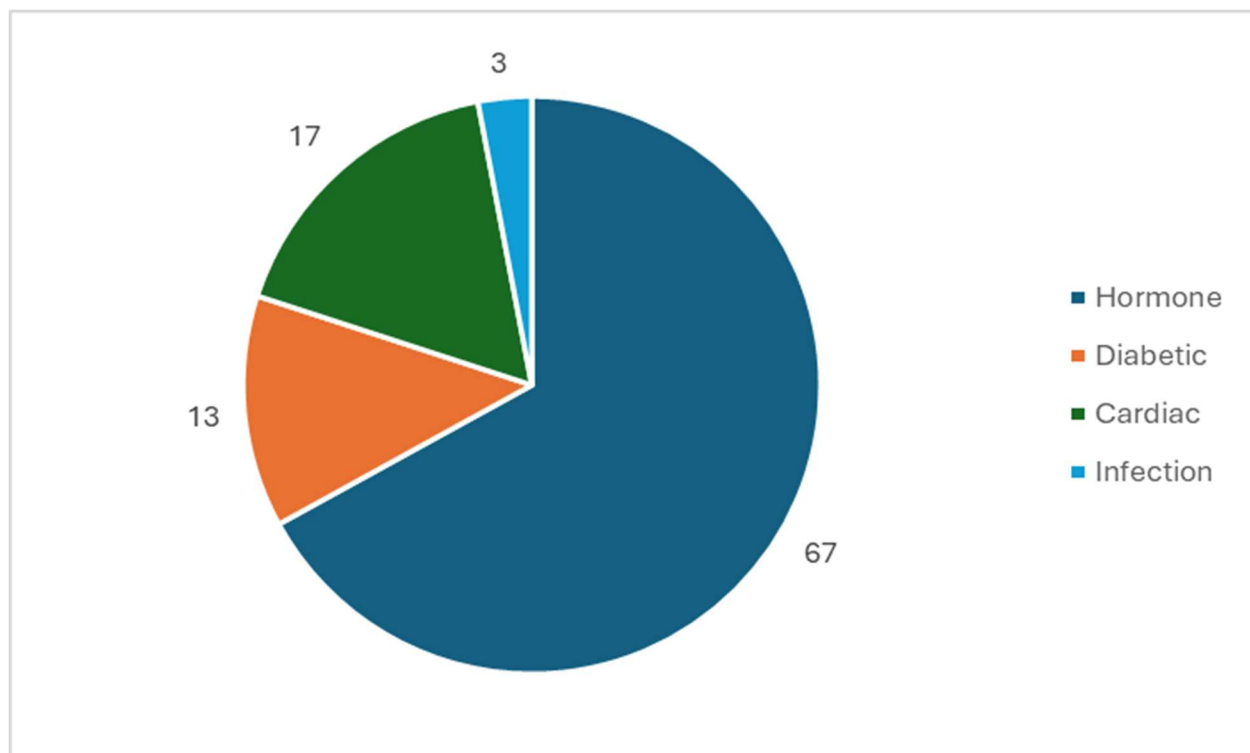
#### Product Portfolio in India:

- **EXR110/120:** Compact, semi-automatic POCT analysers. EXR120 includes a built-in battery.



- **Q8 Pro:** High-throughput benchtop analyser with 25 channels and a 15-inch HD touch screen.

**Profile-wise Business Distribution:**



**viii) Other Notable Players**

- **Diasys Instacheck (Germany/India):** Offers the **QDx Instacheck™** and **Instacheck™ II** (TRF technology) analysers. Has a stronger presence in **physicians' clinics**, likely benefiting from a legacy orientation passed down from Piramal/Boehringer Mannheim.
- In April 2025, **Acon** has launched their FIA Plex in India through their national distributors Entero Peerless Biotech. In the very first month they sold 280 units. They intend to be a price player competing with Finecare; with price points lower than that of Fine care.
- **Athanese Dx** has recently launched their FIA reader by the brand name ALTA.
- **Strumed Solutions Pvt Ltd**, the only indigenous company with manufacturing facility in Surat, has launched FIA analyser in the brand name InstaXplo, with about 10 parameters presently available and adding newer parameters. They are ramping up their sales organisation and have close to 100 units sold in the market.

#### 4. Substitute Technologies and players

There are a few other established players marketing their Point-of-Care Readers to perform similar assays, but on different techniques such as Lateral Flow Immuno Assay and Photometry. From a customer choice point of view there would be lesser differentiation between FIA or Lateral Flow assay. The differentiators are Convenience, TAT, Menu, and performance. In that sense, these Devices also directly compete with FIA devices to win customers.

The major players this segment are :

##### 1. Quidel

- **Head Quarters – San Diego, USA**
- **Financials:** Estimated sales revenue of ₹42 crores.
- **Product: Triage® MeterPro® Analyzer**
  - **Workflow:** Simple 3-step process (add sample, insert device, read results).
  - **Test Time:** 15-20 minutes.
  - **Features:** Barcode scanning, LIS/HIS integration, Test Select™ feature for running specific assays to control costs.
- **Key Panels:** Cardiac (Troponin I, hs-Troponin I, BNP, NT-proBNP), Coagulation (D-Dimer), Toxicology (9-panel urine drug screen).
- Quidel will very soon launch their Quidel SoFIA benchtop FIA analyser in India, mainly for the infectious assays.

##### 2. Roche Diagnostics

- **Headquarters:** Rotkreuz, Switzerland
- **Technology Focus:** Photo signal (Cobas hs 232), Microfluidic (Lumira)
- **Last Year Revenue:** Approx Rs 14.0 crores from POC for immune assay tests and meters.
- **OEM Partners:** NIL
- **Distribution Network:**
  - Direct marketing through multi-distribution model

##### Product Portfolio:

- **Cobas hs 232** – Focused on cardiology with parameters such as Highly Sensitive Troponin T, NT ProBNP , Myoglobin, D Dimer, CK MB.
- **Lumira** – Micro fluidic based. Main parameters – NT ProBNP, CRP, D Dimer and infectious. Roche is yet to launch Lumira in India.

Other major players : Affinion by Abbott, Innovastar by Diasys, PTS Diagnostics etc

#### 4. Alternatives to FIA and LFIA

When it comes to Immuno Assay Parameters, CLIA platforms offered larger menu, and slightly better performance parameters (Accuracy / Precision / Linearity). However, FIA had the advantage of smaller devices to cater to lower work load requirements as well as individual cartridge-based test that can be performed instantly.

As CLIA manufacturers develop smaller compact analysers there is a competition from CLIA in the horizon. Smaller CLIA systems like Accre 8 (Wondfo), Mispa i60 (Fujirebio) etc can be an early example of CLIA getting compact.

#### 5. Strategic Insights & Outlook

1. **The Automation Imperative:** The market is rapidly moving beyond semi-automated systems. The success and premium positioning of Boditech's AFIAS, coupled with the introduction of fully automated platforms by competitors like Finecare and Getein, establish a new industry standard. **New market entrants must offer fully automated solutions to be competitive.**
2. **Price vs. Performance:** The market is segmented. While Finecare's success demonstrates a large, price-sensitive customer base, the strong performance of premium players like Boditech and Quidel Triage shows a willingness to pay for quality, automation, and reliability, especially in critical care settings.
3. **Localization is Key:** The move by Boditech and SD Biosensor to establish local manufacturing facilities in India is a strategic masterstroke. It mitigates supply chain risks, potentially lowers costs, and demonstrates a strong, long-term commitment to the market, which can be a key factor in securing large contracts and building trust.
4. **Distribution is Power:** The market is controlled by a web of exclusive and semi-exclusive distribution agreements. The share of a distributor (e.g., Matrix Labs for Finecare, CPC for Boditech) is directly tied to the principal company's success.
5. **Untapped Potential:** The negligible share of the government sector represents the single largest growth opportunity. Companies that can successfully navigate public procurement processes and place instruments in government hospitals and PHCs at scale could significantly alter the market share landscape.

In conclusion, the Indian FIA market is on a high-growth trajectory, driven by the increasing need for rapid and reliable diagnostics at the point of care. The future of the market will be defined by a battle between cost-effective solutions and advanced, fully automated platforms, with strategic localization and strong distribution networks serving as the critical pillars for success.

#### 5. References:

**Boditech Med Inc.**

- **Official Website:** <https://www.boditech.co.kr/>
- **Product Information:** <https://www.boditech.co.kr/en/product>
- **India Distributor:** <https://www.medikabazaar.com/brands/boditechboditech.co.kr+2boditech.co.kr+2boditech.co.kr+2boditech.co.krmedikabazaar.com+1medikabazaar.com+1>

**Finecare (Wondfo)**

- **Product Details:** <https://www.ankkcares.co.in/portable-immunoassay-reader.html>
- **India Distributor:** <https://www.matrixlabs.in/finecare-fia-meter-plus-manufacturers-in-chennai.phpankkcares.co.in+1indianbiosystem.com+1>

**Getein Biotech Inc.**

- **Official Website:** <https://www.getein.com/>
- **Product Information:** [https://www.getein.com/fia\\_c20\\_2](https://www.getein.com/fia_c20_2)
- **India Distributor:** <https://www.cosmic.net.in/product/getein-1160-immunofluorescence-quantitative-analyzer/getein.comcosmic.net.in>

**QuidelOrtho (Triage® System)**

- **Product Information:** <https://www.quidelortho.com/in/en/products/triage-meter-pro/triage-meterpro-instrument>
- **Official Website:** <https://www.quidelortho.com/in/en>

**Lansion Biotechnology Co., Ltd.**

- **Official Website:** <https://www.lansionbiotech.com/>
- **Product Information:** <https://www.lansionbiotech.com/shoplansionbiotech.com>

**Zybio Inc.**

- **Official Website:** <https://www.zybio.com/>
- **Product Information:** <https://www.zybio.com/product/40.html>
- **India Distributor:** <https://hospitalstore.in/zybio-exr110-fluorescence-immunochromatography-analyzer/zybio.com+6zybio.com+6zybio.com+6zybio.com+2zybio.com+2zybio.com+2>