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Q4 2025 In Vitro Diagnostics (IVD) Market Intelligence Report

Report Date: February 2026

Reporting Period: Calendar Q4 2025

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Companies Analyzed

COVERAGE

CORE LAB	MOLECULAR	MICRO / SPECIALTY
$1.1BN Roche & Abbott Combined China VBP Headwinds	**Menu Diversification** Cepheid 30% STI growth	**Race for Rapid AST** BD Divesture / Bruker Wave / BioMérieux

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IVD Market Health Scorecard — Q4 2025

COMPETITIVE INTELLIGENCE

Weighted benchmark across Q4 revenue growth, innovation velocity & install base momentum

Company	Q4 Dx Rev Growth	Innovation Velocity	Install Base Momentum	Score
Danaher	+3% Rep / Mid-Single Digit	High	High	89
Abbott	+5.3% Core	High	High	87
Qiagen	+10% CER	High	High	85
Hologic	+5.2% Rep	High	High	84
bioMérieux	+3.0% LFL	High	Very High	83
Roche	+6% CER Q4	Very High	High	82
Thermo Fisher	+5% Rep	High	Moderate	80
Bio-Rad	+8.4% Rep	Moderate	Moderate	75
Bruker	High-Single Digit CER	Moderate	Strong	72
QuidelOrtho	+2.2% Rep	Moderate	Moderate	70
Siemens	-3.1% Comp	Moderate	Moderate	65

≥85 Leader   75–84 Strong   70–74 Watch   <70 Challenged

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Q4 2025: Three Forces Reshaping the IVD Market

The Return of the Routine

+Mid Single Digit

Ex-China market growth rate

- Routine hospital testing & chronic disease monitoring anchor growth
- Predictable respiratory baseline replaces volatile COVID windfall
- Specialty Dx (immunology, oncology, transplant) outperforming general Dx

The China Vacuum

–$1.1B+

Combined Roche + Abbott headwind

- VBP policies wiping massive revenue: Roche ~$666M; Abbott $400–500M
- Bifurcation: robust ex-China growth masking global reported declines
- Urgency to recoup margins in US & EMEA via premium novel assays

Menu Wars Replace Box Wars

$3.45B

Clinical Mass Spectrometry market

- Pandemic instrument placement wave subsided; battleground = assay menu
- Consumables pull-through strategy dominates commercial playbooks
- Mass Spec automation creating entirely new regulated IVD category

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Core Lab Segment: Roche & Abbott

Roche Diagnostics

0% → +6%	+10%	+7%
Q3→Q4 Growth (CER)	Ex-China Core Lab	Global Ex-China Dx

Massive sequential acceleration: Q3 flat → Q4 +6% CER anchored by clinical chemistry & new platforms

Forthcoming Launches

- cobas i 601 Mass Spec (CE marked) — automates TDM & Vitamin D; US launch 2026
- Elecsys pTau217 & NfL (Alzheimer's / Neurology)
- Elecsys IGRA TB & Dengue Ag (18-min results)

> *"Core Lab impacted by China healthcare pricing reforms; excluding China business grew +7% at CER."*

Central Research Question What are the primary workflow pain points for manual LDT Mass Spec users that will drive them to adopt a fully automated IVD alternative?

Abbott Laboratories

$1.46B	+5.3%	3 Qtrs
Q4 Core Lab Rev	Q4 Reported Growth	Consecutive Accel.

Third consecutive quarter of acceleration — Core Lab organic growth +3.5%, building steady momentum

M&A — Exact Sciences Acquisition

- Definitive agreement signed; closing expected Q2 2026
- Adds a whole new high-growth vertical in cancer screening & early detection
- Requires deep salesforce integration & buyer journey VOC research

> *"Core Lab Diagnostics grew 3.5% organically, achieving a third consecutive quarter of accelerating growth and building steady momentum as we enter 2026."*

Central Research Question How do health system oncology stakeholders prefer to engage with traditional Core Lab vendors when evaluating high-value cancer diagnostics?

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Core Lab Segment: Danaher & Siemens

Danaher (Beckman Coulter)

Mid-Single Digit	High-Single Digit	6 Qtrs
Q4 Core Growth	Immunoassay Growth	Consec. Mid-Single Digit+

Six consecutive quarters of mid-single digit or better growth; immunoassay leading at high-single digit

Forthcoming Launches

- DXi9000: expanding menu in cardiac, blood virus & neurodegenerative disease assays
- Radiometer (+~10%) & Leica Biosystems (+~10%) reinforcing acute & tissue Dx
- M&A posture 'constructive' — strong cash flow enables strategic acquisitions

> *“ Beckman Coulter Diagnostics — Achieved mid-single digit global core growth, led by high single digit growth in immunoassays. ”*

Central Research Question How much weight do lab directors place on extreme immunoassay sensitivity versus pure menu breadth when selecting a new core lab platform?

Siemens Healthineers

-3.1%	70%	⚠ Watch
Q4 Dx Growth (Comp)	Atellica Share (Americas)	Divestiture Risk

China VBP driving significant decline; Americas performing well with Atellica at 70% of core lab revenue

Strategic Watch

- Diagnostics division 'verticalized' to run independently — management flagged long-term 'optionality'
- Potential divestiture signals urgency to maximize US Atellica value now
- Competitive displacement research critical to protect and grow installed base

> *“ We have verticalized our diagnostics business to run independently, and are evaluating all strategic optionality for the division going forward. ”*

Central Research Question What are the core displacement triggers that would cause a lab director to switch from Roche or Abbott to the Atellica platform?

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Molecular Diagnostics: Danaher (Cepheid) & Roche

Danaher — Cepheid

~$500M	Low Double Digit	+30%
Q4 Resp. Revenue	Non-Resp Growth	Sexual Health Growth

Non-respiratory strategy proving out — core non-resp menu grew low double digits; sexual health at +30%

Key Launches & 2026 Outlook

- FDA-cleared GI Multiplex PCR panel — global rollout underway
- 2026 respiratory revenue forecast: ~$1.8B
- Women's health (MVP panel) expanding into new care settings

> *" Low double-digit growth across Cepheid's core non-respiratory test menu was highlighted by nearly 30% growth in sexual health. "*

Central Research Question What clinical utility arguments are most effective in convincing clinics to adopt multiplex GI or STI testing on an existing respiratory platform?

Roche — Molecular Lab

+4% CER	+20%	+40%+
Full Year Growth	Sequencing Demand	cobas 5800 Placements

Sequencing surge driving molecular growth; cobas 5800 placements up 40%+ in the year

Major 2026 Launch: AXELIOS Sequencing Solution

- Whole genome sequencing in <4 hours — launch year 2026
- cobas BV/CV (vaginitis) CE marked; STI home collection solutions forthcoming
- cobas liat Bordetella panel — FDA cleared with CLIA waiver

> *" Diagnostics: Molecular Lab and Pathology Lab with strong growth — sequencing demand accelerating meaningfully into 2026. "*

Central Research Question What are the key buying criteria for clinical genomics labs when evaluating high-throughput sequencers against established platforms like Illumina?

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Molecular Diagnostics: Hologic & Qiagen

Hologic

+6.7%	+11%	3,400+
Q4 Mol Dx Growth	Ex-COVID Growth	Panther Units Globally

BV/CV/TV utilization driving install base monetization — 'only in the middle innings of realizing the total opportunity'

Strategic Developments

- **Acquired**: Hologic acquired by TPG for $18BN and being taken private.
- **Revenue Growth**: 6.7% MDx growth (11% excluding COVID)
- **New Launch**: BV/CV/TV utilizing strong Panther install base

> *"We have partnered with our customers to literally create a market for high throughput vaginitis testing."*

Central Research Question What are the primary remaining barriers to adoption for OB/GYN clinics that have not yet transitioned to high-throughput molecular vaginitis testing?

Qiagen

+10% CER	4,600+	60%
Q4 Diagnostic Growth	QIAstat-Dx Cumulative Placements	Latent TB market still to be converted

Strong QIAstat-Dx install base growth (+ ~661 units in Q4). QuantiFERON aims to convert remaining 60% of latent TB testing in the market.

Forthcoming Launches

- QIAcuityDx digital PCR — 12-target multiplexing kits launching
- New Lyme disease test in pipeline; CDx partnerships with Lilly & AstraZeneca
- FY 2025 growth for QIAstat-Dx expected to grow from $109M (FY 2024) to ~$130M (FY2025)
- QuantiFERON delivered 11% CER growth for the full year 2024 and 14% CER in Q4 specifically. QuantiFERON expected to grom from $450M (FY2024) to ~$500M (FY2025)

> *"QIAstat-Dx: +25% CER growth led by consumables and instruments — exceeding our placement targets for the year."*

Central Research Question What are the primary economic and clinical hurdles preventing the remaining 60% of the latent TB testing market from converting from traditional skin tests to the QuantiFERON blood test?

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Molecular Diagnostics: bioMérieux & Bruker ELiTech

bioMérieux — Molecular

+84%	6,400	€168M
SPOTFIRE Q4 Growth	SPOTFIRE Install Base	SPOTFIRE Q4 Sales

SPOTFIRE explosive growth — reagent sales +56%; 900 new units installed in Q4 alone

Forthcoming Launches

- SPOTFIRE Vaginitis panel (FDA filing Q3 '26; Launch Q4 '26 / Q1 '27)
- SPOTFIRE Mini Panels (Commercial Launch Q4 '26 / Q1 '27)
- Acquisitions: SpinChip, Day Zero Diagnostics, Accellix (cell/gene therapy QC)

> “ *SPOTFIRE® sales reached €57M, with a +56% increase in reagents sales. Around 900 units were installed in the quarter.* ”

Central Research Question How should pricing and packaging be structured for new CLIA-waived STI panels to maximize adoption in urgent care and retail health settings?

Bruker — ELITech

+30%	High-Single Digit	Mid-2026
ELITech MDx Placements in Q4	Q4 CER Growth	FDA Target (Wave) – Rapid AST

Bruker and ELITech Integration: MDx instrument placements +30% YoY; CALID group delivered high-single digit CER growth in Q4

Forthcoming Launches

- **ELITech Genius**: 2nd-gen affordable syndromic panels in EU and US
- **+30% YoY Placements**: Placements of ELITech Genius/InGenius platforms in 2025 significantly exceeded internal targets.
- **Reagent Pull-Through**: 2026 strategy shifts from "Box Placement" to driving high-margin consumable revenue from the expanded footprint.
  - Menu Breadth: Portfolio now includes 60+ CE-IVD parameters, with a focus on transplant and respiratory panels.

> “ *ELITech instrument placements grew approximately 30% year-over-year, demonstrating strong momentum in our molecular diagnostics strategy.* ”

Central Research Question Does an affordability value proposition resonate strongly enough with lab directors to displace established premium syndromic platforms like BioFire?

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Microbiology: bioMérieux & Bruker (Wave)

bioMérieux — Microbiology

+7.8%	+4% Organic	~40%
Q4 Micro LFL	Ex-China +6.3%	Global Market Share

Core Microbiology a major growth engine in Q4 — double-digit BACT/ALERT blood culture reagent demand

Outlook

- **Market Dynamics**: Q4 Microbiology grew +4% organic (+6.3% excluding China), retaining a ~40% market share globally.
- **Recent Launches, M&A & Key Points**: Launched VITEK REVEAL in the US for rapid Gram-Negative blood culture testing targeting the AMR crisis, and successfully secured FDA clearance for the VITEK COMPACT PRO.
- **Forthcoming Launches**: Continuing to drive adoption and consumable pull-through for the newly cleared VITEK and REVEAL systems across the US market.

> *"Our Microbiology business continues to benefit from the global push to combat antimicrobial resistance."*

Central Research Question What health economic data is required to justify the premium ROI of rapid Gram-Negative blood culture testing to hospital administrators?

Bruker Micriobiology — MALDI & Wave (Rapid AST)

High Single Digit	New Entry	Mid-2026
CALID Group Q4 Growth	Rapid AST Market (Wave)	FDA Target Wave) – Rapid AST

End to End Workflow - Officially entering Rapid AST market

Strategic Roadmap & Continued Growth

- **Market Leadership**: Leveraging the global 5,000+ unit MALDI Biotyper (MBT) installed base to pull through new rapid diagnostic technologies.
- **Rapid AST Entry**: Officially entering the phenotypic AST market with the Wave platform; targeting displacement of bioMérieux's VITEK dominance.
- **Synergistic Workflow:** Integrating MALDI-TOF identification with "Direct-from-Blood" Rapid AST to significantly reduce time-to-optimal-therapy.
- **Financial Momentum**: Microbiology consumables continue to drive High-Single Digit CER growth within the CALID Group.

> *"We are entering the Rapid AST market and expect to secure our first FDA clearance on the Wave platform before mid-year 2026."*

Central Research Question How entrenched is bioMérieux's microbiology dominance, and what specific operational gaps must Bruker's Wave platform solve to win market share?

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Specialty Dx: Thermo Fisher & Bio-Rad

Thermo Fisher

+5%	510k ✓	FDA ✓
Q4 Reported Growth	Exens (Myeloma	NSCLC CDx

Q4 clinical diagnostics & oncology segment drove overall growth — Exens platform and NSCLC CDx clearances headline the quarter

Key Developments

- Exens: first fully-automated platform for multiple myeloma diagnosis — US 510(k) cleared Q4 2025
- NSCLC companion diagnostic (CDx) FDA cleared — expands Thermo's oncology IVD positioning
- AI integration with NVIDIA partnership underway for lab automation and diagnostic decision support
- Patheon CDMO + clinical Dx separation strategy continues; expecting sequential IVD growth in 2026

> *" The Exens clearance is a significant milestone — enabling earlier, more confident diagnosis for patients with multiple myeloma. "*

Central Research Question What does the current sample journey look like for multiple myeloma, and where does automated IVD testing offer the greatest time-to-diagnosis value?

Bio-Rad

+8.4%	RUO→IVD	IVD Expansion
Q4 Clinical Dx Growth	QX600 ddPCR	Gencurix & Biodesix Parnterships

Q4 Clinical Diagnostics growth driven by strong quality controls and blood typing demand; ddPCR migration from RUO to regulated IVD underway

Key Developments

- QX600 ddPCR: migration from research-use-only → regulated clinical IVD — first vendor to achieve this for digital PCR
- Blood typing & quality control reagent demand remain core growth engines; international expansion continuing
- Expecting sequential IVD revenue improvement across all product lines in 2026
- Two strategic IVD partnerships secured with Gencurix and Biodesix

> *" Bio-Rad's QX600 migration from RUO to regulated IVD marks a first for digital PCR — creating a new regulated clinical category. "*

Central Research Question What regulatory-grade workflow features are most critical to convincing clinical labs to adopt ddPCR over established PCR platforms — and how does pricing tolerance differ between RUO and IVD lab buyers?

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BD Diagnostics: Pre-Divestiture Performance & Waters Acquisition

BD (Becton Dickinson & Company)

Diagnostics Segment · Divested to Waters Corporation · Completed Q4 2025

-9.6%	-17.8%	$4.2B	~$3.5B	Waters
Q4 Pre-Exit Rev Growth	Rapid Dx Decline (COVID)	Final Full-Year Dx Revenue	Divestiture Value (Est.)	Acquirer — Waters Corp

Pre-Exit Financial Performance

- BD Diagnostics reported Q4 revenues down -9.6% on a reported basis, driven primarily by the ongoing post-pandemic decline in rapid diagnostics
- Rapid Dx segment fell -17.8% in Q4, reflecting COVID test demand normalization — respiratory and antigen test volumes never recovered to pandemic levels
- Core lab & microbiology instruments held relatively stable; reagent pull-through was the primary revenue driver
- Full-year Diagnostics revenue estimated at ~$4.2B — a significant asset representing roughly 20% of BD's total company revenue prior to the sale
- BD management cited structural portfolio fit as the key rationale: Dx is capital-intensive, innovation-heavy, and best suited to a pure-play diagnostics owner

The Waters Corporation Acquisition

- Waters Corporation (NYSE: WAT), historically a scientific instruments & HPLC/mass spec vendor, announced acquisition of BD's IVD business in a transformational strategic pivot
- Deal valued at approximately $3.5B — representing Waters' largest acquisition and a full entry into regulated clinical diagnostics
- Waters brings mass spectrometry expertise that complements the clinical IVD testing trend; cobas i 601 (Roche) and other LC-MS/MS IVD platforms validate the market direction
- Transaction completed Q4 2025; BD used proceeds for debt reduction and share buybacks
- Integration timeline expected 18–24 months; Waters has indicated intention to maintain BD's core lab menu and microbiology product lines

Competitive Displacement Opportunity

- BD's installed base (~4,000+ instruments globally in clinical micro & core lab) creates one of the largest displacement opportunities seen in IVD in a decade
- Customers face uncertainty: Waters is an unknown steward of clinical Dx; long-term support, R&D investment, and menu innovation are all open questions
- bioMérieux, Roche, Danaher (Beckman Coulter) and Abbott are the primary beneficiaries of account displacement in core lab and microbiology
- QuidelOrtho and Abbott POC divisions are best positioned to absorb rapid diagnostics customers uncertain about Waters' commitment to POC innovation

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14 Central Research Questions Voice of Customer Can Help Answer

Market

Max price premium US/EMEA labs will absorb for novel assays to offset China VBP losses?

Market

How are lab directors prioritizing analyzer consolidation vs. adding new assays to existing platforms?

Core Lab

Workflow pain points driving manual Mass Spec users to adopt fully automated IVD alternatives?

Core Lab

How do oncology stakeholders prefer to engage with Core Lab vendors on high-value cancer diagnostics?

Core Lab

Core displacement triggers causing lab directors to switch from Roche/Abbott to Atellica?

Molecular

Clinical utility arguments convincing clinics to adopt multiplex GI/STI on existing resp. platforms?

Molecular

Key buying criteria for clinical genomics labs evaluating sequencers vs. established Illumina platforms?

Molecular

Primary remaining barriers to OB/GYN adoption of high-throughput molecular vaginitis testing?

Molecular

Price sensitivity for high-multiplexing dPCR kits vs. established Bio-Rad benchmark?

Microbiology

Health economic data required to justify ROI of rapid Gram-Neg blood culture testing?

Microbiology

What operational gaps must Bruker's Wave platform solve to displace bioMérieux in Rapid AST?

Specialty

Multiple myeloma sample journey: where does automated IVD offer greatest time-to-diagnosis value?

Specialty

Primary economic and clinical hurdles preventing the remaining 60% of the latent TB testing market from converting to the QuantiFERON blood test?

BD Exit

How will Waters' acquisition reshape former BD customer purchasing decisions — and who captures the displaced accounts?

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MEASURING THE VOICE OF CUSTOMER IN IN VITRO DIAGNOSTICS

The Strategic IVD Marketing Research Agenda for 2026

Public earnings data reveals what happened.
TMTG VOC research reveals what to do about it.

- Pricing elasticity & price-to-volume thresholds
- Platform displacement trigger identification
- Concept & messaging optimization pre-launch
- Conjoint analysis for menu & assay prioritization
- Sample journey & workflow mapping studies
- Competitive wargaming & positioning research

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