

Q2 2026 In Vitro Diagnostics (IVD) Market Insights & Competitive Intelligence

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Reporting Period

Q2 2026

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Companies Covered

12 IVD Players

CORE LAB

Abbott · QuidelOrtho · Roche ·
Danaher/Beckman · Siemens · Sysmex

Clinical Chemistry · Immunoassay · Hematology

MOLECULAR

Abbott · Roche · Cepheid · bioMérieux

Syndromic · PCR · Precision Oncology · Near-
Patient

SPECIALTY / MICRO

Thermo Fisher · Waters/ADx · Roche
(Pathology) · Bio-Rad · Qiagen · bioMérieux

Blood Culture · Companion Dx · Pathology · QC

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bioMerieux · Cepheid (Danaher) · Abbott · Roche, plus scorecard, watchlist & research agenda

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Q2 2026 Core Lab Diagnostics: Lab Automation Loops & Central Lab Placements

Stable routine testing volumes are masking a widening commercial performance gap as market leaders secure long-term hospital placements through total lab automation loops, while laggards are severely dragged by China pricing reforms and platform transition volume leakage.

01 AUTOMATION LOOPS

Immunoassay & Lab-In-A-Loop Adoption Accelerates

Staffing shortages and hospital laboratory throughput demands continue to accelerate the rollout of high-volume clinical automation tracks. Beckman Coulter (Danaher) is heavily leveraging this trend with strong demand for the DxI 9000 immunoassay analyzer.

\$1.4B

 Abbott Core Lab |
Revenue (+3.2%)

+8.0%

 Roche Core Lab |
Growth Ex-China

+2.0%

 Beckman Coulter |
Core Growth

+12.7%

 Sysmex | Constant-
Currency Growth

02 CHINA VBP PRESSURE

Centralized Bidding Continues to Compress Multinational Sales

Volume-Based Procurement (VBP) centralized bidding, anti-corruption campaigns, and Diagnostic-Related Group (DRG) hospital budget controls continued to heavily compress multinational sales, forcing rapid localization of manufacturing and bottling.

-10.3%

 Siemens Dx | China
Comparable
Decline

-23%

 QuidelOrtho |
China Revenue
Decline

-33.8%

 Sysmex | China
Local-Currency
Decline

-5.5%

 Siemens Dx | Total
Comparable
Decline

03 STRUCTURAL SHIFTS

Carve-Outs and Platform Bundling Reshape the Competitive Map

Siemens Healthineers is advancing preparations for a formal carve-out of its Diagnostics division, while Sysmex's newly integrated BioMajesty clinical chemistry business signals a broader push toward unified hematology-plus-chemistry central lab bundles.

\$814.2M

 Sysmex | Q1 FY27
Global Dx Revenue

\$1.1B

 Siemens Dx | Q2
Global Revenue

\$2.5B

 Beckman Coulter |
Dx Segment
Revenue

\$631M

 QuidelOrtho |
Total Dx Segment
Sales

Q2 2026 Core Lab Diagnostics Scorecard: Strategic Positioning

Qualitative positioning across four operational dimensions: revenue growth, M&A activity, product innovation, and market sentiment. Tiers: Leader · Resilient · Under Pressure · Challenged/Restructuring.

Company	Growth	M&A	Innovation	Sentiment	QoQ	Position / Catalyst
Sysmex Corporation	High	Solid	Solid	High	New	LEADER Unrivaled hematology/hemostasis placement velocity in the
Abbott Diagnostics (Core Lab)	Solid	None	Solid	High	→	RESILIENT Deep instrument stickiness and consistent Alinity placement momentum
Roche Diagnostics Core Lab	Solid	None	High	Solid	→	RESILIENT High-growth non-China immunodiagnostics; upcoming cobas Mass Spec
Beckman Coulter (Danaher)	Solid	None	Solid	Solid	→	RESILIENT High automation demand and rollout of the high-throughput Dxl 9000
QuidelOrtho Labs	Muted	None	Muted	Cautious	↓	UNDER PRESSURE Severe China VBP delay and soft respiratory season forcing guidance cuts.
Siemens Healthineers Diagnostics	Challenged	None	Muted	Cautious	→	RESTRUCTURING Formal division carve-out prep; legacy system retirement and China declines

Core Lab: Beckman Coulter (Clinical Chemistry & Immunoassay)

\$2.5B

Dx Segment Revenue

+2.0%

Core Growth

+4.0%

Growth From Acquisitions

Dxl 9000

Immunoassay Platform

REVENUE

- Global Diagnostics segment revenue \$2.5B (+2.0% core, +4.0% acquisitions, +1.0% FX)
- Beckman Coulter Diagnostics growing in the mid-single digits globally

MARKET INTELLIGENCE

- Dxl 9000 immunoassay platform driving high-throughput central lab placements
- “Lab-in-a-loop” autonomous science integrations capturing long-term contracts
- China declines moderating sequentially as pricing stabilizes

STRATEGIC IMPLICATIONS

- Automated immunoassay-automation loops lock in long-term customer accounts
- High switching costs make displacement difficult for competitors

COMPETITIVE ALERT

- Dxl 9000's hands-free efficiencies are a key differentiator vs. labor-constrained accounts
- China pricing stabilization is a signal worth tracking for broader VBP relief

VOC

“We are seeing demand across our portfolio, including at Beckman, with increased automation for these lab-in-a-loop or autonomous science applications.” (Rainer M. Blair, CEO)

Core Lab: Roche Diagnostics (Core Lab Division)

\$2.2B

Q2 Core Lab Revenue

+4.0%

H1 CER Growth

+8.0%

Growth Ex-China

Summer '26

cobas Mass Spec Launch

REVENUE

- Q2 2026 global Core Lab sales: \$2.2B
- H1 2026 Core Lab CER growth +4.0% (+8.0% excluding China pricing reform impact)

MARKET INTELLIGENCE

- Growth led by immunodiagnostics and clinical chemistry (infectious disease, bone health menus)
- High-margin specialty menus cushion Roche against China VBP headwinds
- Resilient momentum outside China maintains central lab leadership

STRATEGIC IMPLICATIONS

- High-single-digit ex-China growth demonstrates strong brand equity
- Massive cobas installed base supports specialty chemistry panel upselling

COMPETITIVE ALERT

- cobas installed base creates pricing-discount resistance against Tier 1 entrants
- The 4% vs. 8% reported-vs-ex-China growth gap signals China upside if VBP eases

VOC

“Sales in our largest franchise, the Core Lab, increased at 4%... excluding this effect, the Core Lab grew at 8%.” (Matt Sause, CEO of Roche Diagnostics)

Core Lab: Abbott Laboratories (Clinical Chemistry & Immunoassay)

\$1.4B

Q2 Core Lab Revenue

+3.2%

Comparable Growth

+7.5%

U.S. Core Lab Growth

Alinity

High-Throughput Platform

REVENUE

- Q2 2026 Core Lab sales: \$1.4B (+3.2% comparable growth); 1H2026 sales \$2.7B, also +3.2%
- U.S. Core Lab accelerated to +7.5% comparable growth in Q2

MARKET INTELLIGENCE

- Robust hospital chemistry and immunoassay demand in the U.S. and Latin America
- Continued high-throughput Alinity systems placement momentum
- China VBP impact subsiding to a 7–8% headwind range, down from steeper prior levels

STRATEGIC IMPLICATIONS

- Standardized Alinity immunoassay/chemistry tracks create high switching costs
- Highly defensive installed base across multi-site hospital networks

COMPETITIVE ALERT

- Unified Alinity footprint functions as a defense mechanism against competitive displacement
- Hologic addition broadens Abbott's cross-sell reach within existing Core Lab accounts

VOC

"Our test volume data, that's sourced directly from our diagnostic instruments located across the United States and around the world, continues to reflect strong and stable demand for testing." **(Robert B. Ford, Chairman and CEO)**

VOC

"Our diagnostics portfolio with the addition of Hologic, the VBP impact in China subsiding a little bit is now a 7% to 8% kind of range that we think about." **(Robert B. Ford, Chairman and CEO)**

Core Lab: Sysmex Corporation (Hematology, Hemostasis & Clinical Chemistry)

\$814.2M

Q1 FY27 Global Dx Revenue

+12.7%

Constant-Currency Growth

+26.1%

Americas Local-Currency Growth

-33.8%

China Local-Currency Decline

REVENUE

- Q1 FY27 (Calendar Q2 2026) global Dx revenue \$814.2M (+12.7% CC growth)
- Americas \$263.3M (+26.1%), EMEA \$257.1M (+11.0%), China \$84.0M (-33.8%), Japan \$109.2M (+57.9%)

STRATEGIC IMPLICATIONS

- Rapid hematology/hemostasis installs plus the new chemistry business build a competitive Core Lab portfolio
- Unified hematology-plus-chemistry menus threaten Beckman and Abbott's hospital footprints

MARKET INTELLIGENCE

- Americas driven by next-gen XN-Series hematology installs and Brazil hemostasis growth
- EMEA driven by hemostasis tender wins (Germany, Italy) and XR-Series growth in France/Austria
- Japan boosted by JEOL's BioMajesty chemistry business, closed April 1,

COMPETITIVE ALERT

- BioMajesty integration gives Sysmex a chemistry cross-sell into its hematology base for the first time
- China distributor inventory adjustments bear watching for H2 stabilization

VOC

"In the hematology field in North America, the installation and start-up of instruments for orders previously received progressed smoothly, resulting in sales growth above our expectations." (Sysmex Q1 Q&A Summary)

VOC

"Q1 results in China were broadly in line with expectations. The impacts of the principle of minimal necessity and distributor inventory adjustments were within the range we had assumed." (Iwane Matsui, President)

Core Lab: Siemens Healthineers (Diagnostics Division)

\$1.1B

Q2 Global Dx Revenue

-5.5%

Comparable Decline

-10.3%

China Comparable Decline

Carve-Out

Formal Diagnostics Separation

REVENUE

- Q3 FY26 (Calendar Q2 2026) global Diagnostics revenue \$1.1B
- -5.5% comparable decline overall; -10.3% comparable decline in China specifically

MARKET INTELLIGENCE

- Atellica placements continue but are offset by legacy system retirements diluting reagent pull-through
- China healthcare procurement price standardization continues to delay purchasing decisions

STRATEGIC IMPLICATIONS

- Formal Diagnostics division carve-out now in active preparation
- Carve-out creates organizational uncertainty during the transition period

COMPETITIVE ALERT

- Carve-out process opens a displacement window for expiring Atellica contracts
- Lab directors are weighing Siemens' long-term Diagnostics roadmap amid the separation

VOC

"For fiscal year 2026, we now expect comparable revenue growth between 3.5% and 4.0% over fiscal year 2025 (previously between 4.5% and 5.0%), primarily as a result of the performance of the Diagnostics segment." **(Siemens Healthineers Earnings Release)**

Core Lab: QuidelOrtho (Labs & Immunohematology Division)

\$631M Total Dx Segment Sales	+2.0% Constant-Currency Growth	-23% China Revenue Decline	+9.0% Ex-China Labs Growth
REVENUE - Q2 2026 Labs revenue \$382.9M (+2.4%); Immunohematology \$134.2M (+0.7%) - Total Diagnostics segment sales \$631M (+2.0% constant-currency growth)	MARKET INTELLIGENCE - Absent national VBP pricing guidelines, China customers are delaying purchases and drawing down inventory - Ex-China: Labs +9.0%, Immunohematology +5.0% on healthy core demand		
STRATEGIC IMPLICATIONS - High China VBP exposure has forced a defensive commercial posture - Ex-China immunodiagnostics and blood-banking base remains a stable core to protect	COMPETITIVE ALERT - Ex-China clinical chemistry and immunohematology accounts are a competitive share-shift watch area - Cut full-year revenue guidance to \$2.52B–\$2.60B on China uncertainty		

VOC

“Uncertainty related to the proposed IVD pricing guidelines has impacted buying behavior as customers reduce their inventories pending the issuance of the final nationwide guidelines.” (Brian Blaser, CEO)

Core Lab Diagnostics: What to Watch Heading Into Q3 2026

Pending deal closes, regulatory milestones, and structural shifts flagged across this segment's battlecards.

01 Siemens Healthineers

Formal Diagnostics carve-out process. Watch for an announced structure and timeline in Q3 disclosures.

02 QuidelOrtho

China's national VBP pricing guidelines remain unissued. Final issuance could unlock or further delay purchasing.

03 Sysmex

First full quarter of BioMajesty integration. Watch H2 for chemistry cross-sell traction into the hematology base.

Core Lab Diagnostics: Customer Research Questions

Ensolve Research partners with leading IVD companies to shape winning product roadmaps, marketing strategy, and pricing decisions, turning competitive intelligence into commercial advantage.

Q1 PRODUCT

Lab Automation Loops

How do lab directors trade off the upfront costs and workflow changes of Beckman's Dxl 9000 automation against ongoing staffing shortages and tight budget constraints?

Q2 PRODUCT

Hematology Instrument Placements

What are the primary clinical and economic triggers driving lab directors to replace their Beckman Coulter or Abbott hematology lines with Sysmex's new XN/XR-Series?

Q3 PRICING

Clinical Chemistry Bundling

How do hospital laboratory directors respond to Sysmex bundling its newly acquired BioMajesty clinical chemistry analyzers with its market-leading hematology tracks?

Q4 PRICING

Long-Term Consumable Moats

How do hospital committees evaluate 5-to-7 year reagent contracts during central lab placements, and how much does a standardized interface like Abbott's Alinity drive vendor consolidation?

Q2 2026 Molecular Diagnostics: High-Plex POC Ascent & Precision Oncology Moats

The molecular diagnostics market is undergoing a structural transition as decentralized, high-plex syndromic point-of-care platforms and specialized screen-to-therapy companion diagnostic moats rapidly cannibalize standard, low-plex rapid testing.

01 POC DISPLACEMENT

High-Plex Syndromic Platforms Displace Low-Plex Rapid Tests

Syndromic molecular point-of-care platforms are aggressively displacing traditional low-plex rapid antigen and lateral flow tests, driven by rapid, CLIA-waived turnaround times that deliver actionable results during a single patient visit.

\$37M

bioMérieux
SPOTFIRE | Q2
Revenue (+37.7%)

7,200+

bioMérieux
SPOTFIRE | Global
Installs

+2.5%

bioMérieux
Molecular |
Organic Growth

400

bioMérieux
SPOTFIRE | New
Q2 Placements

02 ONCOLOGY MOATS

Screen-to-Therapy Pipelines Lock In Competitive Barriers

Multi-billion-dollar diagnostic-therapeutic oncology pipelines are locking in unparalleled competitive barriers. Abbott's rapid integration of Exact Sciences (Cologuard) is establishing an end-to-end colorectal screening moat.

\$0.9B

Abbott Cancer Dx |
Revenue (+13.3%)

Mid-Teens

Cologuard | User
Growth Rate

**ACS-
Reaffirmed**

Cologuard |
Preferred CRC
Screening (May
'26)

**Cologuard
Plus**

Abbott | Next-Gen
Test Driving Pricing
Tailwind

03 NON-RESP DIVERSIFICATION

Menus Expand Beyond Respiratory to Offset Seasonal Softness

Post-pandemic respiratory normalization is forcing molecular diagnostics divisions to rapidly expand non-respiratory menus. Cepheid delivered low-double-digit non-respiratory growth led by sexual health and hospital-acquired infection assays.

**Low-Double-
Digit**

Cepheid | Non-
Respiratory
Growth

+3.0%

Roche Molecular
Lab | H1 CER
Growth

Multiplex GI

Cepheid | New
Panel Fueling
Menu Expansion

-15%

Danaher |
Molecular
Respiratory
Revenue Decline
(Y/Y)

Q2 2026 Molecular Diagnostics (MDx) Scorecard: Strategic Positioning

Qualitative positioning across four operational dimensions: revenue growth, M&A activity, product innovation, and market sentiment. Tiers: Leader · Resilient · Under Pressure · Challenged/Restructuring.

Company	Growth	M&A	Innovation	Sentiment	QoQ	Position / Catalyst
Abbott Molecular & Cancer (Exact Sciences)	Solid	Major Deal	Solid	High	↑	LEADER Full integration of Exact Sciences; high-growth Cologuard oncology-screening engine.
bioMérieux Molecular Biology	Solid	Solid	High	Solid	↑	RESILIENT Explosive SPOTFIRE POC placements buffering core BIOFIRE respiratory declines.
Cepheid Clinical Diagnostics (Danaher)	Solid	None	Solid	Solid	→	RESILIENT GeneXpert conversion program driving low-double-digit non-respiratory growth.
Roche Molecular Lab	Solid	None	Solid	Solid	→	RESILIENT High-acuity transplant molecular monitoring (+18.0% H1) building durable moats.

Molecular: bioMérieux (SPOTFIRE & BIOFIRE Platforms)

\$415M

Molecular Biology Revenue

+2.5%

Organic Growth

\$37M

SPOTFIRE Revenue (+37.7%)

7,200+

SPOTFIRE Global Installs

REVENUE

- Q2 2026 Molecular Biology revenue \$415M (+2.5% organic growth)
- SPOTFIRE platform revenue \$37M (+37.7% organic growth); reagent sales +40.0%

MARKET INTELLIGENCE

- SPOTFIRE installed base exceeded 7,200 units (400 new placements in Q2)
- BIOFIRE non-respiratory panels +7.0%, offsetting a -6.0% respiratory panel decline
- Capturing meaningful share in decentralized urgent care settings

STRATEGIC IMPLICATIONS

- First-to-market syndromic POC (20-minute multi-pathogen test) bypasses central lab delays
- Non-respiratory menu diversification cushions against low seasonal epidemiology

COMPETITIVE ALERT

- Abbott and Cepheid must defend low-plex footprint on total cost-of-ownership grounds
- SPOTFIRE vaginitis FDA submission and SPINCHIP CE mark both landed in Q2

VOC

"With regards to SPOTFIRE, very strong performance... we've grown 40% in the context of low epidemiology, and 400 instruments installed in Q2 with no specific one-off." **(Pierre Boulud, CEO)**

VOC

"Q2 marked an important quarter for bioMérieux, with solid sales growth and key milestone achievements with the FDA submission of the SPOTFIRE vaginitis panel and the CE marking of the first SPINCHIP assay." **(Pierre Boulud, CEO)**

Molecular: Danaher / Cepheid (GeneXpert System)

Low-Double-Digit

Non-Respiratory Growth

Multiplex GI

New Panel Launch

HAI + Sexual Health

Menu Growth Drivers

Next-Gen

Syndromic Launch Underway

REVENUE

- Q2 2026 non-respiratory revenue: low-double-digit organic growth

MARKET INTELLIGENCE

- Growth led by sexual health and hospital-acquired infection (HAI) assays on GeneXpert
- New Multiplex GI panel launch plus several large hospital network account wins reinforced Q2 menu-driven growth
- Offsetting expected post-pandemic respiratory testing declines

STRATEGIC IMPLICATIONS

- Converting COVID-only GeneXpert instruments into stable, high-margin clinical portfolios
- Donated Xpert Hemorrhagic Fever panels to support Ebola outbreak response in DRC and Uganda, a distinctive global health brand signal

COMPETITIVE ALERT

- Next-gen high-plex syndromic platform in development is a direct competitive threat to bioMérieux's BIOFIRE franchise
- Management guides to a mid-single-digit overall exit rate as respiratory headwinds ease in Q4

VOC

"In molecular diagnostics, Cepheid's core non-respiratory revenue increased low double digits, led by growth in hospital-acquired infection and sexual health assays." (Rainer M. Blair, CEO)

VOC

"This strong performance was supported by continued adoption of recent menu expansions... as respiratory headwinds moderate in Q4, we'll exit at that overall mid-single digit rate." (Rainer M. Blair, CEO)

Molecular: Abbott Laboratories (Cancer Dx (Exact Sciences) & Molecular)

\$0.9B

Cancer Dx Revenue (+13.3%)

\$0.8B

Rapid & Molecular Dx Revenue

-8.0%

Rapid/Mol Dx Decline

Cologuard

Colorectal Screening Engine

REVENUE

- Q2 2026 Cancer Diagnostics (Exact Sciences) revenue \$0.9B (+13.3% comparable)
- Rapid & Molecular Dx revenue \$0.8B (-8.0% organic); 1H2026 sales \$1.6B (-8.8% comparable)

MARKET INTELLIGENCE

- Cologuard mid-teens growth drives Cancer Dx, on a growing new-plus-repeat user base
- Rapid/Molecular decline driven by lower seasonal respiratory testing volumes

STRATEGIC IMPLICATIONS

- Exact Sciences integration builds a dominant colorectal screening moat at primary care
- Difficult for pure-play molecular labs to compete on screening economics

COMPETITIVE ALERT

- Cologuard's repeat-user growth signals a durable, recurring screening revenue base
- Respiratory-driven Rapid/Molecular softness is a seasonal, not structural, headwind

VOC

"In cancer diagnostics, sales growth of 13% was driven by mid-teens growth of Cologuard, which is benefiting from a growing base of both new and repeat users." **(Robert B. Ford, Chairman and CEO)**

Molecular: Roche Diagnostics (Molecular Lab & Transplant Testing)

\$688.0M Q2 Molecular Lab Revenue	+3.0% H1 CER Growth	+18.0% Transplant Testing Growth (H1)	cobas Liat Near-Patient POC System
REVENUE - Q2 2026 global Molecular Lab sales: \$688.0M - H1 2026 CER growth +3.0%	MARKET INTELLIGENCE - Transplant molecular testing grew +18.0% CER in H1, the primary growth driver - Growth offset declines in respiratory and cobas Liat near-patient testing		
STRATEGIC IMPLICATIONS - Transplant testing dominance and high-volume centralized menu insulate against seasonality - Non-respiratory specialty menu breadth is a durable clinical moat	COMPETITIVE ALERT - Transplant-anchored moat forces competitors toward more advanced molecular menus to compete - Elecsys IGRA latent TB assay expansion signals Roche widening its molecular screening menu beyond transplant testing		
VOC <i>“Sales in the Molecular Lab grew at +3% with, and I would call it the strong performance of our transplant business, which grew 18%.”</i> (Matt Sause, CEO of Roche Diagnostics)			

Molecular Diagnostics (MDx): What to Watch Heading Into Q3 2026

Pending deal closes, regulatory milestones, and structural shifts flagged across this segment's battlecards.

01 Cepheid (Danaher)

Next-gen high-plex syndromic platform in development. Watch for a launch timing announcement.

02 Roche

AXELIOS 1 (RUO sequencing). Watch for any signal of a future clinical/IVD regulatory pathway.

03 Abbott

Cologuard repeat-user growth trajectory. Watch its compounding effect on H2 Cancer Dx growth.

Molecular Diagnostics (MDx): Customer Research Questions

Ensolve Research partners with leading IVD companies to shape winning product roadmaps, marketing strategy, and pricing decisions, turning competitive intelligence into commercial advantage.

Q1 PRODUCT

Syndromic POC Menu Utility

What is the preferred panel menu for bioMérieux's upcoming SPOTFIRE vaginitis, STI, and meningitis assays among urgent care directors, and what triggers a shift from central labs to POC?

Q2 PRODUCT

Colorectal Cancer Screening Paradigms

How do gastroenterologists and primary care physicians compare the clinical utility and patient compliance of blood-based colorectal cancer tests against stool-based DNA tests (Cologuard)?

Q3 PRICING

Non-Respiratory Menu Conversion Barriers

As COVID/flu testing volumes normalize, what strategies most effectively convert Cepheid GeneXpert users from respiratory tests to non-respiratory menus (sexual health, HAIs)?

Q4 PRICING

Specialty Central Lab Reagent Premium

What is the optimal pricing structure for high-acuity, non-respiratory molecular panels like Roche's transplant monitoring, and how sensitive are lab directors to premium reimbursement changes?

Q2 2026 Specialty Diagnostics: Sepsis Speed Wars & Digital Pathology Moats

Clinical microbiology sepsis speed wars and digital-clinical companion pathology consolidations are redefining long-term competitive moats, leaving legacy, commodity-driven testing vendors highly vulnerable to displacement.

01 SEPSIS SPEED WARS

Blood Culture Clearances Trigger Rapid Replacement Cycles

Waters' newly FDA-cleared BD BACTEC™ FXI blood culture system boasts a 3-hour faster time-to-detection for sepsis, immediately targeting 4,500 instruments in the U.S. awaiting replacement and directly threatening bioMérieux's BACT/ALERT market share.

\$521M

Waters ADx | Q2 Revenue (+7.0%)

4,500

Waters | US Instruments Awaiting Replacement

\$365M

bioMérieux Microbiology | Revenue (+6.5%)

3-Hr Faster

BACTEC FXI | Time-to-Detection

02 DIGITAL PATHOLOGY

Companion Diagnostics Consolidate Around Digital Platforms

Roche's signed definitive merger with PathAI, alongside its acquisition of SAGA Diagnostics, is building a combined digital-clinical pathology barrier that competitors cannot easily duplicate.

\$501.0M

Roche Pathology Lab | Q2 Revenue

+11.0%

Roche Pathology | H1 CER Growth

\$750M

Roche | PathAI Merger (Upfront)

+23%

Roche | Companion Dx Growth (Q1)

03 NICHE CLINICAL MOATS

Recurring Specialty Revenue Buffers Broader Volatility

Bio-Rad's quality control software, diabetes monitoring, and blood typing platforms, alongside Qiagen's QuantiFERON latent tuberculosis screening (returned to positive growth), maintain strong clinical vendor stickiness.

\$399.0M

Bio-Rad Clinical Dx | Revenue (+2.6%)

\$535M

Qiagen | Total Revenue (Flat)

\$310.3M

Bruker CALID | Revenue (+8.6%)

+1.0%

Qiagen QuantiFERON | CER Growth

Q2 2026 Specialty Dx, Microbiology & Pathology Scorecard: Strategic Positioning

Qualitative positioning across four operational dimensions: revenue growth, M&A activity, product innovation, and market sentiment. Tiers: Leader · Resilient · Under Pressure · Challenged/Restructuring.

Company	Growth	M&A	Innovation	Sentiment	QoQ	Position / Catalyst
Waters Advanced Diagnostics	High	Major Deal	High	High	→	LEADER BDS integration synergies; sepsis land-grab via FDA-
Roche Pathology Lab & CDx	High	Major Deal	Solid	Solid	↑	LEADER Digital pathology expansion via PathAI merger; double-
bioMérieux Clinical Microbiology	Solid	Solid	Solid	Solid	↑	RESILIENT China localized BACT/ALERT assembly bypassing
Bruker Microbiology & Infection	Solid	None	Solid	Solid	→	RESILIENT ELITechGroup placements outperforming plan; MALDI
Qiagen Diagnostics (Specialty)	Muted	None	Solid	Solid	→	UNDER PRESSURE QuantIFERON rebaselines on US immigration declines;
Thermo Fisher Specialty	Solid	Divestiture	Solid	Solid	↓	RESTRUCTURING Strategic exit and pending microbiology divestiture;
Bio-Rad Clinical Diagnostics	Muted	None	Muted	Solid	→	RESTRUCTURING Multi-year restructuring targeting \$30M–\$35M in annualized savings.

Specialty Dx: **bioMérieux (Microbiology (VITEK / BACT-ALERT))**

\$365M Microbiology Revenue	+6.5% Organic Growth	BACT/ALERT Blood Culture Platform	China Localized Manufacturing
REVENUE Q2 2026 global Microbiology revenue \$365M (+6.5% organic growth)	MARKET INTELLIGENCE - Strong BACT/ALERT blood culture and VITEK REVEAL rapid AST placement momentum - Localized manufacturing of two BACT/ALERT systems and VITEK Compact Pro in China - Local blood culture bottle production also underway in China		
STRATEGIC IMPLICATIONS - China localization maintains premium consumables positioning - Forces global competitors to accelerate their own localization efforts	COMPETITIVE ALERT - Abbott and Waters should target accounts via speed-to-result metrics of newer cleared systems - China price increase realized alongside recovery signals pricing power intact		
VOC	<i>“Microbiology, so overall, plus 4% in H1. And notably, very strong dynamic on BACT/ALERT... and the positive price increase that we are able to deliver.”</i> (Pierre Boulud, CEO)		
VOC	<i>“The localization of instrument is working... VITEK COMPACT PRO in China, and we already manufacture locally blood culture bottles. So all of this together has also helped to recover.”</i> (Pierre Boulud, CEO)		

Specialty Dx: Waters Corporation (Advanced Diagnostics (BDS Portfolio))

\$521M

ADx Revenue

+7.0%

Organic Growth

\$449M

BDS Revenue (+5.0%)

BACTEC FXI

FDA-Cleared Blood Culture

REVENUE

- Q2 2026 ADx revenue \$521M (+7.0% organic growth)
- BDS \$449M (+5.0% organic); Clinical Business Unit (Mass Spec) \$72M (+14.0% CC)

MARKET INTELLIGENCE

- Early BDS integration synergies accelerated growth sequentially
- Active list price increases and contract compliance drove a meaningful pricing lift

STRATEGIC IMPLICATIONS

- FDA-cleared BD BACTEC FXI gives an immediate sepsis diagnostics advantage
- 3-hour faster time-to-detection than incumbent blood culture platforms

COMPETITIVE ALERT

- 4,500 U.S. instruments awaiting replacement is a large, well-defined displacement target
- BACTEC FXI already launched in Japan and Europe ahead of the U.S. clearance

VOC

"With these businesses [BDS] under our leadership for the entirety of the quarter, we achieved a 400 basis point improvement in growth versus last quarter's flat full quarter growth rate." (Udit Batra, CEO)

VOC

"For Diagnostic Solutions, BACTEC FXI has launched well in Japan and in Europe, and now available in the U.S. with the 510(k) approval. Roughly 4,500 instruments in the U.S. alone waiting for replacement." (Udit Batra, CEO)

Specialty Dx: Bruker (CALID Group (Microbiology & Molecular))

\$310.3M CALID Group Revenue	+8.6% Q2 Growth	ELITechGroup Molecular Integration	MALDI Biotyper Bacterial ID Platform
REVENUE - Q2 2026 CALID group sales \$310.3M (+8.6% vs. Q2 2025's \$285.8M) 1H2026 CALID sales totaled \$626.6M	MARKET INTELLIGENCE - ELITechGroup molecular integration performing well ahead of business plan - High instrument placement volumes building a base for future consumables pull-through - MALDI Biotyper platforms attracting strong interest for rapid bacterial ID		
STRATEGIC IMPLICATIONS - Aggressive ELITech placement strategy secures early molecular accounts - Threatens mid-market clinical molecular players on price and speed	COMPETITIVE ALERT - Watch Bruker's account footprint for legacy labs resistant to its closed-system consumables - Microbiology (MALDI) growth roughly flat this quarter versus solid molecular growth		
VOC "First half placements in molecular diagnostics, the ELITechGroup business was ahead, well ahead of business plan, and that bodes very well as the consumables pull through." (Frank Laukien, CEO)			
VOC "CALID saw strength in biopharma, security detection, and European Aca/Gov... molecular diagnostics was solid, while microbiology was roughly flat." (Frank Laukien, CEO)			

Specialty Dx: Thermo Fisher Scientific (Transplant & Specialty Diagnostics)

+6.0%

Specialty Dx Revenue Growth

+5.0%

Organic Growth

Divestiture

Pending Microbiology Exit

Transplant Dx

Growth Channel Focus

REVENUE

- Q2 2026 Specialty Diagnostics revenue +6.0% (organic growth +5.0%)

MARKET INTELLIGENCE

- Growth led by the healthcare market channel, transplant diagnostics, and immunodiagnostics
- Pending microbiology divestiture announced to focus resources on core specialty testing

STRATEGIC IMPLICATIONS

- Strategic exit from clinical microbiology sharpens focus on healthcare channel and transplant testing

COMPETITIVE ALERT

- Focused portfolio positioning expected to pressure transplant diagnostics pricing competitively
- Divestiture expected to close Q3 2026

VOC

"Specialty Diagnostics grew 6% year-over-year, and organic revenue grew 5%. Growth in this segment was led by our healthcare market channel."
(Thermo Fisher CFO)



Specialty Dx: Bio-Rad (Clinical Diagnostics & Quality Control)

\$399.0M Q2 Revenue	+2.6% Reported Growth	+0.3% Currency-Neutral Growth	\$30–35M Restructuring Savings Target
REVENUE - Q2 2026 Clinical Diagnostics revenue \$399.0M (+2.6% reported, +0.3% currency-neutral) 1H2026 sales totaled \$762.6M	MARKET INTELLIGENCE - Growth led by quality systems (QC controls), diabetes (HbA1c), and blood typing - Strong Americas demand partially offset by a high-teens China decline on QC order timing - EMEA flat; Middle East rebounding to +7.0% growth		
STRATEGIC IMPLICATIONS - Niche clinical diagnostics positions provide a stable, recurring revenue stream - Buffers Bio-Rad from broader academic life-science spending volatility	COMPETITIVE ALERT - Restructuring targets \$30M–\$35M in annualized savings by late 2027, a cost-position signal to track - China QC order-timing exposure is a near-term regional watch item		

VOC

“Clinical Diagnostics returned to modest currency-neutral growth, led by quality controls in our blood typing portfolio.” (Jon DiVincenzo, President and COO)

Specialty Dx: Qiagen (QuantiFERON & Specialty Immunodiagnostics)

\$535M

Total Q2 Revenue

0.0%

CER Growth

+1.0%

QuantiFERON CER Growth

QIAcuity

Double-Digit Digital PCR Growth

REVENUE

- Q2 2026 total revenue flat at \$535M (0.0% CER growth)
- Diagnostic Solutions -2.0% CER; QuantiFERON +1.0% CER

MARKET INTELLIGENCE

- QuantiFERON returned to growth as clinical testing offset lower U.S. immigration testing
- QIAstat-Dx -7.0% CER on a tough respiratory comp, though GI and meningitis panels grew
- QIAcuity digital PCR grew double-digits CER on clinical consumables

STRATEGIC IMPLICATIONS

- Sample prep automation and digital PCR expansion stabilize oncology and research accounts
- Offsetting continued U.S. instrument spending headwinds

COMPETITIVE ALERT

- QIAcuity's double-digit growth is a potential conversion lever vs. traditional qPCR accounts
- Immigration-testing volatility remains a QuantiFERON risk factor to monitor

VOC

"We achieved solid growth across key pillars, particularly Sample technologies, QIAcuity and QDI, while navigating continued pressure on instrument spending in the U.S." **(Thierry Bernard, CEO)**

Specialty Dx: Roche Diagnostics (Pathology Lab & Companion Dx)

\$501.0M

Q2 Pathology Lab Revenue

+11.0%

H1 CER Growth

\$750M

PathAI Merger (Upfront)

VENTANA

Companion Dx Platform

REVENUE

- Q2 2026 Pathology Lab sales \$501.0M
- H1 2026 CER growth +11.0%

MARKET INTELLIGENCE

- Advanced staining +9% and companion diagnostics +23% in Q1, both continuing into Q2
- Precision oncology therapeutic approvals are driving mandatory companion testing
- VENTANA holds first-to-market CDx status via Roche pharma co-

STRATEGIC IMPLICATIONS

- Pathology franchise is insulated from molecular respiratory seasonality and central lab price wars
- First-to-approval CDx positioning is a durable clinical moat

COMPETITIVE ALERT

- PathAI acquisition (\$750M upfront, up to \$300M in milestones) builds a digital-pathology barrier
- Competitors pushed toward basic anatomical staining rather than high-value companion Dx

VOC

“VENTANA advanced staining grew at +9% and companion diagnostics grew +23% in the first quarter, representing strong underlying demand as companion diagnostics are increasingly integrated with targeted therapeutics.” (Matt Sause, CEO of Roche Diagnostics)

VOC

“By putting VENTANA and PathAI’s clinical decision support algorithms together, we’re going to be even more competitive in this key area of digital and anatomical pathology.” (Matt Sause, CEO of Roche Diagnostics)

Specialty Dx, Microbiology & Pathology: What to Watch Heading Into Q3 2026

Pending deal closes, regulatory milestones, and structural shifts flagged across this segment's battlecards.

01 Thermo Fisher

Pending microbiology divestiture expected to close Q3 2026. Watch for the completion announcement.

02 Roche

PathAI merger integration. Watch for deal-close milestones and the first VENTANA-PathAI product rollout.

03 Waters

BACTEC FXI adoption pace against the 4,500-unit U.S. replacement pool. Watch the conversion rate.

Specialty Dx, Microbiology & Pathology: Customer Research Questions

Ensolve Research partners with leading IVD companies to shape winning product roadmaps, marketing strategy, and pricing decisions, turning competitive intelligence into commercial advantage.

Q1 PRODUCT

Sepsis Speed-to-Result Trade-offs

How do lab directors trade off a 3-hour faster time-to-detect (via Waters' FDA-cleared BD BACTEC™ FXI) against the capital costs and track integration of replacing legacy systems?

Q2 PRODUCT

Digital Pathology & AI Clinical Support

Following Roche's PathAI merger, how do pathologists trade off traditional slide reviews against digital pathology platforms that integrate image-analysis algorithms directly with VENTANA stainers?

Q3 POSITIONING

Sepsis Prevention C-Suite Positioning

How can microbiology vendors position sepsis detection speed improvements directly to hospital C-suites as a cost-saving and clinical prevention mechanism, bypassing lab committees?

Q4 POSITIONING

Specialty QC Sourcing Stability

How do quality control managers perceive the stability, software support, and long-term product availability of Bio-Rad's QC and diabetes platforms amid their ongoing organizational restructuring?

MEASURING THE VOICE OF CUSTOMER IN IN VITRO DIAGNOSTICS

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James Garvin

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James Garvin is a Senior Consultant at Ensolve Research with more than two decades of experience in the in vitro diagnostics (IVD) and MedTech industries. Prior to rejoining Ensolve in 2025, he held senior commercial and marketing leadership roles at Thermo Fisher Scientific and Beckman Coulter, leading global commercial strategy, product management, and market expansion initiatives. James holds an MBA and a BS in Biomedical Sciences.