

A CUSTOMER STORY

Scaling With Confidence:

How Gravity Diagnostics Transformed High-Complexity Toxicology Review with Analytical Operations Software™

In 2020, Gravity Diagnostics, a CAP-accredited and CLIA-certified laboratory, faced rapidly accelerating demand for its high-complexity toxicology laboratory developed test (LDT). Its 133-compound LC-MS/MS panel required three to five hours of manual data review per batch, placing growing pressure on turnaround time, reviewer consistency, documentation demands, and staffing capacity. Traditional manual workflows, incremental process improvements, and continued hiring could no longer provide the scalability, consistency, governance, and operational rigor required to support sustained growth.

In response, Gravity launched a search to find a solution capable of standardizing review, reducing manual workload, and supporting long-term growth without compromising its core values of care, compliance, and confidence. The team selected ASCENT®, Indigo BioAutomation's Analytical Operations Software (AOS) for LC/GC-MS/MS workflows.

Through a rigorous and phased implementation, Gravity codified scientific rules, automated routine interpretation, and strengthened documentation. As a result, review time dropped by up to 75%, daily sample volume capacity increased more than tenfold, and scientific staff were freed to focus on assay optimization, method refinement, and operational improvement.

Today, ASCENT, ARQ® for q/RT-PCR workflows, and Indigo's data warehouse form Gravity's analytical operations environment, providing their team with a foundation for continuous improvement, operational insight, and sustainable scale.



Figure A: Select results for Gravity Diagnostics' LC-MS/MS operations with ASCENT.

The Challenge: New Solution to Support Growth

- Testing demand grew from <100,000 to >1 million samples/year.
- Manual review required; 3–5 hours/batch for a high-complexity 133-compound toxicology LDT.
- CAP requirements intensified demands for standardization, traceability, and documentation.
- Review activities consumed significant scientific time.
- Scaling manual review created a cost-prohibitive staffing model.

The Solution: ASCENT from Indigo BioAutomation

- Codified laboratory-specific rules for a complex 133-compound toxicology LDT.
- Automated review by exception workflows across instruments, batches, and reviewers.
- Produced traceable audit-ready documentation for system and end-user actions.
- Enabled anywhere, anytime access, knowledge-sharing, and collaboration.

The Impact: New Capabilities and Expanded Capacity

- Average toxicology data review time reduced by up to 75% per batch.
- Sample capacity increased 10–15x without proportional increases in headcount.
- Samples processed per reviewer increased by more than 500%.
- Reviewer variability decreased while traceability and documentation capabilities strengthened.
- Scientific staff reallocated time toward assay optimization, method refinement, and operational improvement.

The Future: Continuous Improvement and Expansion

- Deploying ARQ for q/RT-PCR workflows, to strengthen rigor, consistency, and automation across molecular testing.
- Deploying Indigo's data warehouse to translate released-batch data into operational, quality, and performance insights.
- Expanding ASCENT maturity across laboratory, including continued rule refinement, additional assays and instruments, workflow optimization, and exploring upstream integration opportunities.

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The Story

In less than a decade, Covington-based Gravity Diagnostics grew from a small local laboratory into a CAP-accredited and CLIA-certified organization processing more than one million samples annually across COVID-19, Upper Respiratory, Toxicology, Pharmacogenomics, Sexually Transmitted Infections, and Blood testing. As demand accelerated, Gravity remained focused on the principles that shaped the company from the beginning: delivering rapid, reliable diagnostic results while maintaining its commitment to care, compliance, and confidence.

One of the most significant operational pressures emerged within Gravity's flagship urine toxicology laboratory developed test (LDT), a large-panel LC-MS/MS assay central to the laboratory's continued growth. As testing demand increased, the assay's manual, rule-intensive review process placed growing strain on turnaround time, quality oversight, and specialized staffing resources. Recognizing that incremental fixes would not be sufficient, Gravity sought a software solution. In late 2020, following a structured vendor evaluation, the Gravity team selected ASCENT, Indigo BioAutomation's AOS for LC/GC-MS/MS workflows. Through a deliberate implementation led by the Gravity team and supported by Indigo, the laboratory achieved faster review cycles, improved batch consistency, and reduced manual workload across their toxicology operations. The deployment and associated practices reinforced Gravity's broader culture of continuous improvement by enabling deeper assay optimization, stronger operational standardization, and the deepening of quality capabilities across LC-MS/MS workflows. More recently, Gravity extended this operational foundation by incorporating Indigo's data warehouse and deploying ARQ for their molecular workflows.

As Gravity expanded, the team closely tracked operational and staffing demands of scaling its proprietary toxicology panel. The assay includes 133 compounds comprised of 90 drug analytes and 43 internal standards and quality controls (QCs), spanning multiple drug classes with distinct chromatographic behaviors. Each compound requires careful interpretation of retention time windows, ion ratios, internal standard recovery, and class-specific quality patterns. To remain compliant with testing requirements, each batch required three to five hours of manual peak review by credentialed staff.

Kelly Hensley, Director of Clinical Toxicology, recalls: "We grew very, very quickly with a huge expansion for toxicology that was difficult to accommodate. We were looking for a partner that could help us handle that growth while maintaining our quality goals."

Without changes, Gravity estimated sustaining volume growth would require doubling or tripling of its data review team. Beyond cost, scaling manual review for a panel of this complexity introduced unacceptable variability and increased operational risk. Additionally, scaling manual workflows constrained scientific time across the workflow, impacting opportunity for assay optimization, method refinement, and test development.

Finally, given the panel is an LDT, Gravity retains full responsibility for assay performance. Ensuring analytical decisions remained traceable, reproducible, and consistently applied across reviewers became increasingly difficult at scale.



Figure B: Gravity Diagnostics' Covington, Kentucky headquarters, home to a portfolio of toxicology, pharmacogenetics, infectious disease, and respiratory testing.

"Gravity was born out of a problem we saw right here in our community. We wanted to build a laboratory that could serve providers and patients who needed faster, more reliable results—something built on care, compliance, and confidence. Those three words have guided every decision we've made since the beginning."

Nick Lykтей
Chief of Laboratory Operations
Gravity Diagnostics

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Specifying and Selecting ASCENT

With these needs in mind, Gravity initiated a structured vendor evaluation in late 2020 to identify a solution capable of supporting both immediate operational pressures and long-term organizational growth. The team established requirements focused on standardization, auditability, review-by-exception workflows, integration with existing laboratory systems, and support for continued operational expansion.

Following this evaluation, Gravity selected ASCENT from Indigo BioAutomation due to its ability to support the laboratory's operational, scientific, and quality objectives (Figure C). Developed in accordance with an ISO 13485:2016-certified quality system and a listed Class I (exempt) Medical Device, ASCENT provided configurable rule-based automation, traceable workflows, and architecture designed to support ongoing assay, instrument, and operational growth.

Requirements Mapping

Gravity's Requirements	ASCENT Capabilities
Codify SOP Rules	Consistent architecture that encodes lab-defined scientific logic.
Standardize Review	Rules engine incorporating standard and custom rules.
Review-by-Exception	Sophisticated result assessment coupled with automated resolution of routine issues.
Transparency and Auditability	Detailed, traceable audit log of system and user actions.
Collaboration and Knowledge Sharing	Centralized scientific rule set, standardized workflows, and embedded chat.
Integration with LIS	LIS-aware data workflows compatible with existing systems.
Scalability and Continuous Improvement	Architecture designed for assay expansion, instrument growth, and ongoing optimization.

Figure C: Gravity Diagnostics' requirements aligned with ASCENT capabilities.

What is Analytical Operations Software?

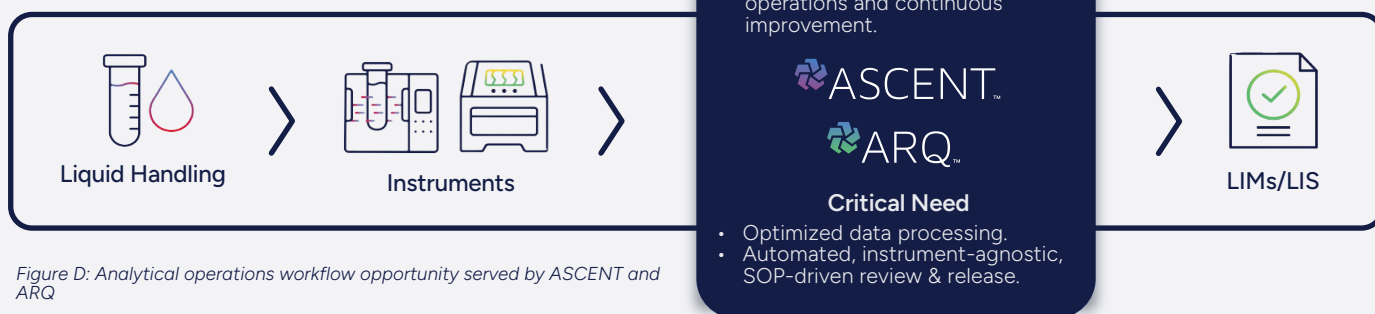


Figure D: Analytical operations workflow opportunity served by ASCENT and ARQ

Analytical Operations Software (AOS) Overview

Analytical Operations Software describes a category of software designed to help clinical and forensic laboratories and organizations standardize, govern, and continuously improve moderate- and high-complexity diagnostic workflows. Solutions such as Indigo's ASCENT for LC/GC-MS/MS and ARQ for q/RT-PCR, built and deployed within a distinct technology infrastructure, help laboratories transform manual, variable, and fragmented review and release processes into scalable, consistent, and audit-ready operations. These operations are better equipped to support the increasing testing demands, analytical complexity, and evolving technologies of modern diagnostics. Purpose-built to govern analytical operations, AOS unifies analytical data, decision logic, and operational dynamics across instruments, assays, teams, and sites supporting more human-centered, connected and continuously improving laboratory operations.

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Implementation and Onboarding

Once Gravity selected ASCENT, the team approached the implementation as more than a software deployment. It became an opportunity to refine workflows and practices, strengthening the operational foundation supporting continued growth and improvement. During the onboarding, the Gravity team worked through existing SOPs, review criteria, flagging logic, and exception handling processes to define how analytical determinations would be consistently evaluated and managed within ASCENT across instruments, batches, and reviewers.

Alongside the scientific and technical work of deployment, Gravity also intentionally involved reviewers, supervisors, and operations staff early in the process. Team members helped validate how encoded rules reflected scientific judgement, shaped how review-by-exception workflows integrated into daily operations, and built confidence in the consistency and reliability of ASCENT across users, batches, and instruments.

Over time, the work of onboarding and deployment evolved into a broader operational maturity initiative (Figure E). What began with implementation, validation, and workflow standardization expanded into continued rule refinement, strengthened reporting and governance practices, workflow optimization, and broader adoption of ASCENT across the laboratory operations. As Gravity's testing volume continued to grow, the laboratory increasingly leveraged ASCENT not only to support review efficiency, but also to strengthen consistency, visibility, and continuous operational improvement across its toxicology workflows.

Gravity Diagnostics Onboarding and Deployment Overview

Consideration and Purchase

Establishing business case and planning.

- Evaluation & Purchase
- Project Planning
- Test Environment
- SOPs, Processes & Practices

Preparation and Go-Live

Building a foundation of trust and confidence.

- Rigorous Testing & Validation
- SOPs & Rules
- Training & Readiness
- Go-Live

Adoption and Learning

Expanding across operations, driving consistency.

- Across Instruments
- Continuous Training
- Strengthen Use & Confidence

Optimization and Capacity Growth

Driving throughput and operations optimization.

- Assay Training
- Rules Refinement & Expansion
- Simplifying Onboarding

Scale and Expansion

Continuous improvement and advancement.

- Workflow Optimization
- Indigo Data Warehouse
- ARQ for q/RT-PCR

Figure E: Gravity Diagnostics' phased onboarding, operational adoption, and ongoing optimization of ASCENT

Codifying Scientific Review at Scale

As onboarding progressed, the work included formalizing how Gravity's toxicology workflows would be evaluated, reviewed, and managed within ASCENT. Beyond reducing manual effort, the objective was to standardize analytical review practices in a way that could support continued growth while maintaining consistency across reviewers, instruments, and batches.

Working from existing SOPs, review criteria, and exception handling practices, the Gravity team translated laboratory-specific scientific judgement into ASCENT's configurable rules framework. Beginning with ASCENT's standard LC-MS/MS rule sets, Gravity worked with the Indigo team to layer in additional logic reflecting the complexity and operational requirements of its workflows.

Central to this phase of work was defining how calibration performance, QC acceptance, retention time alignment, ion ratios, internal standard recovery, and compound-specific thresholds would be evaluated and managed throughout review. The resulting rules-based framework created a more standardized and transparent review environment capable of supporting review-by-exception workflows while maintaining visibility into how analytical determinations were reached.

"ASCENT helped us to ensure that even as we started hitting our milestones, that we would be able to maintain the same quality we could when we were a very, very small lab."

Kelly Hensley
Director of Clinical Toxicology
Gravity Diagnostics

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Building Trust through Rigorous Validation

Before ASCENT could become the operational foundation for ongoing optimization and expansion, Gravity needed to establish confidence that standardized review workflows and encoded analytical logic would perform reliably across the full complexity of its toxicology operations. Validation therefore extended beyond software functionality alone. Gravity approached the process as both a technical and operational exercise designed to confirm that review logic behaved consistently across real-world laboratory conditions and aligned with the laboratory's scientific and quality expectations.

The team validated ASCENT across diverse chromatographic behaviors, known interferences and edge cases, matrix variation, QC and internal standard performance, reviewer consistency scenarios, and batch-to-batch and instrument-to-instrument reproducibility. Attention was given to ensure that encoded review logic behaved consistently across the wide range of analytical conditions routinely encountered within Gravity's operations. Kelly Hensley, Director of Clinical Toxicology, recalls: "Given its importance, we elected to implement the largest validation packet I've ever seen in my career. We wanted to thoroughly test ASCENT, and we wanted to make sure that we hit every single concern and every single situation that our data ever presented to us."

The results achieved during the work of validation served to build confidence among the staff. The process itself also played an important role in fostering organizational trust and adoption. By involving reviewers, supervisors, and operational leadership throughout validation, Gravity built confidence that ASCENT would support scalable review workflows without sacrificing scientific rigor, traceability, or quality oversight.

Results That Reset Expectations

With standardized review validated and operationalized, Gravity began realizing measurable improvements. As demand accelerated, ASCENT enabled Gravity to scale operations while maintaining consistency, traceability, and turnaround expectations.

Operational results to-date included:

- Daily sample volume increased 1150% to ~2,500 samples per day.
- Average review time decreased by 50% from 3 to 5 hours to approximately 1.5 to 2 hours per batch.
- Samples processed per employee increased by more than 500%.

Ongoing Growth and Expansion

The deployment of ASCENT software established more than a scalable toxicology review workflow. It created a structured operational foundation that Gravity continues to expand as testing complexity, analytical demands, and operational expectations evolve. As the organization has matured its use of ASCENT, Gravity has continued refining rules, strengthening workflow visibility, and expanding standardized review across additional instruments. More recently, the Gravity team has extended this operational foundation through Indigo's data warehouse capabilities for released result data and with the deployment of ARQ for molecular workflows.

One area of focus is Indigo's data warehouse environment, which captures and organizes more than 200 structured data elements from every certified ASCENT or ARQ released batch (Figure F). Gravity views the data as an opportunity to strengthen longitudinal visibility and support more proactive monitoring of assay performance, QC trends, instrument health, and workflow optimization.

"We onboarded Indigo BioAutomation's ASCENT software over four years ago, and I can say without a doubt that **it was the best strategic decision our laboratory operations team has ever made**. Our toxicology volume doubled overnight and continued to grow at an unprecedented rate for years. We would not have been able to manage that influx of samples without our strategic partnership with Indigo BioAutomation... and we would not be able to do what we do so well: serve patients suffering from substance use disorder and support the many clients who rely on our toxicology testing to inform treatment decisions for those in need.

Indigo BioAutomation is one of our most important strategic partners and I'm glad that we mutually decided to expand our partnership to encompass their entire product suite."

Nick Lykтей
Chief of Laboratory Operations
Gravity Diagnostics

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Initial areas of focus include:

- Trending assay stability and internal standard performance.
- Detecting early indicators of column wear or instrument drift.
- Supporting automation and standardization of QC reporting.

Building on ASCENT's success in their toxicology lab, Gravity is now in the process of deploying ARQ, Indigo's Analytical Operations Software for governed q/RT-PCR LDT operations across their molecular testing operations.

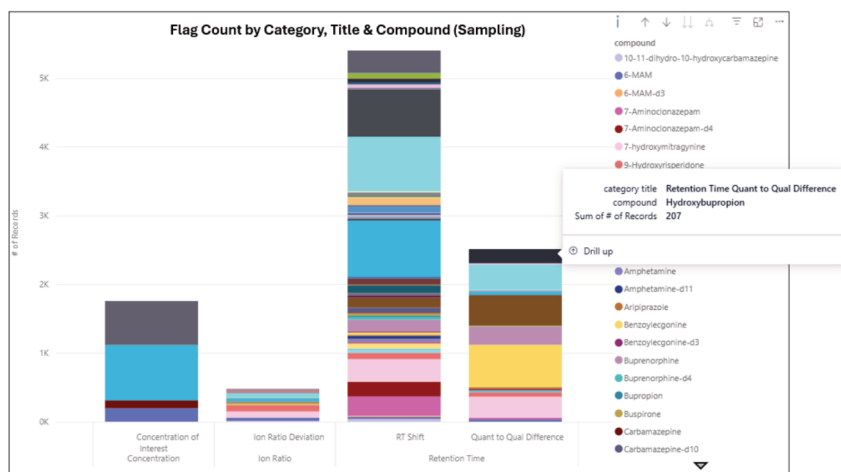


Figure F: Sample dashboard reporting available with Indigo Data Warehouse and ASCENT data.

"Gravity's success shows what's possible when technology, purpose-built for the complexity, rigor, and operational demands of today's diagnostics, is deployed with an appreciation for its impact on people, process, and continuous improvement. With a shared commitment toward operational excellence and a common vision for the future of diagnostics, I look forward to what our combined teams will continue to accomplish together."

Tim Lancaster
President and Chief Operating Officer
Indigo BioAutomation

About Gravity Diagnostics

Gravity Diagnostics is a state-of-the-art, CLIA-certified, and CAP-accredited laboratory dedicated to providing rapid and reliable diagnostic testing founded in 2016. Headquartered in Covington, KY, Gravity is a specialty lab offering COVID-19, Upper Respiratory, Toxicology, Pharmacogenomics, Sexually Transmitted Infections, and Blood testing with a total lab capacity for more than 1 million samples per year. Still growing and expanding, Gravity is guided by its core values of care, compliance, and confidence. The company distinguishes itself through exceptional turnaround times, often delivering toxicology results well within their 48-hour goal and infectious disease results the same day. Their key offering is a highly complex 133 compound urine panel customizable for patient needs. Beyond delivering diagnostic testing, Gravity supports community health initiatives by tracking and sharing regional drug positivity trends to help inform public health efforts.



About Indigo BioAutomation

Indigo BioAutomation combines deep scientific, operational, and software expertise with a distinctive technology infrastructure to deliver Analytical Operations Software™ purpose-built for modern diagnostics. Its flagship products, ASCENT® for LC/GC-MS/MS workflows and ARQ® for q/RT-PCR workflows, help clinical and forensic laboratories standardize analytical review, unify data, decisions, and dynamics, and scale high-complexity testing through governed, rules-based workflows. Cloud-based, instrument-agnostic, and developed within an ISO 13485-certified quality system, ASCENT and ARQ are listed Class I (exempt) Medical Devices. Trusted in the processing of more than 15 million analytical signals associated with nearly 1.5 million samples each week, Indigo products are helping laboratories operationalize analytical complexity through more governed, connected, and scalable operations.

