

Automated Testing Solutions (ATS) for Controlled Environments

A new era of high-precision testing
ensures 100% compliance- every time!



Introduction to CertAir's Automated Testing Solutions (ATS)

In the specialized field of controlled environment test and certification, CertAir ushers in a new level of precision with its Automated Testing Solutions (ATS). Integrating ValidScan software and an advanced suite of third-generation robotics, CertAir equips service providers with enhanced testing capabilities and the introduction of a High-Precision Test & Certification service. Fully compliant with industry standards such as ISO 14644-3, IEST, NSF 49, and regulatory requirements from 21 CFR Pt. 11 and EU GMP Annex 11, the ATS platform is engineered to meet the nuanced operational demands and quality expectations of clients.

Maintaining a steadfast commitment to proven certification methods, CertAir's ATS expands these offerings. It allows for two distinct service levels: a more robust Standard test & certification for reliable compliance and a more rigorous High-Precision test and certification for operations where precision is not just beneficial but essential.

This dual-tiered approach empowers service providers to tailor their offerings to the specific needs and long-term objectives of their clients, setting a new standard of excellence within the industry.

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Controlled Environment Testing & Certification



LEVEL I: STANDARD TEST & CERTIFICATION
MANUAL. COMPLIANT. TRACEABLE.

What it is

The Standard Test & Certification is conducted by skilled technicians applying established, effective testing methods in line with industry protocols. The tests verify that your controlled environments meets fundamental industry standards.

Who it is for

- Facilities that require foundational certification for operational efficiency and quality control, typically Class 7-9.
- Organizations seeking to fulfill industry compliance required by ISO 14644-3, IEST, NSF 49 or similar standards.

Why it matters

Compliant

Verifies cleanroom standards adherence with manual verification, aligning with customer requirements.

Reliable

Standard, reliable testing process by experienced technicians using proven methods.

Documented

Supports robust audit processes with detailed manual documentation and compliance with ALCOA principles.





Controlled Environment Testing & Certification



LEVEL II: HIGH-PRECISION TEST & CERTIFICATION
AUTOMATED. REPRODUCIBLE. UNALTERABLE.

What it is

The High-Precision Test & Certification leverages advanced robotic technology, designed to execute tests with unparalleled precision and accuracy. Guided by trained technicians, any deviation from standards, protocols, and parameters are flagged and addressed in real-time. Encrypted electronic data capture of test results is stored with supplemental metadata, ensures validated results, every time. Reliable. Repeatable. Reproducible. Auditable.

Who it is for

- Class 7 and above, where contamination control is paramount.
- Organizations requiring certification to ISO 14644-3, IEST, NSF 49 or similar standards, but desiring unalterable verification and validation test of each result.

Why it matters

Enhanced Precision

- Automation signifies a new benchmark in quality control, backed by our enhanced data verification processes.
- Benefit for Quality-Focused Clients: Clients who prioritize risk mitigation and quality, will value the precision, repeatability, and consistency.
- Benefit for Cost-Conscious Clients: The Precision LeakID and RepairID intelligently tracks and manages repair history, leading to significant savings by avoiding unnecessary filter replacements and minimizing operational expenses.

Advanced Compliance

- Automated, validated workflows guarantee strict adherence to standards.

Data Integrity, Traceability & Audit Readiness

- Integrates end-to-end traceability, tagging each aspect of the testing process with metadata and unique identifiers.
- Digitally-encrypted records and secure storage offer instant audit readiness.



- Precise capturing of entire filter surface and interstitial space
- Real-time 2D-heatmap visualization



Controlled Environment Testing & Certification Data Integrity & Management



Real-Time Report Generation

Our software enhances workflow with efficient online reporting, data management, and integration of scanned images.



Compliant Record Keeping

Secure electronic records meet FDA (21 CFR Part 11) and EU GMP Annex 11 standards, ensuring your data's integrity.



Enhanced Security

Role-based permissions and encrypted test data offer precise access control.



Collaborative Tools

Share data collection in real-time, including annotations and comments, to improve team collaboration.



Detailed Activity Logs

Monitor user actions for complete audit trails and accountability



Customizable Reports

Personalize reports with customizable text and your company branding for a professional presentation.

Introducing CertAir's Automated Test Solution (ATS)

CertAir's Automated Test Solution (ATS) represents a comprehensive suite of third-generation software and robotic systems, ensuring that certifiers are equipped with a solution that is technologically advanced and validated against pre-loaded customer requirements and industry standards such as ISO-14644-3, IEST, NSF 49, and others.

ValidScan.v3 Software: A Keystone of Certification Precision

The ValidScan.v3 software is an integral component of both Level I and Level II services within the ATS platform. It provides the capability to pre-load customer-specific requirements, creating a bespoke testing service that strictly adheres to industry and individual client needs and enhances the standard certification process.

Robots-as-a-Service: Harnessing Precision, Empowering Technicians

CertAir's robotic solutions are engineered to work with your existing, pre-qualified test equipment, seamlessly integrating into your current operations to enhance efficiency and accuracy.



CertAir's partnerships with leading test equipment manufacturers ensure validated interoperability, all seamlessly controlled by ValidScan software for optimized performance.



ATS

AUTOMATED TESTING SOLUTIONS FOR CONTROLLED ENVIRONMENTS



- Filter integrity and airflow velocity tests for terminal filters, Bio safety cabinets, and flow hoods.
- Validated to industry standards such as ISO 14644-3, IEST 34.5, NSF 49.



- Tests RABS (open/closed) and Isolators.
- Custom-built with 2D layouts and scans.
- Kinematic movements verified for each mounting point.



- Secure, encrypted, electronic data capture.
- Generates validated certification reports in real-time.
- Compliant with 21 CFR Pt 11, EU GMP Annex 11, and ALCOA++.

Comparative Matrix of Test & Certification Offerings

THE MATRIX IS A VISUAL GUIDE OUTLINING THE CAPABILITIES AND BENEFITS OF LEVEL I AND LEVEL II CERTIFICATIONS AND SERVES AS A CONSULTATIVE TOOL FOR CERTIFIERS, HELPING TO ALIGN CUSTOMER NEEDS WITH THE APPROPRIATE LEVEL OF SERVICE.

TEST REQUIREMENTS	Level I: Standard Certification	Level II: High-Precision Certification
Measurements		
Test Results with 100% reproducibility		
Precision Leak ID and Repair ID ¹		
Test Metadata		
Temporal data: % penetration with x-, y- coordinates		
Environmental: temperature, humidity, pressure		
Test Protocol		
Scan Rate ²		
Distance to filter face ³		
Overlap per pass		
Filter Coverage [100% Coverage]		
Interstitial Coverage [100% Coverage]		
Qualified Test Equipment Performance Tracking		
Test Equipment ID: Model, Serial Number, Firmware Version		
Calibration: Valid certificate required		
Test Equipment Check: 28.3 lpm +10% sample rate tracked		
Device Under Test Check: 28.3 lpm +10% exit airflow velocity ⁴		



Documentation & Data Integrity		
Login: Password-protected test equipment & software.		
Data Storage: Backup and recovery plans.		
Methodology: Documented & validated methods and formulae.		

Documentation Requirements		
Test Plan: Detailed methodology, annotated deviations ⁵		
Results: Filter ID, pass/fail, precise leak location, retest results		
Technician: Assigned Equipment ID; Training records		

Rating	Description of Data Capture & Control
5	Fully automated and validated data acquisition with real-time encryption and control, exceeding 21 CFR Pt 11 requirements for electronic records and signatures. No opportunity for manual error or data tampering, ensuring the highest integrity and traceability as per ALCOA++ principles.
4	High level of automation with electronic capture and control; requires minimal manual review. System validation is documented, and electronic signatures are linked to individual users, but not all processes are automated.
3	Mixed methods of data capture with some automated systems. Manual inputs are reviewed electronically. Data control processes are in place but may not be comprehensive for all operations.
2	Primarily manual data capture with some digital assistance. Data integrity reliant on manual quality checks and procedural adherence. Meets basic requirements of ALCOA++ but lacks the rigor of 21 CFR Pt 11 for electronic records, introducing risk for data errors or alterations, with low traceability.
1	Manual processes with no automation. Confirmatory data is unavailable.

1. Patent-pending LeakID and RepairID uniquely characterizes the size of leaks and repairs, cutting down on unnecessary filter replacements and related expenses by meeting exacting industry and client standards.
2. High-precision tests are performed with controlled, uniform scan rates. With manual tests the scan rates cannot be determined but may be inferred if elapsed test time is matched with pre-loaded filter size.
3. Distance to filter face is fixed and uniform throughout scan.
4. Available with integrated airflow velocity sensor.
5. The operating parameters and test protocols for controlled environment are pre-loaded in the software. For high-precision tests, deviations are automatically flagged, with supplemental notes input by technician.

Value Proposition

Our Automated Testing Solutions (ATS) deliver significant benefits, enhancing quality and efficiency in test and certification for controlled environments.

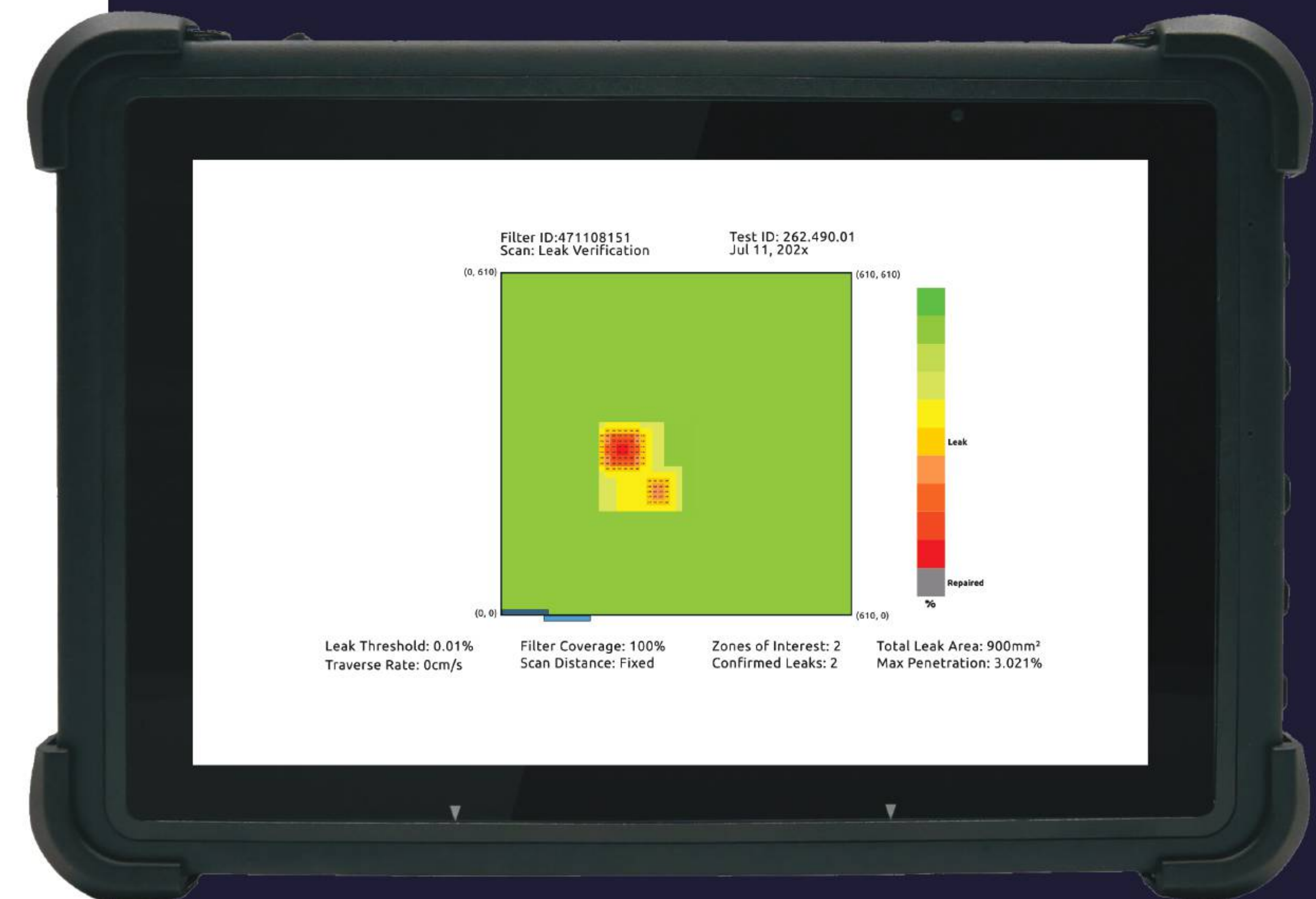
Quality Improvement

- Automation sets a new standard in quality control with enhanced data verification and ValidScan software.
- Benefits for Quality-Focused Clients: Certifiers achieve unmatched precision and strict adherence to high standards for consistent, error-free certification.
- Benefits for Cost-Conscious Clients: LeakID and RepairID manage repairs efficiently, preventing unnecessary filter changes and reducing operational costs.

Staff Health & Safety, Reduced Turnover

- Automation relieves physical strain and monotony in certification processes. It lowers exposure to repetitive strain injuries, enhancing safety, cutting costs, and decreasing high industry turnover rates.

Visualizing Filter Integrity



- The ATS filter integrity scans generates real-time “heat-maps” showing precise penetration zones of interest
- Optional sensors assess HVAC performance, ensuring comprehensive evaluations.
- Areas requiring attention are automatically flagged for precise leak detection.



Operational Efficiency

New Service Offerings

- CertAir's robots-as-a-service, equipped with patent-pending dual-scanning probes, expedite testing and certification, saving time and manual labor. Deploying multiple robots, a single operator can slash scanning time up to 75%, airflow velocity measurements up to 50%. With pre-loaded customer and test requirements, and electronic data capture – nearly eliminate time to collect, collate, process data and generate reports
- **Benefit:** Lower labor expenses by deploying fewer technicians or utilizing robots, which decreases the need for after-hours and overtime during peak times, thereby enhancing productivity.

- **New Service Tier:** Automation enables new high-precision services – higher quality with reduced cost per service.
- **Expedited Services:** With existing staff operating a fleet of robots, offer faster certification services at a premium, leveraging the robot's efficiency and reducing downtime for clients.

Ensuring your Success

We are passionate about our customers' success. Our automated test solutions for controlled environments were designed as tools for our customers to improve the quality of their services and safeguard the health of trained technicians, while also helping to grow their bottom line.

NEXT STEPS

- 1 Experience:** Schedule a live demo of the ATS platform, to experience firsthand the system's efficiency and precision.
- 2 Request for Quote:** Following a needs assessment and demo, receive a customized quote.
- 3 Implement:** Review a clear, step-by-step deployment plan that includes a comprehensive training program for technicians, emphasizing the ease of integration and ongoing support tailored to your business hours.

Call us now to arrange your consultation and see how CertAir can make a difference in your business.



To explore these possibilities and learn more about how CertAir can support your certification services, reach out to us **today**.

✉ info@CertAir.com

☎ 410.870.5969



Automated Testing Solutions (ATS) for Controlled Environments

Delivering New Levels of Precision, Ensuring Trusted Data, and Guaranteeing Certified Results.

ATS

AUTOMATED TESTING SOLUTIONS
FOR CONTROLLED ENVIRONMENTS