

SAAS TERMS OF SERVICE & SUBSCRIPTION AGREEMENT

Standard Online Agreement for Automated Clinical Laboratory Statistical Software

Provider:	ValidToolsLab LLC (the "Provider")
Customer:	The subscribing clinical laboratory entity (the "Customer" or "Subscriber")
Effective Date:	Established automatically upon successful checkout, subscription creation, and electronic acceptance through Stripe.
Agreement Form:	Clickwrap Online SaaS Terms of Service (Electronic Contract)

PLEASE READ THIS SOFTWARE AS A SERVICE (SaaS) AGREEMENT CAREFULLY. BY CREATING AN ACCOUNT, SUBSCRIBING TO A PLAN, AND SUBMITTING PAYMENT VIA STRIPE, YOU (THE "CUSTOMER" OR "SUBSCRIBER") EXPLICITLY AGREE TO BE BOUND BY ALL THE TERMS, CONDITIONS, AND NOTICES CONTAINED HEREIN. IF YOU ARE ENTERING INTO THIS AGREEMENT ON BEHALF OF A CLINICAL LABORATORY, HOSPITAL, OR OTHER LEGAL ENTITY, YOU REPRESENT THAT YOU HAVE THE AUTHORITY TO BIND SUCH ENTITY TO THESE TERMS.

1. Subscription Grant & Scope of License

Subject to the timely payment of subscription fees through Stripe, the Provider grants the Customer a non-exclusive, non-transferable, revocable license to access and use the online statistical analysis software (the "Software") solely for internal clinical laboratory statistical calculations, calibration support, and quality control validation. This is a Software as a Service (SaaS) license; no physical copy or source code of the Software will be delivered to the Customer.

2. Strict Prohibition of Protected Health Information (No PHI / HIPAA Compliance)

 **CRITICAL REQUIREMENT: INTENTIONAL ANONYMITY**

The Software is designed exclusively to process raw analytical numbers, statistical parameters (e.g., means, standard deviations, coefficients of variation), instrument metadata, and names of tests/analytes. **The Software does NOT require, accept, or process Protected Health Information (PHI) or Electronic Protected Health Information (ePHI) as defined under the Health Insurance Portability and Accountability Act (HIPAA).**

- The Customer is strictly prohibited from uploading, typing, parsing, or transferring any Patient Identifiers (including but not limited to patient names, medical record numbers (MRN), dates of birth, social security numbers, or clinical notes containing PHI) into any part of the Software.
- The Customer acknowledges that because the platform does not process PHI, the Provider is not a "Business Associate" of the Customer under HIPAA, and no Business Associate Agreement (BAA) is established or required for this transaction.

- The Customer shall indemnify, defend, and hold harmless the Provider against any legal or financial liability, including federal HIPAA fines, resulting from the Customer's unauthorized input of patient identifiers into the platform.

3. Mandatory Customer Software Validation (CLIA / CAP / COLA Compliance)

The Customer acknowledges that federal and state regulations (including CLIA, CAP, and COLA guidelines) mandate that clinical laboratories validate any software system used to establish, monitor, or verify equipment and assay performance parameters before using it in a live production or clinical reporting capacity.

- **Customer Validation Obligation:** The Customer assumes 100% sole responsibility for performing all software installation qualifications (IQ), operational qualifications (OQ), and performance qualifications (PQ) necessary to establish compliance with its specific regulatory frameworks.
- **No Regulatory Pre-Validation:** ValidToolsLab LLC provides the statistical calculations, restricting algorithms, and immutable logging capabilities "as is" as an analytical tool, but does not certify, validate, or guarantee regulatory compliance within the Customer's unique infrastructure.
- **Risk of Regulatory Deficiencies:** Failure by the Customer to thoroughly validate this Software in their own local clinical setting may lead to non-compliance findings, deficiency citations, or suspension of testing credentials during standard laboratory inspections conducted by state or federal authorities. The Provider shall not be held liable for such outcomes.

4. Data Integrity & Architectural System Protocols (21 CFR Part 11)

The Software generates analysis reports (such as "Pass/Fail" validations) automatically based on parameters extracted from uploaded instrument CSV files or manual entries.

CORE SYSTEM RESTRICTIVE CONTROLS

- **Immutable Reports:** Once a module run is executed and a "Pass" or "Fail" report is generated, the record is immediately locked. "Fail" evaluations cannot be edited or modified to force a "Pass" result. A new experiment must be run, re-uploaded, and processed.
- **Audit Trail:** The platform records an automated, permanent log (Audit Trail) of all user actions, detailing exactly which user (by electronic signature/license number) created, accepted, or rejected an experiment, including timestamps.

5. Cloud Architecture & Database Security Measures

ValidToolsLab LLC utilizes industry-standard architectural frameworks to protect the integrity of the Customer's analytical datasets:

- **Database Encryption:** All data stored within the Provider's cloud infrastructure is encrypted at rest using industry-standard AES-256 encryption. All network communication between the Customer's workstations and the Software is encrypted in transit using Transport Layer Security (TLS 1.2 or higher).
- **Access Controls & Storage Integrity:** User accounts are password-protected and mapped directly to technical user profiles containing names and professional license numbers for electronic signatures. The backend database holding the automated Audit Trail logs is structured on an append-only basis, preventing any user or administrator from deleting or modifying historical system actions.

6. Customer Boundary & Local Internal Security Disclaimer

The Provider enforces stringent cloud infrastructure security, but **assumes absolutely zero responsibility or liability for the Customer's internal local network, workstation security, or credential hygiene.**

- **Local Security Failures:** The Customer is solely responsible for maintaining robust endpoint protection, active firewall rules, browser security patches, and preventing unauthenticated physical access to active terminal sessions.
- **Credential Management:** If a Customer's employee leaves an account logged in on an unmonitored laboratory PC, shares user passwords, or fails to report a compromised account, unauthorized parties may generate, accept, or reject statistical evaluations.
- **Implications of Compromise:** Such local credential compromises could lead to fraudulent user entries, contaminated data integrity logs, and potential regulatory violations during external laboratory inspections. The Customer agrees that all actions executed via valid credentials issued under its subscription are legally binding and are the exclusive operational liability of the Customer.

7. No Clinical or Diagnostic Liability (Analytical Support Tool Only)

The Software is an **analytical support tool** and does not perform clinical diagnoses, make medical decisions, or directly affect patient care. The Customer agrees that the Software is utilized strictly to verify the performance criteria of laboratory equipment and statistical standards. The Provider is not responsible for any diagnostic errors, clinical outcomes, or administrative fines incurred by the laboratory.

8. Limitation of Liability

TO THE MAXIMUM EXTENT PERMITTED BY LAW, IN NO EVENT SHALL VALIDTOOLS LAB LLC (OR ITS MEMBERS, EMPLOYEES, AND AFFILIATES) BE LIABLE FOR ANY INDIRECT, INCIDENTAL, SPECIAL, CONSEQUENTIAL, OR PUNITIVE DAMAGES, INCLUDING BUT NOT LIMITED TO LOSS OF LAB DATA, INSTRUMENT DOWNTIME, LOSS OF PROFITS, OR REGULATORY PENALTIES ARISING OUT OF THE USE OR INABILITY TO USE THE SOFTWARE. THE PROVIDER'S TOTAL AGGREGATE LIABILITY FOR ANY CLAIM ARISING UNDER THIS AGREEMENT SHALL NOT EXCEED THE TOTAL FEES PAID BY THE CUSTOMER TO THE PROVIDER DURING THE TWELVE (12) MONTHS IMMEDIATELY PRECEDING THE EVENT GIVING RISE TO THE LIABILITY.

9. Disclosure of Potential Employee Conflict of Interest

The Customer acknowledges and agrees that ValidToolsLab LLC may be owned, operated, or co-founded by individuals who are also employed as clinical laboratory technologists, clinical specialists, or supervisors in the healthcare sector (including, potentially, employees of the Customer).

- The Customer represents that its decision to subscribe to the Software is based purely on the technical merits, commercial value, and competitive advantages of the platform.
- The subscription has been purchased via automated public channels (Stripe/Self-service) at the standard public market rate (Fair Market Value).
- The Customer agrees that no employee of the Customer who holds an ownership stake in the Provider has exercised decision-making authority or improper influence over the Customer's purchasing department to secure this subscription.

10. Intellectual Property Rights

The Customer acknowledges that all rights, title, and interest in and to the Software, including its source code, database structures, UI/UX layouts, mathematical algorithms, logos, and report formats, belong exclusively to ValidToolsLab LLC. No ownership rights are transferred via this subscription.

11. Governing Law and Jurisdiction

This Agreement and any dispute arising out of or related to it shall be governed by, and construed in accordance with, the laws of the ****State of Florida, United States****, without regard to conflict of law principles. Any legal action or proceeding arising under this Agreement shall be brought exclusively in the federal or state courts located in the State of Florida.

12. Termination & Automatic Renewal

Subscriptions will automatically renew annually through Stripe unless canceled by the Customer prior to the billing cycle. Upon termination, the Customer's access to the Software will be revoked. The Customer is responsible for exporting any necessary statistical reports prior to the effective cancellation date.