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## Quality Information Packet Accuratus Lab Services

Dear Valued Client,

Due to the large volume of supplier surveys Accuratus Lab Services receives each year from its Clients and in order to provide you with the most complete information to assist you in your evaluation of Accuratus Lab Services, this Quality Information Packet has been assembled in the place of completing the questionnaire you have sent. Included in this packet are the following:

- Quality Systems Procedures Index
- Regulatory Overview Document
- Organizational Chart
- Facility Map

If there is any additional information you require to complete your evaluation of our facility, please do not hesitate to contact me.

Kind Regards,

A handwritten signature in blue ink, appearing to read "Stephanie Beane", is positioned above the typed name.

**Stephanie Beane, B.A. RQAP-GLP**

Quality Assurance Manager  
Accuratus Lab Services  
1285 Corporate Center Drive, Suite 110  
Eagan, MN 55121  
651.395.5614 (Direct)  
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## General Facility and Quality System Information

General Information	
<b>Company Name</b>	Accuratus Lab Services
<b>Address of Facility</b>	1285 Corporate Center Drive, Suite 110 Eagan MN 55121
<b>Phone Number</b>	651-379-5510 (Toll Free 1-877-287-8738)
<b>Fax</b>	651-379-5549
<b>Website</b>	www accuratuslabs.com
<b>Services Provided</b>	Full range of microbiology, virology, analytical chemistry, EPA stability testing
<b>Years in Business</b>	25 +
<b>Type of Business</b>	Privately Owned
<b>Federal Tax ID</b>	81-3510615

Key Personnel Information			
Function	Name	Email	Phone
CEO	Alan Roth	alan.roth@analyticallabgroup.com	651-379-5516
Director of Operations	Kelleen Gutzmann	kelleen.gutzmann@accuratuslabs.com	651-379-5539
Director of Business Development	Dave Rottjakob	dave.rottjakob@accuratuslabs.com	651-379-5519
Quality Assurance Manager	Stephanie Beane	stephanie.beane@accuratuslabs.com	651-395-5614

Organizational & Personnel Information	
<b>Total number of employees</b>	58
<b>Number of Quality Assurance employees</b>	5
<b>Number of laboratory analysts</b>	34
<b>Number of shifts</b>	1
<b>Days of operation</b>	Monday through Friday
<b>Unionized</b>	No
<b>Are there written job descriptions?</b>	Yes
<b>Do you have an organizational chart? Can you provide us with a copy?</b>	Yes, a copy is attached to this document.
<b>Is there an SOP for training, addressing both permanent and temporary employees?</b>	Yes
<b>Are training and qualifications documented for each employee, including temporary employees?</b>	Yes
<b>Are there ongoing GLP training and job-specific training for analysts?</b>	Yes
<b>Is training performed and documented when SOP's are created or updated?</b>	Yes
<b>Are changes in EPA, FDA and other regulatory requirements tracked and communicated to employees?</b>	Yes
<b>Do employees have adequate training, experience, and qualifications for their responsibilities?</b>	Yes

Facility Information	
Total size of facility	26,000 sq.ft.
Area of facility utilized for office space	~17,400sq.ft.
Area of facility utilized for testing labs	~8,600sq.ft.
Construction of facility	Single Story Building
Year operations began at this facility	2003
Does your facility have a fire suppression system?	Yes
Is there adequate security to assure that there is no entry by unauthorized persons?	Yes
Are there provisions for power backup sources for critical systems if main power should fail?	Yes
Is there an appropriate pest control program?	Yes

Regulatory Information			
Recognized external authority	Registration number	Date of Inspection	Results of last inspection
U.S. FDA	Not Applicable	August 2017	No Adverse Findings
U.S. EPA	Not Applicable	September 2016	No Adverse Findings
U.S.D.A	Not Applicable	April 2016	No Adverse Findings
U.S.D.A	Not Applicable	April 2014	No Adverse Findings
U.S. EPA	Not Applicable	September 2013	No Adverse Findings
U.S.D.A	Not Applicable	May 2013	No Adverse Findings
U.S. EPA	Not Applicable	May 2010	No Adverse Findings
U.S. EPA	Not Applicable	December 2006	No Adverse Findings

Quality Systems Information	
<i>Responsibilities and Authority</i>	
Do you have a quality policy manual?	Yes; available upon request
Are QA/QC organization's authority and responsibilities clearly defined in writing?	Yes
Is there a mechanism to assure that only current test methods and specifications are in use?	Yes
Are data reviewed and trends monitored? Are adverse trends addressed, and is appropriate management notified?	Yes
<i>Complaint Handling</i>	
Accuratus Lab Services Eagan, MN facility is compliant with U.S. EPA and U.S. FDA GLPs (Good Laboratory Practices). A formal complaint procedure is not required by either of these regulations. However, Accuratus Lab Services Eagan, MN facility responds/investigates to all client complaints as they are received and when necessary. When necessary these complaints are escalated to the Management Team and are reviewed during Management Review.	
<i>Change Control</i>	
Is there an adequate system, described in an SOP, for controlling changes to methods, documents, and equipment, and requiring evaluation of need for re-qualification or revalidation?	Yes
Is QA involved in the change control process?	Yes
Is there a system in place to assure that changes are approved prior to implementation?	Yes

<b>Quality Systems Information Continued</b>	
<i>Audit Program</i>	
<b>Do you host customer audits?</b>	Yes
<b>If Yes; How many per year?</b>	5-10
<b>Is there an internal quality audit program that covers all areas of the operation to verify that SOPs and other procedures and policies are being followed, and to determine effectiveness of the quality systems?</b>	Yes
<b>Based on the audit findings and recommendations, are steps taken to correct any areas of noncompliance? Are corrective actions documented? Is their effectiveness verified in subsequent audits?</b>	Yes
<b>If any contractors (e.g., laboratories, off-site storage facilities) are used, are they periodically audited and their performance monitored?</b>	Yes
<i>Test Substance (Sample) Control</i>	
<b>Is there an SOP for receipt, identification, and storage of incoming test substance (samples)?</b>	Yes
<b>How are test substances (samples) received?</b>	Per SOP, ALS-0036, current revision
<b>Is the test substance (sample) log-in procedure computerized?</b>	Currently both paper based and computerized
<b>How are test substances (samples) stored?</b>	Per Client specifications as stated on the Test Substance Submission Form.
<b>Is there adequate security for stored test substances (samples)?</b>	Yes
<b>Is test substance (sample) flow and chain of custody tracked?</b>	Yes
<b>Are test substances (samples) reconciled and any discrepancy investigated and reported to the client?</b>	Yes
<b>Is there an SOP controlling retention and/or destruction of excess samples?</b>	Yes
<i>Laboratory Investigation Procedure (OOS)</i>	
Accuratus Lab Services Eagan, MN facility is compliant with U.S. EPA and U.S. FDA GLPs (Good Laboratory Practices). A formal Out of Specification procedure is not required by either of these regulations. However, Accuratus Lab Services Eagan, MN facility has a laboratory investigation procedure (ALS-0005, current revision) in place to investigate and document all unexpected test results.	
<b>Is there an SOP for laboratory investigations of unexpected test results to assure that a uniform procedure is followed to determine why the unexpected result occurred and that corrective actions are implemented when necessary?</b>	Yes
<b>Are clients promptly notified of unexpected test results?</b>	Yes
<i>Deviation Procedure</i>	
<b>Is there an SOP for method or protocol deviations to ensure that a uniform procedure is followed and that the impact is appropriately assessed and documented?</b>	Yes

<b>Document Control Information</b>	
<i>Standard Operating Procedures (SOPs)</i>	
Are there written SOPs for all areas of the operation?	Yes
Is there an SOP for writing, handling and updating of SOPs? Are SOPs periodically reviewed and updated?	Yes
Is a history of SOP revisions maintained?	Yes
Are current SOPs readily available to employees?	Yes
Is there an adequate system to assure that unneeded or obsolete documents are removed from use?	Yes
Is there an SOP for document control?	Yes
If a client's test procedures or specifications are reformatted, does the client review and approve the reformatted document?	Yes
<i>Testing Records</i>	
Is appropriate information recorded in test records concerning instruments used in tests (ID number, HPLC column used, etc.)?	Yes
If chromatograms, charts, spectra are stored separate from other test records, are there adequate cross-references to their locations?	Yes
Are records legible? Are they appropriately signed and dated where required?	Yes
Are there overwrites, whiteouts, or pencil entries in official records?	No
Are changes to data properly initialed, dated, and explained based on an SOP that describes acceptable methods for recording data and correcting errors in official documents?	Yes
Are records reviewed for completeness before filing?	Yes
Is there appropriate security for data and records?	Yes
Are raw data/records retained for an appropriate length of time?	Yes
How long are records retained for?	Paper records are retained for a minimum of 5 years and electronic records are maintained indefinitely.

<b>Operations Information</b>	
<i>Analytical Control of Supplies</i>	
Are appropriate reference standards used and are they stored in a proper manner to ensure stability?	Yes
Are their expiration dates adequately monitored so they are not used beyond expiration dates?	Yes
If reference standards are not USP, has appropriate characterization (including purity and stability) been performed?	Yes
Are reagents adequately controlled and monitored to assure that they are periodically replaced and that old reagents are not used?	Yes
Are all containers of materials or solutions adequately labeled to determine identity, preparer, and dates of preparation and expiration (if applicable)?	Yes
Are preparation records maintained, including manufacturer and lot number, preparer, and date?	Yes
<i>Analytical Testing</i>	
Are there complete written instructions for testing, including methods, equipment, operating parameters, and acceptance specifications?	Yes
Are test methods readily available to the analysts?	Yes
Are test methods followed without approved modification?	No
Is there an SOP describing how numbers are to be rounded?	Yes

<b>Operations Information Continued</b>	
<i>Analytical Testing Continued</i>	

Are data and calculations reviewed, verified, and signed by a second person?	Yes
<i>Laboratory Cleaning Procedures</i>	
Based on an SOP, is the laboratory cleaned and disinfected?	Yes
Is there an adequate procedure for disposal of microbiological waste?	Yes
<i>Laboratory Control of Supplies</i>	
Are reagents and microbiological media adequately controlled and monitored to assure that they are periodically replaced and that old reagents are not used?	Yes
Are all containers of materials or solutions adequately labeled to determine identity, preparer, and dates of preparation and expiration (if applicable)?	Yes
Are preparation records maintained, including manufacturer and lot number, preparer and date?	Yes
Is an expiration date assigned to prepared media and are prepared media stored at manufacturers' recommended storage temperatures?	Yes
Is each lot of biological indicators checked for identity and viability?	Yes
Are positive controls periodically included in autoclave runs?	Yes
Based on an SOP, is there appropriate control and documentation of stock cultures, including storage, propagation, assurance of purity, and traceability?	Yes
<i>Laboratory Testing</i>	
Are there complete written instructions for testing, including methods, equipment, operating parameters?	Yes
Are methods validated (when applicable) based on an SOP?	Yes
Are test methods readily available to the laboratory technicians?	Yes
Are test methods followed without approved modification?	No
Is testing conducted with appropriate technique and in such a manner and place to preclude laboratory contamination of samples?	Yes
Are controls used for testing? Are their results recorded?	Yes
Are data and calculations reviewed, verified and signed by a second person?	Yes
<i>Stability Testing</i>	
Is stability testing methods stability-indicating? If so, have they been validated?	Yes, if requested by the Sponsor. Method validation is product-specific so every individual product should be validated under its own project.
Is stability testing performed in the marketed container/closure systems according to intervals and tests specified in a written stability program?	Yes, if the Sponsor provides us with the product packaged accordingly.
Is stability testing done on time within the specified cycle times appropriate for the test intervals?	Yes
Are stability failures investigated (when unexpected) and appropriately documented?	Yes

<b>Equipment Information</b>	
<i>Installation and Qualification</i>	
<b>Is there an SOP for qualifying new or significantly changed equipment and instruments?</b>	Yes
<b>Do qualifications of stability chambers, autoclaves, and ovens include temperature distribution studies?</b>	Yes
<b>Is equipment available in sufficient quantity to perform all required testing within required time frames?</b>	Yes
<i>Installation and Qualification Continued</i>	
<b>Are there operational SOPs for all equipment and instruments?</b>	Yes
<i>Maintenance and Calibration</i>	
<b>Are there SOPs for inspection and maintenance of equipment and of measuring and testing instruments?</b>	Yes
<b>If so, do SOPs assign responsibilities; including schedules; describe methods, equipment, and materials to be used; and require maintenance of records?</b>	Yes
<b>If instruments malfunction or are determined to be defective, are they immediately taken out of use?</b>	Yes
<b>Are there SOPs for calibration of equipment and instruments?</b>	Yes
<b>If so, do SOPs assign responsibilities; including schedules; describe methods, equipment, and materials to be used, including calibration over actual range of use and standards traceable to national standards, and include specifications and tolerances; and require maintenance of records?</b>	Yes
<b>Does an SOP specify that equipment cannot be used if it is beyond the calibration due date, and describe actions to be taken if equipment is used that is found to have been beyond the due date or is found to be out of calibration limits?</b>	Yes
<b>Are calibrated instruments labeled with date calibrated and date next calibration is due?</b>	Yes
<b>Is equipment in use observed to be within calibration dating?</b>	Yes
<b>Are periodic verifications performed on analytical balances (using a range of weights) to assure that they remain within calibration in the time between full calibrations?</b>	Yes
<b>Are records maintained for maintenance and calibration operations?</b>	Yes
<b>Computerized Systems Information</b>	
<b>List computerized systems used with regulatory implications</b>	MasterControl MS Office – Excel MFiles
<b>Are these computerized systems validated?</b>	MasterControl/MFiles -Yes; systems have been validated Excel- all formulas are printed and verified with each use. Also we have an SOP for validating excel spreadsheets.
<i>Network Back-up Procedures</i>	
<b>Are suitable backup systems in place, such as copies of programs and files, duplicate tapes, or microfilm?</b>	Yes
<b>Is the network back-up procedure outlined in an SOP?</b>	Yes
<i>Change Control</i>	
<b>Is there a system to control changes to systems and programs?</b>	Yes
<b>Does the system assure that changes receive the proper review and approval with regard to potential effects before being instituted and that only authorized personnel can make such changes?</b>	Yes
<b>If necessary, are personnel trained subsequent to changes?</b>	Yes
<b>Is a record of system and program changes maintained?</b>	Yes

<b>Computerized Systems Information Continued</b>	
<i>Security</i>	
<b>Is there an appropriate security system to limit access to computerized systems, protect records from tampering, and prevent data alterations?</b>	Yes
<b>If anyone leaves the department or company or otherwise loses authority to access the systems, are there procedures to immediately remove that person's access codes from the system?</b>	Yes

<b>Computerized Systems Information Continued</b>	
<i>Electronic Records</i>	
<b>Is there an SOP or written policy that describes the electronic records retention system that is used?</b>	Yes
<b>Is the system capable of producing accurate and complete copies of records in both paper and electronic formats?</b>	Yes
<b>If a change is made, is the previous information still available?</b>	Yes



## Quality Systems Procedures Index

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ALS-0005	Laboratory Investigation
ALS-0006	Confirmatory Testing Procedures
ALS-0007	Format and Content of Controlled Documents
ALS-0008	Good Documentation Practices
ALS-0009	Confidentiality Policy
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ALS-0011	Documentation Control and Records Maintenance
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ALS-0013	Facility Inspections
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<b>SOP#</b>	<b>Title</b>
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CEL-0002	Continuous Cell Line Preservation and Recovery
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CGT-0002	Preparation of EN (European) Hard Water
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CGT-0007	Cleaning Validation for Reusable Medical Devices
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SOP#	Title
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SOP#	Title
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SOP#	Title
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<b>SOP#</b>	<b>Title</b>
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EQM-0008	Incubator Monitoring and Cleaning
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EQM-0023	Decontaminating/Cleaning Reagent Preparation and Work Area Decontamination Documentation
EQM-0024	Liquid Nitrogen Tank Maintenance
EQM-0025	Anaerobic/Microaerophilic Gas Generating Systems
EQM-0026	Shaker Monitoring and Cleaning

<b>SOP#</b>	<b>Title</b>
EQM-0027	Wrist Action Shaker Use and Monitoring
EQM-0028	Maintaining Chart Recorders
EQM-0030	Biological Safety Cabinet Monitoring, Maintenance and Certification
EQM-0031	Fume Hood Operation and Certification
EQM-0032	Room Temperature Monitoring
EQM-0033	Use of the Beckman Du Series 500 (Du 520) Spectrophotometer
EQM-0034	Use and Calibration of Laboratory Thermometers
EQM-0035	Use and Calibration of Timers
EQM-0036	Vacuum Pump Operation/Maintenance
EQM-0037	Use and Calibration of the Digital Barometer Module
EQM-0038	Lyon Electric Profi I Egg Incubator Operation and Maintenance
EQM-0039	Documenting Equipment Monitoring
EQM-0040	AND GX-6100 Balance Calibration Check and General Use
EQM-0041	Documentation of Equipment Cleaning, Maintenance, and Repair
EQM-0043	Compulab 3 Modular Dispensing System Operation and Maintenance
EQM-0044	Use of the Traceable® Dual-Display Light Meter
EQM-0045	Ohaus CS200 Scale Calibration and General Use
EQM-0046	Soxhlet Condenser Apparatus Operation and Maintenance
EQM-0047	Lauda Ecoline RE120 Low Temperature Bath
EQM-0048	Rainin EDP-Plus M8 Pipettor
EQM-0049	Preparation of CDC Biofilm Reactor

<b>SOP#</b>	<b>Title</b>
EQM-0050	Use, Maintenance and Calibration of the Mettler Toledo AB104 Scale
EQM-0051	Use, Maintenance and Calibration of the Mettler Toledo XP205 DeltaRange Analytical Balance
EQM-0052	VWR1410 Vacuum Oven Operation, Monitoring and Cleaning
EQM-0053	Use, Maintenance and Calibration of the Spectronic 20 Genesys Spectrophotometer
EQM-0054	Use, Maintenance and Calibration of the Mettler Toledo NewClassic MS Balance
EQM-0055	Waterline Pressure Gauge
EQM-0056	Use, Maintenance and Calibration of the Denver Instruments APX-323 Balance
EQM-0057	Use of the Testing Room for Laboratory Studies
EQM-0058	Laminar Flow Hood Operation
EQM-0059	Geringe Washer Disinfector (model, 46-4 Series) Operation
EQM-0060	Geringe Model 46-4 Series Washer Disinfector Detergent Flow Rate Determination
EQM-0061	Amsco Lab 250 Sterilizer Operation
EQM-0062	Kaye Validator 2000 Operation
EQM-0063	Kaye HTR 400 Operation
EQM-0064	Kaye IRTD Operation
EQM-0065	Operation of DataTrace Pro with Temperature Data Loggers
EQM-0066	Use, Maintenance and Calibration of the Mettler Toledo AT200 Scale
EQM-0067	DataNet and DataSuite Software Use
EQM-0068	ProtoCOL 3 Colony Counter Use
EQM-0069	Operation of the Millipore Synergy Water Purification System
FAC-0001	Facility Pest Control
FAC-0002	Generac Generator Operational Checks and Preventative Maintenance
FAC-0003	LockOut/TagOut Procedure
FAC-0004	Refrigerator, Freezer and Ultra Low Freezer Preventative Maintenance
FAC-0005	Air Handling, Air Conditioning & Exhaust Fan Preventative Maintenance
FAC-0006	High Pressure Boiler, Autoclave and Dishwasher Preventative Maintenance
FAC-0007	Carbon Dioxide System Monitoring and Maintenance



SOP#	Title
FAC-0008	Walk-In Refrigerator Preventative Maintenance
FAC-0009	Incubator Preventative Maintenance
FAC-0010	Sanitization of the Deionized Water System
FAC-0011	Weekly Checks and Resistivity Limits for the Deionized Water System
FAC-0012	Environmental Chamber and Humidity Chamber Preventative Maintenance
FAC-0013	Preventative Maintenance Documentation
FAC-0014	Biosafety Level 3 Laboratory Annual Preventative Maintenance
IT-0001	Network Backup and Restore Procedures
IT-0002	Security Management
IT-0003	Electronic Signatures
IT-0004	Change Control Procedures for Validated Software Systems
IT-0005	Procedures for Archiving Electronic Data
IT-0006	Master Validation Plan
IT-0007	Computer System Life Cycle Management and 21 CFR Part 11 Compliance
IT-0008	Acceptable Use Policy
IT-0009	Internet Use Monitoring and Filtering Policy
IT-0010	Business Continuity Management and Disaster Recovery Procedure
MPR-0001	Media Production Laboratory Cleaning and Maintenance
MPR-0002	Chemical and Media Receiving, Storage and Stocking
MPR-0003	Quality Control Testing Media and Reagents
MPR-0004	Preparation of Labels for Media and Reagents
MPR-0005	Preparation of Media and Reagents in the Media Production Laboratory
MPR-0006	Media Plates, Slants, Bottle and Flask Production
PCS-0001	Evaluation of Freeze Profile of Source Water, Ice Nucleating Activity (INA) and Microbial Testing of Snomax
PCS-0002	Operation of the AmeriWater HeatSan System
PCT-0001	Color
PCT-0002	Corrosion Characteristics
PCT-0003	Specific Gravity (Density)
PCT-0004	Flash Point
PCT-0005	Odor
PCT-0006	Oxidation/Reduction: Chemical Incompatibility
PCT-0007	pH Measurement
PCT-0008	Physical State
PCT-0009	Storage Stability
PCT-0010	Total Quat (Epton Titration)
PCT-0011	Viscosity Determination
PCT-0012	Waters Alliance e2695 High Performance Liquid Chromatograph

SOP#	Title
PCT-0013	Waters Empower 3 Chromatography Data Software
PCT-0014	Anton Paar DMA 35 Portable Density Meter
PCT-0015	Analytical Method Validation
PCT-0016	Overview of Chemistry Techniques
PCT-0017	Critical Q-value Test / Dixon's Test (Statistical Method)
PCT-0018	Reference Standards
PCT-0019	Chemical Characterization and Preliminary Analysis
PCT-0020	Use and Maintenance of the Agilent 6890 Gas Chromatograph
PCT-0021	Titration of Peracetic Acid
PCT-0022	Analysis of Residual Protein
PCT-0023	Analysis of Residual Carbohydrates
PCT-0024	Analysis of Residual Hemoglobin by UV-Spec
PCT-0025	Analysis of Residual Hemoglobin by HPLC
PCT-0026	Assay of H <sub>2</sub> O <sub>2</sub> by Titration
PCT-0027	Assay of Sodium Hypochlorite by Titration
PCT-0028	Assay of Free Available Chlorine by Titration
PCT-0029	Assay of Hypochlorous Acid by Titration
PCT-0030	Standardization of Silver Nitrate
PCT-0031	Mettler Toledo Titration Excellence T7
QAU-0001	Scheduling and Performance of Quality System Department Audits
QAU-0002	Quality Assurance Review of Controlled Documents
QAU-0003	Monitoring Subcontractors for GLP Compliance
QAU-0004	Quality Assurance Unit (QAU) Responsibilities for Non-Clinical Studies
QAU-0005	Performance of Critical Phase Inspections
QAU-0006	Quality Assurance Report Audit Instructions for Non-Clinical GLP Studies
QAU-0007	Multi-Site Studies: Test Site Quality Assurance Unit (QAU) Responsibilities
QAU-0008	Management Review
SAF-0001	Emergency Procedures
SAF-0003	General Safety
SAF-0004	Exposure Plan for Bloodborne and Other Pathogens
SAF-0005	Exposure Control Plan for Chemicals
SAF-0006	Waste Management
SAF-0008	Employee Right to Know
STE-0001	Preparation of Items for Sterilization
STE-0002	Dishwashing of Laboratory Items
STE-0003	Labconco SteamScrubber Dishwasher Operation and Maintenance

<b>SOP#</b>	<b>Title</b>
STE-0004	Operation of the Autoclaves
STE-0005	VWR International Horizontal Air Flow Oven, Model 1675 Operation and Cleaning
STE-0006	Sterilization Lab Process Flow

## Regulatory Overview Document

Accuratus Lab Services provides antimicrobial and biocide testing services through a comprehensive range of microbiology, virology and analytical chemistry tests. In doing so, we comply with the following regulations:

EPA

40 CFR Part 160      *Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA): Good Laboratory Practice Standards*

FDA

21 CFR Part 58      *Good Laboratory Practice for Nonclinical Laboratory Studies*

On the following page, you will find a Compliance Outline that summarizes how Accuratus Lab Services complies with the regulations stated above.

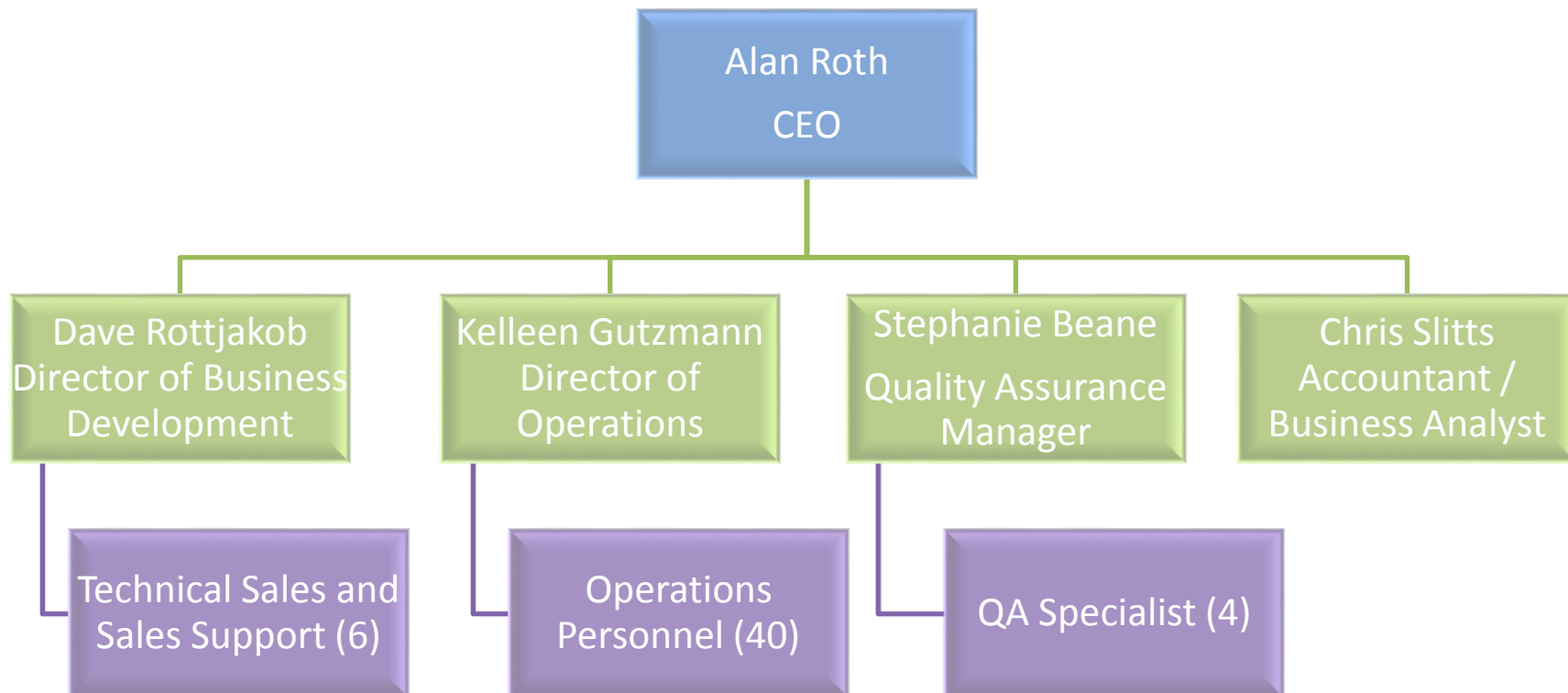
### Accuratus Lab Services: COMPLIANCE OUTLINE

40 CFR part 160	21 CFR Part 58	Section	Section Title	Accuratus Labs SOP	SOP Title
<b>Subpart A - General Provisions</b>					
160.1	58.1		Scope		
160.1	58.1		Applicability to studies performed under grants and contracts	ALS-0009	Confidentiality Policy
160.3	58.3		Definitions		
160.12			Statement of compliance or non-compliance		Compliance Statement is included with each GLP Report
160.15	58.15		Inspection of a testing facility	ALS-0013	Facility Inspections
160.17			Effects of non-compliance		
<b>Subpart B - Organization and Personnel</b>					
160.29	58.29	(a)-(f)	Personnel	ALS-0024	Personnel Outline for Non-Clinical Studies
160.29	58.29	(a)	Personnel	ALS-0001	Personnel Training, Retraining and Competency Evaluation Procedure
160.29	58.29	(b)	Personnel	ALS-0023	Good Laboratory Practice (GLP) Training Program
160.29	58.29	(b)	Personnel	ALS-0002	Training File Contents
160.29	58.29	(b)	Personnel	ALS-0003	Procedure for Company Organizational Chart, Personnel Job Descriptions and CVs
160.29	58.29	(d), (e), (f)	Personnel	CGT-0011	General Safety Precautions for the Testing Laboratories
160.29	58.29	(d), (e), (f)	Personnel	ALS-0022	Safety Training
160.31	58.31	(a)-(c), (e)-(g)	Testing facility management	ALS-0025	Management and Study Director Responsibilities
160.33	58.33	(a)-(f)	Study Director	ALS-0025	Management and Study Director Responsibilities
160.35	58.35	(a), (b)(1)-(7)	Quality Assurance Unit	QAU-0004	Quality Assurance Unit (QAU) Responsibilities for Non-Clinical GLP Studies
160.35	58.35	(c),(d)	Quality Assurance Unit	QAU-0006	Quality Assurance Audit Instructions for Non-Clinical GLP Studies
<b>Subpart C - Facilities</b>					
				FAC-0001	Facility Pest Control
160.41	58.41		General	ALS-0012	Facility Security and Visitor Identification
160.43	58.43		Test system care facilities	CGT-0009	General Laboratory Procedures
160.45	58.45		Test system supply facilities	ALS-0031	Receiving Policies and Procedures
160.47	58.47		Facilities for handling test, control and reference substances	ALS-0036	Receiving, Log In and Accountability of Test and Control Substances

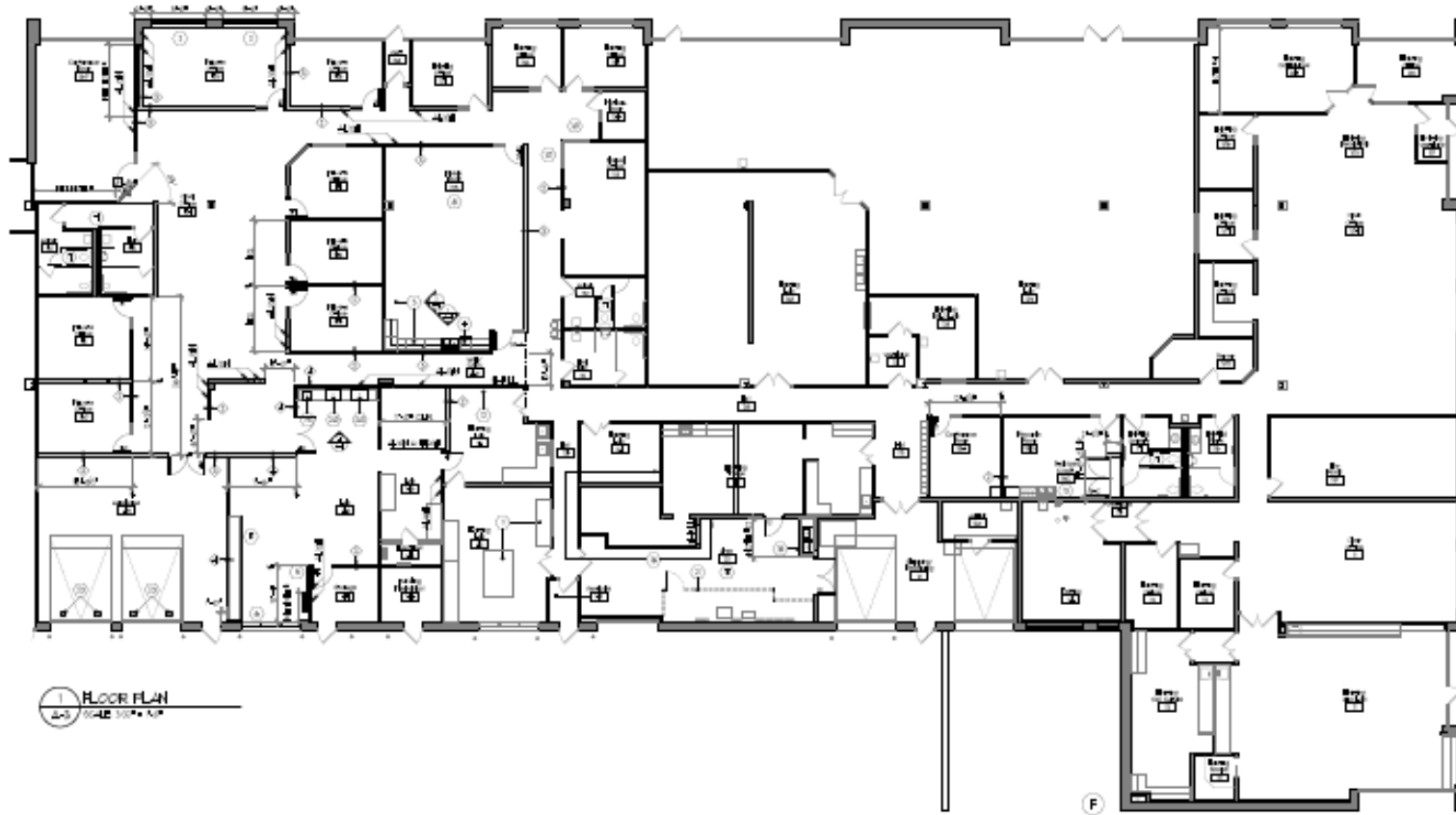
160.49	58.49		Laboratory operation areas		Accuratus has separate areas for microbiology, virology, media preparation and analytical chemistry.
160.51	58.51		Specimen and data storage facilities	ALS-0032	Archive Procedures for Documentation Records
<b>Subpart D - Equipment</b>				EQM SOP Manual	
160.61	58.61		Equipment Design	ALS-0019	Measurement Assurance Program
160.63	58.63		Maintenance and calibration of equipment	ALS-0019	Measurement Assurance Program
<b>Subpart E - Testing Facilities Operation</b>					
160.81	58.81	(a)-(d)	Standard operating procedures	ALS-0011	Documentation Control and Records Maintenance
160.81	58.81		Standard operating procedures	ALS-0007	Format and Content of Controlled Documents
160.81	58.81		Standard operating procedures	ALS-0004	Numbering System for Controlled Documents
160.83	58.83		Standard operating procedures	ALS-0018	Labeling of Laboratory reagents and Solutions
160.90	58.90	(a)-(c)	Reagents and solutions	CGT-0020	Culture Maintenance Record Keeping Guidelines
160.90	58.90		Animal and other test system care	CGT-0074	Procedure for the Preparation of Stock Viral Cultures
160.90	58.90		Animal and other test system care	CGT-0065	Purchasing, Receiving, Rehydrating and Freezing Bacterial and Fungal Organisms
160.90	58.90		Animal and other test system care	CGT-0072	Documentation of Stock Virus Receipt
160.90	58.90		Animal and other test system care	CGT-0009	General Laboratory Procedures
160.90	58.90		Animal and other test system care	CGT-0067	Test Organism Confirmation Procedure
160.90	58.90		Animal and other test system care	CGT-0071	Quality Control of Virucidal Assay
<b>Subpart F - Test and Control Articles</b>					
160.105	58.105		Test and control article characterization	ALS-0028	GLP Protocol requirement
160.107	58.107	(a)-(d)	Test and control article handling	ALS-0036	Receiving, Log In and Accountability of Test and Control Substances
160.113	58.113		Mixtures of articles with carriers	CGT-0009	General Laboratory Procedures
<b>Subpart G - Protocol for and conduct of a non-clinical laboratory study</b>					
160.120	58.120	(a)-(b)	Protocol	ALS-0028	GLP Protocol requirement
160.120	58.120	(b)	Protocol	ALS-0029	Deviations and Protocol Amendments

160.130	58.130	(e)	Conduct of a nonclinical laboratory study	ALS-0008	Good Documentation Practices
160.130	58.130	(c)	Conduct of a nonclinical laboratory study	CGT-0009	General Laboratory Procedures
160.135			Physical and chemical characterization studies		Physical and chemical characterization studies are run under GLP protocols & systems
<b>Subpart J - Records and Reports</b>					
160.185		(a)-(b)	Reporting of nonclinical laboratory study results	ALS-0027	GLP Final Reports
160.185		(c)	Reporting of nonclinical laboratory study results	ALS-0030	GLP Final Report Amendments
160.190		(a)-(e)	Retention of records	ALS-0032	Archive Procedures for Documentation Records
160.190			Retention of records	ALS-0033	Preparing Project Files for Archiving
160.195		(a)-(i)	Storage and retrieval of records and data	ALS-0032	Archive Procedures for Documentation Records

# Accuratus Lab Services Organizational Chart







1285 Corporate Center Drive, Suite #110  
Eagan, Minnesota 55121

Total Sq. Footage = 26,000 sq. ft.