UC Davis Analytical Laboratory Quality Manual

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Introduction and Overview

Introduction

Overview

The UC Davis Analytical Laboratory was established in 1950 at UC Berkeley as an Extension soils testing laboratory. The Lab was relocated to Hoagland Hall at UC Davis in 1959. The Analytical Laboratory has since evolved into a state-of-the-art agricultural and environmental analytical laboratory, testing soil, plant material, water, wastewater, and animal feed. The Analytical Laboratory is a key partner in the success of University of California research.

Laboratory Purpose

The purpose of the Analytical Laboratory is to provide UC researchers with inexpensive, high quality testing service in support of agricultural and environmental research activities. Research quality testing allows researchers to obtain dependable results throughout the lifetime of their research projects, which are often multi-year in duration. Low cost enables researchers to meet the expense of the large number of tests necessary in agricultural and environmental research, and to compete successfully for project funding. The laboratory provides testing support for diagnostic field investigations by CE Advisors.

Laboratory Organization

The laboratory is a self-funded unit within the UC Davis College of Agricultural and Environmental Sciences. The laboratory is headed by a Director, and staffed with a Management Services Officer, a Programmer, a Quality Assurance Officer, a Laboratory Supervisor, one office assistant, one Receiving Area manager, six staff chemists and several part-time student assistants. The use of state-of-the-art analytical equipment, methods and facilities is critical to the success of the laboratory. The laboratory occupies over 5000 square feet in Hoagland Hall and the Hoagland Annex.

Mission – Quality Policy Statement

To provide high quality and timely analyses of soil, plant, water, feed, and other samples and to continuously meet the requirements and expectations of our clients.

Core Values
At the UC Davis Analytical Laboratory we hold the following principles and values to be the most important, and we consider these values in making decisions:

- **honesty**
- **safety of our employees and community**
- **good science**
- **fairness**
- **quality**

Ethics Policy
Ethics is a set of moral principles, a code for right and wrong, or behavior which conforms to accepted professional practices.

All employees at all times shall conduct themselves in an honest and ethical manner.

Examples of unethical behavior include, but are not limited to the following:

- Improper manipulation of data or software
- Improper handling of data errors, non-compliant data, or QC outliers
- Lack of reporting unethical behavior by others
- Artificially fabricating results
- Misrepresenting data such as peak integration, calibration, tuning, or system suitability
- Improper clock setting to meet holding times
- Intentional deletion of non-compliant data

An employee must report any suspected unethical behavior or fraudulent activities to a supervisor. An employee has the right to remain anonymous.

Confidentiality
Client information is confidential and will not be discussed with anyone, even those affiliated with the client not designated as a contact, without permission from the client. Confidential information includes test results, origin of samples, business relationship with the client, any procedures and testing that they conduct or investigate, and information about their research.

Instrument Services
The laboratory maintains state-of-the-art analytical equipment. Major pieces of equipment include:

- Thermo Iris inductively coupled plasma emission spectrometer (ICP-AES)
- Thermo iCAP 6500 inductively coupled plasma emission spectrometers (ICP-AES)
- Perkin-Elmer/Sciex API 2000 HPLC/MS/MS

- Perkin-Elmer AAnalyst 800 flame/graphite furnace atomic absorption spectrometer
- Perkin-Elmer AAnayst 300 flame atomic absorption spectrometer (AA)
- CEM microwave sample digestion system
- Lachat Flow Injection Analyzers (FIA)
- Timberline Flow Injection Ammonium Analyzer
- LECO-FP528 Nitrogen Analyzer
- LECO TruSpec carbon/nitrogen analyzer
- Thermo-Finnegan Series 1112 carbon/nitrogen analyzer
- Dionex ICS-2000 Ion Chromatograph
- Varian 3800 Gas Chromatograph with Saturn 2000 GC/MS
- Skalar Formacs ^{HT} TOC/TN Analyzer

Testing Services information - details available on the laboratory website

- Soils testing services include salinity, alkalinity and toxicity tests, soil fertility tests, soil characteristics and physical properties, and mineral analysis.

- Plant and feed testing includes carbon and nitrogen testing, nutrient and mineral analysis, fiber testing and carbohydrate testing.

- Water and wastewater testing includes tests for water quality, including sediment, nutrients, salinity, alkalinity and toxicity, and soluble and acid digestible elements.

Quality Control and Quality Assurance

Quality Control (QC) refers to steps taken to ensure and monitor precision and accuracy of test results. Quality Control practices include the analysis of quality control samples with each set of samples. These include calibration standards, certified reference materials, spiked samples, duplicate sample analysis, and blanks. Additional QC measures include the analysis of blind duplicate samples and participation in various proficiency testing programs.

Quality Assurance (QA) refers to a completely separate and independent monitoring of laboratory studies and Quality Control activities. Quality Assurance activities include the internal audit program, review of data packages, evaluation of non-conformances, and an annual Management Review of quality data. The laboratory follows ISO 17025 and ISO 9001 international standards as they are applicable and significant for the testing requested by client.

Section 1. Scope of the Quality Manual

The Quality Manual contains the policies and procedures used for the quality management system of the UC Davis Analytical Laboratory:

- to generate test results that are technically sound and have the required accuracy and precision
- to meet client requirements
- to meet regulatory requirements
- to maintain client satisfaction

The policies and procedures of the Quality Manual are applicable to all testing performed in the laboratory, unless superseded by a project or client-specific quality plan.

The Quality Manual is divided into five sections:

- Section 1, “Scope of the Quality Manual”, describes the scope of the Quality Manual.
- Section 2, “References”, lists normative documents referenced by this manual.
- Section 3, “Terms and Definitions”, defines terms used in this manual.
- Section 4, “Management Policies and Procedures”, specifies how sound management is demonstrated and client satisfaction is maintained.
- Section 5 “Technical Procedures and Policies” specifies how technical competence in the laboratory is demonstrated.

Section 2. References

The laboratory complies with the requirements of this Quality Manual.

To the extent that is reasonable and feasible, ISO 17025 requirements are addressed in laboratory systems and procedures. The UC Davis Analytical Laboratory is not fully compliant with ISO 17025 requirements or ISO 17025 certified. The Quality Manual is intentionally numerically aligned with ISO 17025 requirements to provide a standard format.

The following normative documents contain provisions which, through reference in this text, constitute provisions of this Quality Manual.

- Certification of Environmental Laboratories. California Code of Regulations, Title 22, Division 4, Chapter 19.
- ISO 17025:2005, "General Requirements for the Competence of Testing and Calibration Laboratories."
- ISO 9001:2000, "Quality Management Systems – Fundamentals and Vocabulary."
- ISO/IEC 17000, "Conformity Assessment – Vocabulary and General Principles."
- National Institute of Standards and Technology (NIST), Standard Reference Materials Program, Gaithersburg, MD 20899.

Section 3. Terms and Definitions

Accreditation – formal recognition of a laboratory by an independent science-based organization that the laboratory is competent to perform specific tests (CASCO).

Document - a hard copy or electronic file containing information, data, or procedures that are generally in use. A current SOP is an example of a document. An obsolete version of a SOP that has been archived is an example of a record.

Frozen - temperature of 0°C to -5°C (per EPA Manual for the Certification of Laboratories Analyzing Drinking Water)

Non-standard testing - a laboratory term that describes any analysis that is not listed on the Analytical Laboratory website as a standard analysis that is offered by the laboratory.

Record - a hard copy or electronic file containing data, results, observations, or other information relevant to laboratory testing and operations. In general, a record has been completed and stored, and is no longer in daily use. Examples include results reports, data packages, obsolete versions of SOPs, and non-conformance reports.

Refrigerated - temperature range of 6°C +/- 2°C (per EPA Manual for the Certification of Laboratories Analyzing Drinking Water)

Room Temperature - ambient temperature 20-30°C (per EPA Manual for the Certification of Laboratories Analyzing Drinking Water)

Standard Method - a laboratory term that describes any laboratory method for which a Standard Operating Procedure has been established.

Standard Testing - A laboratory term that describes any analysis that is listed on the UC Davis Analytical Laboratory website as a standard analysis offered by the laboratory.

Work Request - a form that is completed by the client with sample information and the analysis requested. A completed Work Request Form must be submitted with the samples.

Work Request number - a unique identification number assigned to a set of samples. The format for the Work Request number is the last two digits of the fiscal year-code letter for the sample type- a three digit sequential number. For example 10 F 012 would be the twelfth set of feed samples submitted in fiscal year 10-11.

Section 4. Management Policies and Procedures

The laboratory is divided into five groups in the following manner:

Group	Components
Laboratory	Analytical Testing
Administrative	Administrative Management and Support
Information Technology	IT Support
Lab Support	Sample Receiving and Preparation
Quality Assurance	Quality Assurance

The Analytical Laboratory Management System has the following components:

4.1 Organizational Structure. The laboratory has an organizational structure that:

- gives managerial and technical personnel the authority and resources needed to carry out their duties, identify the occurrence of departures from the quality system and to initiate actions to prevent such departures (non-conformances)
- has policies and procedures to ensure the protection of clients' confidential information and proprietary rights
- has policies and procedures to avoid involvement in any activities that would diminish confidence in the laboratory's competence, impartiality, judgment or operational integrity
- provides adequate supervision of testing staff, including trainees, by persons familiar with methods and procedures
- has technical management with overall responsibility for the technical operations and the provision of the resources needed to ensure the required quality of laboratory operations
- has a quality officer who has defined responsibility and authority for ensuring that the quality system is implemented and followed at all times

4.2 Quality Management System. The laboratory has a Quality Management System that supports the laboratory management's commitment to good professional practice and to the quality of its testing. The effectiveness of the Quality Management System is assessed in several ways:

- by a program of planned internal audits, covering all aspects of the operation of the quality management system
- by regular management reviews of the suitability and effectiveness of the quality management system

- by analysis of potential and actual problems as documented in the non-conformance report system, by client complaints, and other relevant assessments

4.3 Document Control. The Laboratory controls all documents that form part of its quality system, such as the Quality Manual, test methods (method SOPs), other laboratory procedures (SOPs), and instrument manuals. Regulations, standards, and published test methods are referenced, when used.

4.4 Review of Test Requests and Contracts. The laboratory has procedures for the review of requests for work to ensure that the requirements, including the methods to be used, are adequately defined, that the laboratory has the capability and resources to meet client requirements, and that the appropriate test method is selected and is capable of meeting clients requirements.

- The laboratory provides each client with a pre-printed Work Request Form to capture the client's request for testing and associated requirements. The Work Request Form lists the analyses available for each sample type. The Work Request Form must be completed, signed by the client, and submitted with the samples to be tested.

- If review of the work request highlights any ambiguities or uncertainties, the client is contacted and the problem resolved. A confirmation email with a fee estimate and the completed Work Request Form as a scanned file is sent to the client.

- The client has an opportunity to notify the laboratory if any changes are required or requested. Testing is commenced according to the completed Work Request Form unless the laboratory is otherwise notified by the client.

4.5 Sub-contracting of Tests. The laboratory has a procedure for sub-contracting tests such that this work is placed with a competent sub-contractor, that the client is notified of the arrangement, and that the laboratory's responsibility for the testing is defined to the client.

4.6 Purchasing Services and Supplies. The laboratory has procedures for the selection, purchasing, receipt, and storage of supplies that affect the quality of the tests, including reagents and laboratory consumables.

4.7 Service to the client. The Laboratory cooperates with clients to clarify the client's request and to monitor the laboratory's performance in relation to the work performed. Service to the client includes:

- affording the client reasonable access to relevant areas of the laboratory for the witnessing of work performed for the client. Such access must not conflict with rules of confidentiality of work for other clients or with safety.
- maintaining open communication. Contact with the client, especially in large assignments, is maintained throughout the work. The laboratory informs the client of any delays or major deviations in the performance of the tests.
- preparing, packaging, and dispatching of samples needed by the client for verification purposes.
- the laboratory seeks feedback from clients.

4.8 Complaints. The Laboratory has a policy and procedure for the resolution of complaints received from clients. Records of complaints are documented on the non-conformance report form and include the following information:

- details of the complaint
- investigation
- corrective and preventive actions
- follow-up verification

4.9 Control of Non-Conforming Testing. The laboratory has procedures that are implemented when any aspect of its testing does not conform to relevant procedures or the requirements agreed upon with client. These include defining the responsibilities for the management of non-conforming work, actions taken when non-conforming work is identified, an evaluation of the significance of the non-conforming work, remedial actions taken, and client notification.

Situations that require a non-conformance report include:

- failure or suspected failure to comply with test method, or other laboratory SOPs such that the integrity of the test results may be jeopardized
- calibration results or maintenance activities that indicate an equipment malfunction has occurred and may have impacted test results
- test results do not meet the regulatory or client defined acceptance criteria
- results of quality control samples (duplicates, SRMs, blanks, spikes) that are outside of established ranges
- proficiency testing program results that are outside of expected ranges
- client complaints

4.10 Corrective Action. The laboratory has a policy and procedure for implementing corrective action when non-conforming work or departures from the policies and procedures in the quality system or technical operations have been identified.

4.11 Preventive Action. Needed improvements and potential sources of non-conformances are identified. If preventive action is required, action plans are developed, implemented and monitored to reduce the likelihood of the occurrence of such non-conformances and to take advantage of the opportunities for improvement.

4.12 Control of Records. The laboratory has procedures for identification, collection, indexing, access, filing, storage, maintenance and disposal of quality and technical records.

- All records are legible and are retained in such a way that they are readily retrievable. The retention time for hard copy records is one year. Electronic records are retained five years.
- All records, including test reports, are safely stored in locked areas.
- Procedures are in place for the identification, access, maintenance, and storage of electronic records to prevent unauthorized access or modification of these records.

4.13 Internal Audits. The laboratory conducts internal audits of its activities to monitor compliance with the requirements of the quality system. The internal audit program involves periodic audits of all elements of the Quality Manual. These audits include system audits, such as Training, and the Non-Conformance System, and also data package audits.

4.14 Management reviews. The laboratory's management team periodically conducts a review of the laboratory's quality system and testing activities for continuing suitability and effectiveness, and to introduce necessary changes or improvements.

4.15 Improvements. The laboratory continually improves the effectiveness of its management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective actions, preventive actions, and management review.

Section 5. Technical Procedures and Policies

5.1 General Information. The UC Davis Analytical Laboratory has technical procedures and policies in place to determine the correctness and reliability of test results. The correctness and reliability of test results are impacted by many factors:

- analyst technique/staff performance
- facility and environmental conditions
- test methods and method validation
- equipment
- measurement traceability (reference materials and calibration)
- sampling
- sample handling

These factors are addressed by the technical procedures and policies of the Analytical Laboratory. The extent to which these factors contribute to total measurement uncertainty differs between types of tests. These factors are taken into consideration and evaluated during testing, the training and qualification of personnel, the development and validation of test methods and procedures, and in the selection and calibration of equipment.

5.2 Personnel. Management ensures the competency of all personnel, including those performing tests and support functions, those evaluating results, and those signing test reports. Training is documented to ensure all procedures are performed by trained personnel. Management authorizes specific personnel to operate particular types of equipment, to perform particular types of testing, and to issue test reports.

5.3 Accommodation and Environmental Conditions. The laboratory is equipped to provide a suitable environment for correct performance of the tests.

- Environmental conditions are monitored, controlled, and recorded as required by the test methods and procedures or where they may influence the quality of test results. Testing is stopped when the environmental conditions jeopardize the results of the tests.

- Effective separation between neighboring areas is made when the activities are incompatible. Measures are taken to prevent cross-contamination.

5.4 Test Methods and Method Validation.
Routine methods are documented in the Analytical Laboratory Standard Operating Procedures (SOP) manual. SOPs are reviewed annually and revised as needed; revision dates and summary of changes are documented in each SOP. The references used for each method are documented in the SOPs.

- The laboratory uses appropriate methods and procedures for all tests within its scope. These include handling, storage and preparation of samples to be tested.
- The laboratory has instructions on the use and operation of all relevant equipment, and on the handling and preparation of samples, where the absence of such instructions could jeopardize the results of tests.
- The laboratory uses test methods which meet the needs of the client and which are appropriate for the tests it undertakes.
- Methods that are developed or modified in-house are detailed in method SOPs and are validated to the degree appropriate for their intended use.
- Calculations and data transfers are subject to appropriate checks in a systematic manner. Procedures are established and implemented for protecting the data.
- The laboratory estimates the uncertainty of test methods by identifying the significant components of measurement uncertainty, making a reasonable estimation, and ensuring that the format of reporting of the results does not give an exaggerated impression of the uncertainty.

5.5 Equipment. The laboratory is furnished with all items of test equipment required for the correct performance of the tests. The equipment is capable of achieving the accuracy required, and is calibrated before use.

- Instrument Calibration and Standard Operating Conditions. Specifications, settings and instructions for calibrating are described in specific method SOPs.
- Instrument Maintenance Logs. A log is maintained for all major equipment. Operators include a continuing record of problems, repairs, and maintenance actions in each instrument log.
- Instrument Performance Checks. A description of how to evaluate instrument performance by performance checks is contained in the individual Analytical Method SOPs. If an analysis fails to meet performance criteria, the cause is investigated.
- Calibration of Support Equipment. Balances are calibrated against NIST traceable weights. Pipettes and Pipettors are calibrated and checked by weight. Refrigerator and freezer temperatures are monitored and recorded on the log attached to each unit. All exhaust or fume hoods are checked annually for average face velocity with the sash open to the indicated mark.

5.6 Measurement Traceability. The traceability of measurements is ensured through equipment calibration and maintenance, and the use of analytical standards with appropriate traceability.

The program for calibration of equipment is designed and operated to ensure measurements are traceable to the International System of Units (SI) to the extent necessary and appropriate relative to the stated uncertainty of the test or measurement. This is typically accomplished via the use of standards that are certified to be traceable to NIST or other national standards.

Where traceability to SI units of measurement is not possible and/or not relevant, other means for providing confidence in the results are applied such as:

- the use of certified reference materials provided by a supplier suitable to give a reliable physical or chemical characterization of the material.
- mutual-consent standards or methods which are clearly specified and agreed upon by all parties concerned.
- participation in a suitable program of inter-laboratory comparisons or proficiency testing.
- in-house reference material verified by inter-laboratory comparisons or proficiency testing.

5.7 Sampling. The UC Davis Analytical Laboratory does not perform sample collection. Sampling recommendations are provided on the laboratory website.

5.8 Sample Handling. Procedures are established for the receipt, handling, protection, storage, retention and disposal of samples, including all provisions necessary to protect the integrity of the sample and the interests of the laboratory and the client.

- Sample Submission. Samples are submitted to the laboratory with a Work Request Form. The Work Request Form documents the sampling, holding, and shipment of samples from the client to the laboratory. The Work Request Form also serves as the client's request/order to perform specific tests.

- Sample Log-In. Samples are received in the Sample Receiving area (110 Hoagland Annex) where the Receiving Manager or trained personnel are responsible for logging in the samples in accordance with the Sample Receiving SOP. At log-in, each client uses a customized work request form that has the following information:
    - Client ID (assigned by the Lab)
    - Client Name / phone number / Email / Alternate Contact information
    - Billing information
    - Number of samples

- Sample information and descriptions
- Desired sample disposition on completion of the testing
- Required sample preparation
- Tests requested
- Signature of the Client or responsible party
- Delivery method or name of person delivering samples

A sequential number is assigned to each Work Request.

- Identification of Samples. Samples are systematically identified using unique tracking numbers (consisting of the Work Request number followed by a unique sequential number) after they arrive at the laboratory. This identification is retained throughout the life of the item in the laboratory. The system is designed and operated so as to ensure that items cannot be confused physically, or when referred to in records or other documents.

- Chain of Custody. The location of the samples are tracked internally using a bar-coding system. Internal tracking of sample location is followed for all samples. External Chain-of-Custody (CoC) procedures are followed for samples received with CoC forms. The CoC record is used to document the change in possession from sampling to delivery to receipt by the laboratory. Each sample must be clearly identifiable. The condition of the sample is noted upon receipt. Signatures of parties relinquishing custody as well as the date are documented on the Work Request Form and any external CoC form.

- Client Notification of Sample Receipt. The Laboratory Information Management System (LIMS) organizes sample data in such a manner that log-in entries can be verified, sample progress can be tracked, analytical data can be appended to the record, and final reports can be created. When log-in has been reviewed, a sample confirmation email is sent to the client.

- Sample Storage Prior to Analysis. Samples are logged in within one working day of receipt. Samples are stored appropriately after receipt. Samples requiring immediate processing such as drying are processed immediately following log-in. Samples that have been logged in and processed are stored by Work Request Number. Separate storage is maintained to segregate sample types where cross-contamination is a possibility.

- Shipping and Receiving. The Lab is open for sample receipt from 8:00 a.m. to 5:00 p.m., Monday through Friday, excluding University of California holidays. A drop box is available for after-hours sample drop-off. Late night, weekend, or holiday sample

receipt can be arranged. For employee safety, any known sample hazards must be explained in the paperwork sent with samples.

- Sample Disposition. Sample Disposition: Clients can select sample disposition preference on the Work Request Form. Samples are discarded or returned to the client 30 days after the final report is issued.

5.9 Quality Control / Quality Assurance. Quality control procedures are used for all test methods performed in the laboratory to monitor the validity of test results. The resulting data are evaluated by the analyst and supervisor. Results are also tracked and trended at least annually or as needed. These procedures include the following:

- regular use of reference standards, where available, for calibration
- analysis of at least one reference material sample with each batch
- participation in inter-laboratory comparisons and proficiency testing programs
- analysis of blanks and spiked samples as appropriate
- replicate tests of the same sample during analysis (duplicates)
- re-testing of retained samples (blind duplicate program)
- correlation of results for different characteristics

The quality control program consists of both internal and external checks on precision and accuracy of analytical results. The responsibility for maintaining the program rests with the Quality Assurance Officer. Employees are trained in quality control procedures and concepts.

Internal Quality Control.
The following QC samples are analyzed with client samples:

- Blank. A reagent blank is analyzed with every set of samples that is extracted or digested. This reagent blank includes any and all reagents that are used in the analytical process and is carried through the entire process, including extraction and filtering or digestion.
- Duplicates. At least ten percent of samples are analyzed in duplicate to yield data on the precision of the analysis. Duplicate results are included in the report.
- Reference Materials. At least one reference material is analyzed with each set of samples. The values for the reference materials are included in the final report. Samples run with a reference material that falls outside the control limit are reanalyzed, including digestion or extraction if necessary. The use of data outside of warning limits is at the discretion of the Lab Supervisor or reviewing analyst.
- Spike Samples. Sample fortifications or spikes are used to verify accuracy of tests requiring extensive sample manipulation (such as acid digestion) or for non-standard sample types.

Blind Duplicates. Periodic testing is performed on a sub-set of samples that have been previously analyzed. These samples are re-logged in to the laboratory as new samples, and the results compared to the original results.

External Quality Control Programs
The UC Davis Analytical Laboratory participates in a number of sample exchange and certification programs.

- International Plant – Analytical Exchange (IPE) – plant tissue analyses
- Manure Analysis Program (MAP) - manure analyses
- North American Proficiency Testing Program (NAPT) - plant tissue analyses
- North American Proficiency Testing Program (NAPT) - soil analyses
- North American Proficiency Testing Program (NAPT) - water analyses
- National Forage Testing Association (NFTA) - feed analyses
- Agricultural Laboratory Proficiency program (ALP) - plant tissue analyses

5.10 Reporting Test Results. The results of each test are reported accurately, clearly, unambiguously and objectively, and in accordance with any specific instructions in the test methods.

Test reports include the following information, as appropriate:

- client provided information: commodity, sample type, date sampled, grower/ location/project
- method SOP used
- analysis date
- units of measurement
- sample identification number
- sample description (if submitted by client)
- test results
- a summary of quality control results
    - method detection limit (MDL) – which is typically a quantitation limit for the analysis
    - reference material results and criteria
    - results of duplicate analyses
- notes and comments related to test results
- signature and title of person(s) reviewing and approving report (may be electronic)

Data reported to the client contains the appropriate significant digits for each test method. Test results that are below the laboratory MDL are noted as such. All appropriate warnings and notes are included on the final report.