



Quality Program Statement

TO WHOM IT MAY CONCERN

The following information is an overview of the CAHFS Quality program.

CAHFS Mission Statement

To provide the citizens of California with the highest quality diagnostic laboratory support service for:

- Surveillance and response to foreign animal diseases
- Livestock and poultry disease control
- Enhancement of livestock and poultry health management
- Ensuring the safety of foods of animal origin
- Protection from diseases common to animals and humans
- Equine health and performance
- Recognition and dissemination of new knowledge

Quality System Statements

The CAHFS laboratory system implements and maintains quality systems in order to effectively:

- Provide timely, consistent, accurate and legally defensible diagnostic test results using test methods and procedures that are considered fit for purpose
- Meet or exceed the requirements of our private and public clients and funding agencies
- Maintain accreditation through compliance with requirements of AAVLD accreditation.
- Comply with ISO17025 requirements in the Equine Analytical Chemistry Laboratory (EACL).
- Comply with state and federal regulatory requirements.

The laboratory's quality system is integrated into the daily activities. It is the responsibility of all employees to be familiar with all aspects of the quality system and to implement and comply with them in their daily work.

Key elements of the quality system are:

Management requirements:

- Quality Manual – outlines requirements, policies and structure of quality system
 - o Supporting documents include systemwide procedures and policies, test method and supporting standard operating procedures (SOPs) and records.
 - o All testing activities are to be carried out in accordance with the current approved version of the test method or technical procedure and to meet client's needs.
- Document Control – ~ 3000 controlled standard operating procedures and policies.
 - o Documents are approved by appropriate personnel, reviewed periodically and available for personnel at work area
- Corrective Action –
 - o Record and follow up on any instances where we are not in compliance with our requirements.
 - o If the issue is severe or minor but recurs, a root cause analysis is performed and actions are implemented to prevent recurrence.



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- Preventive Action –
 - Pro-active approach to prevent non-compliances before they occur and affect test results.
- Internal Audits – conducted at least once/year by trained auditor
 - All aspects of the quality system are audited to identify gaps, non-compliances, best practices and areas for improvement
- Client Feedback – is recorded and monitored
 - Turn-around-time requirements for client complaints ensure they are addressed in a timely manner and the resolution meets our client's expectations.
- External Assessments –
 - External assessments are conducted at a regular interval by our accrediting body (and other agencies depending on the program) to ensure compliance with all requirements

Technical requirements:

- Trained/competent personnel –
 - All personnel performing test related work must be trained and competent to do so.
 - Objective evidence is used to evaluate initial and ongoing competency of personnel.
- Validated test methods –
 - Methods that are performed routinely are validated as fit for use or stated if under validation.
- Equipment maintenance –
 - All test critical equipment is maintained and calibrated to ensure it is working properly.
- Reagent traceability –
 - Test critical reagents must be traceable to source to ensure they are verified and fit for the intended use
- Quality control measures –
 - Quality control measures are used to ensure consistent test performance over time.
 - Control charts enable trend tracking to identify if a test is moving out of acceptable limits
- Proficiency testing –
 - CAHFS regularly participates in voluntary and mandatory external proficiency programs to document initial and ongoing competency of individuals conducting testing.
 - Internal QC programs are also utilized to document competency on an on-going basis.
- Technical records require attribution to personnel -
 - Detailed records for all testing are made to establish an audit trail of who did what and when.
 - Technical records for testing are retained for a period of at least 10 years.

CAHFS administration is committed to good professional practice, quality of test results and compliance with AAVLD requirements for CAHFS, and ISO17025 for the EACL.

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