



VETERINARY & BIOMEDICAL SCIENCES DEPARTMENT (VBSD)
Animal Disease Research and Diagnostic Laboratory (ADRDL)

Quality Management

Outsourcing

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1. Introduction and Purpose:

This procedure provides instructions for selection of laboratories whenever outsourcing (subcontract or referral testing) is required.

2. Definitions of Outsource laboratories

2.1. **Subcontract Laboratory:** A laboratory to which the ADRDL forwards the testing work for unforeseen reasons (excessive workload, lack of personnel, need for further expertise or other temporary incapacity). The subcontractor shall comply with the AAVLD or other quality standards for the work in question. ADRDL will receive the reports for subcontracted work for inclusion in the client report.

2.2. **Referral Laboratory:** A laboratory to which the ADRDL forwards the testing work when the ADRDL does not perform the service.

3. Procedure

3.1. The laboratory maintains a list of approved subcontracted laboratories (QUA.FORM.0004.XX). A subcontractor is approved based on any of the following criteria;

3.1.1. Federal Reference Laboratory

3.1.2. The AAVLD accreditation status

3.1.3. ISO 17025 accreditation status

3.1.4. Other recognized or regulatory authorities or accrediting agencies

3.2. When it is necessary forward the samples to one of the laboratories listed in the attached table (QUA.FORM.0004.XX) with the ADRDL accession # referenced on the submission form / paperwork that goes along with the samples.

3.2.1. A laboratory that does not meet the ADRDL Quality System criteria (listed at 3.1) for subcontract work, but is uniquely positioned to perform a requested test, may be used at the discretion of the case coordinator/section leader.

3.2.1.1. In this event, case coordinator/section leader needs to forward documentation of respective laboratory's quality system to quality manager (e.g. accreditation certificate).

- 3.3. When ADRDL does not offer a diagnostic service (e.g. due to lack of resources, feasibility issues, etc.), the testing will be forwarded to a referral laboratory. For example, Clinical Pathology testing work sent to Antech Diagnostics.
- 3.4. Document the outsource event in VADDS.
- 3.5. Typically clients are informed of the outsourcing at the time of reporting. However, it is recommended to notify the client in advance when testing is outsourced to a non-approved lab.
- 3.6. If the client wants the test be performed at a specific outsource laboratory, the ADRDL cannot be held responsible for the outcome of the test. In these situations, maintain a record of communication with the client with the case.
- 3.7. Identify the outsource laboratory on the case report and report the results as determined by the outsource laboratory.

4. Other related policies/forms

- 4.1. List of Outsource Laboratories - QUA.FORM.0004.XX

5. References

- 5.1. Current AAVLD Requirements

6. Revision History:

- 6.1. Added subcontract or referral testing under introduction.
- 6.2. At 2.1, removed “This is for tests that the ADRDL normally performs”.
- 6.3. At 3.6, removed “Under these circumstances, the clients are responsible for the shipping and testing cost”.
- 6.4. Converted sentences with passive voice to active voice, e.g. it will be forwarded to forward the sample.
- 6.5. Updated links for Outsourced Laboratories (QUA.FORM.0004.XX).

List of Subcontract Laboratories

Name of the Laboratory
AAVLD accredited laboratories (https://www.aavld.org/accredited-labs)
ISO 17025 accredited diagnostic or clinical laboratories
National Veterinary Services Laboratory, http://www.aphis.usda.gov/wps/portal/
Federal USDA FSIS laboratories (https://www.fsis.usda.gov/science-data/laboratories-procedures/fsis-laboratories)
South Dakota Department of Health, Pierre (http://doh.sd.gov/lab/)

List of Referral Laboratories

Name of the Laboratory
ANTECH Diagnostics