



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

Quality Management

Outsourcing Policy

Number: VBSD.POL.QUA.0004.06

Replaces: VBSD.POL.QUA.0004.05

Contact person: QM Leader

Approval: _____ Date: _____

Quality Manager

_____ Date: _____

Head / Director, VBSD / ADRDL

1. Introduction and Purpose:

This policy describes the procedure followed at the ADRDL for selection of laboratories whenever outsourcing is required.

2. Definitions of Outsource laboratories

- 2.1. **Subcontract Laboratory:** A laboratory to which the ADRDL forwards the testing work for unforeseen reasons (such as work load, or temporary incapacity). This is for tests that the ADRDL normally performs. The subcontractor shall comply with the AAVLD or other quality standards for the work in question. For example, an instrument breaks down and the ADRDL temporarily forwards testing work to an AAVLD accredited laboratory in an adjacent state.
- 2.2. **Referral Laboratory:** A laboratory to which the ADRDL forwards the testing work when the ADRDL does not perform the service. For example, Salmonella serotyping is forwarded to USDA NVSL.
- 2.3. **Reference Laboratory:** A designated or recognized laboratory that is an authority for a particular test. For example, USDA NVSL is the designated Animal Health Reference Laboratory for the U.S.
- 2.4. **Referee Laboratory:** A subcontract or reference laboratory to which the ADRDL forwards testing work for a second opinion or to resolve a dispute.

3. Procedure

- 3.1. The laboratory shall have a list of approved outsource laboratories (FORM.QUA.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 to outsource a testing work, it will be forwarded to one of the laboratories listed in the attached table (FORM.QUA.0004.XX) with the ADRDL accession # referenced on the submission form / paperwork that goes along with.
 - 3.2.1. A laboratory that does not meet the ADRDL Quality System criteria (listed at 3.1) for outsourcing, 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. The outsource event will be documented in VADDS and a copy of the paperwork will be kept with the case file by the employee making such decision or the section leader's designee.

- 3.4. 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.
- 3.5. 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, communications with the client will be recorded on the submission forms and in VADDS. Under these circumstances, the clients are responsible for the shipping and testing cost.
- 3.6. The outsource laboratory will be identified on the case report and the results will be reported as determined by the outsource laboratory.

4. Other related policies/forms

- 4.1. Contract review POL.QUA.0003.XX
- 4.2. List of Outsource Laboratories FORM.QUA.0004.XX

5. References

- 5.1. Current AAVLD Essential Requirements

6. Revision History:

- 6.1. List of Outsourced Laboratories has been updated (FORM.QUA.0004.XX).

List of Outsource Laboratories

Name of the Laboratory
AAVLD accredited laboratories (http://www.aavld.org/mc/page.do?sitePageId=33930)
ISO 17025 accredited diagnostic or clinical laboratories
National Veterinary Services Laboratory, http://www.aphis.usda.gov/wps/portal/
Federal USDA FSIS laboratories (http://www.fsis.usda.gov/wps/portal/informational/aboutfsis/structure-and-organization)
South Dakota Department of Health, Pierre (http://doh.sd.gov/lab/)
ANTECH Diagnostics