QUALITY SYSTEM BASICS & ACCREDITATION

Brian Ladman

Standards Organization

- ISO
  - International organization for standardization (https://www.iso.org/home.html)
- OIE
  - World organization for animal health (http://www.oie.int/)
- AAVLD
  - American Association of Veterinary Laboratory (https://www.aavld.org/)

World Organization for Animal Health

- OIE
  - Management and technical competence ……basis for accreditation of labs that conduct tests for infectious animal diseases, especially those labs involved in testin for international trade

International Organization for Standardization

- ISO
  - ISO 17025:2005
    - Competence of testing and calibration laboratories
    - Accrediting bodies such as A2LA prove competency using this standard
    - Transitioning to ISO17025:2017
- AAVLD
  - American Association of Veterinary Laboratory Diagnosticians

American Association for Laboratory Accreditation (A2LA)

- American Association for Laboratory Accreditation (https://www.a2la.org/)
- Uses the ISO 17025 Standard for calibration laboratories
- Includes everyone
  - You pay, you meet the standard, you pass an audit, you get accredited

American Association of Veterinary Laboratory Diagnosticians

- AAVLD
  - American Association of Veterinary Laboratory Diagnosticians
  - North American program (….starting to expand)
  - Full service veterinary diagnostic laboratory standard
  - Limited to publicly funded US and Canadian laboratories
    - Expanding beyond US and Canada
  - Not for everyone

Accreditation Is…..

- Assessment of competency
  - Must adhere to the Scope of Work (SOW)
  - It is NOT a guarantee

Example SOW

SCOPE OF ACCREDITATION TO ISO/IEC 17025:2005

THE UNIVERSITY OF DELAWARE POULTRY HEALTH SYSTEM[3]
Charles C. Allen Biotechnology Laboratory
601 Sincock Lane
Newark, DE 19716
Brian Ladman (302) 831 8734

BIOLOGICAL

Valid To: August 31, 2018 Certificate Number: 3585.01

In recognition of the successful completion of the A2LA evaluation process (including an assessment of compliance with the A2LA Veterinary Laboratory Accreditation Program Requirements, containing the OIE *Quality Standard and Guidelines for Veterinary Laboratories: Infectious Diseases*, 2008) accreditation is granted to this laboratory at the location listed above as well as the satellite laboratory location listed below to perform the following tests on specimens of avian origin:

Test	Test Method
Avian Influenza (rRT-PCR, including H5 and H7 subtyping)	UDPD113, SOP-AV-0068
Avian Paramyxovirus (rRT-PCR, including vNDV)	UDPD113, SOP-AV-0068

[3]This accreditation covers testing performed at the main laboratory listed above, and the following satellite laboratory listed below:

THE UNIVERSITY OF DELAWARE POULTRY HEALTH SYSTEM
Lasher Laboratory
16483 County Seat Highway
Georgetown, DE 19947

Test	Test Method
Avian Influenza (rRT-PCR, including H5 and H7 subtyping)	UDPD113, SOP-AV-0068
Avian Paramyxovirus (rRT-PCR, including vNDV)	UDPD113, SOP-AV-0068

5202 Presidents Court, Suite 220 | Frederick, MD 21703-8398 | Phone: 301 644 3248 | Fax: 240 434 9449 | www.A2LA.org

Accreditation…..

- Provides a product that is reliable and accurate
- Validation of process
- Includes continuous monitoring of performance and continuous improvement

Why Seek Accreditation

- Provides reliable and accurate client services
- Client centric
  - What are the needs of your clients?
  - Can you afford to hold an accreditation?
  - Can you afford not to hold an accreditation?

Why Delaware? Why Not!

- Charles C. Allen Biotechnology Laboratory
  - Allen Lab
- University of Delaware Poultry Health System
- Avian Biosciences Center
- Department of Animal & Food Sciences
- College of Agriculture and Natural Resources
- University of Delaware

University of Delaware Poultry Health System (UDPHS)

- University of Delaware Poultry Health System (UDPHS) is a member of USDA's National Animal Health Laboratory Network (NAHLN), the organization directing the elite animal diagnostic labs in the U.S.
- NAHLN laboratories perform routine diagnostic tests for endemic animal diseases as well as targeted surveillance and response testing for foreign animal diseases.

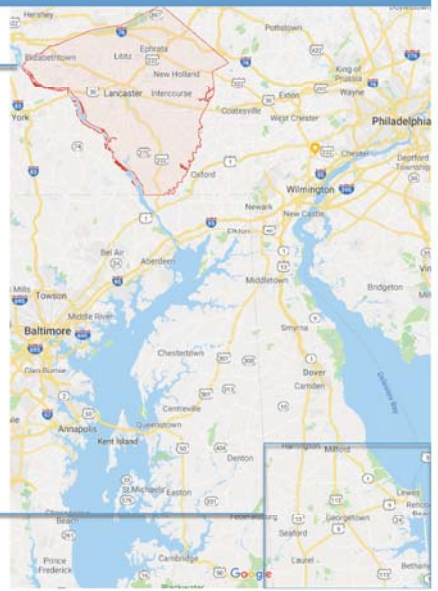
University of Delaware Poultry Health System (UDPHS)

- Delaware and the Delmarva region are among the most productive areas in the world for raising broiler chickens. UDPHS diagnostic findings directly support poultry farmers and companies in their disease control efforts. Faculty in UD's Avian Biosciences Center work with UDPHS staff to monitor evolving diseases, develop new poultry vaccines, and other disease control measures.
- The partnership between DDA and UD in supporting poultry diagnostic and research activities has grown tremendously over the years and has never been stronger than it is now.

Poultry in the Area

5th most dense poultry producing county

1st most dense poultry producing county



UD Poultry Health System

Selected Activity Category	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
Total Lab Accessions	3,914	5,940	9,640	7,844	8,456	8,617	8,450	8,606	7,110	7,352	7,237	8,085
Necropsy Cases (flocks)	620	987	1,000	1,095	1,390	1,114	815	823	1,103	1,450	990	1,125
Avian Influenza PCR Surveillance Tests	1,224	1,621	4,332	3,879	3,699	3,718	3,701	3,233	3,926	3,889	4,229	5,249
ELISA Serology (flocks)	2,439	2,874	1,969	1,869	1,689	2,013	1,494	1,833	2,053	2,181	1,493	1,499
Food Safety Testing	0	0	259	599	1,195	2,085	2,292	2,601	462	894	1,464	1,144
Infectious Bursal Disease Progeny Challenge Testing (No. of broilers)	8,000	20,000	16,000	13,000	13,000	14,000	7,000	6,000	12,000	9,000	8,000	8,000

Total Lab Accessions (red font) represent the post-2004 low path H7N2 avian influenza level of surveillance testing. The University of Delaware Poultry Health System (UDPHS) began charging fees for lab services on July 1, 2014, with the exception of avian influenza (AI) PCR testing. The cost of AI PCR testing is subsidized by USDA via flow through cooperative agreement funds from the Delaware Dept. of Agriculture. Other diagnostic testing activities (not shown) include PCR respiratory virus panel and pathogenic microbiology.

The UDPHS (Lasher Lab, Allen Laboratory, & Worrilow Hall) and its ongoing commitment to poultry disease diagnostics and surveillance is well-recognized by the Delmarva poultry companies and growers. The UDPHS is a member of USDA's National Animal Health Laboratory Network (NAHLN). Funding is provided through State Lines "Poultry Diagnostic Lab" and "Poultry Disease Research" from the state of Delaware, and USDA APHIS for NAHLN-related activities.

Delmarva Poultry Facts (2014): 569 million broiler chickens raised in 4,761 broiler chicken houses managed by 1,564 growers
Approximate wholesale value of broiler chickens: $3.2 billion

Delaware's Meat Chicken Industry Facts 2017

In 2017, the Delmarva chicken industry:	1-year change	10-year change	20-year change
Raised 605 million chickens.	+2%	+7%	-1%
Processed 4.2 billion pounds of chickens.	+2%	+22%	+34%
Raised in 5,091 chicken houses.	+8%	-5%	-12%
The houses had a capacity of 138 million chickens.	+13%	+7%	+11%
There were 1,549 chicken growers.	+3%	-20%	-41%
They earned $256 million in contract income.	+5%	+17%*	+30%*
There were 18,500 chicken company employees.	+28%**	+25%	+31%
They earned $752 million in wages, excluding benefits.	+13%**	+60%*	+59%*
Feed ingredients for chickens were purchased for $984 million.	-1%	+18%*	-3%*
The wholesale value of chicken produced was $3.4 billion.	+6%	+43%*	+38%*

* Inflation-adjusted. ** For 2017, one company added a previously uncounted business unit.

University of Delaware Poultry Health System (UDPHS)

- Main Lab and Branch Lab
  - BSL2 enhanced Lasher Lab
    - Diagnostic lab
  - BSL3 capable Allen Lab
    - Research lab

Labs work very closely and function as a single unit

-1.5hr drive

Service to Industry/the State of Delaware

- Regulation of foreign animal disease (FAD) testing
- Commercial meat chicken producers were required to test flocks prior to slaughter
  - Testing performed at approved labs
  - Approved protocols
- Labs were required to be accredited or have a quality management system
  - Audit of quality system by NAHLN

Selection of Accrediting Partner

- They should be a partner
  - Aligned
- Clear standard
  - Checklist
- Cost
- Needs of clients/customers
  - Importance of international recognition

Foundation of Accreditation

- Starts with a documented and functional Quality Management System
- Management requirements and technical requirements
  - Operation of quality management system vs competence of staff, methods, equip, environment and reporting

The Standards

- The Standards of Accreditation describes the accreditation process and sets for the criteria for evaluation and accreditation

Requirements

- Language that must be met
  - Prove with a record
- Fail to meet the Requirement
  - Non-conformance

Needs

- One person does not make a system
- Input and effort of many
  - Roles defined within system documents

Accreditation Foundation

- Clear Standard
  - All are held to
  - Consistent but open to interpretation
- Checklist
  - Used to verify actions related to meeting the Standard
- Audit
  - Internal and External
  - Collection of “proof” of actions performed to meet the Standard

Other Accrediting Bodies

- What can you share with us?
- Local, National accrediting bodies
  - What Standard is followed?

UDPHS: Experts In Accreditation?

- Not exactly
- Maturing system
- Defined accreditation by A2LA
  - NVSL Influenza A Virus
  - NVSL Avian Paramyxovirus
- Growing pains
- Small system, high output

My Vision

- Facilitate discussions about quality management systems
  - The foundation of any accreditation activities
- Help create and/or improve quality system documents

Fact

- Most will never seek accreditation
- You CAN go home and improve your lab by implementing all or portions of quality management system
- You CAN do this but not alone
- You WILL FAIL
- Quality management is about LOOKING, FINDING, FIXING and then PREVENTING MISTAKES

THE QUALITY MANUAL

Brian Ladman

The Quality Manual

- An official document that details how a quality management system operates.
  - A typical quality manual will include the company's quality policy and goals, as well as a detailed description of its quality control system that might include staff roles and relationships, procedures, systems and any other resources that relate to producing high quality goods or services.

The Quality Manual

- What it is….
  - A quality manual is the main, top-level document of a quality management system. It is similar to a constitution of a country or a manifesto of a party. This type of document establishes the policy level position of a government, party or in the case of a quality manual, a company.
- What it is not…...
  - The only document needed for a system
  - The most important document in the system

The Quality Manual and the Standard (2005)

- 4.2.2 The laboratory's ***management*** system policies ***related to quality, including a quality policy statement,*** shall be defined in a quality manual (however named).
- 4.2.5 The quality manual shall include or make reference to the supporting procedures including technical procedures. It shall outline the structure of the documentation used in the ***management*** system.

The Quality Manual and the Standard (2005)

- 4.2.6 The roles and responsibilities of technical management and the quality manager, including their responsibility for ensuring compliance with this International Standard, shall be defined in the quality manual.

Writing a Quality Manual

- Practically written for you
  - Should follow the checklist fairly closely
  - May say a lot yet say nothing

Interpreting the Checklist

- …shall
- ….have
- …provide
- …specify
- …define

Easy Peasy?

You may find that you simply need to commit in the quality manual to all applicable requirements of the standard.

Transform the standard from a set of requirements into your group's commitment to satisfy those requirements with the appropriate level of details.

Sell Yourself!

- A marketing tool
  - Sell yourself and your company
    - Shows a quality-conscious organization, but that it also knows how to document and communicate its commitment to quality.
  - A resume for quality!

…..And the Standard Changes (2017)

- Not really needed any longer
- Still a helpful document
  - Should have or retain
  - Helpful to new employees
- …..yet another a document in what could be a sea of documents

DOCUMENTS, RECORDS, AND CONTROL OF SYSTEM DOCUMENTS

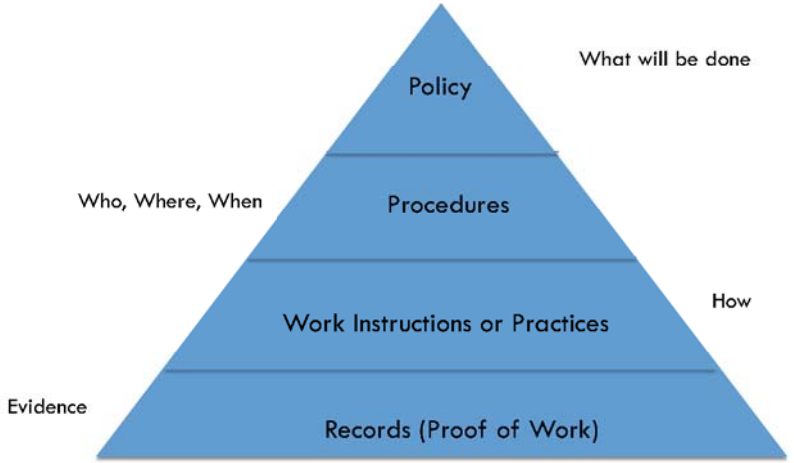
Brian Ladman

What is a Document

Documents

- Quality manual
- Procedures
- Work instructions
- Original observation

The Documentation Pyramid



What is a Record

Obvious Records

- Original observations, data (testing and/or calibration), staff forms, equipment documents…...any information necessary to recreate the activity
- Primary auditable data

Perhaps Less Obvious Records

- Packing slips, half completed forms, incorrect forms, observations, data and/or notes written on scrap paper
- Also auditable and should be treated in accordance with your document control protocol

Records

- Clear
- Permanent record
- Identifiable to the specific test at the time are made

Record Storage & Retention

- Readily retrievable
  - Produce in 1 work day
- Proper environment
- Secure
- Storage defined with a procedure
  - Minimum of 3 years is standard
  - May also be defined by accrediting organization

Mistakes

- Unacceptable
  - Cross outs
  - Erased
  - Scratched out
  - Deleted
- Corrected beside
  - Dated, signed/initialed
- Covers paper and electronic
- Procedure should be defined in a protocol

Record

- Original observations
  - Times, temperatures, measurements, pH
  - Visual observations
    - Clinical disease, necropsy findings
  - Results
    - PCR data
    - ELISA data

Records

- Derived data
  - Statistical analysis
    - Means, SD
  - Ratios
    - S/N, S/P
  - R-PCR copy number

Records

- Calibration and Equipment Records
  - Calibrations
  - Function checks
  - General equipment records
    - Preventive maintenance, service

Records

- Staff records
  - Authorization forms
  - Proficiency testing results
  - Competency check
  - Training documentation

Records

- Test reports
  - Objective evidence that tests were performed
- Submission forms
  - Objective evidence of a contract

Records

- Other information necessary to recreate the activity
  - Lot numbers
  - Client contact
  - Staff initials and dates
  - Reviews of documents and contract
    - System open to define the documents and “contracts”

Quality Records

- Internal audit reports
  - Objective evidence of continual improvement process
  - Requirement of all Standards

Quality Records

- Management Reviews
  - Objective evidence of continual improvement process
  - Requirement of all Standards

Quality Records

- Corrective and Preventive Actions
  - Objective evidence of continual improvement process
  - Requirement of all Standards

What is Needed: Ask and Answer

- • What is the policy & procedure on document control?
  • How is document amendment carry out?
  • Who is authorized to approve the changes?
  • Is there a record of change?
  • Is there a distribution list?
  • How do you issue out new doc and retrieve the obsolete copy?
  • How do you dispose the obsolete copy?
  • How do you track the revision number?
  • Do you have a doc control number system?
  • Where to you keep/file all obsolete copies for future reference?
  • How long do you keep them?

Requirement

- Ensure documents are reviewed and approved by authorized personnel prior to issue, and are included on a master list which identifies the revision status and distribution

Requirement

- All management system documents must be uniquely identified and include date of issue and/or revision identification, page numbering, total number of pages or a mark to signify the end of the document, and the issuing authority(ies)

Questions to Consider?

General terms of document control

- • What is the policy & procedure on document control?
  • How is document amendment carry out?
  • Who is authorized to approve the changes?
  • Is there a record of change?
  • Is there a distribution list?
  • How do you issue out new doc and retrieve the obsolete copy?
  • How do you dispose the obsolete copy?
  • How do you track the revision number?
  • Do you have a doc control number system?
  • Where to you keep/file all obsolete copies for future reference?
  • How long do you keep them?
- **4.3.1 General**
- • Are there documented procedures established and responsibilities defined to control all documents and data that form part of the quality system?

Questions to Consider?

- **4.3.2 Document Approval & Issue**
  - • Do policy and procedure documents have unique identifiers?
  - • Are these documents clearly marked?
  - • Do all documents carry revision status and date?
  - • Is it ensured the latest revision of document is available at the relevant places?
  - • Are obsolete documents: removed from all points of used; clearly marked as obsolete or destroyed; retained for legal or knowledge preservation and identified as such?
  - • Is all documents review periodically to ensure continuing suitability?

Questions to Consider?

- **4.3.3 Document Changes**
  - Are procedures and responsibilities for handling changes defined and documented?
  - Are all changes to controlled documents reviewed and approved by the same functions that performed the original review?
  - If not, are there documented procedures for the designated functions/organizations to follow and do they have access to the background information?
  - Are responsibilities and time for storage of quality system documents defined and documented?

Document Control Requirements

- 4.3.1 General
- The laboratory shall establish and maintain procedures to control all documents that form part of its ***management*** system (internally generated or from external sources), such as regulations, standards, other normative documents, test and/or calibration methods, as well as drawings, software, specifications, instructions and manuals.

Document Approval

- 4.3.2.1 All documents issued to personnel in the laboratory as part of the ***management*** system shall be reviewed and approved for use by authorized personnel prior to issue.
- A master list or an equivalent document control procedure identifying the current revision status and distribution of documents in the ***management*** system shall be established and be readily available to preclude the use of invalid and/or obsolete documents.

Document Control SOP

- 4.3.2.2 The procedure(s) adopted shall ensure that:
- a) authorized editions of appropriate documents are available at all locations where operations essential to the effective functioning of the laboratory are performed;
- b) documents are periodically reviewed and, where necessary, revised to ensure continuing suitability and compliance with applicable requirements;
- c) invalid or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use;
- d) obsolete documents retained for either legal or knowledge preservation purposes are suitably marked.

Document Control Information

- 4.3.2.3 ***Management*** system documents generated by the laboratory shall be uniquely identified. Such identification shall include the date of issue and/or revision identification, page numbering, the total number of pages or a mark to signify the end of the document, and the issuing authority(ies).

Tracking Changes

- 4.3.3.1 Changes to documents shall be reviewed and approved by the same function that performed the original review unless specifically designated otherwise. The designated personnel shall have access to pertinent background information upon which to base their review and approval.
- 4.3.3.2 Where practicable, the altered or new text shall be identified in the document or the appropriate attachments.
- 4.3.3.3 If the laboratory's ***document*** control system allows for the amendment of documents by hand pending the re-issue of the documents, the procedures and authorities for such amendments shall be defined.
- Amendments shall be clearly marked, initialed and dated. A revised document shall be formally re-issued as soon as practicable.
- 4.3.3.4 Procedures shall be established to describe how changes in documents maintained in computerized systems are made and controlled.

UDPHS Approach

- Documents controlled with limited distribution
  - Computer database
    - Not appropriate for everyone
- Consistent formatting
  - Defined by Standard

University of Delaware Poultry Health System	
Document Title: Performing NAHLN Approved Real-Time RT-PCR Protocols	
Author/Position: Brian Ladman/CCABL Quality Manager Brenda Sample/LL Quality Manager	Document Number: SOP012-UDPHS-6
Page 1 of 15	Supersedes: SOP012-UDPHS-5
Effective Date: 4/22/2016	Approved: 4/5/2016

UDPHS Approach

- No hand edits
- Blank fields filled with "N/A", "0" or a line with date and initial
- Error correction with single cross-through
  - Date and initial
- All defined in an QSOP and/or QSM
- All documents retained for 3 years and then destroyed

What is Your Approach

- How do you handle documents and records?
- UDPHS system may not be the best model for you.

Summary

- Set up and document procedures for a records system
- Keep records easily identified, secure in confidence, accurate, contemporaneous, attributable and legible
- Have suitable storage and retrieval system
- Retain records as long as needed

CONTINUAL IMPROVEMENT PROCESS

Brian Ladman

- ***Quality is the responsibility of each employee.***
- ***…. pledge to continuously provide services that meet or exceed customer expectations.***

A Living, Ever Changing System

- Standard contains elements to ensure periodic review and evolution of quality system
  - Audits
    - Internal
    - External
  - Reviews
    - Document
    - Management
  - Corrective Actions
    - Issues from normal operations
    - Issues discovered during audits

Very, Very Clear

- ***4.10 Improvement***
- ***The laboratory shall continually improve the effectiveness of its management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.***

- 4.2.2 e) the laboratory management's commitment to ***comply*** with this International Standard ***and to continually improve the effectiveness of management system.***
- 4.2.3 ***Top management shall provide evidence of commitment to the development and implementation of the management system and continually improving its effectiveness.***

- ***4.7.2*** ***The laboratory shall seek feedback, both positive and negative, from its customers. The feedback shall be used and analyzed to improve the management system, testing and calibration activities and customer service.***
- **4.8 Complaints**
- The laboratory shall have a policy and procedure for the resolution of complaints received from ***customers*** or other parties. Records shall be maintained of all complaints and of the investigations and corrective actions taken by the laboratory (see also ***4.11***).

Corrective Actions

- ***4.11.1*** General
- The laboratory shall establish a policy and a procedure and shall designate appropriate authorities for implementing corrective action when nonconforming work or departures from the policies and procedures in the ***management*** system or technical operations have been identified.
- ***4.11.2*** Cause analysis
- The procedure for corrective action shall start with an investigation to determine the root cause(s) of the problem.
- ***4.11.3*** Selection and implementation of corrective actions
- Where corrective action is needed, the laboratory shall identify potential corrective actions. It shall select and implement the action(s) most likely to eliminate the problem and to prevent recurrence.
- Corrective actions shall be to a degree appropriate to the magnitude and the risk of the problem.
- The laboratory shall document and implement any required changes resulting from corrective action investigations.
- ***4.11.4*** Monitoring of corrective actions
- The laboratory shall monitor the results to ensure that the corrective actions taken have been effective.
- ***4.11.5*** Additional audits
- Where the identification of ***nonconformities*** or departures casts doubts on the laboratory's compliance with its own policies and procedures, or on its compliance with this International Standard, the laboratory shall ensure that the appropriate areas of activity are audited in accordance with ***4.14*** as soon as possible.

Preventive Actions

- ***4.12.1*** Needed improvements and potential sources of ***nonconformities***, either technical or concerning the ***management*** system, shall be identified.
- ***When improvement opportunities are identified or*** if preventive action is required, action plans shall be developed, implemented and monitored to reduce the likelihood of the occurrence of such ***nonconformities*** and to take advantage of the opportunities for improvement.
- ***4.12.2*** Procedures for preventive actions shall include the initiation of such actions and application of controls to ensure that they are effective.

Internal Audits

- ***4.14*** **Internal audits**
- ***4.14.1*** The laboratory shall periodically, and in accordance with a predetermined schedule and procedure, conduct internal audits of its activities to verify that its operations continue to comply with the requirements of the ***management*** system and this International Standard.
- The internal audit program shall address all elements of the ***management*** system, including the testing and/or calibration activities.
- It is the responsibility of the quality manager to plan and organize audits as required by the schedule and requested by management.
- Such audits shall be carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited.
- ***4.14.2*** When audit findings cast doubt on the effectiveness of the operations or on the correctness or validity of the laboratory's test or calibration results, the laboratory shall take timely corrective action, and shall notify ***customers*** in writing if investigations show that the laboratory results may have been affected.
- ***4.14.3*** The area of activity audited, the audit findings and corrective actions that arise from them shall be recorded.
- ***4.14.4*** Follow-up audit activities shall verify and record the implementation and effectiveness of the corrective action taken.

Management Review

- ***4.15*** **Management review**
- ***4.15.1*** In accordance with a predetermined schedule and procedure, the laboratory's ***top*** management shall periodically conduct a review of the laboratory's ***management*** system and testing and/or calibration activities to ensure their continuing suitability and effectiveness, and to introduce necessary changes or improvements. The review shall take account of:
- (OIE, 4.13.1) The management system and test related activities shall be reviewed by management at least once per year.
- the suitability of policies and procedures;
- reports from managerial and supervisory personnel;
- the outcome of recent internal audits;
- corrective and preventive actions;
- assessments by external bodies;
- the results of interlaboratory comparisons or proficiency tests;
- changes in the volume and type of the work;
- ***customer*** feedback;
- complaints;
- ***recommendations for improvement;***
- other relevant factors, such as quality control activities, resources and staff training.
- ***4.15.2*** Findings from management reviews and the actions that arise from them shall be recorded.
- The management shall ensure that those actions are carried out within an appropriate and agreed timescale.

Improvement Happens Daily

- Monitoring
  - Controls
  - Temperatures
  - Schedules
  - Corrective actions
  - Release of data

Audits

- Formal and informal
- Internal and External
  - Utilize vertical audit

SAMPLES, SAMPLE TRACKING, & REPORTS

LAUREN SAUBLE, RESEARCH ASSOCIATE II
UDPHS DEPUTY QUALITY MANAGER
AUGUST 1ST, 2018

HOW DO YOU RECEIVE SAMPLES?

- Are they shipped to you?
- How do you know what is in the shipment?
- Do you receive warning that the shipment is coming?
- Do you have an area for people to bring samples?
- Are the samples appropriate for the test?

HOW DO YOU RECEIVE SAMPLES?

- Do you take samples in the field and bring them back yourself?
- Do you have a procedure to train field technicians?
- How are your samples treated before they get to you? Are they sealed? Are they frozen? Are they on ice packs?
- How do you notify people if the sample is not sufficient or incorrect?

SAMPLE RECEIPT

- Samples received into laboratory system must be inspected for appropriateness for test(s) requested
- Must have appropriate submission form and be complete
- If sample is not appropriate or is not a quality sample, you have the right to refuse sample
  - Notify submitter to resubmit with appropriate sample

ISO17025 7.3 SAMPLING

- 7.3.1 "The laboratory shall have a sampling plan and method when it carries out sampling of substances, materials, or products for subsequent testing or calibration. The sampling method shall address the factors to be controlled to ensure the validity of subsequent testing or calibration results. The sampling plan and method shall be available at the site where sampling is undertaken. Sampling plans shall, whenever reasonable, be based on appropriate statistical methods."

SAMPLE RECEIPT - UDPHS

- Capture appropriate information
- Gives us a record of the submitters request
- Serves as a contract

University of Delaware Poultry Health System	
Document Title: Avian Influenza Surveillance Program AI Testing Submission Form	
Author: Brenda Sample/ LL Quality Manager	Document Number: UDPD018-UDPHS-1.3 (was DSDW08-UDPH5)
Page 1 of 1	Supersedes: UDPD018-UDPHS-1.2
Effective Date: 3/11/2013	Approved: 3/8/2013

AVIAN INFLUENZA SURVEILLANCE PROGRAM
University of Delaware Lasher Laboratory
16483 County Seat Highway
Georgetown, DE 19947
Phone (302) 856-1997

LIMS Accession #: _____ **Accessioned By:** _____

Type of Samples Submitted (CIRCLE ONE) **Swabs** **Serum**

Date Collected	
Collected By	
Company Name	
Processing Plant Location	
Grower Name	
Grower Number	
Flock Age (Days)	
Delivered By	

Tests Requested For (Circle One)

Preslaughter	Within Quarantine Area	2miles	6 miles
High Mortality (>4/1000/day)	/1000/day		
Dead Bird Surveillance			
Clinical Case	EpiLink		
Were swabs obtained from sick or dead birds? (circle one)	YES	NO	

SAMPLE RECEIPT

- How do you know that the sample being tested is the same as the one submitted?
- LABELING!! -- Labeled appropriately to ensure tracking through the testing process

SAMPLE TRACKING

- How do you handle samples once they come in?
- Is there a way to know where the samples are in the testing easily?
- How do you handle moving samples from test to test? How do you know it is the same sample?

SAMPLE TRACKING - UDPHS

- Samples will be handled and documented through the proper chain of custody (UDPD020 – Chain of Custody Log Sheet)

University of Delaware Poultry Health System

Document Title: Chain of Custody Log Sheet	
Author: Brenda Sample/ LL Quality Manager	Document Number: UDPD020-UDPHS-3 (see QSOP006-UDPHS)
Page 1 of 1	Supersedes: UDPD020-UDPHS-2.0
Effective Date: 07/27/2013	Approved: 07/25/2013

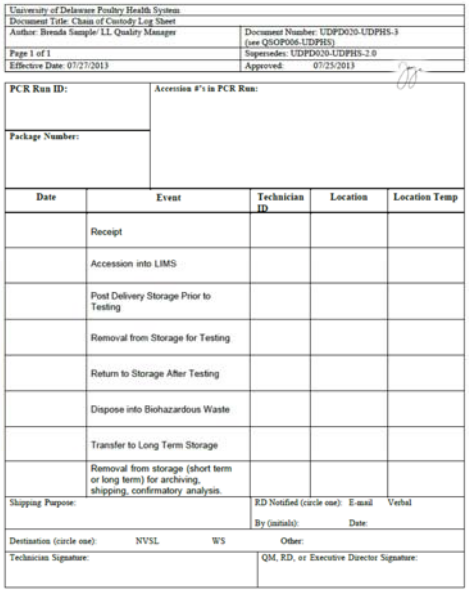
PCR Run ID:	**Accession #'s in PCR Run:**
Package Number:	

Date	Event	Technician ID	Location	Location Temp
	Receipt			
	Accession into LIMS			
	Post Delivery Storage Prior to Testing			
	Removal from Storage for Testing			
	Return to Storage After Testing			
	Dispose into Biohazardous Waste			
	Transfer to Long Term Storage			
	Removal from storage (short term or long term) for archiving, shipping, confirmatory analysis.			

Shipping Purpose:	RD Notified (circle one): E-mail Verbal By (initials): Date:
Destination (circle one): NVSL WS Other:	
Technician Signature:	QM, RD, or Executive Director Signature:

SAMPLE TRACKING - UDPHS

- Capturing data such as storage temperature, storage location, technician, accession number



University of Delaware Poultry Health System

Document Title: Chain of Custody Log Sheet	
Author: Brenda Sample/ LL Quality Manager	Document Number: UDPD020-UDPHS-3 (see QSOP006-UDPHS)
Page 1 of 1	Supersedes: UDPD020-UDPHS-2.0
Effective Date: 07/27/2013	Approved: 07/25/2013

PCR Run ID:	**Accession #'s in PCR Run:**
Package Number:	

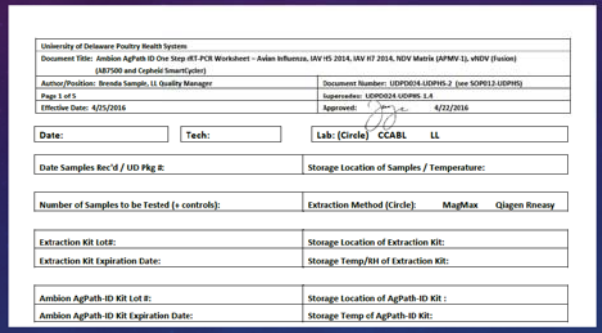
Date	Event	Technician ID	Location	Location Temp
	Receipt			
	Accession into LIMS			
	Post Delivery Storage Prior to Testing			
	Removal from Storage for Testing			
	Return to Storage After Testing			
	Dispose into Biohazardous Waste			
	Transfer to Long Term Storage			
	Removal from storage (short term or long term) for archiving, shipping, confirmatory analysis.			

Shipping Purpose:	RD Notified (circle one): E-mail Verbal By (initials): Date:
Destination (circle one): NVSL WS Other:	
Technician Signature:	QM, RD, or Executive Director Signature:

SAMPLE TRACKING - UDPHS

- UDPD024 – Ambion AgPath ID One Step rRT-PCR Worksheet
  - Tracks all pertinent information for samples, sample handling, methods used to carry out appropriate test methods

SAMPLE TRACKING - UDPHS



University of Delaware Poultry Health System

Document Title: Ambion AgPath ID One Step rRT-PCR Worksheet – Avian Influenza, IAV rt5 2014, IAV H7 2014, NDV Matrix (APMV-1), vNDV (Fusion) (ABI7500 and Cepheid SmartCycler)	
Author/Position: Brenda Sample, LL Quality Manager	Document Number: UDPD024-UDPHS-2 (see SOP012-UDPHS)
Page 1 of 5	Supersedes: UDPD024-UDPHS 1.4
Effective Date: 4/25/2016	Approved: 4/22/2016

Date:	**Tech:**	**Lab: (Circle) CCABL LL**

Date Samples Rec'd / UD Pkg #:	**Storage Location of Samples / Temperature:**
Number of Samples to be Tested (+ controls):	**Extraction Method (Circle): MagMax Qiagen Rneasy**
Extraction Kit Lot#:	**Storage Location of Extraction Kit:**
Extraction Kit Expiration Date:	**Storage Temp/RH of Extraction Kit:**
Ambion AgPath-ID Kit Lot #:	**Storage Location of AgPath-ID Kit :**
Ambion AgPath-ID Kit Expiration Date:	**Storage Temp of AgPath-ID Kit:**

REPORTING – ISO17025 7.8

- 7.8.1.1 "The results shall be reviewed and authorized prior to release."
- 7.8.1.2 "The results shall be provided accurately, clearly, unambiguously and objectively, usually in a report (e.g. a test report or a calibration certificate or report of sampling), and shall include all the information agreed with the customer and necessary for the interpretation of the results and all information required by the method used. All issued reports shall be retained as technical records."

REPORTS

- What do you think SHOULD go on a report?

REPORTS – 7.8.2

- A) a title (example: Test Report)
- B) the name and address of the laboratory
- C) the location of performance of the laboratory activities, including when performed at a customer facility or at sites away from the laboratory's permanent facilities, or in associated temporary or mobile facilities
- D) unique identification that all its components are recognized as a portion of a complete report and a clear identification of the end
- E) the name and contact information of the customer
- F) identification of method used
- G) a description, unambiguous identification, and, when necessary, the condition of the item
- H) the date of receipt of the test or calibration item(s), and the date of sampling, where this is critical to the validity and application of the results

REPORTS – 7.8.2

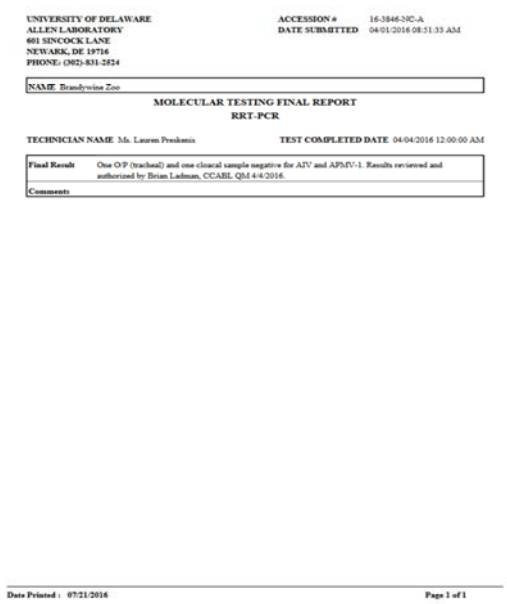
- I) the date(s) of performance of the laboratory activity
- J) the date of issue of the report
- K) reference to the sampling plan and sampling method used by the laboratory or other bodies where these are relevant to the validity or application of the results
- L) a statement to the effect that the results relate only to the items tested, calibrated or sampled
- M) the results with, where appropriate, the unites of measurement
- N) additions to, deviations, or exclusions from the method
- O) identification of the person(s) authorizing the report
- P) clear identification when results are from external providers

REPORTS – 7.8.2

- Who should review results?
- How will you indicate quality review?
- When will this quality check take place?

REPORTS - UDPHS

- Gather all results data
- Technician will review data with Quality Manager
- Quality Manager verifies the results and prepares report for release
- Accessible from our LIMS system as well as e-mail



UNIVERSITY OF DELAWARE
ALLEN LABORATORY
601 SINCOCK LANE
NEWARK, DE 19716
PHONE: (302)-831-2824

ACCESSION # 16-3846-NC-A
DATE SUBMITTED 04/01/2016 08:51:33 AM

NAME Brandywine Zoo

MOLECULAR TESTING FINAL REPORT
RRT-PCR

TECHNICIAN NAME Ms. Lauren Preskenis
TEST COMPLETED DATE 04/04/2016 12:00:00 AM

Final Result	One O/P (tracheal) and one cloacal sample negative for AIV and APMV-1. Results reviewed and authorized by Brian Ladman, CCABL QM 4/4/2016.
Comments	

Date Printed : 07/21/2016 Page 1 of 1

REPORTS

- What do your reports look like currently?
- How do you get results to your customers?

SUMMARY

- Samples must be appropriate for test method
- Samples must have proper documentation
- Samples must be labeled correctly
- Tracking of samples and storage conditions throughout process

SUMMARY

- Tracking of reagents and methods used
- Reports are complete with all testing information
- Reports are reviewed and verified before release

QUESTIONS?

Training Personnel

LAUREN SAUBLE, RESEARCH ASSOCIATE II
UDPHS DEPUTY QUALITY MANAGER
AUGUST 2ND, 2018

6.2 Personnel

6.2.1 All personnel of the laboratory, either internal or external, that could influence the laboratory activities shall act impartially, be competent and work in accordance with the laboratory's management system

6.2.2 The laboratory shall document the competence requirements for each function influencing the results of laboratory activities, including requirements for education, qualification, training, technical knowledge, skills and experience.

Who are your Personnel?

Executive Director

Quality Manager/Deputy Quality Manager

Technicians

Support Staff

What are the primary responsibilities of each category?

What kind of training is needed?

Unviersity of Delaware Poultry Health System (UDPHS) Lab Organizational System & Structure
Lasher Laboratory (LL) and Charles C. Allen Biotechnology Laboratory (CCABL)

Executive Director

is a University of Delaware employee that holds a terminal degree will represent the entire UDPHS. The Executive Director may be part of a team that directly interacts with external Quality Assurance groups following the ISO17025 standard. The Executive Director may also serve as the Resident Director of a UDPHS site. The Executive Director may handle budget issues associated with the UDPHS and may interact directly with University, state and federal government agencies. They will serve on the Quality Assurance Committee to help guide the future direction of the UDPHS.

Resident Director

is a University of Delaware employee that holds a terminal degree will represent the UDPHS at a given site. The Resident Director may approve UDPHS documents. The Resident Director at each site will be part of a team that is responsible for the overall supervision of local NAHLN testing activities and the Quality Program. They will serve on the Quality Assurance Committee to help guide the future direction of the UDPHS.

Quality Manager

is a University of Delaware employee that will lead and oversee activities of the UDPHS Quality System. Quality Managers will provide technical and managerial guidance and support to all system employees as needed. Quality Managers will develop and implement effective CAR/PARs when needed. They will serve on the UDPHS Quality Assurance Committee and disseminate information to UDPHS members. Along with the Directors, Quality Managers will liaise with NAHLN and accrediting bodies such as A2LA. Quality Managers will participate and execute audits, both internal and external. Quality Mangers will ensure the up-to-date quality documents are available to employees. They will monitor all in-house quality control and quality assurance programs as defined within the UDPHS Quality System and mandated by NAHLN and/or accrediting bodies. Quality Mangers will oversee all equipment maintenance and ensure calibration schedules are followed. Quality Mangers will be responsible for UPDHS training efforts and serve as technical managers offering support to all UDPHS members operating within the Quality System. Quality Mangers from a given site may serve as the Quality Manager for other sites as needed. Quality Managers may approve and/or authorize the release of system documents.

Deputy Quality Manager

is a University of Delaware employee that will serve as Quality Manager when the site Quality Manager is not available. The Deputy Quality Manager may be a properly trained NAHLN Approved Technician or Support Staff. Specific roles assigned to a Quality Manager in all UDPHS documents may be completed by a Deputy Quality Manager.

NAHLN Approved Technician

is a University of Delaware employee that completes in-house training as described within the UDPHS Quality System and successfully complete all necessary NAHLN administered proficiency tests. Once charged with the ability to execute UDPHS technical SOPs, NAHLN Approved Technicians will operate in an independent fashion and seek final review of test results from a second NAHLN Approved Technician/Quality Manager/Deputy Quality Manager/ Resident Director. NAHLN Approved Technicians may author protocols and will participate in all Quality System audits and reviews. NAHLN Approved Technicians are expected to be proficient in all pertinent technical SOPs and QSOPs. In extraordinary circumstances, technicians not employed by the University of Delaware yet operate within an approved Quality Management System permitting the execution of NAHLN/NVSL protocols, may be temporarily granted the title of NAHLN Approved Technicians after receiving proper UDPHS training.

Support Staff

are University of Delaware employees that function within the UDPHS Quality System however are not NAHLN proficiency tested and do not execute technical protocols. Support Staff may directly interact with all members of the UDPHS and will be trained accordingly. Support Staff may author protocols and will participate in all Quality System audits and reviews. Support Staff are expected to be proficient in pertinent SOPs and QSOPs.

6.2 Personnel

6.2.3 The laboratory shall ensure that the personnel have the competence to perform laboratory activities for which they are responsible and to evaluate the significance of deviations.

6.2.4 The management of the laboratory shall communicate to personnel their duties, responsibilities and authorities.

Why Train Personnel?

- Confidence in your results
- Updates to standard operating procedures (SOPs)
- To show continued competence – Example: Proficiency Testing

How to train personnel?

- A system that establishes and maintains a training program relevant to your laboratory's needs.
  - System documents define training program which defines training
- Support Staff should be trained if their duties could affect testing and results
  - Example: Secretary sends out results.

Training Recommendations

Watch & Do

- Test techniques
- Operation of equipment
- Apprenticeship

Training Recommendations

Read & Understand

- Quality Manual
- System procedures for quality, safety, facility and operations
- New versions of previously authorized SOPs

Training Recommendations

Initial Training Evaluations

- Verbal or Written exams
- Technical reviews or demonstrations by personnel

6.2 Personnel

6.2.5 The laboratory shall have procedure(s) and retain records for:

- A) determining the competence requirements
- B) selection of personnel
- C) training of personnel
- D) supervision of personnel
- E) authorization of personnel
- F) monitoring competence of personnel

6.2 Personnel

6.2.6 The laboratory shall authorize personnel to perform specific laboratory activities, including but not limited to, the following:

- A) development, modification, verification and validation of methods
- B) analysis of results, including statements of conformity or opinions and interpretations
- C) report, review and authorization of results

UDPHS Example

- Documents training on pertinent safety training, quality system training and proficiency testing
  - Shows ongoing competence

University of Delaware Poultry Health System
Document Title: Employee Training Documentation Form

Author: Brian Ladman/CCABL Quality Manager	Document Number: UDPD005-UDPHS-3 (see QSOP001)
Page 1 of 3	Supersedes: UDPD006-UDPHS-2
Effective Date: 9/23/2017	Approved: 9/20/2017

Employee Training Documentation Form
UNIVERSITY OF DELAWARE POULTRY HEALTH SYSTEM (UDPHS)

Employee/UDPHS Responsibility:	**Year** (Sept 1 – Aug 31):
Employee Signature:	**Audit Year (Circle One):** Even Year Odd Year
Employee Initials:	Technical Quality System
Site: ☐ LL ☐ CCABL	

SECTION I: UNIVERSITY OF DELAWARE LABORATORY SAFETY TRAINING

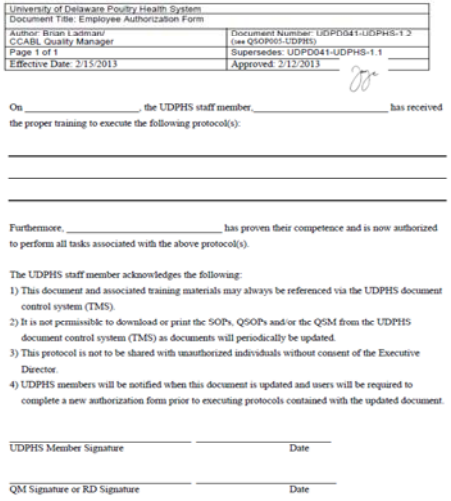
TOPIC	DATE COMPLETE	TRAINING DOCUMENT	QM INITIALS	DATE
Biosafety				
Advanced Chemical Hygiene				
Right-To-Know Safety				
Chemical Waste Disposal				
Biological Shipping				
Autoclave Other:				
Other:				

SECTION II: UDPHS QUALITY SYSTEM TRAINING

DOCUMENT NAME	TYPE / #	VERSION	DATE COMPLETE	TRAINING DOCUMENT	QM INITIALS	DATE
UDPHS Quality Manual	QSM 001					

UDPHS Example

- After a document update, during our monthly meetings, we train on the changes.
- After the training and quiz have been completed, each employee fills this form out.
- Document the training!



University of Delaware Poultry Health System
Document Title: Employee Authorization Form

Author: Brian Ladman/ CCABL Quality Manager	Document Number: UDPD041-UDPHS-1.2 (see QSOP005-UDPHS)
Page 1 of 1	Supersedes: UDPD041-UDPHS-1.1
Effective Date: 2/15/2013	Approved: 2/12/2013

On _____, the UDPHS staff member,_____ has received the proper training to execute the following protocol(s):

_____

_____

_____

Furthermore, _____ has proven their competence and is now authorized to perform all tasks associated with the above protocol(s).

The UDPHS staff member acknowledges the following:

1) This document and associated training materials may always be referenced via the UDPHS document control system (TMS).
2) It is not permissible to download or print the SOPs, QSOPs and/or the QSM from the UDPHS document control system (TMS) as documents will periodically be updated.
3) This protocol is not to be shared with unauthorized individuals without consent of the Executive Director.
4) UDPHS members will be notified when this document is updated and users will be required to complete a new authorization form prior to executing protocols contained with the updated document.

_____ _____
UDPHS Member Signature Date

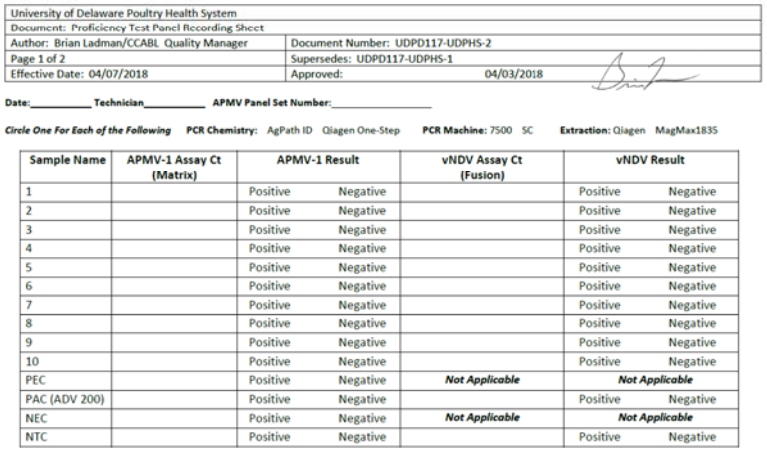
_____ _____
QM Signature or RD Signature Date

Ongoing Competence

- Proficiency Testing
  - Accredited governing body who administers test
    - NVSL provides yearly proficiency panel for AIV and APMV for participating laboratories
  - Cooperating laboratory with known samples to trade
  - In-house known samples

UDPHS Proficiency Panels

- External Yearly Proficiency Panel administered by NVSL and NAHLN (Quarter 2 – Apr – Jun)
  - Provides a yearly check against the national laboratory's samples
- Internal Yearly Proficiency Panel administered by UDPHS Quality Managers (Quarter 4 – Oct – Dec)
  - Provides ongoing competence throughout the year to ensure technician, reagent and equipment proficiency.
- Quarter 1 – new reagent checks (Jan – Mar)
- Quarter 3 – Running of any test that is not run during that quarter (Jul – Sep)



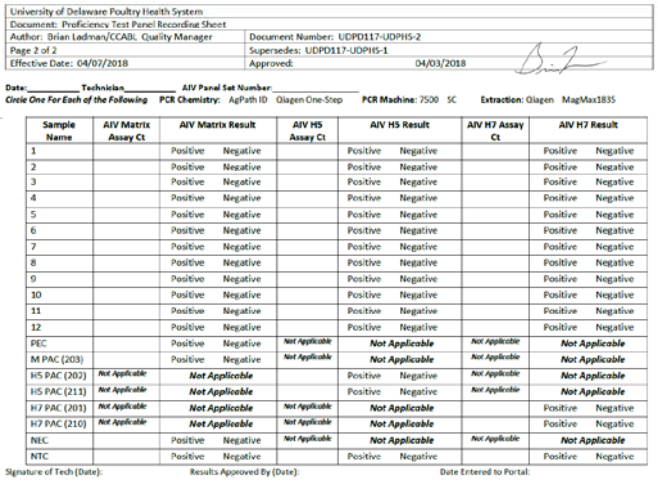
University of Delaware Poultry Health System
Document: Proficiency Test Panel Recording Sheet

Author: Brian Ladman/CCABL Quality Manager	Document Number: UDPD117-UDPHS-2
Page 1 of 2	Supersedes: UDPD117-UDPHS-1
Effective Date: 04/07/2018	Approved: 04/03/2018

Date:_____ **Technician**_____ **APMV Panel Set Number:**_____

Circle One For Each of the Following **PCR Chemistry:** AgPath ID Qiagen One-Step **PCR Machine:** 7500 SC **Extraction:** Qiagen MagMax1835

Sample Name	APMV-1 Assay Ct (Matrix)	APMV-1 Result	vNDV Assay Ct (Fusion)	vNDV Result
1		Positive Negative		Positive Negative
2		Positive Negative		Positive Negative
3		Positive Negative		Positive Negative
4		Positive Negative		Positive Negative
5		Positive Negative		Positive Negative
6		Positive Negative		Positive Negative
7		Positive Negative		Positive Negative
8		Positive Negative		Positive Negative
9		Positive Negative		Positive Negative
10		Positive Negative		Positive Negative
PEC		Positive Negative	***Not Applicable***	***Not Applicable***
PAC (ADV 200)		Positive Negative		Positive Negative
NEC		Positive Negative	***Not Applicable***	***Not Applicable***
NTC		Positive Negative		Positive Negative



University of Delaware Poultry Health System
Document: Proficiency Test Panel Recording Sheet

Author: Brian Ladman/CCABL Quality Manager	Document Number: UDPD117-UDPHS-2
Page 2 of 2	Supersedes: UDPD117-UDPHS-1
Effective Date: 04/07/2018	Approved: 04/03/2018

Date:_____ **Technician**_____ **AIV Panel Set Number:**_____

Circle One For Each of the Following **PCR Chemistry:** AgPath ID Qiagen One-Step **PCR Machine:** 7500 SC **Extraction:** Qiagen MagMax1835

Sample Name	AIV Matrix Assay Ct	AIV Matrix Result	AIV H5 Assay Ct	AIV H5 Result	AIV H7 Assay Ct	AIV H7 Result
1		Positive Negative		Positive Negative		Positive Negative
2		Positive Negative		Positive Negative		Positive Negative
3		Positive Negative		Positive Negative		Positive Negative
4		Positive Negative		Positive Negative		Positive Negative
5		Positive Negative		Positive Negative		Positive Negative
6		Positive Negative		Positive Negative		Positive Negative
7		Positive Negative		Positive Negative		Positive Negative
8		Positive Negative		Positive Negative		Positive Negative
9		Positive Negative		Positive Negative		Positive Negative
10		Positive Negative		Positive Negative		Positive Negative
11		Positive Negative		Positive Negative		Positive Negative
12		Positive Negative		Positive Negative		Positive Negative
PEC		Positive Negative	*Not Applicable*	***Not Applicable***	*Not Applicable*	***Not Applicable***
M PAC (203)		Positive Negative	*Not Applicable*	***Not Applicable***	*Not Applicable*	***Not Applicable***
H5 PAC (202)	*Not Applicable*	***Not Applicable***		Positive Negative	*Not Applicable*	***Not Applicable***
H5 PAC (211)	*Not Applicable*	***Not Applicable***		Positive Negative	*Not Applicable*	***Not Applicable***
H7 PAC (201)	*Not Applicable*	***Not Applicable***	*Not Applicable*	***Not Applicable***		Positive Negative
H7 PAC (210)	*Not Applicable*	***Not Applicable***	*Not Applicable*	***Not Applicable***		Positive Negative
NEC		Positive Negative	*Not Applicable*	***Not Applicable***	*Not Applicable*	***Not Applicable***
NTC		Positive Negative		Positive Negative		Positive Negative

Signature of Tech (Date): Results Approved By (Date): Date Entered to Portal:

Further Training Recommendations

- Provide sufficient time and direction to accomplish task
- Enhance knowledge
  - Background/History of test method
  - Mechanisms
  - Importance of procedure
  - Any hazards involved

Training Challenges

- Experienced technicians and staff
  - May feel they already know what they're doing
  - Resistant to training or paperwork
  - Emphasize that the ISO17025 standard helps to reinforce their results

Summary

- Personnel know their roles in the quality management system
- Training is required of all based on their role
- Use a variety of training techniques
- Show ongoing competence

Questions?

PURCHASING EQUIPMENT, SUPPLIES & SERVICES FOR AN AVIAN TESTING LABORATORY

Lauren Sauble, Research Associate II
UDPHS Deputy Quality Manager
August 2nd, 2018

DOES IT AFFECT THE QUALITY OF RESULTS?

- "…shall have access to equipment that is required for the correct performance of laboratory activities…"
  - Sampling
  - Preparation of test/calibration items
  - Processing and analysis of test and/or calibration data

RECORDS

- Document actions
  - Purchasing equipment, supplies and services
  - Calibration/Maintenance Records
  - Equipment Monitoring
  - No records = it didn't happen!

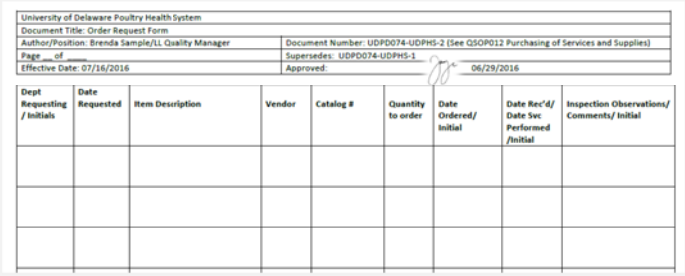
APPROVED TEST METHODS

- Requirements and standards will dictate equipment, supplies & services
  - UDPHS Example: RNA/DNA Extraction Protocol
- Each item will have approved vendors

HOW WE ORDER AT UDPHS

- Any UDPHS employee notifies the Quality Manager of needs
  - Record request on Order Request Form
  - Quality Manager will order
  - Packing slip compared to what was requested and ordered
  - Log information onto the Order Request Form

HOW WE ORDER AT UDPHS



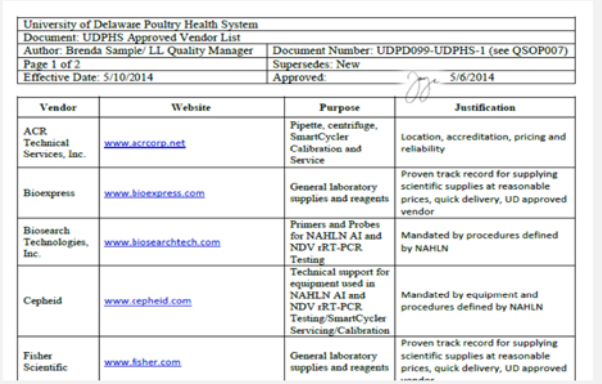
University of Delaware Poultry Health System	
Document Title: Order Request Form	
Author/Position: Brenda Sample/LL Quality Manager	Document Number: UDPD074-UDPHS-2 (See QSOP012 Purchasing of Services and Supplies)
Page __ of ____	Supersedes: UDPD074-UDPHS-1
Effective Date: 07/16/2016	Approved: 06/29/2016

Dept Requesting / Initials	Date Requested	Item Description	Vendor	Catalog #	Quantity to order	Date Ordered/ Initial	Date Rec'd/ Date Svc Performed /Initial	Inspection Observations/ Comments/ Initial

HOW WE CHOOSE OUR VENDORS

- Evaluate and select vendors based on the requirements of University of Delaware and the ISO 17025 accredited testing methods.
- Use ISO 17025 accredited vendors whenever possible!

EXTERNALLY PROVIDED PRODUCTS AND SERVICES– ISO17025 6.6



University of Delaware Poultry Health System	
Document: UDPHS Approved Vendor List	
Author: Brenda Sample/ LL Quality Manager	Document Number: UDPD099-UDPHS-1 (see QSOP007)
Page 1 of 2	Supersedes: New
Effective Date: 5/10/2014	Approved: 5/6/2014

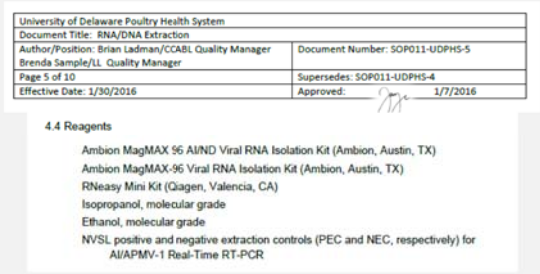
Vendor	Website	Purpose	Justification
ACR Technical Services, Inc.	www.acrcorp.net	Pipette, centrifuge, SmartCycler Calibration and Service	Location, accreditation, pricing and reliability
Bioexpress	www.bioexpress.com	General laboratory supplies and reagents	Proven track record for supplying scientific supplies at reasonable prices, quick delivery, UD approved vendor
Biosearch Technologies, Inc.	www.biosearchtech.com	Primers and Probes for NAHLN AI and NDV rRT-PCR Testing	Mandated by procedures defined by NAHLN
Cepheid	www.cepheid.com	Technical support for equipment used in NAHLN AI and NDV rRT-PCR Testing/SmartCycler Servicing/Calibration	Mandated by equipment and procedures defined by NAHLN
Fisher Scientific	www.fisher.com	General laboratory supplies and reagents	Proven track record for supplying scientific supplies at reasonable prices, quick delivery, UD approved

EQUIPMENT – ISO17025 6.4.13

- A) The identity of equipment, including software and firmware version;
- B) The manufacturer's name, type identification, and serial number or other unique identification
- D) The current location;

EQUIPMENT – ISO17025 6.4.13

- C) Checks that equipment complies with the specification
  - Copy of applicable SOP indicating equipment specifications



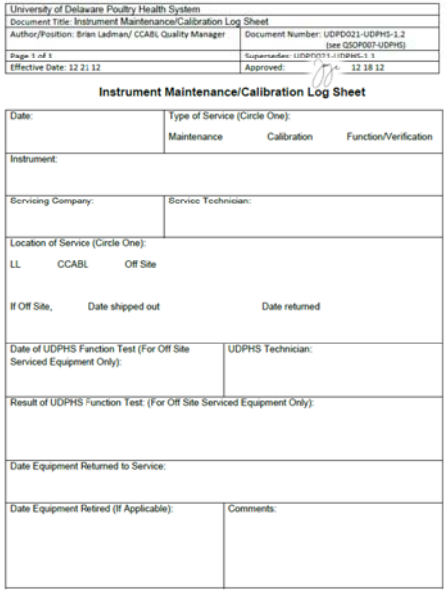
University of Delaware Poultry Health System	
Document Title: RNA/DNA Extraction	
Author/Position: Brian Ladman/CCABL Quality Manager Brenda Sample/LL Quality Manager	Document Number: SOP011-UDPHS-5
Page 5 of 10	Supersedes: SOP011-UDPHS-4
Effective Date: 1/30/2016	Approved: 1/7/2016

4.4 Reagents

Ambion MagMAX 96 AI/ND Viral RNA Isolation Kit (Ambion, Austin, TX)
Ambion MagMAX-96 Viral RNA Isolation Kit (Ambion, Austin, TX)
RNeasy Mini Kit (Qiagen, Valencia, CA)
Isopropanol, molecular grade
Ethanol, molecular grade
NVSL positive and negative extraction controls (PEC and NEC, respectively) for AI/APMV-1 Real-Time RT-PCR

EQUIPMENT – ISO17

- E) Calibration dates, results of calibrations, adjustments, acceptance criteria, and the due date of the next calibration or the calibration interval.



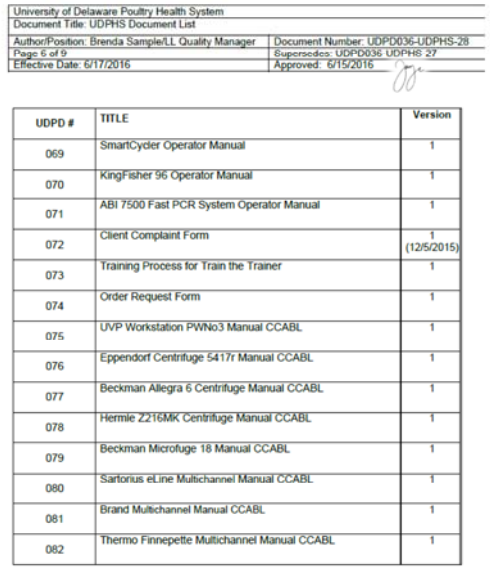
University of Delaware Poultry Health System	
Document Title: Instrument Maintenance/Calibration Log Sheet	
Author/Position: Brian Ladman/ CCABL Quality Manager	Document Number: UDPD021-UDPHS-1.2 (see QSOP007-UDPHS)
Page 1 of 1	Supersedes: UDPD021-UDPHS-1.1
Effective Date: 12 21 12	Approved: 12 18 12

Instrument Maintenance/Calibration Log Sheet

Date:	Type of Service (Circle One): Maintenance Calibration Function/Verification	
Instrument:		
Servicing Company:	Service Technician:	
Location of Service (Circle One): LL CCABL Off Site If Off Site, Date shipped out Date returned		
Date of UDPHS Function Test (For Off Site Serviced Equipment Only):	UDPHS Technician:	
Result of UDPHS Function Test: (For Off Site Serviced Equipment Only):		
Date Equipment Returned to Service:		
Date Equipment Retired (If Applicable):	Comments:	

EQUIPMENT – IS

- F) Documentation of reference materials, results, acceptance criteria, relevant dates and the period of validity;



University of Delaware Poultry Health System	
Document Title: UDPHS Document List	
Author/Position: Brenda Sample/LL Quality Manager	Document Number: UDPD036-UDPHS-28
Page 6 of 9	Supersedes: UDPD036-UDPHS-27
Effective Date: 6/17/2016	Approved: 6/15/2016

UDPD #	TITLE	Version
069	SmartCycler Operator Manual	1
070	KingFisher 96 Operator Manual	1
071	ABI 7500 Fast PCR System Operator Manual	1
072	Client Complaint Form	1 (12/5/2015)
073	Training Process for Train the Trainer	1
074	Order Request Form	1
075	UVP Workstation PWNo3 Manual CCABL	1
076	Eppendorf Centrifuge 5417r Manual CCABL	1
077	Beckman Allegra 6 Centrifuge Manual CCABL	1
078	Hermle Z216MK Centrifuge Manual CCABL	1
079	Beckman Microfuge 18 Manual CCABL	1
080	Sartorius eLine Multichannel Manual CCABL	1
081	Brand Multichannel Manual CCABL	1
082	Thermo Finnepette Multichannel Manual CCABL	1

EQUIPMENT – ISO17025 6.4.13

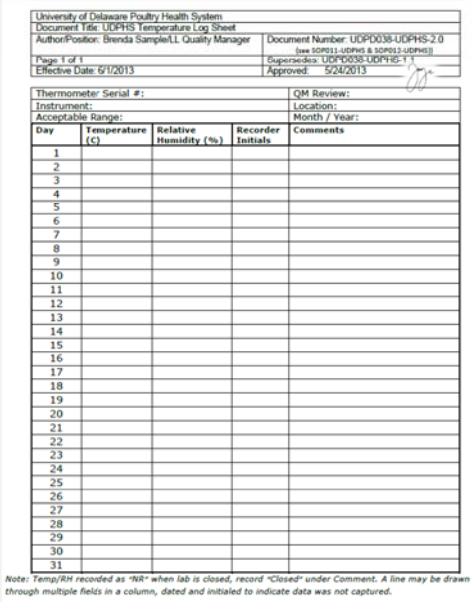
- G) Maintenance plan and maintenance to be carried out to date, where relevant to the performance of the equipment;
- H) Details of any damage, malfunction, modification to or repair of the equipment

EQUIPMENT PROBLEMS OR MALFUNCTION

- Remove equipment from service, label to indicate its status and store until it has been returned to function
  - Refrigerator is not keeping temperature
  - Autoclave is not functioning

STORAGE TEMPERATURES

- How do you know your storage temperature is accurate?
- Fluctuations in temperature of refrigerator? freezer?



University of Delaware Poultry Health System
Document Title: UDPHS Temperature Log Sheet
Author/Position: Brenda Sample/LL Quality Manager | Document Number: UDPD038-UDPHS-2.0 (see SOP011-UDPHS & SOP013-UDPHS)
Page 1 of 1 | Supersedes: UDPD038-UDPHS-1.1
Effective Date: 6/1/2013 | Approved: 5/24/2013

Thermometer Serial #: | QM Review:
Instrument: | Location:
Acceptable Range: | Month / Year:

Day	Temperature (C)	Relative Humidity (%)	Recorder Initials	Comments
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				
16				
17				
18				
19				
20				
21				
22				
23				
24				
25				
26				
27				
28				
29				
30				
31				

Note: Temp/RH recorded as "NR" when lab is closed, record "Closed" under Comment. A line may be drawn through multiple fields in a column, dated and initialed to indicate data was not captured.

CALIBRATION AND MAINTENANCE

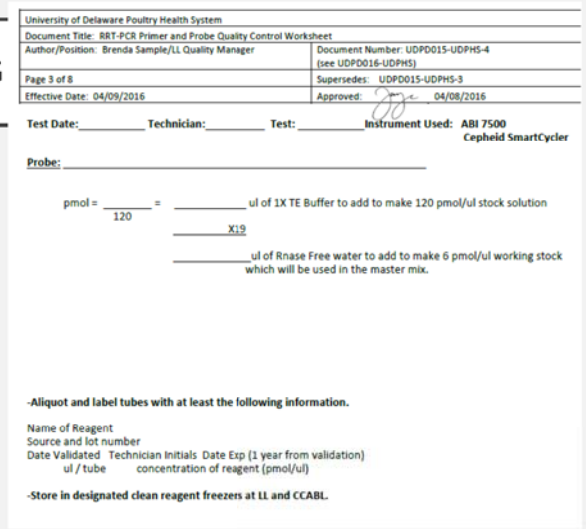
- Key to ensuring ongoing accurate results
- Manufacturer's instructions are a good place to start
- Have to send off-site? **TEST** before putting it back into service

CALIBRATION/MAINTENANCE

- Equipment Maintenance
  - Easily referenced in the manufacturer's manual
  - If any changes to recommendations, MUST be justified
  - Maintenance will be done on all equipment significant to testing
    - Annual check/cleaning
    - Weekly/Monthly/Quarterly function check
    - Daily replacement of critical components

REAG

- Annual Check of NVSL Controls, Primers and Probes
  - Dilution of new Primer and Probe Stocks
    - UDPD015 – RRT-PCR Primer and Probe Quality Control Worksheet
      - Outlines how to label each primer with our UDPHS lot number and the dilution procedure to get to working stock



University of Delaware Poultry Health System

Document Title: RRT-PCR Primer and Probe Quality Control Worksheet	
Author/Position: Brenda Sample/LL Quality Manager	Document Number: UDPD015-UDPHS-4 (see UDPD016-UDPHS)
Page 3 of 8	Supersedes: UDPD015-UDPHS-3
Effective Date: 04/09/2016	Approved: 04/08/2016

Test Date:_____ **Technician:**_____ **Test:** _____**Instrument Used: ABI 7500 Cepheid SmartCycler**

Probe: _____

pmol = _____ = _____ ul of 1X TE Buffer to add to make 120 pmol/ul stock solution
120
X19

_____ul of Rnase Free water to add to make 6 pmol/ul working stock which will be used in the master mix.

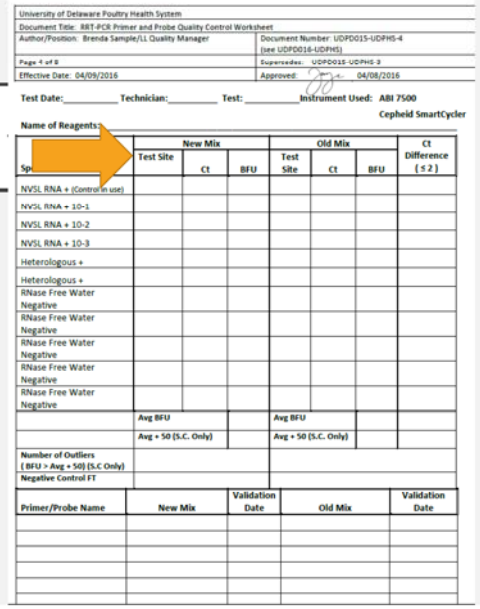
-Aliquot and label tubes with at least the following information.

Name of Reagent
Source and lot number
Date Validated Technician Initials Date Exp (1 year from validation)
ul / tube concentration of reagent (pmol/ul)

-Store in designated clean reagent freezers at LL and CCABL.

REAGENT

- Annual Check of NVSL Controls, Primers and Probes
  - Run current positive and negative controls with both newly diluted primers/probe as well as previously validated primers/probe



University of Delaware Poultry Health System

Document Title: RRT-PCR Primer and Probe Quality Control Worksheet	
Author/Position: Brenda Sample/LL Quality Manager	Document Number: UDPD015-UDPHS-4 (see UDPD016-UDPHS)
Page 4 of 8	Supersedes: UDPD015-UDPHS-3
Effective Date: 04/09/2016	Approved: 04/08/2016

Test Date:_____ **Technician:**_____ **Test:** _____**Instrument Used: ABI 7500 Cepheid SmartCycler**

Name of Reagents:

Sp	New Mix Test Site	New Mix Ct	New Mix BFU	Old Mix Test Site	Old Mix Ct	Old Mix BFU	Ct Difference (≤ 2)
NVSL RNA + (Control in use)							
NVSL RNA + 10-1							
NVSL RNA + 10-2							
NVSL RNA + 10-3							
Heterologous +							
Heterologous +							
RNase Free Water Negative							
RNase Free Water Negative							
RNase Free Water Negative							
RNase Free Water Negative							
RNase Free Water Negative							
	Avg BFU			Avg BFU			
	Avg + 50 (S.C. Only)			Avg + 50 (S.C. Only)			
Number of Outliers (BFU > Avg + 50) (S.C Only)							
Negative Control FT							

Primer/Probe Name	New Mix	Validation Date	Old Mix	Validation Date

REAGENT CHECKS

- NVSL Supplied Positive and Negative Controls
  - UDPD 061 – NAHLN Supplied Reagent Quality Control Worksheet

University of Delaware Poultry Health System
Document Title: NAHLN Supplied Reagent Quality Control Worksheet

Author/Position: Brenda Sample/LL Quality Manager	Document Number: UDPD061-UDPHS-2 (See SOP012-UDPHS-12)
Page 1 of 2	Supersedes: New
Effective Date: 7-6-2013	Approved: 7-2-2013

Attach appropriate UDPD's for test method used.

Negative Extraction Control (NEC) Lot #:_____ Date Tested:_____

Instrument	Test Name	Chemistry	PCR Run #	Ct Value	Technician

Positive Extraction Control (PEC) Lot #:_____ Date Tested:_____

Instrument	Test Name	Chemistry	PCR Run #	Sample ID	Ct Value	Technician
				First Extract 1		
				First Extract 2		
				First Extract 3		
				First Extract 4		
				First Extract 5		
				Second Extract 1		
				Second Extract 2		
				Second Extract 3		
				Second Extract 4		
				Second Extract 5		

University of Delaware Poultry Health System
Document Title: NAHLN Supplied Reagent Quality Control Worksheet

Author/Position: Brenda Sample/LL Quality Manager	Document Number: UDPD061-UDPHS-2 (See SOP012-UDPHS-12)
Page 2 of 2	Supersedes: New
Effective Date: 7-6-2013	Approved: 7-2-2013

Positive Amplification Control (PAC) Lot #:_____ Date Tested: _____

Instrument	Test Name	Chemistry	PCR Run #	Sample ID	Ct Value	Technician
				1:10 – 1		
				1:10 – 2		
				1:100 – 1		
				1:100 – 2		
				1:1,000 – 1		
				1:1,000 – 2		
				1:10,000 - 1		
				1:10,000 – 2		
				1:100,000 – 1		
				1:100,000 – 2		
				1:1,000,000 – 1		
				1:1,000,000 – 2		
				Current PAC		
				Negative (Water)		

EXTERNALLY PROVIDED PRODUCTS & SERVICES– ISO17025 6.6

University of Delaware Poultry Health System
Document Title: Performing NAHLN Approved Real-Time RT-PCR Protocols

Author/Position: Brian Ladman/CCABL Quality Manager Brenda Sample/LL Quality Manager	Document Number: SOP012-UDPHS-6
Page 4 of 14	Supersedes: SOP012-UDPHS-5
Effective Date: 4/25/2016	Approved: 4/5/2016

4.4 Equipment, Materials, and Reagents

Purchasing of all equipment, reagents and materials used to accomplish AIV and NDV NALHN testing shall be done in accordance with NAHLN protocols (UDPD008, UDPD009, UDPD010, UDPD014, UDPD015, UDPD016, UDPD109). Manuals for the Smart Cycler and ABI 7500 Fast PCR System are available at the LL and CCBL (see UDPD069 and UDPD071).

EXTERNALLY PROVIDED PRODUCTS & SERVICES– ISO17025 6.6

- 6.6.1 The laboratory shall ensure that only suitable externally provided products and services that affect laboratory activities are used, when such products and services:
  - A) are intended for incorporation into the laboratory's own activities
  - B) are provided, in part or in full, directly to the customer by the laboratory, as received from the external provider
  - C) are used to support the operation of the laboratory

EXTERNALLY PROVIDED PRODUCTS & SERVICES– ISO17025 6.6

- Products can include measurement standards and equipment, auxiliary equipment, consumable materials and reference materials. Services can include calibration services, sampling services, testing services, facility and equipment maintenance services, proficiency testing services and assessment and auditing services.

EXTERNALLY PROVIDED PRODUCTS & SERVICES– ISO17025 6.6

- 6.6.2 The laboratory shall have a procedure and retain records for:
  - A) defining, reviewing and approving the laboratory's requirements for externally provided products and services
  - B) defining the criteria for evaluation, selection, monitoring or performance and re-evaluation of the external providers
  - C) ensuring that externally provided products and services conform to the laboratory's established requirements or to the relevant requirements of this document, before they are used or directly provided to the customer
  - D) taking any actions arising from evaluations, monitoring of performance and re-evaluations of the external providers

EXTERNALLY PROVIDED PRODUCTS & SERVICES– ISO17025 6.6

- 6.6.3 The laboratory shall communicate its requirements to external providers for
  - A) the products and services to be provided
  - B) the acceptance criteria
  - C) competence, including any required qualification of personnel
  - D) activities that the laboratory, or its customer, intends to perform at the external provider's premises.

SUMMARY

- Equipment, Services and Supplies will be selected based on approved methods
- Use ISO17025 vendors when possible
- Document purchasing, calibration, maintenance and monitoring

QUESTIONS?

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P*A*D*L*S
PENNSYLVANIA ANIMAL DIAGNOSTIC LABORATORY SYSTEM
THREE INSTITUTIONS ONE LABORATORY

Non-Conformances
Corrective Action Reports (CAR)
Preventive Action Reports (PAR)

Michelle Lucey Gibison
Lisa Murphy
PADLS-New Bolton Center
University of Pennsylvania

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"To improve is to change; to be perfect is to change often"

-Winston Churchill

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Goals

- The importance of process improvement
- Difference between corrective and preventative actions
- Writing non-conformances and root cause analysis in terms of the corrective action process

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Continuous Process Improvement

- Ongoing effort by a laboratory to assess and improve upon all steps that are part of the procedures for services offered the laboratory
- Important to integrate into the culture at work, and establish it as an ongoing concern

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Continuous Process Improvements

- Activities that can be used to drive continuous improvement
  - Reactive: improvement by fixing a nonconformance
    - Corrective Action
    - Customer Feedback
  - Proactive: improvement by prevention of a potential nonconformance
    - Preventive Action
    - Management reviews

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So What is a Non-Conformance?

- Not meeting a requirement or a specification
  - In the standard
  - In laboratory policies and procedures
  - In client's expectations or technical requirements
  - Deficiency vs. finding
    - Finding- can be a single observation (minor or major)
      - Missing signature, equipment calibration, due date missed, obvious safety hazard
      - Important to document
      - May or may not require corrective action
    - Deficiency- reported when more than one observation of nonconformance is noted
      - Requires corrective action

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Non-Conformance

- Examples
  - As simple as data transfer error
  - Testing where quality control (QC) data are outside the acceptable limits
  - Testing performed using malfunctioning instruments or during the malfunctioning of environmental systems (maintaining it properly?)
  - Missing deadlines for reporting results
  - Incorrect results reported/wrong client/wrong address

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AAVLD Standard

4.8 Control of nonconforming testing and test results

- Laboratory *shall* have a policy and procedure that ensures that nonconforming testing is detected and promptly corrected
- *Shall* have procedures for informing clients if test results are questionable or incorrect, particularly if this possibility is identified after test results have been reported to the client
- Procedures *shall* describe who has the authority to withhold test results, implement corrective action and authorize resumption of work
- When a serious issue or a risk to the quality of the test results is identified, the laboratory *shall* ensure that appropriate corrective action procedures given in 4.9 shall be promptly implemented

(ISO 17025 section 4.9)

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Policy and Procedure

- Policy and Procedure
- Requires a policy and procedure that describes
  - How nonconforming work is detected and *promptly corrected*
  - Communication to clients
  - Who can stop work
  - What shall fix the problem
  - Who can restart work

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So How Do You Identify Your Nonconformance?

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Identification of Nonconformance

- May be identified by
  - Data review
    - Review of manual data transfers
  - Internal/external audits
  - Proficiency test (PT) results
  - Quality Control (run and review)
  - Management reviews
  - Client complaints/feedback
  - Personnel observation

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Audit Deficiencies

- Nonconformity detected during an internal or external audit
  - Contractor
  - American Association of Laboratory Accreditation (A2LA)
  - American Association of Veterinary Laboratory Diagnosticians (AAVLD)

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Complaints/Feedback

- A nonconformity was detected and communicated back to the lab
  - Data entry error
  - Wrong test performed
  - Results not received
  - Incorrect test result

- Feedback can be solicited/unsolicited
- Compliments/Positive feedback should be tracked as well

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Departures from P&P

- Client confidentiality policy violated
- Scheduled internal audits not performed
- Previous version of method procedure in use
- Untrained employee performing testing

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Proficiency Test Failures

- National Veterinary Service Laboratory (NVSL)
- Veterinary Laboratory Association (VLA)
- College of American Pathologists (CAP)

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Equipment Failure

- Reoccurring equipment failure leading to frequent and prolonged down times
  - Poorly maintained equipment
  - Insufficient operator training
  - Aging equipment

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So Now What Do You Do With A Nonconformance?

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Correct the Nonconformance

- Write and document the Nonconformance
- Evaluate the nonconformance and decide course of action
  - Stop/restart work if necessary
- Correct the immediate problem
- Initiate the corrective action process if necessary

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Writing the Nonconformance

- Important to document the nonconformance
- Be specific
- Provide enough details for lab to identify the problem
  - Accession #
  - Document ID
  - Date of occurrence
- Include evidence
- Cite or refer to the requirement, test method, client specification, or lab policy and procedure

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Writing the Nonconformance

- Bad
  - Compliance with the laboratory's chain-of-custody procedures is inadequate
- Better
  - Three out of six chain-of-custody records (cases numbers N1, N3 and N4) reviewed were not signed in the box indicated as required by the laboratory's own procedures (SOP-123)

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Writing the Nonconformance

- Bad
  - The laboratory needs records for equipment maintenance.
- Better
  - There were no observed records for maintenance for balances in molecular diagnostics room 24 and 26, and serology room 28 as required by section 5.5.5 of the AAVLD requirements.

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Non-Conformance

So Remember…

If you cannot express a non-conformance in the words of the standard, the test method, the client's expectations, or laboratories own policies and procedures then…

It's Not A Non-Conformance

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Evaluation

- The supervisor, QA manager, and/or QAO
  - Determine the significance of non-conforming work in terms of whether the work has or could adversely affect the reliability of test results
  - Determine if/when work has to be halted
    - Work shall not be restarted if investigation shows that the nonconformance could reoccur/ has not been fixed
    - May be restarted once the cause of the nonconformance has been removed and it is determined that the test results are valid

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Aftermath

- **Immediate correction** must be taken to correct the cause of the nonconformance
  - Clients, who may have received the results when validity of the results has been affected, must be notified
  - Clients, who may be affected by a delay in turn-around time, must be notified
  - Perform rework
  - Send corrected report
- Corrective action process must be started *as per the laboratories procedures*
  - Some SOPs may allow for retesting after initial failure
  - Important to know/define the process

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The Corrective Action Process

Corrective and Preventive Actions (CAPA)

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The CAPA System

- Communicates corrective actions (CA) and preventive actions (PA) to the appropriate people
- Provides information for management reviews
- Documents activities
- Aids in the continuous process improvement

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AAVLD Standard
4.9 Corrective and preventive action

- Laboratory shall have
  - Policy- Principle/rule
  - Procedure- Step by step
  - Shall ensure
    - Implemented by appropriate authorities
    - Root Cause analysis
    - Implementation
    - Changes are documented
    - Monitoring
    - Where appropriate, subject to internal audit

(ISO 17025 section 4.11)

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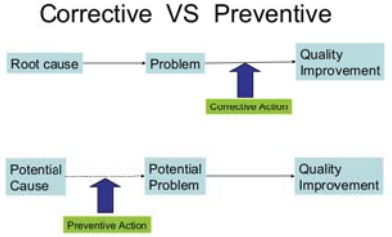
Corrective vs Preventive Actions

- Corrective Action is designed to eliminate the reoccurrence of a nonconformity (reactive)
- Preventive Action is designed to eliminate the occurrence of a potential nonconformity (proactive)



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Corrective Action

- An action taken to eliminate the initiating cause of a detected nonconformity
  - Nonconforming work
  - Audit deficiencies
  - Complaints
  - Departures from policies and procedures
  - PT failures
  - Equipment failures
- Identifies the root cause of the nonconformity
- Attempts to eliminate root cause and improves the system through corrective actions
- Is monitored for effectiveness

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Preventive Action

- Action taken that identifies a potential nonconformity and prevents its occurrence
  - Define potential nonconformity
  - Determine possible causes
- Objectives
  - Improve QC schemas
  - Improve monitoring and review
  - Improve equipment maintenance
  - Improve documented procedures and work instructions
  - Improve record keeping
  - Improve test method
  - Improve training
  - Etc…

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Everyday Examples

Preventive	Corrective
• Brushing and Flossing	• Root Canal
• Oil Change	• Engine Repair
• Replace Furnace Filter	• Furnace Replacement
• Routine Eye Care	• Prescription Glasses
• Vaccination	• Treatment of Illness

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Laboratory Examples

Preventive	Corrective
• Wearing PPEs	• Need to use Eyewash Station
• Routine Equipment Maintenance	• Replacing expensive equipment
• Proper Reagent Management	• Reruns due to Reagent Problem

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Preventive vs Corrective Action Example

- The laboratory has come close to running out of reagent on a number of occasions. The inventory and purchasing processes are evaluated and revised to prevent the occurrence of the potential nonconformity

- The laboratory is out of reagent and cannot perform testing for 10 days. Reagent is ordered and the inventory and purchasing processes are evaluated and revised to prevent the reoccurrence of the nonconformity.

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How the CAPA process works

- Define the problem/nonconformance (use official form)
  - Use only facts
  - Inform the QM section
- Immediate Action
- Perform root cause analysis
  - Investigate
- Corrective Action/s
  - Come up with action/response plan
- Implement and monitor action plan
- Review &Verify
- Close CAR

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Define the problem

- Be specific
- Cite in terms of the requirement
- Describe the problem
- Use titles only, no personal names

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Inform the Quality Management Section

- Forward form to Quality Manager
- Quality Manager will
  - Assign number (ex CAR 160210-1)
  - Investigate
  - Help decide on plan
  - Monitor and review plan
  - Maintain log of CA/PA
  - Close out when complete

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Investigate

- Be familiar with the process
- Read the SOP/Procedure
- Interview employees
  - Don't be a cop
  - No personal agenda
  - Explain the purpose
  - Take notes
  - Check documents/records

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Conduct Root Cause Analysis

- 5 why's
- Fishbone diagram
- Fault tree analysis

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5 Whys (Cause and Effect)

Problem: Car Won't Start

Why? • Engine won't turn over

Why? • Battery is dead

Why? • Alternator not functioning

Why? • Belt is broken

Why? • Maintenance not performed as required

Root Cause: Not following the manufactures maintenance schedule

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Fishbone (Ishikawa) Diagram

- System failure is described in the box to the right
- Add bones (4-6 categories)
  - Categories
    - Personnel
    - Equipment
    - Materials
    - Procedures
  - Primary causes
  - Secondary causes

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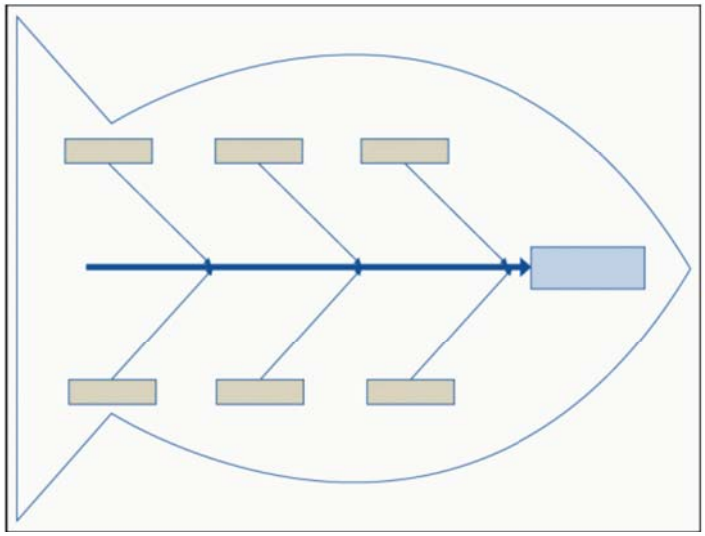
Fishbone Diagram



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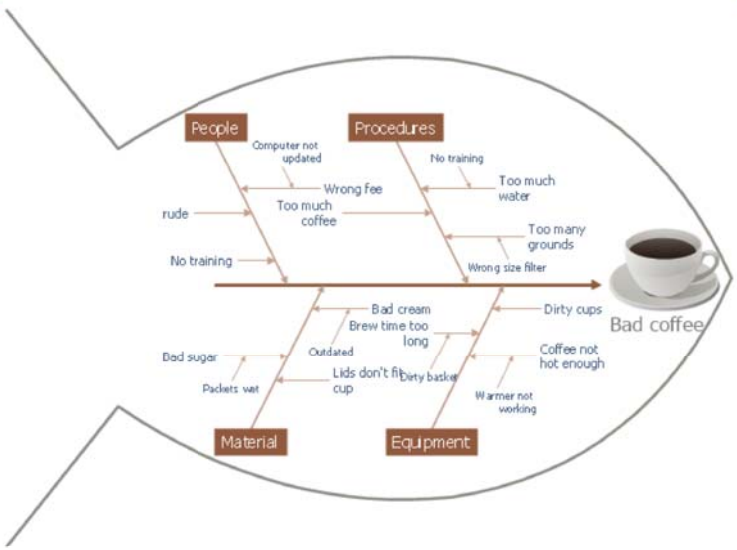
Fish Bone Diagram



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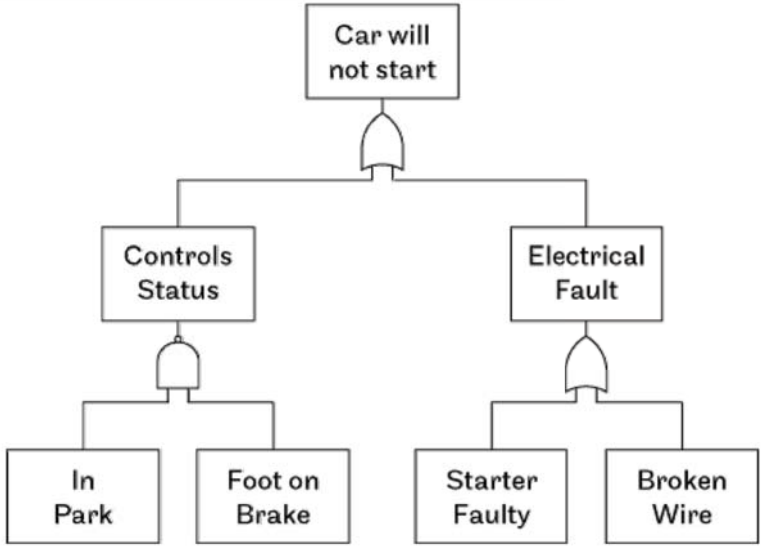
Fault Tree Analysis (top down)



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Root Cause Analysis Advice

- Don't (rarely) let human error be the cause
  - Improper Instructions?
  - Improper Tools?
  - Improper Training?
- Don't let retraining be the corrective action. Better to fix or improve the training program

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Examples

Problem	Causes
• Kit controls not working as expected	• Old kit/improper storage/ wrong incubation temps
• Errors in reporting results	• Lack of training/no proof reading/ client info not updated
• False positive ELISA results	• Non validated kit/ sample mix up/ pipetting error
• Uncontrolled work instructions	• Not part of SOP/No distribution list
• Inadequate training	• High employee turnover/High Workload/lack of training program

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Action Plan

- Pick most likely causes
- Determine actions to be taken
  - Be specific!
  - Ensure resources are available (budget/staff/supplies)

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Implement/Monitor

- Delegate to responsible individuals
- Fix tentative due date for completion
- Verify completion of action plan
  - Check SOPs for revisions
  - Review training records
  - Check calibrations
- Train and communicate changes
- Fix a timeframe to monitor for effectiveness

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What if the plan doesn't work?

- Close the previous CA/PA
- Start over with a new CA/PA
- Consider other potential causes
- May need to think outside the box
  - Get different perspectives

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When a CA is not required

- If the SOP indicated to first repeat any nonconforming work
  - There are no perfect specimens and no perfect tests
  - Repeating work too often may indicate a potential problem, and may need investigation!

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Things to Remember!

- Train and encourage employees to use the CAPA process
- Management must promote CAPA
- Maintain good documentation of CAPAs
- Maintain a log of CAPAs to keep track of trends
- Review CAPAs and trends during management reviews

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How many CA/PA do you need?

- More than zero
  - No lab is perfect!
- Less than a million
  - Would imply serious problems

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Summary

- Mistakes happen, it's how you react to them that matters
- CA/PA are not a waste of time, in the long run they should improve the lab and save time
- Encourage management and personnel to be involved
- If it's not documented, it didn't happen, so maintain good documents and records!

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NBC CORRECTIVE ACTION INVESTIGATION REPORT

SECTION I: INITIATION (Submitter – Complete Section I)

Date:	CAR #:
Submitter:	Discipline:
Accession # (if applicable):	Correction ☐ or Non-Conformance ☐

Describe Issue and Potential Causes: (Attach relevant records or documents, use titles rather than names)

Initial Response:

Suggested Solution(s):

SECTION II: SUPERVISOR NOTIFICATION

I hereby acknowledge I have been notified of this initiation:
Supervisor: Date:

SECTION III: INVESTIGATION (To be completed by Quality Manager)

Root Cause Analysis: (Include names of personnel involved)

Quality Document(s) Involved:

Root Cause:

	Corrective Action Plan	Responsible Individual	Due Date	Completion Date
1				
2				

SECTION IV: FOLLOW-UP (To be completed by Quality Manager)

Follow-Up Required: ☐ NO ☐ YES Date for Completion:

Follow-Up Action:

Follow-Up Complete
Quality Manager: Date Completed:

SECTION V: VERIFICATION OF CORRECTIVE ACTIONS

Controlled Form: NBC.FORM.QA-10 v1.0 Associated SOP: NBC.QA.101
Please check TMS for the most current version prior to making additional copies. Page 1 of 2

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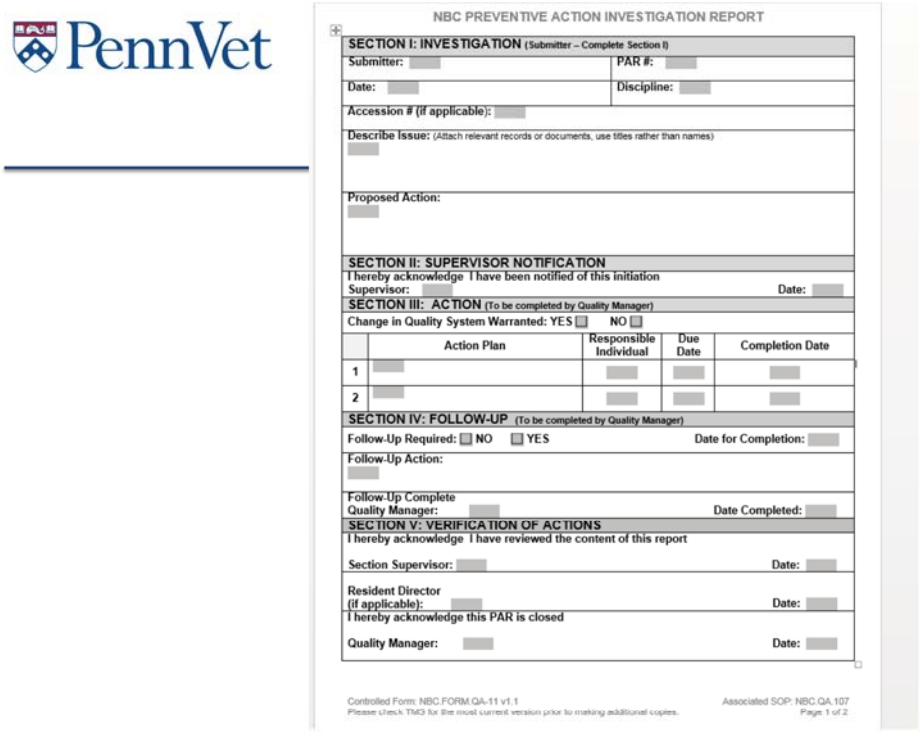

NBC PREVENTIVE ACTION INVESTIGATION REPORT

SECTION I: INVESTIGATION (Submitter – Complete Section I)

Submitter:	PAR #:
Date:	Discipline:

Accession # (if applicable):

Describe Issue: (Attach relevant records or documents, use titles rather than names)

Proposed Action:

SECTION II: SUPERVISOR NOTIFICATION

I hereby acknowledge I have been notified of this initiation
Supervisor: Date:

SECTION III: ACTION (To be completed by Quality Manager)

Change in Quality System Warranted: YES ☐ NO ☐

	Action Plan	Responsible Individual	Due Date	Completion Date
1				
2				

SECTION IV: FOLLOW-UP (To be completed by Quality Manager)

Follow-Up Required: ☐ NO ☐ YES Date for Completion:

Follow-Up Action:

Follow-Up Complete
Quality Manager: Date Completed:

SECTION V: VERIFICATION OF ACTIONS

I hereby acknowledge I have reviewed the content of this report

Section Supervisor: Date:

Resident Director
(if applicable): Date:

I hereby acknowledge this PAR is closed

Quality Manager: Date:

Controlled Form: NBC.FORM.QA-11 v1.1 Associated SOP: NBC.QA.107
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CAPA Form on TMS

- TMS

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Acknowledgements

- AAVLD Requirements for and Accredited Veterinary Medical Diagnostic Laboratory
- AAVLD Essential Requirements & Auditing Principles and Course Notes, Version 1.0 – 2007
- Ed Gill, ADL Quality Manager
- Matt Sweger, PVL Quality Manager

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Examples

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Example 1: The Process

Lab receives samples with a test request for a SHI-Test for Caseous Lymphadenitis

Lab prepares samples and runs the SHI-Test

Technician observes for endpoints and enters numerical data on the worksheet and into the laboratory information system (LIMS)

Final report is checked in the LIMS and approved for release to the client by the lab manager

Report auto generates to the client

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Example 1: The problem

The client receives a test report with the results for Caseous Lymphadenitis test. One animal previously reported as negative, is reported as positive. The client calls the laboratory to question the positive result.

The client complaint is logged into the laboratory's quality system.

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Example 1: Review and Investigate

- QA manager reviews the CL worksheet and the report issued to the client.
- The CL worksheet has the correct information on it, having the animal in question as testing negative.
- The report issued to the client and entered into LIMS shows that the animal is listed as positive

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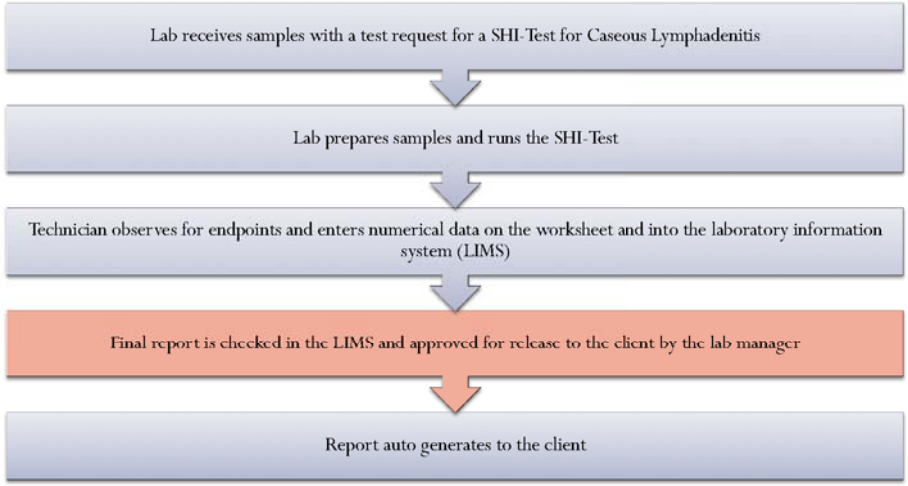
Example 1: The Process



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How would you fix the immediate problem?

A. Repeat the test, perform the required titer, and resend the results to the client

B. Perform a root cause analysis to determine the initiating cause of the problem

C. Issue a corrected report to the client

D. Retrain the technician performing the test

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Example 1: Fix the immediate problem

The lab enters the correct test result data from the worksheet into their LIMS.

A corrected report is issued to the client with the corrected results for all specimens submitted.

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Are we done?

A. Yes

B. No

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Root Cause Analysis

- Review the evidence
  - Tech entered incorrect test results into LIMS
  - Final report check did not catch the error because the worksheet data is not available at that step
  - Equipment interface for automated data transfer is not available at this time
- Lets try the fishbone diagram
- This can apply to any test in the lab that has manual data transfer

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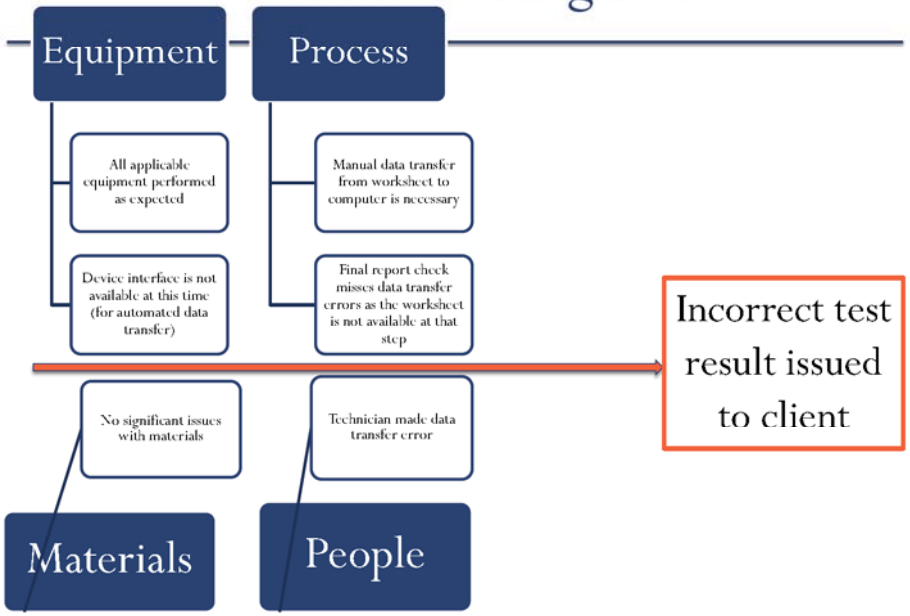
Fishbone Diagram



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What is the root cause?

A. Technician needs retraining on the testing procedure

B. The laboratory's equipment used for this test is inadequate

C. The final review of reports for release to the client is inadequate

D. Manual data transfer error from the worksheet to the computer

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What is the root cause?

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B. The laboratory's equipment used for this test is inadequate

C. The final review of reports for release to the client is inadequate

D. Manual data transfer error from the worksheet to the computer

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What Corrective Action would you implement?

A. Require review of raw test data at the lab manager's final report approval step

B. Retrain tech to be more attentive to detail

C. Add a secondary review of the data transfer from worksheet to computer

D. Discontinue the test until equipment is available to automate data transfer

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A. Require review of raw test data at the lab manager's final report approval step

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Corrective Action

- Add a procedure for computer data transfer checks to the process and train the laboratory staff
- Also revise worksheet to indicate a place to document the data transfer check

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Are you done?

A. Yes

B. No

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How would you monitor?

A. Monitor during the regularly scheduled internal audit

B. Monitor client complaints for additional occurrences of this problem

C. Monitor the worksheets for documentation of the data review check

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Outcome

- Over the next 4 months the laboratory monitors the documentation of data transfer review check of test worksheets
- The resulting number of instances where data entry was found to be in error were zero
- The corrective action is closed.

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Example 2

- Technician failed proficiency test for potassium recovery levels in Toxicology, with a deviation greater than 20% from average
- Potential causes: contamination or insufficient sample mixing

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Example 2: Immediate Response?

A. Stop all testing for potassium

B. Repeat PT until you tests are within acceptable ranges

C. Repeat PT with proper mixing of sample

D. Tell agency that you cannot perform testing with such sample type

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Example 2: Immediate Response?

A. Stop all testing for potassium

B. Repeat PT until you tests are within acceptable ranges

C. Repeat PT with proper mixing of sample

D. Tell agency that you cannot perform testing with such small quantities

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Example 2

- Testing is repeated with extra mixing of sample. Results produce a test result within acceptable deviation from average.

Are we Done?

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Example 2: Investigation

- During the investigation with the lab, it was seen that all equipment maintenance was current, the technician was trained and authorized to perform testing, and testing was performed according to the current SOP.

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Possible root cause?

- Why did the PT fail?
  - Results greater that 20% from average
- Why was there such a great deviation?
  - Samples were not mixed prior to testing
- Why did the samples need to be mixed prior to testing
  - Different sample types needed to be handled differently
- Why weren't the samples mixed prior to testing?
  - SOP did not indicate that samples needed to be mixed

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Corrective Action

A. Retrain the employee on the current SOP

B. Rewrite the SOP to include mixing prior to testing for certain types of samples

C. Calibrate all equipment to make sure it is functioning correctly

D. Buy new, more sensitive equipment

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Corrective Action

A. Retrain the employee on the current SOP

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Monitor

- SOP is re written to include mixing of samples prior to testing. After the SOP revision is complete, employees are trained on the new method for testing. Testing is monitored for 6 months and reviewed and showed that all testing was within acceptable ranges.
- Corrective action is closed.

Date/Time: 1/9/2018 3:17:02 PM	Corrective Action/Preventive Action Request Form Report Title: Coggins 1-6-2018	Report ID: CAPA-18-01-09-039

Section I: SUBMITTER SECTION

Submitter:	Sweger, Matt		
Submitter Laboratory	NBC	**Report Type**	Corrective Action
Laboratory Section	Microbiology	**Laboratory Affected**	NBC
Describe the Non-Conformance and Potential Causes	8 Coggins samples were received from Dr. Cassie Mahoney on January 3, 2018. There was no notice on the submissions sheet that results were needed by any specific date. These samples were set up at 1:00PM on Wednesday January 3. Due to hazardous weather conditions, New Bolton Center shut down normal operations on Thursday (1/4/18) and Friday (1/5/18), which includes normal PADLS operations. On Friday (1/5/18), the Microbiology department answering machine had no new messages pertaining to testing. The facility returned to weekend operations on Saturday (1/6/18). The owner of the Coggins samples requested results by that Saturday for an upcoming event to Dr. Cassie Mahoney, but that information was not conveyed to the laboratory. After various communications attempts to secure the status of the report, the message was relayed to the Microbiology department. The technician available was certified, and was able to read the Coggins results. The technician notified the front desk of ongoing issue and updated front desk with turnaround time. Samples were processed on Wednesday (1/3/18), however, paperwork was not accessioned into LIMS and therefore, results could not be immediately released. All samples for January 3 were partially accessioned that day, Saturday January 6th by non-routine technician, so that paperwork could be distributed that day. Once paperwork was signed and organized, the Coggins owner and veterinary paperwork for these horses (V1800079 – V1800086) were delivered in separate envelopes to the front desk.		
Remedial Action(s) Taken:	**Results were obtained and reported out as soon as possible. Communication errors are being investigated.** **Sean Loughrey is the actual submitter of this CAPA - Matt Sweger mistakenly "submitted" the CAPA and is therefore listed as the submitter for the CAPA. (mbs 1/25/2018)**		
Affected Accessions	**V1800059 – V1800086**		
Attachment			

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Section III: CORRECTIVE/PREVENTIVE ACTION PLAN

Action Plan	Responsible Party	Due Date	Action Performed	Attachments
Review current procedures for planned and unplanned closures of the University or NBC Hospital with staff and managers.	Murphy, Lisa	1/31/2018	Completed at NBC-PADLS quarterly meeting on Jan 23rd, 2018. See attached summary.	
Generate document with PADLS closure policy and contact information for distribution within the hospital, for clients and posting as needed.	Lucey, Michelle	2/28/2018	Completed on February 7th. See attached list.	PADLS Emergency Contact Information.pdf

Action Plan Approval Signatures	Murphy, Lisa 2/16/2018 4:33:34 PM

Section IV: FOLLOW-UP

Action Plan	Responsible Party	Due Date	Action Performed	Attachments
Review client complaints related to lab closures and access effectiveness of communication with hospital and clients.	Lucey, Michelle	3/31/2019		

Section V: APPROVAL

Final Approval Signatures	

Section II: ROOT CAUSE ANALYSIS

Individual responsible for Root Cause Analysis	Lucey, Michelle
List additional personnel contributing to the Root Cause Analysis	Murphy, Lisa, Loughrey, Sean, Lucey, Michelle, Kelly Donna, Habecker, Perry
Enter findings of the Root Cause Analysis	Due to unexpected inclement weather, the University was shut down for 2 consecutive days before a weekend. The PADLS labs are currently not considered essential personnel, and while emergency cases and time sensitive tests were completed as staff could address them, AGID Coggins testing was not considered an emergency. In discussion with the front desk of the hospital, it was found that the client was not directed to contact the appropriate PADLS managers, nor the Pathologist on duty, so there was not an immediate resolution to their need for

	the testing results. Future meetings with the hospital staff have indicated a need for specific instructions and contact information for PADLS labs during closures both planned and unplanned to prevent this situation from occurring regardless of test request or type.		
Attachments			
Quality Manual Section	5.10 Reporting of test results		
Root Cause Summary	Reporting of Test Results	**If Other**	

Section I: SUBMITTER SECTION

Submitter:	Gill, Ed		
Submitter Laboratory	NBC	**Report Type**	Corrective Action
Laboratory Section		**Laboratory Affected**	NBC
Describe the Non-Conformance and Potential Causes	Test were incorporated into the laboratory service without validation or with deficient validation results. Examples: a. NBC – Results of samples tested as part of the EHV-1 real-time PCR validation differed from results expected and were not further analyzed b. NBC and PVL – Pullorum/typhoid plate agglutination antigen designed for whole blood testing is used to test serum without validation to do so (NBC.AV.104 v2.4, no SOP available for PVL)		
Remedial Action(s) Taken:	**Example a Remedial Action Response:** **The PADLS-NBC lab had UC Davis (Research lab) sample extracts left from the EHV-1 validation, but no original swabs. On the suggestion made by the site visit team, NBC sent the samples in question to PVL to confirm concordant results on December 9th, 2017. Samples sent to PVL also contained patient samples confirmed positive and negative by NBC for EHV-1. Both NBC and PVL perform the same method of extraction and PCR for EHV-1, and PVL has acceptable validation documentation for this assay through an AAVLD offered inter-lab assay. The comparison testing resulted in the same number of positive and negative samples as NBC had previously obtained during their validation (samples from UC Davis Research Lab) as well as their (NBC) diagnostic samples. It is important to note that part of the rush for validation of this assay was due to a request of the acting state vet during an EHV-1 outbreak. The only way to obtain a large number of samples for testing was from UC Davis' research lab (that is not AAVLD accredited). Their extraction method and viral load determination is different than the methods that the PADLS labs use and previous inter-lab comparisons have shown that there can be slight variance in the outcomes at higher Cts >35 based on the assay used. These samples were also obtained and stored in conditions unknown to the PADLS labs. Testing was put in place for animals being admitted to the hospital and showing clinical signs with follow up possibilities still intact at PVL for quarantine release issues. NBC and PVL will continue to share a portion of their EHV-1 samples as documentation of ongoing competency for this test.** **Example b Remedial Action Response:** **The Pullorum/typhoid plate agglutination test historically has been a part of PADLS testing since before the implementation of PADLS test validation requirements. For this reason, no PADLS lab has validation documentation for this test method. The PADLS labs participated in an Inter-laboratory Comparison Panel in November 2017 for verification of this test method. Results show 100% agreement between all participants across the three PADLS labs and were**		

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Section II: ROOT CAUSE ANALYSIS			
Individual responsible for Root Cause Analysis	Lucey, Michelle		
List additional personnel contributing to the Root Cause Analysis	Gill, Ed, Lucey, Michelle, Sweger, Matt		
Enter findings of the Root Cause Analysis	Test validation is one of the most important aspects of developing a quality laboratory system. This is an area that we are constantly striving to improve and develop. On 6/1/2016 we updated our Guidelines for Instituting New tests or Changing Test (PD 120-400-300) to include PD FORM 008 "Test Implementation/ Change of Test Checklist" that more clearly helps to define the process for new test implementation and validation/verification. This checklist includes review by the Scientific Discipline Committee and vertical audits by the Quality Management to ensure compliance with our verification/validation SOPs. PADLS Section Managers working in concert with PADLS Scientific Discipline Committees and Quality Managers is necessary to ensure all new tests meet validation/verification standards set forth in those PADLS SOPs. The labs will continue to review and assess our validation methods and proceed with inter-laboratory testing as needed across all areas of testing. · QSOP 038 - Validation of Test Methods · PD 120-300-110 - Validation for Bacteriology Tests · PD 120-300-120 - Validation or Verification of Molecular Detection Tests · PD 120-300-125 - Verification/Validation of Serological Tests · PD 120-300-130 - Verification/Validation of Virus Detection Assays		
Attachments			
Quality Manual Section	5.4 Test Methods		
Root Cause Summary	Test Methods	**If Other**	

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Section III: CORRECTIVE/PREVENTIVE ACTION PLAN				
Action Plan	**Responsible Party**	**Due Date**	**Action Performed**	**Attachments**
Inter-lab comparison of EHV-1 validation and diagnostic samples.	Lucey, Michelle	1/1/2018	EHV-1 diagnostic and validation samples sent to PVL for confirmation of results with 100% agreement of diagnostic sample cases.	NC19a - EHV-1 testing results.pdf
Inter-lab comparison of Salmonella Pullorum/typhoid plate agglutination testing	Sweger, Matt	1/1/2018	Salmonella Pullorum/typhoid plate agglutination inter-lab comparison was completed in November of 2017 with 100%	NC19b - Salmonella Pullorum Typhoid RPA Interlab Comparison.pdf

Pennsylvania Animal Diagnostic Laboratory System — Effective July, 2017
Related SOP, PD 100-320-500

PADLS CAPA TEMPLATE
PD QA FORM 101 v1.5 — **Page 3 of 3**

			agreement between all three labs.	
Review by Scientific Discipline and Quality Assurance Committees of · QSOP 038 - Validation of Test Methods · PD 120-300-110 - Validation for Bacteriology Tests · PD 120-300-120 - Validation or Verification of Molecular Detection Tests · PD 120-300-125 - Verification/Validation of Serological Tests · PD 120-300-130 - Verification/Validation of Virus Detection Assays	Lucey, Michelle	12/31/2018	QSOP 038 was renamed QSOP 5.4.2.2 to align with the AAVLD requirements sections. All of these SOPs were revised and now include the statement "that any discussion regarding validation data be included in the Scientific Discipline meeting minutes to record sufficient information to provide justification for accepting or rejecting a new test or change to tests"	Validation SOPs.pdf

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Section IV: FOLLOW-UP				
Action Plan	**Responsible Party**	**Due Date**	**Action Performed**	**Attachments**
At least one QA manager (or designee) attends the SD meetings and reviews the minutes for accuracy and details over the 2018 time period.	Lucey, Michelle	12/31/2018		

Section V: APPROVAL	
Final Approval Signatures	

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Example 3

- A human exposure rabies specimen, P1519271 (kitten) and a non-human exposure rabies specimen, P1519272 (raccoon) were sent to the incorrect labs for testing but were accompanied by the correct paperwork for their destination.
  - Kitten went to lab A with raccoon paperwork
  - Raccoon went to lab B with kitten paperwork
- The correct forms were scanned into LIMS

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Immediate Actions?

- What would you do?
- Who is responsible to do it?

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Root Cause Analysis

- Ask questions on what may have happened?
- What documents and records may you want to look at?
- Brainstorm

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Corrective Action and Monitoring

- What is your corrective action?
  - Any other ideas to improve the procedure?
- How would you monitor it? How long?

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