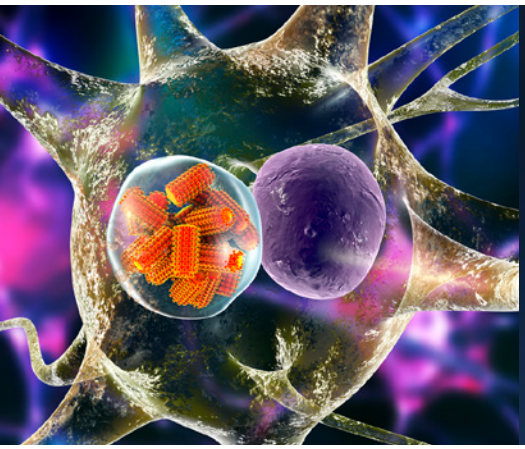
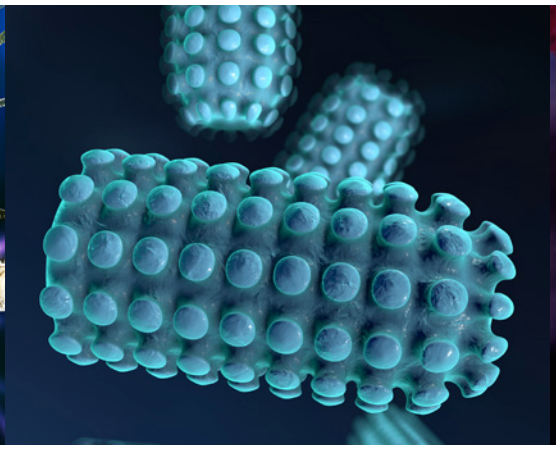
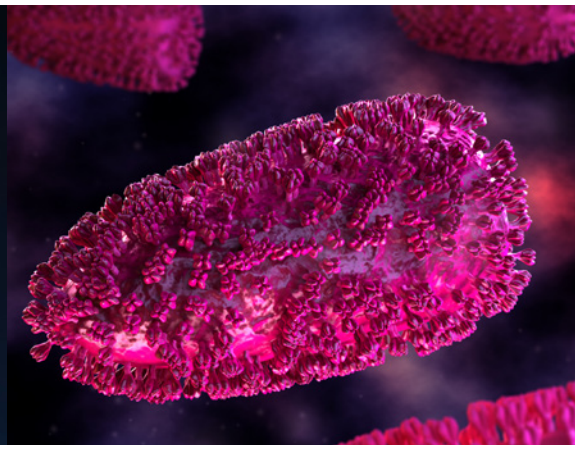

JUNE 2017

RABIES DIAGNOSTICS:

Assessing Your Public Health Laboratory

APHL ASSOCIATION OF PUBLIC HEALTH LABORATORIES™

BACKGROUND:

Rabies is a serious but preventable disease that primarily affects wild animals in the US. In 2014, more than 6,000 animal cases and one human case were reported to the US Centers for Disease Control and Prevention (CDC). When contact is made with a potentially rabid animal, the suspect animal must be tested to determine whether or not an exposure has occurred. This testing is routinely done in a public health laboratory or a state veterinary diagnostic laboratory. It is crucial that high quality testing capabilities are maintained and protocols are closely followed to ensure appropriate disease control practices are conducted and proper prophylaxis is initiated. Rabies testing services provided by public health laboratories provide an invaluable medical cost-saving in post-exposure prophylaxis for individuals potentially exposed to rabies.

Quality laboratory testing is essential to ensure proper treatment to those exposed. It is imperative that laboratories deliver accurate direct fluorescent antibody (DFA) results to healthcare providers within acceptable turn-around times, while also providing a safe environment for laboratorians to perform testing. *Rabies Diagnostics: Assessing Your Public Health Laboratory* has been developed by APHL to facilitate routine self-assessment of rabies testing practices for quality and safety. It is intended to be used as a self-assessment tool to provide laboratories with an opportunity to evaluate overall best practices when reviewing their own rabies testing program.

INTENDED USE:

This document is intended for any public health laboratory performing rabies testing in the US. It is designed to be a self-assessment tool and scores will not be compiled. Information is strictly for a laboratory's internal quality assurance, but information from this tool can be used to prepare laboratories to identify a future accreditation process that fits within their own public health laboratory quality system. Ultimately, it is the purview of the laboratory director, along with input from the quality assurance and safety management team, to decide how to best address deviations from practices found during the assessment. For example, when applied as a peer-to-peer laboratory audit program by the Northeast Environmental and Public Health Laboratory Directors, laboratories have shared the added benefit of insight on additional best practices beyond those captured in this assessment.

This document consists of five sections with a total of 91 questions based on the CDC's *Protocol for Postmortem Diagnosis of Rabies in Animals by Direct Fluorescent Antibody Testing*.

It consists of the following sections:

SECTION I: General Safety

- General Safety
- Medical Surveillance/Respiratory Protection / PPE
- Risk Assessment

SECTION II: Pre-Analytical

- Sample Collection and Handling

SECTION III: Analytical

- Rabies DFA Procedure
- Necropsy/ Dissection
- Fixation
- Staining
- Wash Procedure
- Mounting
- Microscopy
- Confirmatory Testing
- Variant Typing and Public Health Significance

SECTION IV: Post-Analytical

- Results Reporting
- Communications
- Turn-around Time
- Records Retention/Specimen Archive

SECTION V: Quality Assurance

[Questions included in this document are not all inclusive.]

Interpreting Your Results:

All questions will be answered with **"Yes," "No,"** or **"Not Applicable"** responses. A "Yes" answer indicates acceptable laboratory practices in a given area, while a **"No"** answer indicates there is room for improvement in this area. Guidance pertaining to this document will be published in the future. *NOTE: some questions may be acceptably answered as "No" due to state regulations or other mechanisms not captured in this document.*

It is recommended that laboratories with a high number of negative answers look into the reasons why a negative response was identified and reassess their rabies laboratory practices. It may be helpful to retake the assessment every six months to one year to determine your laboratory's progress.

Rabies Diagnostics:
Assessing Your Public Health Laboratory

Facility Name: _____

Audit Date: _____

Voluntary Auditors: (insert names) _____

_____

_____

Voluntary Auditees: (insert names) _____

_____

_____

SECTION I: GENERAL SAFETY

General Safety:

1 **Does your rabies laboratory maintain and follow a written, rabies laboratory-specific biosafety plan that includes the following components?**

A. Defines safe laboratory practices? ☐ Yes ☐ No ☐ Not Applicable

B. Includes a section on procedures for handling spills, potential exposures and other emergencies within the rabies laboratory? ☐ Yes ☐ No ☐ Not Applicable

C. Includes a section on procedures for handling spills, potential exposures and other emergencies within the specimen receiving area? ☐ Yes ☐ No ☐ Not Applicable

D. Defines (potentially) infectious waste disposal protocols? ☐ Yes ☐ No ☐ Not Applicable

E. Defines sterilization procedures for re-usable equipment? ☐ Yes ☐ No ☐ Not Applicable

F. Include a section on aerosol prevention techniques for all employees before assigning work with rabies specimens? ☐ Yes ☐ No ☐ Not Applicable

G. Include provisions for routine maintenance and service of equipment used by the rabies laboratory? ☐ Yes ☐ No ☐ Not Applicable

H. Include an after-hours policy for notification of supervisor prior to performing urgent testing in the laboratoryoutside of the laboratory's normal business hours? ☐ Yes ☐ No ☐ Not Applicable

Comments:

2 **Does your rabies laboratory require employees to review the biosafety plan annually?**

☐ Yes	☐ No	☐ Not Applicable
Comments:		

3 **Does your rabies laboratory ensure comprehensive general biosafety training of staff (e.g., bloodborne pathogens, hazardous waste disposal, hazard communication, chemical hygiene plan, etc) with annual renewal requirements?**

☐ Yes	☐ No	☐ Not Applicable
Comments:		

4 **Does your chemical hygiene plan or rabies-specific safety plan define how to dispose of chemical waste generated within your rabies BSL-2 or BSL-3 laboratory?**

☐ Yes	☐ No	☐ Not Applicable
Comments:		

5 **Does your rabies laboratory perform rabies testing within a designated BSL-2 or BSL-3 laboratory in your facility?**
Note: Rabies laboratories may operate within BSL-2 or ABSL-2 laboratory space unless the laboratory is generating aerosols such as using a Stryker saw. If a Stryker saw is in use, BSL-3 containment practices must be maintained. If your rabies laboratory performs testing in a BSL-2, then skip to question #9.

☐ Yes	☐ No	☐ Not Applicable
Comments:		

6 **If your rabies laboratory utilizes a Stryker saw for brain removal, are necropsies performed in a way that contains potential aerosols (biosafety cabinet, fume hood, Stryker saw HEPA filtered vacuum attachment)?**

☐ Yes	☐ No	☐ Not Applicable
Comments:		

7 **Does your BSL-3 rabies laboratory have a one-pass (non-recirculating) ventilation system?**

☐ Yes	☐ No	☐ Not Applicable
Comments:		

8 **If your rabies laboratory uses a BSL-3, are the environmental conditions monitored daily in the isolation room and is the facility recertified at least annually?**

☐ Yes	☐ No	☐ Not Applicable
Comments:		

9 Does your rabies laboratory perform all aerosol-generating manipulations such necropsy of rabies specimens in a biosafety cabinet?

☐ Yes	☐ No	☐ Not Applicable
Comments:		

10 Does your rabies laboratory use a centrifuge equipped with aerosol-free carriers with O-rings if working with potentially live virus? (There may be exceptions for some methods, e.g. PCR.)

☐ Yes	☐ No	☐ Not Applicable
Comments:		

11 Does your rabies laboratory decontaminate (eg: steam sterilization, chemical disinfection, and/or incineration) all personal protective equipment (PPE) and laboratory waste before it leaves the area?

☐ Yes	☐ No	☐ Not Applicable
Comments:		

12 Does your laboratory verify autoclave performance by using a biological indicator containing *Bacillus stearothermophilus* spores? If so, how often?

☐ Yes	☐ No	☐ Not Applicable
Comments:		

13 Indicate all of the types of hoods that your rabies laboratory utilizes for necropsy work.

A. Fume Hood? ..... ☐ Yes ☐ No ☐ Not Applicable

B. Class II BSC? ..... ☐ Yes ☐ No ☐ Not Applicable

C. Open bench top with splash guards and proper PPE worn by technicians? ..... ☐ Yes ☐ No ☐ Not Applicable

D. Down Draft/Back Splash with proper PPE worn by technicians? ..... ☐ Yes ☐ No ☐ Not Applicable

Comments:

14 **Does your rabies laboratory ensure that biosafety cabinets are certified at least annually?**

☐ Yes	☐ No	☐ Not Applicable
Comments:		

15 **Does your rabies laboratory provide annual biosafety cabinet training that includes:**

A. How to determine if BSC is functioning properly? ..... ☐ **Yes** ☐ **No** ☐ **Not Applicable**

B. How to properly work within/arrange items inside the BSC? ..... ☐ **Yes** ☐ **No** ☐ **Not Applicable**

C. How to de-contaminate the BSC between specimens? ..... ☐ **Yes** ☐ **No** ☐ **Not Applicable**

D. How to clean the BSC including lifting the grate to remove debris? ..... ☐ **Yes** ☐ **No** ☐ **Not Applicable**

Comments:

Medical Surveillance/Respiratory Protection/PPE:

16 **Does your rabies laboratory have a written rabies-specific or general laboratory Medical Surveillance Plan?**

☐ Yes	☐ No	☐ Not Applicable
Comments:		

17 **Within the Medical Surveillance Plan, does your rabies laboratory provide the following for all employees?**

A. Rabies vaccination for new employees? ..... ☐ **Yes** ☐ **No** ☐ **Not Applicable**

B. Ensure protective antibody response following vaccination of new employee prior to working in the rabies laboratory? ..... ☐ **Yes** ☐ **No** ☐ **Not Applicable**

C. Periodic rabies titer testing by RFFIT (CDC recommendation of every 2 years)? ☐ **Yes** ☐ **No** ☐ **Not Applicable**

D. Maintenance of a permanent record of rabies titers? ..... ☐ **Yes** ☐ **No** ☐ **Not Applicable**

Comments:

18 **Does your rabies laboratory limit access into the laboratory to vaccinated personnel only when specimens are being processed?**

☐ Yes	☐ No	☐ Not Applicable
Comments:		

19 **Does your rabies laboratory provide personal protective equipment that includes the following:**
(Note: A laboratory-specific biosafety risk assessment will inform the best choice of PPE for your individual operations)

A. Disposable, waterproof laboratory coats or gowns?	☐ Yes	☐ No	☐ Not Applicable
B. Disposable, waterproof aprons?	☐ Yes	☐ No	☐ Not Applicable
C. Latex or nitrile gloves?	☐ Yes	☐ No	☐ Not Applicable
D. Puncture resistant gloves for necropsy?	☐ Yes	☐ No	☐ Not Applicable
E. Disposable sleeve protectors?	☐ Yes	☐ No	☐ Not Applicable
F. Respiratory protection (N-95 or PAPR)?	☐ Yes	☐ No	☐ Not Applicable
G. Face & eye protection (specifically full-face protection)?	☐ Yes	☐ No	☐ Not Applicable
H. Shoe covers?	☐ Yes	☐ No	☐ Not Applicable

Comments:

20 **Does your rabies laboratory have a written Respiratory Protection Plan that includes annual training?**

☐ Yes	☐ No	☐ Not Applicable
Comments:		

21 **Does your rabies laboratory provide annual fit testing for N-95 respirators?**

☐ Yes	☐ No	☐ Not Applicable
Comments:		

Risk Assessment:

22 **Does your rabies laboratory have a written procedure and has it performed a formal risk assessment spanning all of the processes from specimen receiving to results reporting?**

☐ Yes	☐ No	☐ Not Applicable
Comments:		

23 **Does your rabies laboratory perform a formal risk assessment (includes biosafety and chemical safety) for all of the following reasons:**

A. On an annual basis? ☐ Yes ☐ No ☐ Not Applicable

B. Upon training a new employee to perform necropsy? ☐ Yes ☐ No ☐ Not Applicable

C. Whenever new staff is assigned to rabies testing? ☐ Yes ☐ No ☐ Not Applicable

D. Prior to instituting changes in the routine laboratory testing operations (prior to moving to new space; prior to a renovation)? ☐ Yes ☐ No ☐ Not Applicable

E. When a current staff member reports a change in risk status (such as immune compromised status, medication usage or pregnancy)? ☐ Yes ☐ No ☐ Not Applicable

Comments:

SECTION II: PRE ANALYTICAL

Sample Collection and Handling:

24 Does your public health laboratory maintain an up-to-date Laboratory Test Manual posted on your website (or available electronically) that includes rabies-specific information pertaining to specimen requirements, testing methods, and testing algorithms for submitters?

☐ Yes	☐ No	☐ Not Applicable
Comments:		

25 Does your public health laboratory provide instructions for specimen collection, storage and transport that are easily understood by the person collecting the specimen (this may include the general public in some states)?

☐ Yes	☐ No	☐ Not Applicable
Comments:		

26 As a part of your quality assurance (QA) program, does your rabies laboratory communicate regularly with submitters both to ensure that adequate specimens are obtained and to promote an understanding of quality assurance parameters?

☐ Yes	☐ No	☐ Not Applicable
Comments:		

27 **From the list below, what information do you include on the rabies laboratory submission form?**
Note: States may differ on their responses due to local requirements for epidemiologic demographics.

A. Identification information: to include submitter's Animal ID #/city/county/area of collection?	☐ Yes	☐ No	☐ Not Applicable
B. Date and time of collection?	☐ Yes	☐ No	☐ Not Applicable
C. Type of animal?	☐ Yes	☐ No	☐ Not Applicable
D. Animal gender?	☐ Yes	☐ No	☐ Not Applicable
E. Animal age?	☐ Yes	☐ No	☐ Not Applicable
F. Animal's vaccination status (when relevant)?	☐ Yes	☐ No	☐ Not Applicable
G. Name, phone number and address of person/persons exposed?	☐ Yes	☐ No	☐ Not Applicable
H. Type of Exposure (bite/pet/in the vicinity of/etc)?	☐ Yes	☐ No	☐ Not Applicable
I. Name, phone number and address of physician (s) responsible for exposed persons care?	☐ Yes	☐ No	☐ Not Applicable
J. Name and address of submitter or Health Department to contact with results?	☐ Yes	☐ No	☐ Not Applicable
K. Clinical information (symptoms of animals, reason for testing)?	☐ Yes	☐ No	☐ Not Applicable

Comments:

28 **Does your rabies laboratory or website have submitter instructions for specimen labeling and packaging of a Category B Biological Substance?**

☐ Yes	☐ No	☐ Not Applicable
Comments:		

29 **Does your rabies laboratory have personnel annually certified to package and ship Category B Biological Substances?**

☐ Yes	☐ No	☐ Not Applicable
Comments:		

30 **Does your rabies laboratory provide shipping containers for specimen transport via US Postal Service, commercial carrier or courier?** *Note: Some states may only provide shipping and packaging instructions.*

☐ Yes	☐ No	☐ Not Applicable
Comments:		

31 **Does your rabies laboratory have the following information available on its website or provide paper copies to the submitter:**

A. Criteria for acceptable specimens? ..... ☐ **Yes** ☐ **No** ☐ **Not Applicable**

B. Criteria for rejecting specimens? ..... ☐ **Yes** ☐ **No** ☐ **Not Applicable**

C. Reporting policy? ..... ☐ **Yes** ☐ **No** ☐ **Not Applicable**

D. Instructions for emergency or after-hours submission of specimens? ..... ☐ **Yes** ☐ **No** ☐ **Not Applicable**

Comments:

SECTION III: ANALYTICAL

Rabies DFA Procedure

32 Does your rabies laboratory maintain a current copy of CDC's *Protocol for Postmortem Diagnosis of Rabies in Animals by Direct Fluorescent Antibody Testing, a Minimum Standard for Rabies Diagnosis in the United States?*

☐ Yes	☐ No	☐ Not Applicable
Comments:		

33 Does your rabies laboratory follow this protocol in its entirety?

☐ Yes	☐ No	☐ Not Applicable
Comments:		

34 Does your rabies laboratory process and test, on average, at least 100 specimens per year as recommended in the ***Protocol for Postmortem Diagnosis of Rabies in Animals by Direct Fluorescent Antibody Testing?*** *Note: While testing less than 100 specimens per year may raise questions of proficiency, it may be beyond the control of the public health laboratory and be dependent on state-specific statutes requiring rabies testing.*

☐ Yes	☐ No	☐ Not Applicable
Comments:		

35 Does your rabies laboratory prepare its own control slides? If so, how often and what expiration date do you give them?

☐ Yes	☐ No	☐ Not Applicable
Comments:		

Necropsy/Dissection:

36 Does your rabies laboratory staff have a procedure for euthanizing live bats that have been submitted (either purposefully or accidently)?

☐ Yes	☐ No	☐ Not Applicable
Comments:		

37 If Eastern Equine Encephalitis virus is detected in your state, does your rabies laboratory practice necropsy procedures in accordance with the CDC's *Guidance on Containment for Work with Eastern Equine Encephalitis Virus?*

☐ Yes	☐ No	☐ Not Applicable
Comments:		

38 Does your rabies laboratory prepare separate slides for brain stem and cerebellum? *Note: If touch impressions are made, they both may be on the same slide in different wells.*

☐ Yes	☐ No	☐ Not Applicable
Comments:		

39 On bats, does your rabies laboratory prepare slides from the posterior half (brainstem and cerebellum) of the brain?

☐ Yes	☐ No	☐ Not Applicable
Comments:		

40 Does your rabies laboratory use a biosafety cabinet, fume hood or analogous exhaust system to dry brain impression/smear slides before acetone fixation?

☐ Yes	☐ No	☐ Not Applicable
Comments:		

41 When repeat testing is required, does your rabies laboratory prepare additional slides from the original tissue?

☐ Yes	☐ No	☐ Not Applicable
Comments:		

42 Does your rabies laboratory speciate all bats submitted to your laboratory?

☐ Yes	☐ No	☐ Not Applicable
Comments:		

Fixation:

43 Does your rabies laboratory fix slides in a -20°C acetone for at least one hour?

☐ Yes	☐ No	☐ Not Applicable
Comments:		

44 Does your rabies laboratory use ACS reagent-grade acetone?

☐ Yes	☐ No	☐ Not Applicable
Comments:		

45 Does your rabies laboratory use fresh acetone for each specimen to avoid cross contamination?

☐ Yes	☐ No	☐ Not Applicable
Comments:		

46 Does your rabies laboratory process a previously unfixed positive and negative control slide with all batches of slides processed?

☐ Yes	☐ No	☐ Not Applicable
Comments:		

Staining:

47 Does your rabies laboratory titrate all new lots of conjugate for determination of an optimal working dilution?

☐ Yes	☐ No	☐ Not Applicable
Comments:		

48 Does your rabies laboratory use syringe-filter system for the addition of conjugate to test slides?

☐ Yes	☐ No	☐ Not Applicable
Comments:		

49 Does your rabies laboratory use low-protein binding filters for the filtering of conjugates?

☐ Yes	☐ No	☐ Not Applicable
Comments:		

50 Does your rabies laboratory use Evans Blue counterstain in the DFA procedure?

☐ Yes	☐ No	☐ Not Applicable
Comments:		

51 Does your rabies laboratory stain all tissues (brain stem and cerebellum and/or hippocampus) with two different FITC-conjugates?

☐ Yes	☐ No	☐ Not Applicable
Comments:		

Wash Procedure:

52 Does your rabies laboratory use separate coplin jars or analogous slide containers for washing each specimen?

☐ Yes	☐ No	☐ Not Applicable
Comments:		

Mounting:

53 Does your rabies laboratory utilize the slide mountant and check the pH monthly (0.05 M Tris-buffered saline pH 9.0 with 20% glycerol) as described in the standard protocol or an acceptable commercial source: Scientific Products/ Baxter, Cat. #7644-1. *Note: Use of any other mountant, such as 90% glycerol, could produce false negative results.*

☐ Yes	☐ No	☐ Not Applicable
Comments:		

Microscopy (including equipment)

54 Does your rabies laboratory evaluate all specimens by two microscopists working independently?

☐ Yes	☐ No	☐ Not Applicable
Comments:		

55 Do microscopes employed by the rabies laboratory have annual maintenance performed by a certified microscope technician?

☐ Yes	☐ No	☐ Not Applicable
Comments:		

56 Has your laboratory purchased a microscope that meets the specifications (for objectives lenses, oculars and filter cube glass) described in the ***National Standard Protocol*** for rabies diagnosis in the last 10 years? *Background Note: It is recommended that the microscope purchased for rabies diagnosis represent the best that the manufacturer has in terms of light transmission and clarity which will typically come from the mid to upper range of their product line.*

☐ Yes	☐ No	☐ Not Applicable
Comments:		

57 Are the microscopes used for reading rabies DFA slides equipped with one of the following light sources?

- 100 Watt Mercury Arc Lamp ..... ☐ Yes ☐ No ☐ Not Applicable
- 75 Watt Xenon Arc Lamp ..... ☐ Yes ☐ No ☐ Not Applicable
- Metal Halide Lamp ..... ☐ Yes ☐ No ☐ Not Applicable

Comments:

58 If your rabies laboratory's microscope is equipped with a metal halide lamp, is the liquid light guide (cable attachment) changed with each lamp change?

☐ Yes	☐ No	☐ Not Applicable
Comments:		

59 **Does your rabies laboratory track usage time on the arc lamps and replace the arc lamps within their specified lifetimes or when performance drops off noticeably?** *Note: The useful life of an arc lamp (HBO, XBO and Metal Halide) depends on the conditions of use and may be less than the time limits defined by the manufacturer if the lamp is subjected to an excessive number of ignition cycles (ignition cycles should number no more than half the number of hours of lamp life, so for the HBO lamp this would be no more than 100 ignition cycles). The lamps are under the greatest stress during ignition and useful lamp life is compromised by short burn times (when the lamp does not reach full operating pressure and temperature) or during re-ignitions when the lamp is still warm.*

☐ Yes	☐ No	☐ Not Applicable
Comments:		

60 **Does your rabies laboratory use a 20X Plan Apochromatic* or 40X Plan Fluorite* objective lens for routine reading of rabies DFA slides? **Numerical aperture greater than or equal to 0.75.***

☐ Yes	☐ No	☐ Not Applicable
Comments:		

61 **If the 20X Plan Apochromatic objective is used for routine reading of rabies DFA slides, is a 40X Plan Fluorite also available for observation of the fine detail of rabies virus inclusions?**

☐ Yes	☐ No	☐ Not Applicable
Comments:		

62 **Does your laboratory monitor the condition and routinely clean oculars, objectives, and check lamp alignment of your DFA microscope at least once per month?**

☐ Yes	☐ No	☐ Not Applicable
Comments:		

Confirmatory Testing:

63 **When questions of specificity arise on the primary DFA test, does your rabies laboratory perform confirmatory testing employing Millipore Negative Control reagents?**

☐ Yes	☐ No	☐ Not Applicable
Comments:		

64 **When there are inconclusive rabies DFA results, does your rabies laboratory perform one or more of the following to try and complete a diagnosis?** *(Please contact Dr. Yu Li (lay4@cdc.gov) of CDC's Molecular Group in regards to LN34 real-time PCR and validation for use in your lab before initiating testing. Note:As of May 2017, rabies PCR is still under evaluation for use in routine diagnostics.)*

- Mouse inoculation? ☐ Yes ☐ No ☐ Not Applicable
- Cell culture inoculation? ☐ Yes ☐ No ☐ Not Applicable
- Send specimens to a reference laboratory for confirmation? ☐ Yes ☐ No ☐ Not Applicable
- Nucleic acid testing (PCR; sequencing)? ☐ Yes ☐ No ☐ Not Applicable

Comments:

Variant Typing and Public Health Significance:

65 **Does your rabies laboratory perform variant typing by one of the following methods?**

A. Monoclonal antibody panel? ☐ Yes ☐ No ☐ Not Applicable

B. Nucleic acid sequencing? ☐ Yes ☐ No ☐ Not Applicable

C. Send specimens to a reference laboratory for variant typing? ☐ Yes ☐ No ☐ Not Applicable

Comments:

66 **To support your state's rabies control efforts, does your rabies laboratory perform variant typing shortly (in real time) after a positive diagnosis is made or in compliance with your state's regulations?**

☐ Yes	☐ No	☐ Not Applicable

Comments:

67 Does your rabies laboratory have sufficient access to positive control samples for each variant type being tested?

☐ Yes	☐ No	☐ Not Applicable
Comments:		

68 Does your rabies laboratory perform monoclonal antibody typing or genetic sequencing on DFA positive specimens as part of surveillance for the potential introduction of new or novel variants of rabies virus?

☐ Yes	☐ No	☐ Not Applicable
Comments:		

69 If novel variants of rabies virus are detected by your rabies laboratory, does your rabies laboratory have a policy to share the results of variant typing with your state epidemiologists and CDC?

☐ Yes	☐ No	☐ Not Applicable
Comments:		

SECTION IV: POST ANALYTICAL

Results Reporting:

70 Does your rabies laboratory have a protocol for review of DFA test results in the context of the case exposure history and clinical signs of the animal tested, prior to result entry and verification in the laboratory information management system (LIMS)?

☐ Yes	☐ No	☐ Not Applicable
Comments:		

71 Does your rabies laboratory have adequate manual or electronic LIMS in place to ensure test results and demographics were accurately and reliably sent from the point of data entry to final report?

☐ Yes	☐ No	☐ Not Applicable
Comments:		

72 Does your rabies laboratory have a standard operating procedure for review and maintenance of quality data from each test prior to reporting of test results?

☐ Yes	☐ No	☐ Not Applicable
Comments:		

73 Does your rabies laboratory have a standard operating procedure that separates the result entry step in the LIMS from the verification step, each step ideally performed by separate technologists?

☐ Yes	☐ No	☐ Not Applicable
Comments:		

Communications:

74 Does your rabies laboratory have policy for documenting all communication related to individual specimens (electronic or manual such as a telephone log)?

☐ Yes	☐ No	☐ Not Applicable
Comments:		

75 Does your rabies laboratory have a communication process with other laboratories (internal to your public health laboratory) or with a veterinary diagnostic laboratory in your state if rabies specimens are tested for other agents such as eastern equine encephalitis virus?

☐ Yes	☐ No	☐ Not Applicable
Comments:		

76 Does your public health laboratory designate a positive or inconclusive test as a critical value that must be immediately communicated to the submitter and public health officials?

☐ Yes	☐ No	☐ Not Applicable
Comments:		

Turn-around Time:

77 Does your rabies laboratory report results to the submitter within a predetermined turn-around time (e.g., routinely within 24 hours of sample receipt)?

☐ Yes	☐ No	☐ Not Applicable
Comments:		

Records Retention/ Specimen Archiving

78 Does your rabies laboratory follow a policy on control and storage of test records and requisition forms according to your state's record retention regulations for health records?

☐ Yes	☐ No	☐ Not Applicable
Comments:		

79 Does your public health laboratory have an overall specimen retention policy that includes the rabies laboratory and is written in conjunction with your State Epidemiologist?

☐ Yes	☐ No	☐ Not Applicable
Comments:		

SECTION V: QUALITY ASSURANCE

Quality Assurance:

80 If a test result error is identified on the final report, does your rabies laboratory notify the submitter?

☐ Yes	☐ No	☐ Not Applicable
Comments:		

81 Does your rabies laboratory maintain a problem log?

☐ Yes	☐ No	☐ Not Applicable
Comments:		

82 Does your rabies laboratory have a system for implementing a corrective action and perform root cause analysis for any corrective actions? (Examples of situations that require corrective actions include missed PT challenges, misreporting of results, etc,)

☐ Yes	☐ No	☐ Not Applicable
Comments:		

83 Does your rabies laboratory document daily the performance of all equipment including temperature charts for freezers, refrigerators, incubators or a log of light bulb hours for microscopes for all equipment utilized in the rabies laboratory, during the work week?

☐ Yes	☐ No	☐ Not Applicable
Comments:		

84 Does your rabies laboratory perform an annual pipette calibration?

☐ Yes	☐ No	☐ Not Applicable
Comments:		

85 Does your rabies laboratory strive to eliminate procedures that could produce cross contamination if you are performing DFA and PCR procedures?

☐ Yes	☐ No	☐ Not Applicable
Comments:		

86 Does your rabies laboratory require annual review of all policies and laboratory testing SOPs by the staff using them and the laboratory director?

☐ Yes	☐ No	☐ Not Applicable
Comments:		

87 Does your rabies laboratory staff review QA records at least monthly?

☐ Yes	☐ No	☐ Not Applicable
Comments:		

88 For all reagents used in the rabies testing, does your rabies laboratory have a system for documenting receipt of reagents, QC test date of a reagent, and the date the reagent was put into use by the laboratory?

☐ Yes	☐ No	☐ Not Applicable
Comments:		

89 Does your rabies laboratory maintain the following quality assurance-associated personnel records?

- Training Records? ..... ☐ Yes ☐ No ☐ Not Applicable
- Annual Competency assessment that includes the six components (direct observation, monitoring resulting/reporting, review of intermediate test results/QC/PT/PM, direct observation, assessment of test performance, and problem solving skills/exam)? ..... ☐ Yes ☐ No ☐ Not Applicable
- Annual procedure/policy review? ..... ☐ Yes ☐ No ☐ Not Applicable

Comments:

90 Does your rabies laboratory subscribe to an external PT program that provides specimens twice per year?

☐ Yes	☐ No	☐ Not Applicable
Comments:		

Additional Comments:

General Comments:

The Association of Public Health Laboratories

The Association of Public Health Laboratories (APHL) works to strengthen laboratory systems serving the public's health in the US and globally. APHL's member laboratories protect the public's health by monitoring and detecting infectious and foodborne diseases, environmental contaminants, terrorist agents, genetic disorders in newborns and other diverse health threats.

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