Republic of the Philippines
Department of Agriculture
BUREAU OF ANIMAL INDUSTRY
VETERINARY LABORATORY DIVISION
ANIMAL DISEASE DIAGNOSIS AND REFERENCE LABORATORY

REQUIREMENTS CHECKLIST FOR VETERINARY DIAGNOSTIC LABORATORY ACCREDITATION

Application Number:		Application Date:
Company Name:		Company Address:
Laboratory Name:		Laboratory Address:
Contact Person:		*Laboratory* E-mail Address:
Designation:		Contact Number:
TYPE OF LABORATORY *(Check Applicable)*	☐ Government (Public Institution) Specify:	☐ Non-Government (Private Institution) Specify:

Type of Application (Check Applicable):

☐ **Initial** – comply all items in the list ➢ *New Applicant* ➢ Inactive for more than 3 years; ➢ Accredited test/s expired for more than 6 months ➢ *Provisional for 1 year upon accreditation*	☐ **Renewal** – comply all items <u>except Item No. 2.0</u> ➢ With accredited test/s expiring within 6 months during application

ITEM NO	GENERAL DOCUMENTARY REQUIREMENTS	*COMPLIED*	REMARKS
1.0	Duly accomplished application form with **signed statement of Intent** and agreement to officially apply for accreditation accompanied by the documentary requirements listed below.		
	1.1 Accomplished **Application form** for Veterinary Diagnostic Laboratory Accreditation **(GF ADDRL-06)** filed in a blue hard folder (presentation binder or lever arch file folder) with all the requirements arranged and tabbed according to Checklist in the Veterinary Diagnostic Laboratory Accreditation Requirements (GF ADDRL-04) and additional supporting documents, if necessary.		
	REMINDER: Applications filed with incomplete information, (incomplete general and specific documentary requirements) will not be accepted.		
Proof of Business Registration (Non-Government/Private)			
2.0	2.1 For Corporations - Securities and Exchange Commission (**SEC**) Registration		
	2.2 For sole proprietorships or partnerships - Department of Trade and Industry (**DTI**) Registration		
	2.3 Cooperative Development Authority (**CDA**) Registration for Cooperatives		

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3.0	Current **Mayor's or Business Permit**		
4.0	*4.1 Latest Audited Financial Statement; such document shall be the same as the one submitted to the Bureau of Internal Revenue and, in case of corporations, to SEC.*		
	4.2 For start-up businesses, in lieu of Audited Financial Statement, a fairly conservative feasibility study with at least five years of financial projection and sensitivity analysis.		
5.0	**Company Profile with defined organizational structure** (Management Structure of the Laboratory, and its place in any parent organization)		
	5.1 Company's Organizational Structure and Plantilla positions, Office and establishment location map with geo-tagged photos;		
	Government / Public:		
	5.2 Department/Agency's Organizational Structure and Plantilla positions or officers and positions for Colleges / Universities etc.		
6.0	***Compliance Certificate/s*** (whichever is applicable/available)		
	6.1 Environmental Compliance Certificate (**ECC**)		
	6.2 Certificate of Non-Coverage (**CNC**)		
	6.3 Certification/Accreditation to the following International Standards or its equivalent, *6.3.1* ISO 9001:2015 Certification *6.3.2* ISO 17025:2017 Accreditation *6.3.3* Certificate of Proficiency testing (PT) for the test applied for, if applicable. (PT should be operated by an independent authority) *6.3.4* Others (Specify)		
SPECIFIC DOCUMENTARY REQUIREMENTS:			
DOCUMENTARY AND TECHNICAL EVIDENCES (to objectively demonstrate technical competence to provide services such as testing, technical assessment or evaluation, on behalf of the DA Regulatory Agency)			
STRUCTURAL REQUIREMENTS:			
7.0	**Floor Plan** – Laboratory design/ layout or photos of rooms with appropriate labels compiled in a PDF file.		
	7.1. Facilities are designed and constructed with safety controls to minimize the risk of injury, occupational illness, *and biological release to the environment.* *7.1.1* Ample space is provided for the safe conduct of laboratory work and for cleaning and maintenance.		

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	7.1.2 Optimize to increase work efficiency and create a unidirectional workflow (**from the clean area to the dirty area)** to prevent cross contamination and separate rooms for incompatible activities		
	Personnel complement		
8.0	*8.1* Sufficient Number of employees/ Personnel with assigned understudy or reliever relative to task/s performed *8.1.1 Permanent/ Resident Veterinarian: 1* *8.1.2. Laboratory Technician/ Analyst: minimum of 2* *8.1.3 Laboratory Aide: 1* *8.1.4 Utility Worker/ Janitor: 1* *8.2 Laboratory Head:* *The head of the laboratory shall be a competent and experienced professional veterinarian, with a specialized skill set related to and proportionate to the laboratory category, to ensure that the laboratory runs efficiently. The head of the laboratory is essentially responsible for the operation of the entire laboratory, its personnel, functions, and data, all of which shall meet the quality assurance criteria and regulatory requirements.* *The head of the laboratory shall* be responsible for conducting safety studies, analysis of the results and interpretation, documentation and reporting of the test results and **notifiable diseases**. *8.3 Analyst* 1. *Doctor of Veterinary Medicine* 2. *Registered Medical Technologist* 3. *Microbiologist* 4. *Or any allied health professionals with training and minimum of 3 years of experience with animal diagnostic.* 5. Analysts must have a valid PRC License Number; (especially when authorized to sign the test results) 6. Analyst's relevant training records / certificates to *establish* competency to perform laboratory activities for which they are responsible (including biosafety training.) o *Training certificates may also be given by a*		

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	licensed mentoring senior staff duly trained for the specific test. *8.4 Approved signatories can only be from the following professions:* *8.4.1 Performed by: DVM/RMT/Microbiologist* *8.4.2 Reviewed/Approved by: Head of Laboratory* *8.5* Employees should be well qualified (with relevant educational background, experience or training as per the job assigned) *8.6* Signed Job Description of each Personnel (Documented job profiles, tasks and responsibilities. (Technical knowledge, and skills noted by the immediate supervisor to perform / conduct, monitor, record, report and ensure quality of specific laboratory activities)		
TECHNICAL PROCEDURES:			
9.0	Documented **STANDARD OPERATING PROCEDURES (SOP)** - Used to ensure the consistent application of its laboratory activities and the validity of its results. *9.1 SOPs should be:* *9.1.1 Printed with headers (Company name and Logo)* *9.1.2 Each document must contain the following details:* *9.1.2.1 Document Name/Title* *9.1.2.2 Document type (Technical Procedure / Work Instruction)* *9.1.2.3 Document Code* *9.1.2.4 Revision number, date of effectivity and page number of total pages.* *9.1.2.5 Person responsible /Process owner for the conduct of each technical procedure (TP) and the reviewing/approving authority for the said procedure.* *9.1.2.6 Reference used where the procedure was taken from. (Must be valid and reliable or from updated published and printed references). References used as external documents are also coded and may be required or presented for verification.* *9.1.2.7 Records and supporting documents.* *9.2* SOP's specifies the manner in which the protocol or specific activities are carried out and derived from valid or published updated references. *9.3* SOP's to be followed are written or documented by the		

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	operators in charge (process owner) and reviewed by the supervisor. *9.4* SOP's ensure that *information* in the working protocols are accurate and are reliable for routine use. *9.5* SOP's ensure that quality assurance is available to control internal functions and check if there's any discrepancy /nonconformity that occurred during the entire test process. *9.6* SOP's ensure that facilities, equipment, personnel, practices, protocols, records, reports, handling of tests/ analysis, interpretation, and reporting of the test results are controlled and documented. *9.7* SOP's ensure that raw data are processed or analyzed and retained accordingly.		
FACILITIES AND ENVIRONMENTAL CONDITIONS:			
10.0	Facilities and environmental conditions suitable for the laboratory activities and shall not adversely affect the validity of test results. *10.1* Facilities include limited access to the building where laboratory activities are performed, with rooms of adequate size and construction for different activities *10.2* *There should be* effective separation between areas with incompatible laboratory activities. *10.3* Monitor, control and record environmental conditions in accordance with relevant specifications, methods or procedures or where they influence the validity of the results *(Room temperature, relative humidity)* *10.4* Measures to control facilities such as access to and use of areas affecting laboratory activities *(Logbooks, biometric locks, etc.)*		
EQUIPMENT: Calibration and Maintenance			
11	Equipment (measuring instruments, software, measurement standards, reference materials, reference data, reagents, consumables or auxiliary apparatus) that is required for the correct performance of laboratory activities and that can influence or having an effect on the validity of the reported test results. *11.1* Master list / Inventory of Equipment (Identity of equipment and its software/firmware version; manufacturer's name, type identification and serial number; condition (evidence of verification that equipment conforms with specified requirements); current location; (with details on age or date acquired),		

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	○ **Essential Biosafety Equipment**- (not limited to the following) Pipetting Aids, Biosafety Cabinets, water bath, autoclave, etc. *11.2* Labeled, coded or otherwise identified to allow the user of the equipment to readily identify the status of calibration or period of validity. *11.3* Calibration Program for measuring equipment being *used* *11.3.1* calibration dates, and the due date of the next calibration or the calibration interval; *11.3.2* results of calibrations, adjustments, (acceptance criteria); *11.3.3* carried out *by* a calibration laboratory with accreditation as a calibration body specific to the equipment *11.4* Procedure for *proper* handling, transport, storage and use. *11.5* Maintenance Plan of equipment (preventive maintenance) and the maintenance carried out to date, relevant to the performance of the equipment; *11.6* User's Equipment Maintenance Checklist to verify that the equipment conforms to specified requirements before being placed for use or returned into service. *11.7* Records of Equipment Maintenance and other documents pertaining to the equipment (Details of any damage, malfunction, modification to, or repair including disposal of the equipment.)		
12	Master List of Reference Materials or Reference Standards and reagents *12.1* Documentation of reference materials / standards/ controls should include results, acceptance criteria, relevant dates and the period of validity; *12.2* Reagents or Test Kits (with certificate of product registrations from BAI, if applicable)		
TECHNICAL RECORDS: Records for each laboratory activity (contain the results, report and sufficient information to facilitate, and if possible, identification of factors affecting the measurement result). Records shall include the date and the identity of personnel responsible for each laboratory activity and for checking data and results. Original observations, data and calculations shall be recorded at the time they are made and shall be identifiable with the specific task. Ensure that amendments to technical records can be tracked to previous versions or to original observations. Both the original and amended data and files shall be retained, including the date of alteration, an indication of the altered aspects and the personnel responsible for the alterations. Retain legible records to demonstrate fulfillment of the requirements in this document.			
13	Use of Updated Laboratory Forms (Blank or unfilled-up forms preferably with codes, revision number and date of effectivity)		

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	13.1 Worksheets (Raw Data Sheets) *13.2* Test Request Form (with sufficient information to identify the test sample, when and where it was taken or prepared, and which test/s and/or procedure/s are to be performed. *13.3* Test Report Form (with description of the test sample submitted; methodology used and its test result, customer information and authorized signatories) *13.4* Laboratory Equipment maintenance checklists *13.5* Retention and retrieval of Records - Filled-up blank forms and Logbooks, etc. with identification labels or codes (Manner of storing, retrieving and disposal of records)		
REPORTING OF RESULTS (All issued reports shall be retained as technical records.)			
14	Test reports are provided accurately, clearly, unmistakably and objectively 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. *14.1* Reviewed and authorized prior to release. *14.2* Reports can be issued as hard copies or by electronic means, provided that the requirements of this document are met. *14.3* Test reports must include at least the following information, (unless the laboratory has valid reasons for not doing so, thereby minimizing any possibility of misunderstanding or misuse): a. a title (e.g., "Test Report") b. the name and address of the laboratory; c. unique identification that all its components are recognized as a portion of a complete report and a clear identification of the end; d. the name and contact information of the customer; e. identification of the method used; f. a description, unmistakable identification, and, the condition of the item; g. the date of receipt of the test sample h. the date(s) of performance of the laboratory activity; i. the date of issue of the report; j. a statement to the effect that the results relate only to the items tested, or sampled; k. the results with the units of measurement; l. identification of the person(s) conducting the test and authorizing the issuance of the test report; m. clear identification when results are from external		

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	providers **NOTE:** Including a statement specifying that the report shall not be reproduced except in full without approval of the laboratory can provide assurance that parts of a report are not taken out of context.		
BIOSAFETY AND WASTE MANAGEMENT PLAN			
15	○ *Handling of Test Items* Procedure for the transportation, receipt, handling, protection, storage, retention, and disposal or return of test items, including all provisions necessary to protect the integrity of the test item, and to protect the interests of the laboratory and the customer. *15.1* Precautions taken to avoid deterioration, contamination, loss or damage to the item during handling, transporting, storing/waiting, and preparation for testing. *15.2* Handling instructions provided with the item are followed. *15.3* Have a system for the unmistakable identification of test samples to ensure that items will not be confused physically or when referred to in records or other documents. *15.4* Acceptance and Rejection criteria for test samples to avoid doubts about the suitability of an item for testing *15.5* Maintain record and monitor the storage of test samples (if there is a need to be stored or conditioned under specified environmental conditions.) *15.6* Biological samples, reagents and other items shipped to other laboratories / reference laboratories are clearly labeled for biosafety hazards. *15.7 Minimum requirements for Biosafety-related documents* *15.7.1 Use of Personal Protective Equipment (PPE)* *15.7.2 Procedures for cleaning-up and decontaminating spills for the laboratory performed by suitably trained personnel.* *15.7.3 Clear reporting structure is established for reporting of safety incidents, accidents and/ or near-misses. (Staff should know whom to consult for biosafety reporting at all times. Chain of responsibility leading to the head of the organization)* *15.7.4 All safety practices and policies are in use and available.* *15.7.5 Vaccination records for staff testing for Avian Influenza (Flu vaccine) and Rabies (Pre-exposure Prophylaxis) are appropriately completed,*		

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	maintained and easily recovered. *15.7.6 Use of chemical and biological indicator for autoclave run.* *15.7.7 Designated person as Biosafety Officer* *Safety systems should cover fire, electrical emergencies, and emergency shower and eyewash facilities.* *15.8 Biosecurity-related documents* *Statements/provision regarding the following pillars of biosecurity:* *15.8.1 Material Control and accountability* *15.8.2 Information security* *15.8.3 Transport security* *15.8.4 Emergency response* *15.9 Risk Assessment* *15.9.1 List of identified/ potential risks in the laboratory and its mitigation* *15.9.2 List of identified/ potential risks in the laboratory and its mitigation*		
ANIMAL FACILITY DESIGN AND LAYOUT (*if applicable*)			
16	Conforming to the minimum standards set by the Animal Welfare Act (RA 8485 s1998, Sec. 2) *16.1* Registered with BAI Animal *Health* and Welfare Division *16.2 Program for* arthropod and rodent control. *16.3* Physical and fire security measures are considered.		
LABORATORY SERVICES AND FEES / CHARGES			
17	List of laboratory services offered and corresponding fees *17.1* Acceptance and rejection criteria for samples submitted		