

Animal Diseases (Veterinary Laboratories) Regulations 2025

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THE ANIMAL DISEASES ACT

Regulations made by the Minister under section 17 of the Animal Diseases Act

1. These regulations may be cited as the **Animal Diseases (Veterinary Laboratories) Regulations 2025**.

2. In these regulations -

"Act" means the Animal Diseases Act;

"designated personnel" means an employee of the veterinary laboratory designated as such by the licensee;

"DVS" means the Division of the Veterinary Services of the Ministry;

"laboratory manual" means the manual of the veterinary laboratory;

"licence" means a licence issued under regulation. 4(4)(a);

"licensee" means the holder of a licence;

"veterinary laboratory" means a facility, State-owned or private, where -

(a) samples of animal origin are received, stored, processed and tested -

(i) for the purpose of diagnosis and research of animal diseases;

(ii) for residues of veterinary medicinal products and antimicrobial resistance and doping agents; or

(b) embryo, follicles or semen is collected, evaluated and stored for the purpose of animal breeding.

3. Veterinary laboratory

No person shall operate a veterinary laboratory unless he holds a licence.

4. Application for licence

- (1) Any person who intends to operate a veterinary laboratory shall make an application in the form set out in the First Schedule.
- (2) The application under paragraph (1) shall be accompanied by -
 - (a) the address of the premises where a veterinary laboratory will be set;
 - (b) the name and registration certificate of the veterinarian who will conduct any experiment or testing;
 - (c) the proposed laboratory manual; and
 - (d) such other information as the DVS may require.
- (3) Where the DVS -
 - (a) grants the application, it shall, on payment of the fee specified in the Second Schedule, issue a licence in the form set out in the Third Schedule on such terms and conditions as it may determine; or
 - (b) rejects the application, it shall, not later than 21 days of its decision, inform the applicant accordingly.
- (4) A licence issued under paragraph (3)(a) shall be valid for a period of one year and may be renewable for further periods of one year.

5. Application of renewal of licence

- (1) An application for the renewal of a licence shall be made prior to the expiry of the licence and shall be accompanied by the information and documents required under regulation 4(2).
- (2) Where the DVS -
 - (a) grants the application, it shall, on payment of the fee specified in the Second Schedule, issue a licence in the form set out in the Third Schedule on such terms and conditions as it may determine; or
 - (b) rejects the application, it shall, not later than 21 days of the decision, inform the applicant accordingly.

6. Lost, defaced or destroyed licence

(1) Where a licence is lost, defaced or destroyed, the licensee shall, as soon as possible, report such loss, damage or destruction to the Police and apply to the DVS for a duplicate.

(2) (a) The DVS shall, on receipt of an application under paragraph (1), and on payment of the appropriate fee specified in the Second Schedule, issue a duplicate licence to the licensee.

(b) The licence issued under subparagraph (a) shall be marked "DUPLICATE".

(3) Where, after the issue of duplicate licence, the original licence is found, the licensee shall forthwith surrender the original licence to the DVS.

7. Register

Every licensee shall, for the purposes of these regulations, keep a register where the following shall be recorded -

- (a) the name, address, contact details and working hours of the designated personnel of the veterinary laboratory;
- (b) the name of the veterinary surgeon responsible for validating test results;
- (c) the experiment or testing carried;
- (d) the date of the experiment or testing carried;
- (e) the species of animals for collection of embryo, semen, follicles or such other gametes;
- (f) the types of diseases tested; and
- (g) the result of the experiment or testing, as the case may be.

8. Designated personnel

(1) Every veterinary laboratory shall, at all times, be under the responsibility of a designated personnel.

(2) The designated personnel shall be responsible to ensure that all employees adhere to the conditions specified in the licence and the laboratory manual approved by the DVS.

9. Deviation in procedures and operation of veterinary laboratory

(1) A designated personnel shall make an application to the DVS of any intended deviation in the procedures or operation of the veterinary laboratory which differ from the conditions specified in the licence or laboratory manual one month prior to such deviation.

(2) The designated personnel shall await the reply of the DVS prior to the implementation of any intended deviation.

(3) The DVS shall approve or disapprove any intended deviation within 28 days of an application made under paragraph (1).

10. Laboratory manual

A laboratory manual shall be approved by the DVS and shall contain the following -

- (a) an organisational structure and hierarchy of its employees;
- (b) a site plan and a structural plan of the veterinary laboratory detailing the operation mechanism of the laboratory which shall be inclusive of the sample flow of samples and waste;
- (c) training protocol for its employees;
- (d) biosecurity and biosafety measures;
- (e) protocol for the reception of sample, labelling, storage and disposal;
- (f) methodologies being used at the laboratory for the diagnosis of diseases;
- (g) methodologies for the diseases listed by the World Health Organisation which shall be in line with the recommendations of the World Organisation for Animal Health;
- (h) standard operating procedures and job aids for diseases tested;
- (i) protocol for waste management;
- (j) breeds and species for animals used as sire, donor or recipient animals;
- (k) number of animals used at the veterinary laboratory;
- (l) capacity per day for the production of semen or embryo; and
- (m) capacity for the number of samples to be processed per day.

11. Offences

Any person who contravenes these regulations shall commit an offence and shall, on conviction, be liable to a fine not exceeding 1,000 rupees and to imprisonment for a term not exceeding one year.

12. Commencement

These regulations shall come into operation on 21 August 2025.

FIRST SCHEDULE

[Regulation 3]

APPLICATION FORM FOR REGISTRATION AS PRIVATE VETERINARY LABORATORY

1. Name of owner.....

2. Address

3. Contact details

Phone no.....	Mobile no.
Fax no.	Email address

4. Details of laboratory

Name	Address.....
Phone no.	Fax no.
Email address	Name of responsible person.....
Name of supervising veterinary surgeon of diagnostic test	

5. Object of the laboratory.....
.....

6. Types of diseases tested.....

7. Breeds and species of donor, sire and recipient animals to be kept.....

8. Reproductive techniques to be used at the laboratory.....
.....

9. Methods for testing for each disease
.....

10. Name and qualification of person responsible for conducting the reproductive techniques and contact details

Name Phone no..... Email address.....	Qualifications Mobile no.....
Name..... Phone no..... Email address	Qualifications..... Mobile no.....
Name Phone no..... Email address	Qualifications..... Mobile no.

Name	Qualifications.....
.....	
Phone no.....	Mobile no.
Email address	

11. Details of laboratory staff

Name	Qualifications
.....	
Phone no.....	Mobile no.....
Email address.....	
Name.....	Qualifications.....
.....	
Phone no.....	Mobile no.....
Email address	
Name	Qualifications.....
.....	
Phone no.....	Mobile no.
Email address	

12. Number of employees in the laboratory.....

13. Laboratory manual submitted.....

SECOND SCHEDULE

[Regulations 4(4)(a), 5(2)(a) and 6(2)]

FEES

	(Rs)
1. Issue of licence	10,000
2. Renewal of licence	5,000
3. Issue of duplicate licence	10,000

THIRD SCHEDULE

[Regulation 3]

LICENCE FOR VETERINARY LABORATORY

.....
(name of laboratory), located at.....
(address), is allowed to operate for a period of.....(month/year*) under the following conditions -

- (a) the approved laboratory manual shall be complied with;
- (b) only the test for the diseases and use of the methodologies specified below shall be conducted -

	DISEASES	METHODOLOGIES
1.		
2.		
3.		

- (c) the reproductive techniques approved are as follows –

.....
.....
.....

(d) the species of sire, donor and recipient animal kept are as follows –

.....
.....
.....

(e) the number of sire, donor and recipient animals allowed to be kept are as follows –

.....
.....
.....

(f) a list of officers responsible for the following duties are maintained -

- (i) sample reception;
- (ii) sample processing;
- (iii) conducting tests;
- (iv) interpretation of results;
- (v) validation of results;
- (vi) taking care of sire, donor and recipient animals;
- (vii) conducting reproductive techniques
