15. REQUIREMENTS FOR SETTING UP A DIAGNOSTIC LAB

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Complete Laboratory Set-up

The queries that arise upon for setting up a diagnostic lab are

1. What equipment and supplies are best suited for your needs?
2. What is it going to take to set up all the equipment and who is going to do it?
3. What about all the compliance issues and necessary manuals?

Select and purchase all necessary equipment and supplies, and:

- Arrange for transportation to the final destination
- Arrive with the package to carefully unpack all items
- Arrange and organize each department
- Certify all equipment operational

Arrange for equipment training by either:

- Onsite training by experts.
- On site training by equipment manufacturers representatives.
- In house training at manufacturing location within the location.

Perform supplemental training on:

- Specimen knowledge
- Diagnostic Test Kits
- Patient Reporting
- Quality Control
- Quality Assurance
- Record Keeping
- Hazardous Waste
- Health & Safety

- Cost Control
- Inventory Control
- Supply Ordering

I. Definition of Diagnostic Specimens:

A Diagnostic Specimen is defined as "any human or animal material including excreta, secreta, blood and its components, tissue, and tissue fluids being transported for diagnostic or investigational purposes, but excluding live infected humans or animals."

Plates or cultures of bacterial or viral organisms are NOT included in the definition of "Diagnostic Specimen" and may only be shipped under much more stringent requirements and regulations.

Specimens from suspected cases of foreign animal diseases (FADs) and other very highly infectious and virulent diseases do not fall within these guidelines.

II. Packaging Required For Shipment of Diagnostic Specimens:

Unless Diagnostic Specimens are transported by "ground based private or contract carriers using dedicated vehicles and these materials must conform to the standards."

The stringent parcel size limitation for "Shipments by Air of Diagnostic Specimens" is important for any routine ships by air.

A. Diagnostic Specimens must be packaged in triple packaging consisting of:

1. A primary receptacle:
   Those cannot break, be punctured, or leak their contents into the secondary packaging.
2. Leak-proof secondary packaging:
Secondary packaging(s) must be secured in outer packaging(s) with suitable cushioning material such that any leakage of the contents will not impair the protective properties of the cushioning material or the outer packaging.

3. Outer packaging:
- Outer packaging must be clearly and durably marked with the words "Diagnostic Specimens".
- The completed package must be capable of successfully passing the drop test at a drop height of at least 1.2 meters (3.9 feet).

4. Liquid Diagnostic Specimens must be packaged where the:
- Primary receptacle is leak-proof with a volumetric capacity of not more than 500 ml (16.9 ounces)
- Absorbent material of sufficient quantity to absorb the entire contents of the primary receptacle(s) is placed between the primary receptacle and secondary packaging
- Multiple fragile primary receptacles placed in a single secondary package must be individually wrapped or separated as to prevent contact between them
- Secondary packaging must be leak-proof

LABORATORY DIAGNOSTICS
Lab diagnostics fall under several categories as
- Clinical Lab Tests, Pathology Laboratory Tests, Genetic Laboratory Tests ~ Neuro-muscular Laboratory Testing Medical Tests (Infants, Children & Adults that include Diagnostic Techniques & Procedures, Lab Techniques pertinent to those labs.

Biochemistry laboratory techniques & chemical experiments include
- Bio laboratory protocols, methods & techniques , Molecular Biology Protocols, Apoptosis Protocols ~ Histology Protocols, Methods & Techniques HPLC, HPLC Columns, Spin Columns, Electrophoresis Gels

Microbiological laboratory: Microbiological Analyses of Foods & Cosmetics
Microfluidics: Lab-on-a-Chip Technology
Microscopy techniques & protocols
- Microscopy, Photomicrography & Digital Imaging Techniques Transmission Electron Microscopy
- TEM, Cryosectioning, Immunocytochemistry, etc. Each and every lab requires Multimedia Teaching Modules (Text & Images). Laboratory Methods include: Susceptibility Testing; Culture Techniques and Media; Microscopy Techniques and Stains; & Specimen Collection and Processing etc., of its own kind.

Differential Diagnosis, Laboratory Techniques & Procedures, etc.

The National Guidelines Clearinghouse (NGC) is an Internet Web site intended to make evidence-based clinical practice guidelines and related abstract, summary, and comparison materials widely available to health care professionals and the details may be collected from this site as and when it is needed.

Quality control and quality assurance

The threat posed by emerging and re-emerging communicable diseases and, more recently, by the intentional release of infectious agents in a susceptible population, has been receiving considerable attention at the national and international levels. Public health efforts to strengthen disease detection, surveillance and control have been intensified. However, clinicians and clinical microbiology laboratories play an important role in the early detection of disease, the identification of the putative agent, and notification of the appropriate authorities. To be effective in this role, laboratories must be specially prepared to handle infective agents safely, and need, among other things, the appropriate rapid and sensitive diagnostic tests. A public website is available at http://www.enivd.de/ to know about infectious agents and the related topics.
Equipment in PCR Laboratories

Development of the polymerase chain reaction (PCR) as a basic component of the molecular biology laboratory has occurred very rapidly from its inception in 1985.

To ensure that pre-PCR and post-PCR events remain separated, each room must have its own separate set of equipment, including pipettors, reagents, pipettor tips, racks, and so forth. Moreover, these items should not leave the area to which they are assigned. Each should be labeled as to location and used in that location only. Lab coats should be dedicated for both areas as well. Because pipetting forms the basis for most PCR analysis, each area needs its own dedicated pipettors that are never exchanged between work areas. To assist with this, color-coded pipettors (e.g., green for pre-PCR work, red for post-PCR work) can be used. When pre-PCR pipettors and tips are not in use, they should be stored in airtight bags to keep them clean. Reactions should be constructed using master mixes, and the template should always be added last using positive displacement tips to prevent pipettors from becoming cross-contaminated while pipetting samples that contain template. These types of pipettors and tips are available from several sources and can be purchased in sterilized packs. It is important to remember that barrier tips cannot be autoclaved.

Hazardous Waste and Health & Safety

Practices, safety equipment, and facilities are appropriate for any laboratory and the safety measures fall under categories as follows.

Biosafety Level 1 (BL1): Many agents not ordinarily associated with disease processes in humans are, however, opportunistic pathogens and may cause infection in the young, the aged, and immunodeficient or immunosuppressed individuals. Vaccine strains which have undergone multiple in vivo passages should not be considered avirulent simply because they are vaccine strains.

Biosafety Level 1 represents a basic level of containment that relies on standard microbiological practices with no special primary or secondary barriers recommended, other than a sink for handwashing.

Biosafety Level 2 (BL2):

Practices, equipment, and facilities are applicable to clinical, diagnostic, teaching and other facilities in which work is done with the broad spectrum of indigenous moderate-risk agents present in the community and associated with human diseases of varying severity.

Biosafety Level 2 is appropriate when work is done with any human-derived blood, bodily fluids, or tissues where the presence of an infectious agent may be unknown.

(Biosafety Level 3 (BL3):

At Biosafety Level 3, more emphasis is placed on primary and secondary barriers to protect personnel in contiguous areas, the community, and the environment from exposure to potentially infectious aerosols. For example, all laboratory manipulations should be performed in a BSC or other enclosed equipment, such as a gas-tight aerosol generation chamber. Secondary barriers for this level include controlled access to the laboratory and a specialized ventilation system that minimizes the release of infectious aerosols from the laboratory.

Biosafety Level 4 (BL4):

Viruses such as Marburg or Congo-Crimean hemorrhagic fever are manipulated at Biosafety Level 4.

The primary hazards to personnel working with Biosafety Level 4 agents are respiratory exposure to infectious aerosols, mucous membrane exposure to infectious droplets, and autoinoculation.

The laboratory worker’s complete isolation of aerosolized infectious materials is accomplished primarily by working in a Class III BSC or a full-body, air-supplied positive-pressure personnel suit. The Biosafety Level 4 facility itself is generally a separate building or completely isolated zone with complex, specialized ventilation and waste management systems to prevent the release of viable agents to the environment.
NIH guidelines can be referred for a specific list of agents per risk group: http://www4.od.nih.gov/oba/rac/guidelines_02/APPENDIX_B.htm

Organizational Aspects

Staff should consist of professionals with veterinary and/or PhD degrees and the remainder with technical (BSc degrees) and clerical.

Budget allocations:

The least amount of money for its animal disease diagnostic laboratories on a per head of livestock basis.

Technological Developments

Laboratory testing is a rapidly changing field. Testing procedures are constantly being upgraded for accuracy, sensitivity and speed.

Other quick and easy to perform specialized veterinary diagnostic kits should become available directly to the veterinarian or animal owner.

Other Legal issues

Should not anticipate any significant impact from pending court cases.

Self Evaluation and Opportunities for Improvement is very important for any vital organization.

Link with other laboratories should be encouraged to cope up with the other international Standards and speed.

To conclude the public should perceive as providing an unbiased, accurate and much needed source of information and diagnostic help in diseases.