LABORATORY SERVICES FOR PRIMARY HEALTH CARE:

REQUIREMENTS FOR ESSENTIAL CLINICAL LABORATORY TESTS
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1. INTRODUCTION

The World Health Organization has, in successive programmes of work, stressed the interrelation of health with economic and social conditions, the importance of health as a human right and the need to overcome inequities in access to health services.

Health laboratories play a pivotal role in health care, particularly at the first referral level. The function of health laboratories has already been discussed on various occasions. A WHO Consultation on Essential Laboratory Tests, was held at Karos Lodge, Mpumalanga Province, South Africa, from 1 to 5 July 1996, where experts reviewed the minimal list of laboratory tests that should be available for primary health care laboratories in developing countries.

The purpose of this document is to advise staff of health centres and rural hospitals on developing their clinical diagnostic laboratory facilities; it should also be useful for national authorities concerned with planning the organization of primary health care.

Diagnostic laboratory services are regarded as an integral part of the national health structure in all countries. At the 32nd World Health Assembly in 1979 Member states were urged to give due consideration to the development of laboratory services with appropriate technology for primary health care (WHA 32.16). Health Centres (together with dispensary or health post) mainly provide outpatient diagnostic, curative and disease preventive services. The next level of service is usually provided at District hospitals with general and some specialist outpatient as well as inpatient services; they may provide the first opportunity for patients to be seen by a medical officer (doctor), and they are referral centres for the smaller health units. However, Health Centres in peripheral areas will usually provide the first-line of comprehensive medical care for the majority of the population.

Experience from field studies on peripheral laboratories in several countries led to the publication of a seminal document on Laboratory Services at the Primary Health Care Level, 1987 (WHO/LAB/87.2), and other WHO publications (see References 1 - 4).

Circumstances and technologies are constantly changing and any new document should update previous documents by incorporating what will be reasonably expected to exist during the next few years. Furthermore, there is clear need to consider the selection of tests from the perspective of clinicians, especially those working in developing countries, who must take into account the reality of restricted laboratory facilities and the need for strict cost containment within very limited budgets. It is, however, essential that a percentage of the cost of primary health care services be earmarked specifically for the laboratory component as an annual budget.

Critical consideration must be given to deciding which tests might be provided:

(a) tests that are clinically useful in influencing diagnosis and management;
(b) one test rather than two or more tests where one selected test can provide adequate information;
(c) tests that can be performed easily, rapidly and with cheaper reagents, but without compromising reliability, rather than those which need more sophisticated equipment;
(d) "screening" sets of tests ("profile testing") or only individually specified tests.

Taking account of these basic principles, this document has been written in recognition of the need to
provide laboratory facilities to meet the requirements of health care services at the peripheral level, both rural and urban. These requirements are for disease control, health promotion, clinical diagnosis and patient management.

In this context the peripheral level is defined as either a Health Centre or a Dispensary/Health post manned by a single health care worker who would, in addition to other duties, perform simple laboratory tests. The hierarchy may vary between countries, but in general the following structure is followed:

- **Peripheral**
  - Dispensary/Health post with single health care worker
  - Health Centre (rural or local urban community)
  - Primary level hospital (rural)

- **Intermediate**
  - District or Regional Hospital

- **National**
  - Central Reference laboratory; may be linked to tertiary health care facility

2. **TEST SELECTION FOR PERIPHERAL SERVICES**

Essentially test selection must satisfy clinical and public health needs. They may vary from region to region, depending on local epidemiology. The requirements of any test are that it must:

(a) lead to intervention or alter the current intervention
(b) assist in diagnosis
(c) permit disease monitoring

Selection of techniques for the tests will take account of their reliability, available equipment, basic utilities required, cost, ease of performance, level of expertise/technical training required. For any test the following aspects must be clearly defined:

(1) Appropriateness of test for the required purpose
(2) Most appropriate method/technique
(3) Technical training required to do it?
(4) How results should be interpreted.

Each test or set of tests in each of the clinical categories will be considered in terms of (a) clinical utility, (b) technical reliability, (c) implications for laboratory organization and management, as follows:

(a) **Clinical utility**

1. What is the clinical significance (physiopathological interpretation) of an isolated measurement and/or sequential measurements of the analyte?
2. Is there adequate information on normal reference values, environmental influences and diurnal variations?
3. How critical is the relationship of an individual result to the normal reference distribution and prevalence of a specific disease?
4. What levels (limits) of precision and accuracy are required for clinical purposes?
5. Ease of interpretation by clinicians with different levels of clinical training
(b) **Technical Reliability**

1. How easily is the test performed, taking account of available level of technical skill?
2. What equipment and reagents are required?
3. What basic utilities are required?
4. What levels of precision and accuracy can be achieved?
5. What standards and quality control are available?
6. Is the test included in IEQAS and/or a national EQA scheme (see Appendix 4)

(c) **Organizational considerations:**

1. Clinical and/or public health reasons for selection of tests
2. Any safety hazard with reagents and test procedure
3. Specimen collection and anticoagulation procedure
4. Effects of transit delays and storage on specimen integrity
5. Audit of test reliability and clinical utility
6. Interpretation of results with reference to established normal values
7. Communication of results and comment on their significance to clinicians

3. **TRAINING**

There are several categories of health care workers whose structured career path should include training in performing specified laboratory tests. The nurse practitioner must be given on-site training. A community doctor may also be able to undertake the appropriate laboratory tests, while in some centres it will be appropriate to have a technician/technical aide. In addition to training in the technical methods for specific tests at the appropriate level, each group will be required to understand the application of algorithms which include referral of the patient to a higher level facility for more complex investigations (see Appendix 2).

4. **QUALITY ASSURANCE**

An appropriate quality programme must be built in at all levels together with a system of laboratory management and supervision including standardization, to ensure interlaboratory comparability and maintenance of equipment (see Appendix 4).

5. **SERVICING CLINICAL NEEDS**

The clinical circumstances for which a laboratory service is required will normally include features which lead the clinician to consider one of the following conditions:

- **Haematological disorders**
  - Anaemia
  - Other conditions
Bacterial infections

- Specific - e.g. tuberculosis, leprosy
- Non-specific - including STDs

Viral infections

- HIV
- Hepatitis
- Other

Parasitic infections

- Malaria and other blood parasites
- Non-blood parasites

Metabolic disorders

- Diabetes mellitus
- Hypercholesterolaemia
- Others

Systemic disorders

- Hepatic
- Renal
- Diarrhoea
- Inflammatory - including rheumatoid conditions

Toxic effects of agricultural and industrial chemicals

Environmental health

Some of the generally prevalent conditions are discussed briefly below in the context of primary health care. Other conditions may be added to the list as determined by the prevalence of disease in the particular location.

5.1 Anaemia detection and management

The main global causes of anaemia are: malaria, iron deficiency (with or without hookworm), folate deficiency, haemoglobinopathies, thalassaemia, G6PD deficiency, chronic disease especially Tuberculosis and HIV. Anaemias arising from malaria, worm infestation and poor nutrition are all treatable by specific measures but many patients present late with anaemia of such severity that blood transfusion may be necessary. Thus, early detection of anaemias is a high priority at all health centres. Treatment of the primary disease can then be given according to standard regimes.
The diagnosis of anaemia is especially important at antenatal, clinics, in lactating mothers, in children under 5 years, e.g. when attending for vaccination, and also in all sick persons. All anaemic African children should have haemoglobin S solubility test in endemic areas. Breathlessness at rest and physical signs of impending cardiac failure are indications for referral of the patient.

5.2 Infectious diseases

Tuberculosis

This is a common treatable disease. Laboratory diagnosis is essential for early detection, monitoring and tracing of contacts; it should be an integral component of local and national control programmes. The mainstay of diagnosis is direct microscopy of sputum, and results should be available on the same day. Up to 60% of cases are diagnosed in this way, but it may be desirable to give a quantitative result rather than a simple ‘positive’ or ‘negative’ to assess response to treatment.

Sexually transmitted diseases

For syphilis, a simple and reliable serodiagnostic tests is available; this is the rapid plasma reagin (RPR) card test which is suitable as an antenatal screen test at Health Centre level. Gram-staining of genital discharge for Neisseria can also be undertaken at the Health Centre, but it might be more realistic to refer the patient to the District Hospital.

5.3 Viral infections

Virus detection is not recommended at the primary health care level but universal precautions must be followed when collecting and handling blood or other specimens from any patient.

Testing for infection by HIV-1 or HIV-2 at the primary health care level should only be introduced when:

1. Tests of an acceptable sensitivity and specificity are available and positive results can be confirmed by a second test and preferably a second specimen;
2. Therapeutic decisions (including choice of anti-tuberculosis drugs) depend on the result;
3. Pre-test counselling, a protocol for obtaining informed consent, post-test counselling and support conducted by staff with the necessary skills are available.

5.4 Parasitic infections

Malaria and other blood parasites

Target populations for testing in regions where malaria and/or other blood parasites are endemic include children, early pregnancy (especially primigravidae), any patient with fever; any patient with altered consciousness; any patient with anaemia. Microscopy of blood films is the essential procedure; for the
diagnosis of malaria an antigen test is now available for *P. Falciparum* which is rapid and reliable, but expensive. Quantitative estimate of parasitaemia is essential in patients with malaria which is unresponsive to treatment. Training manuals on methods for blood parasite diagnosis and identification of type, algorithms for treatment and indications for referral, are required.

Other parasitic infestations

Diagnosis depends on identifying the parasites microscopically, recognizing their characteristic features by reference to the illustrations in a text book (see references 5 - 8). The specimens to be provided include: stool, urine, blood, rectal biopsy, nasal swab, fine needle aspirate of lymph node, skin biopsy.

5.5 Metabolic disorders: Diabetes mellitus/hypercholesterolaemia

Urinary glucose testing is a simple procedure which provides an indication of the clinical state rather than a firm diagnosis, and it may be useful to monitor well controlled confirmed cases of diabetes. It should be performed routinely at antenatal clinics, but at-risk mothers should be referred to a higher level of care. Blood glucose measurement is more informative; quantitative measurement of reaction on a test strip can be performed by visual reading, or more reliably with a glucose meter.

Cholesterol testing need not be undertaken at primary level in Africa, but would be justified in Asian countries where the populations are more at risk of coronary artery disease.

5.6 Systemic disorders

(i) Hepatitis, presenting with jaundice, requires tests for an increase in plasma bilirubin (suggested by dark yellow colour of the plasma).

(ii) Renal disease will be indicated by detection of protein and blood in the urine, together with microscopic demonstration of casts, bacteria, leucocytes. Severe renal disease may result in the presence of characteristic distorted and fragmented red cells in a blood film. It is helpful to distinguish haemoglobinuria from haematuria.

(iii) Diarrhoea requires investigation of stools for cysts, ova and parasites and for the presence of blood and/or pus. Culture of stools and blood is beyond the facilities of the Health Centre; if the condition remains undiagnosed and does not resolve within 1-2 weeks, the patient should be referred to the District hospital.

(iv) The erythrocyte sedimentation rate is still widely used in some places as a non-specific test for inflammatory conditions. But it has been discarded by many as it may be misleadingly affected by anaemia and by various physiological factors (stage of menstrual cycle, pregnancy, age etc.); moreover, the usual manual method is potentially extremely biohazardous. C-reactive protein is a more reliable and less hazardous alternative.

5.7 Toxic effects of agricultural and industrial chemicals

A number of potentially toxic substances are widely used as pesticides and in industrial processes. Pesticides used in agriculture include paraquat, sodium chlorate, hormonal weed killers and organophosphorus compounds. Acute and chronic exposure to these chemicals may cause renal, hepatic, respiratory and/or bone-marrow failure; some may cause intravascular haemolysis or red-cell enzyme damage giving rise to methaemoglobinemia. As the patients frequently have severe anaemia haemoglobin must be
checked. Presenting clinical features will depend on which system has been especially affected, and this will determine what other investigations should be carried out.

5.8 Environmental health

Primarily, this requires check of water supplies for bacterial pollution and, conversely, for the amount of chlorine present. This is generally the function of public health laboratories who conduct sanitary surveys, but they may require support from the Health Centre laboratory, who should have the appropriate reagent for measurement of chlorine concentration.

6. CATEGORIES OF TEST

Depending on staffing, either Category A tests alone, or Categories A and B could be carried out at the Health Centre. With some specialist training Category C tests might also be undertaken (references 9 - 15, 18-19).

6.1 Category A tests: performed by clinical staff of health centre or dispensary

- Urinalysis - protein, glucose, blood, nitrites, bilirubin, urobilin, ketones.
- Specimen collection for referral to the next level (District Hospital laboratory).
- Test for the diagnosis of anaemia.

6.2 Category B tests: performed by laboratory staff in any health centre

- Haemoglobinometry by photometer/spectrophotometer.
- Microscopy of blood, urine, stool, sputum, genital discharge and skin. Stains will include Romanowsky, Ziehl-Neelsen, Gram, iodine, eosin, KOH. Binocular microscopes are essential with a dry X40 lens for examination of stool and urine, and oil-immersion x100 lens for identification of blood parasites.
- White blood cell count
- Microhaematocrit and MCHC (alternative to haemoglobin determination at antenatal clinics). This also provides the opportunity to observe the colour of the plasma - deep yellow in jaundice; pale in iron deficiency.
- Haemoglobin S solubility or slide test
- Pregnancy testing.
- Blood glucose, by visual reading of test strip chromogenic reaction or with a glucose meter.

6.3 Category C tests: additional tests suitable for larger health Centres with a technician or laboratory aide

- HIV - but subject to availability of a second test and counselling (see above)
- Differential white cell count
- Red cell morphology on blood film for assessing cause of anaemia
- Estimate of platelets on blood film
- Bilirubin:
Neonatal jaundice is important and constitutes a major problem. Significant jaundice in the neonate is a definite indication for referral. It is not difficult to differentiate jaundice from no-jaundice but it is difficult to differentiate physiological jaundice from pathological jaundice. Ideally a robust method is necessary but may not be available, and bilirubinometers are difficult to maintain. The alternative approach is to refer all cases of jaundice to a referral centre (i.e. District Laboratory upwards) for further investigation.

- Serological screen test (RPR) for syphilis
- Blood grouping and cross-matching
- C-reactive protein in systemic inflammatory conditions

6.4 Other tests

Other tests require referral to a higher level laboratory. The Health Centre staff must know what specimens are required, how to collect them, how to prepare them for transport to the referral laboratory, and how to ensure that they will not undergo excessive deterioration before reaching their destination.
APPENDIX 1: TEST SELECTION - COST ANALYSIS AND TEST EFFICIENCY

The selection of appropriate diagnostic tests should be guided by diagnostic reasoning and evaluation of test characteristics. There are two fundamental criteria against which all health care procedures are judged. The first is outcome of health care activity (the benefit to the individual patient and to society as a whole). The second is cost. Using these two criteria a model for measuring the outcome of a test procedure can be constructed using six components:

- analytical performance (method precision and accuracy)
- diagnostic performance (diagnostic sensitivity and diagnostic specificity)
- diagnostic importance (impact on diagnostic reasoning of clinician)
- therapeutic importance (influence on treatment of patient)
- patient outcome (impact on health status of patient)
- disease surveillance (impact on community health).

It must be appreciated that efficiency in technical outcome or diagnostic accuracy does not automatically lead to high efficiency at patient level. Adequate test selection implies thorough evaluation at each of these levels. Only rigorous, prospective, well designed data collection and analysis can provide the correct information for appropriate selection and utilization of tests.

Laboratory tests possess inherent imprecision and inaccuracy, whilst specific technical errors during measurement will impair the correctness of the test result. Evaluation is a process to establish the validity or otherwise of an analytical procedure. Analytical evaluation procedures are designed primarily to ensure that performance claims can be substantiated in routine practice. Primary analytical evaluation is not the remit of the peripheral laboratory although the principles and methods must be understood, but the reliability of the procedure in a primary health care setting (in contrast to a higher level laboratory) will require to be established.

Analytical evaluation

The evaluation protocol recommended by the International Council for Standardization in Haematology (ICSH) serves as an exemplary model. It is divided into a number of phases:

1. Preliminary - the assembly of all existing information on the procedure and from this a judgement on whether or not the procedure satisfies the basic requirements.

2. Planning of technical assessment

3. Preliminary assessment - this is an important phase serving the multiple functions of allowing the evaluator (i) to become familiar with the test procedure, (ii) to abort the evaluation should the procedure prove unacceptable for use in the laboratory environment, and (iii) to identify major components of variance in result.

4. Performance assessment - this is a more rigorous process of measuring the performance of the procedure by analysing specimens from a representative sample of the usual subject population. There are several components to this phase:
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(a) effect of dilution (the establishment of linearity over the anticipated working range of the instrument);
(b) assessment of procedure imprecision (includes within- and between batch precision, carryover, effect of specimen aging), and
(c) comparability assessment (usually performed against the routine method in the laboratory) but when discrepancies occur these must be resolved by the use of reference methods (accuracy assessment).

5. Efficiency assessment - this includes estimation of procedure throughput of specimens, data presentation, reliability, and laboratory staff acceptability.

This process establishes the validity of the procedure. The procedure now requires to be tested against the rigours of the potential laboratory environment.

Evaluation of medical usefulness

Laboratory procedures are used for a variety of purposes and these must not be confused in the evaluation process. In general, tests are used in:

- diagnosis of disease
- screening asymptomatic individuals to detect disease and potential source of infection
- making treatment decisions
- formulating a prognosis
- surveillance studies of disease prevalence

The diagnostic process involves two processes. First the clinician establishes a differential diagnosis and then reduces this by progressively ruling out specific diseases. This process requires tests which are sensitive. Sensitivity is defined as the probability that a test result will be positive when the disease is present, so that when it is normal it permits the clinician to exclude the disease with confidence. Having narrowed the differential diagnosis, the next step is to pursue a strong clinical suspicion. This requires a test with high specificity. Specificity refers to the probability that the test result will be positive only when the disease is present, and negative when it is not. It is thus important when screening for uncommon diseases, as an abnormal test result should essentially confirm the existence of the disease.

The assessment of clinical sensitivity and specificity for a particular test requires expression of this type of analysis in terms of true positives, true negatives, false positives and false negatives. Although the results can be heavily biased by the proportion of abnormal specimens in the total number of specimens tested, generally. Using prevalence (i.e. number of existing cases) and incidence (i.e. number of new cases in a population in a defined time period) it is possible to estimate the predictive value of a positive or a negative result in the particular population studied. However, it must be remembered that results can be heavily biased by the proportion of abnormal specimens in the total number tested. Thus, as this type of study is usually performed under controlled conditions in selected institutions against a reference method and by technically trained workers, different conclusions may be reached if undertaken in a routine service situation and especially if by individuals with low skill in test performance.

During the course of patient treatment, laboratory tests are frequently repeated; thus, known and acceptable reproducibility is one of the most important requirements for any procedure.
The situation is more complex in formulation of prognosis, because time variation must be taken into account and the statistical treatment to define valid rules is very complicated.

**Economic evaluation**

This is an increasingly important part of health care technology assessment. There are three main approaches to economic appraisal, each involving systematic identification, measurement, and evaluation of all the relevant costs and consequences of the options that are being considered.

1. Analysis of cost-minimization will identify the least costly option for the same outcome.
2. Analysis of cost-effectiveness will assess outcomes for different procedures expressed in common natural criteria, e.g. per life saved, or per symptom-free day.
3. Analysis of cost-benefit is restricted to evaluation in which a monetary value is placed on the outcome.

The method selected will depend on the context of the choice required to be made. The most straightforward method is cost-minimization which can be applied when outcomes are identical. Cost-effectiveness analysis has certain limitations. Cost-benefit analysis while offering the most comprehensive and theoretically sound form of economic evaluation is fraught with practical problems in the context of health care.

**Budget control and cost accounting**

15-20% of the total budget for a Primary Health Centre should be earmarked as an allocation for the laboratory component. Within this budget the laboratory should be expected to provide the service which is demanded of it. This will require a systematic approach to expenditure decisions and budget control by the laboratory, with careful analysis of the cost of each of the tests that are provided.

Actual costs are defined as all money expended on labour, materials and all the expenses required to provide a test result. These can be divided into two categories: (1) direct costs - test-specific costs which are easily identified (supplies, reagents, labour, instruments), and (2) indirect costs - necessary for overall production (management, space, utilities, etc). The formula shown in Appendix 6 gives a reasonable approximation.
APPENDIX 2: TRAINING PROGRAMME

Training programmes may vary from one country to another because of different circumstances. This Appendix provides an example of a structured programme. It consists of three levels of training for laboratory functions, based on the personnel who are involved. These are as follows:

1. Clinical officers and ancillary clinical aides
   Nurse practitioners
   General medical practitioners
2. Technicians and technical laboratory aides
3. Medical laboratory technologists

The key person is the clinical officer who occupies a position between the nurse and the doctor. He or she may be in charge of administration of the Centre. All categories of the clinical staff may perform a number of simple investigations and should receive adequate training to perform and interpret laboratory results as part of their formal and continuing education programmes. Training is divided into (1) preliminary basic instruction; (2) support and on-site instruction by supervisors (who have a key role in education) and specialists during their visits which should last for at least three or four days at regular intervals; (3) attendance at courses, seminars and workshops; (4) access to technical manuals. Distance learning materials have an important role in education, and suitable programmes should be developed.

The laboratory technician will acquire the skills required for the provision of a medical laboratory diagnostic service at the primary health care level. These will:

- comply with the health care needs of the community;
- enhance the diagnostic, therapeutic, monitoring and referral capabilities of the health care team;
- contribute to the investigation of epidemics of water-borne or other diseases;
- meet the requirements to ensure quality.

To these ends, the trainee will learn the basic aspects of:

- human anatomy and physiology
- human pathology
- microbiology, the vectors and transmission of common infectious diseases
- immunology
- simple mathematics, chemistry and physics
- principles of microscopy
- the purpose, principles, methodology, sensitivity, specificity and interpretation of a range of laboratory tests
- specimen collection, registration, storage and packaging for transport
- recording and reporting of laboratory test results
- preventive maintenance of equipment
- managerial skills, including personnel management, stock-keeping and ordering
- quality assurance
- laboratory safety
- requirements and methods of sterilization, disinfection and waste disposal
professional ethics, including relationships with colleagues and patients, and maintaining confidentiality.

Formal training should be supplemented by informal and continuous training at the bench. On-site training of an interactive nature between the clinician and the laboratory worker should be encouraged and continuous, as this will be to their mutual benefit.

The training should be supervised (see below) and should lead to an examination which tests the knowledge and practical skills of the trainee, and if a satisfactory level has been achieved, results in certification or registration by a statutory national body.

There must also be a recognizable form of career progression for these individuals towards qualification as a technologist. The overall aim of the training programme is to eradicate all untrained staff. Technical aides should have the opportunity to understudy a trained and certificated technician, and to carry out some tests under direct supervision.

Technologists require four years of training, starting from a higher educational level, including the previous training at the technician level. There would be additional training in medical laboratory disciplines and some additional instruction in basic sciences and in laboratory administration and quality system management. The technician working single-handed in a Health Centre will be required to have a minimum period of two years training in laboratory work at a District hospital level. While a degree of flexibility in the training programme is desirable, national professional authorities should be advised to consider the contextual content of the curriculum in order to provide opportunities for specialization and academic degree qualification.

Supervision of training

Supervision should be available for all health care workers involved in laboratory practice, by the next level of expertise, i.e. from a District or Regional laboratory. Supervisor check lists should be created and these should be followed through at each visit. Supervisory visits should be combined with support, and the visit should be of sufficient duration to permit both activities. An advantage of this is that it avoids the trepidation ("examination nerves") which a supervisory visit alone might engender. The support aspect implies working with the staff to find out exactly what is happening and to identify problems first hand. The supervisor must carry reagents and sufficient tools to effect on-site repairs where possible, while an important part of the visit is to scrutinize the quality assurance procedures and to provide materials for them (see Appendix 4).
APPENDIX 3: EQUIPMENT AND REAGENTS

The following list illustrates the general requirements for the functions of a basic Health Centre laboratory as described in this document. An expanded service may require other items to be added to the list after consulting the references at the end of this section. The items on the list have been classified under the headings: Major equipment; Minor equipment; Basic reagents; Specific reagents; Diagnostic kits (references 1, 5, 7, 16 - 18).

Major equipment

Microscope

Binocular with mechanical stage, condenser with iris diaphragm
Illuminated by low voltage (e.g. 6V) tungsten lamp with mains transformer or battery
x10 eyepieces; x10, x40(dry) and x100 (oil immersion) lenses
Eye piece micrometer and stage micrometer

Photometer/Spectrophotometer

A photometer (colorimeter) has a fixed wavelength (or colour filter) to measure haemoglobin at 540nm. The spectrophotometer is a more versatile instrument which has the facility to measure various analytes at appropriate wavelengths of the spectrum. Both types of instrument require a stable light source (mains transformer or battery) and cuvettes of good quality glass or scratch-resistant plastic (if scratches occur on the walls of the cuvettes they must be discarded).

Centrifuge

Angle or swing-out with place for four to six tubes of 15-mL volume.
Adjustable speed up to 2300 g (c 4000 rpm)
Guard bowl with top lid which can remain tightly sealed during operation to prevent risk of biohazard from spray or breakage.

Microhaematocrit centrifuge

Capacity of 24 capillary tubes
Fixed speed of at least 10 000 g for 5 minutes with built-in timer
Metal cover plate to hold tubes in position during operation, and hinged lid with automatic locking device during operation.

Specimen mixer

Roller/rotator or roller/tilt type. This is unnecessary for small numbers of specimens which can be mixed satisfactorily by hand.
RPR Rotator

Required for use with the rapid plasma reagin (RPR) card test for syphilis. Improved Neubauer type with bright-line etched ruling; dedicated cover glasses - care must be taken when cleaning the cover glasses as they tend to break, and it is sensible to have a few in reserve.

Glucose meters

These are battery-operated devices with various measurement principles for reading the end-point of reaction of a drop of blood with a dry reagent chromogenic test strip. In the past misleading results have occurred from inadequate blood sample, faulty application of the blood to, and removal of the blood from the test strip, inappropriate wiping technique, poor maintenance and lack of quality control. The instruments which are now available use non-wipe technique and nearly all operator-dependent steps have been eliminated. The meters are precalibrated by the manufacturers, but require checking with control solutions. When correctly used results should be reasonably precise with CV of about 5-6%, although some types may be less accurate at low glucose concentrations; measurements may also be affected by severe anaemia and when the PCV is below 0.30 there may be a positive bias of 20-30%. They are relatively expensive.

Timer

Digital with display of one hour in one-minute steps, and audible alarm...

Balance

Weighing capacity of 1000 g with sensitivity of 100 mg with weights

Refrigerator

Domestic type capable of maintaining a stable temperature of 4 °C within a range of 2-8 °C, with a storage capacity of at least 30 L and a freezer compartment for storage of sera and antisera. Electric, gas, kerosene or solar power
Interior maximum-minimum thermometer

High temperature facility

Autoclave: domestic pressure cooker type with pressure gauge, set at 121 °C - 105 kN/m² or Hot-air oven capable of maintaining temperatures up to 200 °C, with thermostat Portable steam sterilizer capable of a temperature of 121 °C.

Small incinerator

Pure water supply

Water filter with 20 litre capacity and/or Still to provide 2 litre/h distilled water.
Minor equipment

Buckets and/or basins, plastic
Beaker 100 mL, glass or polypropylene
Bottles/containers -
  Universal containers, 28 mL capacity
  Urine specimen, glass or plastic
  Sputum specimens
  Stool specimens
Brushes for cleaning bottles, flasks and test-tubes
Bunsen burner or spirit lamp
Centrifuge tubes, 15 mL capacity
Cylinder, graduated 100 mL capacity, glass or polypropylene
Flasks -
  Erlenmeyer, narrow mouth, glass (heat resistant) 100 mL capacity
  250 mL capacity
  Volumetric, glass or polypropylene, with stopper, 100 mL capacity
  250 mL capacity
Funnel, glass or polypropylene
Microhaematocrit capillaries
Microscope slides, 75 x 22 mm
Coverglasses, square (22 x 22 mm) and/or rectangular
Pasteur pipettes, plastic disposable
Pipettes -
  10 mL
  20 μL (0.02 mL) for haemoglobin and WBC dilution
Stoppers, various sizes, plastic, rubber and/or cork
Teats, rubber
Test tubes, glass or polypropylene, 75 x 10 mm
  75 x 12 mm
  100 x 12 mm
Test tubes, heat-resistant glass, 150 x 16 mm
Thermometer (0-50 °C)
Wire loop

Basic reagents
Acetone
Alcohol, ethanol 95%
Alcohol, methanol
Buffer tablets for phosphate buffers (pH 6.8 and 7.2)
EDTA anticoagulant
Filter paper
Formalin (35-40%)
Glass-writing pen/pencil
Hypochlorite, for disinfection
Lancets, disposable
Lens cleaning paper  
Oil for microscope immersion lens  
Sodium chloride (saline solution)  
Sodium dichromate (cleaning solution)  
Thymol crystals (for specimen preservation)  
Universal indicator paper, pH 1-10  
Xylene

Specific reagents

These will depend on the tests and methods to be undertaken. The following list is intended only for guidance; some of the items are also included in the list of general reagents and some are available as diagnostic kits (see below).

Haemoglobin:
Oxyhaemoglobin: Ammonium hydroxide, if available
Haemoglobin cyanide: Potassium cyanide-ferricyanide (Modified Drabkin's) reagent
Leukocyte counts (WBC): 2% Acetic acid
Gentian violet stain
Hb S solubility test: 1% Sodium dithionite
Phosphate buffer pH 7.1-7.2
Blood film staining: Giemsa stain
Other Romanowsky-Giemsa type stains - see diagnostic kits
Phosphate buffer pH 6.8; pH 7.2 for malaria
Gram stain: 2% Crystal violet or 0.5% Gentian violet
Gram's iodine solution
Decolorizer solution (e.g. acetone)
Safranin counterstain
Ziehl-Neelsen stain: Carbol fuchsin 1% in 10% ethanol/methanol
Acid alcohol - 3% HCL in 95% ethanol
Methylene blue counterstain
Microscopy of fungi: 10% potassium hydroxide
Parasitology: Lugol's iodine
1% Eosin in saline

Rapid plasma reagin (RPR) card test
Chlorine assay - N-N-diethyl-para-phenylenediamine (DPD) or ortho-tolidine

Urinary screen tests

Reagent test strips can be read visually against a colour scale to obtain a semi-quantitative approximation. They are available for the following analytes:
Glucose, protein, blood (haemoglobin), bilirubin, nitrite, pH.
They may also include ketones and urobilinogen.
Diagnostic kits

A diagnostic kit is a package containing two or more reagents and/or other materials and a method protocol designed for performance of a specified analytic procedure. The reagents listed above are often available as diagnostic kits. Others which are relevant are included below:

Haemoglobin (haemiglobincyanide method) (see reference 11)
Modified Drabkin’s solution
HiCN Reference

Romanowsky stains
Several combinations are suitable; e.g. May Grunwald-Giemsa
Azure B-Eosin Y
Eosin-Methylene blue rapid stain (Field’s)

A comprehensive list of equipment and reagents is provided in (references 5,10,16,17).

Preventive maintenance of equipment

The major cause of failure of equipment to function properly is lack of ongoing maintenance, with deterioration of reagents and water, and use of damaged glassware. Skill and knowledge are required to use the various items of equipment listed above correctly, to ensure that they are calibrated and to keep them in good working order. This requires cooperation by the appropriate supervisor at a reference centre. In addition to any specific instruction manuals provided by the manufacturers, the available WHO publications are listed in references 16 - 17).
APPENDIX 4: QUALITY ASSURANCE

Quality assurance has an essential role in good laboratory practice. It ensures that tests are selected appropriately on the basis of clinical needs, and that they are performed reliably with results that are meaningful and useful for diagnosis and for assessing the patient’s response to treatment. It is therefore important for every laboratory to have a quality system in place, and the same principles apply to all laboratories although the actual way in which the system is applied will vary, depending on the size and staffing level of the laboratory, the repertoire of tests which are undertaken, the number of tests carried out each day and the complexity of the methods and equipment used. There are several components in a quality system, as follows (see reference 18):

1. Pre-analytic control
2. Post-analytic control
3. Internal quality control (IQC)
4. Standardization
5. External quality assessment
6. Record keeping and documentation.

Pre-analytic control

This starts with the collection of the specimen; it is the responsibility of the laboratory to ensure that the specimen is collected correctly by a standardized method. It is necessary to check the following aspects:

- For venous blood, correct type of container;
- If for non-clotted samples, correct type and amount of anticoagulant;
- Free flow of blood during collection - i.e. minimal use of tourniquet during venous blood collection; no squeezing of finger for capillary blood;
- Collection from the right person;
- Correct name and/or identification written on the container label;
- Correct information on test-request form;
- Specimen sent without delay to the laboratory, properly stoppered, and during transit kept cool, and not exposed to direct sunshine;
- When plasma or serum is required prompt separation and correct storage.

Post-analytic control

After the analytic process (see below) the test results must be recorded, checked and prepared as a legible and intelligible report. If necessary the report should draw attention to abnormal features, and indicate if the test should be repeated and/or whether other tests should be done. The report must then be sent without delay to the appropriate clinician or clinical unit. The day and time of receipt of the specimen in the laboratory and the day and time of despatch of the report should both be recorded.

Internal quality control (IQC)

This is a method to demonstrate how reproducible the results are likely to be, and if there is any fluctuation or bias because of poor technique or if a defect has developed in a reagent, kit or instrument. It is an immediate check that allows the laboratory to decide whether the results are reliable enough before the report is sent. The methods to be used for IQC depend on the number of samples being tested at one time.
Duplicate tests

If there are only a few samples to be tested they should be measured in duplicate. The duplicates should not differ from each other by more than a certain amount. This is based on the precision of the method as determined by a reference laboratory - e.g. 5% for PCV, 15% for WBC by haemocytometer count.

Control chart

A control chart is a simple presentation on arithmetic graph paper of results for a particular test on identical samples on consecutive days. These come from a specimen which has been prepared in a special way to ensure that it is stable for at least several days or weeks. The samples should be provided at regular intervals by a referral centre. Initially several repeat (replicate) measurements are performed sequentially on one of the samples to establish the mean and standard deviation. A plot is made on the graph paper with results of the analyte on the vertical scale, and the date of measurements on the horizontal scale. The upper and lower limits of 2 SD are drawn. Thereafter, a daily single measurement is made and the results are plotted. If the test is well controlled the results will hover around the mean; if several results occur on one side of the mean, this may indicate a systematic drifting which needs to be checked; a result outside the 2SD limit indicates that a serious error or defect may have occurred - provided that the control material itself has not deteriorated.

It is relatively easy to make stable and reliable control material. Methods for their preparation have been described in WHO publications which also give details of preparing and interpreting the control chart (see below).

Patient data

If there is only a small variation in the daily mean value from the patients' results for a particular test from day-to-day, this can be used to check that the test is in control. From the daily means from 15-20 consecutive days the "mean of means" and its standard deviation (SD) are calculated. The test will be out of control if on any subsequent day the mean value for that day falls outside the 2SD limits. This method is usually used in laboratories with a large number of specimens and sophisticated automated instruments. A simple adaptation of the principle can be used in a small laboratory by restricting the method to the MCHC, and using only those results where the haemoglobin is within normal range.

Microscopy

With each staining procedure positive and negative smears or preparations should be included to check that the stain is working satisfactorily. For blood cells the control should be a fresh normal smear.

Correlation

Any unexpected result of a test must be checked to see whether it can be explained on clinical grounds or whether it correlates with inter-related tests; e.g. a low MCHC must be confirmed by demonstrating hypochromic red cells on a blood film.
Standardization

Control preparations provide a measure of precision; the actual value obtained in the measurement is only required for comparison with the previous measurement on the same specimen. To ensure accuracy of a quantitative test it is necessary to use a calibrator with a stated and reliably measured value. This is used to calibrate an instrument, for checking an auto-calibrated instrument, and for checking a new method or for preparing a calibration curve to determine the linearity of the method and its upper and lower limits of reliability. Calibrators are made by reference laboratories and by commercial manufacturers; the most reliable preparations are based (directly or indirectly) on international standards. They are expensive to prepare and are not intended to be used for daily control.

External quality assessment (EQA)

In contrast to IQC, EQA is a retrospective assessment of the performance on specified tests in comparison with the results from other laboratories. Participants in EQA schemes are provided with batches of specimens at regular intervals. They examine the specimens by their routine methods and return their results to the organizing centre where they are assessed. A report is issued comparing the individual laboratories with overall national performance, usually by a scoring system by which they can judge their performance. In most surveys the participant consensus is taken to be the result to be aimed at, but in some the “correct” result is determined by one or more reference centres, while for qualitative tests such as the morphological features of a blood film the correct result is obtained as the consensus by a small group of consultants.

Larger laboratories will generally take part in a national scheme (NEQAS) or a regional scheme, and some laboratories also take part in an international scheme (IEQAS) which is sponsored by WHO. Health Centres should, if possible, participate in these large schemes but if this is impractical because of limited supplies of material, they need to adopt the same principles, albeit in a limited way, with the assistance of a district or higher level laboratory who would be expected to serve as a co-ordinating centre, providing the samples and analysing the results. The supervisors referred to in Appendix 2 would be expected to undertake this function. It is important that the higher level laboratory participates in the centrally organized scheme in order to ensure, via this network, that results are harmonized nationally.

Records and documentation

The importance of keeping complete and accurate records of test results and of all the activities associated with the laboratory cannot be overstated. They should include the following (see references 2, 6, 18 and 19):

- Test request register
- Copies of test reports
- Reference values of various analytes for population groups
- Quality control results
- External quality assessment results and performance scores
- Equipment inspection and maintenance inventory
Reagent, chemical and kit stock control
Budget control
Log of accidents and incidents
Duty schedule
Laboratory methods workbook and Bench-aid manuals.
APPENDIX 5: STANDARDIZATION, REFERENCE AND SELECTED METHODS

The following definitions are extracted from the recommendations of the International Council for Standardization in Haematology (ICSH):

**Reference Method**: A clearly and exactly described technique for an analyte which has been shown to provide sufficiently accurate and precise laboratory data for it to be used to assess the validity of other methods for a measurement and for characterising reference materials.

**Selected Method**: A method which has been approved by a defined authority as being suitable for routine use, taking account of the limits of its inaccuracy and imprecision in the context of its intended (clinical) purpose, economy of materials and labour, ease of performance and safety. Its validity must be verified by comparability with a reference method. A reference method may be used as a selected method in some instances. When a reference method is not available or is not practical, in order to ensure harmonization one selected (routine) method may be designated as a Standardized Method; for this, the equipment, reagents and test procedure must be clearly and exactly specified.

**Reference Material**: Also known as a reference preparation or reference standard, this refers to a material or substance to be used for the calibration of an apparatus, for the assessment of a measurement method, or for assigning values to materials. It requires a collaborative study in several designated centres in accordance with a specific protocol in order to establish its measurement value and its stability. WHO has a number of international reference preparations for use as laboratory standards. They are provided on request to central laboratories and national standardization organizations.
APPENDIX 6: MANAGEMENT PRINCIPLES

Peripheral laboratory services are frequently provided in locations removed from the administrative controls, standards and regulatory forces of the central laboratory. They must, however, come under the management structure as an integral part of a central laboratory service. This must be recognized and appropriate funds identified either from the central laboratory or from the total budget of the Health Centre. Within this overall structure there has to be clear management of the peripheral facility with planning, organizing, training, motivating and controlling staff in order to achieve defined goals within the resources provided. National guidelines need to be adapted in consideration of the specific circumstances appertaining to the Health Centre, but formulation of management plans for the peripheral facility and their supervision remain with the central laboratory who must be responsible for monitoring the standards and compliance to national policies. A useful document on this subject has been published by the WHO Eastern Mediterranean Regional Office: Principles of Management of Health Laboratories (see reference 3).

The following management roles should be taken into account:

- administrative responsibilities
- technical responsibilities
- facilities
- personnel
- inventory management
- financial control

Administrative responsibilities

These are numerous. In fulfilling these management staff must be aware of their legal responsibilities and any legislation and statutory regulations. Proper scheduling of work is an important responsibility. Personnel must be available when work requires to be done but, at the same time, staff must be effectively used since their cost is high compared with other components of the service. The need for emergency procedures must be considered. The formulation of a safety policy is discussed in Appendix 7.

The preparation of technical manuals which form the basis of standard operating procedures is another responsibility of management and must encompass all aspects of laboratory practice:

- patient preparation
- specimen handling
- analytical process
- equipment maintenance
- quality assurance
- safety of patient and staff
- communication of results
- referral algorithms
- record keeping
- inventory
- waste disposal
All procedures must be written in the language in common use in the laboratory. Procedures must be regularly reviewed. This forms the basis of the laboratory quality system.

**Technical responsibilities**

The technical responsibilities of management involve:

- distribution of duties
- supervision of quality system
- supervision of communication
- compliance with standard operating procedures
- maintenance of equipment
- updating of procedures

The choice of measurement procedures will be influenced by the clinical situations encountered, the number of tests to be performed, the degree of urgency for results and the limits of tolerable uncertainty for the procedure in the particular environment. The complexity of the procedure and the availability of trained staff will also influence choice of procedure. Additionally equipment purchase and running costs, availability of reagents and spare parts and the ease of preventive maintenance all impact on the decision making process.

**Facilities**

The role of management in this context involves provision of adequate space, services, furnishings, equipment and materials.

**Personnel**

Management is required to prepare both job specifications and job descriptions. The former is designed to protect management and defines those requirements both professional and personal which best suit an individual to that job. The latter defines for each employee those tasks which the employee is expected to perform and serves to protect the employee. The job description defines the conditions of service including salary, hours of work and annual leave.

Qualifications required by different categories of health care worker reflect the range, complexity and technical requirements of the procedures to be undertaken. Training is described in Appendix 2.

**Inventory management**

The procurement of laboratory supplies is greatly assisted by an inventory system which identifies all supply needs and the quantity of items to be kept on immediate availability. This enables timely triggering of ordering. The “standing order” system is useful for frequently used items, but it is important that contingency arrangements also exist to meet unexpected demand, and to take account of different rates of usage of various components for the same set of tests. The objective is to ensure that adequate supplies exist to meet need but that the minimum of capital is tied up and that wastage through out-dating is minimized. This process will be assisted by implementation of standard operating procedures established by the central laboratory.
Financial control

Cost control is the means by which the most effective balance between production and quality on one side and cost of service on the other can be achieved. Accurate predictions of workload are necessary to forecast laboratory expenditure and thus the required budget. Budget control requires careful identification of all categories of expenditure and includes:

- salaries
- supplies
- equipment maintenance
- quality assurance
- records/communication
- housekeeping
- general maintenance
- services
- fabric repairs
- rent
- miscellaneous

The normal budgetary period is one year with workload and revenue reports provided quarterly to permit expenditure modification if necessary. The annual costs for the tests performed can be calculated from the following formula:

Annual cost = \[ L \times T ] + [C \times T] + E + M + O + A, \]  where

- \( L = \) Labour costs for each test from an estimate of the time taken and the salary rate of the staff member(s) performing the test,
- \( C = \) Cost of consumables per test (including control material),
- \( T = \) Number of tests per year,
- \( E = \) Annual cost of equipment, based on the original cost divided by the expected life of the item,
- \( M = \) Annual maintenance and servicing of the equipment,
- \( O = \) Laboratory overheads such as lighting, heating, waste disposal,
- \( A = \) Laboratory administration, including salaries of non-technical staff.
APPENDIX 7: LABORATORY SAFETY

It is the responsibility of each laboratory or site where laboratory tests are performed, in the light of prevailing circumstances, to evolve a strategy to protect the health and safety of health care workers and others with right of entry. This strategy must apply whether or not the test is actually performed in the laboratory or the latter has only responsibility for the collection and transportation of the specimen to another laboratory. In peripheral sites safety requirements must be no less stringent than in the central laboratory and protocols no less detailed, only more simply expressed. Each individual laboratory worker must be aware of the hazards occurring in the clinical laboratory and the risks that these hazards carry as well as the mandatory steps that must be taken to prevent accidents. This is an important component of the training given to health care workers. Safety requirements can be categorized under several headings although not all are applicable in the peripheral laboratory context (see references 20-22). These include:

1. Design and care of premises
2. Development of standard operating procedures
3. Safety training
4. Microbiological safety
5. Electrical safety
6. Chemical safety
7. Fire prevention
8. Gas safety
9. Waste disposal
10. Mechanical and other hazards
11. First-aid
12. Decontamination procedures
13. Procedure for reporting any incidents.

Design and care of premises

Proper structure and layout of premises are important to the safe operation of any laboratory procedure. The area where work is carried out should be sufficiently large to easily accommodate items of equipment. All equipment should be installed on fixed surfaces or stable trolleys. Optimal lighting should be ensured and there should be adequate ventilation with protection from dust. Reagent storage merits consideration. Dangerous chemicals such as strong acids and alkalis must be stored at floor level; chemicals which are likely to react together must be stored well apart; poisons should be stored in locked containment. Fire extinguishers, suitable for dealing with electrical and chemical fires should be available. Restricted access to the laboratory working area should be enforced where possible.

Development of standard operating procedures

Fully documented analytical operating procedures must be provided and these should contain relevant safety and decontamination protocols. It is the responsibility of the supervisor to ensure that these are enforced.
Safety training

Safety at a peripheral laboratory site depends on the adequate training of staff working there. Staff must not be allowed to use equipment until they have completed training according to a designated safety training programme and have demonstrated their proficiency. The following should be covered in the form of written instructions:

1. Relevant safe work practices including dealing with patients, handling samples, use of centrifuges, use of any mechanical devices which might trap the operator's hands, clothing or hair, use of electrical equipment.
2. Decontamination procedures including benches, centrifuges and any other equipment; spillage containment of both infective material and dangerous chemicals.
3. Waste disposal
4. Pipetting instructions stressing the dangers of mouth pipetting; instruction in the use of safety bulbs and other pipetting devices.
5. First-aid
6. Eye protection instructions
7. Personal hygiene:
   - eating, drinking, smoking and the application of cosmetics are absolutely forbidden in areas where specimens are collected and where analytical work is carried out.
   - staff should not wear jewellery in the analytical work area and ideally watches and rings should be removed.
   - gloves should be worn during handling of samples and during analytical work.
   - personal clothing should not be allowed to protrude beyond the sleeves of protective clothing.
   - any exposed cuts or abrasions must be kept covered with waterproof dressings
   - hands must be washed before dealing with a new patient and when leaving analytical work areas.
8. Fire precautions
9. Use of protective clothing

Microbiological safety

In the health care laboratory, transmission of infection poses the greatest threat. The health care worker is at risk on two occasions; first when collecting and handling biological materials (whole blood, plasma, urine, saliva, sputum, other body fluids and faeces); secondly when undertaking the analytical procedure. Because it is often impossible to know which might be infective, all body fluids should be treated with universal precautions. "Universal precautions" comprise a set of guidelines developed by the Centers for Disease Control and Prevention (CDC) recognising the infectious potential of any patient specimen (See next section).

The laboratory worker must understand (1) the principles of hazard grouping of organisms in terms of risk to laboratory staff, spread to the community, pathogenicity and the availability of effective prophylaxis and treatment and (2) the division of laboratories into four different biosafety levels. Level 1 is intended for work with organisms of the lowest risk and level 4 for work with organisms of highest risk.
Universal precautions

Universal precautions include thorough hand washing and in particular washing hands and other skin surfaces immediately if they are contaminated with blood or other body fluids. In case of accidental skin puncture, wash the affected part gently in running tap water without scrubbing.

Disposable plastic or thin rubber gloves should be worn when performing phlebotomy on an agitated or uncooperative patient, when collecting capillary blood and in all cases if the operator has cuts, scratches or other abrasions or skin breaks on his/her hands. A fresh pair of gloves must be used for each patient. Gloves must not be reused as they may deteriorate when washed.

For "housekeeping" and decontamination procedures (see below) wear general purpose rubber household gloves. These may be washed and decontaminated for re-use but should be discarded if they have punctures, tears or other signs of deterioration.

Care must be taken to prevent injuries when handling syringes and disposing of needles. Do not recap used needles or bend or otherwise manipulate them by hand, but place disposable syringes, needles and any other sharp items such as glass slides in a puncture-resistant container for disposal.

All patient specimens should be sent to the laboratory in individual closed plastic bags, with request forms kept separately from the specimen to prevent contamination should there be any leakage from the specimen.

Immediately after completion of the day's work disinfect the working area with freshly prepared solution of sodium hypochlorite (household bleach) at a dilution of 1%; soak pipettes in 2.5% solution for 30 minutes or longer, and use a 10% solution for cleaning up spilled material or breakage in a centrifuge. It is helpful to add detergent to the disinfectant as this aids cleaning and thus efficient disinfection as disinfectants are most active on clean surfaces.

Electrical safety

All electrical equipment used should be certified by its manufacturer to comply with national or international safety standards. Electrical equipment should not interfere electrically with any device attached to a patient, e.g. a cardiac pacemaker. Before installation all electrical devices should be inspected by staff trained in electrical maintenance to make sure that basic requirements such as earth contact, suitable plugs and fuses are functional. There should be a planned programme of preventive maintenance for each item of electrical equipment. All equipment should be decontaminated before inspection or repair. It is the duty of the manufacturer to specify the correct procedures to be undertaken.

Fire hazard

Most fires result from accidents with flammable substances such as alcohol and solvents. All manipulations with such substances must be carried out away from naked flames. Bulk stocks should be kept in a storage area separated from the laboratory and clearly marked as FIRE RISK.

Fire-fighting equipment (buckets of water and sand, hoses and fire extinguishers) should be placed near to doors of rooms and at strategic points in corridors. The extinguishers should be inspected regularly.
Gas safety

Bunsen burners must never be left unattended and pilot lights must never be left on overnight. They should be as close as possible to the gas source, and overlong gas tubing must be avoided.

Chemical safety

Ideally reagents used in peripheral sites should present the minimum chemical risk. Where possible the use of strong acids, alkalis and flammable solvents should be avoided. If toxic chemicals are required they should be supplied from the central facility in a dilute form ready for use. Staff should be made aware of the dangers of consuming laboratory reagents, notably alcohol, and there should be regular audit of the use of such chemicals.

Waste disposal

The safe disposal of laboratory waste is of prime importance. Laboratory waste and contaminated materials presents a hazard both to laboratory workers and to the community. The careless dumping of solid and liquid, chemical and biological waste also is a threat to the environment. Used syringes and hypodermic needles pose an infection risk if blood-bone micro-organisms remain viable.

Laboratory waste is classified under the following headings:

- sharps
- chemicals
- infectious materials
- pressurized containers
- general, non-hazardous waste
- equipment effluents

Sharps are defined as items which can cause a cut or skin puncture (needles, syringes, scalpels, saws, blades and broken glass) and when contaminated pose the greatest infection hazard. To avoid needle-stick injury the complete syringe/needle assembly should be placed in the sharps container. The latter should be incinerated. Other infectious waste should be carefully segregated by placing it in colour-coded bags which should be sealed when three parts filled. Ideally autoclaving is the safest method of treating infectious waste, otherwise it must be incinerated. The use of chemical disinfectants is restricted to re-usable pipettes.

Chemical waste carries the same hazard as that of the pure substance. Information about the disposal of specific chemicals is usually given in the manufacturer’s safety data sheet, however a waste control strategy should be established. Chemical waste arises from diagnostic work, from house-keeping and disinfection procedures and includes carcinogens, teratogens, corrosive substances, flammable substances and reactive substances (e.g. risk of explosion).

Pressurized containers must not be incinerated. They should be carefully punctured in the open air and left to allow residual gas to escape. They can then be placed in non-hazardous waste containers.
General waste includes domestic, packaging and other substances not hazardous to human health. This may either be incinerated or land-filled. Where these services are not available such waste can be burned on site or buried.

Analyzer effluents which do not contain chemicals which potentially react with metal waste piping can be discharged directly into a main sewer if available. Potentially infected liquid waste should be ducted into holding tanks where they are steam- or chemically treated before final discharge to the public sewers.

A number of disposal methods are available to health care laboratories.

- to public sewers
- to the atmosphere (only small volumes of suitably diluted volatile material)
- to landfill sites
- thermal treatment.

Mechanical and other hazards

Equipment should not present mechanical risk to the operator. Such risks usually arise from poorly designed instrument casings presenting sharp edges or corners. It is important that all moving parts are shielded to ensure that items of clothing, fingers or hair cannot become trapped in the mechanism. The use of compressed gases should be avoided where possible.

First-aid

First-aid boxes must be available, clearly marked and stored in an environment free from dust and damp. The contents of a first-aid box must comply with any national industrial health and safety legislation. It should at least include the following:

Card giving general first-aid guidance
Individually wrapped sterile adhesive dressings
Sterile eyepads with means of attachment
Triangular bandages (sterile if possible)
Sterile coverings for serious wounds
Safety pins
Sterile unmedicated wound dressings 10 cm x 8 cm
Sterile unmedicated wound dressings 13 cm x 9 cm
Sterile unmedicated wound dressings 28 cm x 17.5 cm
Sterile water or "physiological saline, 300 mL where tap water is unavailable (eye irrigation)"

Soap and water and disposable drying materials should be available. If antidotes to rapidly lethal poisons are known they should be available when such reagents are in use in the laboratory.
REFERENCES

Laboratory organization


2. *Health laboratory services in support of primary health care in developing countries*. New Delhi, World Health Organization, Regional Publication, SEARO No. 24, 1994\(^2\).


Technical methods


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\(^1\)Available on request from the Unit of Health Laboratory Technology, World Health Organization, 1211 Geneva 27, Switzerland; Fax: +41 22 791 4836

\(^2\)Available on request from the World Health Organization, Regional Office for South-East Asia, World Health House, Indraprastha Estate, Mahatma Gandhi Road, New Delhi 110002, India; Fax: +91 11 331 8607

\(^3\)Available on request from the World Health Organization, Regional Office for the Eastern Mediterranean, P.O. Box 1517, Alexandria - 21511, Egypt; Fax: +203 48 38 916

\(^4\)Available from Distribution and Sales, World Health Organization, 1211 Geneva 27, Switzerland


**Preventive maintenance of equipment**


**Quality management**


See also reference 2.

**Laboratory safety**


ANNEX

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