1. INTRODUCTION

1.1. Pathology is a clinical service which carries out investigations on specimens from patients as an aid to the diagnosis, management and treatment of disease. Departments of Pathology also provide specialist interpretation of the tests and advice.

1.2. The practice of pathology is continuously changing. Currently the four traditional branches of pathology - anatomical pathology, microbiology, haematology and chemical pathology have been joined by an increasing number of subspecialties such as immunology, genetics and molecular pathology. The list and the work undertaken will continue to expand.

1.3. Investigations performed by laboratories in Singapore cover a wide range of disciplines and they range from the very simple tests to the more complex. Many simple tests are presently easily available to the general public as over the counter (OTC) test kits that are sold by licensed pharmacies. As these are on the open market, the uses of such tests are not addressed in this paper. The more sophisticated tests are a more difficult issue and it is to these that we address our remarks.

1.4. Modern technology has provided improved laboratory information systems and electronic communication. Technical advancements and new methodology have resulted in new ways to investigate, archive and preserve human samples, be it tissue, body fluids and cells or blood and blood products. Pathologists now find themselves gatekeepers of a plethora of information and archival specimens, the value and potential implications of which are not properly understood or specifically addressed in law.

1.5. It is the purpose of this document to highlight possible problems that may arise and suggest guidelines for ethical laboratory practice. Matters pertaining to issues arising from post-mortem (both coronial and non-coronial) examinations will be addressed in a separate paper.

2. RESPONSIBILITY

2.1. In Singapore, pathologists are medical specialists recognised and named on the register of specialists kept by the Singapore Medical Council and are governed by the ethical code of the Singapore Medical Council.

2.2. As a member of the medical profession, the pathologist has professional
obligations to his patients, to the profession and to society. This is set out in the Ethical Code of the Singapore Medical Council. (Published 1995)

2.3. As a medical laboratory professional, the pathologist has a duty to ensure that tests performed in the laboratory are of a high professional standard, and that the requirements of regulatory authorities and professional organisations are complied with in the laboratory.

2.4. The purpose of laboratory investigation is to aid the physician in making an accurate diagnosis so as to be able to counsel his/her patient and institute correct treatment where possible. Pathology tests should be considered a consultation between clinician and laboratory physician and should be accorded due professional care and courtesy. The pathologist has a responsibility to report the results of the test to the requesting clinician who would then further advise the patient.

2.5. A professional laboratory has a moral obligation to its patients and this encompasses the whole spectrum from ensuring the origins of the sample, advising on the mode of collection and transport, the correct identification of the specimen to the final accuracy of the reporting, safekeeping and maintenance of confidentiality of the reports.

3. SPECIMEN ACCESSION and CONSENT

3.1. The pathologist should be aware that no medical action or investigation can proceed without the patient's consent.

3.2. The medical laboratory usually receives 'sent in' specimens (tissue, blood, body fluids) with a request for examination. In these cases, the laboratory is entitled to assume that the requesting doctor has obtained the requisite consent and will proceed to process the specimen in good faith.

3.3. For this reason, the Chapter recommends that pathology laboratories only accept 'sent in' requests/specimens from registered medical practitioners, as these persons would be bound by the same professional code of ethical practice.

3.4. When a patient willingly presents himself to the laboratory for a specific test procedure, the laboratory usually infers that consent is given. However Chapter strongly recommends that the pathologist in charge of the laboratory ensure that the patient understands the test procedure and the implications of the test. This should be documented as part of the laboratory's standard procedure.

4. REQUESTS FROM NON REGISTERED MEDICAL PRACTITIONERS

4.1. The laboratories with which members of the Chapter of Pathology are associated with offer tests which have been developed for use in 'classical' (or 'western' as in general local usage) medicine. As such the terminology used in the reporting of these tests, and the range of values used are designed to be interpreted and used within this school of practice.

4.2. The results of the tests performed are meaningless unless interpreted and no test value is absolute in itself. The significance of a positive or negative test, a higher or lower value may vary according to circumstance. The clinician has to be cognizant of the concept of false positives or false negatives, and of spurious results. For instance a report stating that acid fast bacilli are not identified in a specific sputum sample does not negate the fact that the patient may have tuberculosis.

4.3. Tests for screening in particular should not be made freely available without the presence or availability of trained interpretation and counsel. Raised serologic values of a specific oncologic related protein for example prostate specific antigen are not the sine qua non of the presence of malignancy. This still has to be proven by tissue biopsy.

4.4. The therapeutic decisions and diagnostic steps influenced by the results of these tests should be based on guidelines issued by the respective medical colleges and specialty disciplines. Cut off levels and parameters used by one school of medicine may need be altered if used by another school. These issues and the medicolegal implications of these have yet to be addressed or tested. In view of this, the Chapter advises all members that in order to prevent misinterpretation and misuse of test results, only physicians registered with the Singapore Medical Council (or equivalent National Medical Councils of their country of practice) be allowed to request and receive the results of laboratory tests.

5. MEMBERS OF THE GENERAL PUBLIC

5.1. Members of the public should not be encouraged to request for laboratory tests by themselves without prior medical consultation. The Chapter recognises however that there may be special circumstances where a
laboratory may decide to process such a request. Should this occur, the laboratory must have a registered medical practitioner who would assume the responsibility of the attending doctor on site. The import of abnormal tests should be explained and the patient advised to consult, or be given the opportunity to be referred to a qualified, registered doctor for further management.

5.2. In the case of screening programmes, and such, the participating laboratory should ensure that there are sufficient qualified medical personnel to supervise the testing and that there is adequate counseling for participants with abnormal tests.

5.3. Patients and the general public are at their most vulnerable when confronted with illness or potential disease. As such the import of any abnormal test, and the subsequent plan of management should be handled by a registered medical practitioner whose conduct and ethics of practice are accountable to the Singapore Medical Council.

6. LABORATORY RECORDS

6.1. Laboratory records are part of a patient’s medical records and should be treated with the same degree of confidentiality. Unauthorised disclosure of information obtained from patients in confidence or in the course of attending to a patient is a breach of the doctor’s professional duty of confidence. However, disclosure may be required by law, or in interests of public safety.

6.2. Pathology tests carried out in the medical laboratory are requested by registered doctors in the course of investigation or treatment. The pathologist/laboratory on completion of the test usually reports or transmits the results of the tests through the requesting physician.

6.3. The Chapter is of the opinion that if a patient is transferred to another institution, or changes his/her primary physician, copies of the laboratory results should ideally be furnished by the original/referring physician as part of the patient’s case records. The laboratory is generally not party to the transfer and has no way of corroborating this information.

6.4. The laboratory may be presented with requests for test results from other doctors or other hospitals (which were not originally indicated on the request or accession form). The laboratory, in these cases assumes that the patient has been referred for further management and releases results in good faith. In these cases, the Chapter suggests that such requests be accompanied by a simple statement stating that the patient is now under the care of that particular doctor and that the patient consents to releasing of results.

6.5. All other requests for release of information, especially to third parties e.g. insurance agencies, should be accompanied by written documentation of the patient’s consent.

6.6. In the case of genome and DNA testing, similar principles of privacy, confidentiality and security apply. Sampling of DNA for analysis should remain a medical act and be part of medically recognised practice. Results of these tests should be revealed only to the patient and the attending physician. Parents and family members may not have the automatic right of access, except when the person being tested is a minor.

6.7. The Chapter strongly recommends that all laboratories should have written guidelines regarding release of information. The laboratory has a right, and duty to first satisfy itself as to the identity of the person requesting information. The laboratory has a right to refuse release of information.

6.8. The pathologist/laboratory should also take reasonable precautions to ensure that the method of release of information is secure and reliable. There should be safeguards regarding accidental release of information, including electronic information.

7. DATA REGISTRIES

7.1. Disclosure of medical records to data registries e.g. cancer registries, tissue registries, are often asked for. While this is an important resource for epidemiological research, laboratories should be cognizant that there may be legal and ethical issues as regards collection, storage and use of such information.

7.2. Release of information regarding infectious diseases, for instance HIV is governed by acts of law and statutory obligations will have to be complied with.

7.3. The French National Consultative Ethics Committee advises that laboratories should disclose information only to accredited organisations which have:
   i) guarantees of confidentiality
ii) an accountable person in charge
iii) policies whereby researchers given access to the information are restricted from contacting patients.

a. Except where notification is governed by law, the best policy would be to obtain consent from the patient for inclusion into a registry. This is to avoid potential disputes arising between patients and laboratories regarding disclosure of confidential medical records. Laboratories may be held responsible for unauthorised disclosure.

b. Pathologists generally do not have direct contact or communication with the patient. To avoid misunderstanding, the French National Ethics Committee suggests that release of confidential medical information to accredited organisations or registries be made by the attending physician, after first obtaining consent from the patient. Although individual practices may differ, the Chapter would like to bring this arrangement to the attention of its members.

c. The Chapter suggests that all requests for disclosure of patient data records for research projects be covered by express permission from the ethics committee of their respective institution or hospital.

d. The ethical principles surrounding keeping and using of medical registers also apply to DNA banks. An individual’s genome is part of his bodily person and should be treated with similar respect.

8. HUMAN TISSUE

8.1. The pathology laboratory receives specimens e.g. tissue, blood, blood products, body fluids, for analysis and testing. All tissue removed in the course of investigation, for diagnosis or therapeutic/prognostic procedures should be submitted to the pathologist/pathology laboratory for analysis, as diagnosis is of paramount importance. This is the duty of care owed to the patient.

8.2. Tissue which remains after diagnostic sampling and examination has been completed is residual tissue. Residual tissue/blood/ fluids from therapeutic or investigational procedures which are no longer required for diagnostic purposes have traditionally been regarded as ‘abandoned goods’ and have been used as a time honoured source of research/teaching material or as material for clinical controls. This includes excess fluids e.g. plasma from a clinical blood test which may be used in a clinical laboratory to ensure quality of instrument analysis. The current accepted practice when so using these samples is to anonymise them so that they can no longer be linked to a particular patient.

8.3. Until recently, specific consent for use of this tissue has not been sought, but as illustrated in the recent revision of guidelines regarding tissue use by the RCPath, UK, the legal and ethical concepts concerning these areas are rapidly changing and will need to be reviewed to ensure conformity with public expectation. Please refer to para 8.4 and 9.3.

8.4. The Chapter of Pathologists recommend that standard consent forms include the possibility that tissue removed in the course of treatment be stored or used for medical research or education. This is also recommended by the Royal College of Pathologists and the Nuffield Council on Bioethics. It should be noted that the patient, their legal guardians or other legally authorised persons have a right to refuse this request.

8.5. In the case of archived diagnostic material e.g. paraffin tissue blocks, the pathology laboratory has substantially transformed fresh specimens from their original state to waxed blocks and glass slides. The Chapter agrees with the statement of the Royal College of Pathologists (c. 1999) that ‘The durable material thus produced can be considered the property of the entity which produced them’. Within this framework the pathologist or hospital acts as the custodian or steward of this tissue which should be considered as part of the patient’s medical records.

8.6. As stewards or custodians of the patient’s tissue, the laboratory providing the primary diagnostic analysis is responsible for the maintenance and integrity of the archival tissue. While researchers should not be prevented from using this tissue, the pathologist must ensure that there are sufficient safeguards regarding patient confidentiality, that archival tissue be anonymised, and also that sufficient tissue is left for diagnostic review or for subsequent prognostication.

8.7. Tissue removed expressly for research should have approval from national/institutional ethics boards and must have documentation of informed consent. The Chapter recommends that unless tissue removed is to be used only for that one single project, that consent for continued storage and future use also be obtained.

8.8. The Chapter joins other pathology associations in recommending that
each laboratory should have guidelines regarding provision of tissue (archival or residual) for research, and strongly advises that all projects to be approved by relevant authorities. The laboratory should have the right to refuse release of tissue should any of the above criteria not be fulfilled.

8.9. The laboratory must also have guidelines and records regarding proper disposal of excess or discarded tissue.

9. TISSUE BANKS

9.1. Pathologists involved in tissue banking should ensure that the bank has been approved by the Ministry of Health, Singapore. Hospitals, clinics and other entities covered by the Private Hospitals and Medical Clinics Act are required to secure written permission from the Director of Medical Services in advance of starting tissue or sperm banking.

9.2. Laboratories should be aware of problems associated with commercial use of human tissue. Trading of organs and blood is prohibited under the Human Organ Transplant Act. Laboratories involved in tissue banking should also ensure that the bank has guidelines to prevent misuse and mishandling of tissue and that tissue samples are anonymised.

9.3. A large part portion of tissue holdings in any tissue bank is derived from residual tissue (from surgical diagnostic/therapeutic procedures) which is no longer required for diagnostic purposes. Notwithstanding this, the medical community still has an ethical obligation to inform patients of how it intends to use this tissue. An informed consent is recommended if residual tissue is to be stored for tissue banking.

9.4. This view is supported by the World Health Organisation and the Council of Europe which states that 'when in the course of intervention, any part of the human body is removed, it may be stored and used for a purpose other than that for which it was removed only if this is done in conformity with appropriate information and consent'. The Chapter endorses this view.

10. FINANCIAL ISSUES

10.1. In accordance with the guidelines issued by the National Medical Ethics Committee entitled ‘An Ethical Approach to Financial Issues in Medical Practice’, laboratories should not provide financial inducements to referring physicians. Any discounts given by laboratories should be passed on to patients.

These guidelines have been prepared by the Academy’s Chapter of Pathologists Committee 1999, 2000, comprising the following members:

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REFERENCES


APPENDIX I

Extracted from Letter of Reply Dated 20 February 2000, to the Medical Audit & Accreditation Unit -Request For Laboratory Investigations By Non-Medical Practitioners

1. Investigations performed by laboratories in Singapore cover a wide range of disciplines and they range from the very simple tests - presence of blood in urine for example, to the more specialised requests - for instance gene analysis of tumours. Many simple tests are today available to the general public as over the counter (OTC) test kits that are sold by pharmacies. As these are already on the open market, we will not address the use of such tests. The more sophisticated investigations however are a more difficult issue and it is to these that we address our remarks.

2. The purpose of laboratory investigation is to aid a physician in making an accurate diagnosis, so as to be able to counsel his/her patient and to institute correct treatment. Therapeutic regimens and potential adverse reactions are known and documented in medical literature.

3. The laboratories with which members of the Chapter of Pathologists are associated with offer tests which by and large have been developed for use in classical medicine - or as the general public here would deem ‘western medicine’. Graduates or practitioners in other disciplines, or alternative medicine may not have the depth of knowledge to understand the limitations of the tests and their results. For instance, a report stating that acid fast bacilli are not detected in a sputum sample does not negate the fact that the patient may have tuberculosis. Conversely a raised serum prostate specific antigen may not indicate the presence of prostatic carcinoma.

4. The results of the tests performed are meaningless unless interpreted. No test value is absolute in itself. The significance of a positive or negative test, a higher or lower value may vary according to circumstance. For instance, the clinician needs to be cognizant of false positives or false negatives. A good example would be VDRL results, which may be affected by concomitant disease such as viral infections or autoimmune diseases. Yet another well-documented example is in HIV serology where negative results may occur during a ‘window’ period.

5. Tests for screening in particular should not be made freely available without availability of trained interpretation and counsel. For instance IgA-VCA
for the Ebstein Barr virus has been used in studies to screen segments of population at risk for nasopharyngeal carcinoma. Although this has been found to be of some significance, a raised value (within the significant range) does not mean that the patient has carcinoma. This still has to be proven by tissue biopsy.

The **therapeutic** decisions influenced by the results of these tests should be based on guidelines issued by the respective medical colleges and specialty disciplines. Raised serum cholesterol, altered serum calcium levels, altered serum iron, come to mind. Many forms of therapy - drugs, dietary supplements and such have been associated with alterations in these entities and these are open to potential abuse.

A **professional** laboratory has a moral obligation to its patients. This extends from ensuring the origins of the sample, the mode of collection, the identification of the specimen, to responsibility of issuing reports. The laboratory staff should ensure that all test results are channelled to a qualified physician who is able to institute therapy, or refer for specialist attention if required. A good example would be a patient who is positive for hepatitis B, and who subsequently has raised α fetoprotein.

**Practitioners** of alternative forms of medicine differ from the 'western' physicians in therapeutic approaches. Cut off levels designed for use with one system may require adjustments of different guidelines. These are issues which have yet to be addressed.

**Monitoring** of a patient's parameters can of course be delegated once a diagnosis and a therapeutic regimen has been instituted, however, the adjustment of therapy based on laboratory results is still the physician's responsibility, in a court of law.

Patients and the general public are at their most vulnerable when confronted with illness or potential disease. As such the Government has guidelines pertaining to qualifications and the standards of practice required of physicians in Singapore. Physicians also have a code of ethics underpinning good medical practice and are held accountable for their conduct by a professional body, the Singapore Medical Council.

As pathologists we feel strongly that in order to prevent misinterpretation and misuse of test results, only registered physicians/physicians designate who fulfill these criteria be allowed to request and receive the results of laboratory investigations.

### APPENDIX II

Extracted from Letter of Reply Dated 30 September 1999, to the Medical Audit & Accreditation Unit - Laboratory Requests by General Public

1. We are of the opinion that members of the general public **should not** be encouraged to request for laboratory tests by themselves, without prior medical advice or consultation for the following reasons:-

1.1 A member of the general public may not have the knowledge to request for **pertinent** tests, and indeed may ask for tests which are not related to his/her complaint.

1.2 Laboratory tests are **specialised** and are geared towards a specific diagnosis. The results of the tests, particularly if abnormal, need interpretation within the context of the patient's clinical condition. Positive tests may carry different connotations for example a positive result for stool for occult blood. Raised serum levels of triglycerides, for example, may not be clinically significant.

1.3 Laboratory tests are in actual fact, a **consultation** between a clinician and a laboratory physician. The pathology laboratory report, which contains the results of tests performed are designed to be read by a medically qualified person.

2. In case of **screening** programmes, wellness clinics and other similar programmes, the laboratory analysing these specimens should ensure that there is qualified medical personnel supervising the programme and that there is adequate counselling for patients/participants.

3. The Committee is cognizant of the fact that there **may** be occasion where a laboratory may decide to process a request from a member of the general public. Should this occur, the laboratory must have qualified medical personnel on site. The import of abnormal results should be explained and the patient referred to a qualified, medically registered physician, of the patient's choice, for further management. These exchanges must be documented by the laboratory.

4. The Chapter will issue guidelines regarding referral by general public and referrals by non medical practitioners.