

GUIDELINES ON SAMPLE MANAGEMENT (VERSION 1/2004)

College of Pathologists, Academy of Medicine of Malaysia

1. Sample Collection and Transportation

The Pathology Laboratory shall make available a Sample Collection Manual to those responsible for primary sample collection. The manual shall contain:

- (a) a list of pathology laboratory tests offered;
- (b) instructions for patient preparation before sample collection;
- (c) instructions to primary sample collectors, which shall include type of sample, volume (amount) of sample and type of container to use;
- (d) instructions for requesting a test and the completion of the request form (electronic or manual) which shall contain sufficient information to identify the person requesting for the pathology laboratory test(s), name, identity number, sex and age of the patient or subject; pertinent clinical data; name of test requested, type of primary sample and anatomic site of origin where appropriate and date and time of sample collection.
- (e) instructions for labeling of sample; all samples accepted by the laboratory shall be identifiable by at least two personal identifiers (i.e. name and unique identity number), the type of sample and date of sampling;
- (f) instructions for sample transportation.

2. Sample receiving, handling and recording

The Pathology Laboratory shall:

- (a) ensure that all samples and requests received are checked and acknowledged receipt by the laboratory staff
- (b) develop and document criteria for acceptance and rejection of primary samples
- (c) ensure that all samples and requests are screened using the following procedures for acceptance of the request -
 - (i) correctly matching the two personal identifiers between the sample and the request form for the laboratory test (electronic or manual);
 - (ii) ensuring that the correct container is used;
 - (iii) ensuring that there are no other reasons for rejection of the primary sample;
- (d) ensure that all rejected requests are recorded and the authorized requestor informed
- (e) ensure that all samples and requests received are recorded. The date and time of receipt of sample as well as the identity of the receiving officer, shall be recorded.
- (f) ensure that all secondary samples are adequately labeled to ensure traceability to the primary sample (when separation of sample is required)
- (g) ensure that all samples are safely stored under the conditions to ensure stability of sample properties, safe and its identity maintained.
- (h) ensure that samples no longer required for testing shall be safely disposed off in accordance with the relevant regulations for clinical waste management

3. Analysis of Samples

The Pathology Laboratory shall ensure that :

- (a) the methods and procedures selected for use be evaluated and found to give satisfactory results before being used. Records of evaluation including the person performing the evaluation shall be retained.
- (b) all procedures are authorized and dated by the responsible staff member and be available at the relevant workstation.
- (c) the tests performance are evaluated using internal quality control before the tests can be run.
- (d) records of the critical steps of the tests performed are retained.

4. Release of laboratory results and laboratory reports

The Pathology Laboratory shall ensure that:

- (a) results or reports are legible, without mistakes in transcription and reported to the requester. The report shall also include but not be limited to the following:
 - (i) clear, unambiguous identification of the examination
 - (ii) the identification of the laboratory that issued the report
 - (iii) unique identification and location of the patient, where possible and destination of the report
 - (iv) name of the requester and the requester's address
 - (v) date of receipt by the laboratory
 - (vi) date of release of the report
 - (vii) biological reference ranges (where relevant)
 - (viii) Identification of person authorizing the checking and/or release of report
- (b) all laboratory results /reports are recorded.
- (c) procedures to validate laboratory results or reports are available
- (d) procedures are available for immediate notification of a physician (or other clinical personnel responsible for patient care) when examination results for critical tests fall within established "critical criteria". All verbal laboratory results/reports shall be followed by a written laboratory results/reports. Details of the verbal laboratory result/report including the date, time, person giving and person receiving the laboratory result/report shall be documented.
- (e) clearly documented procedures for the release of laboratory results/reports including details of who may release laboratory results/reports and to whom are available. The procedure shall also include guidelines for the release of laboratory results/reports directly to the patients.
- (f) procedures for verifying the correctness of all transcriptions from the referral laboratory (if the laboratory results or laboratory reports need to be transcribed) shall be in place
- (g) written policies and procedures regarding alteration of laboratory results/reports are available. When altered, the record must show the time, date and name the person(s) responsible for change. Original entries shall remain legible when alterations are made. Original electronic records shall be retained and alterations trail record kept.

Prepared by College of Pathologists, Academy of Medicine Malaysia Working Group:

Professor Dr. Looi Lai Meng (Chairperson)
Professor Dr. Victor Lim Kok Eow
Dr. Halimah Yahaya
Dr. Jamilah Baharom
Dr. Roshida Hassan
Dr. Rohani Yassin

7 September 2004