1. **INTRODUCTION**

Clinical Toxicology Unit was established as an independent unit under Department of Pathology on 1st April 2015. The laboratory provides Toxicology, Therapeutic Drug Monitoring, Tumor Markers, Special Proteins and Trace Element services to Hospital Kuala Lumpur and other government hospitals which previously offered by Drug & Research Laboratory. The laboratory operates during office hours and by appointment basis on weekends and public holidays.

2. **LIST OF SERVICES**

Clinical Toxicology Laboratory provides the following services:

2.1 Therapeutic Drug Monitoring (TDM), to assist in dosage regimen.

(Amikacin, Gentamicin, Vancimycin, Carbamazipime, Phenolbarbital, Valporic acid, Phenytoin, Theophylline Digoxin Methotrexate)

2.2 Immunosuppressant Drugs (Cyclosporin, Tacrolimus, Sirolimus, Everolimus and Mycophenolic acid)

2.3 Toxicology (Benzodiazepine and Ethanol)

2.4 Tumor Markers (alpha-fetoprotein, β-HCG, CA125, CA 15-3, CA 19-9, CEA, PSA total and free.

2.5 Special Proteins (C3, C4 and C-reactive protein)

2.6 trace Element (Serum Copper and Urine Copper)

3. **REQUEST FORMS**

3.1 Therapeutic Drug Monitoring (TDM) Form

TDM form should be used for all TDM and toxicology request. The form is available at the Integrated Store, Department of Pathology, Hospital Kuala Lumpur. Complete information and correct sampling time are essential to obtain correct and meaningful results.

3.3 PER PAT 301 Form

This form is used for Specific Proteins, Tumour Markers and Trace Element test request.
4. SPECIMEN COLLECTION

4.1 Therapeutic Drug Monitoring

The ultimate goal of drug therapy is to maintain therapeutic steady state, return the system to homeostasis and prevent an acute or chronic pathological state. By monitoring the plasma drug concentration, an individual’s pharmacokinetic idiosyncrasies can be identified and the drug dosage adjusted to provide effective therapy without the risk of toxic and/or therapeutic failure. Proper timed specimen collection is essential to ensure a meaningful result. Please refer to collection guidelines. Therapeutic range and Toxic Concentration for TDM is available at the back of the TDM form (available in Reference section). All samples should be sent in plain tube without gel (red cap) except for immunosuppressants in EDTA tubes.

4.2 Tumor Marker

Tumor Markers test are used to detect abnormal increase of certain compounds in the body which suggests onset of cancer. Most of the markers are not organ specific. Currently, eight (8) markers are available for request by specialist. All tests are offered during office hours and will be ready within 2 working days. All samples can be sent to pre-analytical counter in the Core Lab. Urgent β-HCG test requests can be directed straight to Clinical Toxicology Laboratory, where results will be relayed back to the requesting clinicians within 24 hours. All requests should use PER-PAT 301 form, signed by the requesting doctor complete with diagnosis. All samples should be sent in plain tube (yellow cap). Samples can be taken at random times and fasting is not required.

4.3 Specific Protein

Specific protein tests are commonly used to detect raised metabolites in the body which suggests inflammation or infection. Currently a total of three analytes are being offered. Requests should come from a doctor using PER-PAT 301 form and samples to be sent in plain tube (yellow cap). Carefully planned periodical sampling for monitoring all tests are only available during office hours and results for C-Reactive Protein, Complement 3 and Complement 4 can be obtained within 2 working days. Random sample can be taken as fasting is not required. All samples should be sent to Pre-Analytical Counter in Core Lab.

5. RECEIVING OF SPECIMEN

All specimens are to be sent to the Reception Counter (Pre-Analytical Counter) at Core Laboratory, Department of Pathology, Hospital Kuala Lumpur.
6. REPORTING OF RESULT

For TDM Section, all results will be validated by a Chemical Pathologist or Scientific Officer before they are reported. Test result will be ready according to the Laboratory Turn around Time (LTAT) as listed below:

- Toxicology (Benzodiazepine & Alcohol) : 18 hrs (working days)
- TDM tests : 18 hrs (working days)
- Tumor Marker & Specific Proteins : 2 working days

All results will be dispatched into the respective pigeon holes according to ward and clinic located within the Pathology Department for collection.

7. ENQUIRY OF RESULT

All TDM, Toxicology, Specific Proteins, Tumor Markers and TraceElement results can be inquired by telephone at 6077. Result tracing should be kept to a minimum. For external hospital, result tracing should be write to the Head of Department of laboratory within two months of outsourcing.

8. SERVICE AFTER OFFICE HOUR

TDM testing is available on weekends and public holidays on appointment basis. Appointment should be made during office hours.

9. SUPPLIES

Clinical Toxicology Laboratory is responsible for the supplying of the TDM request forms.