

UNC PROJECT LABORATORY
LILONGWE, MALAWI

COAGULATION TESTING

By

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035 STUDY PREPARATIONS

- Purchase of coagulation factors analyser from fisher diagnostics
- Training of lab staff on the instrument
- Validation of instrument
- Normal reference range survey
- Quality control ranges

INSTRUMENT FEATURES

- Photo-optical two channel analyser
- Designed for all clotting based assays
- Weighs about 1.8 kg
- Has three reagent positions and external thermal printer
- Has in-built thermometer which can be externally verified

ThermbScreen 200



REAGENTS

- Pacific hemostasis reagents includes thromboplastin-D, APTT-XL and calcium chloride
- Thromboplastin-D reagent has ISI value which is used to calculate INR
- New lot of Thromboplastin-D is validated before putting it to use.
- Reagent validation may have an effect on the PT and INR normal reference range hence study coordinator or designee is always informed about the change

TESTING PROCEDURE

- PT and APTT are measured at 37°C
- Samples are manually pipetted into the sample cuvettes and incubated on the instrument block at specific time period
- Incubated samples are measured in duplicate and average result is printed on the thermal paper
- Instrument calculates INR from PT result $(PT/\text{mean NRR})^{ISI}$
- Results are logged in the LIS and lab form

QUALITY CONTROL

- Pacific hemostasis
- Stable for 8hrs after reconstitution
- Three levels 1, 2 & 3 where level 1 is considered a normal control, levels 2 & 3 are abnormal.
- Controls are run before testing patient samples and when techs change in the course of running same batch of samples
- Proficiency testing

CHALLENGES

- Reagent validation not clearly understood by lab techs at the start of the study
- Wrong INR results for a certain period of time as a result of incorrect mean NRR
- The clinic had to re-transcribe all affected INRs which also included samples from Blantyre site
- Stability of control materials

SOLUTIONS

- Re-training of lab techs to understand the use of validation data
- Making sure that stock levels are monitored monthly so that new reagent lot can be ordered and validated before the old lot finishes
- Samples for coagulation testing are batched and run twice or thrice a week to minimize usage of controls

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Thank you!