No.E-C/Micro/RIMS-62/14 Imphal, the 22nd Oct. 2014.

Annexure-A

Item No.1:- **Specifications for automated blood/body fluid culture system: (US FDA approved/ CE Certified).**

i) The system should be for minimum of 60 positions.

ii) The system should be fully automated and should be capable of detecting growth of the pathogenic micro-organism from blood & Sterile body fluids.

iii) The system should have the facility of detection of Mycobaterium tuberculosis and other atypical mycobacterium from the blood, blood fluids and sputum.

iv) The system should be able to detect fungal, aerobic and anaerobic organism from the blood.

v) The system should have the capability to process samples of adult and pediatric patients and should have dedicated media for pediatric samples.

vi) The system should have the capability of continuous monitoring of the clinical samples.

vii) It should have automated continuous instrument quality check facility.

viii) The system should be provided with printer and UPS and should be able to display growth kinetics on the screen. The system should be modular and upgradable for future requirements.

ix) The system should have the capability of analyzing and detection of delayed entry of specimens at growth, stationary and decline stage (both log & lag phase).

x) The media provided for blood, sterile body fluid or fungal culture should be provided with additional antimicrobial substances.

xi) Detection principle of the system should not have any bottle puncturing during sample analysis and thus no dangerous aerosols formation.

xii) The system should use plastic bottles for safety and ease of disposal.

xiii) 5 KVA UPS for use of automated blood/body fluid culture system.

Item No.2:- **Specifications for fully automated bacterial identification and antimicrobial susceptibility system.** (US FDA approved/ CE Certified).

i) The system should have user interface screen and keyboard having the following specification.

- Comprise the instrument User Interface (UIF)
- Fill indicator LED-alerts user of the fill status
- Load indicator LED
- Fill door-provides access to the filler station
- Front user access door-provides access to the optics, incubator, and a portion of the card transport system.
- Top user access door-opens only when the front user access.
- Door is open. Provides access to the optics and carousel. This door lifts from the front and remains in the open position until the operator closes it.
- Load door-provides access to the cassette load/ unload station
- A locking mechanism prevents the opening of this door during operation.
- Waste collection door-provides access to the waste collection station where ejected cards are removed from the instrument. The door is held in place magnetically and opens from the right.
- Optical sensor – senses when the door is opened or closed.
- Door latch and lock- the latch holds the door closed. The locking mechanism consists of a pin extending from inside the cabinet into the latch.

ii) The system should be made up of the following components.

- Computer
- Data terminal
- Printer
- Test Cassette

iii) The system software should run in a windows XP environment with Advanced Expert system (AES)

- Interface connection software
- Easy to use to increases usability and speed to perform diagnostic test
- Advanced colorimetric ID analysis
- Automated susceptibility testing

- Test result validation & resistance detection
- MIC determination and therapeutic interpretation
- Should alert resistance mechanism.

iv) Test kits should be

- Compact and light: 16g minimized biohazard
- Closed test reagents minimized risk of contamination
- Closed integrated transfer tube (Blue= ID, Gray =AST)
- Minimised risk of error in card selection
- Pre- inserted for optimal workflow
- No risk of contamination
- Positive ID of cards (Individual barcode)
- Maximized security
- No external mark required optimized workflow.

v) The system should have

identification card menu with advanced colorimeter gram negative bacilli identification.

gram positive bacilli identification.

The identification results should be obtained from 2 hrs.

(vi) The system should have optics which allows the measurement of 3 wavelengths for identification card

.568nm & 428 nm for T X 3

.660 nm for T X 1

(vii) 5 KVA UPS for use of fully automated bacterial identification and antimicrobial susceptibility system.

22/10/14

(Prof. Ch. Arun Kumar Singh)
Director,
Regional Institute of Medical Sciences,
Imphal.