Research Article

Quality Assurance Programme of Laboratory In Hospital Pharmacy

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Policy

Quality Assurance programme of laboratory is focused on following key characteristics. These key characteristics shall meet the specified acceptance criteria / norms.

These key characteristics are monitored on regular basis to ensure that they meet the acceptance criteria. A record for this is maintained in quality assurance register of the department.

Departmental coordinator shall be vigilant about these key characteristics. Based on the observation, every week departmental coordinator shall record his / her remark against the key characteristics as to whether the key characteristics meet the acceptance norms or not. Specific comments for the key characteristics may also be written.

These records shall be reviewed by Quality Assurance committee every week.

S No.	Key characteristics	Acceptance norms / criteria	Responsibility and conformance verification.	Frequency
1.	Surveillance of test results	Weekly surveillance of a sample of test results	HOD / Laboratory In-charge	Weekly
2.	Check of calibration and maintenance of equipments according to standard.	As per the manufacturer's instruction.	Technician	Weekly
3	Compliance monitoring	Compliance as per standards, SOP and policies	Laboratory staff	Continuous
4	Third party human matrix internal quality control should be used	QCI - Essential Standards for registration of medical testing laboratories in India	Technician	Minimum 2 levels – daily
5	External Quality Assessment	QCI - Essential Standards for registration of medical testing laboratories in India	Technician	At least once in a month
6	Timely intimation of critical results	Within ½ hour	Technician	Daily
Biochemistry				
1.	Daily washing of equipments with methanol and distilled water.	Clean glassware	Technician	Weekly
2.	Washing of equipments with FLOW -SHELL (reagent)	As per the manufacturer's instruction.	Technician	Fortnightly
3.	Calibration through control (Biochemistry Kit)	As per the manufacturer's instruction.	Technician	Quarterly
Hematology				
1.	Maintenance of equipment	As per the instruction in operation manual.	Technician	Daily

2.	Calibration through control. (Hematology kit)	As per the manufacturer's instruction.	Service Engineer of the company.	Once in three months
Pathology				
1.	Tests to be done on fresh specimens received in containers with lids.	Proper covering of sample with lid	Technician	Daily
Microbiology				
1.	Preparation of media under strict aseptic precautions	Sterility	Technician	Weekly
2.	Checking of gas cylinder for any leakage	Offensive smell	Technician	Daily

1. Internal Quality Control

1.1. Quality control material

1.1.1. The QC material used must cover the analytical range of the testing system. Low /normal/ high, normal/abnormal, positive/negative, reactive/non-reactive controls as appropriate for the test must be used.

1.1.2. Controls independent of those produced by the manufacturer of the test or analyzer must be used.

1.1.3. Laboratory should obtain control material to last for at least one year, where practical. This will help in long term monitoring of testing systems.

1.1.4. For most analytes, a minimum of two level of QC is recommended.

1.1.4.1. Where possible the analyte concentrations should be at the clinically relevant levels.

1.2. QC Application

1.2.1. Frequency of control measurements

1.2.1.1. The QC samples should be analyzed at least once during the analytical run length.

1.2.1.2. Manufacturers (of reagents & instruments) recommendation should be used only as guidelines.

1.2.2. Location of control samples

1.2.2.1. The location of QC sample should be such that it allows for reporting the QC before the patient sample.

1.2.2.2. It is advisable to keep the QC samples in between and at the end of the run to detect errors.

1.2.3. Setting control limits

1.2.3.1. Acceptable ranges must be defined for the quality control material.

1.2.3.2. Values provided in the assay sheets should be used only as guidelines.

1.2.3.3. The range should be calculated as +/- 2 SD.

1.2.4. QC Analysis & Out of control situations

1.2.4.1. Numerical QC should be presented graphically to assist in early detection of trends.

1.2.4.2. The laboratory should have a system of long term monitoring of internal quality control results to assess method performance.

1.2.4.3. There must be documented evidence of review of internal quality control results.

1.2.4.4. The lab should establish guidelines to respond to out of control situations. The actions should be documented.

1.2.5. Inter laboratory participation

1.2.5.1. Laboratory should actively participate in inter laboratory programs for the control materials where such programs are available.

1.2.6. Calibrators

1.2.6.1. Where calibration of an assay is required appropriate material must be used as a calibrator.

1.2.6.2. Record of the traceability certificate of the calibrator must be maintained.

1.2.6.3. If the material selected is not intended for use as a calibrator, assigned calibrator values must be substantiated.

2. External Quality Assurance / Proficiency Testing

2.1. Where available labs must participate in EQAS / PT programs.

2.2. Program which includes laboratories in other countries / region should be preferred.

2.3.The EQAS/PT program must be from an accredited provider.

2.4. Labs should submit data EQAS data regularly as per the submission dates specified by the program organizers.

2.5.EQAS performance should be reviewed and the evidence of review should be documented.

2.6.The EQAS /PT samples should be treated a patient samples.

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