






BIOGENIX

POLICY PROCEDURE FOR EXTERNAL SERVICES AND SUPPLIES

	NAME	DESIGNATION	SIGNATURE	DATE
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BIOGENIX

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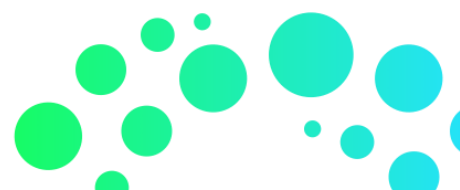
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2. REVISION HISTORY

#	Version	Date	Changes Made by	Reason for Changes	Clause Changed
1	1.0				





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4. POLICY STATEMENT

The selection and purchasing of external services, equipment, reagents and consumables supplies that affect the quality of its service are done as per this policy and procedure.

5. PURPOSE

The main objective of this procedure is to guide in selection and purchasing of external services, equipment, reagents and consumables supplies that affect the quality of its service.

Assure quality of procured services as well as on schedule delivery. Minimize the risk associated with goods and services.

Procedure applies to all type of procurements and contracts including, but not limited to: Lab consumable, Lab equipment/ Machines, Chemical/reagents, Consumables, Emergency purchase.

- 5.1. Selection of suppliers is based on their ability to supply in accordance to the requirements.
- 5.2. A set criterion is followed for selection external service providers and suppliers.
- 5.3. A list of selected and approved suppliers is maintained.
- 5.4. The performance of these suppliers is monitored annually, or if there is an adverse incident / issue

This procedure is as per clause 4.6. of ISO 15189:2012 Medical Laboratories –Requirement for Quality and Competence

6. SCOPE

- 6.1. All the purchases in the laboratory related to equipment, reagents, consumables and external services.
- 6.2. BIOGENIX Management
- 6.3. BIOGENIX Staff.

7. DEFINITIONS

- 7.1. Procurement: the act of obtaining equipment, materials, or supplies
- 7.2. New items: are the items which are not included in the contracts with vendors
- 7.3. Vendor: One that provides products or services to a business for a fee.
- 7.4. Reagents: includes reference materials, calibrators and quality control materials.
- 7.5. Consumables: includes culture media, pipette tips etc.
- 7.6. Laboratory equipment: includes hardware and software of instruments, measuring systems, and laboratory information system.





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8. ACRONYMS

- 8.1. MM: Material Management
- 8.2. PPM: Planned Preventive maintenance

9. RESPONSIBILITIES

- 9.1. BIOGENIX Management
- 9.2. BIOGENIX Staff

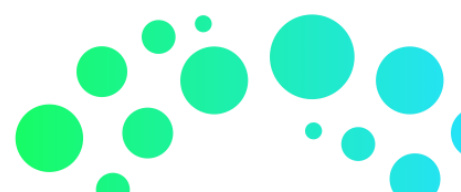
10. PROCEDURE

10.1. PROCUREMENT ETHICS:

- 10.1.1. Maintain the highest possible standards of integrity in all the business relationships;
- 10.1.2. Declare any personal interest which affect negatively on staff to his or her duty;
- 10.1.3. Conduct business with current and prospective supplier fairly and without intentional misrepresentation;
- 10.1.4. Respect and safe guard the confidentiality of information received in the course of duty and avoid disclosing such information without obtaining the permission from the owner of the information;
- 10.1.5. BIOGENIX has procedure in place for the selection and use of purchased external services like out sourced test, technical consultancy, equipments and consumable supplies which affect the quality of services.

10.2. Selection Criteria for Equipment & Equipment Supplier:

- 10.2.1. Customer expectations (Need of User)
- 10.2.2. Medical appropriateness of examination equipment
- 10.2.3. Credibility of supplier in the market
- 10.2.4. Equipment function and features
- 10.2.5. Stability and availability of reagents
- 10.2.6. Cost to place equipment into use





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- 10.2.7. After Sales service
- 10.2.8. Ongoing cost to maintain and operate equipment
- 10.2.9. Time and effort needed to maintain and operate equipment
- 10.2.10. Time and effort needed to place equipment into use
- 10.2.11. Laboratory staff (e.g., "end user") considerations
- 10.2.12. Facility/environment requirement
- 10.2.13. Payment terms and conditions

10.3. SELECTION CRITERIA FOR REAGENT AND CONSUMABLE SUPPLIERS:

- 10.3.1. Credibility of supplier in the market
- 10.3.2. Accreditation Status of the store
- 10.3.3. Location and environmental conditions of Ware house
- 10.3.4. Delivery time
- 10.3.5. Delivery of reagents by maintaining proper environmental conditions
- 10.3.6. Payment terms and condition
- 10.3.7. Acceptability test for reagent/kit (Comparison with existing method)

10.4. SELECTION CRITERIA OF MAINTENANCE AND CALIBRATION CONTRACTOR

- 10.4.1. Accredited for ISO17025 compliance
- 10.4.2. Competitive Prices
- 10.4.3. Qualified engineers
- 10.4.4. Timeliness of services
- 10.4.5. Payment Term and condition
- 10.4.6. Reputation in the market
- 10.4.7. Content of Report

All the small instruments e.g. Pipettes, Centrifuges, microscopes, shaker, balance, refrigerators, incubator, Bio- safety cabinet, Autoclave etc. are under maintenance contract from outside vendor, which includes calibration and PPM from the maintenance company.

The main analyzers are maintained by the service engineers of the manufacture e.g. Abbott service engineers take care for Alinity I and Cell Dyn Emerald.

10.5. SELECTION CRITERIA OF MISCELLANEOUS SERVICES

Miscellaneous services are like Waste management, laundry etc.

- 10.5.1. HAAD/ Municipality/ any other concerned department approved
- 10.5.2. Competitive Prices
- 10.5.3. Qualified staff





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- 10.5.4. Timeliness of services
- 10.5.5. Payment Term and condition
- 10.5.6. Reputation in the market.
- 10.6. BIOGENIX ensures that all purchased items consistently meet the laboratory's quality requirement by clearly defining the specifications
 - 10.6.1. BIOGENIX maintains records of purchased items fulfilling national, regional and local regulations.
 - 10.6.2. Quotations are taken from the companies.
 - 10.6.3. Comparison is prepared and selection is done.
 - 10.6.4. After final negotiation contract is signed by Laboratory director.
 - 10.6.5. Renewal of contract is upon satisfactory services.
 - 10.6.6. BIOGENIX has a procedure addressing evaluation of suppliers of critical reagents, suppliers of support services which affect the quality of examinations. Provides details on the records of supplier evaluations, list of approved supplier and supplier rating. Evaluation is done on annual basis.
- 10.7. **EVALUATION OF VENDOR/SUPPLIER**
 - 10.7.1. Timeliness of Supply
 - 10.7.2. Supply maintaining the proper conditions
 - 10.7.3. Invoice in Time
 - 10.7.4. Flexibility in returning item if short expiry
 - 10.7.5. Communication
 - 10.7.6. Timeliness in Resolving any issue
- 10.8. **SERVICE SUPPLIER EVALUATION**
 - 10.8.1. Response to Critical Breakdown Calls
 - 10.8.2. PPM Performance as Per Schedule
 - 10.8.3. Spare Parts Availability and Delivery Time
 - 10.8.4. Equipment/Device Performance
- 10.9. **GRADING SYSTEM**

Accepted Score: 80%

GRADE:

- 1: Poor response, does not – or barely meets user requirements
- 2: Average response, will meet most of user requirements
- 3: Good response – meets all users requirements
- 4: Very good response, meets all user requirements with some additional value.





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5: Excellent response, exceptional, innovative, meets all user requirements and exceeds in some cases.

*N. A: Not Available

Persistent poor performance by any contractor or supplier is looked at seriously and early termination of the agreement is considered. Conversely, good performance is rewarded through ongoing business.

10.10. CONTRACT MONITORING:

Regular monitoring is done by concerned department leaders and provides feedback if any incident happened due to contractor supply. It is recorded with evidence and informed to laboratory director.

10.11. CONTRACTOR SATISFACTION

10.11.1. Contractor /supplier relationship is managed such that the user is at all times satisfied that their performance is adequate to ensure compliance with contractual requirements.

10.11.2. Each year there is a satisfaction survey conducted from the LMC to evaluate the contractor.

11. CROSS REFERENCE

- 11.1. HAAD standard for clinical laboratory
- 11.2. ISO 15189: 2012 Medical laboratory requirements for quality and competence.
- 11.3. CLSI guidelines QMS 13A.

12. RELEVANT DOCUMENTS & RECORDS

- 12.1. BG/REC/BME/002 Checklist Criteria for selection of Equipment and Equipment Suppliers
- 12.2. BG/REC/GEN/044 Checklist for Criteria for selection of Reagent and consumable suppliers;
- 12.3. BG/REC/GEN/045 Checklist for contractor/ vendor evaluation.
- 12.4. BG/REC/GEN/046 Checklist for service supplier evaluation
- 12.5. Checklist for Maintenance/calibration Contractor
- 12.6. BG/REC/GEN/048 List of Selected and Approved Suppliers
- 12.7. BG/REC/GEN/047 Checklist for service & calibration Supplier evaluation





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