






BIOGENIX

POLICY PROCEDURE FOR SELECTION AND EVALUATION OF REFERRAL LAB

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DOCUMENT CONTROL: BG/PP/GEN/026

VERSION: 1.0

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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 PURPOSE:

4.1. This procedure explains the method of selecting and evaluating the referral laboratories before making an agreement as well as consultants who provide opinions and interpretation for complex testing in any discipline.

However, BIOGENIX refers the samples to other lab in case:

- a. Test is not available in BIOGENIX lab.
- b. Inter laboratory comparison;
- c. As a backup service provider;
- d. For advisory services.

This procedure is as per clause no.4.5. Of ISO15189:2012 requirements for quality and competence

5 SCOPE:

5.1. Applicable to laboratory's selected for reporting of the out sourced samples, Inter Laboratory Comparison and to consultants who give opinion and interpretation of the test results and evaluate them with provision for review.

6 DEFINITION/ABBREVIATIONS:

6.1. Referral Laboratories: External Laboratory to which a sample is submitted for examination.

6.2. Advisory Service: Service provided by professional.

6.3. Backup service: Help or Support Service;

6.4. ILC: Inter Laboratory Comparison.

6.5. Lab: Laboratory

6.7. TAT: Turn Around Time



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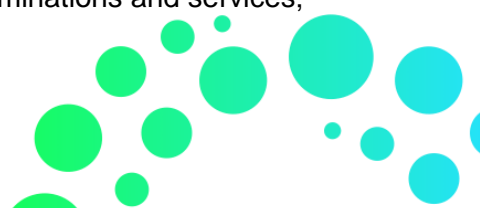
6.8. CRITERIA OF SELECTION:

Laboratory Director is responsible for selecting and monitoring the quality of the referral lab and the consultants by keeping in view following points:

- 6.8.1 Licensure and accreditation status of the referral laboratory;
- 6.8.2 Customer service of referral laboratory, how they support the BIOGENIX Lab. in case of query or how prompt they are in telephone or web base services or how they resolve the technical issues.
- 6.8.3 Comprehensive test menu;
- 6.8.4 Sample transport services;
- 6.8.5 The TAT of the referral laboratory
- 6.8.6 Technical staffs that are performing the examination are well qualified and knowledgeable or not;
- 6.8.7 Equipment used in the laboratory are up to date maintained, and also verified before using for examination;
- 6.8.8 The referral laboratories participate in proficiency testing or alternative methods of assessment and their reports;
- 6.8.9 In situation in which referral laboratory uses third laboratory, the third laboratory is clearly identified and all reports has the name and address of the third laboratory;
- 6.8.10 Keep us updated if a new test is added in the test menu or new equipment purchased and if any new staff joined the team, if its affect our tests results;
- 6.8.11 Reports are clear with the patient information, BIOGENIX lab.ID, referral lab ID. Age, Sex, Reference ranges and interpretation.
- 6.8.12 Costs for service.
- 6.8.13 Transportation of the samples by their messenger in a manner that the integrity of the samples is maintained.
- 6.8.14 Selection of examination procedures is appropriate for the intended use, and respective responsibilities for the interpretation of examination results are clearly defined. BIOGENIX maintains Records of such reviews in accordance with national, regional or local requirements.
- 6.8.15 BIOGENIX laboratory send a detail form to the referral laboratory which is filled by responsible staff of the referral laboratory.

6.9. REQUIREMENTS FOR US (BIOGENIX LAB.):

- 6.9.1 BIOGENIX lab. Director is responsible for ensuring that referral lab and referral consultant are competent to perform the requested examinations and services;





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- 6.9.2 Agreements between the BIOGENIX and Referring lab is reviewed annually and records are maintained;
- 6.9.3 Records are maintained for the samples referred to referral lab. and also for the results received.

6.10. EVALUATION OF REFERRAL LABORATORY

- 6.10.1 The evaluation is carried out at the end of each year;
- 6.10.2 Requirements including the pre-examination & post examination procedures, are adequately defined, documented and understood;
- 6.10.3 Evaluation is based on timeliness, accuracy quality of results and interpretation of results which are monitored by BIOGENIX, based on this evaluation, agreement is reviewed or revised.
- 6.10.4 Accuracy of invoicing;
- 6.10.5 The referral laboratories are able to meet the requirements
- 6.10.6 Laboratory Director is responsible for approval to renewal or to terminate the contract with the referral lab., based on the previous year reports.
- 6.10.7 Competency of Referral Laboratory pathologist is judged on annual basis

6.11. TRANSPORT OF SAMPLES:

- 6.11.1 Samples for reporting and Inter Laboratory Comparison are clearly identified and transported to the Referral laboratory by the messenger of the referral laboratory or BIOGENIX along with a test requisition form, in a closed box maintaining appropriate temperature conditions as per the test requirements.
- 6.11.2 The BIOGENIX technical staff send samples to the referral lab for reporting, second opinion and ILC only;
- 6.11.3 The details of the sample sent to the referral lab for reporting is mentioned in out sourced sample register and ILC is recorded in the respective department Inter Laboratory Comparison file;
- 6.11.4 Sample tracking form is filled and handover to the messenger and is returned to the BIOGENIX lab. With the details and signature of the person who received the sample.

6.12. RECEIVING THE REPORTS



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6.12.1 Results are received both ways soft copy as well as hard copy from the referral laboratories. Hard copies are sent to BIOGENIX through referral laboratory messenger.

6.12.2 Results are forwarded by BIOGENIX messenger to the requesting physicians in the same format in which they are received. There is not any alteration in the context of the report.

For ILC the results are evaluated by making reports on EP evaluator, if the results of the two labs are not comparable & acceptable, reason for the varying results is analyzed. Based on the root cause analysis, suitable corrective and preventive action is planned and communicated to all concerned

7 TARGET AUDIENCE:

- 7.1. Laboratory Director;
- 7.2. Laboratory Staff;
- 7.3. Referral Laboratory Staff.
- 7.4. BIOGENIX Reception Staff;
- 7.5. BIOGENIX accounts and admin staff.

8 RESPONSIBILITY:

- 8.1. Primary responsibility: Laboratory Director;
- 8.2. Secondary responsibility: Laboratory Technical Staff.

9 PROCEDURE:

- 9.1. BIOGENIX follows the below mentioned steps before the agreement:

10 REFERENCES:

- 10.1 CLSI guidelines for referral laboratories;
- 10.2 HAAD Standard.
- 10.3 ISO 15189:2012 Medical Laboratories requirement for Quality and Competence.



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11 APPENDIX:

- 11.1 BG/REC/GEN/040 List of Approved Referral Labs
- 11.2 BG/REC/GEN/042 Selection form for Referral Lab
- 11.3 BG/REC/GEN/043 Evaluation form for Referral Lab
- 11.4 BG/REC/SAMP/002 Send Out Sample Form for Referral Lab
- 11.5 BG/REC/GEN/041 Referral Lab. Register

