	GUIDELINES FOR SAMPLE COLLECTION CENTERS OF MEDICAL LABORATORIES	G-23/09 Issue Date: 03/04/17 Rev No: 00
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1. Scope:

This guideline provides the requirements that are to be complied with by sample collection centers which provide samples to medical laboratories.

2. Responsibility: Manager of Sample Collection Centers or their Designees

3. Definitions:

3.1 Sample Collection Centre: A place where materials derived from human body are collected and delivered under specific conditions for clinical examination purposes under an agreement or contract with a medical laboratory.

Note: A sample collection center (SCC) can be an organization which may fall in to one of the categories given below.

Type A - A center collecting samples to its own laboratory and the personnel are employees of either the center or the laboratory or its parent organization.

Type B - A center collecting samples to a laboratory which is not affiliated to the center or its parent organization but the laboratory or its parent organization is entirely responsible for day to day operations and employees of the center.


4. Guidelines:

4.1 SCC shall be a legally registered entity or the part of legal entity.

4.2 SCC shall be currently functional and the times of operation shall be declared.

4.2 SCC shall have adequate number of staff who is qualified and competent to perform the assigned tasks. The assigned tasks shall be issued to each employee with updated job descriptions.

4.3 SCC shall ensure that confidentiality of samples and the information related to samples including test results, if available is maintained.

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4.4 The staff of SCC shall be adequately trained and training records shall be maintained. The training shall include but not be restricted to the following.

- (a) Policies, procedures and guidelines of good sampling and laboratory practices,
- (b) Maintenance of proper hygiene and environmental conditions,
- (c) Methodology for collection of sample and the amount required,
- (d) Handling of collected samples
- (e) Labeling of samples
- (f) Packaging of samples,
- (g) Proper transportation of the samples / specimen,
- (h) Operational health safety requirements
- (i) Action including first aid measures to be taken, in case of abnormal events, and
- (j) Waste disposal

4.5 Specific instructions for proper collection and handling of primary samples at the collection centre and, storage and transportation of these samples to laboratories shall be documented in a primary sample collection manual and which shall be made available at the SCC.

4.6 The SCC shall maintain adequate hygienic, lighting and environmental conditions such that the integrity of the samples is not affected during collection, storage and transportation. Special care should be taken to ensure that the work area is clean and well maintained.

4.7 The SCC should arrange to prevent cross contamination. During the sample collection, safety, comfort and privacy of the patients as well as preservation of sample identity shall be ensured.

4.8 The SCC shall ensure that the environmental conditions are maintained as required during storage and transportation of sample to avoid deterioration of sample. Records of environmental conditions recommended for samples in the SCC shall be maintained.


4.9 The SCC shall ensure that sample wastes are disposed as per the national laws (waste disposal Act/law) and the local regulations for waste disposal.

4.10 If the samples are separated at the SCC prior to sending to laboratories, SCC shall take measures to maintain the integrity of samples.

4.11 Test reports may be issued by the SCC. SCC shall ensure that the name and address of the SCC is included in the test report issued by laboratories and retain such information in related documentation.

4.12 Only those SCCs which have been approved by PNAC to collect samples shall be claimed as PNAC Approved Sample Collection Centers. If SCC wishes to declare its recognition with regard to the approval shall declare that using the words “PNAC approved Sample Collection Center for Collection of Samples for Medical Testing”.

4.13 The SCC shall never claim that it is accredited.

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5. GUIDELINES FOR SELECTION OF SAMPLE COLLECTION CENTERS FOR ASSESSMENTS

5.1 Authorized Representative of Medical Laboratory in consultation with the Lead Assessor/Technical Assessor/ Expert shall select the number of sample collection centers to be visited during different types of assessments as given in the Table below. The sample collection centers that were visited previously within the accreditation cycle shall not be selected unless there is any reason to do so.

No. of centers	Sample collection centers to be selected (minimum)			
	Pre + Initial	1st Surveillance	2nd Surveillance	Re-assessment
1 - 30	1/3 of the centers	1/4 of the centers	1/4 of the centers	1/3 of the centers
31 - 60	1/4 of the centers	1/6 of the centers	1/6 of the centers	1/4 of the centers
61 - 90	1/5 of the centers	1/8 of the centers	1/8 of the centers	1/5 of the centers
Above 90	1/6 of the centers	1/10 of the centers	1/10 of the centers	1/6 of the centers

5.2 Program officer (PM) shall maintain a list of the sample collection centers of the laboratory in the CAB case file.

5.3 PM shall update a Sampling Plan indicating the Sites visited and to be visited during an accreditation Cycle.

References:

1. ML-GL(P)-01-Guideline-For-Sample-Collection-Centers-Of-Medical-Laboratories, SLAB, SRI LANKA
2. ML-FN(P)-24-SCC- Checklist for assessing Medical laboratories sample collection centers, SLAB, SRI LANKA