Guidelines for operating and assessing Sample Collection Centers of medical laboratories

1. Scope:
This guideline provides a framework for operating and assessing Sample Collection Centers in a given medical laboratory.

2. Responsibility:
Authorized Officer
Authorized Representative of Laboratory
Technical Assessor

3. Reference:
ILAC-G26:11/2018: Guidance for the Implementation of a Medical Accreditation Scheme

4. Definitions:
4.1 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.

5. Guidelines:
5.1 Authorized Officer shall select the Sample Collection Centers (SCC) to be assessed for each assessment and all SCCs will be covered during the whole accreditation cycle. The status of SCC visits shall be indicated in the Assessment programme of each relevant laboratory (ML-PL-09).

5.2 A laboratory shall declare its SCCs to the SLAB prior to assessments. Laboratories may have sample collection centers in the following three categories.

(a) SCCs owned by the laboratory or its parent organization and the personnel are employees of the laboratory.

(b) SCCs not owned by the laboratory or its parent organization but the laboratory is entirely responsible for day to day operations and employees of the SCC.

(c) SCCs not owned by the laboratory or its parent organization but which are operational as franchisees for sample collection under a contractual agreement.

5.3 SCCs to be included in the scope of accreditation shall be currently functional. All SCCs which are providing samples to the laboratory pertaining to an accredited test shall be declared to the SLAB. If any SCC separate samples received from other SCCs prior to sending to the laboratory, declaration of such SCCs may be adequate provided that either the laboratory or said SCC take measures to maintain the integrity of samples sent by other SCCs. Only those SCCs which are declared to the SLAB shall be claimed by the laboratory as to be covered by the scope of accreditation. The times of operation of SCCs shall be declared and available with the laboratory.

5.4 All issues related to the operation of SCCs and maintenance of quality shall be addressed by the laboratory in the quality system of the main laboratory. Specific instructions for proper collection and handling of primary samples at the collection centre and transportation of these samples to the laboratory shall be documented. A copy of this document shall be available at the SCC.

5.5 Laboratory should document policies and procedures for proper hygiene, lighting, environmental conditions and privacy in its SCCs sample. It is the responsibility of the laboratory to ensure that its SCCs maintain adequate hygiene, 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.

5.6 SCCs should have arrangements to prevent cross contamination. During the sample collection in SCCs, laboratory shall ensure the safety, comfort and privacy of the patients as well as preserving sample identity.

5.7 SCCs or otherwise the laboratory shall ensure that the environmental conditions are maintained as required during the transportation of sample to avoid deterioration of sample.

5.8 Laboratory shall ensure that its SCCs dispose waste as per the national laws (eg. CEA waste disposal Act) and the local regulations on waste disposal.

5.9 The staff employed in SCCs shall be adequately trained. The training shall include but not be restricted to issues such as:

(a) Policies, procedures and guidelines,
(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.

5.10 Laboratory should ensure the evaluation of training imparted to staff in SCCs and maintain training related records.

5.11 Laboratory should have a plan to conduct internal audit of its SCCs to ensure relevant requirements of ISO 15189 are fulfilled. Laboratory should conduct internal audit of each of its SCC at least once a year. Management review of the laboratory should also include the internal audit of its SCCs.

5.12 Only those SCCs which have been declared to the SLAB shall be claimed by the laboratory as a part of its laboratory system. The laboratory shall include the name and address of its SCC in the test report and retain such information in related documentation. Neither the laboratory nor the SCCs shall claim that SCCs are accredited.

5.13 The test report may be issued by the laboratory or the respective SCC. If a report is re-issued by any SCC adding the results of accredited test(s), that report issued by the SCC shall indicate that the results pertaining to the test(s) have been extracted from an accredited test report issued by the laboratory.

5.14 The laboratory or SCC may declare that the SCC has been accepted by the SLAB to collect samples if the laboratory or any SCC wishes to declare its recognition with regard to acceptance shall declare the status using the words "SLAB accepted SCC for Collection of Samples for Laboratory X".

5.15 Records of environmental conditions recommended for samples in the SCCs shall be maintained. Records of temperature and conditions of the sample on receipt by the laboratory shall also be maintained.

5.16 During the assessment of a SCC, the technical assessors shall check how the primary samples are transported from the collection centre to the main laboratory and the efficacy of containers used for transportation, so that the integrity of the samples is maintained. Assessors shall assess the records maintained by the SCCs including the internal audit records of collection centers and other records pertaining to the sample collection process. Checklist for Assessing Medical Laboratory Sample Collection Centers (ML-GL(P)-24 will be filled in for each SCC.

5.17 If there are non-conformities or a total system failure during the assessment of a SCC, the laboratory shall be asked to take corrective actions. In case the laboratory fails to take corrective actions or there is a consistent system failure, an appropriate and proportionate action against the laboratory shall be taken.

6. Reference documents:

6.1 ML-GL(P)-24- Checklist for Assessing Medical Laboratory Sample Collection Centers

6.2 ML-PL-09- Assessment Programme