

GUIDELINES FOR SELECTION OF SITES AND SAMPLE COLLECTION CENTERS FOR ASSESSMENTS

1. Scope:

This guideline provides a framework for selecting sites and sample collection centers in a given multi-site medical laboratory for different stages of assessments.

2. Responsibility: Lead Assessor/ Team Leader/Authorized Officer/ Authorized Representative of Laboratory

3. Procedure

3.1 Authorized Officer in consultation with the Lead Assessor/ Team Leader/Technical Assessor/ Authorized Representative of Laboratory shall select the number of sites in a multi-site laboratory to be visited during different types of assessments as given in the Table below. When the number of sites exceeds three (3), those laboratories which were visited previously within the accreditation cycle shall not be selected unless there is any reason to do so. However in case of scope extension, all sites requesting scope extension shall be visited.

No. of sites	Laboratory sites to be selected (minimum)			
	Pre + Initial	1 st Surveillance	2 nd Surveillance	Re-assessment
1 - 3	All sites	All sites	All sites	All sites
4 - 8	All sites	1/2 including the main laboratory	The rest including the main laboratory	1/2 including the main laboratory
Above 8	All sites	1/3 including the main laboratory	1/3 including the main laboratory	1/2 including the main laboratory and other sites not visited for the last two years

3.2 When sites are selected, the sample shall be representative enough and shall include all the activities which are required to assure a complete evaluation of the competence of the laboratory.

3.3 Authorized Officer in consultation with the Lead Assessor/ Team Leader 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	1 st Surveillance	2 nd 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

3.4 Authorized Officer shall maintain a list of the sites and sample collection centers dealt by the laboratory on or attached to the CAB information sheet (ML-FM-13) of the case file.

3.5 Authorized Officer shall update a Sampling Plan indicating the Sites visited and to be visited during an accreditation Cycle.

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