Laboratory Assessment Tool for Bacterial Meningitis Surveillance

MenAfriNet

Toolkit

Use this tool to conduct an initial laboratory assessment of the overall laboratory capacity for the detection of bacterial meningitis pathogens.

INTRODUCTION

Bacterial meningitis remains a global health concern. It is critical that laboratories have the capacity to identify the causative pathogen for clinical and public health decision making. In order to ensure that the laboratory is equipped to perform this task, this quick and simple tool serves as a guide for the assessor for evaluating the overall laboratory capacity for the detection of bacterial meningitis pathogens. This tool will help assessors identify the strengths and areas for improvement in the current infrastructure, laboratory processes, test services, equipment, and skillsets of the individual, which can inform how to strengthen the laboratory. The intended user of this tool could be an individual, preferably someone familiar with meningitis testing, interested in expanding a laboratory's capability for meningitis testing. This document can also be used by an individual interested in strengthening their own laboratory for meningitis testing.

TOOL INSTRUCTIONS:

Planning the assessment

The assessor should inform the laboratory of the assessment date and request that essential staff be present on the day of. In preparation for the assessment, the assessor should thoroughly review the checklist to become familiar with the content. It is important to plan out which tests and processes should be observed, protocols and documents to be reviewed, and questions to ask in order to maximize efficient use of the visit.

This tool may be used internally by laboratories wishing to assess their own capacity and identify gaps or externally as part of a formal assessment by partners. It is recommended that formal assessments begin with an opening meeting with key staff to communicate the goals, provide an overview of the process, and reinforce that the findings will help improve the overall capacity for meningitis testing. During the walk-through, the assessor should communicate any minor finding to allow the laboratory to remediate the issue. The assessor should note major finding(s), along with recommendations for improvement, on the document for future action.

Prior to initiating the assessment, permission/clearance should be obtained from the senior laboratory official on-site to view laboratory logbooks and databases, and to take pictures. Pictures can be helpful in illustrating certain aspects of the laboratory, especially with regard to overall infrastructure, spacing and zoning of activities, condition of equipment, and biosafety practices.

Upon completion of the assessment, the assessor should conduct a summary meeting, highlighting the strengths and areas for improvement. The assessor could also consider sharing a copy of this checklist with the laboratory.

Completing the assessment

The laboratory assessment questions are designed to capture a snapshot of the laboratory during normal operating hours. Areas evaluated consist of electrical issues, presence/absence and correctness of protocols, condition of equipment, laboratory biosafety practices, quality control testing programs, training for staff members, and recordkeeping of laboratory results. Typical methods employed during the assessment include this checklist, but is not limited to: interviews, observations, and review of laboratory notebooks and reports for completeness of entries.

During the laboratory walk-through, the assessor should note:

- Expired reagents
- Adherence of laboratory staff to safety practices
- Condition of equipment
- Daily temperature monitoring and recording
- Observation of testing procedures
- Use of personal protective equipment
- Cleanliness of the laboratory
- Supply inventory

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Laboratory Assessment Tool for Bacterial Meningitis Surveillance

A. LABORATORY INFORMATION

Date: Name and title of interviewer:

Name of laboratory:

Location: ☐ Region ☐ District ☐ Community ☐ National Reference Laboratory

Type of laboratory: ☐ Hospital laboratory ☐ Public health laboratory ☐ Other:

Key contacts

Name:	Title:	Email:	Phone:
Name:	Title:	Email:	Phone:
Name:	Title:	Email:	Phone:
Name:	Title:	Email:	Phone:

B. GENERAL QUESTIONS

1. Number of laboratory staff performing: Meningitis testing: Molecular testing:
2. Unique identifier used to link epidemiologic data with lab results? ☐ Yes ☐ No At which laboratory level is it assigned?:
3. How many meningitis specimens have been received since the beginning of this year?:
   Culture attempted: Tested by PCR: Other (*specify*):
4. Are staff available to receive/process specimens 24/7? ☐ Yes ☐ No Hours of operation:

C. SPECIMEN TRANSPORT AND RECEIPT

1. Does the laboratory receive specimens for testing from other laboratories? ☐ Yes ☐ No Number of laboratories:
2. Is there an organized system for transporting specimens? ☐ Yes ☐ No How?:
3. Are there accepting/rejecting criteria for receiving specimens? ☐ Yes ☐ No Specimen Accessioning SOP? ☐ Yes ☐ No
4. What is the average time for specimen accessioning?:
5. Which types of specimens are received?

CSF for testing/culture	Frequency:	Arrival condition:
☐ Yes ☐ No	Average delay between collection and arrival at laboratory:	
CSF for PCR	Frequency:	Arrival condition:
☐ Yes ☐ No	Average delay between collection and arrival at laboratory:	
Trans-Isolate (TI) Media	Frequency:	Arrival condition:
☐ Yes ☐ No	Average delay between collection and arrival at laboratory:	
Blood	Frequency:	Arrival condition:
☐ Yes ☐ No	Average delay between collection and arrival at laboratory:	
Serum	Frequency:	Arrival condition:
☐ Yes ☐ No	Average delay between collection and arrival at laboratory:	
Tissue	Frequency:	Arrival condition:
☐ Yes ☐ No	Average delay between collection and arrival at laboratory:	

6. What percentage of specimens are accompanied by: Case report form: % Test request: % Other: %
7. How is specimen information recorded upon receipt in the laboratory? ☐ Logbook ☐ Computer ☐ Other (*specify*):
8. Are CSF specimens collected in this facility? ☐ Yes ☐ No If yes, by whom?: SOP? ☐ Yes ☐ No
9. Where do the samples come from: ☐ Your facility ☐ Region ☐ District ☐ Community ☐ Other:

D. SPECIMEN TESTING

1. Does the laboratory perform the following tests? (Check all that apply).

	SOP in lab?		SOP in lab?		SOP in lab?
☐ Pre-processing for RDT/culture	☐ Yes ☐ No	☐ Protein	☐ Yes ☐ No	☐ Species identification	☐ Yes ☐ No
☐ Macroscopic examination	☐ Yes ☐ No	☐ Glucose	☐ Yes ☐ No	Slide agglutination:	
☐ White cell count	☐ Yes ☐ No	☐ Culture	☐ Yes ☐ No	☐ Serogrouping (Nm)	☐ Yes ☐ No
☐ Gram stain	☐ Yes ☐ No	☐ PCR		☐ Serotyping (Hi, Sp)	☐ Yes ☐ No
Fix: ☐ Flame ☐ Methanol ☐ Other: _____		☐ Conventional	☐ Yes ☐ No	☐ Antimicrobial susceptibility	
☐ Latex agglutination	☐ Yes ☐ No	☐ Real-time	☐ Yes ☐ No	☐ Disc diffusion	☐ Yes ☐ No
				☐ Other: _____	☐ Yes ☐ No

2. What is the testing algorithm for meningitis specimens?

A:

B:

C:

D:

E:

3. Is a quality control program in place? ☐ Yes ☐ No Is QC performed on each individual test? ☐ Yes ☐ No

List:

4. Where is culture media prepared? ☐ In-house ☐ Another laboratory: ☐ Commercial:

If in-house, is an SOP available? ☐ Yes ☐ No Is media QC'd for: ☐ Sterility ☐ Growth

Are the following reagents/equipment for making media available and functional today?

☐ Balance ☐ Glassware ☐ Water bath ☐ pH meter ☐ Dehydrated culture media

☐ Stirring hot plate ☐ Blood Source of blood:

5. How are specimen results recorded? ☐ Logbook ☐ Computer ☐ Other (*specify*):

Who enters the lab data?:

E. SPECIMEN STORAGE

1. What is the long-term storage for CSF? ☐ Not stored ☐ – 20°C freezer ☐ –80°C freezer ☐ Other (*specify*):

2. How many CSF specimens are in storage?:

3. Which medium is used to store bacterial isolates? ☐ Greaves ☐ Blood ☐ Skim milk/glycerol ☐ Other:

4. How are isolates stored long-term? ☐ Not stored ☐ –20°C freezer ☐ –80°C freezer ☐ Other (*specify*):

5. How many isolates are in storage?:

6. PCR type: ☐ Conventional ☐ Direct

7. PCR detection: ☐ Species ☐ Nm serogrouping ☐ Hi serotyping ☐ Sp serotyping Are SOPs available? ☐ Yes ☐ No

Source of primers and probes: Are SOPs available for DNA extraction? ☐ Yes ☐ No

8. Which of the following areas/equipment are available and functional today?

☐ Area/room for clinical extraction ☐ Separate pipette sets If real-time PCR: ☐ Updated antivirus on computer

☐ "Dirty" area/room for DNA addition ☐ PCR workstation(s) ☐ Surge protection ☐ Backup UPS

☐ "Clean" area/room for PCR prep Brand/Model of PCR machine:

F. DATA MANAGEMENT

1. Functional computer available for lab data? ☐ Yes ☐ No Updated antivirus? ☐ Yes ☐ No Functional printer? ☐ Yes ☐ No

Back-up system? ☐ Yes ☐ No Secure/protected access? ☐ Yes ☐ No Operating system:

2. Do you send a standardized report to officials? ☐ Yes ☐ No If yes, to whom? ☐ Surv official(s) ☐ Referring lab ☐ Other:

Type of report: How? ☐ Email ☐ Phone ☐ Paper ☐ Other: Frequency:

3. What is the turnaround time for reporting results back to clinicians?: How? ☐ Email ☐ Phone ☐ Paper

G. EQUIPMENT

1. Generator? ☐ Yes ☐ No Is there a logbook for equipment maintenance? ☐ Yes ☐ No

2. What type of electric outlet(s) are used?: _____

3. Is the temperature monitored and recorded daily for refrigerators, freezers, and incubators? ☐ Yes ☐ No

4. Is the following equipment available and functional? (*check all that apply and please verify function*)

☐ Centrifuge (Max 14,000 rpm): Type: _____ ☐ Candle jar ☐ Vortex Freezer: ☐ −20°C Incubator: ☐ CO_2
☐ Biosafety cabinet (Level 2) ☐ Jar with CO_2 generators ☐ Heat block ☐ −80°C ☐ non-CO_2
☐ Refrigerator (4-8°C) ☐ Autoclave ☐ Microscope ☐ Gas burner(s)

9. PCR type: ☐ Conventional ☐ Direct Manufacturer: _____

PCR detection: ☐ Species ☐ Nm serogrouping ☐ Hi serotyping ☐ Sp serotyping Are SOPs available? ☐ Yes ☐ No

Source of primers and probes: _____ Are SOPs available for DNA extraction? ☐ Yes ☐ No

10. Which of the following areas/equipment are available and functional today?

☐ Area/room for clinical extraction ☐ Separate pipette sets If real-time PCR: ☐ Updated antivirus on computer
☐ "Dirty" area/room for DNA addition ☐ PCR workstation(s) ☐ Surge protection
☐ "Clean" area/room for PCR prep Brand/Model of PCR machine: _____ ☐ Backup UPS

H. SUPPLY MANAGEMENT

1. Does the laboratory experience procurement problems? ☐ Yes ☐ No

2. From whom do you procure supplies/reagents (by %)? MoH: % WHO: % Private vendor: % Other lab: %

3. Average estimated delay in receiving regular supplies/reagents?: _____

4. Master list of laboratory supplies/reagents available (with vendor, product #)? ☐ Yes ☐ No

5. Does the laboratory track the expiration date of the reagents? ☐ Yes ☐ No

6. Are the following materials available and adequate supplies? (*check all that apply*)

☐ Latex agglutination kit	☐ Yes ☐ No	☐ T-I Media	☐ Yes ☐ No	Gram stain kit	☐ Crystal Violet	☐ Yes	☐ No
☐ Sterile cryotubes	☐ Yes ☐ No	☐ Venting needles	☐ Yes ☐ No		☐ Gram's Iodine	☐ Yes	☐ No
☐ LP kits	☐ Yes ☐ No	☐ Reference strains	☐ Yes ☐ No		☐ Ethanol (95%)	☐ Yes	☐ No
☐ Oxidase	☐ Yes ☐ No	☐ Antisera	☐ Yes ☐ No		☐ Safranin	☐ Yes	☐ No
				Culture media	☐ Blood agar	☐ Yes	☐ No
					☐ Chocolate agar	☐ Yes	☐ No

I. LABORATORY STAFF TRAINING AND BIOSAFETY

1. Is training available for the technical staff? ☐ Yes ☐ No If yes, what kind? ☐ Microbiological ☐ Biosafety ☐ Data management

2. Which PPE is available and required: ☐ Lab coat ☐ Gloves ☐ Respiratory protection ☐ Other: _____

3. Specific biosafety SOPs? ☐ Yes ☐ No Chemical safety? ☐ Yes ☐ No Disposal of infectious/hazardous waste? ☐ Yes ☐ No

4. Does the laboratory have a restricted access policy? ☐ Yes ☐ No