Annual Supervision Checklist for Bacterial Meningitis Laboratories

MenAfriNet

Toolkit

Assessors can use this checklist as a guide to conduct a laboratory supervisory visit to improve laboratory quality and provide technical support.

INTRODUCTION

A supervisory site visit is an essential component of a laboratory quality assurance program. The purpose of this guide is to provide the assessor with guidance on what to observe and evaluate when conducting a laboratory supervisory visit for bacterial meningitis testing. These visits allow the assessor to evaluate the current condition and practices of a laboratory during normal operating hours to identify and immediately correct any potential source of errors, and to ensure operations according to good laboratory practices and regulatory standards. These visits should occur routinely, while more frequent visits may be needed for those laboratories suspected of having serious problems.

The checklist provided should be completed by an individual from a higher level laboratory who has experience with the identification of bacterial meningitis pathogens. Laboratories of all levels can be assessed with this tool: district/peripheral, regional/intermediate, and national/reference laboratories.

BEFORE YOU START:

The assessor should notify the laboratory of the assessment date and request that all essential staff be present the day of the assessment. If the laboratory has been evaluated previously, the assessor should also review the previous report and place an emphasis on the previous gaps observed.

In preparation for the visit, the assessor should thoroughly review the checklist to become familiar with the content. As the checklist is comprehensive, there may not be enough time to assess all the areas. 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 supervisory visits. Moreover, it is important to be tactful with questions and discrete with note-taking to encourage open and honest communication from laboratory staff.

DURING THE VISIT:

An opening meeting, detailing the process, with all key staff should be initiated prior to starting the assessment. It is important to explain to the laboratory that the findings are not punitive but rather to help improve the overall laboratory capacity for bacterial meningitis testing. During the walk-through, the assessor should communicate any minor findings to allow the laboratory to remediate the issue. The assessor should note major findings on the report along with recommendations for corrective action. It is important to balance positive and negative feedback to improve motivation.

Pictures can be helpful in illustrating certain aspects of the laboratory, especially with regard to overall infrastructure in spacing and zoning of activities, condition of equipment, and biosafety practices. It is imperative that pictures taken are approved ahead of time with the director of the facility and consent is provided from individuals appearing in the photos.

CONCLUSION OF VISIT:

Immediately after the assessment, the assessor should conduct a closing meeting to discuss the overall findings. Inform the laboratory that a report, along with the checklist, will be shared with the laboratory within a month of the assessment.

It is recommended to provide immediate feedback during a debrief at the end of the visit, followed by a report that outlines any outstanding findings, items to be corrected, recommendations for laboratory improvement, and items for follow up to laboratory leadership. A supervisory visit is recommended to take place each year for all laboratories.

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TOOL INSTRUCTIONS:

To begin the assessment, complete the first portion of the checklist by filling in all the required information. It is important to complete all information in this section in case you may need to contact them after the visit.

It is important to be as thorough and detailed as possible. If a question does not apply or an observation was not performed, please write or check the "N/A" box as appropriate. If there are special considerations, please explain. At the end of each section, there are extra lines for additional comments. If extra sheets of paper are used, make sure to include them with the report.

I. Type of laboratory

In this section, check the box that best describes the level of the laboratory you are visiting: district, regional, reference, or national laboratory.

A power failure may affect the integrity of the specimen for testing, create potential loss of test reagents and kits, interrupt laboratory testing, and damage equipment. These two questions look at whether the laboratory experiences power failures, and the frequency and duration of the failures. It is important to ask the laboratory what their contingency plan is when these events occur. If the laboratory experiences frequent but short disruptions, it is important to check if critical equipment is connected to a universal power source (UPS). A laboratory without electricity for long periods should consider using a generator.

II. Staff

Training should be offered to new laboratory staff prior to working in the laboratory. Ask the laboratory to describe the processes involved in training new staff. If training materials are documented, make sure to request the documents ahead of time for review.

Annual refresher training and/or competency testing is recommended for all staff performing the tests to ensure that staff are competent with the testing and are able to perform the tests correctly.

III. Biosafety practices

Laboratory staff are at risk of lab-acquired infections when working in the laboratory. As a result, it is important that staff adhere to laboratory safety practices. Besides asking questions, observe some of the laboratorians working in the laboratory for evidence of donning the appropriate personal protective equipment (PPE). Document any additional PPE observed in the box marked "other". In addition to PPE, observe whether staff perform proper decontamination of the workbenches upon completion of testing. If not, point out this finding and suggest the corrective action.

All biohazardous waste should be autoclaved as it is harmful to humans, animals, and the environment. Determine the laboratory's procedure for waste disposal.

IV. Laboratory procurement and inventory

Maintaining an adequate inventory of laboratory supplies, consumables, and reagents will prevent stock-outs and reduce disruptions with laboratory testing. Procurement of supplies ahead of the meningitis season helps ensure that the laboratory will have sufficient supplies for the testing season. However, the laboratory needs to know the current inventory and how much to procure for the season. Ask the laboratory to describe the process for forecasting supplies for the meningitis season. If the laboratory encounters issues with procurement, have them explain some of the issues.

In the table provided, the format is a simple "Yes/No" evaluation. This can be done by checking the inventory stock room and by questioning staff. Additionally, ask staff if supplies are monitored regularly to avoid stockouts, if the laboratory has an inventory tracking system, and if the laboratory has a set minimum stock level for reagents and consumables at which orders need to be placed. For example, if the laboratory only has two tubes of Quanta mastermix available, ask staff what the minimum stock-out threshold is. While conducting the walk-through, check that the laboratory stores reagents and specimens at the correct temperature. Additionally, expired reagents should not be used for testing as they may not provide accurate test results; therefore, they should be discarded.

V. Accessioning

Cerebrospinal fluid (CSF) is the preferred specimen type for diagnosing bacterial meningitis. Other specimens such as blood, joint fluid, and tissues (e.g., brain, liver, skin, spleen) are acceptable. Ask the laboratory to describe how specimens are documented upon arrival at the laboratory. During this section, it is also important to review the logbook for completeness and for documentation of specimen integrity issues such as leaking of containers, cracked tubes, illegible labeling, improper packaging or specimen collection container, and incorrect transport conditions. It is also important to document whether the laboratory experiences issues with lack of the case investigation forms accompanying the specimen or incomplete information on the form.

Transport of specimens at the proper temperature and in a timely manner can improve the recovery of the pathogen and reduce chances of contamination. Inquire if there are any delays with specimen transport. If there are delays, have them describe some of the issues that are encountered. It is important to find out the average time it takes for specimens to arrive at the laboratory. This can be assessed by looking at the laboratory logbook. This information can be found by subtracting the time between specimen collection to receipt in the laboratory and can be recorded in hours, days, weeks, and/or months.

Determine what the lab's procedure is for proper specimen labeling. While the laboratory can describe the procedure, it is also important to verify, through observation, if this is performed as stated and whether the labeling is legible. At a minimum, information such as name, date of collection, and laboratory identification/epidemiology identification (ID/EPID) should be labeled on the specimen. The EPID number could also be used and should be in the following format: (CCC-RRR-DDD-YY-NNNN). Hand-written information should be written in blue or black permanent pen or marker and should be legible. Labels using Band-Aids or written in pencil should not be used.

VI. Equipment/instrument

Ensuring that equipment, instruments, and measuring devices are operational, maintained, and function in accordance with the manufacturer's requirements is necessary to ensure accurate and reliable test results. Equipment operation, calibration, and routine maintenance can be found in the operations manual for each instrument. These recommendations should be compared against the laboratory's standard operating procedure (SOP) to ensure the laboratory is adhering to the minimum stated manufacturer requirement. While manuals have recommended schedules, more frequent maintenances or calibrations may be needed depending on the testing volume of the laboratory.

In the table, please verify the laboratory equipment is functioning properly through review of temperature and maintenance logs, observation of staff performing the test, and in some cases, a quick test of the instrument. If equipment is waiting for repair, indicate the reason for the issue, the corrective action taken by the laboratory, and length of time the equipment has been out of service.

Indicate if equipment maintenance is being performed for any of the pieces of equipment. Equipment log sheets should be reviewed for complete entries. If there are blanks on the documents, inquire as to why this may be the case. Documentation of maintenance, calibrations, and repair events should include: the initials of the operator performing the procedure, date performed, the task that was performed, and the corrective action (adjustments or repairs). Maintain records as evidence of proper equipment management. In compliance with records maintenance procedures, keep records for the lifespan of the equipment.

Observe the capacity inside the refrigerators, freezers, and incubators. Are they full to capacity, or is there still space? Temperature inside the equipment may not be optimal if the equipment is too full. It is important to also emphasize that equipment should not be used for personal use by staff to store food and/or beverages.

VII. Documents

In this section, review for accuracy any SOPs, job-aids, and flowcharts the laboratory has on hand. While observing tests being performed, having these documents on hand allows the assessor to be able to verify consistency of what is written and what is being performed. Copies of documents should also be requested for later review.

VIII. Testing

Observe the microbiologist(s) performing one or more of the following techniques and provide any comments, as necessary: T-I inoculation, cytology, Gam stain, biochemistry, RDT, culture, antibiogram, and PCR. Verify that the correct consumables and reagents are used for the laboratory testing and proper use of PPE. It is important that expired reagents are not used. Having the SOP during testing observation will allow the assessor to verify whether the laboratory is following its own laboratory procedures and whether the laboratory is interpreting the tests correctly.

IX. Quality control (QC)

The purpose of quality control is to detect immediate errors due to test systems failure, adverse environmental conditions, and operator performance with the goal of correcting these errors before patient results are reported. Incorporating well-characterized controls with known results during the run of an assay ensures that the test system and process accomplish this objective.

In this section, specify the laboratory quality control procedures for the following: T-I, cytology, Gram stain, biochemistry, RDT, culture, antibiogram, and PCR. If one or more of these tests is not performed in the laboratory, please document this as well. Previous quality control issues should be included along with the laboratory's corrective actions to ensure that the laboratory has taken appropriate steps to resolve the issue. It is also important to note the frequency of the quality control testing, as some tests require more frequent testing compared to others. Along with internal quality control, laboratories should participate in an external quality assurance program, which can provide objective evidence of the laboratory's testing quality. Indicate if the laboratory participates in an internal or external proficiency testing program. If the laboratory participates in an external program, indicate which program(s). The assessor should also consider re-reading the laboratory's previously trained Gram stain slides to assess the quality of the smear preparation, staining quality, and interpretation for accurate reporting of results.

X. Laboratory data management

Management and organization of laboratory data allows laboratories to be able to quickly retrieve historical information on specimens tested and conduct analysis of the data for public health response and/or research. In addition to the national reporting line list, the laboratory should maintain its own database or logbook consisting of laboratory results from all tests. Moreover, the laboratory should be reporting results to both the national level and back to the referring laboratory or physician.

The first few questions assess reporting results back to the national level. Indicate which staff are responsible for completing this line list for surveillance. This could be the microbiologist, data manager, or other staff. Determine the method and frequency of reporting. Results should be reported frequently to provide a more accurate picture of the current situation. The next set of questions attempts to determine whether the laboratory has a good process in place for documenting all test results and whether the laboratory can perform some basic analysis of data to monitor for trends and patterns in the data. Items that would be considered basic analysis tools are the use of pivot tables, statistical analysis, etc.

Fill out the bottom section with your name, title, and date.

Acronyms:

CO = carbon monoxide
CSF = cerebrospinal fluid
ID/EPID = identification/epidemiology identification
rt-PCR = real-time polymerase chain reaction
PPE = personal protective equipment
RDT = rapid diagnostic test
SOP = standard operating procedure
T-I = Trans-Isolate
UPS = universal power source

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Annual Supervision Checklist for Bacterial Meningitis Laboratories

Date: _____/_____/_____ (dd/mm/yyyy)

Name of laboratory:

Laboratory director:

Date of last supervisory visit:

Key contacts (include name, title, email, and phone):

Type of laboratory: ☐ Sub-district ☐ District ☐ Regional ☐ Reference laboratory

Do you experience power outages? ☐ Yes ☐ No If yes, how often? ☐ Daily ☐ Weekly ☐ Monthly

How long do the power outages last? ☐ Hours ☐ Days ☐ NA Comment:

Personnel:

a. Do you have any new members since the last visit? ☐ Yes ☐ No

b. How is training conducted for new members?:

c. Who provides the trainings?:

d. Are there any refresher trainings for current members? ☐ Yes ☐ No

Additional Comments:

I. SAFETY PRACTICES:

Do staff wear the following PPE every time they conduct testing? ☐ Lab Coat ☐ Gloves ☐ Goggles ☐ Other:

Are staff decontaminating work benches upon completion of testing? ☐ Yes ☐ No

Disinfectant(s) used:

Is there final waste disposal procedure? ☐ Yes ☐ No

If yes, please describe:

Additional comments:

II. LAB PROCUREMENT AND INVENTORY:

How do you forecast supplies for the season?:

What are some of the issues you encounter when ordering supplies?:

Does the laboratory have supplies for the following?

PPE	☐ Yes ☐ No	☐ NA	Qty:	Comments:	
Media production	☐ Yes ☐ No	☐ NA	Qty:	Comments:	
T-I	☐ Yes ☐ No	☐ NA	Qty:	Comments:	
Cytology	☐ Yes ☐ No	☐ NA	Qty:	Comments:	
Gram stain	☐ Yes ☐ No	☐ NA	Qty:	Comments:	
Biochemistry	☐ Yes ☐ No	☐ NA	Qty:	Comments:	
RDT	☐ Yes ☐ No	☐ NA	Qty:	Comments:	
Culture	☐ Yes ☐ No	☐ NA	Qty:	Comments:	
Antibiogram	☐ Yes ☐ No	☐ NA	Qty:	Comments:	
PCR	☐ Yes ☐ No	☐ NA	Qty:	Comments:	
Storage of isolates	☐ Yes ☐ No	☐ NA	Qty:	Comments:	

Are supplies monitored regularly so that procurement can be made on time to avoid stock-outs? ☐ Yes ☐ No

Is there a system in place for inventory tracking? ☐ Yes ☐ No Software:

Does the laboratory have a set minimum stock level for reagents and consumables at which orders need to be placed? ☐ Yes ☐ No

Are any reagents expired? List them:

What is the rate of expired reagent in the last two years? Name them: %

% % %

% % %

Additional comments:

III. SPECIMEN ACCESSIONING

How do you accession specimens when they arrive?:

Is all specimen information in the log book/electronic database complete? ☐ Yes ☐ No ☐ NA

Are there any issues with specimen transport? ☐ Yes ☐ No ☐ NA

If yes, please describe what are some of the issues encountered:

What is the average time from specimen collection to receipt in the laboratory?:

Are there any specimen integrity issues? ☐ Yes ☐ No ☐ NA

If yes, what are the most common issues encountered?:

Are specimens labeled appropriately (name, date of collection, laboratory ID/EPID) and legibly? ☐ Yes ☐ No ☐ NA

If yes, provide approximate percentage of specimens that have integrity issues:

Please explain some of the issues encountered:

How are specimens stored prior to testing?:

Additional comments:

IV. EQUIPMENT/INSTRUMENT

Is the following equipment functioning properly?

Centrifuge	☐ Yes	☐ No	☐ NA	Comments:
Biosafety cabinet	☐ Yes	☐ No	☐ NA	Comments:
Refrigerator	☐ Yes	☐ No	☐ NA	Comments:
Incubator	☐ Yes	☐ No	☐ NA	Comments:
–80°C freezer	☐ Yes	☐ No	☐ NA	Comments:
–20°C freezer	☐ Yes	☐ No	☐ NA	Comments:
CO_2 incubator	☐ Yes	☐ No	☐ NA	Comments:
Non-CO_2 incubator	☐ Yes	☐ No	☐ NA	Comments:
CO_2 gas tank	☐ Yes	☐ No	☐ NA	Comments:
Autoclave	☐ Yes	☐ No	☐ NA	Comments:
Vortex	☐ Yes	☐ No	☐ NA	Comments:
Heat block	☐ Yes	☐ No	☐ NA	Comments:
Microscope	☐ Yes	☐ No	☐ NA	Comments:
Gas burner	☐ Yes	☐ No	☐ NA	Comments:
Pipettes	☐ Yes	☐ No	☐ NA	Comments:
PCR machine	☐ Yes	☐ No	☐ NA	Comments:
Other	☐ Yes	☐ No	☐ NA	Comments:

Is equipment maintenance being performed for any of the above items? ☐ Yes ☐ No

If yes, please list the equipment and frequency:

Is this information documented on a maintenance log? ☐ Yes ☐ No

When monitoring equipment daily, do you document the temperatures and/or CO_2 levels for applicable equipment? ☐ Yes ☐ No

How much space is currently available inside the refrigerator/freezer/incubator? Please approximate.

Refrigerator	☐ 100%	☐ 99% - 75%	☐ 74% - 50%	☐ 49% - 25%	☐ 24% and below
Freezer	☐ 100%	☐ 99% - 75%	☐ 74% - 50%	☐ 49% - 25%	☐ 24% and below
Incubator	☐ 100%	☐ 99% - 75%	☐ 74% - 50%	☐ 49% - 25%	☐ 24% and below

Is there a backup UPS for power failures for critical equipment? ☐ Yes ☐ No

Does this laboratory have a back-up generator? ☐ Yes ☐ No

Additional Comments:

VI. DOCUMENTS

Are there SOPs for all procedures? Review the SOPs, job-aids, and flowcharts for accuracy.

T-I inoculation	☐ Yes	☐ No	☐ NA	Comments:
Cytology	☐ Yes	☐ No	☐ NA	Comments:
Gram stain	☐ Yes	☐ No	☐ NA	Comments:
Biochemistry	☐ Yes	☐ No	☐ NA	Comments:
RDT	☐ Yes	☐ No	☐ NA	Comments:
Culture	☐ Yes	☐ No	☐ NA	Comments:
Antibiogram	☐ Yes	☐ No	☐ NA	Comments:
Specimen and isolate storage	☐ Yes	☐ No	☐ NA	Comments:
PCR	☐ Yes	☐ No	☐ NA	Comments:

Does each SOP include a quality control section? ☐ Yes ☐ No ☐ NA

Additional Comments:

V. TESTING:

How many specimens have been received this year?:

Observe one or more of the following techniques and provide any comments on techniques:

T-I inoculation:

Cytology:

Gram stain:

Biochemistry:

RDT:

Culture:

Antibiogram:

PCR:

Additional comments:

VI.QUALITY CONTROL (QC)

Does each SOP include a quality control section? ☐ Yes ☐ No ☐ NA

Media preparation	☐ Yes	☐ No	☐ NA	Comments:
T-I inoculation	☐ Yes	☐ No	☐ NA	Comments:
Cytology	☐ Yes	☐ No	☐ NA	Comments:
Gram stain	☐ Yes	☐ No	☐ NA	Comments:
Biochemistry	☐ Yes	☐ No	☐ NA	Comments:
RDT	☐ Yes	☐ No	☐ NA	Comments:
Culture	☐ Yes	☐ No	☐ NA	Comments:
Antibiogram	☐ Yes	☐ No	☐ NA	Comments:
PCR	☐ Yes	☐ No	☐ NA	Comments:

What are some of the QC issues in the last 6 months?:

Were the steps taken to resolve the QC issues appropriate? ☐ Yes ☐ No

Does the laboratory participate in an internal/external proficiency testingprogram? ☐ Internal ☐ External ☐ NA

If internal, how do you conduct the proficiency testing?:

If external, which program(s)?:

Additional comments:

VII. LABORATORY DATA MANAGEMENT:

1. Who enters in the line list for laboratory results? ☐ Microbiologist ☐ Data manager ☐ Other:
2. Who enters in the line list for surveillance? ☐ Microbiologist ☐ Data manager ☐ Other:
3. How often are reports sent to officials? ☐ Daily ☐ Weekly ☐ Monthly To whom?:
4. How is it reported? ☐ Paper copy ☐ Fax ☐ Phone ☐ Electronic
5. Is the laboratory able to use basic analysis tools to look for trends and patterns? ☐ Yes ☐ No
6. Are all laboratory test results entered into an electronic database or laboratory logbook?:

VIII. OTHER:

Is there a process in place for specimens arriving after hours or on the weekends? ☐ Yes ☐ No

1. How does the laboratory resolve problems with recurring issues of nonviable and/or contaminated cultures?:
2. What would you like to improve in this laboratory?: