LABORATORY ASSESSMENT MANUAL

Capacity Building and Strengthening of Hospital Infection Control to Detect and Prevent Antimicrobial Resistance in India

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India Annex

AFTER ANSWERING QUESTION 25 IN THE MAIN DOCUMENT, ANSWER QUESTION A BELOW

A. Does the laboratory have separate incompatible activities

- ☐ Yes
- ☐ No

AFTER ANSWERING QUESTION A, PROCEED TO QUESTION 26 ON PAGE 9 OF THE MAIN DOCUMENT

AFTER ANSWERING QUESTION 28 IN THE MAIN DOCUMENT, ANSWER QUESTION B BELOW

B. Does the laboratory have quality certificates like installation qualification (IQ), operational qualification (OQ) and performance qualification (PQ) for the equipment

- ☐ Yes
- ☐ No

AFTER COMPLETING QUESTION B, PROCEED TO QUESTION 29 ON PAGE 10 OF THE MAIN DOCUMENT

AFTER ANSWERING QUESTION 54 IN THE MAIN DOCUMENT, ANSWER QUESTION C BELOW

C. Review each specimen-specific collection guideline. Are guidelines present and do they address the following items?

If no guidelines exist, circle 'no' under the first column and do not answer the subsequent questions for that specimen type (This is part of Q 54)

	Present?	Collection technique	Approved containers	Min/Max volume	Proper labeling	Transport temperature	Transport time
e. Wounds/Pus	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No
f. CSF	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No
g. Sputum/BAL/ETA	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No

Standard: ISO 15189: 5.4

AFTER COMPLETING QUESTION C, PROCEED TO QUESTION 55 ON PAGE 15 OF THE MAIN DOCUMENT

AFTER ANSWERING QUESTION 141 IN THE MAIN DOCUMENT, ANSWER QUESTION D BELOW

D. Approximately how many bacterial cultures are performed each month from the following specimens?

Specimen Type	<20	21-30	>30
Wound/Pus			
CSF			
Sputum/BAL/ETA			

AFTER COMPLETING QUESTION D, PROCEED TO QUESTION 142 ON PAGE 30 OF THE MAIN DOCUMENT

AFTER ANSWERING QUESTION 150 IN THE MAIN DOCUMENT, ANSWER QUESTION E BELOW

E. Are instructions given to the patients regarding the sample collection like for urine or sputum collection?

☐ Yes

☐ No

AFTER COMPLETING QUESTION E, PROCEED TO QUESTION 151 ON PAGE 31 OF THE MAIN DOCUMENT

AFTER ANSWERING QUESTION 166 IN THE MAIN DOCUMENT, ANSWER QUESTIONS F TO M BELOW

WOUND/SURGICAL SITE/PUS CULTURES

F. How often do you perform Gram-staining on wound/surgical site/pus specimens?
- ☐ Always
- ☐ Sometimes
- ☐ Never

CEREBROSPINAL FLUID CULTURES

G. How often do you perform Gram-staining on CSF specimens sent for culture?
- ☐ Always
- ☐ Sometimes
- ☐ Never

H. How often do you proceed with culture of CSF when the Gram-stain is negative?
- ☐ Always
- ☐ Sometimes
- ☐ Never

I. What best describes how CSF is cultured in this laboratory?
- ☐ Centrifuge CSF and plate the pellet for culture*
- ☐ Inoculate media with non-centrifuged CSF
- ☐ Centrifuge CSF and plate the supernatant for culture
- ☐ Other, specify:_____

SPUTUM/BAL (Broncho alveolar lavage)/ETA (endotracheal aspirate) CULTURES

J. How often are sputum specimens evaluated for quality via gram stain prior to culture?
- ☐ Always
- ☐ Sometimes
- ☐ Never

K. Does the lab have appropriate criteria for determining contamination of a sputum culture specimen?
- ☐ Yes
- ☐ No

L. How often are sputum specimens incubated in a manner to recover organisms requiring CO_2?
- ☐ Always
- ☐ Sometimes
- ☐ Never

M. Are instructions given to the patients regarding the sample collection?
- ☐ Yes
- ☐ No

AFTER COMPLETING QUESTION M, PROCEED TO QUESTION 167 ON PAGE 33 OF THE MAIN DOCUMENT

Laboratory

Antibacterial Resistance Surveillance

Readiness Tool

Updated June 2017

Modified for India September 2017

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Introduction

The Global Health Security Agenda (GHSA) is an effort by nations and international organizations to accelerate progress toward a world safe and secure from infectious disease threats. Antimicrobial Resistance (AMR) is one of the 11 GHSA action packages. The AMR action package focuses on strengthening laboratory capacity to detect AMR and implementation of AMR surveillance to report and follow resistance trends.

The purpose of this tool is to systematically assess individual laboratory capacity to perform microbiologic techniques required for AMR detection (e.g. culture, identification and resistance testing). Use of this assessment tool can provide a baseline assessment of capacity of individual laboratories included in the national AMR surveillance network in a country. Then through evaluation, assessors can help countries develop an action plan to improve laboratory capacity needed to isolate, identify priority pathogens, and to detect and report antimicrobial resistance.

Laboratory capacity within countries should focus on the identification of World Health Organization (WHO) priority AMR pathogens and pathogens covered by WHO's Global Antimicrobial Resistance Surveillance System (GLASS) initiative. The WHO list of AMR pathogens of concern includes:

- *Staphylococcus aureus*
- *Streptococcus pneumoniae*
- *Neisseria gonorrhoeae*
- *Escherichia coli*
- *Klebsiella pneumoniae*
- *Salmonella* species
- *Shigella* species
- *Acinetobacter baumannii**

Other priority pathogens (including other bacteria, fungi or viruses) may be selected for inclusion in national AMR surveillance plans pursuant to national priorities. However, the current tool is intended for assessing bacteriology laboratories, and focuses on the priority pathogens listed above. Thus, it is not intended for assessments of AMR detection capacity of a laboratories in the following areas: virology, mycology, mycobacteriology or parasitology. **In addition, PLEASE NOTE: The antibiotics referenced in this document are important for antimicrobial resistance surveillance purposes. They may not be first-line options for testing or treatment and should not be interpreted as such.**This tool was initially adapted from the WHO Antimicrobial Resistance Surveillance Questionnaire for Assessment of National Networks with additional questions from laboratory assessment tools from the American Society of Microbiology (ASM).Technical experts on laboratory and AMR surveillance at the Centers for Disease Control and Prevention (CDC), the American Public Health Laboratories, ASM and Indian experts under the CDC-ICMR-AIIMS project from PGIMER, Chandigarh were involved in the drafting and review of this document.

The Government of India (GOI) has placed high priority on combating AMR, and has taken a leadership role in working toward the AMR targets of the Global Health Security Agenda (GHSA). The National Centre for Disease Control, India is the focal public health agency leading the response to combatting AMR. The AMR laboratory surveillance network initiated by NCDC provides antimicrobial susceptibility testing, isolates and data for priority pathogens at selected tertiary referral hospital facilities. As the network grows, it is anticipated that surveillance will be expanded to additional facilities that provide clinical care and microbiologic testing, including those at the district level.

*Most labs are unable to definitively differentiate *Acinetobacter calcoaceticus* from *A. baumannii*, so in practice this refers to *Acinetobacter calcoaceticus-baumanni* complex

GENERAL INFORMATION

1. Assessor's names and affiliations:

   _____

   _____

   _____

2. Date of assessment (dd/mm/yyyy) : _____/_____/_____

3. Laboratory name and address:

   _____

   _____

4. Indicate the title, name and contact information of the laboratory leadership, including Laboratory Head (Director or Chief), Laboratory Manager, Microbiology Section Head/Supervisor, and others as relevant.

Role	**Name**	**Email address**
Director/Chief of Laboratory		
Head of Laboratory Department		
Head of Microbiology Section		

5. Indicate the level of the laboratory
   - ☐ Health clinic laboratory
   - ☐ Local hospital laboratory
   - ☐ District hospital laboratory
   - ☐ Provincial hospital laboratory
   - ☐ Regional non-hospital based laboratory
   - ☐ National/reference/public health laboratory
   - ☐ Other, specify_____

6. Indicate the laboratory affiliation (check all that apply)
   - ☐ Public
   - ☐ Private
   - ☐ Academic institution
   - ☐ Non-governmental organization (NGO)
   - ☐ Faith-based institution
   - ☐ Military
   - ☐ Other, specify:_____

7. If the lab is located within a hospital, what is the bed size of the facility?

   _____

8. Does the laboratory provide bacteriology testing for other health care facilities?
   (If so, please note how many)
   - ☐ None
   - ☐ _____ Hospitals
   - ☐ _____ Outpatient clinics
   - ☐ _____ Others, specify:_____

Part 1: BASIC LABORATORY CAPABILITY AND INFRASTRUCTURE

Please note: all questions refer only to clinical patient specimens, NOT to research specimens

General

9. Is the bacteriology lab **currently** accredited to either ISO 15189 or CAP standards for any of the following? (Check all that apply)
   - ☐ Blood cultures
   - ☐ Stool cultures
   - ☐ Urine cultures
   - ☐ Gonorrhoeae cultures
   - ☐ Other _____
   - ☐ No

10. If accredited, when was accreditation awarded and who performed the accreditation inspection (which accrediting body)? (Review certificate to ensure accreditation is current)
    - ☐ N/A
    - ☐ Accredited in (most recent year) _____ by: _____

11. When the microbiology lab is closed, does another laboratory department process (plate) the specimens?
    - ☐ Always
    - ☐ Sometimes
    - ☐ Never
    - ☐ N/A (bacteriology lab is staffed 24/7)

Laboratory staff

12. Indicate the highest level of microbiology training achieved by the technical staff reading bacteriology cultures and performing antibiotic susceptibility testing, and the number of staff that fall into each training level category.

Training level	Number of staff
Advance degree level (e.g., PhD, MD)	
Graduate degree level (e.g., MS)	
Undergraduate degree in Medical Microbiology (e.g. BS, BA)	
Undergraduate degree **other than** Med Micro (e.g. BS, BA in food microbiology)	
Medical Microbiology lab training program	
Non-degree certificate/diploma course	
In-laboratory training only	
No specific laboratory training	
Other (specify)	

13. Does the lab have bacteriology -specific training policies and procedures for orienting new employees?
    - ☐ Yes
    - ☐ No

    Standard: **ISO 15189: 4.12.5, 5.1.6, 5.1.9 In** *line with national laboratory training plans, each laboratory should have functional training policies and procedures that meet the needs of laboratory personnel through both internal and external training.*

14. Does the lab have up-to-date documentation showing which benches/tests each staff member has been trained on and approved to work independently? (Review such records)
    - ☐ Yes
    - ☐ No

15. Do lab staff receive regular competency assessments for each of the areas in which they perform testing? (Review competency records)
    - ☐ Yearly or more frequently
    - ☐ Other frequency, please specify:_____
    - ☐ No

    Standard: *Newly hired lab staff should be assessed for competency before performing independent duties and again within six months. All lab staff should be regularly assessed for testing competency at least once a year. Staff assigned to a new section should be assessed before fully assuming independent duties. When deficiencies are noted, retraining and reassessment should be planned and documented. If the employee's competency remains below standard, further action might include supervisory review of work, re-assignment of duties, or other appropriate actions. Records of competency assessments and resulting actions should be retained in personnel files and/or quality records. Records should show which skills were assessed, how those skills were measured, and who performed the assessment.*

Laboratory facility

16. Observe the laboratory work benches, are they:

	Yes	No	Comments
a. Separate from patient care areas?			
b. Organized with minimal clutter?			
c. Adequately ventilated?			
d. Free of excess moisture?			
e. Adequately lit?			

17. Does the laboratory have a functional heating/air conditioning system?
    - ☐ Yes
    - ☐ No **(skip to Q19)**

18. Is the temperature in the laboratory maintained between 20°-25°C?
    - ☐ Yes
    - ☐ No

19. Is deionized water (DI) or distilled water available at the laboratory?
    - ☐ Yes
    - ☐ No

20. Is critical equipment supported by uninterrupted power source (UPS) systems?
    - ☐ Yes
    - ☐ No

21. Is there a functioning generator to provide backup power to the lab in the case of power failure?
    - ☐ Yes
    - ☐ No

22. Is there a contingency plan in place for continued testing in the event of prolonged electricity disruption (e.g. power outage lasting several days)?
    - ☐ Yes
    - ☐ No

Standard: **ISO 15189: 5.2.5 & 5.2.10** *The laboratory space should be sufficient to ensure that the quality of work, the safety of personnel, and the ability of staff to carry out quality control procedures and documentation. The laboratory should be clean and well organized, free of clutter, well-ventilated, adequately lit, and within acceptable temperature ranges. Emergency power should be available for sensitive instruments, temperature controlled storage, and other essential equipment to prevent damage and disruption due to unexpected power fluctuations and outages. Sensitive instruments should be equipped with surge controls. Distilled and de-ionized water should be available, if required.*

23. Describe the internet services available at the facility
    - ☐ Continuous (service interruptions are rare *or* are common but fixed quickly)*
    - ☐ Sporadic (service interruptions are common and fixed slowly)
    - ☐ Unreliable
    - ☐ No internet available

24. Observe the refrigerators and freezers where media and reagents are stored. Are they:

	Yes	No	Comments
a. Designated specifically for storage of media/reagents?			
b. Free of staff food items?			
c. Free of patient samples?			
d. Well organized and free of clutter?			

25. Observe the areas where room temperature media and reagents are stored. Are they:

	Yes	No	Comments
a. Designated specifically for storage of media/reagents?			
b. Free of staff food items?			
c. Free of patient samples?			
d. Well organized and free of clutter?			
e. Clean and free of pests?			
f. Shielded from direct sunlight?			
g. Adequately ventilated?			

AFTER ANSWERING QUESTION 25, PROCEED TO QUESTION A ON PAGE 1 OF THE INDIA ANNEX

26. Has the laboratory had a safety audit within the last year (e.g., via WHO Lab assessment tool or ASM checklist)?
    - ☐ Yes, date: _____
    - ☐ No **(if checked, please fill out Safety Appendix)**

Laboratory instruments and equipment

27. Indicate in the table below whether the lab has at least one functional piece of each equipment listed. If the lab has a functional piece of equipment, indicate if it is calibrated annually, if a user manual is present, and has a functional thermometer placed in or integrated within.

If at least one piece of functional equipment is **not** present, tick the first 'no' column and do not answer the rest of the questions for that piece of equipment

	At least one functional		Annual calibration records present?	User manual present?	Functional thermometer present?	Comments
	Y	N				
a. Wickerham card			N/A	N/A	N/A	
b. McFarland QC standards of known densities including 0.5			N/A	N/A	N/A	
c. Ruler or caliper with millimeter markings			N/A	N/A	N/A	
d. Bunsen burner or micro-incinerator			N/A	N/A	N/A	
e. Wire loops for streaking			N/A	N/A	N/A	
f. Calibrated loops for plating urines (1uL and 10uL **wire** loops require regular QC)			Yes / No	Yes / No	N/A	
g. Optical Densitometer (for determining McFarland density)			Yes / No	Yes / No	N/A	
h. Pipettes (e.g., Eppendorf)			Yes / No	Yes / No	N/A	

i. Centrifuge			Yes / No	Yes / No	N/A	
j. Microscope			Yes / No	Yes / No	N/A	
k. Thermometers			Yes / No	N/A	N/A	
l. CO_2 incubator or candle jars (circle which)			Yes / No	N/A	N/A	
m. Non-CO_2 incubator			N/A	N/A	Yes / No	
n. Refrigerator (2-8°C)			N/A	N/A	Yes / No	
o. Freezer, -20°C			N/A	N/A	Yes / No	
p. Freezer, -80°C			N/A	N/A	Yes / No	
q. Hot air oven			N/A	Yes / No	Yes / No	
r. Hot plate with magnetic stirrer			Yes / No	Yes / No	Yes / No	
s. Water bath			Yes / No	Yes / No	Yes / No	
t. Biological Safety Cabinet **Class IIA**			Yes / No	Yes / No	N/A	
u. Autoclave			N/A	Yes / No	Yes / No	

28. Indicate in the table below whether the lab has at least one functional piece of each equipment listed. If the lab has a functional piece of equipment, indicate if a user manual is present, if routine user maintenance records exist, if preventive (annually by vendor) maintenance records exist, and if current service contracts are in place.

    <u>If at least one piece of functional equipment is **not** present, tick the first 'no' column and do not answer the rest of the questions for that piece of equipment</u>

	At least one functional		**User manual present**	**Routine (user) maintenance records**	**Preventive (vendor) records**	**Service contracts in place**	**Comments**
	Y	**N**					
Automated blood culture system (Brand_____)			Yes / No	Yes / No	Yes / No	Yes / No	
Automated bacterial identification and AST system (e.g., Vitek, Microscan, Phoenix)			Yes / No	Yes / No	Yes / No	Yes / No	

AFTER ANSWERING <u>QUESTION 28</u>, PROCEED TO <u>QUESTION B</u> ON PAGE 1 OF THE INDIA ANNEX

29. Is a contingency plan in place to provide continued microbiology testing services in the event of prolonged equipment failure (not due to power outage)?
    - ☐ Yes
    - ☐ No

30. In the last 6 months, has prolonged equipment failure caused a disruption in routine bacteriology services?
    - ☐ No
    - ☐ Yes

Inventory and storage

31. Does the lab have an inventory control system in place?
    - ☐ Yes
    - ☐ No
32. Are all media, reagents and test kits in use and in stock currently within the manufacturer-assigned expiry dates or within stability from date of reconstitution? (Verify by random sampling)
    - ☐ Yes
    - ☐ No

Standard: *All reagent and test kits in use, as well as those in stock, should be within the manufacturer-assigned expiry dates. Expired stock should not be entered into use and should be documented before disposal.*

33. In the last 6 months, have media/reagent/test kit stock outs caused a disruption in routine bacteriology services?
    - ☐ No
    - ☐ Yes

Standard: *Testing services should not be subject to interruption due to stock outs. Laboratories should pursue all options for borrowing stock from another laboratory or referring samples to another testing facility while the stock out is being addressed.*

Data management and reporting

Please note: all questions refer only to clinical patient specimens, NOT to research specimens

34. Where does the lab record the bench testing results (e.g., colony morphology, hemolysis, reagent +/- results, zone sizes/MICs)? Check all that apply.
    - ☐ Handwritten on a paper work card or logbook
    - ☐ Recorded in a commercial Lab Information System (List vendor: _____)
    - ☐ Recorded in some other electronic database/computer program. Specify: _____
    - ☐ Other, please describe:_____
    - ☐ These results are not systematically recorded **(skip to Q 37)**

35. Does the lab retain these bench testing result records for a defined length of time?
    - ☐ Yes, how long? _____
    - ☐ No

36. For AST results, how does your lab record the bench testing results?

a. For Disk Diffusion	b. For MIC methods
☐ Both zone size and interpretation*	☐ Both MIC and interpretation*
☐ Zone size only, no interpretation	☐ MIC only, no interpretation
☐ Interpretation only, no zone sizes	☐ Interpretation only, no MIC values

☐ Do not use this method	☐ Do not use this method

37. How does the lab report the final organism ID and AST results back to the physician?
    - ☐ Handwritten paper form
    - ☐ Printout from Lab Information System or other electronic database/computer program (Name of LIS/computer program: _____)
    - ☐ Electronically via an HIS or EMR interface to the LIS. (Name the HIS/EMR system used by physicians: _____)
    - ☐ Other, please describe:_____

38. Does the lab retain a copy of the final organism ID and AST report for a defined length of time?
    - ☐ Yes, how long? _____
    - ☐ No

39. If final organism ID and AST results are stored electronically, how often is the data backed up? (e.g., on USB, CD, facility server, or external hard drive)
    - ☐ Weekly or more frequently
    - ☐ Monthly
    - ☐ Other frequency, specify:_____
    - ☐ Never
    - ☐ N/A – we do not use an electronic database to store these results **(Skip to Q44)**

40. Does the lab's electronic database currently perform any of the following actions?
    - ☐ Receive information (e.g., patient demographics) electronically from upstream systems like the EMR or HIS
    - ☐ Send information (e.g., lab results) electronically to downstream systems like the EMR or HIS
    - ☐ Neither of the above
    - ☐ Don't know the answer

41. Is the database interfaced with other electronic systems? (Check all that apply)
    - ☐ No, it is not interfaced with any other systems
    - ☐ Yes, with the AST software (e.g., Vitek, Microscan, Phoenix, SIRscan, BIOMIC, Adagio, etc.)
    - ☐ Yes, with the National Health Lab system
    - ☐ Yes, other (e.g., WHONET, other Epi software: _____)

42. Describe any difficulties encountered while using the electronic database:
    - ☐ No difficulties
    - ☐ Don't know how to use software
    - ☐ No training on using software
    - ☐ Software doesn't meet needs
    - ☐ Infrequent access to software or computer/internet
    - ☐ Other (describe) _____

43. Does the LIS/electronic database permit the laboratory to produce a cumulative annual antibiogram?
    - ☐ Yes
    - ☐ No

44. How is data sharing with the National Health Lab, Ministry of Health, or other central authority accomplished? (For example, if labs are required to report the isolation of certain pathogens like *V.cholerae*, how is that information shared?)
    - ☐ No such data sharing occurs
    - ☐ Electronic interface with National system
    - ☐ Mail/Email
    - ☐ Fax
    - ☐ Phone
    - ☐ Other, describe_____

PART 2. QUALITY ASSURANCE

Please note: all questions refer only to clinical patient specimens, NOT to research specimens

Pre-analytical

Specimen quality

45. Does lab utilize a two-identifier system? (e.g., both patient name and other numeric identifier on requisition and specimen).
    - ☐ Yes
    - ☐ No

46. Does lab policy require that specimens are labeled with all three of the following: patient ID, date of collection, time of collection?
    - ☐ Yes
    - ☐ Partial
    - ☐ No

47. Does lab policy require that all test requests are accompanied by a laboratory-approved test requisition form?
    - ☐ Yes
    - ☐ No

48. Are specimens logged appropriately upon receipt in the lab (including date, time, name of receiver)?
    - ☐ Yes
    - ☐ Partial
    - ☐ No

49. Are received specimens evaluated according to written acceptance/rejection criteria?
    - ☐ Yes
    - ☐ Partial
    - ☐ No **(skip to Q 51)**

50. Is there evidence that specimen rejection criteria are enforced (review rejection log)?
    - ☐ Yes
    - ☐ No

51. Is each **specimen** assigned a unique identifying number upon arrival at the laboratory? (Note: this does NOT refer to the unique number assigned to the *patient*, e.g., medical record number)
    - ☐ Yes
    - ☐ No

52. Are specimens stored properly prior to and following testing?
    - ☐ Yes
    - ☐ Partial
    - ☐ No

Standard: ISO 15189: 5.4.1, 5.4.5, 5.4.7, 5.4.8, 5.4.10, 5.4.11, 5.4.13 ***Standard:*** ISO 15189: 5.2.9, 5.4.14, 5.7.3 *Specimens should be stored under the appropriate conditions to maintain the stability of the specimen. Specimens no longer required should be disposed of in a safe manner, according to biosafety regulations.*

53. Does the lab provide specimen collection guidelines to patient sample collection areas?
    - ☐ Yes
    - ☐ No **(skip to Q55)**

54. Review each specimen-specific collection guideline. Are guidelines present and do they address the following items?

If no guidelines exist, circle 'no' under the first column and do not answer the subsequent questions for that specimen type

	Present?	Collection technique	Approved containers	Min/Max volume	Proper labeling	Transport temperature	Transport time
a. Blood Culture	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No
b. Stool Culture	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No
c. Urine Culture	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No
d. GC Culture	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No

Standard: ISO 15189: 5.4.2

AFTER ANSWERING QUESTION 54, PROCEED TO QUESTION C ON PAGE 1 OF THE INDIA ANNEX

Analytical

Temperature & Atmosphere monitoring

55. Observe if acceptable min/max temperature ranges have been clearly defined on record sheets for the following areas/equipment and if temperature checks are documented daily. Tick N/A if the piece of equipment in question in not in use in the lab.

	Acceptable ranges clearly defined on record sheet?			Temperatures are recorded and documented daily?			Comments
	Y	N	N/A	Y	N	N/A	
a. Room temperature							
b. Freezers							
c. Refrigerators							
d. Incubators							
e. Water baths							

Standard: *Acceptable ranges should be defined for all temperature dependent equipment*

56. Is there documentation of action taken in response to out of range temperatures?
    - ☐ Yes
    - ☐ No, records indicate that temperatures are never out of range
    - ☐ No, records indicate occasional out of range temperatures, but no action is documented.
    - ☐ N/A, temperatures are not recorded

Standard: *Procedures should be available with instruction as to what action(s) should be taken when temperatures are out of range*

57. Are CO2 incubators checked **and documented** daily (or each day of use if not used daily) for adequate CO2 levels?
    - ☐ Always
    - ☐ Sometimes
    - ☐ Never
    - ☐ N/A

Standard: **CAP MIC.21813** *Some organisms require CO_2 to grow sufficiently to form visible colonies. CO_2 monitoring is required in all CO_2 incubators.*

58. How frequently are the following indicators used to monitor autoclave performance?

Review records for the following:	No	Each run	Daily	Weekly	N/A	Other (describe)
a. Mechanical indicators (i.e., cycle time, temperature, pressure recorded on a log)						
b. Chemical indicators (e.g., autoclave tape)						
c. Biological indicators (e.g., Attest or other spore testing)						

Reference Strains

59. What kind of quality control organisms does the laboratory use? (check all that apply)
    - ☐ Certified Reference Microorganisms
      Specify which type(s): ATCC, NCTC, other _____
    - ☐ Organisms retained from prior patient specimens and/or EQA challenges

☐ Other, specify source:_____

☐ No quality control organisms are used **(Check N/A for question 60)**

60. Are reference strains stored appropriately?

	Yes	No	N/A	Comments
a. **Reference culture** stored in original container and frozen at -80C				
b. **Reference stock culture** frozen broth preparation derived from reference culture and stored at -20C or lower				
c. **Working stock culture** maintained on a refrigerated slant no longer than one week				
d. **Subculture** on a fresh sub plate each day of use				

Standard: **SANAS TG 28-02: 7.2.2** *A reference culture is a microorganism preparation that is obtained from a culture type collection such as ATCC. A reference stock culture is a microorganism preparation derived from a reference culture. A working stock culture is growth derived from a reference stock culture. A subculture is the transfer of established microorganism growth on media to fresh media.*

QC of Media

61. Is media stored at the correct temperature?
    - ☐ Yes, all media
    - ☐ Yes, some media
    - ☐ No

62. Are ATCC or ATCC-derivative strains used to QC media?
    - ☐ Yes for all media
    - ☐ Yes, for some media
    - ☐ No

63. Do records demonstrate that QC is performed on each newly reconstituted batch or newly received lot number/shipment of media?
    - ☐ Yes
    - ☐ No

64. Do QC records for blood agar plates demonstrate that they are checked for their ability to support growth of fastidious organisms such as *Streptococcus pneumoniae*?
    - ☐ Yes
    - ☐ No
    - ☐ N/A – the lab does not have the ability to recover CO2 dependent organisms

65. Do QC records for blood agar plates demonstrate that they are checked for their ability to show beta, alpha, and gamma hemolysis?
    - ☐ Yes
    - ☐ No

66. Do QC records for chocolate agar plates demonstrate that they are checked for their ability to support the growth of fastidious organisms, such as *Neisseria gonorrhoeae* or *meningitidis*?
    - ☐ Yes
    - ☐ No; QC is done but does not include checking for growth of such organisms
    - ☐ No; QC is not done at all on chocolate agar plates
    - ☐ N/A – the lab does not have the ability to recover CO2 dependent organisms

67. Do QC records for MAC and/or EMB plates demonstrate that they are checked for their ability to suppress growth of gram positive organisms while allowing the growth of gram negative organisms?
    - ☐ Yes
    - ☐ No; QC is done but does not include checking for suppression/growth characteristics
    - ☐ No; QC is not done at all on MAC/EMB plates **(Skip to Q69)**

68. Do QC records for MAC or EMB plates demonstrate that they are checked for their ability to allow visualization of lactose fermentation?
    - ☐ Yes
    - ☐ No

69. Do QC records for selective stool agar plates demonstrate that they are checked for their ability to suppress growth of gram positive organisms while allowing the growth of gram negative organisms?
    - ☐ Yes
    - ☐ No; QC is done but does not include checking for suppression/growth characteristics
    - ☐ No; QC is not done at all on selective stool agar plates **(Skip to Q72)**
    - ☐ N/A; lab does not use selective stool agar **(Skip to Q72)**

70. Do QC records for selective stool agar plates demonstrate that they are checked for their ability to allow for visualization of H_2S (hydrogen sulfide) production?
    - ☐ Yes
    - ☐ No; QC is done but this aspect is not checked

71. Do QC records for selective stool agar plates demonstrate that they are checked for their ability to allow for visualization of the acid byproducts of carbohydrate fermentation?
    - ☐ Yes
    - ☐ No; QC is done but this aspect is not checked

72. Do QC records for selective GC plates demonstrate that they are checked for their ability to suppress growth of gram positive organisms while allowing the growth of gram negative organisms?
    - ☐ Yes
    - ☐ No; QC is done but does not include checking for suppression/growth characteristics
    - ☐ No; QC is not done on these plates **(Skip to Q74)**
    - ☐ N/A, the lab does not perform GC cultures **(Skip to Q74)**

73. Do QC records for GC susceptibility testing media demonstrate that each batch is checked for its ability to obtain expected susceptibility results using commercial reference QC strains, such as ATCC?
    - ☐ Yes
    - ☐ No; QC is done but this is not checked

74. Do QC records for Mueller Hinton agar demonstrate that each batch is checked for its ability to obtain expected susceptibility results using commercial reference QC strains, such as ATCC?
    - ☐ Yes
    - ☐ No; QC is done but this is not checked
    - ☐ No; QC is note done on these plates

75. Do QC records for Mueller Hinton with Blood agar demonstrate that each batch is checked for its ability to obtain expected susceptibility results using commercial reference QC strains, such as ATCC?
    - ☐ Yes
    - ☐ No; QC is done but this is not checked
    - ☐ No; QC is note done on these plates

76. Does the lab reconstitute any media in-house (including agar plates and/or blood culture bottles)?
    - ☐ Yes
    - ☐ No **(skip to Q83)**

77. Indicate in the table below whether the lab has at least one functional piece of the equipment listed. If the lab has a functional piece of equipment indicate if it is calibrated routinely and if a user manual is present.

<u>If at least one piece of functional equipment is not present, circle the first 'no' column and do not answer the rest of the questions for that equipment</u>

Equipment	At least 1 functional	Calibrated routinely	User manual present
pH meter	Yes / No	Yes / No	Yes / No
Weighing balance	Yes / No	Yes / No	Yes / No

78. Does the laboratory have SOPs for each type of media reconstituted in house?
    - ☐ Yes, specific SOPs are available for each kind of media (request to see a copy)
    - ☐ Some, but not all of the media have a specific SOP
    - ☐ A general SOP for media production exists (e.g. not specific to type of media)
    - ☐ There are no SOPs regarding making media

Standard: **CAP MIC.21300; SANAS TG 28-02: 6.1** *The suitable performance of culture media, diluents, and other suspensions prepared in-house should be checked, where relevant, with regard to recovery or survival maintenance of target organisms, inhibition or suppression of non-target organisms, biochemical (differential and diagnostic) properties, physical properties (e.g. pH, volume, and sterility).*

79. Are media preparation records kept, including name of media, date made, batch number, staff responsible for preparation, date of expiry, volume made?
    - ☐ Yes, all above elements present
    - ☐ Partial, some of above elements present
    - ☐ No

80. Observe the media reconstituted in house, is each batch clearly labeled with the following?
    a) Name of media All/Some/None
    b) Date of preparation All/Some/None
    c) Expiration date All/Some/None
    d) Date of opening All/Some/None

81. Review records for each type of media reconstituted in-house. Is each batch checked for:
    a) Proper pH (using a pH meter)? All/Some/None
    b) Sterility? All/Some/None
    c) Proper volume dispensed? All/Some/None

82. If blood culture bottles are made in-house, do QC records demonstrate that each batch is checked for its ability to support growth of fastidious organisms such as *Strep pneumoniae* or *Neisseria meningitidis*?
    - ☐ Yes
    - ☐ Some QC is done but growth of fastidious organisms is not checked
    - ☐ QC is not done on these bottles
    - ☐ N/A – no ability to recover CO_2 dependent organisms
    - ☐ N/A – blood culture bottles are not made in-house

QC of Reagents and Phenotypic Identification Methods

83. Is QC performed and results recorded on each new preparation or lot number of gram stain reagents?
    - ☐ Yes
    - ☐ Partial
    - ☐ No

    Standard: **CAP MIC.21540, MIC.21624** *All staining procedures (gram stains, special stains, and fluorescent stains) should be checked and results recorded for each new batch of stain.*

84. Are positive and negative controls run and results recorded weekly with all gram stains?
    - ☐ Yes
    - ☐ Partial
    - ☐ No

    CAP MIC.21540

85. Are tubed media, reagents, and kits stored at the temperatures indicated by the manufacturer?

☐ Yes
☐ Partial
☐ No

86. Observe the working reagents in use by the laboratory, are they labelled with the following?
    a) Name of reagent All/Some/None
    b) Reconstitution date (e.g., tube coag) All/Some/None
    c) Date of opening All/Some/None
    d) Expiration date All/Some/None

87. Do QC records demonstrate that both positive and negative controls are used and that QC is done on each new batch made or lot number/shipment received of the following differential tests?
    NOTE: This question applies only to tubed media and liquid reagents in use by the lab, **NOT** to biochemical reagent wells incorporated into pre-defined identification systems or kits, such as Vitek, API, Liofilchem, etc.

If the reagent in question is **not** used, tick the first column and do not answer remaining questions for that reagent

	Not in use?	Positive Control	Negative Control	QC done on each new batch/lot number	Comments
a. Catalase		Y / N	Y / N	Y / N	
b. Coagulase plasma		Y / N	Y / N	Y / N	
c. Staph latex		Y / N	Y / N	Y / N	
d. PYR		Y / N	Y / N	Y / N	
e. Optochin		Y / N	Y / N	Y / N	
f. Bile solubility		Y / N	Y / N	Y / N	
g. Oxidase		Y / N	Y / N	Y / N	
h. Indole reagents		Y / N	Y / N	Y / N	
i. Methyl Red		Y / N	Y / N	Y / N	
j. Voges-Proskauer		Y / N	Y / N	Y / N	
k. Citrate		Y / N	Y / N	Y / N	
l. TSI or KIA		Y / N	Y / N	Y / N	
m. Urease		Y / N	Y / N	Y / N	
n. Motility		Y / N	Y / N	Y / N	
o. Lysine decarboxylase		Y / N	Y / N	Y / N	
p. OF dextrose		Y / N	Y / N	Y / N	
q. Nitrate reduction		Y / N	Y / N	Y / N	

Standard: **CAP MIC.21624** *Positive and negative controls must be tested and recorded for all differential test procedures. Controls must be performed and recorded at the specific periodic intervals listed for the tests.*

88. Are ATCC or ATCC-derivative strains used to QC the tubed media and reagents referenced above?
    ☐ Yes, for all
    ☐ Yes, for some
    ☐ No

89. Indicate whether the following aspects of QC for Salmonella and/or Shigella serology reagents are performed at this lab. *If serology testing is not performed, tick the first column and do not answer subsequent questions.*

	Not in use?	Positive Control	Negative Control	Controls are reference strains?	Each new lot/shipment?	At least every 6 months?
Shigella serogoup		Y / N	Y / N	Y / N	Y / N	Y / N
Salmonella serotype		Y / N	Y / N	Y / N	Y / N	Y / N

90. If commercial test kits are used for organism identification (e.g., API, Liofilchem, RapID), do QC records confirm that QC is performed on every new lot numbers/shipment before kits are placed into use? (Review QC records to confirm)
    - ☐ Yes for all kits
    - ☐ Yes, for some kits
    - ☐ No, QC is not done on these commercial test kits **(skip to Q92)**
    - ☐ N/A – the lab does not use these commercial test kits **(skip to Q92)**
91. Are ATCC or ATCC-derivative strains used for QC of the commercial kits for organism identification, per manufacturer instructions?
    - ☐ Yes, QC for all kits use these strains
    - ☐ Yes, QC for some kits use these strains
    - ☐ No

92. If automated instruments are used for ID, (e.g., Vitek, Phoenix, Microscan) is QC performed on every new lot number/shipment of ID cards/cartridges before they are placed into use? (Review QC records to confirm)
    - ☐ Yes, for all cards/cartridges
    - ☐ Yes, but only for some cards/cartridges
    - ☐ No, QC not done on these automated instruments **(skip to Q94)**
    - ☐ N/A – the lab does not use these automated instruments **(skip to Q94)**

93. If automated instruments are used for ID, (e.g., Vitek, Phoenix, Microscan) are ATCC or ATCC-derivative strains used for all QC, per manufacturer instructions? (Review QC records to confirm)
    - ☐ Yes, these strains are used for all automated ID QC
    - ☐ Yes, these strains are used for some automated ID QC
    - ☐ No

94. For any identification method, are patient results reported if QC of the identification method used was not performed?
    - ☐ Yes
    - ☐ No
    - ☐ N/A – QC not performed on identification methods **(skip to Q97)**

95. For any identification method, are patient results reported if QC of the identification method used failed to produce acceptable results?
    - ☐ Yes
    - ☐ No

96. Is there evidence that the lab troubleshoots unacceptable QC results for tubed media, reagents, kits or automated ID systems?
    - ☐ Yes
    - ☐ No

QC of AST Methods

97. Are antibiotics (whether in disk form, gradient strips, trays, cards, liquid, or powder) stored at the correct temperatures?
    - ☐ Yes
    - ☐ Some
    - ☐ No
98. Is the disk diffusion method of AST performed at your lab?
    - ☐ Yes
    - ☐ No **(skip to Q104)**

99. Is QC of newly received or prepared batches/lot numbers/shipments of each antibiotic disk performed before being placed into use? (Review QC records to confirm)
    - ☐ Yes, QC performed on all
    - ☐ Yes, QC performed on some
    - ☐ No

100. Is QC of newly received or prepared batches/lot numbers/shipments of each antibiotic disk performed using all of the recommended ATCC or ATCC-derivative reference strains? (Review QC records to confirm)
    - ☐ Yes, all recommended reference strains are in use
    - ☐ Yes, some recommended reference strains are in use
    - ☐ No

101. Has the lab completed a 20-30 day QC conversion plan for each antibiotic in use with disk diffusion?
    - ☐ Yes, for all
    - ☐ Yes, for some
    - ☐ No **(Skip to Q103)**

102. How often do you perform QC on the antibiotic disks for which the QC conversion plan has been completed? (Confirm by reviewing QC records).
    - ☐ Daily when AST is performed
    - ☐ Weekly
    - ☐ With each new lot number/shipment
    - ☐ Other _____
    - ☐ Never

103. If the 20-30 day conversion plan is not completed, how often do you perform QC on the antibiotic disks? (Confirm by reviewing QC records).

- ☐ Each day that AST is performed
- ☐ Weekly
- ☐ With each new lot number/shipment
- ☐ Other _____
- ☐ Never
- ☐ N/A, conversion plan completed

104. Is the gradient strip method of AST used at your lab (Etest)? (ungraded)

- ☐ Yes
- ☐ No **(if no, skip to Q110)**

105. Is QC of new lot numbers/shipments of each antibiotic strip performed before being placed into use? (Review QC records to confirm)

- ☐ Yes, QC performed on all
- ☐ Yes, QC performed on some
- ☐ No

106. Is QC of new lot numbers/shipments of each antibiotic strip performed using all of the recommended ATCC or ATCC-derivative reference strains? (Review QC records to confirm)

- ☐ Yes, all recommended reference strains are in use
- ☐ Yes, some recommended reference strains are in use
- ☐ No

107. Has the lab completed a 20-30 day QC conversion plan for each antibiotic in use with gradient strips?

- ☐ Yes, for all
- ☐ Yes, for some
- ☐ No **(Skip to Q109)**

108. How often do you perform QC on the gradient strips for which the QC conversion plan has been completed? (Confirm by reviewing QC records)

- ☐ Daily when AST is performed
- ☐ Weekly
- ☐ With each new lot number/shipment
- ☐ Other _____
- ☐ Never

109. If the 20-30 day conversion plan is not completed, how often do you perform QC on the antibiotics in use with gradient strips? (Confirm by reviewing QC records)

- ☐ Each day that AST is performed
- ☐ Weekly
- ☐ With each new lot number/shipment
- ☐ Other _____
- ☐ Never
- ☐ N/A, conversion plan completed

110. Does your lab utilize any automated instrument for AST testing? (check all that apply)

- ☐ Vitek
- ☐ Phoenix
- ☐ Microscan
- ☐ Other (please list) _____
- ☐ No **(Skip to Q116)**

111. Is QC of new lot numbers/shipments of AST cards/cartridges performed before cards/cartridges are placed into use? (Review QC records to confirm)

- ☐ Yes, QC performed on all
- ☐ Yes, QC performed on some
- ☐ No

112. Is QC of new lot numbers/shipments of AST cards/cartridges performed using all of the recommended ATCC or ATCC-derived reference strains? (Review QC records to confirm)

- ☐ Yes, all recommended reference strains are in use
- ☐ Yes, some recommended reference strains are in use, but not all
- ☐ No

113. Has the lab completed a 20-30 day QC conversion plan for all antibiotics in use with automated systems?

- ☐ Yes
- ☐ No **(Skip to Q115)**

114. How often do you perform QC on the AST cards/cartridges for which the QC conversion plan has been completed? (Confirm by reviewing QC records).

- ☐ Each day that AST is performed
- ☐ Weekly
- ☐ With each new lot number/shipment
- ☐ Other _____
- ☐ Never

115. If the 20-30 day conversion plan is not completed, how often do you perform QC on the AST cards/cartridges? (Confirm by reviewing QC records)

- ☐ Each day that AST is performed
- ☐ Weekly
- ☐ With each new lot number/shipment
- ☐ Other _____
- ☐ Never
- ☐ N/A, conversion plan completed

116. Does your lab perform any of the following methods of AST? (check all that apply)

- ☐ Broth macrodilution
- ☐ Broth microdilution
- ☐ Agar dilution
- ☐ No **(if no, skip to Q122)**

117. For the above methods in use, is QC of newly prepared batches/lot numbers/shipments of each antibiotic performed before being placed into use? (Review QC records to confirm)

- ☐ Yes, QC performed on all
- ☐ Yes, QC performed on some
- ☐ No

118. For the above methods in use, is QC of newly prepared batches/lot numbers/shipments of each antibiotic performed using all recommended ATCC or ATCC-derived reference strains? (Review QC records to confirm)

- ☐ Yes, all use recommended reference strains
- ☐ Yes, some use recommended reference strains
- ☐ No

119. Has the lab completed a 20-30 day QC conversion plan for all antibiotics in use with the systems in question 116?

- ☐ Yes
- ☐ Partial
- ☐ No **(Skip to Q121)**

120. How often do you perform QC on the antibiotics? (Confirm by reviewing QC records).

- ☐ Each day that AST is performed
- ☐ Weekly
- ☐ With each new lot number/shipment
- ☐ Other _____
- ☐ Never

121. If the 20-30 day conversion plan is not completed, how often do you perform QC on the antibiotics? (Confirm by reviewing QC records).

- ☐ Daily when AST is performed
- ☐ Weekly
- ☐ With each new lot number/shipment
- ☐ Other _____
- ☐ Never
- ☐ N/A, conversion plan completed

122. Regardless of the AST method used, if QC was not performed in the assigned time period (e.g. that day/week) are patient AST results ever reported?

- ☐ Yes
- ☐ No
- ☐ NA – this lab does not do QC on any of the AST methods in use **(Skip to Q125)**

123. Regardless of the AST method used, if QC failed to produce acceptable results are patient AST results ever reported?

- ☐ Yes
- ☐ No

124. Is there evidence that the lab troubleshoots unacceptable QC results?

- ☐ Yes
- ☐ No

Post-analytical

QC Review

125. Is there an SOP defining the post-analytical QC practices in use at this lab?

- ☐ Yes
- ☐ No

126. Are QC results recorded and archived after testing is performed?

- ☐ Yes, all
- ☐ Yes, some are retained
- ☐ No

127. Does a supervisor (or QC officer designated by the supervisor) review **all** QC results (including AST)?

- ☐ Weekly or more frequently
- ☐ Monthly or less frequently
- ☐ Not routinely
- ☐ No

128. Is there evidence that supervisory level QC review is performed at the stated frequency?

- ☐ Yes for all QC result
- ☐ Yes, but only for some QC results
- ☐ No
- ☐ N/A

Results review

129. Does a supervisor review positive culture results every day?

- ☐ Yes
- ☐ No

130. Are there written guidelines stating who is permitted to modify erroneous lab results after they have been reported?

- ☐ Yes
- ☐ No

131. Who is permitted to modify erroneous lab results?

- ☐ Supervisors and/or persons with supervisory permission
- ☐ All microbiologists
- ☐ No one

132. When corrections to patient results are made, what is done with the erroneous result?

- ☐ Erroneous results remain in place but are amended to reflect that they are erroneous
- ☐ Erroneous results are deleted from the record
- ☐ Other _____

External Quality Assurance

133. Answer the following questions about lab participation in an External Quality Assessment (EQA) or Proficiency Testing (PT) program.
If the lab does not participate in these PT/EQA programs (e.g., 133 a.-f. marked No), **skip to Q140**.

Tests	Participate in PT/EQA	PT/EQA supplier	List the dates and scores of the last 3 challenges
a. Gram stain	☐ Yes ☐ No	☐ CAP ☐ NHLS ☐ UK NEQAS ☐ Digital PT/OneWorld Accuracy ☐ Other _____	☐ _____ ☐ _____ ☐ _____

b. Aerobic Bacteriology: culture and organism identification only	☐ Yes ☐ No	☐ CAP ☐ NHLS ☐ UK NEQAS ☐ Digital PT/OneWorld Accuracy ☐ Other _____	☐ _____ ☐ _____ ☐ _____
c. Aerobic Bacteriology: culture, organism identification, and antibiotic susceptibility testing	☐ Yes ☐ No	☐ CAP ☐ NHLS ☐ UK NEQAS ☐ Digital PT/OneWorld Accuracy ☐ Other _____	☐ _____ ☐ _____ ☐ _____
d. Urine culture: colony count, organism identification, and susceptibility testing	☐ Yes ☐ No	☐ CAP ☐ NHLS ☐ UK NEQAS ☐ Digital PT/OneWorld Accuracy ☐ Other _____	☐ _____ ☐ _____ ☐ _____
e. GC culture; organism identification and antibiotic susceptibility testing	☐ Yes ☐ No	☐ CAP ☐ NHLS ☐ UK NEQAS ☐ Digital PT/OneWorld Accuracy ☐ Other _____	☐ _____ ☐ _____ ☐ _____
f. Stool culture: organism identification and antibiotic susceptibility testing	☐ Yes ☐ No	☐ CAP ☐ NHLS ☐ UK NEQAS ☐ Digital PT/OneWorld Accuracy ☐ Other _____	☐ _____ ☐ _____ ☐ _____
g. Blood culture and organism identification and susceptibility testing	☐ Yes ☐ No	☐ CAP ☐ NHLS ☐ UK NEQAS ☐ Digital PT/OneWorld Accuracy ☐ Other _____	☐ _____ ☐ _____ ☐ _____

134. Are PT/EQA specimens handled and tested the same way as patient specimens? (No special treatment or additional testing above and beyond what would be done for a patient; not sent to other labs for confirmation before submitting results.)

- ☐ Yes
- ☐ Partial
- ☐ No

135. Are PT/EQA specimens tested by the same staff performing patient testing? (Not just by supervisors or senior staff; look for evidence that **all** staff participate in the challenges)

- ☐ Yes
- ☐ Partial
- ☐ No

136. On average, how long does it take for EQA performance results to come back to the lab?

- ☐ Less than 2 months

- ☐ 2 – 6 months
- ☐ More than 6 months

137. Is a root cause analysis performed when unacceptable PT/EQA results are obtained? (Request to see a recent example)
- ☐ Always
- ☐ Sometimes
- ☐ Never
- ☐ N/A – no unacceptable results have been obtained

138. Is corrective action based on the findings of the root cause analysis documented?
- ☐ Always
- ☐ Sometimes
- ☐ Never
- ☐ N/A – no unacceptable results have been obtained

139. Is laboratory leadership notified of all unacceptable EQA results as soon as they are received?
- ☐ Yes
- ☐ No
- ☐ N/A – no unacceptable results have been obtained

Part 3: SPECIMEN PROCESSING AND ORGANISM ISOLATION

Please note: all questions refer only to clinical patient specimens, NOT to research specimens

140. If blood agar plates are reconstituted on site, what is the source of the blood?
- ☐ Commercially purchased sheep blood
- ☐ Locally bled sheep
- ☐ Human blood
- ☐ Other source (please describe) _____
- ☐ N/A

141. Approximately how many bacterial cultures are performed each month from the following specimens?

	≤20	21-30	≥30		≤10	11-20	≥20
Blood				Stool			
Urine				Gonorrhoeae			

AFTER ANSWERING QUESTION 141, PROCEED TO QUESTION D ON PAGE 2 OF THE INDIA ANNEX

Blood Cultures

142. Does the laboratory perform blood cultures?

- ☐ Yes
- ☐ No **(Skip to Urine Culture section)**

143. Are blood culture bottles purchased ready-made or prepared on-site?

- ☐ Purchased ready-made
- ☐ Prepared on site

144. Do your blood culture bottles contain charcoal or resin designed to neutralize some antibiotics?

- ☐ Yes
- ☐ No

145. What blood culture incubation systems are used? (check all that apply)

- ☐ Manual system
- ☐ Automated system **(Skip to Q147)**

146. If a manual system is used, please answer the following questions

	Always	Sometimes	Never	Comments
a. Are incubating blood cultures visually examined each day?				
b. Are Gram stains performed for all blood cultures showing any sign of positive growth (e.g. turbidity, hemolysis, or gas production?)				
c. Are subcultures performed for all blood cultures showing any sign of positive growth (e.g. turbidity, hemolysis, or gas production?)				
d. Are apparently negative bottles sub-cultured to chocolate agar within 24 hours and again at 48 hours?				
e. Are blood cultures incubated between 5 to 7 days before a final negative report is issued?				

147. Does the laboratory have an SOP for how to process blood for bacterial culture?

- ☐ Yes
- ☐ No

148. Specify whether the following media are used:

Specimen	Media	Always	Sometimes	Never
a. Blood	Aerobic blood culture bottles			
b. Subculture of blood culture bottle broth	Blood agar			
	Chocolate agar			

149. Does the lab have a blood culture SOP that defines appropriate organisms that should be considered contaminants?

- ☐ Yes
- ☐ Partial
- ☐ No

150. Are blood culture *subculture plates* incubated to recover organisms with different atmospheric requirements?

	Always	Sometimes	Never
Aerobic organisms			
CO_2 dependent organisms			

AFTER ANSWERING QUESTION 150, PROCEED TO QUESTION E ON PAGE 2 OF THE INDIA ANNEX

Urine Cultures

151. Does the lab perform urine cultures?

- ☐ Yes
- ☐ No **(Skip to GC Culture section)**

152. Does the laboratory have an SOP for how to process urine for bacterial culture? (request to see)

- ☐ Yes
- ☐ No

153. Which media are used for primary culture of urine? (check all that apply)

- ☐ Blood agar
- ☐ MacConkey/EMB or other selective gram negative agar
- ☐ Other, describe_____

Standard: **CAP MIC.22210;SANAS TR 34-04:3.2.1.2** *Media and procedures must be used to ensure isolation and identification of common uropathogens such as Enterobacteriaceae, Enterococcus sp., and Staphylococcus sp.*

154. Are quantitative cultures (colony counts) performed?

- ☐ Yes
- ☐ No

Standard: **CAP MIC.22200; SANAS TR 34-04: 3.2.1.2** *The minimal standards for evaluation of urine cultures should include an estimate of number of organisms, i.e. quantitative culture expressed as CFU/L.*

155. Are urines plated using a calibrated 1uL loop?

- ☐ Yes

- ☐ No, they are plated using a calibrated 10uL loop
- ☐ Calibrated loops are not used to plate urines

156. Does a urine culture SOP exist which provides guidance to the technologist in determining which organisms to work up based on relative quantities and pathogenicity?
- ☐ Yes
- ☐ Partial
- ☐ No

GC (Neisseria Gonorrhoeae) Cultures

157. Does the lab perform GC cultures? (ungraded)
- ☐ Yes
- ☐ No **(Skip to Stool Culture section)**

158. Are specimens for culture of *Neisseria gonorrhoeae* either inoculated directly to **selective** GC culture media at the time of collection **or** received in appropriate transport media within 24 hours?
- ☐ Yes
- ☐ No

Standard: SANAS TR 34-04: 3.2.1.3 *Cultures for Neisseria gonorrhoeae must be planted directly on plates at the time of collection, or a suitable transport medium must be used to ensure survival of the organism.*

159. Does the laboratory have an SOP for how to process specimens for *Neisseria gonorrhoeae* culture?
- ☐ Yes
- ☐ No

160. Which media are used for primary culture of specimens for *Neisseria gonorrhoeae*?
- ☐ GC selective agar (e.g., TM, MTM, ML, GC-Lect, JEMBEC; specify which one)

  _____
- ☐ GC non-selective agar (e.g., GC-chocolate, Chocolate)*
- ☐ Other

  _____

161. Are GC cultures incubated in CO2 enriched environments?
- ☐ Yes
- ☐ No

Stool Cultures

162. Does the laboratory perform stool cultures? (ungraded)
- ☐ Yes
- ☐ No **(skip to Part 4)**

163. Does the laboratory have an SOP for how to process stool for bacterial culture? (request to see)

☐ Yes
☐ No **(Skip to Q165)**

164. Does the SOP describe how to identify potential pathogens on all primary media? *(SOP should describe colony appearance of potential pathogens on MAC other selective & differential media used, and define how to proceed when a potential pathogen is encountered, and should be written in a language all staff can read fluently)*
☐ Yes
☐ Partial
☐ No

165. Which media are used for primary culture of stool? (check all that apply)
☐ Blood agar
☐ MacConkey or Eosin Methylene Blue agar
☐ Selective and differential screening agar for Salmonella and Shigella (e.g., Salmonella/Shigella agar, Hektoen Enteric agar, Xylose Lysine Deoxycholate agar, or Deoxycholate Citrate Agar)
☐ Selective enrichment broth (Selenite, GN, etc.)
☐ Other (describe) _____

166. Which organisms are cultured for **routinely** in every stool culture submitted? (Check all that apply)
☐ Salmonella spp
☐ Shigella spp
☐ Other _____

AFTER ANSWERING QUESTION 166, ANSWER QUESTIONS F TO M IN THE INDIA ANNEX

Part 4: IDENTIFICATION OF BACTERIAL ISOLATES

Please note: all questions refer only to clinical patient specimens, NOT to research specimens

Automated ID Methods

167. If your lab uses automated biochemical methods for organism ID (e.g., Vitek, Microscan, Phoenix), are adequate* SOPs in place for the instrument in question?

**An adequate SOP contains all of the following elements: instrument maintenance and troubleshooting; defined QC organisms, QC frequency, and expected QC results; step-by-step instructions for preparing the inoculum in the correct medium and at the correct density; clear guidance around interpreting results generated by the software and how to recognize unacceptable results.*

☐ Yes
☐ Partial

☐ No
☐ N/A – automated methods are not used **(Skip to Q173)**

168. Is the SOP available in your country's native language or in a language that all those referencing the document are able to read fluently?
☐ Yes
☐ No

169. Is the lab using the inoculation medium recommended by the manufacturer?
☐ Yes
☐ No, specify what is being used:_____

170. Following card/cartridge inoculation, does the lab use the remaining inoculum to make purity plates?
☐ Yes
☐ No

171. Is the instrument software up to date?
☐ Yes, date of last update _____
☐ No
☐ Don't know

172. When the software flags an ID result as questionable, is there **evidence** that appropriate action is taken, such as repeating the test by another method or performing additional biochemical tests?
☐ Yes
☐ No evidence available

Kit-based ID Methods

173. If your lab uses rapid biochemical kits for organism ID (e.g., API, Liofilchem, RapID), are adequate* SOPs in place for the kit in question?

**An adequate SOP contains all of the following elements: defined QC organisms, QC frequency, and expected QC results; step-by-step instructions for the following: preparing the inoculum in the correct medium and at the correct density; instructions on how to inoculate and incubate the device; instructions around reading the results, including use of additional reagents, clear guidance on interpreting results generated and how to recognize unacceptable results.*

☐ Yes
☐ Partial
☐ No
☐ N/A – this lab does not use rapid biochemical kits **(skip to Q179)**

174. Is the SOP available in your country's official language or in a language that all those referencing the document are able to read fluently?

☐ Yes
☐ No

175. Is the lab using the inoculation medium recommended by the manufacturer?

☐ Yes
☐ No, specify what is used_____

176. Following device inoculation, does the lab use the remaining inoculum to make purity plates?

☐ Yes
☐ No

177. Is the database used for result interpretation up to date?

☐ Yes
☐ No

178. When an ID result does not reach the acceptable threshold, is there **evidence** that appropriate action is taken, such as repeating the test by another method or performing additional biochemical tests?

☐ Yes
☐ No evidence available

Manual/Conventional ID Methods

Staphylococcus aureus

179. Does the lab use conventional methods to identify *S. aureus*?

☐ Yes
☐ No - **(Skip to *S. pneumoniae* section)**

180. On average, approximately how many isolates of *S. aureus* are identified manually each month?

☐ 0-4
☐ 5-10
☐ 11-50
☐ >50

181. Answer the following questions for each manual method/biochemical in use at the lab.

skip *the remaining questions regarding SOPs for that item.*

skip *the remaining questions in that row.*

	Is this reagent in use in your lab?	**Has an up-to-date SOP been fully implemented?***	**Is the SOP readily available** to bench staff?**

	Yes	No	Yes	Partial	No	Yes	No
a. Catalase							
b. Coagulase plasma							
c. Staph latex agglutination							
d. Staph chromagar							

*Fully implemented indicates that the SOP has been approved and signed by a lab supervisor or designee, and that laboratory staff have been trained on the contents and utilize the SOP. An SOP that is complete but has not been approved or is not in routine use is not considered fully implemented.

**Readily available indicates that technologists can easily access the necessary SOP at or near the bench, either in electronic or paper form, and that the information sought is easily located within the SOP, not buried in a larger document, and is written in a language that all using the SOP can read fluently.

	Does the SOP define QC organisms, QC frequency, and expected QC results?			Does the SOP provide stepwise instructions for inoculation and incubation?			Does the SOP provide stepwise instructions for reading and interpretation?		
	Yes	Partial	No	Yes	Partial	No	Yes	Partial	No
a. Catalase									
b. Coagulase plasma									
c. Staph latex agglutination									
d. Staph chromagar									

182. Is catalase testing performed prior to coagulase testing on suspected Staph isolates?
- ☐ Always
- ☐ Sometimes
- ☐ No

183. What is the source of the plasma used for coagulase testing?
- ☐ Commercially purchased rabbit plasma
- ☐ Locally bled rabbits
- ☐ Human plasma
- ☐ Other (please describe) _____
- ☐ N/A

184. If your lab performs slide coagulase, are negative results confirmed with a tube coagulase test?
- ☐ Always
- ☐ Sometimes
- ☐ No
- ☐ N/A, we do not perform slide coagulase testing

185. If your lab uses latex agglutination to identify Staph aureus, are disposable cards discarded and not reused?
- ☐ Always
- ☐ Sometimes
- ☐ No
- ☐ N/A

Streptococcus pneumoniae

186. Does the lab use conventional methods to identify *S. pneumoniae*?

- ☐ Yes
- ☐ No - **(Skip to *N. gonorrhoeae* section)**

187. On average, approximately how many isolates of *S. pneumoniae* are manually identified each month?

- ☐ 0-4
- ☐ 5-10
- ☐ 11-50
- ☐ >50

188. Answer the following questions for each manual method/biochemical in use at the lab.

*r the first question and **skip** the remaining questions regarding SOPs for that item.*

***skip** the remaining questions in that row.*

	Is this reagent in use in your lab?		Has an up-to-date SOP been fully implemented?*			Is the SOP readily available** to bench staff?	
	Yes	**No**	**Yes**	**Partial**	**No**	**Yes**	**No**
a. PYR							
b. Bile solubility (deoxycholate)							
c. Optochin "P" disk							
d. S. pneumo latex							

*Fully implemented indicates that the SOP has been approved and signed by a lab supervisor or designee, and that laboratory staff have been trained on the contents and utilize the SOP. An SOP that is complete but has not been approved or is not in routine use is not considered fully implemented.

**Readily available indicates that technologists can easily access the necessary SOP at or near the bench, either in electronic or paper form, and that the information sought is easily located within the SOP, not buried in a larger document, and is written in a language that all using the SOP can read fluently.

	Does the SOP define QC organisms, QC frequency, and expected QC results?			Does the SOP provide stepwise instructions for inoculation and incubation?			Does the SOP provide stepwise instructions for reading and interpretation?		
	Yes	**Partial**	**No**	**Yes**	**Partial**	**No**	**Yes**	**Partial**	**No**
a. PYR									
b. Bile solubility (deoxycholate)									
c. Optochin "P" disk									
d. S. pneumo latex									

189. If your lab uses Optochin disks and the Optochin result is questionable (9-13mm), is bile solubility or other additional testing performed?

- ☐ Always
- ☐ Sometimes

☐ No

☐ N/A, the lab does not use Optochin disks

Neisseria gonorrhoeae

190. Does the lab use conventional methods to identify *Neisseria gonorrhoeae*?

☐ Yes – (please answer questions in N.gonorrhoeae annex)

☐ No - **(Skip to Enterobacteriaceae section)**

Enterobacteriaceae

191. Does the lab use conventional methods to identify enterobacteriaceae?

☐ Yes

☐ No – **(Skip to *Acinetobacter* section)**

192. On average, approximately how many isolates of the organisms below are identified each month?

	0-1	2-10	11-49	≥50
a. *Escherichia coli*				
b. *Klebsiella pneumoniae*				
c. *Salmonella* species				
d. *Shigella* species				

193. Answer the following questions for each manual method/biochemical in use at the lab.

skip *the remaining questions regarding SOPs for that item.*

skip *the remaining questions in that row.*

	Is this reagent in use in your lab?		Has an up-to-date SOP been fully implemented?*			Is the SOP readily available** to bench staff?	
	Yes	No	Yes	Partial	No	Yes	No
a. Oxidase							
b. Indole							
c. Methyl Red							
d. Voges-Proskauer							
e. Citrate							
f. TSI or KIA							
g. Urease							
h. Motility							
i. LIA or LDC							
j. Shigella serology							
k. Salmonella serology							

*Fully implemented indicates that the SOP has been approved and signed by a lab supervisor or designee, and that laboratory staff have been trained on the contents and utilize the SOP. An SOP that is complete but has not been approved or is not in routine use is not considered fully implemented.

**Readily available indicates that technologists can easily access the necessary SOP at or near the bench, either in electronic or paper form, and that the information sought is easily located within the SOP, not buried in a larger document, and is written in a language that all using the SOP can read fluently.

	Does the SOP define QC organisms, QC frequency, and expected QC results?			Does the SOP provide stepwise instructions for inoculation and incubation?			Does the SOP provide stepwise instructions for reading and interpretation?		
	Yes	Partial	No	Yes	Partial	No	Yes	Partial	No
a. Oxidase									
b. Indole									
c. Methyl Red									
d. Voges-Proskauer									
e. Citrate									
f. TSI or KIA									
g. Urease									
h. Motility									
i. LIA or LDC									
j. Shigella serology									
k. Salmonella serology									

Acinetobacter species

194. Does the lab use conventional methods to identify *Acinetobacter* species?
- ☐ Yes
- ☐ No - **(Skip to 199)**

195. On average, approximately how many isolates of *Acinetobacter* spp are identified each month?
- ☐ 0-4
- ☐ 5-10
- ☐ 11-50
- ☐ >50

196. Which reagents does your lab typically use to identify *Acinetobacter species* to the Genus level? (Check all that apply)
- ☐ Catalase
- ☐ Oxidase
- ☐ Motility

197. Does your lab identify Acinetobacter to the species level using conventional methods?
- ☐ Yes
- ☐ No - **(Skip to 199)**

198. Answer the following questions for each manual method/biochemical in use at the lab.
*If the reagent is not in use in your lab tick no for the first question and **skip** the remaining questions regarding SOPs for that item.*
*If no SOP exists, tick no for second question and **skip** the remaining questions in that row.*

	Reagent used to speciate Acinetobacter?		Has an up-to-date SOP been fully implemented?*			Is the SOP readily available** to bench staff?	
	Yes	No	Yes	Partial	No	Yes	No
a. Urease							
b. Citrate							

c. OF Glucose							
d. Nitrate reduction							
e. Gelatin hydrolysis							
f. Chloramphenicol R/S							
g. Arginine hydrolysis							
h. Growth at 42C							

*Fully implemented indicates that the SOP has been approved and signed by a lab supervisor or designee, and that laboratory staff have been trained on the contents and utilize the SOP. An SOP that is complete but has not been approved or is not in routine use is not considered fully implemented.

**Readily available indicates that technologists can easily access the necessary SOP at or near the bench, either in electronic or paper form, and that the information sought is easily located within the SOP, not buried in a larger document, and is written in a language that all using the SOP can read fluently.

	Does the SOP define QC organisms, QC frequency, and expected QC results?			Does the SOP provide stepwise instructions for inoculation and incubation?			Does the SOP provide stepwise instructions for reading and interpretation?		
	Yes	Partial	No	Yes	Partial	No	Yes	Partial	No
a. Urease									
b. Citrate									
c. OF Glucose									
d. Nitrate reduction									
e. Gelatin hydrolysis									
f. Chloramphenicol R/S									
g. Arginine hydrolysis									
h. Growth at 42C									

Part 5: ANTIMICROBIAL SUSCEPTIBILITY TESTING (AST)

Please note: all questions refer only to clinical patient specimens, NOT to research specimens

General information

PLEASE NOTE: The antibiotics referenced in this section are important for antimicrobial resistance surveillance purposes. They may not be first-line options for testing or treatment and should not be interpreted as such.

199. Indicate whether the following AST methods are used for each bacteria listed below (check all that apply).

Organism	Disk Diffusion		Etest/ Gradient		Microdilution kit*		Automated method		Other, e.g., broth macrodilution, lab-made broth microdilution, agar dilution (specify)
	Yes	No	Yes	No	Yes	No	Yes	No	
a. S.aureus									

b. S.pneumoniae									
c. N.gonorrhoeae									
d. E.coli									
e. Kleb.pneumoniae									
f. *Salmonella* spp									
g. *Shigella* spp									
h. *Acinetobacter* spp									

*Commercially purchased microdilution kit, e.g., Sensititre

200. Does the lab have SOPs in place for each of the different AST methods used?
- ☐ Yes, for all methods
- ☐ Yes, for some methods
- ☐ No

201. Is each SOP written in your country's native language or a language that everyone using the SOP can read fluently?
- ☐ Yes
- ☐ No

202. When performing AST, are fresh isolates (<24 hours old) used?
- ☐ Always
- ☐ Sometimes
- ☐ Never

203. When performing AST, are well-isolated, pure colonies (as evidenced by gram stain, colony morphology, etc.) used?
- ☐ Always
- ☐ Sometimes
- ☐ Never

204. When preparing a bacterial inoculum for AST, is a 0.5 McFarland suspension used?
- ☐ Always
- ☐ Sometimes
- ☐ Never

205. After inoculation, are purity plates always made from the remaining suspension? (Ask to see one)
- ☐ Yes, for all methods of AST
- ☐ Yes, for some methods of AST (specify which ones _____)
- ☐ No

206. Do the AST SOPs define examples of unusual or unexpected patient AST results which might require confirmatory testing (e.g. *K. pneumoniae* S to Ampicillin, *S aureus* R to Vancomycin)?
- ☐ Yes

☐ No

207. Do the AST SOPs outline what actions to take when unusual or unexpected AST results are documented from patient samples (e.g., reconfirm organism ID, reconfirm relevant QC, repeat testing, notify supervisor)?

☐ Yes
☐ No **(skip to Q210)**

208. Is there evidence of such actions being taken?

☐ Yes
☐ No

209. Is the microbiology lead or supervisor informed when unusual AST results are identified?

☐ Always
☐ Sometimes
☐ No

210. Which AST interpretation standard does your lab use (check all that apply)?

☐ CLSI
☐ EUCAST
☐ Other _____

211. Which edition of the standard referenced above does your lab possess?

☐ Current year
☐ 2014 or later
☐ 2013 or earlier
☐ N/A – no copy available in lab

Automated Methods

212. If your lab uses an automated method for antimicrobial susceptibility testing (e.g., Vitek, Microscan, Phoenix), are adequate SOPs in place for the instrument in question?

An adequate SOP contains all of the following elements: instrument maintenance and troubleshooting; defined QC organisms, QC frequency, and expected QC results; step-by-step instructions for preparing the inoculum in the correct medium and at the correct density; clear guidance around interpreting results generated by the software and how to recognize unacceptable results, and is written in a language that all those using it can read fluently.

☐ Yes
☐ Partially
☐ No
☐ N/A, we do not use an automated method **(skip to Manual Methods)**

213. Is the lab using the inoculation medium recommended by the manufacturer (confirm with package insert if available)?

- ☐ Yes
- ☐ No, specify what is being used:_____

214. Following card/cartridge inoculation, does the lab use the remaining inoculum to make purity plates?

- ☐ Yes
- ☐ No

215. Is the instrument software up to date?

- ☐ Yes
- ☐ No
- ☐ Don't know

216. When the software flags an AST result as questionable, is there evidence that appropriate action is taken (such as repeating the test by another method)?

- ☐ Yes
- ☐ No

Manual/Conventional Methods

217. If the lab uses disk diffusion for AST, what kind of disks are used?

- ☐ Commercially manufactured* (list manufacturers)
  _____
- ☐ Disks prepared in-house after antibiotic reconstitution
- ☐ Other (please explain) _____
- ☐ N/A, disk diffusion is not used **(skip to Q 219)**

218. Does the lab have an adequate disk diffusion SOP (as defined below)?

- ☐ Yes, all below elements present
- ☐ Partial, at least half of below elements present
- ☐ No

**An adequate SOP should describe: correct QC organisms and frequency of QC, appropriate inoculation density, appropriate agar selection for each organism or organism group tested, step-by-step instructions for creating an even lawn, indicate waiting 15 minutes between plate inoculation and disk application, define the maximum number of disks to test per plate, proper incubation time and atmosphere for each organism or organism group tested, describe specific criteria for measuring and determining the zone size for each organism or organism group tested, define unusual susceptibility patterns and provide guidance for how to address unusual findings,* written in a language that all those using it can read fluently.

219. If manual MIC methods are used, do the SOPs document specific criteria for measuring and determining the MIC endpoints?

- ☐ Yes
- ☐ Partially
- ☐ No
- ☐ N/A, we do not perform any manual MIC methods

Staphylococcus aureus

220. Which antibiotics does your lab routinely use to detect Methicillin/Nafcillin resistance in *S. aureus*? (check all that apply)
    - ☐ Oxacillin disk
    - ☐ Oxacillin MIC
    - ☐ Cefoxitin disk or MIC
    - ☐ Other, please describe:_____
    - ☐ N/A – we do not do manual AST testing on *S. aureus* **(skip to Q229)**

221. When the oxacillin and cefoxitin results are discrepant (one is S and one is R), how does your lab report the result for Staph aureus?
    - ☐ Report the oxacillin result, regardless of what the cefoxitin result is
    - ☐ Report the cefoxitin result, regardless of what the oxacillin is
    - ☐ If either drug tests R, we report the result as R
    - ☐ Other, please describe:
      _____
    - ☐ N/A, we only test one of these drugs

222. Indicate the average monthly number of manual *S. aureus* ASTs performed at your lab.
    - ☐ >50
    - ☐ 11-49
    - ☐ 2-10
    - ☐ 0-1

223. What kinds of agar do you use for disk diffusion/gradient strip AST testing of *S. aureus*? Check all that apply.
    - ☐ Mueller Hinton agar
    - ☐ Mueller Hinton with blood agar
    - ☐ Blood agar
    - ☐ Other (specify) _____
    - ☐ N/A – we do not use these methods of AST testing for *S. aureus* **(skip to Q227)**

224. In what atmosphere do you incubate the *S. aureus* disk diffusion/gradient strip plate?
    - ☐ 5% CO_2
    - ☐ Ambient air

225. Per your SOP, at what point do you read the disk diffusion/ gradient strip results for Cefoxitin for *S. aureus*? (check all that apply)

- ☐ Between 16-18 hours of incubation
- ☐ Between 20-24 hours of incubation
- ☐ Only at 24 hours of incubation
- ☐ Any time, as long as there is visible growth
- ☐ Other (specify) _____
- ☐ N/A, we do not test Cefoxitin

226. Does the lab routinely use the following ATCC (or ATCC-derivative/equivalent) reference strain(s) for AST QC? (review QC records, check all that apply)

- ☐ *S. aureus* 25923
- ☐ *S. aureus* 43300
- ☐ *S. aureus* 29213 (for MIC methods only)
- ☐ None of the above

Streptococcus pneumoniae

227. When AST is performed on *S. pneumoniae*, which of the following are available for testing in your lab? (Ungraded, check all that apply)

- ☐ Oxacillin **disk** (as a surrogate for penicillin resistance)
- ☐ Penicillin G **MIC method**
- ☐ Ceftriaxone and/or Cefotaxime **MIC method**
- ☐ Co-trimoxazole (aka Trimethoprim-Sulfamethoxazole)
- ☐ None of the above
- ☐ N/A – we do not do manual testing on *S. pneumoniae* **(Skip to Q236)**

228. Indicate the average monthly number of manual *S. pneumoniae* ASTs performed at your lab.

- ☐ >50
- ☐ 11-49
- ☐ 2-10
- ☐ 0-1

229. What kinds of agar do you use for disk diffusion/gradient strip AST of *S. pneumoniae*? Check all that apply

- ☐ Blood Agar Plate
- ☐ Mueller Hinton with Blood
- ☐ Chocolate Agar Plate
- ☐ Other (specify) _____

230. In what atmosphere do you incubate the *S. pneumoniae* disk diffusion/gradient strip plate?

- ☐ 5% CO_2
- ☐ Ambient air

231. At what point do you read the disk diffusion/ gradient strip results?

- ☐ Between 16-24 hours of incubation
- ☐ Before 16 hours of incubation
- ☐ After 24 hours of incubation
- ☐ Any time, as long as there is visible growth
- ☐ Other (specify) _____

232. Does the lab routinely use the following ATCC (or ATCC-derivative/equivalent) reference strain for AST QC? (review QC records)

- ☐ *S. pneumoniae* 49619
- ☐ No

233. If your lab uses an oxacillin disk (1ug) to screen for penicillin resistance, what does your SOP tell you to do when the zone size measures ≤19?

- ☐ Report penicillin resistant
- ☐ Perform additional testing using a penicillin MIC method
- ☐ N/A -We do not perform this screening test

234. When testing co-trimoxazole (SXT) against *Strep pneumoniae*, does the SOP instruct that zone sizes and/or MIC end points are measured at 80% inhibition, rather than 100%?

- ☐ Yes
- ☐ No

235. When *S. pneumoniae* is isolated from a blood culture, does your lab use a disk method or an MIC method to test Penicillin, Ceftriaxone, and/or Cefotaxime?

	Disk Method	MIC Method	Neither Method	Both Methods
Penicillin				
Ceftriaxone				
Cefotaxime				

Enterobacteriaceae and *Acinetobacter spp.*

236. Which of the following antibiotics are available for testing in your lab? Check all that apply

- ☐ Ampicillin
- ☐ Ceftriaxone or Cefotaxime
- ☐ Ceftazidime
- ☐ Cefepime
- ☐ Imipenem or Meropenem

- ☐ Ertapenem or Doripenem
- ☐ Ciprofloxacin or Levofloxacin
- ☐ Co-trimoxazole (aka SXT)
- ☐ Colistin (Polymyxin B)
- ☐ Azithromycin
- ☐ Minocycline or Tigecycline
- ☐ Amikacin
- ☐ Gentamicin
- ☐ N/A – we do not perform manual AST testing for enterobacteriaceae or *Acinetobacter* in this lab **(Skip to end)**

237. If Cefotaxime disks are used, does the disk content correspond to the lab's stated interpretation guideline? (Labs using CLSI breakpoints should use 30ug disks, while labs using EUCAST breakpoints should use 5ug disks).
- ☐ Disks in use correspond correctly to guideline in use
- ☐ Disks in use DO NOT correspond correctly to guideline in use
- ☐ N/A, this lab does not test cefotaxime

238. If Ceftazidime disks are used, does the disk content correspond to the lab's stated interpretation guideline? (Labs using CLSI breakpoints should use 30ug disks, while labs using EUCAST breakpoints should use 10ug disks).
- ☐ Disks in use correspond correctly to guideline in use
- ☐ Disks in use DO NOT correspond correctly to guideline in use
- ☐ N/A, this lab does not test ceftazidime

239. Indicate the average monthly number of ASTs performed at your lab.

Pathogen	**0-1**	**2-10**	**11-49**	**≥50**
Escherichia coli				
Klebsiella pneumoniae				
Salmonella spp.				
Shigella spp.				
Acinetobacter spp.				

240. What kinds of agar do you use for disk diffusion/antibiotic gradient AST of Enterobacteriaceae and *Acinetobacter* spp.? Check all that apply
- ☐ Mueller Hinton agar
- ☐ Mueller Hinton with blood
- ☐ Blood agar
- ☐ Other_____

☐ N/A – we do not use these methods for either of these organisms **(Skip to Q244)**

241. In what atmosphere do you incubate the disk diffusion/antibiotic gradient plate for these organisms?
   - ☐ 5% CO_2
   - ☐ Ambient air

242. At what point do you read the disk diffusion/antibiotic gradient results for Enterobacteriaceae?
   - ☐ Between 16-18 hours of incubation
   - ☐ Between 20-24 hours of incubation
   - ☐ At 24 hours of incubation
   - ☐ Other (specify) _____

243. At what point do you read the disk diffusion/antibiotic gradient results for *Acinetobacter* spp.?
   - ☐ Between 16-18 hours of incubation
   - ☐ Between 20-24 hours of incubation
   - ☐ At 24 hours of incubation
   - ☐ Other (specify) _____

244. Does the lab routinely use the following ATCC (or ATCC-derivative/equivalent) reference strain(s) for AST QC? (review QC records)
   - ☐ *E.coli* 25922
   - ☐ *Pseudomonas aeruginosa* 27853
   - ☐ *E.coli* 35218
   - ☐ *K.pneumoniae* 700603
   - ☐ No

245. Are current cephalosporin breakpoints in use for the Enterobacteriaceae? (Refer to assessor's guide for quick reference table of both CLSI and EUCAST breakpoints)
   - ☐ Yes
   - ☐ No
   - ☐ N/A – we do not test cephalosporins against these organisms

246. Are current carbapenem breakpoints in use for the Enterobacteriaceae? (Refer to assessor's guide for quick reference table of both CLSI and EUCAST breakpoints)
   - ☐ Yes
   - ☐ No
   - ☐ N/A – we do not test carbapenems against these organisms

247. Does the lab test for any of the following during routine AST:
   - ☐ ESBL production **(if yes, please fill out AST Annex)**
   - ☐ Mechanism of carbapenem resistance **(if yes, please fill out AST Annex)**

☐ None of these tests are performed in this lab

Salmonella spp.

248. If the lab performs AST on Salmonella isolates, which of the following are in use for detecting resistance to quinolones and fluoroquinolones? (Check all that apply)

- ☐ Pefloxacin disk or MIC method
- ☐ Nalidixic Acid disk or MIC method
- ☐ Ciprofloxacin disk or MIC method
- ☐ Levofloxacin MIC method
- ☐ Ofloxacin MIC method
- ☐ None of the above

249. If the lab performs Cipro and/or Levo AST on Salmonella isolates, are the appropriate breakpoints in use? (Refer to assessor's guide for current breakpoints tables.)

- ☐ Yes
- ☐ No
- ☐ N/A - do not test these drugs against this organism

Colistin testing

250. If your lab performs AST testing for colistin, which method do you use? (Check all that apply)

- ☐ Agar dilution
- ☐ Automated instrument (e.g., Vitek, Microscan, Phoneix, Sensititre please specify _____)
- ☐ Disk diffusion
- ☐ Etest/gradient strip
- ☐ Broth microdilution with Polysorbate 80
- ☐ Broth microdilution without Polysorbate 80
- ☐ N/A we do not perform colistin AST **(skip to end)**

251. Is Colistin resistance ever detected in your lab in the following organisms? (Check all that apply)

- ☐ Acinetobacter spp
- ☐ Enterobacteriaceae
- ☐ Pseudomonas spp
- ☐ Other, please indicate which organisms _____
- ☐ None

252. When Colistin resistance is detected, is a supervisor notified?

- ☐ Yes
- ☐ No
- ☐ N/A

253. When Colistin resistance is detected, is the isolate sent to another lab for confirmation and/or additional testing?

- ☐ Yes
- ☐ No
- ☐ N/A

Safety appendix

To be completed if no record of other safety audit in the past 12 months (e.g. as part of WHO LAT or accreditation visit).

1. Is standard safety equipment available and in use in the laboratory?

Equipment:	Tick for each item			Comments
	Y	N	N/A	
a. Biosafety cabinets (Class IIA)				
b. Covers on centrifuge buckets				
c. Covers on centrifuge rotors				
d. Hand-washing station				
e. Eyewash station/bottle				
f. Sharps containers				
g. Flame cabinet				

Standard: *It is the responsibility of laboratory management to ensure the laboratory is equipped with standard safety equipment. The list above is a partial list of necessary items. Biosafety cabinets should be in place and in use and all centrifuges should have covers. Hand washing stations should be designated and equipped and eyewash stations (or an acceptable alternative method of eye cleansing) should be available and operable. Spill kits and first aid kits should be kept in a designated place and checked regularly for readiness.*

Standard: **ISO 15189: 5.2.10** *All syringes, needles, lancets, or other bloodletting devices capable of transmitting infection must be used only once and discarded in puncture resistant containers that are not overfilled. Sharps containers should be clearly marked to warn handlers of the potential hazard and should be located in areas where sharps are commonly used.*

2. Does lab policy prohibit eating, drinking, and smoking in the laboratory?

- ☐ Yes
- ☐ No

3. Are hazardous chemicals stored appropriately (acids separate from alkaline, flammables in a flame cabinet)?

- ☐ Yes
- ☐ Partial
- ☐ No

4. Has each biosafety cabinet been recertified within a year of today's date?

- ☐ Yes all
- ☐ Some but not all
- ☐ No
- ☐ N/A

Standard: *A biosafety cabinet should be used for to prevent aerosol exposure to contagious specimens or organisms. For proper functioning and full protection, biosafety cabinets require periodic maintenance and should be serviced accordingly.*

5. Is work area (bench and hood) disinfection documented daily? (Review documentation for completeness)

- ☐ Yes; daily documentation is present and complete
- ☐ Partial; documentation is present but incomplete
- ☐ No

Standard: **ISO 15189: 5.2.10** *The work area should be regularly inspected for cleanliness and leakage. An appropriate disinfectant should be used. At a minimum, all benchtops and working surfaces should be disinfected at the beginning and end of every shift. All spills should be contained immediately and the work surfaces disinfected.*

6. Is **all** necessary personal protective equipment (PPE) available? For BSL2: gloves, gowns, and face protection (goggles, mask, face shield, or other splatter guard)

- ☐ Yes
- ☐ No

7. Does lab policy require microbiology staff to wear close-toed shoes?

- ☐ Yes
- ☐ No

8. Is PPE utilized appropriately and consistently by laboratory staff? (Observe)

- ☐ Yes
- ☐ Partial
- ☐ No

Standard: *Management is responsible to provide appropriate personal protective equipment— gloves, lab coats, eye protection, shields, etc. — in useable condition. Laboratory staff must utilize personal protective equipment in the laboratory at all times. Protective clothing should not be worn outside the laboratory. Gloves should be replaced immediately when torn or contaminated and not washed for reuse*

AST Annex

Please note: all questions refer only to clinical patient specimens, NOT to research specimens

ESBL testing

1. Which cephalosporin breakpoints are in use at your lab? (ungraded)
   - ☐ CLSI M100, 2009 or earlier
   - ☐ CLSI M100, 2010 or later
   - ☐ EUCAST, 2008 or earlier
   - ☐ EUCAST, 2009 or later
   - ☐ Other _____

2. Which methods of ESBL **screening**, if any, are used in your lab?
   - ☐ Manual review of cephalosporin and/or aztreonam zone sizes/MIC results
   - ☐ Automated screen embedded in automated AST system cards/trays
   - ☐ None
   - ☐ Other _____

3. Which methods of ESBL **confirmatory testing**, if any, are used?
   - ☐ Combination disk test (zone of inhibition increase ≥5mm with addition of clavulanate to a cephalosporin)
   - ☐ Double-disk synergy test (augmented zone of inhibition between a cephalosporin disk and an amoxicillin-clavulanate disk)
   - ☐ Gradient test method
   - ☐ Broth microdilution
   - ☐ Molecular method (specify) _____
   - ☐ Other (specify)_____
   - ☐ NA - ESBL confirmatory testing is not performed in this lab (Skip to Q5)

4. Which of the following ATCC (or ATCC-derivative) reference strain(s) does the lab use to QC the antibiotics used for confirmatory ESBL testing?
   - ☐ *K. pneumoniae* 700603*
   - ☐ *E.coli* 25922*
   - ☐ Other _____
   - ☐ None of the above

5. When an ESBL is suspected or confirmed, does your lab change all “S” penicillin, cephalosporin, and aztreonam results to “R”?
   - ☐ Yes
   - ☐ No

6. When an ESBL is suspected or confirmed, is "ESBL" noted on the final report to the clinician?
   - ☐ Yes
   - ☐ No

7. When an ESBL is suspected or confirmed, is infection control notified by the lab?
   - ☐ Yes
   - ☐ No

8. Do you know the rate of ESBL + E.coli seen in your lab? (ungraded)
   - ☐ Yes, (please share)_____
   - ☐ No

9. Does your lab perform any phenotypic testing for production of AmpC? (ungraded)
   - ☐ Yes
   - ☐ No

Carbapenemase testing

The following questions apply to Enterobacteriaceae only

1. Which carbapenem breakpoints are in use at your lab? (ungraded)
   - ☐ CLSI, pre-2011
   - ☐ CLSI, 2011 or later
   - ☐ EUCAST

2. Which carbapenems are used for carbapenemase **screening** in your lab? (ungraded)
   - ☐ Meropenem
   - ☐ Ertapenem
   - ☐ Imipenem

3. Which methods of carbapenemase **confirmatory testing** are used? Check all that apply.
   - ☐ Combination disk test
   - ☐ Modified Hodge test
   - ☐ Carba NP
   - ☐ Modified Carbapenem Inactivation Method
   - ☐ Molecular method _____
   - ☐ Other _____
   - ☐ N/A – confirmatory testing is not done in this laboratory **(Skip to end)**

4. Which of the following reference strain(s) do you use to QC carbapenemase confirmatory tests?
   - ☐ *K. pneumoniae* BAA-1705
   - ☐ *K. pneumoniae* BAA-1706
   - ☐ *E.cloacae* CCUG 59627

- ☐ *K.pneumoniae* CCUG 58547
- ☐ *K.pneumoniae* NTCC 13440
- ☐ *E.coli* NCTC 13476
- ☐ *K.pneumoniae* CCUG 56233
- ☐ *K.pneumoniae* NCTC 13438
- ☐ *K.pneumoniae* NCTC 13442
- ☐ *K.pneumoniae* ATCC 25955
- ☐ Other _____
- ☐ None of the above

5. When a carbapenemase is suspected/confirmed, does your lab change all S carbapenem results to R?
   - ☐ Yes
   - ☐ No

6. When a carbapenemase is suspected or confirmed, is a supervisor notified?
   - ☐ Yes
   - ☐ No

7. When a carbapenemase is suspected or confirmed, is the isolate ever sent to another lab for confirmation?
   - ☐ Always
   - ☐ Sometimes
   - ☐ Never

8. When a carbapenemase is suspected or confirmed, is "CRE" or equivalent noted on the final report to the clinician?
   - ☐ Yes
   - ☐ No

9. When a carbapenemase is suspected or confirmed, is infection control notified by the lab?
   - ☐ Yes
   - ☐ No

10. Do you know the rate of CRE (carbapenem resistant enterobacteriaceae) seen in your lab?
    - ☐ Yes, it is calculated regularly (please write in _____)
    - ☐ We do not calculate it, but I would estimate it to be around _____
    - ☐ No

11. Do you know the rate of carbapenem resistant Acinetobacter seen in your lab?
    - ☐ Yes, it is calculated regularly (please write in _____)
    - ☐ We do not calculate it, but I would estimate it to be around _____
    - ☐ No

Neisseria gonorrhoeae Annex

If your lab does not routinely perform Neisseria gonorrhoeae cultures, please skip this section.

1. On average, approximately how many isolates of *Neisseria gonorrhoeae* are identified manually each month?
   - ☐ 0-4
   - ☐ 5-10
   - ☐ 11-50
   - ☐ >50

2. Which levels of *Neisseria gonorrhoeae* identification does this lab perform? (check all that apply)
   - ☐ Presumptive
   - ☐ Definitive/Confirmatory
   - ☐ Both

3. If your lab performs presumptive identification, is there an adequate SOP* describing the combination of tests required to make such an ID?
   - ☐ Yes
   - ☐ Partial
   - ☐ No

   An adequate SOP would address ALL of the following aspects:* A presumptive diagnosis of N. gonorrhoeae originally isolated on selective medium can be made based upon typical colonial morphology, the observation of typical (gram negative) diplococci in pairs, tetrads or clusters upon Gram stain or simple single stain with Loeffler's methylene blue, and a positive oxidase reaction. A presumptive diagnosis of N. gonorrhoeae originally isolated on non-selective medium can be made based upon these characteristics **plus an appropriate reaction in at least one supplemental biochemical or enzymatic test. (Refer to question 160 for examples of selective and non-selective media).

4. If your lab makes a presumptive identification using a non-selective medium, does the lab use and possess a separate SOP for at least one manual method/biochemical listed below? (Refer to question 160 for examples of selective vs non-selective media)

   If the reagent is not in use in your lab tick no for the first question and skip the remaining questions regarding SOPs for that item.

   If No SOP exists, tick no for second question and skip the remaining questions about SOPs

	Is this reagent in use in your lab?		**Does an SOP exist?**		**Is the SOP readily available* to bench staff?**	
	Yes	**No**	**Yes**	**No**	**Yes**	**No**
a. 30% H_2O_2						
b. Colistin disk for ID						
c. Nitrate reduction						
d. Chromogenic enzyme (e.g., Bacticard Neisseria, Gonocheck II, Neisstrip, etc.)						
e. Sugar fermentation method (CTA, etc.)						

*Readily available indicates that technologists can easily access the necessary SOP at or near the bench, either in electronic or paper form, and that the information sought is easily located within the SOP, not buried in a larger document, and is written in a language that all using the SOP can read fluently.

	Does the SOP define QC organisms, QC frequency, and expected QC results?			Does the SOP provide stepwise instructions for inoculation and incubation?			Does the SOP provide stepwise instructions for reading and interpretation?		
	Yes	**Partial**	**No**	**Yes**	**Partial**	**No**	**Yes**	**Partial**	**No**
a. 30% H_2O_2									
b. Colistin disk for ID									
c. Nitrate reduction									
d. Chromogenic enzyme (e.g., Bacticard Neisseria, Gonocheck II, Neisstrip, etc.)									
e. Sugar fermentation method (CTA, etc.)									

5. When AST is performed on *N. gonorrhoeae*, which of the following are <u>available</u> for testing in your lab?
    - ☐ Cefixime
    - ☐ Ceftriaxone
    - ☐ Azithromycin
    - ☐ Spectinomycin
    - ☐ Ciprofloxacin
    - ☐ Gentamicin
    - ☐ N/A – we do not do manual AST testing of *N. gonorrhoeae* **(skip to end)**

6. Indicate the average monthly number of *N. gonorrhoeae* ASTs performed at your lab.
    - ☐ >50
    - ☐ 11-49
    - ☐ 2-10
    - ☐ 0-1

7. Is a confirmatory (not presumptive) identification of the isolate made prior to AST?
    - ☐ Yes
    - ☐ No

8. What kinds of agar do you use for disk diffusion/antibiotic gradient AST of *N. gonorrhoeae*? Check all that apply
    - ☐ GC Base medium with 1% growth supplement
    - ☐ Other_____
    - ☐ N/A – we do not use these methods for this organism

9. In what atmosphere do you incubate the *N. gonorrhoeae* disk diffusion/antibiotic gradient plate?
    - ☐ 5% CO_2
    - ☐ Ambient air

10. At what point do you read the disk diffusion/antibiotic gradient results?
    - ☐ Between 16-18 hours of incubation
    - ☐ Between 20-24 hours of incubation
    - ☐ At 24 hours of incubation
    - ☐ Other (specify) _____

11. When testing by disk diffusion method, are all intermediate results retested by an MIC method?
    - ☐ Yes
    - ☐ No

12. Which reference strain does the lab use to QC Neisseria gonorrhoeae AST?
    - ☐ *N. gonorrhoeae* 49226
    - ☐ Other (specify) _____
    - ☐ None