Laboratory Assessment of Antibiotic Resistance Testing Capacity

User's Guide and Questionnaire

VERSION 2.0

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U.S. Centers for Disease Control and Prevention
Robert Redfield, MD, Director

National Center for Emerging and Zoonotic Infectious Diseases
Rima Khabbaz, MD, Director

Division of Healthcare Quality Promotion
Denise Cardo, MD, Director

Photo Credit: Daniella Coker
Cover page photo features (l-r) Dr. Hein Bui of CDC, Vietnam; Mr. Truong Nguyen, a healthcare informatics consultant in Vietnam; and Dr. Mai Van Tuan, a clinical microbiologist in Hue, Vietnam. They are examining a lidded and sealed non-infectious petri dish in an anteroom of a non-CDC laboratory in Vietnam.

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DISCLAIMERS

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ACRONYMS

Abbreviation	Term
AMR/AR	Antimicrobial Resistance
AST	Antibiotic Susceptibility Testing
ATCC	American Type Culture Collection
BMD	Broth microdilution
BSL	Biosafety Level
CAP	College of American Pathologists
CDC	U.S. Centers for Disease Control and Prevention (Atlanta)
CIP	Collection de l'Institut Pasteur
CLSI	Clinical & Laboratory Standards Institute
CRE	Carbapenem-Resistant Enterobacteriaceae
CSF	Cerebrospinal Fluid
CSV	Comma Separated Value
EQA	External Quality Assessment
ESBL	Extended-spectrum beta-lactamase
EUCAST	European Committee on Antimicrobial Susceptibility Testing
GHSA	Global Health Security Agenda
GLASS	Global Antimicrobial Resistance Surveillance System
GPS	Global Positioning System
HIS	Hospital Information System
ICR	Inducible Clindamycin Resistance
ID	Identification
ILAC	International Laboratory Accreditation Cooperation
IQLS	Integrated Quality Laboratory Services
ISO	International Standardization Organization
LAARC	Laboratory Assessment of Antimicrobial Resistance Testing Capacity
LIS	Laboratory Information System
LQSI	Laboratory Quality Stepwise Implementation
MALDI	Matrix Assisted Laser Desorption Ionization
MCIM	Modified carbapenem inactivation method
MIC	Minimal Inhibitory Concentration
MRSA	Methicillin-Resistant *Staphylococcus aureus*
NA	Not Applicable
NCTC	National Collection of Type Cultures
NLF	Non-Lactose Fermenting
NRL	National Reference/Referral Laboratory
PCR	Polymerase Chain Reaction
PPE	Personal Protective Equipment
PT	Proficiency Testing
QA	Quality Assurance
QC	Quality Control
QMS	Quality Management Systems
SLIPTA	Stepwise Laboratory Quality Improvement Process Towards Accreditation
SOP	Standard Operating Procedure

Abbreviation	Term
STD	Sexually Transmitted Disease
TB	Tuberculosis
VISA	Vancomycin-Intermediate *Staphylococcus aureus*
VRE	Vancomycin-Resistant *Enterococci*
VRSA	Vancomycin-Resistant *Staphylococcus aureus*
WHO	World Health Organization

EXECUTIVE SUMMARY

The Laboratory Assessment of Antibiotic Resistance Testing Capacity (LAARC) was designed for use in resource limited settings to:

- Evaluate the technical skill and expertise of clinical bacteriology laboratories
- Evaluate the quality management practices related to bacterial identification and antibiotic susceptibility testing (AST)
- Generate numerical indicators of quality and capacity in fifteen domains of laboratory practice
- Aid development of workplans for improvement
- Monitor the status of laboratory improvements over time

The specimen types, organisms and antibiotics addressed by the tool are based on the priorities set by WHO Global Antimicrobial Resistance Surveillance System (GLASS) in 2015.

Assessments using the LAARC require two full days to complete. Due to the technical nature of the questions, assessments must be carried out by bacteriologists with ample AST experience and strong familiarity with ***clinical*** bacteriology laboratory requirements and standards, which may differ from research, industrial, environmental or veterinary laboratory standards.

Questionnaire content is based on internationally accepted standards of clinical laboratory practice including:

- International Organization for Standardization (ISO)
- European Committee on Antimicrobial Susceptibility Testing (EUCAST)
- Clinical & Laboratory Standards Institute (CLSI)
- The World Health Organization (WHO)

The LAARC scoring tool is a Microsoft (MS) Excel® file. It does not contain macros, thus, it can be used on any computer and works independently from operating system type and language. The tool is currently available in English, French, Spanish, and Portuguese. Additional languages may be added to the translation table by the end-user, including non-Latin alphabets.

1. INTRODUCTION

Control of antibiotic resistance (AR) is a global public health priority. Strong AR laboratory networks are critical to inform policy and control efforts. Such networks often obtain AR data from clinical laboratories; thus, the usefulness of the aggregate data largely depends on the ability of the laboratories to produce accurate and reliable bacterial identification (ID) and antibiotic susceptibility testing (AST) results.

1.1 Rationale

Many existing laboratory assessment tools are designed to evaluate the quality management system (QMS) requirements described by international laboratory standards organizations (e.g., ISO and CLSI). These tools are inadequate to detect deficiencies in bench-level testing because they lack technical depth and granularity. The LAARC assessment tool is designed to fill that technical gap and is specifically adapted for laboratories in low- and middle- income countries which have not yet established comprehensive laboratory regulations and/or accreditation requirements. The tool contains extensive Quality Control (QC) and Quality Assurance (QA) questions, but it is primarily technical in nature and does not provide a comprehensive QMS assessment.

1.2 Purpose

The purpose of the LAARC is to objectively evaluate technical proficiency in the bacteriologic techniques and related quality processes that are required for accurate, reliable AR detection. Results

provide a clear pathway toward improvement. The LAARC was designed for use in hospital-based laboratories that receive and process clinical specimens for the purposes of routine patient care. National reference laboratories (NRLs) and other public health laboratories will benefit from the technical assessment, but may find certain sections, such as Specimen Collection, less relevant.

Other areas of importance to public health laboratories and institutions are **not** addressed by this tool, such as:

- Molecular testing capacity and other advanced techniques (PCR, sequencing, MALDI)
- Packaging, shipping, transport, receiving, and storage following testing
- Participation in laboratory-based surveillance systems (e.g., STDs, TB, enterics, vaccine escape, AR)
- Funding and budget
- Non-laboratory personnel: epidemiologists, data managers and analysts, administrative support staff
- Public health roles: Notifiable Diseases, Outbreak response, provider of EQA/PT

A survey[1] addressing several of these topics was developed by WHO and is publicly available for use in conjunction with the LAARC to comprehensively assess the AR capacity of NRLs. The LAARC does not assess the readiness of the national health system to implement AR surveillance. Multiple WHO tools[2,3,4,5] are available to assess national health systems.

1.3 Scope

The LAARC was built around the WHO priority AR specimen types, pathogens and antibiotics included in their Global Antimicrobial Resistance Surveillance System (GLASS) initiative of 2015; see Tables 1 and 2.

Table 1: GLASS priority specimens and pathogens for surveillance of AR

Priority Specimens	Priority pathogens for surveillance
Blood	*Escherichia coli* *Klebsiella pneumoniae* *Acinetobacter baumannii*[*] *Staphylococcus aureus* *Streptococcus pneumoniae* *Salmonella spp.*
Urine	*Escherichia coli* *Klebsiella pneumoniae*
Feces/Stool	*Salmonella spp.* *Shigella spp.*
Urethral and cervical swabs	*Neisseria gonorrhoeae*[†]

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

[†] *N. gonorrhoeae* was excluded from this tool due to the complexities involved with routine culture and recovery, identification and AST, and the existence of other surveillance networks and STD clinics dedicated exclusively to this pathogen.

[1] Laboratory Assessment Questionnaire for Antimicrobial Resistance Testing (https://extranet.who.int/dataform/549586?lang=en)

[2] WHO AR Surveillance Questionnaire for Assessment of National Networks [PDF - 24 pages] (https://www.who.int/antimicrobial-resistance/whocdscsrrmd20031.pdf)

[3] WHO Laboratory Assessment Tool / System Questionnaire [PDF - 42 pages] (https://www.who.int/ihr/publications/Annex1_LAT.pdf)

[4] WHO GLASS Implementation Questionnaire [PDF - 6 pages] (http://apps.who.int/iris/bitstream/10665/251558/1/WHO-DGO-AR-2016.10-eng.pdf)

[5] WHO GLASS Core Components Checklist [PDF - 35 pages] (https://apps.who.int/iris/bitstream/handle/10665/251552/WHO-DGO-AMR-2016.5-eng.pdf)

Table 2: GLASS priority pathogen-antimicrobial combinations for surveillance of AR by priority pathogen

The antibiotics listed below are important for AR surveillance purposes. However, they may not be first-line options for testing or for treatment and should not be interpreted as such.

Staphylococcus aureus

Antibacterial class	Antibacterial agents
Penicillinase-stable beta-lactams	Cefoxitin

Streptococcus pneumoniae

Antibacterial class	Antibacterial agents
Penicillins	Oxacillin (as a screen for Penicillin resistance) Penicillin G
Sulfonamides and Trimethoprim	Co-trimoxazole
Third-generation cephalosporins	Ceftriaxone or cefotaxime

Escherichia coli

Antibacterial class	Antibacterial agents
Penicillins	Ampicillin
Third-generation cephalosporins	Ceftriaxone *or* Cefotaxime + Ceftazidime
Fourth-generation cephalosporin	Cefepime
Carbapenems	Imipenem, Meropenem, Ertapenem, Doripenem
Fluoroquinolones	Ciprofloxacin *or* Levofloxacin
Sulfonamides and Trimethoprim	Co-trimoxazole
Polymyxins	Colistin

Klebsiella pneumoniae

Antibacterial class	Antibacterial agents
Penicillins	Ampicillin
Third-generation cephalosporins	Ceftriaxone *or* Cefotaxime + Ceftazidime
Fourth-generation cephalosporin	Cefepime
Carbapenems	Imipenem, Meropenem, Ertapenem, Doripenem
Fluoroquinolones	Ciprofloxacin or Levofloxacin
Sulfonamides and Trimethoprim	Co-trimoxazole
Polymyxins	Colistin

Acinetobacter baumannii

Antibacterial class	Antibacterial agents
Aminoglycosides	Gentamicin and Amikacin
Carbapenems	Imipenem, Meropenem, Doripenem
Tetracyclines	Tigecycline *or* Minocycline
Polymyxins	Colistin

Salmonella spp.

Antibacterial class	Antibacterial agents
Third-generation cephalosporins	Ceftriaxone *or* Cefotaxime + Ceftazidime
Carbapenems	Imipenem, Meropenem, Ertapenem, Doripenem
Fluoroquinolones	Ciprofloxacin *or* Levofloxacin

Shigella spp.

Antibacterial class	Antibacterial agents
Third-generation cephalosporins	Ceftriaxone *or* Cefotaxime + Ceftazidime
Fluoroquinolones	Ciprofloxacin *or* Levofloxacin
Macrolides	Azithromycin

Neisseria gonorrhoeae

Antibacterial class	Antibacterial agents
Aminocyclitols	Spectinomycin
Aminoglycosides	Gentamicin
Fluoroquinolones	Ciprofloxacin
Macrolide	Azithromycin
Third-generation cephalosporins	Cefixime and Ceftriaxone

Additional culture types, pathogens and antibiotics may be assessed pursuant to national priorities; however, the current iteration of this tool focuses only those listed in Tables 1 and 2. Users cannot edit or modify.

2. ASSESSMENT PLANNING and PREPARATION

2.1 Assessment Team

Due to the highly technical nature of the questions, assessments are most effective when carried out in conjunction with a clinical bacteriologist. This person should be well experienced in the full range of clinical bacteriology laboratory practices, from specimen collection to AST, and the standard quality practices associated with each step.

Ideally, all team members, including translators, would have a background in bacteriology laboratory practices and the general operations of hospitals and clinical laboratories. Preferably, assessors will also have previous experience with performing laboratory assessments. Persons with expertise that is primarily research-based or that is grounded in other areas of microbiology (e.g., parasitology, virology) are not ideal.

2.2 Team Preparation

Read the User's Guide in full and review all LAARC questions in advance to establish familiarity with the contents. Seek clarification if needed, decide how to allocate the work, and prepare a translation if necessary. The questionnaire is provided in both PDF (Appendix 3) and Excel formats. Print the PDF (approximately 70-80 pages depending on the language) for paper data collection and subsequent data entry into the Excel tool. Or, enter answers directly into the Excel tool during the assessment.

Allow two full days to complete each assessment. The assessment must be carried out during laboratory operating hours to observe staff at work. A sample agenda follows:

Table 3: Sample agenda

Day 1	Day 2
8:00 – 8:30 am • Introductions: Laboratory leadership, other laboratory staff, and the assessment team • Review purpose of the evaluation and expected timeline 8:30 – 9:30 am • Tour laboratory • Begin review of pre-assembled documents, begin filling tool 9:30 – 10:00 am • Break for tea 10:00 am – Noon • Continue filling assessment Noon– 1:00 pm • Break for lunch 1:00 – 4:30 pm • Continue filling assessment	7:30 – 09:30 am • Observe laboratory staff at the bench • Continue filling assessment 9:30 – 10:00 am • Break for tea 10:00 am – Noon • Continue filling assessment Noon – 1:00 pm • Break for lunch 1:00 – 2:30 pm • Complete assessment 2:30 – 3:30 pm • Summation/exit meeting with laboratory leadership, other relevant staff

Useful (but not required) items include:

- Digital camera: obtain permission before taking photos; avoid capturing patient identifiers
- GPS device: for GPS positioning (can also be performed using a smartphone application)
- Small infrared thermometer: to rapidly check temperatures of refrigerators, rooms, incubators
- Video projector: to share final results with the team, if a projector is not available at the facility

2.3 Laboratory Preparation

At least one week in advance of the assessment, share an agenda with the laboratory so that they know what to expect and can plan accordingly. Request that the laboratory preassemble key documents and manuals for review; doing so will save a significant amount of time during the actual assessment. There is a sample letter containing an agenda and a list of key documents in Appendix A; send this letter to the laboratory at least one week in advance of the assessment.

2.4 Assessment Process

2.4.1. Take GPS Location

GPS coordinates are not essential but may be useful, especially if performing multiple assessments throughout a country. Record GPS position in digital degrees, using a GPS device or a smartphone application. It is also possible to get latitude and longitude from Google Maps®, (*but not altitude)*:

1. Right-click the location on the map
2. Select "What's here?"
3. A card with latitude (first position) and longitude (second position) will display at the bottom
   - If using Maps in "Lite mode," you'll see a lightning bolt at the bottom and you won't be able to get the coordinates.
4. Record digital degrees to 5 decimals and the + or – sign, if present.
   - For example: latitude 41.40338, longitude -2.17403

2.4.2. Meet with staff

Meet briefly with facility and laboratory leadership and staff. Review the agenda and explain the assessment purpose, process, and expected outcome. Point out that this is not a "regulatory

inspection" intended to penalize the laboratory, but a way to discover areas for improvement and develop a workplan to achieve it. This meeting is also an opportunity to ask about the laboratory organizational structure, the population served, and any known management issues (staffing, procurement, equipment, financing, etc.).

2.4.3 Tour the laboratory

After the preliminary meeting, tour the laboratory in the direction described below. Following this "sample path" provides insight into the general workflow and is an opportunity to ask questions and observe general cleanliness, organization, and staff adherence to biosafety practices.

- Patient reception/sampling rooms (if the laboratory collects specimens)
- Specimen receiving area (observe specimen storage, data processes, generation of specimen ID)
- Specimen culture plating area (BSC, incubators, blood culture instruments, direct Gram stain preparation)
- Culture reading and workup area (Gram staining, benches, reagent refrigerators/freezers)
- ID/AST instruments
- Temporary storage and final disposal of culture plates
- Support rooms (e.g., media preparation room, autoclave room, stock room, glassware washroom, waste management areas)

2.4.4 Review Documents and Fill the Questionnaire

Upon completion of the tour, begin filling out the LAARC questionnaire. Direct questions to the laboratory manager, quality manager, and both senior and junior bench technologists.

Documentation is key. Confirm answers whenever possible by reviewing the supporting documentation. Many questions are intentionally designed to require confirmatory documentation. For example, the question "Do QC records ***demonstrate*** that XXX practice is in place?" demands that the assessor review the pertinent QC records to determine if they meet the defined criteria. This is a core tenant of quality systems. Without confirmatory documentation, the answer to the question must be "no," even if the laboratory claims that the practice is in place.

Partial credit. Some questions have "partial" responses available, but most are either "yes" or "no" for simplicity of scoring. It may be tempting to mark a question as "yes" when a laboratory partially meets the criteria, but if the criteria are not fully met and "partial" is not available, then the answer must be "no." Marking the response as "no" creates an opportunity for the laboratory to make the changes needed to become fully compliant. Marking it as "yes" eliminates this opportunity to improve, which is a disservice to the laboratory. Use the Comment boxes next to each question to add clarifying information.

Research specimens. Many laboratories have equipment, reagents and SOPs that are used for research specimens but are not used for routine patient specimens. The questions in the LAARC questionnaire refer **only** to the equipment, reagents and SOPs that are used with cultures submitted for clinical patient management in the routine course of care.

2.4.5 Professionalism

Establishing a good relationship with laboratory personnel is vital if recommendations are to be received well. Give recommendations and advice in a friendly and supportive manner. If there are findings that may be embarrassing or upsetting for the laboratory, discuss them in private with the laboratory manager and those in charge. Always obtain permission prior to taking photographs.

3. LAARC TOOL STRUCTURE

3.1 Files

The tool is a combination of three files:

- PDF file containing the User's Guide and the LAARC questionnaire for printing (available in each language: English, French, Spanish, Portuguese)
- Multilingual MS Excel tool for data entry and scoring
- (Optional) MS Excel "export reception" file to consolidate output from multiple assessments for further analysis by statistical software; available in English only

3.2 Excel File Organization

The MS Excel tool has 25 worksheets (or "tabs") organized into three groups: yellow, blue, and red.

- Yellow tabs contain introductory information
- Blue tabs contain the LAARC questionnaire
- Red tabs contain the assessment results
- Worksheet tabs are titled in English only

3.2.1 Yellow (5 tabs)

Cover | Introduction | Language | Registration | Assessor's Guide

- **Cover**: Cover page
- **Introduction**: Contextual information about the development and intended use of the tool.
- **Language**: Language table and mechanism for selecting desired language. New languages may be added to column F.
- **Registration**: Information about optional registration and link to registration webpage.
- **Assessor's guide**: Helpful reference materials required to answer specific assessment questions, including select CLSI and EUCAST breakpoint tables.

3.2.2 Blue: Questionnaire (15 tabs)

General 0 | Facility 1 | LIS 2 | Data Mgmt 3 | QA 4 | Media QC 5 | ID QC 6 | AST QC 7 | Specimen 8
Processing 9 | Identification 10 | Basic AST 11 | AST Expert rules 12 | AST Policy 13 | Safety

The LAARC questionnaire is organized into 15 modules; each module contains 3 to 10 indicators. Each indicator contains several closed questions.

Table 4: LAARC Questionnaire Modules

	Modules	# of Indicators	# of Questions
0	**General** Facility demographics, test menu and workload, staffing, accreditation	6	85
1	**Facility** Laboratory conditions, equipment availability, calibration and maintenance, temperature monitoring, autoclave and inventory management	9	135
2	**Laboratory Information System (LIS)** Detailed questions about data field configuration and connective capability of electronic data management systems	6	46

	Modules	# of Indicators	# of Questions
3	**Data management** Patient and specimen identification, request forms, culture and AST data reporting, data backup and sharing	7	73
4	**QA** QMS basics, staff competency assessments, troubleshooting mechanisms and EQA	4	45
5	**Media QC** Routine and specialized media preparation and QC, including Muller Hinton blood culture bottles and distilled water	6	63
6	**ID QC** Quality Control of bacterial identification systems, including Gram stain, manual biochemical methods, enteric serologies, commercial kits and automated identification systems	4	113
7	**AST QC** Quality Control of AST methods including reference strain maintenance, disc diffusion, gradient strips and automated systems	5	49
8	**Specimen** Collection and transport of blood, urine and stool specifically, plus general specimen management and rejection	5	59
9	**Processing** Plating and inoculation of blood cultures, urine cultures and stool cultures	4	30
10	**Identification** Quality of SOPs for conventional biochemical identification methods, kits and automated methods; identification flowcharts	10	185
11	**Basic AST** Maintenance of discs and strips, inoculum preparation, incubation, reading and interpreting results and breakpoints standards	6	66
12	**AST expert rules** Detailed questions to determine if CLSI and/or EUCAST breakpoints and AST expert rules for the priority pathogens are properly applied by the laboratory	10	107
13	**AST policy** Selection and application of routine antibiotic panels, cumulative antibiograms and stewardship	3	33
	Safety Biosafety equipment, safety behaviors, PPE and biosafety training and documentation	4	28
	Total	**89**	**1,117**

3.2.3 Questionnaire Organization and Structure

Module structure and components are described in the graphic and table below.

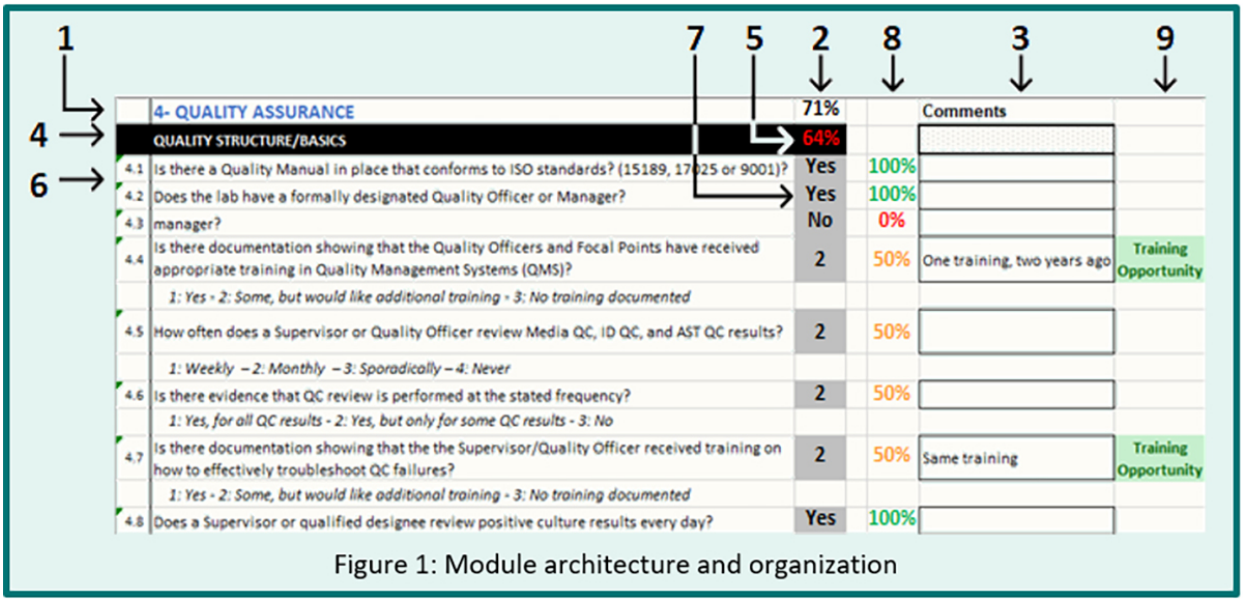


Figure 1: Module architecture and organization

Table 5: Description of Module Structure

Number	Description
1	**Module Name** – Module names are in blue; each module is numbered
2	**Module Score** – Module scores are blue; explained in section 5 of the User's Guide
3	**Comments** – Empty cells where you may enter free text comments for each question, if necessary
4	**Indicator Name** – Indicators have a black background with white letters
5	**Indicator Score** – Indicator scores are color coded; explained in section 5
6	**Question Numbers** – Leading number corresponds to the Module, the second is sequential
7	**Response Cells** – Grey cells contain drop-down boxes with the optional responses to each question
8	**Question Scores** – Question scores are color coded; explained in section 5
9	**Flags** – Responses to some questions generate "flags"; explained in section 5

3.2.4. Red (5 tabs)

- **Summary:** Summary of module and indicator scores, workload statistics, equipment summaries, summary of biochemical identification reagents; four pages when printed
- **Flags:** Summary of all "Flagged" questions and answers; five pages when printed
- **Conclusions:** Includes an embedded Microsoft Word document where the assessor may insert their conclusions in narrative form (recommended); number of pages depends on length of narrative
- **Photos:** Tab for inserting relevant photographs of the laboratory if desired (six positions); two pages
- **Export**: Compiles all scores and other select assessment data for optional export into GIS or statistical analysis software. English only. Must be used in conjunction with Export Reception file

4. ENTERING DATA INTO THE EXCEL TOOL

4.1 Generate a Unique Filename

Before entering any data, save the file using a new filename. This is particularly important when multiple laboratories are being assessed in order to keep the files distinct. Open the master file, click "File, Save As." Select an appropriate location to save the file and assign a new name. The recommended naming convention is: LAARC_[Name of Laboratory]_[Month & Year of assessment]. Example: "LAARC_CDC Hospital _March 2020.xls."

4.2 Select Language

The LAARC Excel file contains four language options: English, French, Spanish, and Portuguese. To select the desired language, go to the Language tab and click the drop-down menu in cell **A3**, then select the appropriate number:

- 1 = English
- 2 = French
- 3 = Spanish
- 4 = Portuguese

The entire tool will convert to your selected language, with two exceptions:

- The drop-down menus for responding to each question remain in English and cannot be translated into other languages.
- The tab labels will remain in English.

Users may add new language translations to column F of the Language tab. The tool will accept Chinese, Russian, or other left-to-right languages, but it is not well designed to accept Arabic or Persian languages.

4.3 Answer Questions

4.3.1 Drop-down boxes

Most of the data is entered using drop-down boxes. If you try to type a value into the drop-down box, an error message will appear.

A simple rule:
Fill in all the grey cells! Do not enter values in any other cells, except comment cells.

Click the response box, then click the small arrow at the right side of the cell to open a box containing the authorized values. The answers to most questions are limited to "yes," "no," or "NA" (not applicable). Select NA if the question doesn't apply to the laboratory.

For example, if the laboratory does not perform stool cultures, select NA for questions pertaining to stool cultures. **Note**: "NA" is not available for all questions, for some it is compulsory to select an answer. **In case of doubts about the appropriate answer, systematically select "no**".

Some questions have a numbered response system (see Figure 2). The corresponding response key is located below the question; keys are translated into all languages.

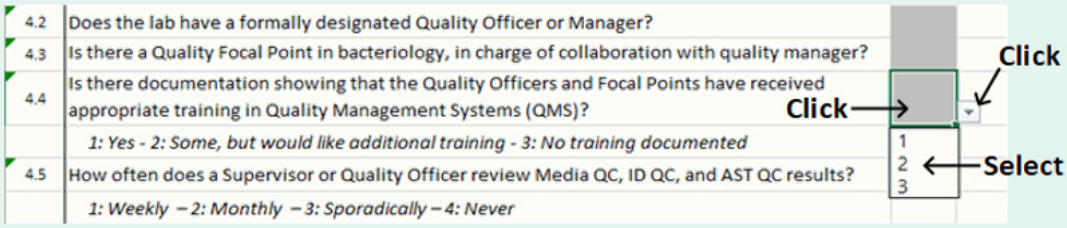


Figure 2: Numeric Responses

4.3.2 Fee-text cells and Comment cells

In the **0-General** module, many of the grey cells are free-text, meaning there is no drop-down box. Answers must be typed into these cells:

- Name of laboratory and key staff
- Assessor names and affiliations
- Number of equipment
- Number of tests performed daily
- Number of technicians

Comment boxes are found next to each indicator and question on all 15 blue modules. Transcribe notes taken during the assessment directly into a comment box, so they are not lost. See example below.

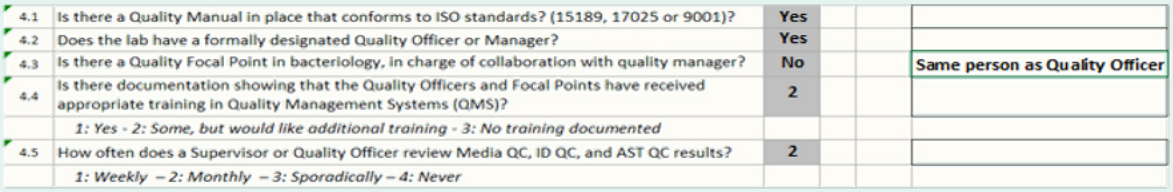


Figure 3: Example of a clarifying comment

4.3.3 Color Coding

As each question is answered, a score between 0% and 100% displays in column G. Scores are color coded as the following:

- Below 50%: Red
- Between 50 - 79%: Yellow
- 80% or more: Green

Unanswered questions and questions answered "NA" display an apostrophe in column G, indicating no score. Question scores are automatically averaged together to generate indicator scores, which follow the same color-coding scheme, and module scores, which are always blue.

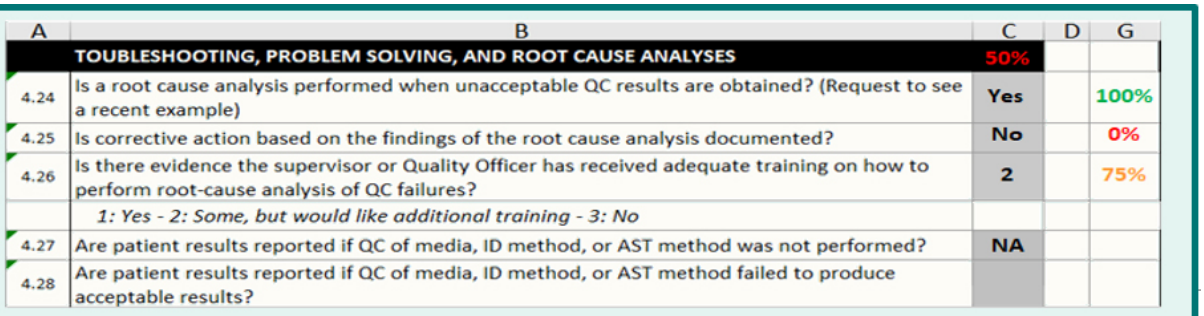


Figure 4: Color coding in the Module tabs

5 SCORING SYSTEM

Scoring occurs automatically as questions are answered, and scores display simultaneously on the Module tabs and on the Summary tab. Four levels of scores are generated: Questions -> Indicators -> Modules -> Overall. Indicator scores are an average of the question scores comprising that indicator. Module scores are calculated by averaging all questions in the module, not by averaging the indicator scores making up the module. The overall score is calculated by averaging the module scores.

Note: The overall score excludes the LIS Module score, since the laboratory is not directly responsible for deficiencies in the LIS.

5.1 Questions

Most questions have three possible answers: Yes, No, or NA (not applicable); some offer partial responses.

- "Correct" answers score 100%
- "Incorrect" answers score 0%
- Partial responses vary in value: 25%, 50%, 75%
- "NA" and unanswered questions have no value and are excluded from score calculations

5.2 Indicators and Modules

Indicator scores display as percentages. When an indicator displays "NA" instead of a percentage, it means none of the questions in that section were applicable to the laboratory being assessed. When an indicator displays "???", it means the questions within that section were left unanswered. Review the section and answer the questions if possible. Refer to Figure 5 for examples.

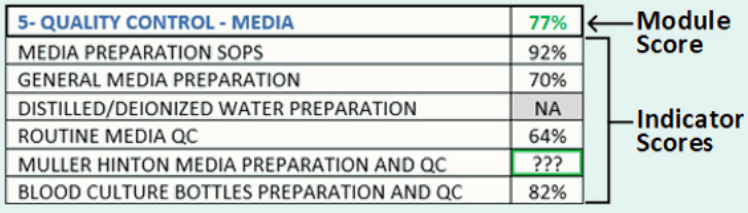


Figure 5: Summary tab showing Module and Indicator Score examples

The example in Figure 6, below, shows a portion of the Quality Assurance Module (blue lettering) and two of the module's indicators (black background).

	4- QUALITY ASSURANCE	77%		← Module Score
	QUALITY STRUCTURE/BASICS	68%		← Indicator Score
4.1	Is there a Quality Manual in place that conforms to ISO standards? (15189, 17025 or 9001)?	Yes		100%
4.2	Does the lab have a formally designated Quality Officer or Manager?	Yes		100%
4.3	Is there a Quality Focal Point in bacteriology, in charge of collaboration with quality	No		0%
4.4	Is there documentation showing that the Quality Officers and Focal Points have received appropriate training in Quality Management Systems (QMS)?	2		50%
	1: Yes - 2: Some, but would like additional training - 3: No training documented			
4.5	How often does a Supervisor or Quality Officer review Media QC, ID QC, and AST QC results?	2		50%
	1: Weekly – 2: Monthly – 3: Sporadically – 4: Never			
4.6	Is there evidence that QC review is performed at the stated frequency?	2		100%
	1: Yes, for all QC results - 2: Yes, but only for some QC results - 3: No			
4.7	Is there documentation showing that the the Supervisor/Quality Officer received training on how to effectively troubleshoot QC failures?	2		50%
	1: Yes - 2: Some, but would like additional training - 3: No training documented			
4.8	Does a Supervisor or qualified designee review positive culture results every day?	Yes		100%
4.9	Are there written guidelines stating who is permitted to modify erroneous lab results after they have been reported?	Yes		100%
4.10	Who is permitted to modify erroneous lab results?	1		100%
	1: Supervisors and/or persons with supervisory permission - 2: All microbiologists			
4.11	When corrections to patient results are made, what is done with the erroneous result?	2		0%
	1: Erroneous results remain in place but are amended to reflect that they are erroneous - 2: Erroneous results are deleted from the record - 3: Other(explain in comments)			
	LABORATORY STAFF EDUCATION/TRAINING/COMPETENCY	100%		← Indicator Score
4.12	Does at least 50% of the technical staff possess formal education in microbiology or medical laboratory science? (Refer to the figure in column D)	Yes	67%	100%
4.13	Is the lab sufficiently staffed to provide high quality services? (Including support staff.)	Yes		100%
4.14	Does the lab have a standardized process for training new employees?	Yes		100%
4.15	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	Yes		100%
	Do records demonstrate that lab staff receive annual competency assessments for each of the following? (Review competency records, select N/A if not on lab's test menu)			
4.16	Blood culture	NA		

Question Scores

Question Scores

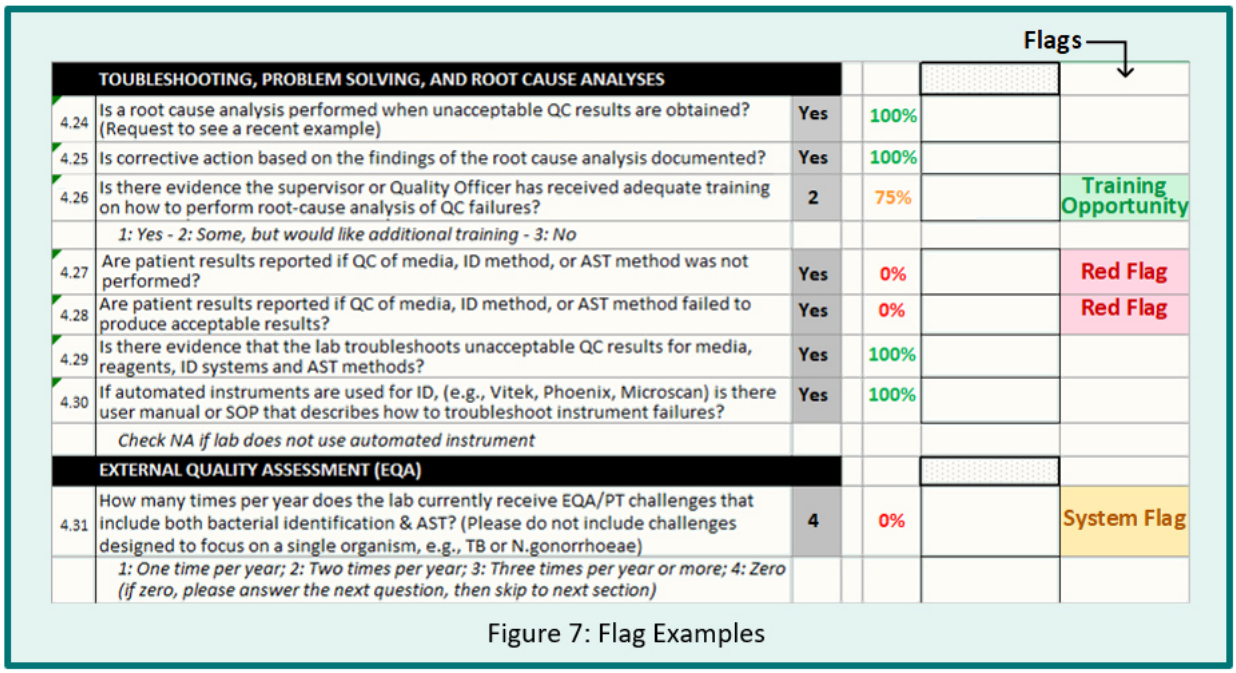
Figure 6: Question, Indicator, and Module Scores

The first indicator score is the average of questions 4.1 – 4.11, which is 68% (750/11). The second indicator score is the average of questions 4.12 – 4.16, which is 100% (400/4). Note that the answer to question 4.16 is NA, so the question is excluded from the denominator of the calculation. The module score is **not** the average of the two indicator scores, which would be 84% (100+68/2). The module score is the average of all questions, 4.1 – 4.16, excluding NA responses, which is 77% (1150/15). The rationale for this method of calculation is that it gives equivalent weight to each question and does not assign greater importance to any indicator.

5.3 Flags

Some questions generate "flags" that appear next to the score. Flags do not impact the score, but they are useful for prioritizing corrective actions.

- **Red Flags** represent practices that may put patients or laboratory staff at risk. The laboratory should correct these items immediately. There are 101 possible red flags
- **Training Opportunity Flags** highlight areas where sufficient training is commonly lacking. There are 10 possible training opportunities
- **System Flags** highlight problems for which the solution is often found at the level of the hospital or national system. Laboratory leadership may need to reach out to hospital, regional, or national leadership for assistance with correcting these issues. There are 24 possible System Flags



					Flags
	TOUBLESHOOTING, PROBLEM SOLVING, AND ROOT CAUSE ANALYSES				
4.24	Is a root cause analysis performed when unacceptable QC results are obtained? (Request to see a recent example)	Yes	100%		
4.25	Is corrective action based on the findings of the root cause analysis documented?	Yes	100%		
4.26	Is there evidence the supervisor or Quality Officer has received adequate training on how to perform root-cause analysis of QC failures?	2	75%		Training Opportunity
	1: Yes - 2: Some, but would like additional training - 3: No				
4.27	Are patient results reported if QC of media, ID method, or AST method was not performed?	Yes	0%		Red Flag
4.28	Are patient results reported if QC of media, ID method, or AST method failed to produce acceptable results?	Yes	0%		Red Flag
4.29	Is there evidence that the lab troubleshoots unacceptable QC results for media, reagents, ID systems and AST methods?	Yes	100%		
4.30	If automated instruments are used for ID, (e.g., Vitek, Phoenix, Microscan) is there user manual or SOP that describes how to troubleshoot instrument failures?	Yes	100%		
	Check NA if lab does not use automated instrument				
	EXTERNAL QUALITY ASSESSMENT (EQA)				
4.31	How many times per year does the lab currently receive EQA/PT challenges that include both bacterial identification & AST? (Please do not include challenges designed to focus on a single organism, e.g., TB or N.gonorrhoeae)	4	0%		System Flag
	1: One time per year; 2: Two times per year; 3: Three times per year or more; 4: Zero (if zero, please answer the next question, then skip to next section)				

Figure 7: Flag Examples

6. RESULTS: SUMMARY, FLAGS, CONCLUSION and PHOTOS

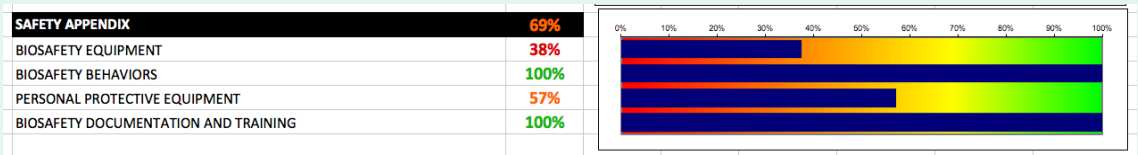
These four tabs summarize the results of the evaluation.

6.1 Summary tab

The Summary tab includes eight parts, four pages when printed:

- Laboratory Identification and Date of Assessment
- Test Menus and Annual Workload data
- Staffing Level
- Module Score Summary and Number of Flags
- Indicator Score Summary
- QC & SOP Scores for Biochemical Identification Reagents
- Equipment Availability Summary
- QMS Mentoring and Laboratory Accreditation Summary

Scores for each Module and Indicator are summarized and displayed in a heat map, shown in Figure 8.



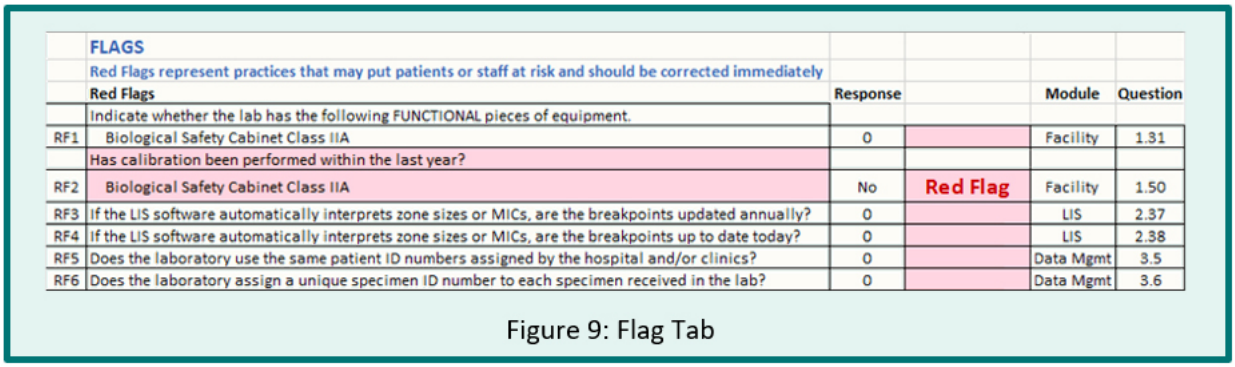
SAFETY APPENDIX	**69%**
BIOSAFETY EQUIPMENT	38%
BIOSAFETY BEHAVIORS	100%
PERSONAL PROTECTIVE EQUIPMENT	57%
BIOSAFETY DOCUMENTATION AND TRAINING	100%

Figure 8: Color coded heat map for the Module: Safety Appendix and its four Indicators

6.2 Flag tab

The Flag tab populates after the questionnaire is completed. This tab will:

- Display all potential flags and the laboratory's response to each
- Highlight all flags generated
- Show where the flagged questions are located within the tool



	FLAGS				
	Red Flags represent practices that may put patients or staff at risk and should be corrected immediately				
	Red Flags	**Response**		**Module**	**Question**
	Indicate whether the lab has the following FUNCTIONAL pieces of equipment.				
RF1	Biological Safety Cabinet Class IIA	0		Facility	1.31
	Has calibration been performed within the last year?				
RF2	Biological Safety Cabinet Class IIA	No	Red Flag	Facility	1.50
RF3	If the LIS software automatically interprets zone sizes or MICs, are the breakpoints updated annually?	0		LIS	2.37
RF4	If the LIS software automatically interprets zone sizes or MICs, are the breakpoints up to date today?	0		LIS	2.38
RF5	Does the laboratory use the same patient ID numbers assigned by the hospital and/or clinics?	0		Data Mgmt	3.5
RF6	Does the laboratory assign a unique specimen ID number to each specimen received in the lab?	0		Data Mgmt	3.6

Figure 9: Flag Tab

6.3 Conclusion tab

The conclusion tab contains an embedded Microsoft Word file where the assessor may summarize their main findings and recommendations in a narrative format. Embedding the Microsoft Word document within the Excel file allows the narrative findings and calculated scores to always remain together in a single file. Double click on the document and a Microsoft Word file will open, which can be saved or printed. To exit the Word document, click anywhere in the Excel grid.

6.4 Photograph tab

Insert up to six photographs (less than 500KB each) here, allowing all materials to exist together in a single file.

1. Click on Insert at the top of the page
2. Click Illustrations
3. Click Pictures
4. Select a file from your computer

Note: Inserting large photos will make the file difficult to share by email.

Before inserting, resize photos to less than 500KB/2MP (size "Medium") to keep the final Excel file small.

Always ask permission before photographing anything, particularly individuals. If photographing laboratory documents, obscure any personally identifying information (PII). Example: covering patient names with a piece of paper.

7. INTERPRETING RESULTS and DEVELOPING A WORK PLAN

Some general recommendations follow for interpreting the LAARC findings and developing an improvement plan for the laboratory.

1. **Review the data**
   Review the Summary and Flag tabs in detail with the laboratory staff. Check for errors and make any necessary corrections before sharing with a wider audience.

2. **Develop a work plan**
   Work plans are at the discretion of the assessor. These are brief suggestions for how to approach a workplan:
   - Develop lists of needed equipment, reagents, supplies, and service contracts
   - Prioritize correction of Red Flags, since these highlight practices that may put patients or staff at risk. If rapid correction is not possible due to lack of funding, the immediate action should be to request the necessary funding from hospital administrators or others as appropriate.
   - Use Training Flags to request specific training for staff

- Use System Flags to request high-level meetings with administrators to discuss remediation
- Review all questions to identify corrections that can be made immediately and/or with very few resources. This may include developing or updating SOPs, QC forms or job aids, implementing temperature monitoring
- Review module and indicator scores to prioritize areas for improvement. Note that the areas with the lowest scores may *not* be the most urgent for correction
- Develop a timeline for improvements based on resources available and resources needed

3. **Summarize findings**
   Use the Word document in the Conclusions tab to write brief narrative summaries of the findings in each module, noting both strengths and weaknesses.

4. **Explain findings and recommendations**
   Use a video projector, if possible, to display the results on a large screen or a blank wall. This will enable more people to attend and view the results.

5. **Leave paper and electronic copies of the file with the laboratory**
   We recommend leaving an electronic copy of the Excel file with relevant members of the laboratory leadership team so that they can revisit each question as a basis for laboratory improvement. They can also use it to monitor improvements over time by changing the answers as deficiencies are corrected.

8. EXPORTING DATA

In some cases, it may be useful to compile data from multiple laboratory assessments for comparison purposes. For example, comparing assessment results from multiple laboratories to one another, or comparing the results of one laboratory to itself over time. For this purpose, there is an Export tab embedded in the file. This tab captures all data from the General, Summary and Flag tabs, as well as answers to select questions from many of the Module tabs. Data from the Export tab may be copied and pasted into another Microsoft Excel spreadsheet that has been developed for this purpose called the "Reception file." Data from the reception file may then be exported into analysis software.

Directions for copying and pasting into the Reception file are as follows:

1. Open both the LAARC Data file and the LAARC Data Reception file.
2. In the LAARC Data file, make sure all questions are answered. Unanswered questions will display as zeros in the export.
3. Go to the Export tab.
   - Select row 6 entirely by clicking on the number "6" at the left edge of the table
   - Copy the selected data to the clipboard
   - Go to the Export Reception file and select row number 8 entirely by clicking on the number "8" at the left edge of the table. Row 8 should be blank
   - Select "Paste Special," then click "Values"
   - **NOTE:** A "regular/simple" paste will **not** allow you to export the data correctly, you must "paste special" as described above
4. Repeat steps 1-3 for each laboratory using the same Data Reception file. Each additional line of data will be pasted on the next available blank line: 9, then 10, etc.
5. Once complete, save the Export Reception file

6. Save the file a second time, this time as a .csv (comma separated value)
   - Go to "File" select "Save as"
   - Keep the same file name, but in "File type," select "CSV" (Comma Separated value" (*.csv)" in the drop-down list
7. Save the file

The .csv file can be opened by any database or GIS software. If you have shapefiles of the country or region, you'll be able to graphically represent indicators and data on maps. The figure below displays examples of GIS mapping of equipment and sample volumes from another assessment tool (not LAARC).

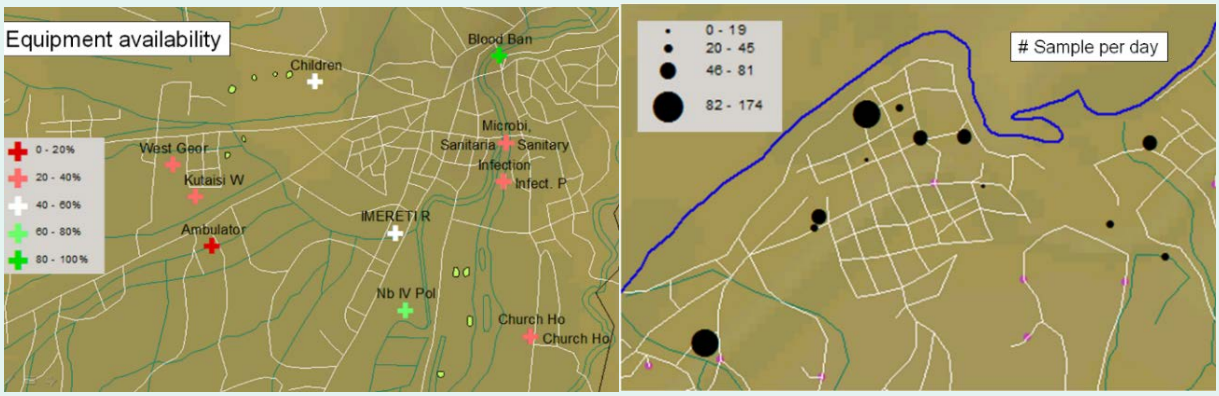


Figure 10 : Geographical representation of indicators

9. REFERENCES

1. Clinical & Laboratory Standards Institute (CLSI). *Performance Standards for Antimicrobial Susceptibility Testing.* 30th ed. CLSI supplement M100. Clinical & Laboratory Standards Institute, 950 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2020.
2. College of American Pathologists Laboratory Accreditation Program Checklists. Laboratory General Checklist and Microbiology Checklist. Northfield, Illinois, College of American Pathologists, 2017.
3. The European Committee on Antimicrobial Susceptibility Testing (https://eucast.org/). Breakpoint tables for interpretation of MICs and zone diameters. Version 10.0, 2020.
4. ISO 15189:2012. Medical laboratories – Particular requirements for quality and competence. International Standardization Organization. 2012.
5. Laboratory Assessment Tool. World Health Organization. 2012.
6. Laboratory Checklist. American Society for Microbiology. 2013.

Appendix 1: Sample Letter

Dear Sir/Madam,

The Ministry of Health of [COUNTRY] is developing a surveillance system for antimicrobial resistance (AR) of priority bacterial pathogens. [LABORATORY NAME] may serve as a sentinel site for the surveillance system. As such, an evaluation of the baseline capacity of the laboratory to perform basic bacteriology including isolation, identification and antibiotic susceptibility testing (AST) has been proposed. The evaluation will be carried out using the Laboratory Assessment of AR Testing Capacity (LAARC) developed by the International Infection Control Program at the U.S. Centers for Disease Control and Prevention. The purpose of the evaluation is to identify gaps in capacity and aid in development of plans for improvement prior to initiating surveillance.

The laboratory assessment may take up to two full days to complete. A proposed schedule is included below:

Day 1	Day 2
8:00 – 8:30 am • Introductions: Laboratory leadership and other laboratory staff, assessment team • Review purpose of the evaluation, and expected timeline 8:30 – 9:30 am • Tour laboratory 9:30 – 10:00 am • Break for tea 10:00 – Noon • Review pre-assembled documents and begin filling questionnaire Noon – 1:00 pm • Break for lunch 1:00 – 4:30 pm • Continue filling questionnaire • Evening – transfer paper responses into Excel tool	7:30 – 9:30 am • Observe laboratory staff at the bench • Continue filling assessment 9:30 – 10:00 am • Break for tea 10:00 – Noon • Continue filling assessment Noon – 1:00 pm • Break for lunch 1:00 – 2:30 pm • Complete assessment 2:30 – 3:30 pm • Summation/exit meeting with laboratory leadership, other relevant staff

The assessment will be carried out by an experienced clinical bacteriologist, [NAME, TITLE, AND AFFILIATION OF ASSESSOR if available], a representative from the Ministry of Health, and [ANY ADDITIONAL PERSONNEL].

We will perform the assessment during regular business hours, on days when staffing levels will be adequate to permit the assessors to interact with the bacteriology technologists without disrupting their workflow. We request that Bacteriology section heads, supervisors, and quality managers are present during the assessment and that their schedules are clear of meetings or other obligations to the extent possible.

The following documents and information will require review by the assessors. To the extent these can be assembled in advance into a single clean room for the team, the time required for the evaluation will be greatly reduced:

- Names, job titles, and email addresses of relevant bacteriology laboratory leadership (e.g., Director, Manager, Supervisor, Section Head, Quality Officer, etc.)
- Copies of any recent assessments by a third party
- Annual test volume for each specimen type

- Records of staff qualifications, training and experience
- Accreditation and/or Certification documents
- Equipment inventory
- Equipment calibration and maintenance records
- Contingency plans in the event of an emergency or extended downtime
- Specimen requisition form
- Bacteriology logbooks or Laboratory Information System records
- Standard form used for reporting ID/AST results to clinicians
- Quality Manual
- Records of the last three AST EQA/PT performance results, and associated discrepancy investigations
- Quality Control records for temperatures, media, reagents, and AST
- Specimen collection guidelines or SOPs
- SOPs for specimen processing, reagents, ID and AST test systems
- Copies of any recent safety audits
- Reserve a room with a video projector, if possible, for the final summation meeting

All findings and recommendations shall be discussed with the bacteriology supervisor in private prior to the final summation. Please reach out to [Assessment Team Lead] with any questions.

The following dates have been proposed [dd/mm/yyyy – dd/mm/yyyy]. Please contact [Ministry Official] to accept or reschedule your assessment dates.

Sincerely,

[Assessment Team Lead]

Appendix 2: Recommended Resources

The following documents are useful resources for clinical bacteriology laboratories. Many are free, others may be obtained for a fee.

Culture and Identification

- CLSI M35: Abbreviated Identification of Bacteria and Yeast
- CLSI M47: Principles and Procedures for Blood Cultures
- CLSI M54: Principles and Procedures for Detection of Fungi in Clinical Specimens-Direct Examination and Culture
- CLSI M56: Principles and Procedures for Detection of Anaerobes in Clinical Specimens
- CLSI M58: Methods for the ID of Cultured Microorganisms using MALDI-TOF Mass Spectrometry

AST/AMR

- CLSI M02: Performance Standards for Antimicrobial Disk Susceptibility Tests
- CLSI M02QG: Disk Diffusion Reading Guide
- CLSI M07: Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically
- CLSI M39: Analysis and Presentation of Cumulative Antimicrobial Susceptibility Test Data
- CLSI M45: Methods for Antimicrobial Dilution and Disk Susceptibility Testing of Infrequently Isolated or Fastidious Bacteria
- CLSI M100 Performance Standards for Antimicrobial Susceptibility Testing
- ETEST Reading Guide [PDF - 2 pages] (http://www.ilexmedical.com/files/ETEST_RG.pdf)
- EUCAST Breakpoint Tables
- EUCAST Disk Test Reading Guide
- EUCAST reading guide for broth microdilution
- EUCAST Manual Disk Test
- EUCAST Preparation of agar plates and broth for EUCAST AST
- EUCAST Intrinsic Resistance and Unusual Phenotypes
- EUCAST Expert Rules for Enterobacterales, Staphylococcus, and other species (http://www.eucast.org/expert_rules_and_intrinsic_resistance/)
- EUCAST guidelines for detection of resistance mechanisms and specific resistances of clinical and/or epidemiological importance

Quality Control

- CLSI M22: Quality Control for Commercially Prepared Microbiological Culture Media
- CLSI M40: Quality Control of Microbiological Transport Systems
- CLSI M50: Quality Control for Commercial Microbial Identification Systems
- CLSI M52: Verification of Commercial Microbial ID and AST Systems
- EUCAST QC tables

Laboratory Quality Management Systems (QMS)

- WHO Laboratory Quality Stepwise Implementation Tool
- CLSI QMS01: A QMS Model for Laboratory Services
- CLSI QMS01CL: Gap Analysis Checklists
- CLSI QMS02: QMS: Development and Management of Laboratory Documents
- CLSI QMS03: Training and Competence Assessment
- CLSI QMS04: Laboratory Design
- CLSI QMS05: QMS: Qualifying, Selecting and Evaluating a Referral Laboratory

- CLSI QMS06: QMS: Continual Improvement
- CLSI QMS11: Nonconforming Event Management
- CLSI QMS12: Developing and Using Quality Indicators for Laboratory Improvement
- CLSI QMS13: QMS: Equipment
- CLSI QMS14: QMS: Leadership and Management Roles and Responsibilities
- CLSI QMS15: Assessments: Laboratory Internal Audit Program
- CLSI QMS16: Laboratory Personnel Management
- CLSI QMS17: External Assessments, Audits, and Inspections of the Laboratory
- CLSI QMS18: Process Management
- CLSI QMS20: Understanding the Cost of Quality in the Laboratory
- CLSI QMS21: Purchasing and Inventory Management
- CLSI QMS22: Management of Paper-Based and Electronic Laboratory Information
- CLSI QMS23: General Laboratory Equipment Performance Qualification, Use, and Maintenance
- CLSI QMS24: Using Proficiency Testing and Alternative Assessment to Improve Medical Laboratory Quality
- CLSI QMS25: Handbook for Developing a Laboratory Quality Manual

Laboratory Biosafety

- WHO Laboratory Biosafety Manual (https://www.who.int/csr/resources/publications/biosafety/WHO_CDS_CSR_LYO_2004_11/en/)
- CLSI M29: Protection of Laboratory Workers from Occupationally Acquired Infections
- CLSI GP05: Clinical Laboratory Waste Management
- CLSI GP17: Clinical Laboratory Safety
- CDC Biosafety in Microbiological and Biomedical Laboratories (BMBL) (https://www.cdc.gov/labs/BMBL.html)

Appendix 3: LAARC Questionnaire

Table of Contents

Introduction

Control of antibiotic resistance (AR) is a global public health priority. Robust AR laboratory networks are critical to inform policy and control efforts. Such networks often obtain AR data from clinical laboratories; thus, the usefulness of the aggregate data largely depends on the ability of the laboratories to produce accurate and reliable bacterial identification (ID) and antibiotic susceptibility testing (AST) results.

Many existing laboratory assessment tools are designed to evaluate the essential quality management system (QMS) requirements described by international laboratory standards organizations such as ISO and CLSI. These tools are inadequate to detect deficiencies in bench-level testing because they lack sufficient technical depth and granularity. The LAARC assessment tool is designed to fill that technical gap and is specifically adapted for laboratories in low- and middle- income countries which have not yet established comprehensive laboratory regulations and/or accreditation requirements. The tool contains extensive Quality Control (QC) and Quality Assurance (QA) questions, but it is primarily technical in nature and does not provide a comprehensive QMS assessment.

The purpose of the LAARC is to objectively evaluate technical proficiency in the bacteriologic techniques and related quality processes that are required for accurate, reliable AR detection. Results provide a clear pathway toward improvement. The LAARC was designed for use in hospital-based laboratories that receive and process clinical specimens for the purposes of routine patient care. National reference laboratories (NRLs) and other public health labs will benefit from the technical assessment, however, the key gaps in assessing NRL capacity include the lack of questions about molecular testing, funding and budget, the non-laboratory personnel required to administer an AMR surveillance program and much more. Other tools are available to assess these areas.

The LAARC was built around the WHO priority AR specimen types, pathogens and antibiotics included in their Global Antimicrobial Resistance Surveillance System (GLASS) initiative of 2015. These are:

- *Staphylococcus aureus* Blood
- *Streptococcus pneumoniae* Blood
- *Escherichia coli* Blood & Urine
- *Klebsiella pneumoniae* Blood & Urine
- *Salmonella species* Stool/Feces
- *Shigella species* Stool/Feces
- *Acinetobacter baumannii*[*] Blood
- *Neisseria gonorrhoeae*[†] Urethral & cervical swabs

Additional culture types, pathogens and antibiotics may be evaluated pursuant to national priorities; however, the current iteration of this tool focuses only on the above; users cannot edit or modify the tool.

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

† *N. gonorrhoeae* was excluded from this tool due to the complexities involved with routine culture and recovery, identification and AST, and the existence of other surveillance networks and STD clinics dedicated exclusively to this pathogen.

Assessor's Guide

Figure for use with Facility Module, question 1.13

McFarland QC Standards in front of a Wickerham card

Figure 2 for use with AST QC Module, questions 7.7 - 7.11

Workflow for subculturing and using reference strains as described in CLSI M02, Subchapter 4.4

Figure 2: Proper maintenance of ATTC stock cultures

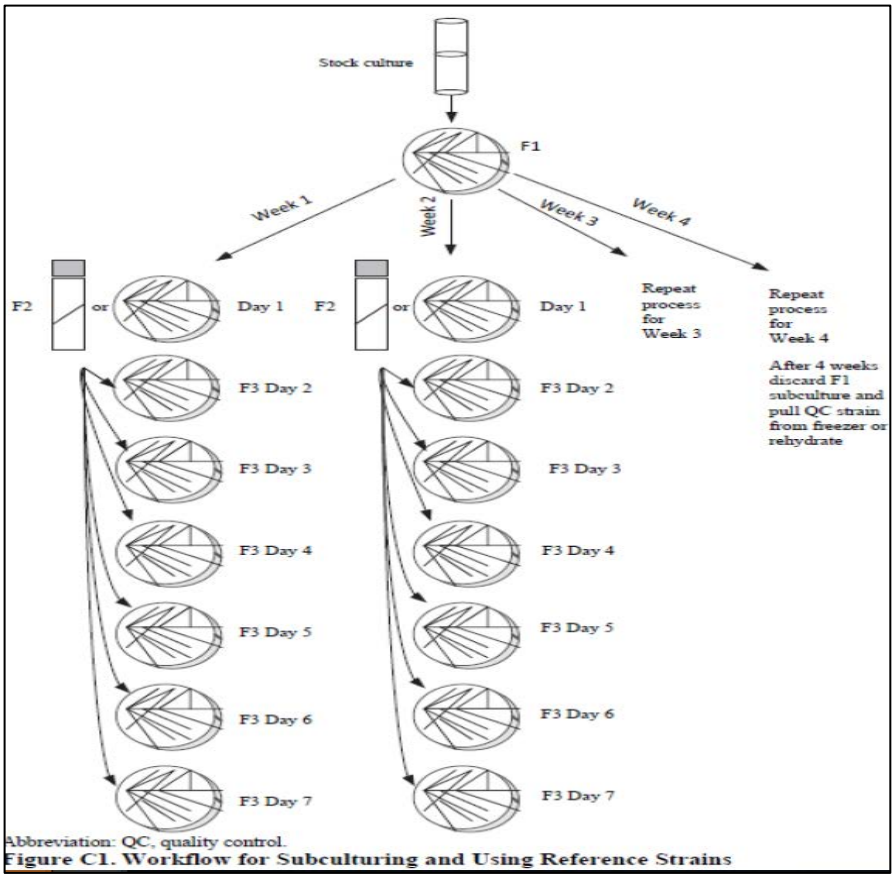


Figure 2 Abbreviations:

"F" indicates the frozen or freeze-dried state of the stock culture

"1" indicates the first passage

"2" indicates the second passage

"3" indicates the third passage from stock culture

"QC" indicates Quality Control

Maintenance of ATCC strains begins with a subculture from the frozen or lyophilized stock to the F1 plate. The F1 plate is then stored for one month.

On day 1, F1 is subcultured to the F2 plate. The F2 plate is stored and used for one week. Each day that a fresh isolate is required, a subculture is made from the F2 plate to an F3 plate. F3 plates are discarded after each use. After one week of storage, the F2 plate is discarded and a new F2 plate is subcultured from the F1 plate. This process repeats for four weeks. After four weeks, the F1 plate is discarded and a fresh F1 plate is subcultured from the frozen or lyophilized stock.

Tables for use with AST Expert Rules Module, questions 12.7 - 12.25

Current CLSI and EUCAST breakpoints for *Salmonella* spp, Enterobacteriaceae, *Acinetobacter* spp, and *Pseudomonas* aeruginosa

S-DD = Susceptible, but dose-dependent

CLSI 2020 breakpoints for *Salmonella* spp

Salmonella spp.	Disk µg	MIC method S	MIC method I	MIC method R	Disk Diffusion S	Disk Diffusion I	Disk Diffusion R
Ciprofloxacin	5	≤0.06	0.12-0.5	≥1	≥31	21-30	≤20
Levofloxacin	-	≤0.12	0.25-1	≥2	-	-	-
Pefloxacin screen	5				≥24	-	≤23

EUCAST 2020 breakpoints for *Salmonella* spp

Salmonella spp.	Disk µg	MIC method S	MIC method R	Disk Diffusion S	Disk Diffusion R
Ciprofloxacin	-	≤0.06	>0.06	-	-
Levofloxacin	-	-	-	-	-
Pefloxacin screen	5	-	-	≥24	<24

CLSI 2020 breakpoints for Enterobacterales

Enterobacterales	Disk µg	MIC method S	MIC method I / S-DD	MIC method R	Disk Diffusion S	Disk Diffusion I / S-DD	Disk Diffusion R
Aztreonam	30	≤4	8	≥16	≥21	18-20	≤17
Cefotaxime	30	≤1	2	≥4	≥26	23-25	≤22
Ceftriaxone	30	≤1	2	≥4	≥23	20-22	≤19
Ceftazidime	30	≤4	8	≥16	≥21	18-20	≤17
Cefepime	30	≤2	4-8 (S-DD)	≥16	≥25	19-24 (S-DD)	≤18
Imipenem	10	≤1	2	≥4	≥23	20-22	≤19
Meropenem	10	≤1	2	≥4	≥23	20-22	≤19
Doripenem	10	≤1	2	≥4	≥23	20-22	≤19
Ertapenem	10	≤0.5	1	≥2	≥22	19-21	≤18

EUCAST 2020 breakpoints for Enterobacterales

Enterobacterales	Disk µg	MIC method S	MIC method R	Disk Diffusion S	Disk Diffusion R
Aztreonam	30	≤1	>4	≥26	<21
Cefotaxime	5	≤1	>2	≥20	<17
Ceftriaxone	30	≤1	>2	≥25	<22
Ceftazidime	10	≤1	>4	≥22	<19
Cefepime	30	≤1	>4	≥27	<24
Imipenem	10	≤2	>4	≥22	<17
Meropenem	10	≤2	>8	≥22	<16
Doripenem	-	-	-	-	-
Ertapenem	10	≤0.5	>0.5	≥25	<25

CLSI 2020 breakpoints for *Acinetobacter* spp.

Acinetobacter spp.	Disk µg	MIC method S	MIC method I	MIC method R	Disk Diffusion S	Disk Diffusion I	Disk Diffusion R
Imipenem	10	≤2	4	≥8	≥22	19-21	≤18
Meropenem	10	≤2	4	≥8	≥18	15-17	≤14
Doripenem	10	≤2	4	≥8	≥18	15-17	≤14

EUCAST 2020 breakpoints for *Acinetobacter* spp.

Acinetobacter spp.	Disk µg	MIC method S	MIC method R	Disk Diffusion S	Disk Diffusion R
Imipenem	10	≤2	>4	≥24	<21
Meropenem	10	≤2	>8	≥21	<15
Doripenem	-	-	-	-	-

CLSI 2020 breakpoints for *Pseudomonas aeruginosa*

Pseudomonas aeruginosa	Disk µg	MIC method S	MIC method I	MIC method R	Disk Diffusion S	Disk Diffusion I	Disk Diffusion R
Aztreonam	30	≤8	16	≥32	≥22	16-21	≤15
Piperacillin	100	≤16	32-64	≥128	≥21	15-20	≤14
Piperacillin-Tazobactam	100/10	≤16	32-64	≥128	≥21	15-20	≤14
Cefepime	30	<8	16	>32	>18	15-17	<14
Imipenem	10	<2	4	>8	>19	16-18	<15
Meropenem	10	<2	4	>8	>19	16-18	<15
Doripenem	10	<2	4	>8	>19	16-18	<15

EUCAST 2019 breakpoints for *Pseudomonas aeruginosa*

Pseudomonas aeruginosa	Disk µg	MIC method S	MIC method R	Disk Diffusion S	Disk Diffusion R
Aztreonam	30	≤16	>16	≥18	<18
Piperacillin	30	≤16	>16	≥18	<18
Piperacillin-Tazobactam	30/6	≤16	>16	≥18	<18
Ticarcillin-Clavulanate	75/10	≤16	>16	≥18	<18
Cefepime	30	≤8	>8	≥21	<21
Imipenem	10	≤4	>4	≥20	<20
Meropenem	10	≤2	>8	≥24	<18
Doripenem	-	-	-	-	-

0- GENERAL INFORMATION

	LABORATORY DEMOGRAPHICS	
	Question	**Answer**
0.1	Assessor 1 (last name and affiliation)	
0.2	Assessor 2 (last name and affiliation)	
0.3	Assessor 3 (last name and affiliation)	
0.4	Date of assessment (dd/mm/yyyy)	
0.5	Laboratory/Hospital name	
0.6	Address	
0.7	City	
0.8	Province	
0.9	District	
0.10	Country	

GPS position of the laboratory (used for GIS representation of indicators). PLEASE ONLY USE DIGITAL DEGREE WITH + OR - SIGN. DO NOT USE DEGREES, MINUTES, SECONDS GPS position of the laboratory (used for GIS representation of indicators). PLEASE ONLY USE DIGITAL DEGREE WITH + OR - SIGN. DO NOT USE DEGREES, MINUTES, SECONDS

	Question	**Answer**	**Example**
0.11	For altitude, enter meters without digits. Altitude		Example: If altitude is 61.49 meters, enter 61
0.12	For latitude, enter digital degrees with 5 digits after the comma. Latitude		Example: 41,40338
0.13	For longitude, enter digital degrees with 5 digits after the comma. Longitude		Example: -2,17403

0.14 Contact information of the relevant bacteriology laboratory leadership; e.g., Director, Manager, Supervisor, Section Head, Quality Officer

Title/Position	**First Name**	**Last name**	**Email address**

	Question	**Answer**	**Comments**
0.15	**Primary Laboratory/Facility funding sources** 1. *Public/Government* 2. *Private* 3. *NGO/Faith-based/Donors* 4. *Other*	**1 2 3 4**	
0.16	**Primary Laboratory affiliation** 1. *Hospital: University Medical Center or Teaching Hospital* 2. *Hospital: Military* 3. *Hospital: (not academic or military)* 4. *Clinic (primarily outpatient)* 5. *Reference/referral lab within a Public Health Institute* 6. *Reference/referral lab not affiliated with a single healthcare facility or public health institute* 7. *Other, e.g., Research Laboratory*	**1 2 3 4 5 6 7**	

	Question	Answer	Comments
0.17	**Laboratory/Facility Level (if primarily government funded)** *1. National* *2. Regional* *3. Provincial* *4. District* *5. NA*	**1 2 3 4 5**	
0.18	**Service level of the Hospital/Healthcare Facility** *1. Primary* *2. Secondary* *3. Tertiary* *4. Other* *5. NA*	**1 2 3 4 5**	
0.19	**Number of beds of the Hospital/Healthcare Facility** *1: <100* *2: 100 - 499* *3: 500 - 1000* *4: >1000* *5: NA*	**1 2 3 4 5**	

	TEST MENU and WORKLOAD			
	Please note: all questions refer only to clinical patient specimens, NOT to environmental or research specimens **Does the lab perform the following types of culture?**	**Answer**	**# cultures last year**	**Comment**
	In the # cultures last year column, please enter the total number of cultures performed last year, both positive and negative			
0.20	Blood Cultures	**Y N**		
0.21	Urine Cultures	**Y N**		
0.22	Stool Cultures (all bacterial enteric pathogens)	**Y N**		
	Please indicate if the lab performs stool culture for the following enteric pathogens. Do not enter the number of cultures.			
0.23	*Salmonella* and/or *Shigella*	**Y N**		
0.24	*Vibrio cholerae*	**Y N**		
0.25	*Yersinia enterocolitica*	**Y N**		
0.26	*Campylobacter jejuni*	**Y N**		
0.27	Enterohemorrhagic/Enterotoxic *E. coli* (e.g., O157:H7)	**Y N**		
0.28	Respiratory Cultures (not TB/AFB)	**Y N**		
0.29	Wound Cultures	**Y N**		
0.30	Cerebrospinal Fluid Cultures	**Y N**		
0.31	Sterile Body Fluid Cultures (pleural, pericardial, peritoneal, synovial)	**Y N**		
0.32	Genital Cultures	**Y N**		
0.33	Anaerobic Cultures	**Y N**		
0.34	Fungal Cultures (Yeast)	**Y N**		
0.35	Fungal Cultures (Mold)	**Y N**		
0.36	MRSA screen for Infection Control purposes (e.g., nares, axilla, groin)	**Y N**		
0.37	VRE screen for Infection Control purposes (e.g., rectal swab)	**Y N**		
0.38	CRE screen (e.g., rectal swab)	**Y N**		
0.39	Identification and/or AST of isolates referred from other laboratories	**Y N**		
0.40	Other cultures of local importance (opportunity to customize via comments)	**Y N**		

	AST/AMR METHODS AND WORKLOAD			
	Question	**Answer**	**# organisms last year**	**Comment**
	Which manual AST methods are in use? *In the # organisms last year column, please enter the approximate number of organisms tested using each method, not the number of antibiotics tested*			
0.41	Disk diffusion	**Y N**		
0.42	Gradient Strip (e.g., Etest/Liofilchem)	**Y N**		
0.43	Broth microdilution (96-well tray)	**Y N**		
0.44	Broth macrodilultion (tube method)	**Y N**		
0.45	Agar dilution	**Y N**		
	Which automated AST methods are in use? *In the # organisms last year column, please enter the approximate number of organisms tested using each method, not the number of antibiotics tested*			
0.46	Vitek	**Y N**		
0.47	Phoenix	**Y N**		
0.48	Microscan	**Y N**		
0.49	Other, please specify in comments.	**Y N**		
	Does the lab use chromagar to detect antibiotic resistant organisms? *In the # organisms last year column, please enter the approximate number of organisms tested using each method*			
0.50	ESBL producers	**Y N**		
0.51	CRE/Carbapenemases	**Y N**		
0.52	MRSA	**Y N**		
0.53	VRE	**Y N**		
0.54	Colistin resistance	**Y N**		
0.55	Other, please specify in comments.	**Y N**		
	Does the lab use PCR to detect antibiotic resistance genes? *In the # organisms last year column, please enter the approximate number of organisms tested using each method*			
0.56	ESBLs	**Y N**		
0.57	Carbapenemases	**Y N**		
0.58	*mecA*	**Y N**		
0.59	*vanA/vanB*	**Y N**		
0.60	*mcr-1*	**Y N**		
0.61	Other, please specify in comments.	**Y N**		

	LABORATORY STAFF EDUCATION/TRAINING			
	Among laboratory leadership and the technical staff in bacteriology, indicate the number that fall into each training level category.	**Answer**	**# staff**	**Comment**
0.62	Advanced degree in Medical Microbiology or Medical Laboratory Sciences (PhD, MD, equivalent)	**Y N**		
0.63	Advanced degree, other concentration (PhD, MD, equivalent)	**Y N**		
0.64	Postgraduate Master's degree in Microbiology or Medical Laboratory Sciences	**Y N**		
0.65	Postgraduate Master's degree, other concentration	**Y N**		
0.66	Graduate Bachelor's degree in Microbiology or Medical Laboratory Sciences	**Y N**		
0.67	Graduate Bachelor's degree, other concentration	**Y N**		
0.68	Undergraduate Certificate or Diploma in Microbiology or Medical Laboratory Sciences	**Y N**		

	Among laboratory leadership and the technical staff in bacteriology, indicate the number that fall into each training level category.	Answer	# staff	Comment
0.69	Undergraduate Certificate or Diploma, other concentration	Y N		
0.70	High school/Secondary school diploma	Y N		
0.71	On-the-job training only	Y N		
0.72	Other (specify in comments)	Y N		

QMS MENTORING PROGRAMS

	Question	Answer	Year	Comment
0.73	Has the laboratory ever been enrolled in the SLIPTA program?	Y N		
0.74	If yes, when was the most recent certification awarded? *1: Within the past 2 years* *2: More than 2 years ago* *3: NA*	1 2 NA		
0.75	If yes, what is the star level of the latest SLIPTA audit? Check the certificate. *0: 0 stars* *1: 1 star* *2: 2 stars* *3: 3 stars* *4: 4 stars* *5: 5 stars* *NA*	0 1 2 3 4 5 NA		
0.76	Has the laboratory ever been enrolled in the WHO LQSI program? What year?	Y N		
0.77	If yes, what was the last overall % score for the 4 phases? What year? *1: ≥90%* *2: 70%-89%* *3: 50-69%* *4: <50%* *NA*	1 2 3 4 NA		
0.78	Has the laboratory ever been enrolled in any other mentoring program for Laboratory Quality Management (National, Regional, International)? When?	Y N		

ACCREDITATION and CERTIFICATION

	Does the lab possess a valid (current) ISO 15189 accreditation certificate for any of the following tests? (Confirm by reviewing certificate)	Answer	Year awarded	Comment
0.79	Blood cultures	Y N		
0.80	Stool cultures	Y N		
0.81	Urine cultures	Y N		
0.82	Organism Identification	Y N		
0.83	Antibiotic Susceptibility Testing	Y N		
0.84	Any other microbiology applied technique such as Gram staining?	Y N		
0.85	Who awarded the most recent accreditation? (Review accreditation certificate and write name of accrediting body in comments) (ILAC = International Laboratory Accreditation Cooperation) *1: ILAC Full Member* *2: ILAC Associate Member* *3: ILAC Affiliate Member* *4: ILAC Stakeholder* *5: ILAC Regional Cooperation Body* *6: Other/Don't know* *7: National Accrediting Board* *NA* ILAC MRA Signatory Search (https://ilac.org/signatory-search/#elementid)	1 2 3 4 5 6 7 NA		

1- FACILITY

Please note: all questions refer to equipment that is used for clinical patient specimens, NOT equipment that is used only for research specimens

	LABORATORY FACILITY		
	Question	**Answer**	**Comment**
	Observe the laboratory work benches, are they:		
1.1	Separate from patient care areas	**Y N**	
1.2	Organized with minimal clutter?	**Y N**	
1.3	Adequately ventilated?	**Y N**	
1.4	Free of excess moisture?	**Y N**	
1.5	Adequately lit?	**Y N**	
1.6	Does the laboratory have a functional heating/air conditioning system?	**Y N**	
1.7	Is the temperature in the laboratory maintained between 20°-25°C?	**Y N**	
1.8	Are all critical equipment (instruments, refrigerators, freezers, incubators, computers, automated instruments) supported by a functioning generator?	**Y N Partial**	
1.9	Are all critical pieces of equipment attached to uninterrupted power source (UPS) devices? (These provide temporary power until the generator can be activated)	**Y N Partial**	
1.10	In the last 6 months, has prolonged power failure disrupted the ability to provide routine bacteriology services?	**Y N**	
1.11	Is there a contingency plan in place for continued testing in the event of prolonged electricity disruption (e.g., power outage lasting several days)?	**Y N**	
	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.		
1.12	Describe the internet service in the laboratory *1: Continuous (service interruptions are rare)* *2: Sporadic (service interruptions are common)* *3: No internet available*	**1 2 3**	

	GENERAL EQUIPMENT AVAILABILITY			
	Question	**Functional?**	**(#)**	**Comment**
	Indicate whether the lab has the following FUNCTIONAL equipment. In column D (#), indicate how many pieces of FUNCTIONAL equipment are present. If the lab only has non-functional equipment, select "No" and write "non-functional" in the comments. Also indicate in the comments if the quantity of equipment is sufficient for the laboratory's volume of testing.			
1.13	McFarland QC standards of known densities, including 0.5, not expired	**Y N**		
1.14	Ruler or caliper with millimeter markings	**Y N**		
1.15	Bunsen burners or micro-incinerators	**Y N**		
1.16	Calibrated 1uL or 10uL loops (for plating urine cultures)	**Y N**		
1.17	Optical densitometer/turbidimeter (for determining McFarland density)	**Y N**		
1.18	Microliter pipettes (e.g., Eppendorf)	**Y N**		
1.19	Centrifuge (not used for TB cultures)	**Y N**		
1.20	Microscope	**Y N**		
1.21	Thermometers	**Y N**		

	Question	Functional?	(#)	Comment
1.22	CO_2 incubators	Y N		
1.23	Candle jars	Y N		
1.24	Ambient (non-CO_2) incubator	Y N		
1.25	Refrigerator (2-8°C)	Y N		
1.26	Non-defrosting freezer, -20°C	Y N		
1.27	Non-defrosting freezer, -60°C	Y N		
1.28	Non-defrosting freezer, -80°C	Y N		
1.29	Rechargeable desiccants (for storage of open antibiotic disks and strips)	Y N		
1.30	Hot air oven (for drying saturated desiccants)	Y N		
1.31	Biological Safety Cabinet Class IIA	Y N		
1.32	Autoclave for media preparation ("clean" autoclave)	Y N		
1.33	Autoclave for sterilizing waste ("dirty" autoclave)	Y N		

MEDIA PREPARATION EQUIPMENT AVAILABILITY

	Question	Answer	Comment
1.34	Does the laboratory prepare any media or distilled water? (e.g., blood agar, Mueller Hinton agar, blood culture bottles) *If No, answer NA until next section*	Y N	

	Indicate whether the lab is currently using the following FUNCTIONAL equipment. If the lab has only non-functional equipment, select "No" and note "non-functional" in the comments.	Functional?	(#)	Comment
1.35	pH meter	Y N NA		
1.36	Weighing balance	Y N NA		
1.37	Conductivity meter	Y N NA		
1.38	Distiller / reverse osmosis equipment	Y N NA		
1.39	Hot plate with magnetic stir bar (for mixing powdered media)	Y N NA		
1.40	Water bath	Y N NA		

EQUIPMENT CALIBRATION RECORDS

	Review the calibration records for each piece of equipment. Has calibration been performed within the last year? *(Select NA only if the lab does not have the equipment.)*	Answer	Comment
1.41	Optical Densitometer (for determining McFarland density)	Y N NA	
1.42	Microliter pipettes (e.g., Eppendorf)	Y N NA	
1.43	Centrifuge	Y N NA	
1.44	Thermometers	Y N NA	
1.45	pH meter	Y N NA	
1.46	Conductivity meter	Y N NA	
1.47	CO_2 incubator	Y N NA	
1.48	Ambient (non-CO_2) incubator	Y N NA	
1.49	Hot air oven for recharging desiccants	Y N NA	
1.50	Biological Safety Cabinet Class IIA	Y N NA	
1.51	Weighing balance	Y N NA	
1.52	Water bath	Y N NA	

THERMOMETERS

	Indicate if manual (non-digital) thermometers are present inside each piece of equipment. (Select NA if the lab does not have the equipment.)	Answer	Comment
1.53	CO2incubator	Y N NA	
1.54	Ambient (non-CO2) incubator	Y N NA	
1.55	Refrigerator (2-8°C)	Y N NA	
1.56	Non-defrosting freezer, −20°C	Y N NA	

	Indicate if manual (non-digital) thermometers are present inside each piece of equipment. (Select NA if the lab does not have the equipment.)	Answer	Comment
1.57	Non-defrosting freezer, −60°C	Y N NA	
1.58	Non-defrosting freezer, −80°C	Y N NA	
1.59	Hot air oven (for recharging desiccants)	Y N NA	
1.60	Hot plate with magnetic stir bar (for mixing powdered media)	Y N NA	
1.61	Water bath	Y N NA	

	TEMPERATURE AND ATMOSPHERE MONITORING		
	Question	**Answer**	**Comment**
	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. Select NA if the piece of equipment in question is not in use in the lab.		
	Room temperature		
1.62	Are temperatures recorded each day of use?	Y N	
1.63	Is the acceptable temperature range (the minimum and maximum) clearly defined on the record sheet?	Y N	
	Freezers, −20°C		
1.64	Are temperatures recorded each day of use?	Y N NA	
1.65	Is the acceptable temperature range (the minimum and maximum) clearly defined on the record sheet?	Y N NA	
	Freezers, −60°C		
1.66	Are temperatures recorded each day of use?	Y N NA	
1.67	Is the acceptable temperature range (the minimum and maximum) clearly defined on the record sheet?	Y N NA	
	Freezers, −80°C		
1.68	Are temperatures recorded each day of use?	Y N NA	
1.69	Is the acceptable temperature range (the minimum and maximum) clearly defined on the record sheet?	Y N NA	
	Refrigerators		
1.70	Are temperatures recorded each day of use?	Y N	
1.71	Is the acceptable temperature range (the minimum and maximum) clearly defined on the record sheet?	Y N	
	Incubators, ambient atmosphere		
1.72	Are temperatures recorded each day of use?	Y N	
1.73	Is the acceptable temperature range (the minimum and maximum) clearly defined on the record sheet?	Y N	
	Incubators, CO_2		
1.74	Are temperatures recorded each day of use?	Y N NA	
1.75	Is the acceptable temperature range (the minimum and maximum) clearly defined on the record sheet?	Y N NA	
1.76	Are CO_2 incubators checked for adequate CO_2 levels and documented daily (or each day of use if not used daily)?	Y N NA	
	Water baths		
1.77	Are temperatures recorded each day of use?	Y N NA	
1.78	Is the acceptable temperature range (the minimum and maximum) clearly defined on the record sheet?	Y N NA	
	Standard: Acceptable ranges should be defined for all temperature dependent equipment		

	Question	Answer	Comment
1.79	Is there documentation of corrective action taken in response to out of range temperatures? *1: Yes* *2: No action is documented* *3: Temperatures are not recorded*	**1 2 3**	
	Standard: Procedures should be available with instruction as to what action(s) should be taken when temperatures are out of range		

AUTOCLAVE MANAGEMENT

	Question	Answer	Comment
	Do records demonstrate that the following mechanical indicators are recorded each time the autoclave is run? (Review logs to confirm)		
1.80	Temperature	**Y N NA**	
1.81	Pressure	**Y N NA**	
1.82	Cycle Time	**Y N NA**	
1.83	Do records demonstrate that chemical indicators (e.g., heat sensitive tape) are used each time the autoclave is run? (Review logs to confirm)	**Y N NA**	
1.84	Do records demonstrate that biological indicators (e.g., Attest or other spore system) are used to confirm the autoclave is achieving sterilization? (Review logs to confirm). *1: Weekly* *2: Monthly* *3: Less than monthly* *4: No records*	**1 2 3 4**	
1.85	Is the same autoclave used for both media preparation and waste sterilization?	**Y N NA**	

INSTRUMENT AVAILABILITY AND MAINTENANCE

	Question	Answer	D (#)	Comment
	Enter quantities in column D (#)			
1.86	Does the laboratory have an automated blood culture instrument? (indicate manufacturer and model in comments)	**Y N**		BRAND:
1.87	Is the instrument functional today?	**Y N NA**		
1.88	Is a user manual present?	**Y N NA**		
1.89	Are routine (user) maintenance records present?	**Y N NA**		
1.90	Are preventive (vendor) maintenance records present?	**Y N NA**		
1.91	Is a service contract in place?	**Y N NA**		
1.92	Is the software up to date?	**Y N NA**		
1.93	Does the laboratory have an automated instrument for bacterial ID and AST? (e.g., Vitek, Microscan, Phoenix)	**Y N**		BRAND:
1.94	Is the instrument functional today?	**Y N NA**		
1.95	Is a user manual present?	**Y N NA**		
1.96	Are routine (user) maintenance records present?	**Y N NA**		
1.97	Are preventive (vendor) maintenance records present?	**Y N NA**		
1.98	Is a service contract in place?	**Y N NA**		
1.99	Is the software up to date?	**Y N NA**		
1.100	Does the laboratory have an automated instrument for reading disk diffusion? (e.g., SIRSCAN, BIOMIC V3, ADAGIO, etc.)	**Y N**		BRAND/ MODEL:
1.101	Is the instrument functional today?	**Y N NA**		
1.102	Is a user manual present?	**Y N NA**		
1.103	Are routine (user) maintenance records present?	**Y N NA**		
1.104	Are preventive (vendor) maintenance records present?	**Y N NA**		
1.105	Is a service contract in place?	**Y N NA**		
1.106	Is the software up to date?	**Y N NA**		

	Question	Answer	D (#)	Comment
1.107	Does the lab have a MALDI instrument for organism ID? (e.g., Bruker, Biomerieux)	Y N		BRAND/ MODEL:
1.108	Is the instrument functional today?	Y N NA		
1.109	Is a user manual present?	Y N NA		
1.110	Are routine (user) maintenance records present?	Y N NA		
1.111	Are preventive (vendor) maintenance records present?	Y N NA		
1.112	Is a service contract in place?	Y N NA		
1.113	Is the software up to date?	Y N NA		
1.114	Does the lab have a PCR instrument used for detecting antibiotic resistance genes? (e.g., GeneXpert)	Y N		BRAND/ MODEL:
1.115	Is the instrument functional today?	Y N NA		
1.116	Is a user manual present?	Y N NA		
1.117	Are routine (user) maintenance records present?	Y N NA		
1.118	Are preventive (vendor) maintenance records present?	Y N NA		
1.119	Is a service contract in place?	Y N NA		
1.120	Is the software up to date?	Y N NA		
1.121	In the last 6 months, has prolonged instrument failure disrupted the ability to provide routine bacteriology services?	Y N		
1.122	In the event of prolonged instrument failure, is a contingency plan in place to provide uninterrupted bacteriology services?	Y N		

INVENTORY & STOCK OUTS

	Question	Answer	Comment
1.123	Does the lab have an inventory control system in place?	Y N	
1.124	In the last 6 months, has the lab/hospital experienced stock outs of specimen collection materials? (e.g., blood culture bottles, sterile cups, sterile swabs)	Y N	
1.125	In the last 6 months, has the lab experienced stock outs of consumables? (e.g., petri dishes, tubes, sterile saline, pipettes, pipette tips, plastic inoculating loops, gloves, paper, gauze, disinfectant)	Y N	
1.126	In the last 6 months, has the lab experienced stock outs of media? (e.g., powdered media, sheep blood, other additives, tubed media)	Y N	
1.127	In the last 6 months, has the lab experienced stock outs of conventional reagents? (e.g., oxidase reagent, indole reagent, catalase reagent, coagulase reagent, etc.)	Y N	
1.128	In the last 6 months, has the lab experienced stock outs of antibiotic disks or strips?	Y N	
1.129	In the last 6 months, has the lab experienced stock outs of ID or AST cards/trays for the automated instruments?	Y N NA	
1.130	In the last 6 months, has the lab experienced stock outs of control materials or reference strains?	Y N	
1.131	In the last 6 months, has the lab experienced stock outs of other key materials?	Y N	
1.132	In the last 6 months, have any stock outs disrupted the lab's ability to provide routine bacteriology services?	Y N	
1.133	In the event of stock outs, is a contingency plan in place to provide uninterrupted bacteriology services?	Y N	
	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.		
1.134	Are all currently in use media, reagents and test kits within the manufacturer-assigned expiry dates? (Verify by random sampling)	Y N	
	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.		

	Question	Answer	Comment
1.135	Are all reconstituted reagents, such as coagulase plasma, within stability from the date of reconstitution? (Coagulase plasma expires 30 days after reconstitution when stored frozen).	**Y N NA**	

2 - LABORATORY INFORMATION SYSTEM (ELECTRONIC)

If the laboratory does not use an electronic LIS, answer No to question 2.1, then skip to 3 - Data Management

The scores for this section reflect the usability of the computer-based LIS and its likely compatibility with AMR surveillance systems, not the quality of the laboratory.

When exporting data from a LIS for data analysis purposes, including AMR surveillance, it is important that each data field is discrete.

	DEMOGRAPHIC DATA FIELDS		
	Question	**Answer**	**Comment**
2.1	Does the laboratory use a computer-based Laboratory Information System (LIS)? *If yes, please record name in comments. PLEASE NOTE: WHONET is not a LIS*	**Y N**	Name of LIS:
	Observe data entry into the LIS. Are individual data fields present for each of the following?		
2.2	Patient Last Name/Surname	**Y N**	
2.3	Patient First Name	**Y N**	
2.4	Patient Identification Number	**Y N**	
2.5	Patient Date of Birth	**Y N**	
2.6	Patient Age	**Y N**	
2.7	Patient Gender	**Y N**	
2.8	Patient Location (Ward or Unit at the time of specimen collection, e.g., "ICU")	**Y N**	
2.9	Patient Date of Admission	**Y N**	

	SPECIMEN DATA FIELDS		
	Question	**Answer**	**Comment**
	Observe data entry into the LIS. Are individual data fields present for each of the following?		
2.10	Specimen identification number	**Y N**	
2.11	Specimen Type (e.g. Wound)	**Y N**	
2.12	Specimen Source/Body Site (e.g., Arm)	**Y N**	
2.13	Additional descriptors (e.g., Left, Right)	**Y N**	
2.14	Date of specimen collection	**Y N**	
2.15	Time of specimen collection	**Y N**	
2.16	Date of specimen receipt	**Y N**	
2.17	Time of specimen receipt	**Y N**	

	CULTURE OBSERVATION DATA FIELDS		
	Question	**Answer**	**Comment**
	Observe culture data entry into the LIS. Are individual data fields present for each of the following?		
	Gram stain of specimen (e.g., sputum Gram stain)		
2.18	Quantity of Epithelial Cells per low power field	**Y N**	
2.19	Quantity of PMNs (WBCs) per low power field	**Y N**	
2.20	Quantity of bacterial cells per high power field	**Y N**	
2.21	Type of bacterial cells (gram-positive cocci, gram-negative bacilli, etc.)	**Y N**	
2.22	Description of colony morphologies (e.g., "mucoid lactose fermenter" or "beta-hemolytic")	**Y N**	
2.23	Description of colony quantities (e.g., "1+, 2+, 3+, 4+" or "few, moderate, many")	**Y N**	
2.24	Gram stain of bacterial colony	**Y N**	
2.25	Biochemical test results (e.g., "catalase-positive") for conventional test methods	**Y N**	
2.26	Organism name	**Y N**	
2.27	Isolate number (e.g., when more than one pathogen is encountered in a culture: isolate #1, isolate #2)	**Y N**	

	AST DATA FIELDS		
	Question	**Answer**	**Comment**
2.28	Can the LIS record the AST method used to obtain each individual antibiotic result (e.g., Etest vs. Vitek vs. disk)?	**Y N**	
	Observe data entry into the LIS. Are individual data fields present for each of the following?		
2.29	Disk diffusion zone sizes	**Y N**	
2.30	Disk diffusion interpretation (S/I/R)	**Y N**	
2.31	MIC values	**Y N**	
2.32	MIC interpretation (S/I/R)	**Y N**	
2.33	Can the LIS record MIC values to three decimal places (e.g., 0.016)?	**Y N**	
2.34	Can the LIS suppress (hide) an individual antibiotic result from the patient report without deleting it from the database (for cascade reporting)?	**Y N**	
2.35	Does the LIS software automatically interpret zone sizes into Susceptible, Intermediate, Resistant?	**Y N**	
2.36	Does the LIS software automatically interpret MICs into Susceptible, Intermediate, Resistant?	**Y N**	
2.37	If the LIS software automatically interprets zone sizes or MICs, are the breakpoints updated annually?	**Y N**	
2.38	If the LIS software automatically interprets zone sizes or MICs, are the breakpoints up to date today?	**Y N**	

	REPORTS AND DATA TRANSFER CAPABILITIES		
	Question	**Answer**	**Comment**
	(An "interface" is an electronic connection that allows information to flow automatically between different computer systems and software applications)		
2.39	Can the LIS de-duplicate data based on select criteria (e.g., patient ID, organism, specimen date)?	**Y N**	
2.40	Can the LIS produce a cumulative antibiogram report?	**Y N**	
2.41	Can the LIS interface with automated AST instruments (e.g., Vitek, Phoenix, SIRScan, BIOMIC)?	**Y N**	
2.42	Can the LIS interface with the Hospital Information System (HIS)?	**Y N**	
2.43	Can the LIS export line lists of data to .txt or .csv files?	**Y N**	

	INTERFACE CONNECTIVITY		
	Question	**Answer**	**Comment**
	(An "interface" is an electronic connection that allows information to flow automatically between different computer systems and software applications)		
2.44	If the lab uses an automated AST instrument, describe the data flow between the LIS and the instrument software. *1: Systems are not currently interfaced* *2: Bidirectional: Patient information (e.g., medical record number, specimen number, specimen type) flows from the LIS into the instrument software, AND results (ID and AST) flow from the instrument software back into the LIS.* *3: Uni-directional: Patient information flows from the LIS into the instrument software, but results do not transmit back into the LIS* *4: Uni-directional: Results transmit from the instrument software into the LIS, but patient information cannot flow from the LIS into the instrument software.* *NA: no automated instruments*	**1 2 3 4 NA**	
2.45	Does the hospital use a Hospital Information System (HIS) or Electronic Medical Record (EMR)? *If yes, please record system name in comments*	**Y N NA**	

	Question	Answer	Comment
2.46	If the LIS and HIS/EMR are interfaced, describe the data flow between the LIS and the HIS/EMR *1: Systems are not interfaced* *2: Bidirectional: Patient information (e.g., demographics, lab orders) flows from the HIS into the LIS, AND patient microbiology (ID/AST) results flow from the LIS back into the HIS.* *3: Uni-directional: Patient demographics transmit from the HIS into the LIS, but patient results do not transmit back into the HIS* *4: Uni-directional: Patient results transmit from the LIS into the HIS, but patient demographics cannot transmit from the HIS into the LIS.* *NA: no LIS or no HIS*	**1 2 3 4 NA**	

3- DATA MANAGEMENT

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

	PATIENT AND SPECIMEN IDENTIFICATION		
	Question	**Answer**	**Comments**
3.1	Are inpatients assigned a unique patient ID number upon admission to the hospital?	Y N	
3.2	Are outpatients assigned a unique patient ID number upon registration at the clinic?	Y N	
3.3	Are patient ID numbers assigned in such a way that no two patients are given the same number in the course of one year?	Y N	
3.4	Do patients retain the same patient ID number each time they are admitted to the hospital?	Y N	
3.5	Does the laboratory use the same patient ID numbers assigned by the hospital and/or clinics?	Y N	
3.6	Does the laboratory assign a unique specimen ID number to each specimen received in the lab?	Y N	
3.7	Are specimen numbers assigned in such a way that no two specimens are given the same number during one year?	Y N	

	SPECIMEN REQUISITION FORM		
	Question	**Answer**	**Comment**
	Review the specimen requisition form. Does it contain each of the following data fields?		
3.8	Patient Name	Y N	
3.9	Patient Identification Number	Y N	
3.10	Patient Date of Birth or Age	Y N	
3.11	Patient Location (Ward or unit at time of specimen collection, e.g., "ICU")	Y N	
3.12	Specimen Type (e.g., Wound)	Y N	
3.13	Specimen Source/Body Site (e.g., Arm)	Y N	
3.14	Date of specimen collection	Y N	
3.15	Time of specimen collection	Y N	
3.16	Test order (e.g., culture & AST)	Y N	
3.17	Name of physician ordering the test	Y N	
3.18	Name or initials of person collecting specimen	Y N	

	ORDER ENTRY		
	Question	**Answer**	**Comment**
	Review the process of specimen receiving/order entry. Are each of the following variables captured in the logbook or computer system?		
3.19	Patient Name	Y N	
3.20	Patient Identification Number	Y N	
3.21	Patient Date of Birth or Age	Y N	
3.22	Patient Location (Ward or unit at time of specimen collection, e.g., "ICU")	Y N	
3.23	Specimen Type (e.g., Wound)	Y N	
3.24	Specimen Source/Body Site (e.g., Arm)	Y N	
3.25	Date of specimen collection	Y N	
3.26	Time of specimen collection	Y N	
3.27	Date of specimen receipt	Y N	
3.28	Time of specimen receipt	Y N	
3.29	Test order (e.g., culture & AST)	Y N	
3.30	Name of physician ordering the test	Y N	
3.31	Name or initials of person receiving specimen	Y N	

	CULTURE OBSERVATIONS		
	Question	**Answer**	**Comment**
	The work card is where culture observations and biochemical test results are recorded. Work cards may be paper or electronic. Review the work card of a recently completed culture. Are the following elements recorded?		
	Gram stain of specimen (e.g., sputum Gram stain)		
3.32	Quantity of Epithelial Cells per low power field	**Y N**	
3.33	Quantity of PMNs (WBCs) per low power field	**Y N**	
3.34	Quantity of bacterial cells per high power field	**Y N**	
3.35	Type of bacterial cells (gram-positive cocci, gram-negative bacilli, etc.)	**Y N**	
3.36	Description of colony morphologies (e.g. "mucoid lactose fermenter" or "beta-hemolytic")	**Y N**	
3.37	Description of colony quantities (e.g. "1+, 2+, 3+, 4+" or "few, moderate, many")	**Y N**	
3.38	Gram stain of bacterial growth colonies (gram-positive cocci, gram-negative bacilli, etc.)	**Y N**	
3.39	Biochemical test results (e.g., "catalase positive") for conventional test methods	**Y N**	
3.40	AST Method used for each antibiotic (e.g., Disk, Etest, Instrument)	**Y N**	
3.41	Disk diffusion zone sizes	**Y N**	
3.42	Disk diffusion interpretation (S/I/R)	**Y N**	
3.43	MIC values	**Y N**	
3.44	MIC interpretation (S/I/R)	**Y N**	
3.45	Describe the laboratory's system for recording culture observations *1: Laboratory Information System (LIS)* *2: Fully electronic, but non-LIS (e.g., Word, Excel)* *3: Handwritten on a paper work card (e.g., the back of the specimen requisition) or in a logbook* *4: Combination of handwritten and electronic recording* *5: Internal results are not routinely recorded*	**1 2 3 4 5**	
3.46	Are culture observations/work cards retained for a defined time period (at least one year)?	**Y N**	

	AST RESULTS REPORTING		
	Question	**Answer**	**Comment**
3.47	Describe the laboratory's system for reporting AST results to the physician/client *1: Fully electronic system – physician does not receive a paper report from the lab* *2: Combination of paper and electronic reporting* *3: Fully paper-based system*	**1 2 3**	
3.48	If AST results are fully or partially issued to physicians on paper, please describe that system. *1: Printout from the Laboratory Information System* *2: Printout from the ID/AST instrument (e.g., Vitek, Phoenix, etc.)* *3: Printout from a non-LIS computer program (e.g., Word, Excel)* *4: Primarily hand-written onto a paper form*	**1 2 3 4**	
3.49	Are AST reports retained for a defined time period (at least one year)?	**Y N**	

	DATA BACKUP & SECURITY		
	Question	**Answer**	**Comment**
3.50	What method is used to back up the lab's electronic patient records? *1: Facility or cloud server* *2: External hard drive, USB, or CD* *3: Internal hard drive (PC or laptop)* *4: None* *NA: do not use an electronic database for patient records*	**1 2 3 4 NA**	
3.51	How frequently are the lab's electronic records backed up? *1: Daily/Continuously* *2: Other frequency, specify in comments* *3: Never* *NA: no electronic database*	**1 2 3 NA**	
3.52	Does the lab or facility have a policy and/or SOP on data backup and restoration?	**Y N NA**	
3.53	Does the lab or facility have a policy and/or SOP on data security and confidentiality?	**Y N NA**	
3.54	Do laboratory computers have antivirus software?	**Y N NA**	
3.55	Do laboratory computers have genuine (not pirated) Operating Systems?	**Y N NA**	

	AMR DATA SHARING		
	Question	**Answer**	**Comment**
	Is the laboratory currently a member of any AMR Surveillance Systems?		
3.56	WHO GLASS (Global Antimicrobial Resistance Surveillance System)	**Y N**	
3.57	Other, please describe in comments	**Y N**	
	Which of the following methods are currently used to submit data to the AMR surveillance network(s)? *More than one method may be selected. If the lab does not currently participate in AMR surveillance, select NA*		
3.58	Lab sends paper forms to an AMR coordinator	**Y N NA**	
3.59	Lab types data into an Excel spreadsheet	**Y N NA**	
3.60	Lab types data into an online database	**Y N NA**	
3.61	Lab types data into WHONET	**Y N NA**	
3.62	Lab exports a file from the automated AST instrument	**Y N NA**	
3.63	Lab exports a file from the LIS	**Y N NA**	
	If the lab has ever tried to use BacLink to transfer data from the LIS into WHONET, were any of the following problems encountered?		
3.64	The LIS export file was missing some of the required data fields	**Y N NA**	
3.65	The LIS export file merged/combined different data fields into a single column	**Y N NA**	
3.66	The LIS export file does not distinguish antibiotic results by AST method	**Y N NA**	
3.67	The LIS export file does not contain zone sizes or MIC values	**Y N NA**	
3.68	Other, please describe in comments	**Y N NA**	
	If the lab has ever tried to use BacLink to transfer data from the automated AST instrument into WHONET, were any of the following problems encountered?		
3.69	The instrument export file was missing some of the required data fields (like patient demographics)	**Y N NA**	
3.70	The instrument export file merged/combined different data fields into a single column	**Y N NA**	
3.71	The instrument export file was missing MIC values	**Y N NA**	
3.72	The instrument export file was missing SIR values	**Y N NA**	
3.73	Other, please describe in comments	**Y N NA**	

4- QUALITY ASSURANCE

	QUALITY STRUCTURE/BASICS		
	Question	**Answer**	**Comments**
4.1	Is there a Quality Manual in place that conforms to ISO standards? (15189, 17025 or 9001)?	**Y N**	
4.2	Does the lab have a formally designated Quality Officer or Manager?	**Y N**	
4.3	Is there a Quality Focal Point in bacteriology, in charge of collaboration with quality manager?	**Y N**	
4.4	Is there documentation showing that the Quality Officers and Focal Points have received appropriate training in Quality Management Systems (QMS)? *1: Yes* *2: Some, but would like additional training* *3: No training documented*	**1 2 3**	
4.5	How often does a Supervisor or Quality Officer review Media QC, ID QC, and AST QC results? *1: Weekly* *3: Sporadically* *2: Monthly* *4: Never*	**1 2 3 4**	
4.6	Is there evidence that QC review is performed at the stated frequency? *1: Yes, for all QC results* *2: Yes, but only for some QC results* *3: No*	**1 2 3**	
4.7	Is there documentation showing that the Supervisor/Quality Officer received training on how to effectively troubleshoot QC failures? *1: Yes* *2: Some, but would like additional training* *3: No training documented*	**1 2 3**	
4.8	Does a Supervisor or qualified designee review positive culture results every day?	**Y N**	
4.9	Are there written guidelines stating who is permitted to modify erroneous lab results after they have been reported?	**Y N**	
4.10	Who is permitted to modify erroneous lab results? *1: Supervisors and/or persons with supervisory permission -* *2: All microbiologists*	**1 2**	
4.11	When corrections to patient results are made, what is done with the erroneous result? *1: Erroneous results remain in place but are amended to reflect that they are erroneous* *2: Erroneous results are deleted from the record* *3: Other (explain in comments)*	**1 2 3**	

	LABORATORY STAFF EDUCATION/TRAINING/COMPETENCY		
	Question	**Answer**	**Comments**
4.12	Does at least 50% of the technical staff possess formal education in microbiology or medical laboratory science?	**Y N**	
4.13	Is the lab sufficiently staffed to provide high quality services? (Including support staff)	**Y N**	
4.14	Does the lab have a standardized process for training new employees?	**Y N**	
4.15	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)	**Y N**	
	Do records demonstrate that lab staff receive annual competency assessments for each of the following? (Review competency records, select NA if not on lab's test menu)		
4.16	Blood culture	**Y N NA**	
4.17	Urine culture	**Y N NA**	

	Question	Answer	Comments
4.18	Stool culture	**Y N NA**	
4.19	Respiratory culture (non-TB)	**Y N NA**	
4.20	Wound culture	**Y N NA**	
4.21	Cerebrospinal Fluid Cultures	**Y N NA**	
4.22	Sterile Body Fluid Cultures	**Y N NA**	
4.23	Antibiotic Susceptibility Testing	**Y N NA**	
	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.		

	TOUBLESHOOTING, PROBLEM SOLVING, AND ROOT CAUSE ANALYSES		
	Question	**Answer**	**Comments**
4.24	Is a root cause analysis performed when unacceptable QC results are obtained? (Request to see a recent example)	**Y N**	
4.25	Is corrective action based on the findings of the root cause analysis documented?	**Y N**	
4.26	Is there evidence the supervisor or Quality Officer has received adequate training on how to perform root-cause analysis of QC failures? *1: Yes* *2: Some, but would like additional training* *3: No*	**1 2 3**	
4.27	Are patient results reported if QC of media, ID method, or AST method was not performed?	**Y N**	
4.28	Are patient results reported if QC of media, ID method, or AST method failed to produce acceptable results?	**Y N**	
4.29	Is there evidence that the lab troubleshoots unacceptable QC results for media, reagents, ID systems and AST methods?	**Y N**	
4.30	If automated instruments are used for ID, (e.g., Vitek, Phoenix, Microscan) is there user manual or SOP that describes how to troubleshoot instrument failures? *Check NA if lab does not use automated instrument*	**Y N NA**	

	EXTERNAL QUALITY ASSESSMENT (EQA)		
	Question	**Answer**	**Comments**
4.31	How many times per year does the lab currently receive EQA/PT challenges that include both bacterial identification & AST? (Please do not include challenges designed to focus on a single organism, e.g., TB or *N. gonorrhoeae*) *1: One time per year* *2: Two times per year* *3: Three times per year or more* *4: Zero (if zero, please answer question 4.32, then skip to 5 – Media QC)*	**1 2 3 4**	
4.32	If the lab does not participate in an EQA program, what is the reason? (Informational, not scored)		
4.33	Is the EQA/PT provider ISO-17043 accredited? *Please list provider in comments*	**Y N**	
4.34	Are the test methods used on EQA isolates the same as the test methods used for routine patient isolates?	**Y N**	

	Question	Answer	Comments
4.35	Does the lab ever perform additional testing on an EQA isolate compared to what would be performed on a typical patient isolate?	**Y N**	
4.36	Does the lab ever send EQA isolates to another lab for confirmation before submitting results?	**Y N**	
4.37	Does the lab ever call another lab to ask what their EQA result was before submitting results?	**Y N**	
4.38	Are PT/EQA specimens tested by the same staff performing patient testing? (Look for evidence that all staff participate in the challenges, not only supervisors or senior staff)	**Y N**	
4.39	On average, how long does the lab have to wait before receiving the results of their PT/EQA performance? *1: Less than 2 months* *3: More than 6 months* *2: 2 – 6 months* *NA: no EQA*	**1 2 3 NA**	
4.40	Review the 3 most recent EQA challenges for organism identification. On how many did the lab score ≥ 80%? *If scores are not made available to review, select "None"*	**1 2 3 None**	
4.41	Review the 3 most recent EQA challenges for AST. On how many did the lab score ≥80%? *If scores are not made available to review, select "None"*	**1 2 3 None**	
4.42	Is a root cause analysis performed when unacceptable PT/EQA results are obtained? (Request to see a recent example)	**Y N**	
4.43	Is corrective action based on the findings of the root cause analysis documented?	**Y N**	
4.44	Is there evidence the supervisor or Quality Officer has received adequate training on how to perform root-cause analysis for EQA failures? *1: Yes* *2: Some, but would like additional training* *3: No*	**1 2 3**	
4.45	Is laboratory leadership notified of all unacceptable EQA results as soon as they are received?	**Y N**	

5- MEDIA PREPARATION AND QUALITY CONTROL

	MEDIA PREPARATION SOPs		
	Question	**Answer**	**Comments**
5.1	Are media-specific SOPs in place for each type of media reconstituted in house?	**Y N NA**	
	Do all media preparation records including the following?		
5.2	Name of media	**Y N NA**	
5.3	Date of preparation	**Y N NA**	
5.4	Batch number	**Y N NA**	
5.5	Quantity made	**Y N NA**	
5.6	pH	**Y N NA**	
5.7	Name of preparer	**Y N NA**	
5.8	Expiration Date	**Y N NA**	
	Observe the media reconstituted in house, is each batch clearly labeled with the following?		
5.9	Name of media	**Y N NA**	
5.10	Date of preparation	**Y N NA**	
5.11	Expiration date	**Y N NA**	
5.12	Date opened	**Y N NA**	

	GENERAL MEDIA PREPARATION		
	Question	**Answer**	**Comments**
5.13	Is media prepared in a separate room, apart from the room where specimens and cultures are processed?	**Y N**	
5.14	Is media prepared in a clean room?	**Y N**	
5.15	Is deionized water (DI) or distilled water used to prepare all media?	**Y N**	
5.16	Are the media suspensions mixed with a magnetic stir bar while boiling?	**Y N**	
5.17	Is the dissolved suspension autoclaved in a clean autoclave at 15 psi, 121°C, for ≥15 minutes?	**Y N**	
5.18	Is the autoclaved suspension cooled to 45-50°C before adding additional compounds (e.g. blood)?	**Y N**	
5.19	What is the source of the blood used to make the blood agar, chocolate, and/or MHB plates? *1: Sheep's blood* *2: Human blood (e.g., from expired packed cells)* *3: Other source (please describe in comments)*	**1 2 3**	
5.20	Is the pH recorded for all media prepared in house?	**Y N**	
5.21	Is all prepared media stored at 2-8°C until use?	**Y N**	
5.22	Are plates stored inside bags/sleeves to avoid dehydration?	**Y N**	

	DISTILLED/DEIONIZED WATER PREPARATION		
	Question	**Answer**	**Comments**
	If the lab or facility produces its own distilled or deionized water, are QC records present for the following?		
5.23	Conductimetry	**Y N NA**	
5.24	pH	**Y N NA**	
5.25	Sterility	**Y N NA**	
5.26	If the lab purchases distilled or deionized water, does it come with a Certificate of Analysis demonstrating proper pH, sterility and conductimetry?	**Y N NA**	

	ROUTINE MEDIA QC		
	Question	**Answer**	**Comments**
5.27	Are new batches of media checked for sterility by incubating a portion of un-inoculated plates?	**Y N**	

	Question	Answer	Comments
5.28	Are media quality controlled by using ATCC or ATCC-derivative strains? *1: All* *2: Some* *3: None*	**1 2 3**	
5.29	Do records demonstrate that QC is performed on each newly reconstituted batch or newly received lot number/shipment of media?	**Y N**	
5.30	Do QC records for blood agar plates (BAP) demonstrate that they are checked for their ability to support growth of fastidious organisms such as Streptococcus pneumoniae?	**Y N**	
5.31	Do QC records for BAP demonstrate that they are checked for their ability to show alpha, beta, and gamma hemolysis?	**Y N**	
5.32	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 *Haemophilus influenzae*?	**Y N**	
5.33	MacConkey (MAC) and Eosin methylene blue (EMB) agars contain bile salts and/or dyes that are toxic for gram-positive bacteria when made properly. Do QC records for MAC and/or EMB plates demonstrate that each batch/lot is challenged using a gram-positive organism?	**Y N NA**	
5.34	Dyes and pH indicators in MAC and EMB plates provide a color indicator to distinguish between lactose fermenting (LF) and non-lactose fermenting (NLF) gram-negative organisms. Do QC records for MAC and/or EMB plates demonstrate that each batch/lot is challenged using both LF and NLF organisms?	**Y N NA**	
5.35	Do QC records for selective stool agar plates (e.g. XLD, SS, HE) demonstrate that they are checked for their ability to suppress the growth of gram-positive organisms?	**Y N NA**	
5.36	Do QC records for selective stool agar plates demonstrate that they are checked for their ability to make hydrogen sulfide (H_2S) production visible using an H_2S producing organism, such as *Salmonella* spp or *Proteus vulgaris*?	**Y N NA**	
5.37	Do QC records for selective stool agar plates demonstrate that they are checked for their ability to make the acid byproducts of carbohydrate fermentation visible using both fermenters and non-fermenters?	**Y N NA**	
	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).		

	MULLER HINTON MEDIA PREPARATION AND QC		
	Question	**Answer**	**Comments**
	Examine the lab's Mueller Hinton plates and SOP for the following:		
5.38	Does the dehydrated Mueller Hinton Agar (dHMA) meet ISO 16782 (CLSI M6) standards? (Low thymine/thymidine content, not supplemented with Mg++ or Ca++ cations)	**Y N NA**	
5.39	Does the lab add calcium or magnesium cations to dMHA?	**Y N**	
5.40	Immediately after autoclaving, is agar allowed to cool in a 45° - 50°C water bath?	**Y N NA**	
5.41	Do plates have a uniform depth of approximately 4mm? Verify by examining a recent batch.	**Y N**	
5.42	Are plates poured on a level surface?	**Y N**	
5.43	Do records demonstrate that pH is 7.2 – 7.4 for each batch?	**Y N NA**	
5.44	Do records indicate that sterility is checked for each batch? (By incubating a portion of un-inoculated plates, ideally 5%)	**Y N**	
5.45	Are plates stored at 2-8°C until use?	**Y N**	

	Question	Answer	Comments
5.46	Are plates stored inside bags/sleeves to avoid dehydration?	Y N	
	Do QC records indicate that each batch of Mueller Hinton (MHA) agar is checked for its ability to produce expected zone sizes using the following ATCC reference strains and antibiotics?		
5.47	*Pseudomonas aeruginosa* 27853 and gentamicin disk	Y N	
5.48	*Enterococcus faecalis* 29212 or 33186 and trimethoprim-sulfamethoxazole disk	Y N	
5.49	Do QC records indicate that each batch of Mueller Hinton Blood (MHB) agar is checked for its ability to produce expected zone sizes using *Streptococcus pneumoniae* ATCC 49619 (or equivalent)? *Check NA if the lab does not use MHB*	Y N NA	

BLOOD CULTURE BOTTLES PREPARATION AND QC

	Question	Answer	Comments
5.50	Does the lab prepare blood culture bottles in-house? *If no, answer NA to remaining questions*	Y N	
5.51	Which base broth is used? (Broth must support growth of a wide range of bacterial species) *1: Brain Heart Infusion* *2: Supplemented peptone* *3: Soybean-casein digest (tryptic soy)* *4: Thioglycolate* *5: Thiol* *6: Colombia* *7: Brucella* *8: Other* *NA*	1 2 3 4 5 6 7 8 NA	
5.52	Is sodium polyanethole sulfonate (SPS) added? (an anticoagulant and growth stabilizer)	Y N NA	
5.53	Are any growth-promoters added? (Such as: Gelatin, Yeast Extract, Hemin (X-factor), NAD (Y-factor), Pyridoxine, Para-amino benzoic acid, Cysteine) *If yes, please describe in comments*	Y N NA	
5.54	Are resins or charcoal added? (to bind antimicrobials present in the patient's blood) *If yes, please describe in comments*	Y N NA	
5.55	Is 50mL of broth dispensed into sterile bottles for adult patients? (1:5 blood:broth ratio)	Y N NA	
5.56	Is 25mL of broth dispensed into sterile bottles for pediatric patients? (1:5 blood:broth ratio)	Y N NA	
5.57	Are the bottles autoclaved at 121°C for ≥15 min?	Y N NA	
	Do QC records for blood culture bottles indicate the following:		
5.58	Visual inspection performed and documented	Y N NA	
5.59	Checked for sterility by incubating a portion of uninoculated bottles? (Ideally 5%)	Y N NA	
5.60	Ability to support growth of *Streptococcus pneumoniae*	Y N NA	
5.61	Ability to support growth of *Haemophilus influenzae*	Y N NA	
5.62	Near the expiration date, is QC repeated on a few of the bottles to confirm the long-term stability of the broth?	Y N NA	
5.63	Are unused bottles labeled correctly (name, batch #, production date and expiration date)?	Y N NA	

6- QUALITY CONTROL - ID METHODS

	GRAM STAIN QC and REAGENT LABELING AND STORAGE		
	Question	**Answer**	**Comments**
6.1	Is QC performed and results recorded on each new preparation or lot number of Gram stain reagents? *1: Yes* *2: Partial* *3: No*	**1 2 3**	
	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.		
6.2	Is Gram stain QC performed using both positive and negative control organisms?	**Y N**	
	Observe the Gram stain, catalase, coagulase, oxidase and indole reagents in use by the laboratory. Are they labeled with: *1: All* *2: Some* *3: None*		
6.3	Name of reagent	**1 2 3**	
6.4	Date of preparation/reconstitution (if relevant, e.g., coagulase)	**1 2 3**	
6.5	Date of opening	**1 2 3**	
6.6	Expiration date	**1 2 3**	
6.7	Are tubed media, reagents, and kits stored at the temperatures indicated by the manufacturer?	**Y N**	

	QC OF INDIVIDUAL BIOCHEMICAL METHODS		
	Question	**Answer**	**Comments**
	NOTE: This question applies only to the tubed media and liquid reagents in use by the lab. ***It does NOT apply to the biochemical reagent wells incorporated into pre-defined identification systems, such as Vitek, API, Liofilchem, etc.*** Do QC records demonstrate the following? If a reagent is not used, check NA		
	Catalase (H_2O_2)		
6.8	Positive control is used	**Y N NA**	
6.9	Negative control is used	**Y N NA**	
6.10	QC is performed on each new batch/lot number	**Y N NA**	
6.11	QC is performed using ATCC or ATCC-derivative strains	**Y N NA**	
	Coagulase plasma		
6.12	Positive control is used	**Y N NA**	
6.13	Negative control is used	**Y N NA**	
6.14	QC is performed on each new batch/lot number	**Y N NA**	
6.15	QC is performed using ATCC or ATCC-derivative strains	**Y N NA**	
	***Staphylococcus* latex agglutination**		
6.16	Positive control is used	**Y N NA**	
6.17	Negative control is used	**Y N NA**	
6.18	QC is performed on each new batch/lot number	**Y N NA**	
6.19	QC is performed using ATCC or ATCC-derivative strains	**Y N NA**	
	***Staphylococcus* Chromagar**		
6.20	Positive control is used	**Y N NA**	
6.21	Negative control is used	**Y N NA**	
6.22	QC is performed on each new batch/lot number	**Y N NA**	
6.23	QC is performed using ATCC or ATCC-derivative strains	**Y N NA**	

	Question	Answer	Comments
	DNase		
6.24	Positive control is used	Y N NA	
6.25	Negative control is used	Y N NA	
6.26	QC is performed on each new batch/lot number	Y N NA	
6.27	QC is performed using ATCC or ATCC-derivative strains	Y N NA	
	PYR		
6.28	Positive control is used	Y N NA	
6.29	Negative control is used	Y N NA	
6.30	QC is performed on each new batch/lot number	Y N NA	
6.31	QC is performed using ATCC or ATCC-derivative strains	Y N NA	
	Optochin ("P") disk		
6.32	Positive control is used	Y N NA	
6.33	Negative control is used	Y N NA	
6.34	QC is performed on each new batch/lot number	Y N NA	
6.35	QC is performed using ATCC or ATCC-derivative strains	Y N NA	
	Bile solubility (deoxycholate)		
6.36	Positive control is used	Y N NA	
6.37	Negative control is used	Y N NA	
6.38	QC is performed on each new batch/lot number	Y N NA	
6.39	QC is performed using ATCC or ATCC-derivative strains	Y N NA	
	***Streptococcus pneumoniae* latex agglutination**		
6.40	Positive control is used	Y N NA	
6.41	Negative control is used	Y N NA	
6.42	QC is performed on each new batch/lot number	Y N NA	
6.43	QC is performed using ATCC or ATCC-derivative strains	Y N NA	
	Oxidase		
6.44	Positive control is used	Y N NA	
6.45	Negative control is used	Y N NA	
6.46	QC is performed on each new batch/lot number	Y N NA	
6.47	QC is performed using ATCC or ATCC-derivative strains	Y N NA	
	Indole reagents		
6.48	Positive control is used	Y N NA	
6.49	Negative control is used	Y N NA	
6.50	QC is performed on each new batch/lot number	Y N NA	
6.51	QC is performed using ATCC or ATCC-derivative strains	Y N NA	
	Methyl Red		
6.52	Positive control is used	Y N NA	
6.53	Negative control is used	Y N NA	
6.54	QC is performed on each new batch/lot number	Y N NA	
6.55	QC is performed using ATCC or ATCC-derivative strains	Y N NA	
	Voges-Proskauer		
6.56	Positive control is used	Y N NA	
6.57	Negative control is used	Y N NA	
6.58	QC is performed on each new batch/lot number	Y N NA	
6.59	QC is performed using ATCC or ATCC-derivative strains	Y N NA	
	Citrate		
6.60	Positive control is used	Y N NA	
6.61	Negative control is used	Y N NA	
6.62	QC is performed on each new batch/lot number	Y N NA	
6.63	QC is performed using ATCC or ATCC-derivative strains	Y N NA	

	Question	Answer	Comments
	Triple Sugar Iron agar or Kligler Iron Agar		
6.64	Positive control is used	Y N NA	
6.65	Negative control is used	Y N NA	
6.66	QC is performed on each new batch/lot number	Y N NA	
6.67	QC is performed using ATCC or ATCC-derivative strains	Y N NA	
	Urease		
6.68	Positive control is used	Y N NA	
6.69	Negative control is used	Y N NA	
6.70	QC is performed on each new batch/lot number	Y N NA	
6.71	QC is performed using ATCC or ATCC-derivative strains	Y N NA	
	Motility		
6.72	Positive control is used	Y N NA	
6.73	Negative control is used	Y N NA	
6.74	QC is performed on each new batch/lot number	Y N NA	
6.75	QC is performed using ATCC or ATCC-derivative strains	Y N NA	
	Lysine Iron Agar (LIA) or Lysine decarboxylase (LDC)		
6.76	Positive control is used	Y N NA	
6.77	Negative control is used	Y N NA	
6.78	QC is performed on each new batch/lot number	Y N NA	
6.79	QC is performed using ATCC or ATCC-derivative strains	Y N NA	
	Glucose or Dextrose Oxidative-Fermentative (OF) test		
6.80	Positive control is used	Y N NA	
6.81	Negative control is used	Y N NA	
6.82	QC is performed on each new batch/lot number	Y N NA	
6.83	QC is performed using ATCC or ATCC-derivative strains	Y N NA	
	Nitrate reduction		
6.84	Positive control is used	Y N NA	
6.85	Negative control is used	Y N NA	
6.86	QC is performed on each new batch/lot number	Y N NA	
6.87	QC is performed using ATCC or ATCC-derivative strains	Y N NA	
	Gelatin hydrolysis		
6.88	Positive control is used	Y N NA	
6.89	Negative control is used	Y N NA	
6.90	QC is performed on each new batch/lot number	Y N NA	
6.91	QC is performed using ATCC or ATCC-derivative strains	Y N NA	
	Chloramphenicol resistance (disk)		
6.92	Positive control is used	Y N NA	
6.93	Negative control is used	Y N NA	
6.94	QC is performed on each new batch/lot number	Y N NA	
6.95	QC is performed using ATCC or ATCC-derivative strains	Y N NA	
	Growth at 42°C		
6.96	Positive control is used	Y N NA	
6.97	Negative control is used	Y N NA	
6.98	QC is performed on each new batch/lot number	Y N NA	
6.99	QC is performed using ATCC or ATCC-derivative strains	Y N NA	
	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.		

	QC OF ENTERIC SEROLOGY		
	Question	**Answer**	**Comment**
	Indicate whether the following aspects of QC for *Salmonella* and/or *Shigella* serology reagents are performed. *If serology testing is not performed, check NA.*		
	***Shigella* serogoup**		
6.100	Positive control is used	**Y N NA**	
6.101	Negative control is used	**Y N NA**	
6.102	QC is performed on each new batch/lot number	**Y N NA**	
6.103	QC is performed using ATCC or ATCC-derivative strains	**Y N NA**	
	***Salmonella* serotype**		
6.104	Positive control is used	**Y N NA**	
6.105	Negative control is used	**Y N NA**	
6.106	QC is performed on each new batch/lot number	**Y N NA**	
6.107	QC is performed using ATCC or ATCC-derivative strains	**Y N NA**	

	QC OF COMMERCIAL ID KITS and AUTOMATED ID SYSTEMS		
	Question	**Answer**	**Comments**
	Review QC records for commercial organism identification kits (e.g., API, Liofilchem, RapID) *Check NA if the lab does not use any commercial test kits for organism ID*		
6.108	Is QC performed on every new lot number/shipment before kits are placed into use, according to manufacturer recommendations?	**Y N NA**	
6.109	Is QC performed using ATCC or ATCC-derivative strains?	**Y N NA**	
6.110	Following manufacturer instructions, are all of the recommended ATCC strains in use for the identification kits? *1: All recommended strains are used;* *2: Some of the recommended strains are used;* *3: None of the recommended reference strains are used;* *NA*	**1 2 3 NA**	
	Review the QC records for the ID cards/trays used with automated ID instruments (e.g., Vitek, Phoenix, Microscan, etc.) Check NA if the lab does not use automated systems for organism ID		
6.111	Is QC performed on every new lot number/shipment of ID cards/trays before they are placed into use?	**Y N NA**	
6.112	Is QC performed using ATCC or ATCC-derivative strains?	**Y N NA**	
6.113	Following manufacturer instructions, are all of the recommended ATCC strains in use for the automated instrument ID cards/trays? *1: All recommended strains are used;* *2: Some of the recommended strains are used;* *3: None of the recommended reference strains are used;* *NA*	**1 2 3 NA**	

7- QUALITY CONTROL - AST METHODS

	ROUTINE AST REFERENCE STRAINS		
	Question	**Answer**	**Comments**
	Does the lab have the following ATCC reference strains in stock? (CIP equivalents are also shown)		
7.1	*Staphylococcus aureus* ATCC 25923/CIP 76.25 (If CLSI standard used)	**Y N NA**	
7.2	*Staphylococcus aureus* ATCC 29213/CIP 103429 (If EUCAST standard used)	**Y N NA**	
7.3	*Enterococcus faecalis* ATCC 29212/CIP 103214 (to assess suitability of Mueller Hinton Agar for trimethoprim-sulfonamide tests)	**Y N NA**	
7.4	*Streptococcus pneumoniae* ATCC 49619	**Y N**	
7.5	*E. coli* ATCC 25922/CIP 76.24	**Y N**	
7.6	*Pseudomonas aeruginosa* ATCC 27853/CIP 76.110	**Y N**	
	Are reference strains stored as follows?		
7.7	Reference cultures (lyophilized state, from the manufacturer) maintained at <−20°C	**Y N NA**	
7.8	Reference stock cultures (broth preparations of reference cultures) maintained at <−20°C in a suitable stabilizer (10% -15% glycerol in tryptic soy broth, 50% fetal calf serum in broth, defibrinated sheep blood, or skim milk)	**Y N NA**	
7.9	Monthly working stock culture, or "F1", stored at 2-8°C for up to 4 weeks, then discarded	**Y N NA**	
7.10	Weekly working stock culture, or "F2", stored at 2-8°C for up to 1 week, then discarded	**Y N NA**	
7.11	Daily subculture, or "F3", discarded after one day of use.	**Y N NA**	
	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.		

	SPECIAL AST REFERENCE STRAINS		
	Question	**Answer**	**Comments**
	Does the lab have the following reference strains in stock? (CIP equivalents are also shown)		
7.12	*Staphylococcus aureus* ATCC 43300 (*mecA* positive, MRSA)	**Y N NA**	
7.13	*Staphylococcus aureus* ATCC BAA-976 (*msrA* positive, Dzone negative)	**Y N NA**	
7.14	*Staphylococcus aureus* ATCC BAA-977 (*ermA* positive, Dzone positive)	**Y N NA**	
7.15	*Enterococcus faecalis* ATCC 51299/CIP 104676 (*vanB* positive, VRE)	**Y N**	
7.16	*E. coli* ATCC 13353 (CTX-M-15 ESBL positive)	**Y N**	
7.17	*E. coli* ATCC 35218 (TEM-1 positive)	**Y N**	
7.18	*Klebsiella pneumoniae* ATCC 700603 (SHV-18, OXA-2) ESBL test QC	**Y N**	
7.19	*Klebsiella pneumoniae* ATCC BAA-1705 (TEM, SHV, KPC-2) Carbapenemase test QC	**Y N**	
7.20	*Klebsiella pneumoniae* ATCC BAA-1706 (Resistant to carbapenems by non-carbapenemase method)	**Y N**	
	Some QC strains with plasmid-mediated resistance have been shown to lose the plasmid when stored at temperatures above −60°C		
7.21	Are these special AST reference strains maintained at <−60°C?	**Y N NA**	

	QC OF DISC DIFFUSION AST METHODS		
	Question	**Answer**	**Comments**
7.22	Does the lab perform the disk diffusion method of AST? *If No, answer NA until 7.31*	**Y N**	
7.23	Is antibiotic disk QC performed before placing newly received lot numbers/shipments into use? (Review QC records to confirm)	**Y N NA**	
	IMPORTANT! Please read the information below before proceeding: **CLSI and EUCAST require that all antibiotic QC is performed each day of patient testing, not only when a new lot number is received.** **Labs that wish to reduce the frequency of antibiotic QC from daily to weekly may do so after demonstrating satisfactory performance with daily QC using one of two plans described in CLSI M02, section 4.7. Either the 20-30 day plan, or the 15-replicate plan.**		
7.24	Is there documentation showing that the lab has successfully completed either the 20-30-day plan or the 15-replicate (3- x 5-day) plan for all antibiotic disks in use? (Request to see)	**Y N**	
7.25	Not including new lot QC, how often is antibiotic disk QC performed? (Confirm by reviewing QC records; go back several months) *1: Each day that disk AST is performed on patients* *2: Weekly* *3: Every other week* *4: Monthly* *5: Other (describe in comments)* *NA: disk method not used*	**1 2 3 4 5 NA**	
	Is antibiotic disk QC performed using the recommended ATCC reference strains below? (Review QC records to confirm)		
7.26	*Staphylococcus aureus* ATCC 25923/CIP 76.25 (If CLSI standard used)	**Y N NA**	
7.27	*Staphylococcus aureus* ATCC 29213/CIP 103429 (If EUCAST standard used)	**Y N NA**	
7.28	*E. coli* ATCC 25922/CIP 76.24	**Y N NA**	
7.29	*Pseudomonas aeruginosa* ATCC 27853//CIP 76.110	**Y N NA**	
7.30	*Streptococcus pneumoniae* ATCC 49619	**Y N NA**	

	QC OF GRADIENT STRIP AST METHODS		
	Question	**Answer**	**Comments**
7.31	Does the lab use the gradient strip method of AST (Etest/Liofilechem)? (ungraded) *If no, answer NA until 7.40*	**Y N**	
7.32	Is gradient strip QC performed before placing new lot numbers/shipments into use? (Review QC records to confirm)	**Y N NA**	
7.33	Is there documentation showing that the lab has successfully completed either the 20-30 day plan or the 15-replicate (3- x 5-day) plan for all antibiotic strips in use? (Request to see)	**Y N NA**	
7.34	Not including new lot QC, how often is antibiotic strip QC performed? (Confirm by reviewing QC records; go back several months) *1: Each day that strip AST is performed on patients* *2: Weekly* *3: Every other week* *4: Monthly* *5: Other (describe in comments)* *NA: strip method not used*	**1 2 3 4 5 NA**	
	Is antibiotic strip QC performed using the recommended ATCC reference strains below? (Review QC records to confirm)		
7.35	*Staphylococcus aureus* ATCC 25923/CIP 76.25 (If CLSI standard used)	**Y N NA**	
7.36	*Staphylococcus aureus* ATCC 29213/CIP 103429 (If EUCAST standard used)	**Y N NA**	
7.37	*E. coli* ATCC 25922/CIP 76.24	**Y N NA**	

	Question	Answer	Comments
7.38	*Pseudomonas aeruginosa* ATCC 27853//CIP 76.110	**Y N NA**	
7.39	*Streptococcus pneumoniae* ATCC 49619	**Y N NA**	

	QC OF AUTOMATED AST SYSTEMS		
	Question	**Answer**	**Comments**
7.40	Does the lab use an automated instrument for AST? (e.g., Vitek, Phoenix, Microscan, etc) *If No, then enter NA until the end of this section*	**Y N**	
7.41	Are the antibiotic cards/trays stored at the manufacturer-recommended temperatures?	**Y N NA**	
7.42	Is QC of the antibiotic cards/trays performed before placing new lot numbers/shipments into use? (Review QC records to confirm)	**Y N NA**	
7.43	Is there documentation showing that the lab has successfully completed either the 20-30-day plan or the 15-replicate (3- x 5-day) plan for all antibiotic cards/trays in use? (Request to see)	**Y N NA**	
7.44	Not including new lot QC, how often is antibiotic card/tray QC performed? (Confirm by reviewing QC records; go back several months) *1: Each day that automated AST is performed on patients* *2: Weekly* *3: Every other week* *4: Monthly* *5: Other (describe in comments)* *NA: automated method not used*	**1 2 3 4 5 NA**	
	Is QC of automated AST systems performed using the recommended ATCC reference strains below? (Review QC records to confirm)		
7.45	*Staphylococcus aureus* ATCC 25923/CIP 76.25 (If CLSI standard used)	**Y N NA**	
7.46	*Staphylococcus aureus* ATCC 29213/CIP 103429 (If EUCAST standard used)	**Y N NA**	
7.47	*E. coli* ATCC 25922/CIP 76.24	**Y N NA**	
7.48	*Pseudomonas aeruginosa* ATCC 27853//CIP 76.110	**Y N NA**	
7.49	*Streptococcus pneumoniae* ATCC 49619	**Y N NA**	

8- SPECIMEN COLLECTION, TRANSPORT & MANAGEMENT

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

	SPECIMEN MANAGEMENT		
	Question	**Answer**	**Comments**
8.1	Does lab policy require that all specimens are accompanied by a laboratory-approved test requisition form?	Y N	
8.2	Does the lab enforce a two-identifier system? (e.g., both patient name and a numeric identifier must be present on the requisition and on the specimen).	Y N	
8.3	Are sensitive specimens processed within one hour of reaching the laboratory?	Y N	
8.4	When the bacteriology lab is closed, does another laboratory department process (culture) the specimens or ensure that they are stored at the proper temperatures? (Select NA if bacteriology lab does not close)	Y N NA	
	Does the lab store specimens properly prior to and following testing?		
8.5	Blood culture	Y N NA	
8.6	Urine culture	Y N NA	
8.7	Stool culture	Y N NA	
8.8	Respiratory culture	Y N NA	
8.9	Wound culture	Y N NA	
8.10	Genital culture	Y N NA	
8.11	Cerebrospinal fluid culture	Y N NA	
8.12	Sterile body fluid culture (pleural, pericardial, peritoneal, synovial)	Y N NA	
	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		

	SPECIMEN REJECTION		
	Question	**Answer**	**Comments**
	Are rejection criteria written down in an SOP or bench aide for each specimen type?		
8.13	Blood culture	Y N NA	
8.14	Urine culture	Y N NA	
8.15	Stool culture	Y N NA	
8.16	Respiratory culture	Y N NA	
8.17	Wound culture	Y N NA	
8.18	Genital culture	Y N NA	
8.19	Cerebrospinal fluid culture	Y N NA	
8.20	Sterile body fluid culture (pleural, pericardial, peritoneal, synovial)	Y N NA	
8.21	Are unlabeled specimens rejected?	Y N	
8.22	Are mislabeled specimens rejected?	Y N	
8.23	Are leaking specimens rejected?	Y N	
8.24	Are specimens rejected if not transported to the lab within established time limits?	Y N	
8.25	Are specimens rejected if there is evidence that they were not maintained in proper conditions during and prior to transport?	Y N	
8.26	Is there evidence that specimen rejection criteria are enforced (review rejection log)?	Y N	
8.27	Does the lab maintain quality indicators regarding the number of specimens rejected?	Y N	
8.28	When specimens are rejected, does the lab notify the ward or clinic immediately so that a new specimen may be collected?	Y N	

	BLOOD SPECIMEN COLLECTION and TRANSPORT		
	Question	**Answer**	**Comments**
8.29	Does the lab provide blood culture specimen collection instructions/SOPs to patient sample collection areas?	Y N	

	Question	Answer	Comments
8.30	Does the lab (or other department) provide annual training to clinical staff on blood culture specimen collection?	Y N	
	Review the blood culture specimen collection instructions. Does it address the following items? *(If specimen collection instructions do not exist or are not available to review, answer "No" to each.)*		
8.31	Collect prior to administering antibiotics to patient	Y N	
8.32	Antiseptic skin preparation and aseptic collection technique	Y N	
8.33	Antiseptic stopper preparation and aseptic inoculation of bottles	Y N	
8.34	Minimum volume for adults (typically 10-15mL per bottle)	Y N NA	
8.35	Minimum volume for children (typically 5-10mL per bottle)	Y N NA	
8.36	Minimum volume for neonates (typically 0.5-1mL per bottle)	Y N NA	
8.37	Does laboratory policy require that two "sets" of blood cultures are drawn?	Y N	
8.38	Does the policy specify that each blood culture should be obtained from a different venipuncture site?	Y N	
8.39	Proper bottle labeling (patient name, ID, date, time, venipuncture site)	Y N	
8.40	Transport bottles to the lab within 1 hour of collection	Y N	
8.41	If transport will be delayed, store bottles for automated systems at room temperature; store bottles for manual systems at 37°C.	Y N	

URINE SPECIMEN COLLECTION and TRANSPORT

	Question	Answer	Comments
8.42	Does the lab provide urine culture specimen collection instructions/SOPs to patient sample collection areas?	Y N	
8.43	Does the lab (or other department) provide annual refresher training to clinical staff on urine culture specimen collection?	Y N	
	Review the urine culture specimen collection instructions. Does it address the following items?		
8.44	Antiseptic cleaning instructions for women, men and infants	Y N	
8.45	Mid-stream or "clean catch" instructions	Y N	
8.46	Sterile containers only	Y N	
8.47	Minimum volume (typically 3mL)	Y N	
8.48	Proper labeling instructions	Y N	
8.49	Transport to lab at room temperature within 2 hours of collection	Y N	
8.50	If transport will be delayed, store refrigerated for up to 24 hours	Y N	

STOOL SPECIMEN COLLECTION and TRANSPORT

	Question	Answer	Comments
8.51	Does the lab provide stool culture specimen collection instructions/SOPs to patient sample collection areas?	Y N	
8.52	Does the lab (or other department) provide annual refresher training to clinical staff on stool culture specimen collection?	Y N	
	Review the stool culture specimen collection instructions. Does it address the following items?		
8.53	Collection technique	Y N	
8.54	Approved containers	Y N	
8.55	Min/Max volume	Y N	
8.56	Proper labeling	Y N	
8.57	Transport to the lab at room temperature within 2 hours	Y N	
8.58	If transport will be delayed, place specimen in an approved transport medium (such as Cary-Blair) for up to 24 hours	Y N	
8.59	If transport will be delayed, do not refrigerate stool since some pathogens, especially *Shigella* spp, will die at low temperatures	Y N	

9- PROCESSING

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

	BLOOD CULTURE PROCESSING		
	Question	**Answer**	**Comments**
	Does the laboratory perform blood cultures?	**Y N**	
9.1	Does the laboratory have an SOP describing how to process blood for bacterial culture?	**Y N NA**	
9.2	When a blood culture bottle shows signs of positivity, (turbidity, hemolysis, or gas production), does the lab perform a Gram stain of the bottle broth?	**Y N NA**	
9.3	If the Gram stain from the bottle is positive, does the lab call the result to the physician immediately?	**Y N NA**	
9.4	When a positive blood culture broth is sub-cultured, is a chocolate plate included to ensure recovery of fastidious organisms?	**Y N NA**	
9.5	Does the lab inoculate more than one patient sample on the same petri dish?	**Y N NA**	
9.6	Does the SOP for blood cultures appropriately define which organisms are commonly considered contaminants? *E.g., Corynebacterium spp., Propionibacterium spp., Micrococcus spp., viridans Strep spp., Bacillus spp., and coagulase-negative Staph spp. isolated from only one culture*	**Y N NA**	
9.7	Does the lab perform AST on organisms that are possible contaminants?	**Y N NA**	
9.8	Which blood culture incubation systems does the lab use? *1: Automated only* *2: Manual System only* *3: Both automated and manual systems*	**1 2 3**	

	MANUAL BLOOD CULTURE SYSTEMS		
	Question	**Answer**	**Comments**
	Review the SOP for manual incubation of blood culture bottles. Does it include each of the following instructions? (If only automated systems are used, answer NA)		
9.9	On each day of incubation, visually examine all bottles for signs of positivity (turbidity, hemolysis, gas production)	**Y N NA**	
9.10	After 24 hours of incubation, subculture all bottles that appear negative	**Y N NA**	
9.11	After 48 hours of incubation, subculture all bottles that appear negative again (if the first subculture was negative)	**Y N NA**	
9.12	Subculture bottles that appear negative to a chocolate agar plate (incubated in 5% CO_2) to ensure recovery of fastidious organisms	**Y N NA**	
9.13	Incubate all bottles between 5 and 7 days before issuing a final negative report	**Y N NA**	
9.14	On the final day of incubation, perform a terminal subculture before the final negative report is issued	**Y N NA**	

	URINE CULTURE		
	Question	**Answer**	**Comments**
	Does the laboratory perform urine cultures?	**Y N**	
9.15	Does the laboratory have an SOP for how to process urine for bacterial culture? (request to see)	**Y N NA**	
9.16	According to the SOP, which media are used for primary culture of urine? *1: Both blood agar and a selective gram-negative agar (e.g., MacConkey, EMB, CLED)* *2: Chromogenic agar designed for urine specimens* *3: Blood agar only* *4: Other, describe*	**1 2 3 4**	

	Question	Answer	Comments
	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 uro-pathogens such as Enterobacteriaceae, Enterococcus sp., and Staphylococcus sp.		
9.17	Are quantitative cultures (colony counts) performed?	**Y N NA**	
	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.		
9.18	Are urines plated using a calibrated loop? *1: Yes, 1µL* *2: Yes, 10uL* *3: No, calibrated loops are not used to plate urines*	**1 2 3**	
9.19	Does the lab inoculate more than one patient sample on the same petri dish?	**Y N NA**	
9.20	Does the urine culture SOP provide guidance to the technologist in determining which organisms to "work up" (ID and AST) based on relative quantities, pathogenicity, and method of specimen collection?	**Y N NA**	
9.21	Have technologists been adequately trained to recognize a poorly collected urine specimen (predominance of fecal or skin flora) based on the relative quantities, types, and mix of organisms present? *1: Yes* *2: Some, but would like additional training* *3: No*	**1 2 3**	

STOOL CULTURES for *Salmonella* and *Shigella*

	Question	Answer	Comments
	Does the laboratory perform stool cultures?	**Y N**	
9.22	Does the laboratory have an SOP for how to process (plate) stool for bacterial culture? (request to see)	**Y N NA**	
9.23	Does the SOP describe how to identify potential pathogens on all primary media? *The SOP should describe the colony appearance of potential pathogens on MAC other selective & differential media used and should define how to proceed when a potential pathogen is encountered.*	**Y N NA**	
	Which media are used for primary culture of stool?		
9.24	Blood agar	**Y N NA**	
9.25	MacConkey or Eosin Methylene Blue agar	**Y N NA**	
9.26	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)	**Y N NA**	
9.27	Selective enrichment broth (e.g., Selenite, GN, etc.)	**Y N NA**	
9.28	Other (describe in comments, not scored)	**Y N**	
9.29	Does the lab inoculate more than one patient sample on the same petri dish?	**Y N NA**	
	Are the following pathogens routinely targeted in every stool culture submitted?		
9.30	*Salmonella* spp.	**Y N NA**	
	Shigella spp.	**Y N NA**	
	Other (describe in comments, not scored)	**Y N NA**	

10- IDENTIFICATION METHODS & STANDARD OPERATING PROCEDURES

Please note: all questions refer only to clinical patient isolates, NOT to research or environmental isolates.

CONVENTIONAL ID METHODS

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

Definitions used in this section:

"Fully implemented**" means that the Standard Operating Procedure (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. A SOP that is complete but has not been approved or is not in routine use is not considered fully implemented.*

***"**Readily available**" means that technologists can easily access the Standard Operating Procedure (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 those using the SOP can read fluently.*

	***STAPHYLOCOCCUS AUREUS*, KEY ID METHODS**		
	Question	**Answer**	**Comments**
	Catalase (H_2O_2)		
10.1	Is this reagent used to test patient isolates? (If No, select NA for the remaining questions about this reagent)	**Y N**	
10.2	Has an up-to-date SOP been fully implemented?* (If the reagent is in use but there is no SOP, answer "no" to all remaining questions about this reagent)	**Y N NA**	
10.3	Is the SOP readily available** to bench staff?	**Y N NA**	
10.4	Does the SOP define QC organisms, QC frequency, and expected QC results?	**Y N NA**	
10.5	Does the SOP provide stepwise instructions for how to perform the test correctly?	**Y N NA**	
10.6	Does the SOP provide stepwise instructions for interpreting the test result correctly?	**Y N NA**	
10.7	Is catalase testing performed prior to coagulase testing on suspected Staphylococcus isolates? *1: Always 3: Never* *2: Sometimes NA*	**1 2 3 NA**	
	Coagulase plasma		
10.8	Is this reagent used to test patient isolates? (If No, select NA for the remaining questions about this reagent)	**Y N**	
10.9	Has an up-to-date SOP been fully implemented?* (If the reagent is in use but there is no SOP, answer "no" to all remaining questions about this reagent)	**Y N NA**	
10.10	Is the SOP readily available** to bench staff?	**Y N NA**	
10.11	Does the SOP define QC organisms, QC frequency, and expected QC results?	**Y N NA**	
10.12	Does the SOP provide stepwise instructions for how to perform the test correctly?	**Y N NA**	
10.13	Does the SOP provide stepwise instructions for interpreting the test result correctly?	**Y N NA**	
10.14	What is the source of the plasma used for coagulase testing? *1: Commercially purchased rabbit plasma* *2: Locally bled rabbit* *3: Human plasma* *4: Other source (please describe in comments)*	**1 2 3 4**	
10.15	Are negative slide coagulase results confirmed with a tube coagulase test before being reported? *1: Always 3: Never* *2: Sometimes NA: lab does not perform slide coagulase testing*	**1 2 3 NA**	

	***STAPHYLOCOCCUS AUREUS*, OTHER ID METHODS**		
	Question	**Answer**	**Comments**
	Staph latex agglutination		
10.16	Is this reagent used to test patient isolates? (If No, select NA for the remaining questions about this reagent)	**Y N**	
10.17	Has an up-to-date SOP been fully implemented?* (If the reagent is in use but there is no SOP, answer "no" to all remaining questions about this reagent)	**Y N NA**	
10.18	Is the SOP readily available** to bench staff?	**Y N NA**	
10.19	Does the SOP define QC organisms, QC frequency, and expected QC results?	**Y N NA**	
10.20	Does the SOP provide stepwise instructions for how to perform the test correctly?	**Y N NA**	
10.21	Does the SOP provide stepwise instructions for interpreting the test result correctly?	**Y N NA**	
10.22	Are disposable reaction cards discarded after use (not reused)? *1: Always* *2: Sometimes* *3: No* *NA: lab does not use latex agglutination to identify Staphylococcus*	**1 2 3 NA**	
	Staph chromagar		
10.23	Is this reagent used to test patient isolates? (If No, select NA for the remaining questions about this reagent)	**Y N**	
10.24	Has an up-to-date SOP been fully implemented?* (If the reagent is in use but there is no SOP, answer "no" to all remaining questions about this reagent)	**Y N NA**	
10.25	Is the SOP readily available** to bench staff?	**Y N NA**	
10.26	Does the SOP define QC organisms, QC frequency, and expected QC results?	**Y N NA**	
10.27	Does the SOP provide stepwise instructions for how to perform the test correctly?	**Y N NA**	
10.28	Does the SOP provide stepwise instructions for interpreting the test result correctly?	**Y N NA**	
	DNase		
10.29	Is this reagent used to test patient isolates? (If No, select NA for the remaining questions about this reagent)	**Y N**	
10.30	Has an up-to-date SOP been fully implemented?* (If the reagent is in use but there is no SOP, answer "no" to all remaining questions about this reagent)	**Y N NA**	
10.31	Is the SOP readily available** to bench staff?	**Y N NA**	
10.32	Does the SOP define QC organisms, QC frequency, and expected QC results?	**Y N NA**	
10.33	Does the SOP provide stepwise instructions for how to perform the test correctly?	**Y N NA**	
10.34	Does the SOP provide stepwise instructions for interpreting the test result correctly?	**Y N NA**	

	***STREPTOCOCCUS PNEUMONIAE*, CONVENTIONAL ID METHODS**		
	Question	**Answer**	**Comments**
	PYR		
10.35	Is this reagent used to test patient isolates? (If No, select NA for the remaining questions about this reagent)	**Y N**	
10.36	Has an up-to-date SOP been fully implemented?* (If the reagent is in use but there is no SOP, answer "no" to all remaining questions about this reagent)	**Y N NA**	
10.37	Is the SOP readily available** to bench staff?	**Y N NA**	
10.38	Does the SOP define QC organisms, QC frequency, and expected QC results?	**Y N NA**	
10.39	Does the SOP provide stepwise instructions for how to perform the test correctly?	**Y N NA**	
10.40	Does the SOP provide stepwise instructions for interpreting the test result correctly?	**Y N NA**	

	Question	Answer	Comments
	Bile solubility (deoxycholate)		
10.41	Is this reagent used to test patient isolates? (If No, select NA for the remaining questions about this reagent)	Y N	
10.42	Has an up-to-date SOP been fully implemented?* (If the reagent is in use but there is no SOP, answer "no" to all remaining questions about this reagent)	Y N NA	
10.43	Is the SOP readily available** to bench staff?	Y N NA	
10.44	Does the SOP define QC organisms, QC frequency, and expected QC results?	Y N NA	
10.45	Does the SOP provide stepwise instructions for how to perform the test correctly?	Y N NA	
10.46	Does the SOP provide stepwise instructions for interpreting the test result correctly?	Y N NA	
	Optochin ("P") disk		
10.47	Is this reagent used to test patient isolates? (If No, select NA for the remaining questions about this reagent)	Y N	
10.48	Has an up-to-date SOP been fully implemented?* (If the reagent is in use but there is no SOP, answer "no" to all remaining questions about this reagent)	Y N NA	
10.49	Is the SOP readily available** to bench staff?	Y N NA	
10.50	Does the SOP define QC organisms, QC frequency, and expected QC results?	Y N NA	
10.51	Does the SOP provide stepwise instructions for how to perform the test correctly?	Y N NA	
10.52	Does the SOP provide stepwise instructions for interpreting the test result correctly?	Y N NA	
10.53	If the Optochin result is equivocal (9-13mm), is bile solubility or other additional testing performed to confirm the ID?	Y N NA	
	***Streptococcus pneumoniae* latex agglutination**		
10.54	Is this reagent used to test patient isolates? (If No, select NA for the remaining questions about this reagent)	Y N	
10.55	Has an up-to-date SOP been fully implemented?* (If the reagent is in use but there is no SOP, answer "no" to all remaining questions about this reagent)	Y N NA	
10.56	Is the SOP readily available** to bench staff?	Y N NA	
10.57	Does the SOP define QC organisms, QC frequency, and expected QC results?	Y N NA	
10.58	Does the SOP provide stepwise instructions for how to perform the test correctly?	Y N NA	
10.59	Does the SOP provide stepwise instructions for interpreting the test result correctly?	Y N NA	

	ENTEROBACTERIACEAE, CONVENTIONAL ID METHODS		
	Question	**Answer**	**Comments**
	Oxidase		
10.60	Is this reagent used to test patient isolates? (If No, select NA for the remaining questions about this reagent)	Y N	
10.61	Has an up-to-date SOP been fully implemented?* (If the reagent is in use but there is no SOP, answer "no" to all remaining questions about this reagent)	Y N NA	
10.62	Is the SOP readily available** to bench staff?	Y N NA	
10.63	Does the SOP define QC organisms, QC frequency, and expected QC results?	Y N NA	
10.64	Does the SOP provide stepwise instructions for how to perform the test correctly?	Y N NA	
10.65	Does the SOP provide stepwise instructions for interpreting the test result correctly?	Y N NA	
	Indole		
10.66	Is this reagent used to test patient isolates? (If No, select NA for the remaining questions about this reagent)	Y N	

	Question	Answer	Comments
10.67	Has an up-to-date SOP been fully implemented?* (If the reagent is in use but there is no SOP, answer "no" to all remaining questions about this reagent)	Y N NA	
10.68	Is the SOP readily available** to bench staff?	Y N NA	
10.69	Does the SOP define QC organisms, QC frequency, and expected QC results?	Y N NA	
10.70	Does the SOP provide stepwise instructions for how to perform the test correctly?	Y N NA	
10.71	Does the SOP provide stepwise instructions for interpreting the test result correctly?	Y N NA	
	Methyl Red		
10.72	Is this reagent used to test patient isolates? (If No, select NA for the remaining questions about this reagent)	Y N	
10.73	Has an up-to-date SOP been fully implemented?* (If the reagent is in use but there is no SOP, answer "no" to all remaining questions about this reagent)	Y N NA	
10.74	Is the SOP readily available** to bench staff?	Y N NA	
10.75	Does the SOP define QC organisms, QC frequency, and expected QC results?	Y N NA	
10.76	Does the SOP provide stepwise instructions for inoculation and incubation?	Y N NA	
10.77	Does the SOP provide stepwise instructions for reading and interpretation?	Y N NA	
	Voges-Proskauer		
10.78	Is this reagent used to test patient isolates? (If No, select NA for the remaining questions about this reagent)	Y N	
10.79	Has an up-to-date SOP been fully implemented?* (If the reagent is in use but there is no SOP, answer "no" to all remaining questions about this reagent)	Y N NA	
10.80	Is the SOP readily available** to bench staff?	Y N NA	
10.81	Does the SOP define QC organisms, QC frequency, and expected QC results?	Y N NA	
10.82	Does the SOP provide stepwise instructions for inoculation and incubation?	Y N NA	
10.83	Does the SOP provide stepwise instructions for reading and interpretation?	Y N NA	
	Citrate		
10.84	Is this reagent used to test patient isolates? (If No, select NA for the remaining questions about this reagent)	Y N	
10.85	Has an up-to-date SOP been fully implemented?* (If the reagent is in use but there is no SOP, answer "no" to all remaining questions about this reagent)	Y N NA	
10.86	Is the SOP readily available** to bench staff?	Y N NA	
10.87	Does the SOP define QC organisms, QC frequency, and expected QC results?	Y N NA	
10.88	Does the SOP provide stepwise instructions for inoculation and incubation?	Y N NA	
10.89	Does the SOP provide stepwise instructions for reading and interpretation?	Y N NA	
	Triple Sugar Iron (TSI) or Kligler Iron Agar (KIA)		
10.90	Is this reagent used to test patient isolates? (If No, select NA for the remaining questions about this reagent)	Y N	
10.91	Has an up-to-date SOP been fully implemented?* (If the reagent is in use but there is no SOP, answer "no" to all remaining questions about this reagent)	Y N NA	
10.92	Is the SOP readily available** to bench staff?	Y N NA	
10.93	Does the SOP define QC organisms, QC frequency, and expected QC results?	Y N NA	
10.94	Does the SOP provide stepwise instructions for inoculation and incubation?	Y N NA	
10.95	Does the SOP provide stepwise instructions for reading and interpretation?	Y N NA	
	Urease		
10.96	Is this reagent used to test patient isolates? (If No, select NA for the remaining questions about this reagent)	Y N	
10.97	Has an up-to-date SOP been fully implemented?* (If the reagent is in use but there is no SOP, answer "no" to all remaining questions about this reagent)	Y N NA	
10.98	Is the SOP readily available** to bench staff?	Y N NA	
10.99	Does the SOP define QC organisms, QC frequency, and expected QC results?	Y N NA	
10.100	Does the SOP provide stepwise instructions for inoculation and incubation?	Y N NA	

	Question	Answer	Comments
10.101	Does the SOP provide stepwise instructions for reading and interpretation?	Y N NA	
	Motility		
10.102	Is this reagent used to test patient isolates? (If No, select NA for the remaining questions about this reagent)	Y N	
10.103	Has an up-to-date SOP been fully implemented?* (If the reagent is in use but there is no SOP, answer "no" to all remaining questions about this reagent)	Y N NA	
10.104	Is the SOP readily available** to bench staff?	Y N NA	
10.105	Does the SOP define QC organisms, QC frequency, and expected QC results?	Y N NA	
10.106	Does the SOP provide stepwise instructions for inoculation and incubation?	Y N NA	
10.107	Does the SOP provide stepwise instructions for reading and interpretation?	Y N NA	
	Lysine Iron Agar (LIA) or Lysine Decarboxylase (LDC)		
10.108	Is this reagent used to test patient isolates? (If No, select NA for the remaining questions about this reagent)	Y N	
10.109	Has an up-to-date SOP been fully implemented?* (If the reagent is in use but there is no SOP, answer "no" to all remaining questions about this reagent)	Y N NA	
10.110	Is the SOP readily available** to bench staff?	Y N NA	
10.111	Does the SOP define QC organisms, QC frequency, and expected QC results?	Y N NA	
10.112	Does the SOP provide stepwise instructions for inoculation and incubation?	Y N NA	
10.113	Does the SOP provide stepwise instructions for reading and interpretation?	Y N NA	

SHIGELLA/SALMONELLA SEROLOGY

	Question	Answer	Comments
	***Shigella* serology**		
10.114	Is this reagent used to test patient isolates? (If No, select NA for the remaining questions about this reagent)	Y N	
10.115	Has an up-to-date SOP been fully implemented?* (If the reagent is in use but there is no SOP, answer "no" to all remaining questions about this reagent)	Y N NA	
10.116	Is the SOP readily available** to bench staff?	Y N NA	
10.117	Does the SOP define QC organisms, QC frequency, and expected QC results?	Y N NA	
10.118	Does the SOP provide stepwise instructions for how to perform the test correctly?	Y N NA	
10.119	Does the SOP provide stepwise instructions for interpreting the test result correctly?	Y N NA	
	***Salmonella* serology**		
10.120	Is this reagent used to test patient isolates? (If No, select NA for the remaining questions about this reagent)	Y N	
10.121	Has an up-to-date SOP been fully implemented?* (If the reagent is in use but there is no SOP, answer "no" to all remaining questions about this reagent)	Y N NA	
10.122	Is the SOP readily available** to bench staff?	Y N NA	
10.123	Does the SOP define QC organisms, QC frequency, and expected QC results?	Y N NA	
10.124	Does the SOP provide stepwise instructions for how to perform the test correctly?	Y N NA	
10.125	Does the SOP provide stepwise instructions for interpreting the test result correctly?	Y N NA	

ACINETOBACTER SPP, CONVENTIONAL ID METHODS

	Question	Answer	Comments
	Glucose Oxidative-Fermentative (OF) test		
10.126	Is this reagent used to test patient isolates? (If No, select NA for the remaining questions about this reagent)	Y N	
10.127	Has an up-to-date SOP been fully implemented?* (If the reagent is in use but there is no SOP, answer "no" to all remaining questions about this reagent)	Y N NA	
10.128	Is the SOP readily available** to bench staff?	Y N NA	

	Question	Answer	Comments
10.129	Does the SOP define QC organisms, QC frequency, and expected QC results?	Y N NA	
10.130	Does the SOP provide stepwise instructions for inoculation and incubation?	Y N NA	
10.131	Does the SOP provide stepwise instructions for reading and interpretation?	Y N NA	
	Nitrate reduction		
10.132	Is this reagent used to test patient isolates? (If No, select NA for the remaining questions about this reagent)	Y N	
10.133	Has an up-to-date SOP been fully implemented?* (If the reagent is in use but there is no SOP, answer "no" to all remaining questions about this reagent)	Y N NA	
10.134	Is the SOP readily available** to bench staff?	Y N NA	
10.135	Does the SOP define QC organisms, QC frequency, and expected QC results?	Y N NA	
10.136	Does the SOP provide stepwise instructions for inoculation and incubation?	Y N NA	
10.137	Does the SOP provide stepwise instructions for reading and interpretation?	Y N NA	
	Gelatin hydrolysis		
10.138	Is this reagent used to test patient isolates? (If No, select NA for the remaining questions about this reagent)	Y N	
10.139	Has an up-to-date SOP been fully implemented?* (If the reagent is in use but there is no SOP, answer "no" to all remaining questions about this reagent)	Y N NA	
10.140	Is the SOP readily available** to bench staff?	Y N NA	
10.141	Does the SOP define QC organisms, QC frequency, and expected QC results?	Y N NA	
10.142	Does the SOP provide stepwise instructions for inoculation and incubation?	Y N NA	
10.143	Does the SOP provide stepwise instructions for reading and interpretation?	Y N NA	
	Chloramphenicol resistance (disk)		
10.144	Is this reagent used to test patient isolates? (If No, select NA for the remaining questions about this reagent)	Y N	
10.145	Has an up-to-date SOP been fully implemented?* (If the reagent is in use but there is no SOP, answer "no" to all remaining questions about this reagent)	Y N NA	
10.146	Is the SOP readily available** to bench staff?	Y N NA	
10.147	Does the SOP define QC organisms, QC frequency, and expected QC results?	Y N NA	
10.148	Does the SOP provide stepwise instructions for inoculation and incubation?	Y N NA	
10.149	Does the SOP provide stepwise instructions for reading and interpretation?	Y N NA	
	Growth at 42°C		
10.150	Is this reagent used to test patient isolates? (If No, select NA for the remaining questions about this reagent)	Y N	
10.151	Has an up-to-date SOP been fully implemented?* (If the reagent is in use but there is no SOP, answer "no" to all remaining questions about this reagent)	Y N NA	
10.152	Is the SOP readily available** to bench staff?	Y N NA	
10.153	Does the SOP define QC organisms, QC frequency, and expected QC results?	Y N NA	
10.154	Does the SOP provide stepwise instructions for inoculation and incubation?	Y N NA	
10.155	Does the SOP provide stepwise instructions for reading and interpretation?	Y N NA	

KIT-BASED ID METHODS

	Question	Answer	Comments
	If the lab uses rapid biochemical kits for organism ID (e.g., API, Liofilchem, RapID), does the SOP for each kit contain the following information? (If kits are not used, select "NA"; if kits are used but there is no SOP, select "3: No") *1: Yes 3: No* *2: Partial NA: The lab does not use rapid biochemical kits*		
10.156	Defined QC organisms, QC frequency, and expected QC results	1 2 3 NA	
10.157	Stepwise instructions for preparing the inoculum in the correct liquid medium and at the correct density	1 2 3 NA	
10.158	Stepwise instructions on how to inoculate and incubate the device	1 2 3 NA	
10.159	Stepwise instructions on how to read the results, including use of additional reagents if necessary	1 2 3 NA	

	Question	Answer	Comments
10.160	Clear guidance on interpreting results and recognizing unacceptable results	**1 2 3 NA**	
10.161	Are the SOPs available in a language that the technologists can read proficiently?	**Y N NA**	
10.162	Is the lab using the inoculation media recommended by the manufacturer?	**Y N NA**	
10.163	Following device inoculation, does the lab use the remaining inoculum to make a purity plate? (A purity plate is a light subculture of the inoculum that is made to ensure the inoculum was not a mixed culture or contaminated; usually streaked like a urine to ensure visualization of individual colonies and checked for purity when reading results)	**Y N NA**	
10.164	Following incubation, are all supplemental reagents available and added according to manufacturer instructions? (e.g., VP1 & 2 for API)	**Y N NA**	
10.165	Are the databases used to interpret the kit results (bionumbers) up to date?	**Y N NA Don't know**	
10.166	When an ID result (bionumber) does not reach the threshold for an acceptable identification, is there evidence that appropriate action is taken, such as repeating the test by another method or performing additional biochemical tests?	**Y N NA**	

AUTOMATED ID METHODS

	Question	Answer	Comments
	If the lab uses automated methods for organism ID (e.g., Vitek, Microscan, Phoenix), do the SOPs contain the following information? (User manuals provided by the manufacturer are not considered SOPs) *1: Yes 3: No* *2: Partial NA: automated methods are not used*		
10.167	Defined QC organisms, QC frequency, and expected QC results	**1 2 3 NA**	
10.168	Stepwise instructions for preparing the inoculum in the correct liquid medium and at the correct density	**1 2 3 NA**	
10.169	Stepwise instructions on how to inoculate and incubate the device	**1 2 3 NA**	
10.170	Stepwise instructions on how to read the results, including use of additional reagents if necessary	**1 2 3 NA**	
10.171	Clear guidance on interpreting results and recognizing unacceptable results	**1 2 3 NA**	
10.172	Is the SOP available in a language that the technologists using the instrument can read proficiently?	**Y N NA**	
10.173	Is the lab using the inoculation medium recommended by the manufacturer?	**Y N NA**	
10.174	Following card/tray inoculation, does the lab use the remaining inoculum to make a purity plate? *A purity plate is a light subculture of the inoculum that is made to ensure the inoculum was not mixed or contaminated; usually streaked like a urine to ensure visualization of individual colonies and checked for purity when reading results. BAP is typically used.*	**Y N NA**	
10.175	When the instrument 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?	**Y N NA**	

IDENTIFICATION FLOWCHARTS

	Question	Answer	Comments
	For questions 10.176 to 10.184: *1: Always* *2: Sometimes* *3: Never*		
10.176	When the primary plate has mixed colony types, is it standard practice to subculture each colony of interest to a fresh plate to ensure purity prior to pursuing identification?	**1 2 3**	

	Question	Answer	Comments
10.177	Is it standard practice to perform a Gram stain on each isolate of interest prior to performing any other testing?	**1 2 3**	
10.178	For gram-negative bacilli, is it standard practice to perform an oxidase test first, before proceeding with any other identification tests (including automated ID)?	**1 2 3**	
10.179	For gram-negative bacilli, is it standard practice to perform an indole test second, before proceeding with other identification tests (including automated ID)?	**1 2 3**	
10.180	For oxidase-negative gram-negative bacilli that do not ferment lactose (clear on MacConkey), are sufficient tests available to achieve a definitive identification?	**1 2 3**	
10.181	For oxidase-positive gram-negative bacilli that are not *Pseudomonas aeruginosa* (lack the characteristic appearance and odor), are sufficient tests available to achieve a definitive identification?	**1 2 3**	
10.182	For gram-positive cocci, is it standard practice to perform a catalase test first, before proceeding with any other identification tests (including automated ID)?	**1 2 3**	
10.183	For catalase positive gram-positive cocci, is it standard practice to perform a coagulase test next, before proceeding with other identification tests (including automated ID)?	**1 2 3**	
10.184	For catalase negative gram-positive cocci, is it standard practice to evaluate the type of hemolysis (alpha, beta, gamma), before proceeding with other identification tests (including automated ID)?	**1 2 3**	

11- ANTIMICROBIAL SUSCEPTIBILITY TESTING (AST) BASICS

Please note: all questions refer only to clinical patient isolates, NOT to research or environmental isolates.

	ANTIBIOTIC DISK AND GRADIENT STRIPS MAINTENANCE		
	Question	**Answer**	**Comments**
11.1	Do the antibiotic disks and strips come with a certificate of analysis from the manufacturer ensuring that they were tested and performed according to ISO quality standards?	**Y N**	
11.2	Are the packages not currently in use stored unopened and in their original packaging in order to prevent moisture ingress?	**Y N**	
11.3	Are unopened antibiotic disks and strips stored in a non-defrosting freezer?	**Y N**	
11.4	If the antibiotic disk cartridge has a cap, is the cap replaced each time the cartridge is opened?	**Y N**	
11.5	Once opened, are in-use antibiotic disks stored in such a way that the lot number and expiration date of each disk is always traceable? (When individual disks are removed and transferred to secondary containers, lot numbers may become mixed and expired disks may inadvertently be used.)	**Y N**	
11.6	Are the in-use antibiotic disks and strips stored in a tightly sealed container with active desiccants?	**Y N**	
11.7	Do the desiccants change color as moisture levels increase (indicating the need to replace or recharge)?	**Y N NA**	
11.8	If desiccants do not have a color indicator, are colorless desiccants replaced at least monthly?	**Y N NA**	
11.9	Are the containers holding open antibiotic disks/strips stored in a refrigerator or non-defrosting freezer when not in use?	**Y N**	
11.10	Are the containers holding open antibiotic disks/strips allowed to equilibrate to room temperature before opening to minimize condensation (typically 1 hour)	**Y N**	

	INOCULUM PREPARATION		
	Question	**Answer**	**Comments**
11.11	When preparing an inoculum using the colony suspension method, are colonies less than 18 hours old ever used?	**Y N**	
11.12	When preparing an inoculum using the colony suspension method, are colonies more than 24 hours old ever used?	**Y N**	
11.13	Observe an AST inoculum preparation. Do technologists use only individual, well-isolated colonies of the same morphological type?	**Y N**	
11.14	Are colonies taken only from non-selective media, such as blood agar (MacConkey agar is acceptable)	**Y N**	
11.15	Does the lab ever intentionally mix two different organisms in the same inoculum for AST?	**Y N**	
11.16	Is an appropriate, sterile inoculation medium (TSB or saline) used?	**Y N**	
11.17	Do records indicate that the saline solution is tested for sterility on a regular basis? (Preferably at least weekly)	**Y N**	
11.18	Is the inoculum brought to a density equivalent to 0.5 McFarland?	**Y N**	
11.19	How is the inoculum density checked for accuracy? *1: Calibrated densitometer/turbidity meter* *2: Visual comparison to a 0.5 McFarland standard that is not expired (check date)* *3: Neither of the above*	**1 2 3**	

	INOCULATION/INCUBATION		
	Question	**Answer**	**Comments**
11.20	Does the lab ever use agar other than Mueller Hinton for AST of non-fastidious organisms?	**Y N**	
11.21	Does the lab ever use agar other than Mueller Hinton with Blood for AST of *Streptococcus pneumoniae?*	**Y N**	
	Observe a MH plate being inoculated.		
11.22	Is the inoculum always used within 15 minutes of preparation?	**Y N**	
11.23	Is a sterile swab used to inoculate the plate?	**Y N**	
11.24	Is the inoculum spread in a way that will create an even lawn? *To create an even lawn, streak a line from top to bottom, then spread left to right across that line from top to bottom. Rotate plate 60° and repeat from beginning; rotate plate another 60° and repeat again.*	**Y N**	
11.25	Before applying disks/strips, are inoculated MH plates allowed to sit, lid-ajar, for 3 to no more than 15 minutes to allow for absorption of excess surface moisture?	**Y N**	
11.26	Are disks/strips ever moved after being placed on the agar?	**Y N**	
11.27	When using multi-disk dispensers, is the bottom of the dispenser disinfected between isolates?	**Y N NA**	
11.28	Are AST plates incubated within 15 minutes of placing disks/strips?	**Y N**	
11.29	After AST inoculation, are "purity plates" made from the remaining suspension? *A purity plate is a light subculture of the inoculum that is made to ensure the inoculum was not mixed or contaminated; usually streaked like a urine to ensure visualization of individual colonies and checked for purity when reading AST results*	**Y N**	
11.30	Are AST plates for non-fastidious organisms ever incubated in CO_2?	**Y N**	
11.31	Are AST plates for *Streptococcus pneumoniae* incubated in 5% CO_2?	**Y N**	
	Observe some currently incubating and/or recently read Mueller Hinton AST plates.		
11.32	Are the lawns of growth confluent (no gaps or individual colonies showing)?	**Y N**	
11.33	Is there a maximum of 6 antibiotic disks per 100mm plate?	**Y N**	
11.34	Is there a maximum of 12 antibiotic disks per 150mm plate?	**Y N NA**	
11.35	Are disks spaced properly? (At least 24mm from center to center, no overlapping zones, not too close to edge, uniformly circular zones)	**Y N**	

	READING AST RESULTS		
	Question	**Answer**	**Comments**
11.36	Are AST results ever read after less than 16 hours of incubation?	**Y N**	
11.37	Are AST results ever read after more than 24 hours of incubation?	**Y N**	
11.38	If individual colonies are apparent within the ellipsis or the zone of inhibition, does the lab repeat the test with a fresh subculture of a single colony from the original plate?	**Y N**	
	Observe a Mueller Hinton AST plate being read.		
11.39	Is the plate held above a black, non-reflective background?	**Y N**	
11.40	Is the plate illuminated adequately with reflected light?	**Y N**	
11.41	Is the plate inverted and zones measured from underneath?	**Y N**	
11.42	Is a ruler or a caliper with millimeter marks used to measure zone sizes?	**Y N**	
11.43	Does the lab possess a guidance document with photos describing how to measure zone sizes, such as the CLSI M02 or the EUCAST disk diffusion reading guides?	**Y N**	
11.44	Does the lab possess a guidance document with photos describing how to measure gradient strip endpoints? *For example, ETEST Reading Guide for Aerobic Bacteria [PDF - 2 pages] (http://www.ilexmedical.com/files/ETEST_RG.pdf)*	**Y N**	

	Question	Answer	Comments
11.45	Does the SOP or bench aide instruct that zone sizes and/or MIC endpoints for co-trimoxazole (SXT) are measured at 80% inhibition of growth, rather than 100%?	**Y N**	
11.46	Does the SOP or bench aide instruct how to measure zones of inhibition and/or MIC endpoints when *Proteus* spp. swarming is present?	**Y N**	
11.47	Is the automated AST instrument software up to date? *Answer NA if the lab does not use automated AST instrument*	**Y N NA**	

INTERPRETING RESULTS

	Question	Answer	Comments
11.48	Is there evidence that appropriate actions are taken when the AST instrument software flags an AST result as questionable (such as checking for purity or repeating the test by another method)? *Answer NA if the lab does not use automated AST instrument*	**Y N NA**	
11.49	Is there evidence that microbiology staff have received adequate training to recognize intrinsic resistance patterns? (*Check SOPs and training/competence assessment records)* *1: Yes* *2: Some, but would like additional training* *3: No* *Note: Intrinsic resistance is defined as inherent or innate (not acquired) resistance which is reflected in the wild-type of all representatives of a species; e.g.,* Citrobacter *spp. and* Klebsiella *spp. are intrinsically (naturally) resistant to ampicillin.*	**1 2 3**	
11.50	Do the AST SOPs or bench aides provide examples of intrinsic resistance patterns? (Such as those found in CLSI M100 Appendix B or EUCAST Expert Rules V3.1) *Check SOPs and training/competence assessment records*	**Y N**	
11.51	Is there evidence that microbiology staff have received adequate training to recognize unusual or unexpected AST results that might require investigation? (e.g. *Klebsiella* spp. S to ampicillin; *Staphylococcus* spp. I/R to vancomycin) *Check SOPs and training/competence assessment records* *1: Yes* *2: Some, but would like additional training* *3: No*	**1 2 3**	
11.52	Do the AST SOPs or bench aides define examples of unusual or unexpected AST results? (Such as those found in CLSI M100 Appendix A or EUCAST Expert Rules V3.1)	**Y N**	
11.53	Do the AST SOPs or bench aides describe what actions to take when unusual or unexpected AST results are encountered (e.g., check purity, reconfirm organism ID, check relevant QC, repeat testing, notify supervisor)?	**Y N**	
11.54	Is there evidence of such actions being taken?	**Y N**	
11.55	Is the microbiology lead or supervisor informed when unusual AST results are identified?	**Y N**	
11.56	Does a supervisor review all AST results for unusual findings before results are given to physicians?	**Y N**	
11.57	Is there evidence that the supervisor received appropriate training on how to recognize unusual AST findings? *1: Yes* *2: Some, but would like additional training* *3: No*	**1 2 3**	

	BREAKPOINTS STANDARDS		
	Question	**Answer**	**Comments**
11.58	Which AST breakpoint standard does the lab primarily use? *1: CLSI* *2: EUCAST* *3: Other (please list in comments)* *4: None/mixed*	**1 2 3 4**	
11.59	Ask to see the lab's most current hard copy of the standard. Is it less than 3 years old?	**Y N**	
11.60	Does the lab obtain updates of the standard in use at least every 3 years?	**Y N**	
11.61	Does the lab review important standards changes, e.g., breakpoint changes, with the relevant hospital committees (e.g., pharmacy and therapeutics, stewardship)?	**Y N**	
11.62	Is there internet in the lab to access free EUCAST PDFs or CLSI M100 online version? EUCAST Guidance Documents in Susceptibility Testing (http://www.eucast.org/ast_of_bacteria/guidance_documents/) CLSI M100 and M60 (http://clsi-m100.com/)	**Y N**	
11.63	Is there evidence that microbiology staff have received adequate training on how to use the CLSI M100 or EUCAST documents effectively? *1: Yes* *2: Some, but would like additional training* *3: No*	**1 2 3**	
	For the next 3 questions, answer NA if the lab does not use considered disks		
11.64	Look at the cefotaxime disks currently in use. Does the drug concentration correspond correctly to the standard the lab uses? (CLSI breakpoints require 30µg disks, EUCAST breakpoints require 5µg disks).	**Y N NA**	
11.65	Look at the ceftazidime disks currently in use. Does the drug concentration correspond correctly to the standard in use? (CLSI breakpoints require 30µg disks, EUCAST breakpoints require 10µg)	**Y N NA**	
11.66	Look at the piperacillin-tazobactam disks currently in use. Does the drug concentration correspond correctly to the standard in use? (CLSI breakpoints require 100/10µg disks, EUCAST breakpoints require 30/6µg disks).	**Y N NA**	

12- AST EXPERT RULES

Please note: all questions refer only to clinical patient isolates, NOT to research or environmental isolates.

	EXPERT RULES FOR *SALMONELLA*		
	Question	**Answer**	**Comments**
	Review a patient AST report for a *Salmonella* or *Shigella* isolate. Were any of the following drug classes tested or reported? *(These drugs may appear active in vitro but are not effective clinically against* Salmonella *or* Shigella *and should not be reported as susceptible, regardless of the AST result.)*		
12.1	1st generation cephalosporins (cefazolin, cephalothin, cephapririn, cephadrine)	**Y N NA**	
12.2	2nd generation cephalosporins (cefuroxime, cefonicid, cefamandole)	**Y N NA**	
12.3	Cephamycins (cefoxitin, cefotetan)	**Y N NA**	
12.4	Aminoglycosides (gentamicin, tobramycin, amikacin)	**Y N NA**	
12.5	Does the lab use Nalidixic Acid to screen *Salmonella* isolates for ciprofloxacin resistance?	**Y N NA**	
12.6	Compare the lab's AST bench aids and SOPs to the *Salmonella* table in the Assessor's Guide. Does the lab use the correct fluoroquinolone (FQ) breakpoints for *Salmonella* spp? *(Enterobacteriaceae FQ breakpoints should not be used for* Salmonella *spp).*	**Y N NA**	

	GRAM NEGATIVES & BETA-LACTAM BREAKPOINTS		
	Question	**Answer**	**Comments**
	IMPORTANT! Please read the information below before proceeding: **Beginning in 2009, CLSI and EUCAST lowered the breakpoints for several beta-lactam antibiotics and Aztreonam in order to enhance the detection of resistance.** **Even if a laboratory has current CLSI or EUCAST manuals, they may have failed to update their bench aids and SOPs to reflect current breakpoints.** **Since the bench aids and SOPs are used by technologists for AST interpretation, it is crucial that these are up to date as well.** **The Assessor's Guide shows the current breakpoints for these antibiotics. Compare this table to the bench aids and SOPs the technologists use for zone size and MIC interpretation.** Do the bench aids and SOPs have the current breakpoints for the following combinations? *(Select NA if the antibiotic is not in use)*		
12.7	Enterobacteriaceae and Aztreonam	**Y N NA**	
12.8	Enterobacteriaceae and Cefotaxime	**Y N NA**	
12.9	Enterobacteriaceae and Ceftriaxone	**Y N NA**	
12.10	Enterobacteriaceae and Ceftazidime	**Y N NA**	
12.11	Enterobacteriaceae and Cefepime	**Y N NA**	
12.12	Enterobacteriaceae and Imipenem	**Y N NA**	
12.13	Enterobacteriaceae and Meropenem	**Y N NA**	
12.14	Enterobacteriaceae and Ertapenem	**Y N NA**	
12.15	Enterobacteriaceae and Doripenem	**Y N NA**	
12.16	*Acinetobacter* and Imipenem	**Y N NA**	
12.17	*Acinetobacter* and Meropenem	**Y N NA**	
12.18	*Acinetobacter* and Doripenem	**Y N NA**	
12.19	*Pseudomonas* and Cefepime	**Y N NA**	
12.20	*Pseudomonas* and Piperacillin	**Y N NA**	
12.21	*Pseudomonas* and Piperacillin-Tazobactam	**Y N NA**	
12.22	*Pseudomonas* and Ticarcillin-Clavulanate	**Y N NA**	

	Question	Answer	Comments
12.23	*Pseudomonas* and Imipenem	Y N NA	
12.24	*Pseudomonas* and Meropenem	Y N NA	
12.25	*Pseudomonas* and Doripenem	Y N NA	

	PHENOTYPIC ESBL TESTING		
	Question	**Answer**	**Comments**
	NOTE: Questions 12.26 and 12.27 only apply to labs that do NOT use current cephalosporin and aztreonam breakpoints. If this lab uses current breakpoints, select NA for both questions and skip to question 12.28		
12.26	Labs that do NOT use current cephalosporin and aztreonam breakpoints must perform routine ESBL phenotype testing. For ESBL-positive isolates, all penicillins, cephalosporins, and aztreonam that test susceptible must be reported as resistant. Is this practice (changing ESBL + interpretations from S to R) in place?	Y N NA	
12.27	Labs that do NOT use current aztreonam and cephalosporin breakpoints should attach a warning comment to the report for ESBL-positive organisms: "ESBL-producers should be considered clinically resistant to all penicillins, cephalosporins, and aztreonam." Is this practice in place?	Y N NA	
12.28	For labs that DO use current cephalosporin and aztreonam breakpoints, CLSI and EUCAST no longer recommend routine testing for ESBL phenotype. Furthermore, if ESBL testing is performed and the test is positive, interpretations for beta-lactam agents do NOT need to be changed from susceptible to resistant. Has the lab discontinued editing AST results based on the ESBL result? *Note: Select NA for the question above if the lab does NOT use current cephalosporin and aztreonam breakpoints*	Y N NA	
12.29	Does the lab perform any phenotypic tests for ESBL production? Including disks, gradient strips, or a screening well in an automated system. *If no, answer NA until Phenotypic Carbapenemase Testing Section*	Y N	
12.30	Does the phenotypic ESBL method include testing both cefotaxime (or ceftriaxone) AND ceftazidime alone and in combination with clavulanic acid?	Y N NA	
12.31	Does the lab perform any genotypic tests for ESBL production? (e.g., PCR)	Y N	
12.32	Do records indicate that quality control for ESBL testing is done either on a weekly basis or each time the test is performed?	Y N NA	
12.33	Do records indicate that lab uses both positive and negative control organisms to QC the ESBL test in use? (A commonly used ESBL-positive strain is Klebsiella pneumoniae ATCC 700603)	Y N NA	
12.34	When an ESBL-positive is confirmed, is infection control notified by the lab?	Y N NA	

	PHENOTYPIC CARBAPENEMASE TESTING		
	Question	**Answer**	**Comments**
12.35	Labs that do NOT use current carbapenem breakpoints must perform routine testing for carbapenemase production (e.g., CarbaNP, mCIM, or a molecular assay). If a carbapenemase is detected, all carbapenems that test susceptible must be reported as resistant. Is this practice (changing results from S to R based on positive carbapenemase test result) in place? *Note: Select NA if the lab uses current breakpoints*	Y N NA	
12.36	For labs that DO use current carbapenem breakpoints, CLSI and EUCAST no longer recommend routine testing for carbapenemase production. Furthermore, if such testing is performed and the test is positive, interpretations for carbapenems do NOT need to be changed from susceptible to resistant. Has the lab discontinued editing AST results based on the carbapenemase result? *Note: Select NA if the lab uses current breakpoints*	Y N NA	
	Does the lab perform any of the following phenotypic tests for carbapenemase production?		

	Question	Answer	Comments
12.37	Modified Hodge test	Y N	
12.38	Other disk method, e.g., combination disk test or double disk synergy	Y N	
12.39	MIC Strip test, e.g., Etest KPC, MBL or Liofilchem MRP/MBO, ETP/EBO	Y N	
12.40	Biochemical (colorimetric) test, e.g., CarbaNP, BCT, or β CARBA	Y N	
12.41	Chromogenic agar specific for carbapenemase producers	Y N	
12.42	Modified carbapenem inactivation method (MCIM)	Y N	
12.43	Does the lab perform any genotypic tests for carbapenemase production? (e.g., PCR, GeneXpert, etc.)	Y N	
12.44	Do records indicate that quality control is done each time carbapenemase testing is performed?	Y N NA	
12.45	Do records indicate that lab uses both positive and negative control organisms to QC the carbapenemase test in use? *Commonly used carbapenemase positive strains include Klebsiella pneumoniae ATCC BAA-1705, K. pneumonaie CCUG 56233, and K. pneumoniae NCTC 13438*	Y N NA	
12.46	When a carbapenemase producer is detected, is it noted on the final report to the clinician?	Y N NA	
12.47	When a carbapenemase producer is detected, is infection control notified by the lab?	Y N NA	

COLISTIN TESTING

	Question	Answer	Comments
	Does the lab perform colistin AST? (Not scored. If No, skip to next section.)	Y N	
	Which methods does the lab use for colistin AST? (Select Y for each method used)		
12.48	Disk diffusion	Y N	
12.49	Gradient strip (e.g., Etest/Liofilchem)	Y N	
12.50	Automated instrument (e.g., Vitek/Phoenix)	Y N	
12.51	Broth microdilution (BMD) with Polysorbate 80	Y N	
12.52	Broth microdilution (BMD) without Polysorbate 80	Y N	
12.53	Colistin Broth Disk Elution (CBDE) Test	Y N	
12.54	Agar dilution (Colistin Agar Test)	Y N	
12.55	Do records indicate that quality control for colistin AST is performed on either a weekly basis or each time the test is performed?	Y N NA	
12.56	Do records indicate that lab uses appropriate organisms to QC the colistin test in use? (*Pseudomonas aeruginosa* 27853 AND *E. coli* NCTC 13846 or *E. coli* AR Bank #0349).	Y N NA	
	When colistin resistance is detected, are any of the following notified?		
12.57	Lab supervisor	Y N NA	
12.58	Infectious Disease team	Y N NA	
12.59	Infection Control team	Y N NA	
12.60	When colistin resistance is detected, is the isolate sent to a reference lab for molecular characterization (e.g., testing for *mcr* genes)?	Y N NA	
12.61	If the lab uses broth microdilution for colistin AST, is colistin sulfate used, not colistin methane sulfonate (sulfomethate)? *The methane sulfonate derivative of colistin ("cms") is an inactive pro-drug that breaks down slowly in solution and therefore cannot be used for AST.*	Y N NA	
12.62	If the lab performs broth microdilution (BMD) for colistin AST, is cation-adjusted Mueller Hinton broth used? *Answer NA if the lab does not perform BMD.*	Y N NA	
12.63	Do laboratory staff understand the current limitations associated with colistin AST? (i.e., the risk of false susceptible results when using disk diffusion, gradient strip, or automated methods.)	Y N	

	Question	Answer	Comments
12.64	Has the lab educated the medical staff about the current limitations and risks associated with colistin AST?	**Y N**	

	EXPERT RULES FOR *STAPHYLOCOCCUS AUREUS*		
	Question	**Answer**	**Comments**
12.65	Does the lab test *S. aureus* isolates against penicillin? *If no, answer NA to next question*	**Y N**	
12.66	Are *S. aureus* isolates with penicillin zones sizes or MICs in the susceptible range tested for β-lactamase production using the zone-edge test before being reported as penicillin susceptible?	**Y N NA**	
12.67	Does the lab use oxacillin disks to test for MRSA?	**Y N**	
12.68	When oxacillin and cefoxitin results are discrepant for *S. aureus* (one is S and one is R), how does the lab report oxacillin? *1: Report the oxacillin interpretation, regardless of what the cefoxitin result is* *2: Report the cefoxitin interpretation, regardless of what the oxacillin result is* *3: If either drug tests R, report the result as R* *NA: the lab only tests one of these drugs, not both*	**1 2 3 NA**	
12.69	Does the lab perform *S. aureus* AST on any beta-lactam antibiotics other than penicillin, oxacillin, cefoxitin, or ceftaroline?	**Y N**	
12.70	Does the lab use vancomycin disks to test for VISA/VRSA?	**Y N**	
12.71	When a manual MIC method is used to test vancomycin against *Staphylococcus aureus*, is the test incubated for a full 24 hours before reading the result? *Answer NA if manual MIC method not used*	**Y N NA**	
12.72	When a vancomycin MIC >8 is detected for *S. aureus*, is the isolate sent to a referral lab for confirmation testing and further characterization? *Answer NA if vancomycin not tested*	**Y N NA**	
12.73	Are *S. aureus* that are resistant to Erythromycin and susceptible or intermediate to Clindamycin tested for inducible clindamycin resistance?	**Y N**	

	GENERAL CONSIDERATIONS FOR *STREPTOCOCCUS PNEUMONIAE*		
	Question	**Answer**	**Comments**
	Observe a *Streptococcus pneumoniae* AST plate being read *If lab does not perform disk or Etest for S. pneumoniae AST, select NA for all answers*		
12.74	Is the upper surface of the agar read with the cover removed?	**Y N NA**	
12.75	Is the plate illuminated adequately with reflected light?	**Y N NA**	
12.76	Are zones measured where growth is inhibited (as opposed to the zone of hemolysis)?	**Y N NA**	
12.77	Are there no more than 4 disks per 100mm plate or 9 disks per 150mm plate?	**Y N NA**	
12.78	If the lab uses an oxacillin disk (1ug) to screen for penicillin resistance in Strep. pneumoniae, what does the lab's SOP instruct when the zone size measures <19? (Referring to penicillin G or Benzylpenicillin, the IV formulation) *1: Report penicillin resistant* *2: Perform additional testing using a penicillin MIC method* *NA: lab does not perform oxacillin screen*	**1 2 NA**	

	EXPERT RULES FOR *STREPTOCOCCUS PNEUMONIAE*		
	Question	**Answer**	**Comments**
	Does the lab perform AST for *S. pneumoniae*? (Not scored. If No, skip to next section.)	**Y N**	
	Does the lab use the disk diffusion method to test any of the following antibiotics against *S. pneumonaie*?		
12.79	Penicillin	**Y N NA**	

	Question	Answer	Comments
12.80	Amoxicillin	Y N NA	
12.81	Ampicillin	Y N NA	
12.82	Cefotaxime	Y N NA	
12.83	Ceftriaxone	Y N NA	
12.84	Cefuroxime	Y N NA	
12.85	Cefepime	Y N NA	
12.86	Ertapenem	Y N NA	
12.87	Meropenem	Y N NA	
12.88	Imipenem	Y N NA	
	When *S. pneumoniae* is isolated from blood or cerebrospinal fluid, does the lab test the following antibiotics using an MIC method?		
12.89	Penicillin	Y N NA	
12.90	Ceftriaxone and/or Cefotaxime	Y N NA	
12.91	When *S. pneumoniae* is isolated from CSF, are penicillin, ceftriaxone, and/or cefotaxime reported using the meningitis breakpoints only?	Y N NA	
12.92	When *S. pneumoniae* is isolated from specimens other than CSF, are penicillin, ceftriaxone, and/or cefotaxime reported using both meningitis and non-meningitis breakpoints?	Y N NA	
12.93	Are *S. pneumoniae* that are resistant to Erythromycin and susceptible or intermediate to Clindamycin tested for inducible clindamycin resistance?	Y N NA	

	INDUCIBLE CLINDAMYCIN RESISTANCE TESTING		
	Question	**Answer**	**Comments**
12.94	Does the lab perform the test for Inducible Clindamycin Resistance (ICR), also known as the "D-test" on *Staphylococcus aureus* and/or *Streptococcus pneumoniae*?	Y N	
12.95	Does the SOP for the ICR test specify that the erythromycin and clindamycin disks must be placed 15-26 mm apart for *Staphylococcus* species?	Y N NA	
12.96	Does the SOP for the ICR test specify that the erythromycin and clindamycin disks must be placed 12 mm apart for *Streptococcus* species?	Y N NA	
12.97	Do records indicate that quality control for ICR testing is done either on a weekly basis or each time the test is performed?	Y N NA	
12.98	Do records indicate that lab uses both positive and negative control organisms to QC the ICR test in use? (Commonly used ICR positive strain is *S. aureus* ATCC BAA-977)	Y N NA	
12.99	When the ICR test is positive, is the clindamycin result changed to resistant?	Y N NA	

	EXPERT RULES FOR CEREBROSPINAL FLUID (CSF)		
	Question	**Answer**	**Comments**
	Review a patient AST report for a positive CSF culture. Were any of the following drug classes tested or reported? *(These are not the drugs of choice and may not be effective for treating CSF infections, regardless of the AST result)*		
12.100	1st generation cephalosporins (cefazolin, cephalothin, cephapirin, cephadrine)	Y N NA	
12.101	2nd generation cephalosporins (cefuroxime, cefonicid, cefamandole)	Y N NA	
12.102	Cephamycins (cefoxitin, cefotetan)	Y N NA	
12.103	Clindamycin	Y N NA	
12.104	Macrolides (Erythromycin, Azithromycin, Clarithromycin)	Y N NA	
12.105	Tetracyclines (Tetracycline, Minocycline, Doxycycline)	Y N NA	
12.106	Fluoroquinolones (Ciprofloxacin, Levofloxacin, Moxifloxacin)	Y N NA	
12.107	Nitrofurantoin	Y N NA	

13- AST PANELS, POLICY & ANALYSIS

Please note: all questions refer only to clinical patient isolates, NOT to research or environmental isolates.

	AST PANELS		
	Question	**Answer**	**Comments**
	Is there an SOP that clearly defines the standard combination of antibiotics ("antibiotic panels") the lab will test against each of the following pathogens? (CLSI and EUCAST documents are not SOPs)		
13.1	*Staphylococcus aureus*	**Y N**	
13.2	*Enterococcus spp*	**Y N**	
13.3	*Streptococcus pneumoniae*	**Y N**	
13.4	Enterobacteriaceae	**Y N**	
13.5	*Salmonella spp*	**Y N**	
13.6	*Acinetobacter spp*	**Y N**	
13.7	*Pseudomonas aeruginosa*	**Y N**	
13.8	Review several patient AST reports for *E. coli*. Is the same combination of antibiotics tested each time?	**Y N**	
	Does the SOP clearly define how to modify the standard antibiotic panels described above based upon the body site of infection? ONLY select NA if the laboratory does not perform testing on the body site listed.		
13.9	Urine	**Y N NA**	
13.10	CSF	**Y N NA**	
13.11	Blood	**Y N NA**	

	CUMULATIVE ANTIBIOGRAMS		
	Question	**Answer**	**Comments**
13.12	Does the lab produce a cumulative antibiogram at least annually?	**Y N**	
13.13	Does the lab have a software program to produce the antibiogram?	**Y N NA**	
	Review the most recent cumulative antibiogram. Does it adhere to the following CLSI M39 recommendations?		
13.14	Clearly displays the inclusive date range (e.g. Jan 1, YYYY – Dec 31, YYYY)	**Y N NA**	
13.15	Clearly displays the name of the hospital/facility	**Y N NA**	
13.16	Data is presented as %S (not %R)	**Y N NA**	
13.17	For each organism, the total N tested is displayed	**Y N NA**	
13.18	Only presents data for organisms/antibiotics where the total N = 30 or more isolates	**Y N NA**	
13.19	Are isolates from environmental cultures and screening cultures (e.g., MRSA screen, VRE screen) excluded from the analysis?	**Y N NA**	
13.20	Is the lab able to de-duplicate the data, so that only the first isolate of a given species per patient, per analysis period is included, irrespective of the body site of recovery?	**Y N NA**	
13.21	Is the lab able to separate Inpatient data from outpatient data?	**Y N NA**	
13.22	If the lab serves multiple hospitals/facilities, are they able to separate the data by Facility?	**Y N NA**	
13.23	Is the cumulative antibiogram reviewed annually by either an Antibiotic Stewardship or a Pharmacy & Therapeutics Committee?	**Y N NA**	
13.24	Is the cumulative antibiogram distributed to all physicians?	**Y N NA**	

	AST POLICY		
	Question	**Answer**	**Comments**
13.25	Does lab policy primarily determine which isolates receive AST, or is AST performed only when it is specifically requested by the doctor? *1: Lab policy primarily determines* *2: Only when requested by clinician* *3: Equal mix of both*	**1 2 3**	

	Question	Answer	Comments
13.26	Does lab policy primarily determine which antibiotics to test and report, or does the lab only test and report the antibiotics specifically requested by the physician? *1: Lab policy primarily determines* *2: Only the antibiotics requested by physician* *3: Equal mix of both*	**1 2 3**	
	"Cascade reporting" is a strategy of selective reporting of AST results in which secondary agents (e.g., broader spectrum, more costly) may be suppressed or excluded from the patient report if an organism is susceptible to primary agents within the same drug class.		
13.27	Does the lab practice "cascade reporting"? *If no, answer NA to next question*	**Y N**	
	With cascade reporting, there is a risk that the AST results excluded from the patient report may also be excluded from the main data repository or LIS. This can lead to highly biased AMR surveillance and cumulative antibiogram statistics.		
13.28	If the lab practices cascade reporting, is it done in a way which ensures that the AST results excluded from the patient report are NOT excluded from the LIS or other main data repository?	**Y N NA**	
13.29	Does the hospital have an Antibiotic Stewardship Committee?	**Y N NA**	
13.30	If the hospital has an Antibiotic Stewardship Committee, is a microbiologist a member?	**Y N NA**	
13.31	Does the hospital have a Pharmacy and Therapeutics Committee?	**Y N NA**	
13.32	If the hospital has a Pharmacy and Therapeutics Committee, is a microbiologist a member?	**Y N NA**	
13.33	Does the hospital's Antibiotic Stewardship or Pharmacy and Therapeutic Committee meet at least annually to review national or international AST panel recommendations and modify them based on the hospital's formulary and cumulative antibiogram?	**Y N NA**	

SAFETY

To be completed if there is no record of another safety audit in the past 12 months. This is not intended to be a comprehensive safety audit.

	BIOSAFETY EQUIPMENT		
	Question	**Answer**	**Comments**
	Is standard safety equipment available and in use in the laboratory?		
SA1	Biosafety cabinets (Class IIA)	**Y N**	
SA2	Covers on each centrifuge bucket	**Y N**	
SA3	Cover over centrifuge rotor	**Y N**	
SA4	Hand-washing station	**Y N**	
SA5	Eyewash station/bottle	**Y N**	
SA6	Sharps containers	**Y N**	
SA7	Flame cabinet (for securely storing flammable liquids, e.g. ethanol)	**Y N**	
SA8	Spill kit	**Y N**	
SA9	First aid kit	**Y N**	
	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.*		
SA10	Have all biosafety cabinets been recertified within a year of today's date?	**Y N**	
	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.		

	PERSONAL PROTECTIVE EQUIPMENT		
	Question	**Answer**	**Comments**
	Is all necessary personal protective equipment (PPE) available for BSL2?		
SA11	Gowns	**Y N**	
SA12	Gloves	**Y N**	
SA13	Eye protection	**Y N**	
SA14	Aerosol face protection (respirator, face shield, or splatter guard)	**Y N**	
SA15	Does lab policy require microbiology staff to wear close-toed shoes?	**Y N**	
SA16	Is PPE utilized appropriately and consistently by laboratory staff? (Observe) *1: Yes* *2: Partial* *3: No*	**1 2 3**	
	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.		

	BIOSAFETY BEHAVIORS		
	Question	**Answer**	**Comments**
SA17	Does lab policy prohibit eating, drinking, and smoking in the laboratory?	**Y N**	
	Observe the refrigerators and freezers where media and reagents are stored. Are they:		
SA18	Designated specifically for storage of media/reagents?	**Y N**	
SA19	Free of staff food items?	**Y N**	
SA20	Free of patient samples?	**Y N**	
SA21	Well organized and free of clutter?	**Y N**	
SA22	Are all hazardous chemicals stored appropriately (acids separate from alkaline; flammables in a flame cabinet)?	**Y N**	
SA23	Is work area (bench and hood) disinfection documented daily?	**Y N**	
	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.		

	BIOSAFETY DOCUMENTATION AND TRAINING		
	Question	**Answer**	**Comments**
SA24	Is a safety/biosafety manual available in the laboratory and easily accessible to all staff?	**Y N**	
SA25	Is a training module in safety/biosafety available in the laboratory?	**Y N**	
SA26	Is there documentation demonstrating that an annual safety/biosafety refresher course is conducted for all staff handling specimens, isolates, or chemicals?	**Y N**	
SA27	Is there documentation demonstrating that accident/incident investigations are systematically conducted?	**Y N**	
SA28	Are risk assessments conducted annually and each time a new analysis/technology/equipment is introduced?	**Y N**	

NOTES:

Centers for Disease Control and Prevention
National Center for Emerging and Zoonotic Infectious Diseases
Division of Healthcare Quality Promotion