WHO-IAMM Network for Surveillance of Antimicrobial Resistance (WINSAR)

Laboratory Assessment Tool for Antimicrobial Resistance Testing

Introduction

Laboratories play a critical role in the process of antimicrobial resistance (AMR) surveillance.

The purpose of this laboratory assessment tool is to assess the capacity of participating laboratories in WHO-IAMM Network for Surveillance of Antimicrobial Resistance (WINSAR) being coordinated jointly by WHO and IAMM to meet requirements for AMR testing and to identify needs for capacity building using a standardized approach and methodology.

This tool has been adapted for WINSAR from the WHO Lab Assessment Tool for assessing the capacity of National AMR Reference Labs.

Questionnaire sections

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A. Laboratory identification

1.	State	
2.	District	
3.	Name of the laboratory	
4.	Type of the laboratory	☐ Medical college (government) ☐ Medical college (autonomous/private) ☐ Private Hospital ☐ Other (kindly specify)
5.	Address	
6.	Telephone (institution)	
7.	E-mail (institution)	
8.	Head, Microbiology laboratory • Name: • Phone: • Email:	
9.	Date of self-assessment (DD/MM/YYYY)	
10.	External assessors (if applicable) • Name: • Organization: • Email:	
11.	AMR surveillance focal point • Name: • Title/designation: • Phone: • Email:	
12.	Indicate for which of these organisms the laboratory carries out identification and antibiotic susceptibility testing (AST) Include any additional information and list any other organisms which are tested.	☐ *Staphylococcus aureus* ☐ *Enterococcus spp.* ☐ *Klebsiella pneumoniae* ☐ *Escherichia coli* ☐ *Acinetobacter spp.* ☐ *Pseudomonas spp.* ☐ *Salmonella spp.* ☐ *Shigella spp.* ☐ *Vibrio cholerae* ☐ *Neisseria gonorrhoeae* ☐ *Streptococcus pneumoniae* ☐ *Haemophilus influenzae* ☐ Other organisms (kindly specify)
13.	Are AMR/AST services provided to other laboratories?	☐ Confirmatory testing (for ID and AST) ☐ AMR/AST training / technical support ☐ Auditing ☐ Other (provide details)
14.	Estimated human population covered	☐ Population covered: ☐ Not known
15.	Number of tests done (in previous calendar year)	☐ Bacterial cultures: ☐ AST: ☐ MICs:
16.	Any additional comments related to this section	

B. Organization and management

1.	Service hours (days and hours of operation of the laboratory service)	☐ Routine working hours: ☐ Emergency services (cultures/AST):
2.	External communication	☐ Computer ☐ Internet access
3.	Is there timely notification to patients or clients (including other laboratories) during service delays?	☐ Yes ☐ No
4.	Financing (for microbiology cultures/AST) Please indicate the source of funds	☐ Department of Health ☐ Municipal Corporation ☐ Other government sources ☐ NGO/autonomous ☐ Private sector ☐ Specific networks (provide details) ☐ Other (provide details)
5.	Is there a dedicated budget for the microbiology lab?	☐ Yes ☐ No
6.	Is the budget for the laboratory sufficient and adequate for its operations and to fully cover all its services and functions?	☐ Yes ☐ No
7.	If there are gaps or challenges in the financing, identify them:	
8.	Does the laboratory have an internal audit programme?	☐ Yes ☐ No
9.	When was the last internal audit carried out?	
10.	Does the laboratory hold any form of valid certification and/or accreditation (ISO 9001, ISO 17025, ISO 15189, NABL, NABH)?	☐ Yes ☐ No
11.	If yes, please provide details of the relevant standards and the names of the certification/accreditation bodies	
12.	If no, are there current plans to acquire any form of certification/accreditation?	☐ Yes (provide details) ☐ No
13.	Any additional comments relevant to this section	

C. Facilities and operational set-up

1.	Work conditions: Does the laboratory face electricity interruption?	☐ Never ☐ Sometimes ☐ Regularly
2.	If applicable, do you have an emergency electric generator or other backup power source?	☐ Yes ☐ No
3.	Is key/sensitive equipment protected by an uninterruptable power supply (UPS)	☐ Yes ☐ No
4.	If there is a machine shutdown or breakdown, do you have a backup plan for it?	☐ Yes ☐ No If yes, kindly provide details
5.	Does the laboratory face water shortages?	☐ Never ☐ Sometimes ☐ Regularly

6.	Is the space allocated sufficient to perform the work without compromising the quality of the work and safety of the personnel?	☐ Yes ☐ No
7.	Any additional comments relevant to this section	

D. Human resources

1.	How many of following staff are working in bacteriology?	☐ Clinical microbiologists Number: ☐ Non-medical microbiologists Number: ☐ Laboratory technologists Number: ☐ Laboratory assistants Number: ☐ Data managers/data entry operators Number: ☐ Others • _____; number: • _____; number:
2.	Qualifications/competency of staff: Are qualifications, training, and experience of staff, job descriptions (or terms of reference) and staff duties documented and available?	☐ Yes ☐ No
3.	CME/training/capacity building: Is there continuous education and training for staff? i.e. regular updates on protocols, procedures, access to journals, etc.	☐ Yes ☐ No
4.	Does your laboratory provide training (regular, planned or random as per availability of funds) or technical support for AMR surveillance?	☐ Yes ☐ No
5.	If yes, does the laboratory do on-site and/or training?	☐ On-site training ☐ Off-site training
6.	If yes to either, briefly describe the trainings provided	
7.	Do you have a budget for training programmes?	☐ Yes ☐ No
8.	Any additional comments or constraints relevant to this section	Number of contractual staff: Problems if any?

E. Quality management system and quality assurance

1.	Has a (laboratory) quality manager been designated?	☐ Yes ☐ No
2.	How often are Quality Management System (QMS) and Quality Assurance (QA) protocols reviewed and updated?	
3.	Is there a risk management system?	☐ Yes ☐ No
4.	Is a quality manual describing the quality system policy and the quality procedures available?	☐ Yes ☐ No
5.	If yes, does it cover these topics:	☐ Documentation and records ☐ Pre-analytical procedures ☐ Analytical procedures ☐ Post-analytical procedures ☐ Documentation & managing non-conformances ☐ Safety and facilities ☐ Equipment ☐ Reagents and consumables ☐ Internal quality control procedures (IQC) ☐ External quality assessment (EQA) procedures ☐ Others (include details)
6.	Are international standards for AST being followed?	☐ Yes ☐ No If yes, kindly specify: ☐ CLSI ☐ EUCAST ☐ Other (kindly specify)
7.	Are all standard operating procedures (SOPs) for bacteriology and AST available to staff?	☐ Yes ☐ No Specify the format ☐ Hard copy ☐ Electronic
8.	Are SOPs reviewed at least annually and any necessary amendments incorporated and tracked?	☐ Yes ☐ No
9.	Are SOPs in place for antimicrobial susceptibility testing methods?	☐ Yes ☐ No
10.	Are current versions of published standards and other similar documents in use in the laboratory available (e.g. guidelines, manuals, kit inserts, etc.)?	☐ Yes ☐ No
11.	Are procedures for the validation and verification of methods and equipment in place?	☐ Yes ☐ No
12.	Are procedures in place to record incidents or complaints?	☐ Yes ☐ No
13.	If yes, are corrective actions implemented and recorded?	☐ Yes ☐ No
14.	Any additional comments relevant to this section?	

F. Referral details

1.	Are sample collection procedures documented and available to staff?	☐ Yes ☐ No
2.	Do these include acceptance and rejection criteria for each specimen?	☐ Yes ☐ No
3.	Do these include minimum patient identification details?	☐ Yes ☐ No Provide details ☐ Name ☐ Age ☐ Sex ☐ Address ☐ Hospital ID/number (MRD/CR number) ☐ Lab ID/number ☐ Patient location ☐ Treating/consulting doctor ☐ Date of admission ☐ Other details (kindly specify)
4.	Does the lab accept samples only on a standard lab requisition form?	☐ Yes ☐ No
5.	Are primary specimens appropriately stored if not immediately examined?	☐ Yes ☐ No
6.	Is there a procedure for the storage of primary specimens once analysed?	☐ Yes ☐ No
7.	Is there a separate area for specimen collection/receipt/storage?	☐ Yes ☐ No
8.	Isolates referral/transport: Does the laboratory have appropriate triple packaging system as per IATA/UN regulations?	☐ Yes ☐ No
9.	Does the lab have enough trained staff to ensure safe shipment of isolates?	☐ Yes ☐ No
10.	Are those in charge of shipments trained in international regulations and transport of infectious substances?	☐ Yes ☐ No
11.	Do they have valid certificates?	☐ Yes ☐ No
12.	Does the laboratory receive specimens or isolates from the field or other laboratories for investigation of public health events/outbreaks?	☐ Yes ☐ No
13.	Is the laboratory equipped to store isolates?	☐ Yes ☐ No If yes, numbers of ☐ Deep freezers: ☐ Lyophilizer:
14.	Any additional comments relevant to this section	

G. Reporting

1.	Do you send/receive critical resistance phenotypes for confirmation/reporting of emerging resistance	☐ Send ☐ Receive If yes, provide details ☐ Ceftriaxone resistant typhoidal *Salmonella* ☐ Colistin resistant *Enterobacteriaceae* ☐ Colistin resistant non-fermenting bacteria ☐ VRSA/VISA

		☐ Others (provide details)
2.	Is a list of national or state "notifiable" diseases for reporting available? *Notifiable means penalty for not reporting to public health authorities*	☐ Yes ☐ No
3.	Is regular "reporting" of AMR/AST to public health authorities (IDSP) established and implemented?	☐ Yes ☐ No
4.	Is information systematically provided to clinicians or infection control specialists about AST patterns (using antibiograms)?	☐ Yes ☐ No
5.	Is the laboratory regularly submitting AST data to any AMR surveillance network?	☐ Yes ☐ No Format ☐ WHONET ☐ Other (kindly specify) Frequency of submission ☐ Monthly ☐ Quarterly ☐ Other (kindly specify)
6.	Any additional comments relevant to this section	

H. Data and information management

1.	Test results and reports: Is there an immediate notification of critical results to relevant clinicians and/or state/district authorities?	☐ Yes ☐ No
2.	Does the laboratory provide basic statistical data (e.g. number of tests ordered, aggregated qualitative and quantitative data, etc.)?	☐ Yes ☐ No
3.	Is lab data stored in a paper-based or electronic system?	☐ Paper-based ☐ Electronic
4.	Data security & confidentiality: Are access and modification of patient data controlled and protected?	☐ Yes ☐ No
5.	Is efficient back-up in place to prevent loss of patient test result data in case of theft or other incidents?	☐ Yes ☐ No
6.	Are reported data (copies) retained as long as medically relevant or required by the authorities?	☐ Yes ☐ No
7.	IT and Laboratory Information Management System (LIMS):	☐ Yes ☐ No If yes, provide details of the LIMS
8.	Is the LIMS used for data analysis?	☐ Yes ☐ No
9.	Is LIMS a part of the Hospital Information System (HIS)?	☐ Yes ☐ No
10.	Is WHONET used by the laboratory?	☐ Yes ☐ No If yes, is it used for preparing hospital antibiograms ☐ Yes ☐ No
11.	Any additional comments relevant to this question	

I. Consumables and reagents

1.	Procurement: Is the procurement centralised or decentralised?	☐ Centralised ☐ Decentralised
2.	Is the purchase of consumables and reagents recorded?	☐ Yes ☐ No
3.	Are consumables and reagents inspected upon receipt?	☐ Yes ☐ No
4.	Does the laboratory experience problems with reagent delivery like delays, temperature not adequate, reference errors, etc.?	☐ Never ☐ Sometimes ☐ Regularly Provide details
5.	Is the supply of media for cultures, identification and AST recorded?	☐ Yes ☐ No
6.	Do you experience challenges with media supply, quality and contamination?	☐ Yes ☐ No
7.	Do you have a continuous supply of AST discs, MIC panels, antibiotic powder for broth microdilution?	☐ Yes ☐ No
8.	If you are using automated AST, do you experience interruptions of reagent or consumable supplies?	☐ Yes ☐ No
9.	Are there protocols in place for acceptance/rejection and quality assurance of consumables and reagents?	☐ Yes ☐ No
10.	Are consumables and reagents appropriately stored (temperature, humidity, etc.)?	☐ Yes ☐ No
11.	Any additional comments relevant to this section	

J. Biorisk management policy

1.	Is a policy concerning the management of laboratory biorisk (biosafety and biosecurity) available?	☐ Yes ☐ No
2.	If yes, does the policy clearly state the risk assessment for extreme drug resistant organisms?	☐ Yes ☐ No ☐ Not applicable
3.	If yes, do these conform to national/state recommendations and/or international standards?	☐ Yes ☐ No ☐ Not applicable
4.	If yes, are the following addressed:	☐ Personal protective equipment (PPE) ☐ Disinfection and sterilisation ☐ Waste disposal ☐ Access restriction ☐ Biosafety of equipment ☐ Emergency protocols ☐ Others (provide details)
5.	Does the laboratory have a biosafety manual	☐ Yes ☐ No
6.	If yes, does it include management of biomedical waste?	☐ Yes ☐ No
7.	Are material safety data sheets (MSDS) available in the laboratory?	☐ Yes ☐ No

8.	What is the containment level of the bacteriology laboratory?	☐ BSL 1 ☐ BSL 2 ☐ BSL 3
9.	Does the lab have a certified biosafety cabinet(s)?	☐ Yes ☐ No If yes, number:
10.	Any additional comments relevant to this section	

K. Public health functions for AMR

1.	Surveillance and response: Is the laboratory part of any surveillance network/s for AMR?	☐ Yes ☐ No
2.	If yes, provide details of participation in city, state, national or international AMR surveillance/networks	
3.	Does the laboratory have defined responsibilities in state preparedness and response to public health emergencies like outbreaks?	☐ Yes ☐ No If yes, provide details
4.	Are specific instructions or guidelines available for the laboratory investigation of public health events?	☐ Yes ☐ No If yes, provide details
5.	Any additional comments relevant to this section	

L. Confirmation of identification, antimicrobial susceptibility testing (AST) and molecular testing

1.	Does the laboratory carry out the following methods for identification of micro-organisms:	Manual identification ☐ Few selected organisms ☐ All organisms, including fastidious ones Automated identification system ☐ Vitek 2 ☐ MicroScan ☐ BD Phoenix ☐ MALDI-TOF ☐ Other (provide details)
2.	Does the laboratory carry out the following methods for AST:	Manual methods ☐ Disk diffusion ☐ Gradient strip ☐ Agar dilution ☐ Broth microdilution Automated methods ☐ Vitek 2 ☐ MicroScan ☐ BD Phoenix ☐ MALDI-TOF ☐ Other (provide details)

3.	Describe the molecular methods and molecular targets used for confirmation of AMR and unusual patterns of AMR	☐ Yes ☐ No If yes, provide details: ☐ Molecular methods: ☐ Molecular targets:
4.	Which guidelines are used for the interpretation of AST	☐ CLSI ☐ EUCAST ☐ Other (please provide details)
5.	Are the AST guidelines updated annually?	☐ Yes ☐ No
6.	Is identification and AST carried out according to a SOP – organisms and antibiotics?	☐ Yes ☐ No ☐ Partial
7.	Any additional comments relevant to this section	

M. Media

1.	Is your media (culture & AST) prepared in-house or outsourced externally?	☐ Prepared in-house ☐ Commercial pre-poured media Provide details
2.	Blood used in Blood/Chocolate agar	☐ Sheep blood ☐ Human blood (from blood bank) ☐ Not used
3.	Medium used for AST	☐ Mueller Hinton Agar Details: ☐ Other (kindly specify):
4.	Are you adjusting media based on the AST interpretation method used by the lab e.g. adjusting pH for AST media (Mueller Hinton)?	☐ Yes ☐ No Provide details
5.	Quality control for media	☐ In-house ☐ QC report from supplier ☐ Not done
6.	Any additional comments relevant to this section	

N. Reference strains

1.	Do you use reference strains to perform routine QC?	☐ Yes ☐ No
2.	If yes, do you use ATCC or other reference strains?	☐ ATCC ☐ NCTC ☐ MTCC (IMTech)
3.	Reference strains used (provide details)	☐ *Staph aureus* ATCC 29213 ☐ *Escherichia coli* ATCC 25922 ☐ *Pseudomonas aeruginosa* ATCC 27853 ☐ *Enterococcus fecalis* ATCC 29212 ☐ *Streptococcus pneumoniae* ATCC 49619

		☐ *Haemophilus influenzae* ATCC 49766 ☐ *Escherichia coli* ATCC 35218 ☐ Others (kindly specify)
4.	How often do you perform QC for AST?	☐ Daily ☐ Weekly ☐ Other (kindly specify)
5.	Any additional comments relevant to this section	

O. Proficiency testing (PT)/ external quality assessment (EQA)

1.	Participation in PT/EQA programmes: Does the laboratory participate in an EQAS programme for ID and AST?	☐ Yes ☐ No	
2.	EQAS provider	☐ IAMM (CMC Vellore) ☐ Other	
3.	Is your EQAS service provider accredited (ISO 15189)?	☐ Yes ☐ No	
4.	Since when has the laboratory been participating in EQAS?		
5.	Total score (in percent)	2017 ☐ Q1: ☐ Q2: ☐ Q3: ☐ Q4:	2018 ☐ Q1: ☐ Q2: ☐ Q3: ☐ Q4:
6.	Score for Bacteriology (identification and AST, in percent)	2017 ☐ Q1: ☐ Q2: ☐ Q3: ☐ Q4:	2018 ☐ Q1: ☐ Q2: ☐ Q3: ☐ Q4:
7.	Which AST methods in your laboratory are subject to EQAS?	☐ Disk diffusion ☐ Automated methods	
8.	Any additional comments relevant to this section		

P. Additional comments
