Troubleshooting form

Record ID 9

Form Approved
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Discrepancies in testing results can often be a result of multiple factors. Providing specific details about the testing conditions will help identify any potential issues. Please fill and submit this form. Files including laboratory/instrument results can be attached in this form.

Many fields are required. If not applicable, please enter "NA"

I. Contact & Order Information

Requester name

* must provide value

Individual filling out this form

Requester Institution

* must provide value

Requester email

* must provide value

AR Bank order number(s) affected

* must provide value

If multiple order numbers, separate each order with a comma (i.e 2023-0944, 2024-2142)

Panel(s) affected

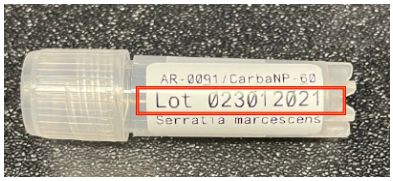
* must provide value

- [ ] Acinetobacter baumannii (ACI)
- [ ] Aspergillus fumigatus (ASP)
- [ ] Aminoglycoside/tetracycline Resistance (ATR)
- [ ] Enterobacteriales Carbapenem Breakpoint (BIT)

- [ ] Staphylococcus with Borderline Oxacillin Susceptibility (BORSA)
- [ ] Drug Resistant Candida species (CAN)
- [ ] Candida auris (CAU)
- [ ] Clostridioides difficile EIP 2016 (CDI)
- [ ] Gram Negative Carbapenemase Detection (CarbaNP)
- [ ] Enterobacteriales Carbapenemase Diversity (CRE)
- [ ] Ceftolozane/tazobactam (CTV)
- [ ] Ceftazidime/avibactam (CZA)
- [ ] Delafloxacin(DLX)
- [ ] Difficult-to-Detect Staphylococcus aureus (DTD)
- [ ] Multi-site Gram-negative Surveillance Initiative (ESBL)
- [ ] Cefepime/zidebactam (FPZ)
- [ ] Neisseria gonorrhoeae (GC)
- [ ] Enteric Pathogen Diversity (GI)
- [ ] IMP-type metallo-β-lactamase Supplement (IMP)
- [ ] Imipenem/relebactam (IMR)
- [ ] Meropenem-vaborbactam (MEV)
- [ ] Multi-mechanism panel (MULTI)
- [ ] Neisseria Ciprofloxacin (NCIP)
- [ ] Isolates with New or Novel Antibiotic Resistance (NEW)
- [ ] Neisseria species Identification (NID)
- [ ] Plazomicin (PLZ)
- [ ] Pseudomonas aeruginosa (PSA)
- [ ] Shigella sonnei and Shigella flexneri (SHG)
- [ ] Salmonella enterica serovar Infantis (SIN)
- [ ] Tedizolid/Linezolid (Oxazolidinones) Resistant Staphylococci (TLZD)
- [ ] Vancomycin Intermediate Staphylococcus aureus (VISA)
- [ ] Vancomycin-Resistant Enterococci (VRE)
- [ ] WHO Neisseria gonorrhoeae Reference (WHO)

Isolate(s) and Aliquot lot number(s)

- ***AR Bank Bank numbers (i.e AR-0001, AR-0085)***
- ***Aliquot lot numbers are located on the aliquot vial, as shown in image below***



* must provide value

If multiple lot numbers, separate each lot with a comma (i.e 022001002, 023012024)

Testing purpose. ***Select all that apply***

* must provide value

- [ ] Validation/Verification
- [ ] Aid development of a diagnostic test
- [ ] Aid development of a new drug
- [ ] Proficiency Testing
- [ ] Research
- [ ] Other

What type of testing are you performing and having issues with?

- [ ] Antimicrobial susceptibility testing (e.g broth microdilution, disk diffusion, etc.)

* must provide value

- [ ] Lateral flow assay (LFA)
- [ ] Molecular (e.g PCR, MALDI-TOF, WGS, etc.)
- [ ] Phenotypic test (e.g Modified CIM test, modified Hodge test, chromogenic agars, etc.)
- [ ] Purity
- [ ] Viability
- [ ] Other

II. General Test Information

1. Which Antimicrobial Susceptibility Testing (AST) and/or method was performed? ***Select all that apply***

* must provide value

- [ ] Reference broth microdilution
- [ ] Agar dilution
- [ ] Disk diffusion
- [ ] Gradient diffusion
- [ ] Commercial MIC/broth microdilution test
- [ ] Other

2. Was the testing performed following the manufacturer's recommendations (for commercial tests)?

- ( ) Yes
- ( ) No

3. Were quality control strains tested?

* must provide value

- ( ) Yes
- ( ) No

4. What drugs have discrepant results? ***Select all that apply***

* must provide value

- [ ] Not Applicable
- [ ] Amikacin
- [ ] Amoxicillin
- [ ] Amoxicillin/clavulanic acid
- [ ] Amphotericin B
- [ ] Ampicillin
- [ ] Ampicillin/sulbactam
- [ ] Anidulafungin
- [ ] Azithromycin
- [ ] Aztreonam
- [ ] Aztreonam/avibactam
- [ ] Caspofungin
- [ ] Cefazolin
- [ ] Cefepime
- [ ] Cefepime/tazobactam
- [ ] Cefepime/zidebactam
- [ ] Cefiderocol
- [ ] Cefixime
- [ ] Cefotaxime
- [ ] Cefotaxime/clavulanic acid
- [ ] Cefoxitin
- [ ] Cefpodoxime
- [ ] Cefquinome
- [ ] Ceftaroline
- [ ] Ceftazidime
- [ ] Ceftazidime/avibactam
- [ ] Ceftazidime/clavulanic acid
- [ ] Ceftiofur
- [ ] Ceftolozane/tazobactam

- [ ] Ceftriaxone
- [ ] Chloramphenicol
- [ ] Ciprofloxacin
- [ ] Clindamycin
- [ ] Colistin
- [ ] Daptomycin
- [ ] Delafloxacin
- [ ] Doripenem
- [ ] Doxycycline
- [ ] Eravacycline
- [ ] Ertapenem
- [ ] Erythromycin
- [ ] Florfenicol
- [ ] Fluconazole
- [ ] Flucytosine
- [ ] Imipenem
- [ ] Imipenem/relebactam
- [ ] Imipenem+chelators
- [ ] Isavuconazole
- [ ] Itraconazole
- [ ] Levofloxacin
- [ ] Linezolid
- [ ] Meropenem
- [ ] Meropenem-vaborbactam
- [ ] Metronidazole
- [ ] Minocycline
- [ ] Moxifloxacin
- [ ] Mupirocin
- [ ] Nalidixic acid
- [ ] Nitrofurantoin
- [ ] Omadacycline
- [ ] Oxacillin
- [ ] Penicillin
- [ ] Piperacillin/tazobactam
- [ ] Polymyxin B
- [ ] Posaconazole
- [ ] Quinupristin/dalfopristin
- [ ] Rifampin
- [ ] Spectinomycin
- [ ] Streptomycin
- [ ] Sulfisoxazole
- [ ] Tedizolid
- [ ] Teicoplanin
- [ ] Telithromycin
- [ ] Tetracycline
- [ ] Tigecycline
- [ ] Tobramycin
- [ ] Trimethoprim/sulfamethoxazole
- [ ] Vancomycin
- [ ] Voriconazole

- [ ] Gentamicin
- [ ] Sulbactam/durlobactam
- [ ] Telavancin

III. Pre-Analytic Troubleshooting

5. How were the frozen stock isolates stored before and after subculture? Include length of time, temperature, and any deviations from normal.

* must provide value

6. When retrieving isolates for subculture, were isolates kept from thawing by using either dry ice or freezer blocks/packs, or equivalent?

- ○ Unknown
- ○ Yes
- ○ No

7. Were isolates subjected to any freeze-thaw cycles?

* must provide value

- ○ Unknown
- ○ Yes
- ○ No

8. For subculture, what media was used?

* must provide value

9. On what passage number (from frozen stock) were the isolates being tested?

* must provide value

10. Were the isolates pure?

* must provide value

- ○ Unkown
- ○ Yes
- ○ No

IV. Analytic Troubleshooting

11. What methodology was used to prepare the organism suspension equivalent to a 0.5 McFarland standard? (i.e., direct colony suspension from agar plate or broth culture method).

* must provide value

12. What device was used to determine density of the inoculum suspension equivalent to a 0.5 McFarland? i.e., Turbidity meter, nephelometer, manual card (Wickerham card). Please list device type and brand.

* must provide value

13. If a device was used, how often is calibration performed?

* must provide value

14. Approximately how much time passed between preparation of the inoculum suspension matching the 0.5 McFarland standard and inoculation of the test?

* must provide value

15. Please include medium used for AST and incubation time and conditions

* must provide value

16. Was repeat testing performed? If so, how many times was the AST performed? Please specify if repeat testing was done by different operators and, if any modifications to original method were introduced.
Please upload repeat testing results in question #25. Do not include any PII

* must provide value

17. What method was used to read the results? Please check all that apply

* must provide value

- [ ] Automated method
- [ ] Manual read aided (i.e., inverted mirror)
- [ ] Manual read un-aided
- [ ] BIOMIC®
- [ ] Sensititre™ Vizion™
- [ ] Reflected light
- [ ] Transmitted light
- [ ] Sliding Caliper
- [ ] Ruler
- [ ] Other (please specify):

18. Do all equipment and instruments used in the testing undergo routine maintenance and calibrations?

* must provide value

- ○ Unknown
- ○ Yes
- ○ No

19. *Describe the issue you are having. (Please include MICs, zone sizes (if disk), drug concentration ranges tested, and category interpretations obtained for AR Bank isolates tested and QC strains along with a brief description of the problem).*
Data can be submitted using a spreadsheet/file in question #25

* must provide value

20. List any special parameters used for reading, when applicable (e.g., 80% inhibition) and any organism effects, if seen (e.g., swarming, trailing, fuzzy edges etc.). *Pictures to show/help explain reading parameters/organism effects can be uploaded in question #21.*

* must provide value

21. Use the upload option to include relevant pictures, if desired. *Do not include any PII*

If multiple files. Upload a single .ZIP file

22. Has the manufacturer been contacted about this issue? If so, please provide troubleshooting details performed after contacting the manufacturer.

* must provide value

23. Has a non-phenotypic test been performed (i.e., PCR) for detection of resistance mechanisms?

- ○ Yes
- ○ No

24. Has selective pressure (e.g., including carbapenem disks on the first sub) been applied?

- ○ Unknown
- ○ Yes
- ○ No

25. Please upload relevant file here. ***Do not include any PII***

If multiple files. Upload a single .ZIP file

26. Any other details you would like to include/ additional information to provide from internal troubleshooting?

CEMB Doc #: ACS.SM.D.0002 Rev #: 3

CDC estimates the average public reporting burden for this collection of information as 10 minutes per response, including the time for reviewing instructions, searching existing data/information sources, gathering and maintaining the data/information needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Information Collection Review Office, 1600 Clifton Road NE, MS H21-8, Atlanta, Georgia 30333; ATTN: PRA (0920-1071)

Form Status

Complete?