The Essential Role of Clinical Microbiology in Antimicrobial Stewardship: Harnessing AST Data as a Driver of Successful Programs

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Disclosures

Consulting: ThermoFisher, Accelerate Diagnostics, Pattern, IHMA, Next Gen Dx, QPex
Objectives

1. Understand the impact clinical microbiology laboratory data can have on accurate treatment decisions and better management of critically ill patients
2. Describe the impact that COVID-19 has had on antimicrobial resistance
3. Review antimicrobial testing challenges in critically ill patients
4. Outline the role the microbiology lab plays to support antimicrobial stewardship during a pandemic
August 2020: VUMC

- 65 YO man
- Diagnosed with COVID-19 at outside hospital
- intubated, high ventilation settings, deep sedation, paralysis
- Completed dexamethasone, remdesivir, vancomycin & piperacillin-tazobactam

- Transferred to VUMC at family’s request
- Arrives septic, sputum produced with deep in-line suctioning
Respiratory cultures

HEAVY GROWTH OF ACINETOBACTER BAUMANNII
### AST RESULTS

<table>
<thead>
<tr>
<th>ANTIMICROBIAL</th>
<th>MIC</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amikacin</td>
<td>32</td>
<td>R</td>
</tr>
<tr>
<td>Amp/sulbactam</td>
<td>&gt;16</td>
<td>R</td>
</tr>
<tr>
<td>Cefepime</td>
<td>&gt;32</td>
<td>R</td>
</tr>
<tr>
<td>Ceftazidime</td>
<td>&gt;32</td>
<td>R</td>
</tr>
<tr>
<td>Ciprofloxacin</td>
<td>&gt;4</td>
<td>R</td>
</tr>
<tr>
<td>Doxycycline</td>
<td>&gt;16</td>
<td>R</td>
</tr>
<tr>
<td>Gentamicin</td>
<td>&gt;16</td>
<td>R</td>
</tr>
<tr>
<td>Meropenem</td>
<td>&gt;16</td>
<td>R</td>
</tr>
<tr>
<td>Pip-tazobactam</td>
<td>&gt;128</td>
<td>R</td>
</tr>
<tr>
<td>Tobramycin</td>
<td>&gt;16</td>
<td>R</td>
</tr>
<tr>
<td>Trimeth-Sulfa</td>
<td>&gt;4</td>
<td>R</td>
</tr>
</tbody>
</table>

**What are our treatment options?**

<table>
<thead>
<tr>
<th>Agent</th>
<th>Activity vs. MDR A. baumannii</th>
<th>Isolate MIC (mcg/mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ceftazidime-avibactam</td>
<td>Limited</td>
<td>&gt;16</td>
</tr>
<tr>
<td>Cefotolozane-tazobactam</td>
<td>No</td>
<td>&gt;32</td>
</tr>
<tr>
<td>Imipenem-relebactam</td>
<td>Limited</td>
<td>&gt;16</td>
</tr>
<tr>
<td>Meropenem-vaborbactam</td>
<td>No</td>
<td>&gt;16</td>
</tr>
<tr>
<td>Cefiderocol</td>
<td>Yes</td>
<td>0.5*</td>
</tr>
<tr>
<td>Plazomicin</td>
<td>Yes</td>
<td>?</td>
</tr>
<tr>
<td>Tigecycline</td>
<td>No</td>
<td>4</td>
</tr>
</tbody>
</table>

*result from reference lab

Adapted from Tamma P & Hsu AJ. 2019. J Ped Infect Dis. 8:251.
February 2021

- 56 YO man, type II diabetes, Crohn’s and asthma
- Early January: COVID-19
  - Receives remdesiver, decadron, convalescent plasma therapy
- Intubated mid-January, transferred to VUMC
- Infectious complications:
  - *C. glabrata* fungemia
  - VAP due to carbapenem resistant *E. cloacae*
E. cloacae

CPO Detect Result:
“Class A Beta-lactamase”

PCR: KPC +

Treated with ceftazidime-avibactam
Patient story, continued

• 2 weeks post-ceftazidime-avibactam, isolate reoccurs
• Isolate is now “R” to ceftazidime-avibactam, “S” to meropenem
• Still has KPC \(\rightarrow\) mutation to KPC that leads to resistance to avibactam
• Patient treated with meropenem-vaborbactam
Antimicrobial resistance and COVID-19

• A lot of reason for concern:
  • ~74% of COVID-19 patients received an antimicrobial prescription
  • Only 4% have a true bacterial infection
  • ~15% of hospitalized patients develop bacterial secondary infection

• Outside the US, huge emphasis on use of antibiotics (e.g., azithromycin) to prevent or treat COVID-19
  • Medical mis-information

• Some evidence of increase in resistance:
  • 10% increase at one institution

Antimicrobial use in COVID-19

- Fluoroquinolones very commonly used in China
- Macrolides more common in USA
- Most common prescriptions in the ICU (86.4%) vs. outpatients (59%)

Trends towards less antimicrobials in later months of pandemic

<table>
<thead>
<tr>
<th>Month</th>
<th>Random effects model</th>
<th>Antimicrobials</th>
<th>95% CI</th>
<th>Heterogeneity: $i^2$</th>
<th>Heterogeneity: $\tau^2$</th>
<th>$\chi^2_{13}$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jan</td>
<td>3240</td>
<td>85.8</td>
<td>[67.9; 94.6]</td>
<td>99%</td>
<td>3.3240</td>
<td>382.93 (p &lt; 0.01)</td>
</tr>
<tr>
<td>Feb</td>
<td>10410</td>
<td>79.4</td>
<td>[70.0; 86.4]</td>
<td>99%</td>
<td>4.3168</td>
<td>1207.63 (p &lt; 0.01)</td>
</tr>
<tr>
<td>Mar</td>
<td>6142</td>
<td>69.4</td>
<td>[53.0; 81.9]</td>
<td>99%</td>
<td>3.8518</td>
<td>1637.48 (p = 0)</td>
</tr>
<tr>
<td>Apr</td>
<td>7552</td>
<td>62.6</td>
<td>[50.7; 73.1]</td>
<td>99%</td>
<td>1.6521</td>
<td>1634.8 (p = 0)</td>
</tr>
<tr>
<td>May</td>
<td>3215</td>
<td>71.4</td>
<td>[39.8; 90.5]</td>
<td>96%</td>
<td>1.6562</td>
<td>62.73 (p &lt; 0.01)</td>
</tr>
<tr>
<td>Not specified</td>
<td>64</td>
<td>52.1</td>
<td>[22.5; 80.3]</td>
<td>83%</td>
<td>0.7535</td>
<td>10.97 (p &lt; 0.01)</td>
</tr>
</tbody>
</table>

Secondary bacterial infections in viral pandemics

<table>
<thead>
<tr>
<th>2009 Influenza</th>
<th>COVID-19</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Community-acquired pneumonia</td>
<td>• Hospital / Ventilator Acquired Pneumonia</td>
</tr>
<tr>
<td>• Nasopharyngeal colonizers cause secondary infections</td>
<td>• Hospital pathogens cause secondary infections</td>
</tr>
<tr>
<td>• <em>S. aureus, S. pneumoniae, S. pyogenes</em></td>
<td>• Gram negative bacteria</td>
</tr>
<tr>
<td></td>
<td>• <em>S. aureus</em></td>
</tr>
<tr>
<td></td>
<td>• Fungi?</td>
</tr>
</tbody>
</table>

Antimicrobial resistance is a huge concern

Rice et al. Crit Care Med 2012 1487
Comparing viral pandemics

COVID-19
- 8% secondary bacterial infections
- 75% receive antibiotics

Influenza
- 23% secondary bacterial infection
- 65% receive antibiotics

What ways can this be mitigated?

• Continued support of antibiotic stewardship
• Appropriate use of diagnostic testing
  • Many patient with COVID-19 never get a sputum culture done; often rejected by lab due to poor quality
• Fewer outpatient physician visits: decreased use of antimicrobials in outpatient domain
• Increased emphasis on hand hygiene, masking, social distancing
Can can the laboratory do?

- Test appropriate drugs
- Results predict clinical response
- Clinically relevant
- Meaningful reporting
- Optimized testing
1. Clinically relevant testing

Perform AST on clinically relevant bacteria only
When should we be performing AST?

- Clinically meaningful isolates
  - Don’t test colonizers
  - Don’t test contaminants
  - If >2 potential pathogens... hard to know what’s relevant

- Only when susceptibility is not predicted

- When there are clinical breakpoints
  - Some exceptions here, but generally hard to interpret and AST should be done only in rare instances if there are not breakpoints
Example: Single set of blood cultures with coagulase-negative *Staphylococcus*

- Coagulase negative staphylococci are the most common contaminant of blood cultures
- VUMC has a high rate of contaminated blood cultures
- Intervention was performed to stop performing AST on single set of skin flora contaminants
  - Significant reduction in use of vancomycin for these patients in the ICU
  - Study conducted in September 2020... at a high COVID time

See Austin Ing’s poster on this study at WFM 2021... and oral presentation
Test relevant antimicrobials

Ensure your testing meets your patient population:

Broad spectrum (newer) agents for resistant organisms
Treatment of choice includes many newer agents

CRE (with and without carbapenemase)
- ceftazidime-avibactam
- imipenem-relebactam
- meropenem-vaborbactam
- cefiderocol,
  - eravacycline

Pseudomonas aeruginosa
- Ceftolozane-tazobactam
- Ceftazidime-avibactam
- imipenem-relebactam
- cefiderocol

*Corresponding Author

Published by IDSA, 9/8/2020

Not on the list? Colistin!!
Testing newer agents: GNRs

<table>
<thead>
<tr>
<th>Agent</th>
<th>Test</th>
<th>Automated Systems</th>
<th>Manual MIC</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Disk</td>
<td>Gradient strip</td>
<td></td>
</tr>
<tr>
<td>Ceftazidime-avibactam</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Cefotolozane-tazobactam</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Imipenem-relebactam</td>
<td>Hardy</td>
<td>Etest, MTS</td>
<td>Sensititre</td>
</tr>
<tr>
<td>Meropenem-vaborbactam</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Cefiderocol</td>
<td>Hardy</td>
<td>-</td>
<td>Sensititre</td>
</tr>
<tr>
<td>Eravacycline</td>
<td>Hardy</td>
<td>Etest, MTS</td>
<td>Mscan, Sensititre, Vitek 2</td>
</tr>
<tr>
<td>Plazomicin</td>
<td>Hardy</td>
<td>Etest, MTS</td>
<td>Sensititre</td>
</tr>
</tbody>
</table>

Labs should be testing ceftazidime-avibactam and ceftolozane-tazobactam in house at this point

Labs should identify where to send for other tests... if you cannot do in house
  Figure this out in advance, so you can be expedient when they are needed

*based on 510(k) summary search on fda.gov Oct 26 2020

Available on most platforms
Value of testing newer agents in-house

- In absence of AST data:
  - Clinicians may use the drug empirically with no information
  - Clinicians may choose to use a sub-optimal drug (e.g., colistin)
- Risk is unexpected resistance for these new agents

### Risk of resistance for MDR Gram negative bacteria vs. newer antimicrobial agents

<table>
<thead>
<tr>
<th>Antimicrobial</th>
<th>Enterobacterales</th>
<th>P. Aeruginosa</th>
<th>A. Baumannii</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ceftaz-avibactam</td>
<td>Low risk</td>
<td>Moderate risk</td>
<td>N/A</td>
</tr>
<tr>
<td>Ceftol-tazobactam</td>
<td>High risk</td>
<td>Moderate risk</td>
<td>N/A</td>
</tr>
<tr>
<td>Meropenem-vabor</td>
<td>Low risk</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Imipenem-rel</td>
<td>Low risk</td>
<td>Low risk</td>
<td>N/A</td>
</tr>
<tr>
<td>Cefiderocol</td>
<td>Low risk</td>
<td>Low risk</td>
<td>? low risk</td>
</tr>
</tbody>
</table>

*Low risk: <5%; moderate risk, 20-30%; high risk: >50%*
Make sure your tests are using up-to-date breakpoints!

Best predictor of clinical response to the MIC/disk tests
Good reference to help with breakpoints changes:

Understanding and Addressing CLSI Breakpoint Revisions: a Primer for Clinical Laboratories

Romney M. Humphries, April N. Abbott, Janet A. Hindler

Minireview

...includes

- Why BPs are updated
- CLSI vs FDA BPs
- FDA clearance of updated BPs on cASTs
- Prioritizing adoption of updated BPs in clinical laboratories
  - Questions to pose to stakeholders
- How to implement updated BPs
- Verification / validation for “off-label” BPs

Case 3

- 48 year old male, No past medical history, admitted 3 weeks ago to OSH with ischemic bowel
- Resection of bowel, re-anastomosis but poor return of GI function
- Today: febrile, intubated, multiple pressors, new leukocytosis, renal failure, shock
- Outside hospital blood culture results: *K. pneumoniae*

<table>
<thead>
<tr>
<th>Antimicrobial</th>
<th>Susceptibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ciprofloxacin</td>
<td>R</td>
</tr>
<tr>
<td>Pip/Tazobactam</td>
<td>R</td>
</tr>
<tr>
<td>Gentamicin</td>
<td>R</td>
</tr>
<tr>
<td>TMP-SMX</td>
<td>R</td>
</tr>
<tr>
<td><strong>Meropenem</strong></td>
<td><strong>S</strong></td>
</tr>
<tr>
<td>Tigecycline</td>
<td>R</td>
</tr>
</tbody>
</table>

Treated with meropenem + gentamicin
Case 3 continued

• 1 day after transfer:
  • Still on pressors, max ventilation, sputum production

• Local lab, blood cultures:
  • *K. pneumoniae with KPC!!*
    • Meropenem MIC = 4 µg/mL R
    • Phone outside lab, using obsolete breakpoints, no molecular testing
Why is it critical to use current carbapenem breakpoints (Enterobacterales)?

• CDC considers carbapenem-resistant Enterobacteriaceae (CRE), including carbapenemase producing CRE (CP-CRE) an urgent threat to the public’s health as there are limited options for treating infections due to CRE.\(^1,2,3\)

• Approximately 20% of CRE would be misclassified by use of outdated breakpoints.\(^5,6\)

• Outdated breakpoints can direct treating physicians to inappropriate antimicrobial therapy, contributing to preventable patient morbidity and mortality.\(^2,3\)

• Outdated breakpoints hinder the ability to identify CRE, impairing infection control initiatives and fueling the spread of CRE.\(^5\)

1. CDC. Antibiotic Resistance Threats in the United States, 2019. CDC, Atlanta, GA.
“Risk” of Using Obsolete Breakpoints

- To date, all CLSI BP updates involved “lowering” the BP
- If use obsolete BPs, there is a risk reporting “False “S” every time isolate is “R” by obsolete BPs and “S” with Updated BPs

**Enterobacterales**

<table>
<thead>
<tr>
<th>Agent</th>
<th>Obsolete Breakpoints (µg/ml)</th>
<th>Current Breakpoints (µg/ml)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>S</td>
<td>I</td>
</tr>
<tr>
<td>Meropenem</td>
<td>≤4</td>
<td>8</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Error</th>
<th>Results</th>
<th>Acceptable Error Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Reference</td>
<td>New Test</td>
</tr>
<tr>
<td>Very major</td>
<td>R</td>
<td>S</td>
</tr>
<tr>
<td>Major</td>
<td>S</td>
<td>R</td>
</tr>
</tbody>
</table>

Meropenem MIC, KPC producers

VME = 12%!
Breakpoint update process

Breakpoint reviewed

Breakpoint set /revised

New data (resistance, PK/PD, clinical)

Laboratory adopts

Updated on commercial AST

May take Years!
Why does it take years?

1. FDA cleared devices MUST use FDA breakpoints
   1. Delay between CLSI publication and FDA recognition

2. Companies need to update their tests for the new breakpoint
   1. Add dilutions, change software
   2. Do a new clinical trial
   3. Get new FDA clearance

3. Labs can validate their tests off-label for the breakpoints
   1. Must do a verification study (see M52)
   2. Labor intensive
   3. Confusing
# Prioritizing Breakpoint Implementation

<table>
<thead>
<tr>
<th>Priority</th>
<th>Considerations</th>
<th>Breakpoints Affected</th>
</tr>
</thead>
</table>
| 1        | If not implemented can result in:  
• Serious patient care concerns  
• Serious public health concerns | Carbapenems – GNRs  
Cephems – *Enterobacterales*  
Pip-tazo – *P. aeruginosa*  
Fluoroquinolones - *Salmonella* |
| 2        | • May not apply to your institution  
• May be handled with comments on report, alternative strategies | Cefazolin – *Enterobacterales*  
Fluoroquinolones – *Enterobacterales & P. aeruginosa*  
Daptomycin - *Enterococcus* |
| 3        | Related to drugs infrequently used or to doses not used in USA | Colistin – GNR  
Piperacillin, ticarcillin, ticar-clav – *P. aeruginosa*  
Ceftaroline – *S. aureus* |

*these are just breakpoint *updates* since 2010... new breakpoints not covered herein

Establishing Priorities for Updating BPs at Your Institution

*Based on institutional-level practices, you should determine:*

• the clinical use of the antimicrobial
• which testing options are available and most appropriate (for MIC tests, the concentrations encompassing lowered breakpoints must be available)
• which breakpoint(s) should be implemented
• if current breakpoints are not yet FDA-cleared on a cASTs, their use would be considered “off label” and a verification / validation is required for implementation

Work with stakeholders...antibiotic stewardship team, pharmacy, infectious diseases (ID), infection control and others, as appropriate

Decision tree for revised BP adoption on cASTs...

Figure S1. Proposed decision tree for revised breakpoint adoption on cASTs

- Is cASTs FDA-cleared for current BP?
  - Yes: Adopt ASAP
  - No: Discuss with Institution (Table S1)
    - Update Now: Update not needed yet (drug not in use, etc)
    - Report on request: Report routinely
      - Report if "R" (concentrations should be adequate)
      - If "S", could be S, i or R by current?
        - Do not report: If "S", could be S, i or R by current?
          - send to reference lab to confirm results
          - use alternative test method and current BP

cASTs, commercial antimicrobial susceptibility test system; BPs breakpoints
Alternative test method options: disk diffusion (if test method appropriate for drug/organism combination); gradient diffusion; other

Meaningful reporting
Supporting antibiotic stewardship: cascade / selective reporting

<table>
<thead>
<tr>
<th></th>
<th>Cascade Reporting</th>
<th>Selective reporting</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Definition</strong></td>
<td>Reporting broader antimicrobials only if more narrow spectrum agents are “R”</td>
<td>Suppressing select agent results from the laboratory reports based on ASP needs (e.g., formulary, select suppressions etc)</td>
</tr>
<tr>
<td><strong>Example</strong></td>
<td>Only report ertapenem if ceftriaxone is “R”</td>
<td>Suppress fluoroquinolone results from urine cultures to support ASP initiative to decrease their use in treatment of cystitis</td>
</tr>
</tbody>
</table>
The VERY basics: AST restrictions

- Make sure your AST reports are not doing potential harm:
  - Do not report drugs with “WARNINGS” in M100 Table 1
  - Be cautious of body-site specific restrictions:
    - Don’t report daptomycin on respiratory sources
    - Don’t report nitrofurantoin only on urine cultures
    - Don’t report clindamycin on urine cultures
    - CSF restrictions (below)
    - Etc

- Search “warning” in M100 electronic document to find these easily!
- Some institutions may expand on M100 (examples):
  - Pip-tazo not reported on CSF
  - Tigecycline not on blood/urine

---

"Warning": The following antimicrobial agents that are included in this document should not be routinely reported for bacteria isolated from CSF. These antimicrobial agents are not the drugs of choice and may not be effective for treating CSF infections caused by these organisms (ie, the bacteria included in Tables 2A through 2J):

- Agents administered by oral route only
- 1st- and 2nd-generation cephalosporins and cephamycins
- Clindamycin
- Macrolides
- Tetracyclines
- Fluoroquinolones
The VERY basics: AST restrictions

- Make sure not reporting intrinsically “R” organisms as “S”
  - *Pseudomonas aeruginosa* and ertapenem, SXT, tetracyclines

- *Salmonella/Shigella* and 1st/2nd generation cephalosporins
  - These will test “S” but are inactive clinically!

- *Enterococcus* spp. and clindamycin, ceph, SXT

- Etc

Go to Appendix B of the CLSI M100 document

Often, AST device “expert rules” will suppress these for you

They don’t ALWAYS test “R”... for lots of reasons
More sophisticated: cascade reporting

- Requires buy-in from institution – antibiotic stewardship team
- There is no “one” right approach
  - Will vary based on lab formulary, patient population, provider biases etc
- Good places to start:
  - CLSI guidelines
  - Clinical guidelines (Sanford, IDSA treatment recommendations, etc)
- It is not easy to implement!
  - Rules may be in place at level of test platform, LIS or even EMR
  - Coordination and testing required!
  - If cascade reporting implemented, technologists MUST review the suppressed results too – to check for test system issues
Impact of cascades

**Days of therapy**

<table>
<thead>
<tr>
<th>Antibiotic</th>
<th>Baseline</th>
<th>Post-Cascade</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pip-tazo</td>
<td>1.0</td>
<td>0.99</td>
<td>0.9</td>
</tr>
<tr>
<td>Cefepime</td>
<td>1.23</td>
<td>0.81</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Cipro</td>
<td>0.86</td>
<td>0.96</td>
<td>0.028</td>
</tr>
<tr>
<td>Ceftriaxone</td>
<td>1.48</td>
<td>1.66</td>
<td>0.004</td>
</tr>
</tbody>
</table>

* Also noted a significant reduction in LOS (14 vs 10.8 days)
Resources

Antimicrobial Stewardship Strategy: Cascading microbiology susceptibility reporting

The selective suppression of an organism’s susceptibility to broader-spectrum or more expensive secondary agents when it is susceptible to preferred primary agents.


Commentary
Selective reporting of antibiotic susceptibility testing results: less is more

Gunnar Kahlmeter 1,2, Nathalie Thilly 3,4, Céline Pulcini 3,5,*

DOI:https://doi.org/10.1016/j.cmi.2020.11.017

Implementing an Antibiotic Stewardship Program: Guidelines by the Infectious Diseases Society of America and the Society for Healthcare Epidemiology of America

Tamar F. Bertram,1* Sara E. Cegiello,1,4 Lilian M. Abbe,1 Cesna MacDougall,1 Audrey N. Schuetz,1 Edward J. Septimus,1 Arjan Srinivasan,1 Timothy H. Dellit,8 Yingye T. Feliz-Yates,1 Neil G. Fishman,3,7 Cindy W. Hamilton,2,7 Timothy C. Jankins,2,7 Pamela A. Lipsert,1 Pradeep H. Malani,4,5,6 Larissa S. May,1 Gregory J. Moran,1,4 Melinda M. Neubauer,1 Jason S. Nevland,1 Christopher A. Oht,1 Matthew H. Samore,1,2 Susan K. See,1 and Kastha K. Troudi2

Clinical Infectious Diseases

IDSA GUIDELINE

CLINICAL AND LABORATORY STANDARDS INSTITUTE

30th Edition

M100
Performance Standards for Antimicrobial Susceptibility Testing

Public Health Ontario
Santé publique Ontario

DOI:https://doi.org/10.1016/j.cmi.2020.11.017
Summary

• AMR is a global, slow-burning pandemic
• The laboratory can help mitigate rising AMR by ensuring testing practices best suit patient needs
Thank you!

Clinical Microbiology
VUMC