

# Unmet Diagnostic Needs in Infectious Disease

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## ABSTRACT

**Background:** Accurate and timely diagnostics can improve patient care and antibiotic stewardship. New technologies for infectious disease (ID) are emerging but gaps remain in test development and availability. The Emerging Infections Network (EIN) and members of the IDSA Diagnostics Task Force surveyed clinical ID physicians to assess their unmet diagnostic needs.

**Methods:** 1572 EIN members were surveyed in March 2013. Respondents ranked or scored [(1) least important to (5) greatest need] unmet diagnostic needs for infectious syndromes, pathogens and antibiotic resistance. Additional free text answers were encouraged.

**Results:** 700 members (44.5%) completed the survey. Identification of resistant Gram-negative bacilli and rapid ESBL testing ranked 1<sup>st</sup> in the pathogen and resistance categories. Culture-negative endocarditis was the syndrome with greatest unmet need followed by infectious diarrhea. Pathogen-based testing for respiratory infection (18% of write-ins), followed by tests to distinguish viral vs. bacterial infection (16%) were named most frequently as potentially useful tests not available in respondents' current practice. Accuracy and turn around time were the most important test characteristics (mean scores 4.72 and 4.61), outranking cost (4.07). A majority (67%) of respondents felt that some testing is too complex for non-ID physicians; 79% thought there should be stewardship for complex or expensive tests (e.g., multiplex testing for respiratory viruses [13% of write-ins] and broad range PCR [9%]).

**Conclusions:** The call for tests to identify resistant Gram-negative bacteria reflects increasing drug-resistant infections and limited drug development. Recognition of the importance of judicious testing through stewardship parallels increased awareness of rising healthcare costs. Information gained from this survey can help inform recommendations for new diagnostic test development in the future.

## INTRODUCTION

Accurate and timely diagnostics can improve patient care and antibiotic stewardship. New technologies for infectious disease (ID) are emerging but gaps remain in test development and availability. The Emerging Infections Network (EIN) and members of the IDSA Diagnostics Task Force surveyed clinical ID physicians to assess their unmet diagnostic needs.

## METHODS

**Ethics Statement**  
 This study was determined to be exempt from review by the University of Iowa Institutional Review Board and is not considered to be human subjects research.

**Study Design**  
 We conducted an electronic survey of all EIN members in the spring of 2013 regarding their perceived unmet diagnostic needs in infectious disease. Members were informed that results from the survey would help inform guidelines for new diagnostics development and implementation in preparation by the Infectious Disease Society of America's Diagnostics Task Force. An "unmet" need was defined as testing not available in the respondent's clinical practice or not available in a timely fashion such that it could affect clinical care. Non-respondents received up to 2 follow up queries.

**Data Source**  
 The EIN maintains demographic data on individual members including scope of practice (adult practice, pediatric practice or both), years of practice, geographic region and practice setting. For this survey we also asked respondents to indicate the proportion of patients within their clinical practice with significant immunosuppression.

**Survey Questions**  
 Respondents were asked to rank or score [from (1) least important to (5 or 6) greatest need] the unmet need for diagnostic testing for infectious syndromes and pathogens. Six syndromes and six pathogens were specifically listed in the survey; free text answers were also encouraged to suggest syndromes or pathogens not specifically addressed in the survey with significant unmet diagnostic needs. Respondents were also asked to choose a single test not currently available to them (not available in their practice or not invented yet) that would be most helpful.

Respondents were also asked to rank the importance of specific test characteristics when choosing a new test as well as consider the appropriate turn-around-time for various tests in terms of usefulness for clinical decision-making. Additionally, respondents were asked to consider the impact of rapid identification of specific genetic determinants of antimicrobial resistance on their clinical practice.

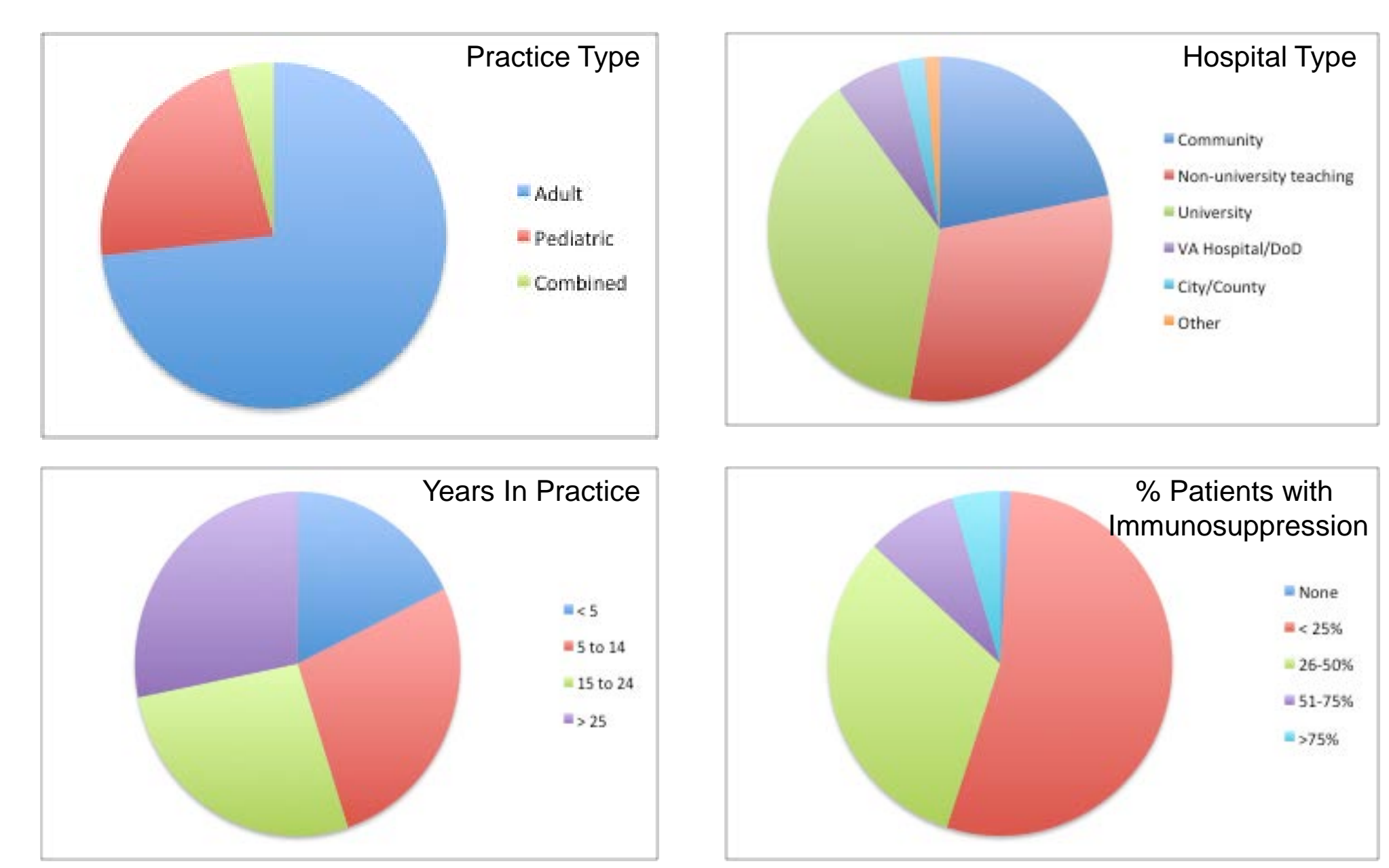
Finally, respondents were asked their opinion regarding whether some infectious diseases diagnostic testing is becoming too complex to be interpreted by non-infectious diseases physicians and if there should be "stewardship" for particularly complex or expensive tests. For those in favor of stewardship, we asked for examples of tests that should be monitored.

**Analysis**  
 Data were analyzed using SAS version 9.3 (SAS Institute, Cary, NC).

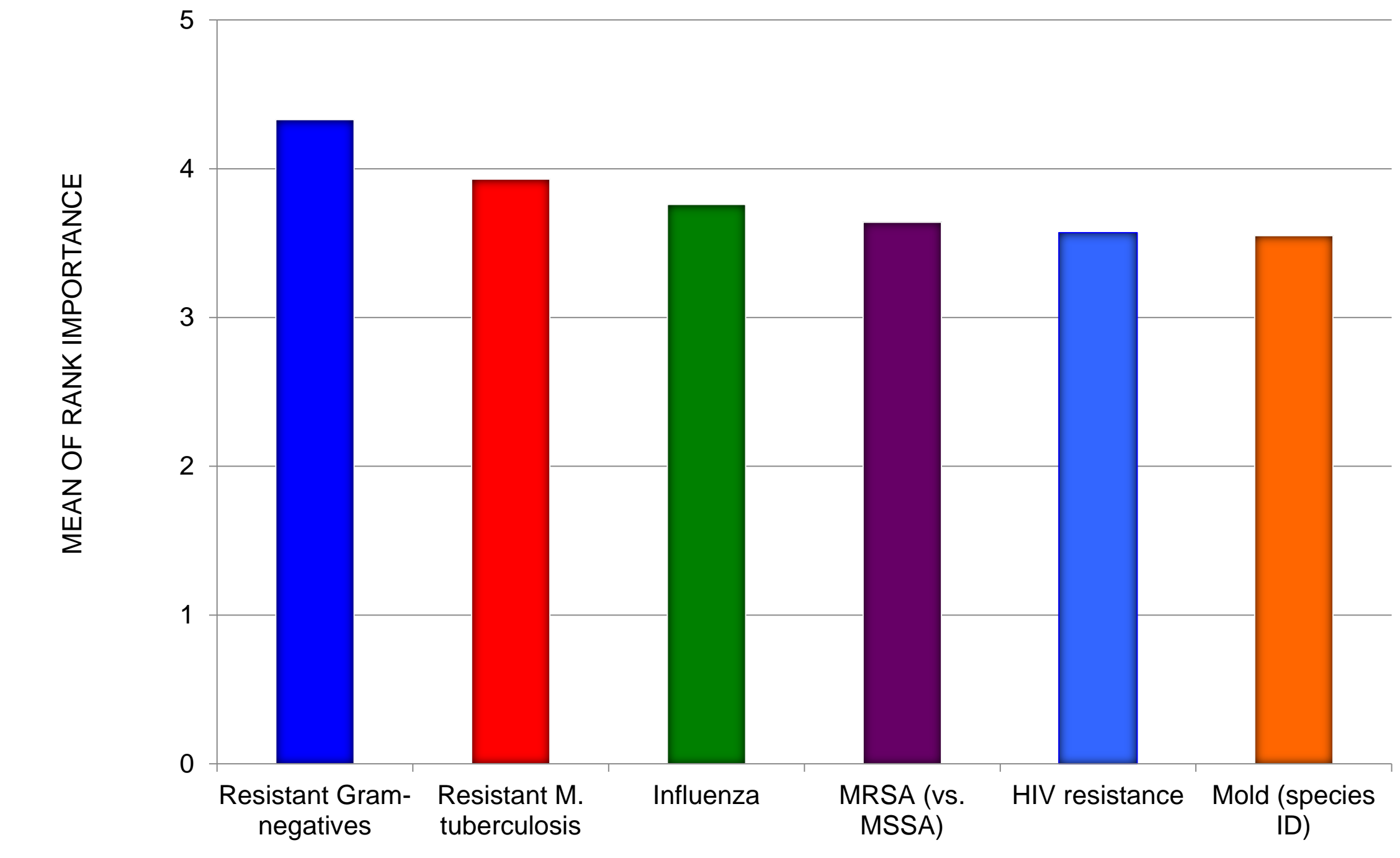
## RESULTS

- 700 members (44.5%) completed the survey.
- Identification of resistant Gram-negative bacilli and rapid ESBL testing ranked 1<sup>st</sup> in the pathogen and resistance categories.
- Culture-negative endocarditis was the syndrome with greatest unmet need followed by infectious diarrhea.
- Pathogen-based testing for respiratory infection (18% of write-ins), followed by tests to distinguish viral vs. bacterial infection (16%) were named most frequently as potentially useful tests not available in respondents' current practice.
- Accuracy and turn around time were the most important test characteristics (mean scores 4.72 and 4.61), outranking cost (4.07).
- A majority (67%) of respondents felt that some testing is too complex for non-ID physicians; 79% thought there should be stewardship for complex or expensive tests (e.g., multiplex testing for respiratory viruses [13% of write-ins] and broad range PCR [9%])

### SURVEY PARTICIPANTS (n = 700)



### UNMET NEED FOR PATHOGEN DIAGNOSIS

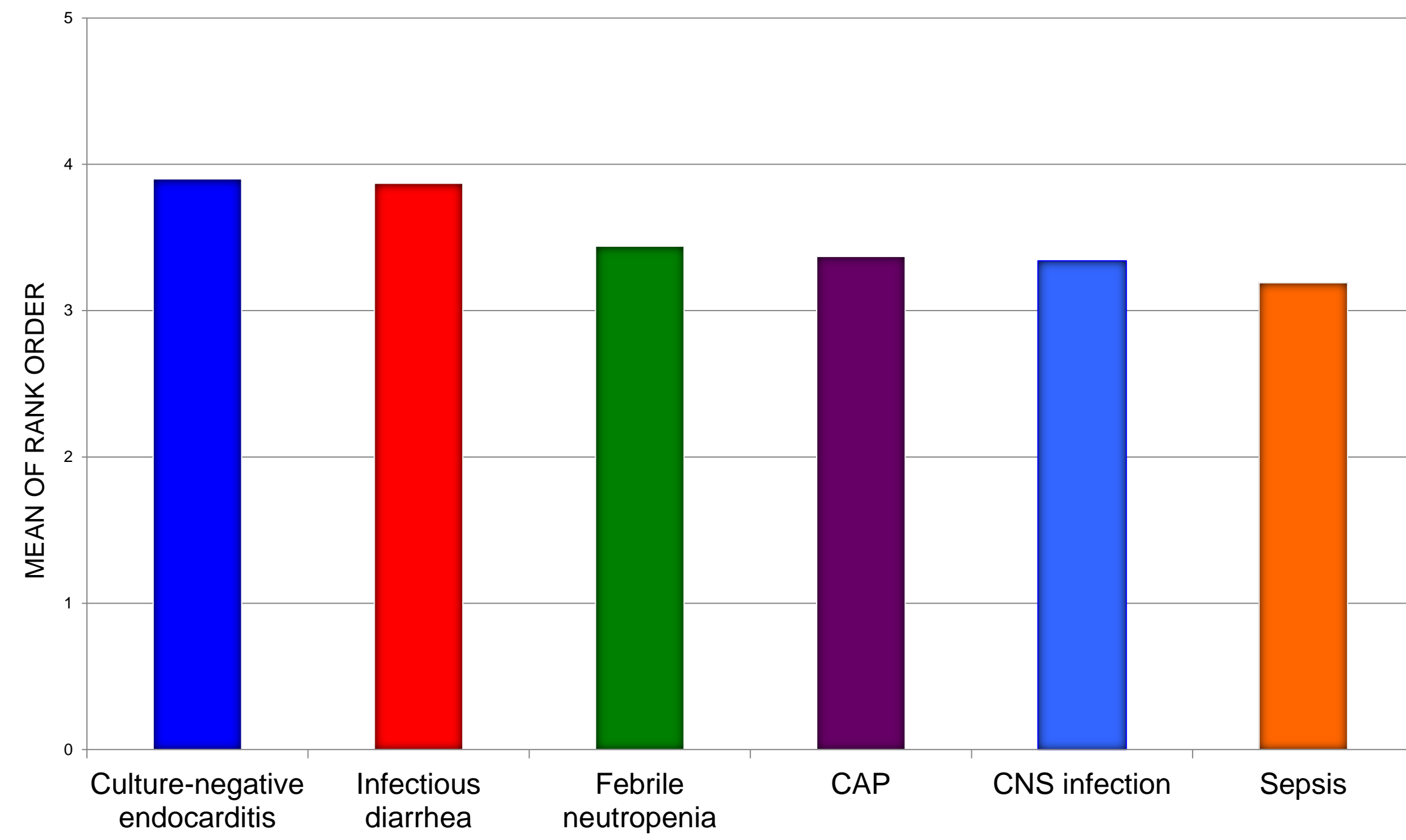


**Other pathogens** mentioned in open text field: *Borrelia burgdorferi* (Lyme disease), *C. difficile*, *Aspergillus*, *Candida* speciation and susceptibilities, *Coccidioides immitis*, *Neisseria gonorrhoeae* (drug-resistant gonorrhea), HSV, CMV, human parechovirus, integrase inhibitor resistance testing, MDR GNR including CRE and ESBLs, *Mycoplasma*, *Naegleria fowleri*, syphilis, anaerobe ID, norovirus, diarrheal pathogens, pertussis in older individuals, histoplasmosis, malaria, dengue, *Nocardia*.

### TESTS THAT WOULD BENEFIT FROM STEWARDSHIP (CITED BY > 5%)

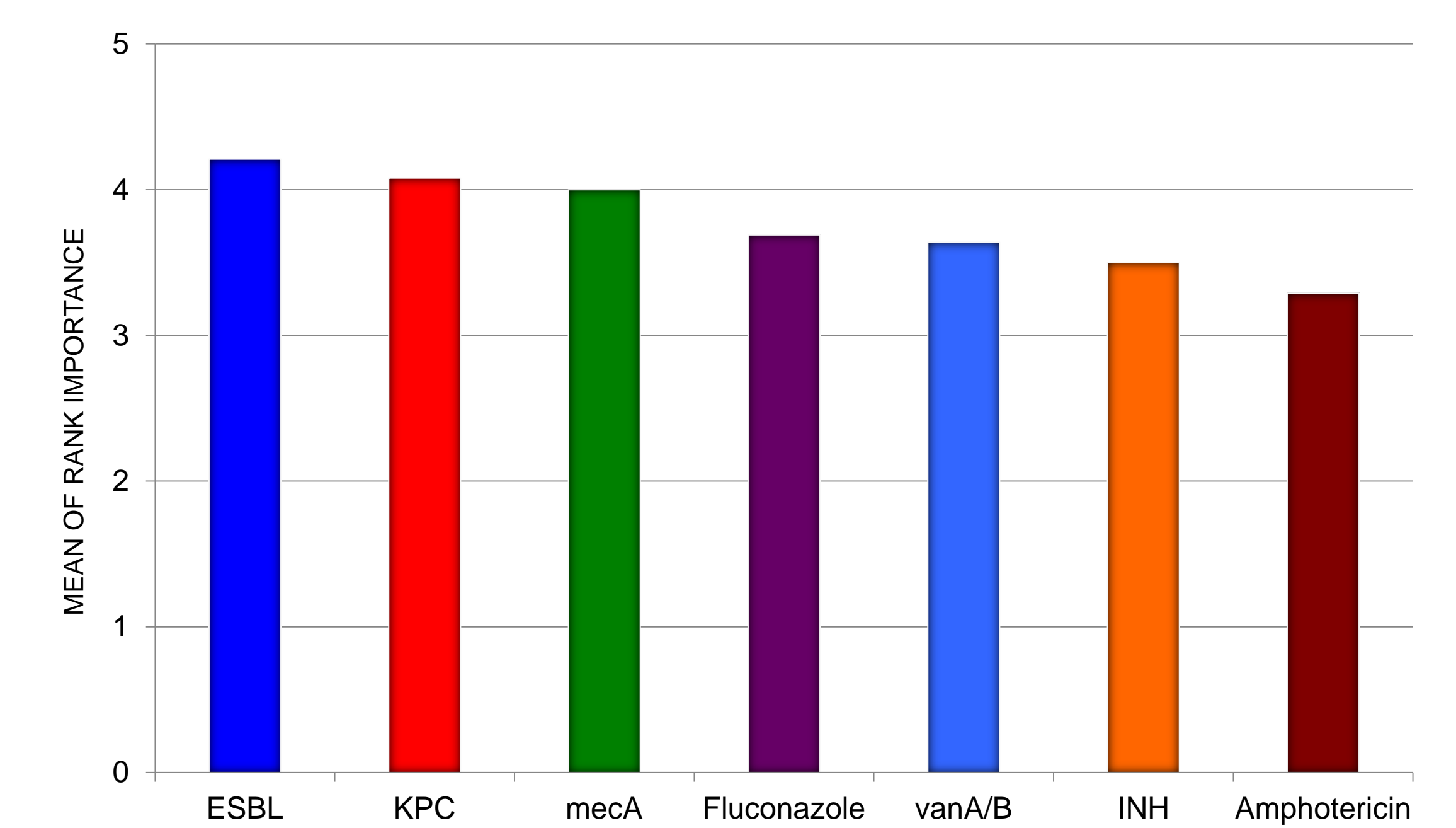
Test Type	% of write-in responses (n=279)
Multiplex Testing for Respiratory Viruses	13%
Broad Range PCR	9%
HIV Resistance Testing	9%
Serum Fungal Markers	8%
Procalcitonin	7%
Lyme Serologies	7%
Viral PCR of CSF	7%
<i>C. difficile</i> testing	5%
Serum TB testing	5%

### RANK OF SYNDROME-BASED NEED



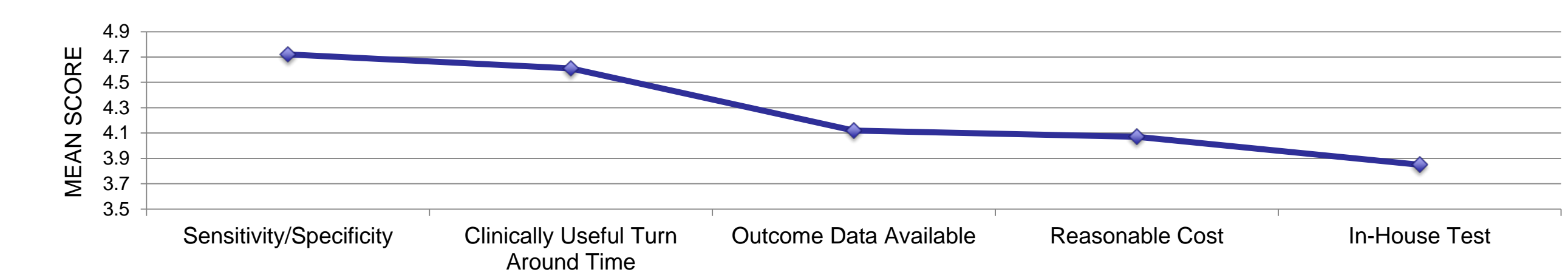
**Other syndromes** suggested in an open text field: Osteomyelitis/septic arthritis (by 11), prosthetic joint infections/orthopedic hardware infections (by 9), HAP/VAP (by 9), tuberculosis/mycobacterial ID (by 7), viral infections including URI and LRTI (by 7), fungal infections including pneumonia and in immunocompromised hosts (by 3), syphilis (by 2), congenital syndromes including syphilis and CMV (by 2)

### UTILITY OF RAPID RESISTANCE TESTING



**Other resistance markers** mentioned in open text field: drug-resistant *Pneumococcus* / pneumococcal susceptibility, VISA, erythromycin resistance in *Mycoplasma* and *Chlamydia*, oseltamivir resistance in influenza, resistance in *C. difficile*, rifampin resistance in *M. tuberculosis*

### IMPORTANCE OF CERTAIN CHARACTERISTICS WHEN CHOOSING A NEW TEST



**Other characteristics** mentioned in open text field: available in office setting, easy specimen collection, reimbursement, testing changes or improves therapy, applicable to pediatrics as well as adults, lab tech time for tests, limited cross-reactivity, reproducible results

### CLINICALLY USEFUL TURN AROUND TIME FOR SELECTED TESTS

[row percentages shown]	<1 hour	12 hours	24 hours
*Rapid influenza	546 (92%)	40 (7%)	9 (1%)
Biomarker to distinguish viral from bacterial respiratory infection	327 (55%)	203 (34%)	61 (10%)
Viral respiratory panel	265 (45%)	230 (39%)	98 (16%)
Direct detection of bacterial bloodstream infection (from whole blood)	254 (43%)	269 (46%)	67 (11%)
Identification of pathogens causing acute gastroenteritis	125 (21%)	200 (34%)	262 (45%)
Detection of pathogens causing viral encephalitis	93 (16%)	217 (37%)	278 (47%)
Identification of drug resistant <i>M. tuberculosis</i>	14 (2%)	66 (11%)	508 (86%)

## CONCLUSIONS

The call for tests to identify resistant Gram-negative bacteria reflects increasing drug-resistant infections and limited drug development. Recognition of the importance of judicious testing through stewardship parallels increased awareness of rising healthcare costs. Information gained from this survey can help inform recommendations for new diagnostic test development in the future.