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AMERICAN SOCIETY FOR MICROBIOLOGY

Rapid antibiotic susceptibility testing: motivation & methods

American Society for Microbiology Webinar
6 November 2025

Daniel D. Rhoads, MD, D(ABMM)
The Belinda Yen-Lieberman, PhD, and James M. Lieberman, MD, Endowed Chair in Clinical Microbiology
Cleveland Clinic Main Campus

Cleveland Clinic

Disclosures

Research Contractor:
Abbott, Altona, BD, bioMerieux, Cepheid, Luminex, Meridian, Pattern Biosciences, Qiagen, Q-Linea, Roche, Selux, Thermo Fisher.

Board Member:
Next Gen Diagnostics, Renascent Diagnostics.

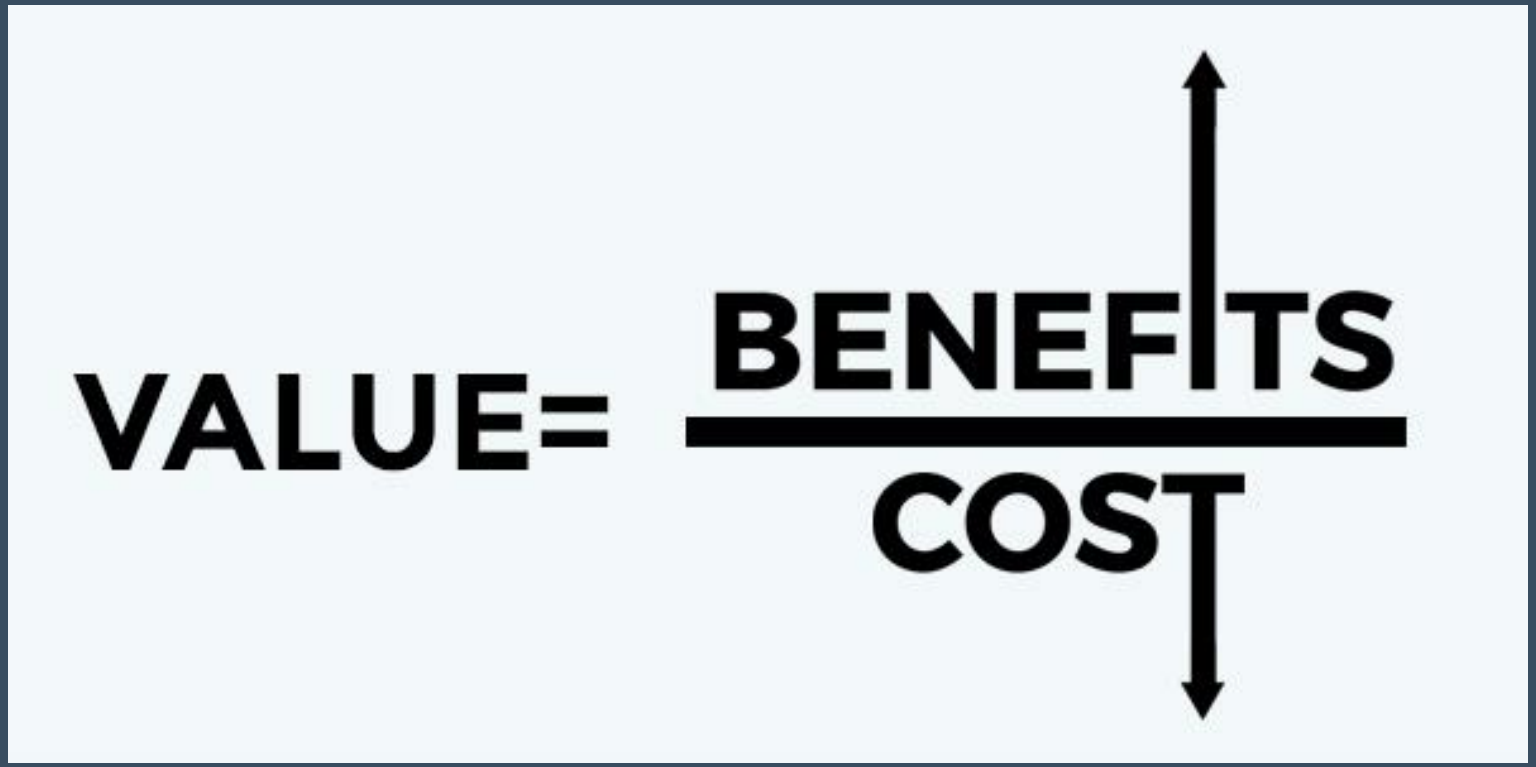
Objectives

- Describe the potential clinical benefits of rapid antimicrobial susceptibility testing
- Recognize the diagnostic devices that currently on the market in the U.S. for rapid antimicrobial susceptibility testing.

What is the goal?

Provide timely, accurate, and clinically actionable findings

What is the goal?



https://www.designerpeople.com/blog/value-proposition-top-marketing-strategy/

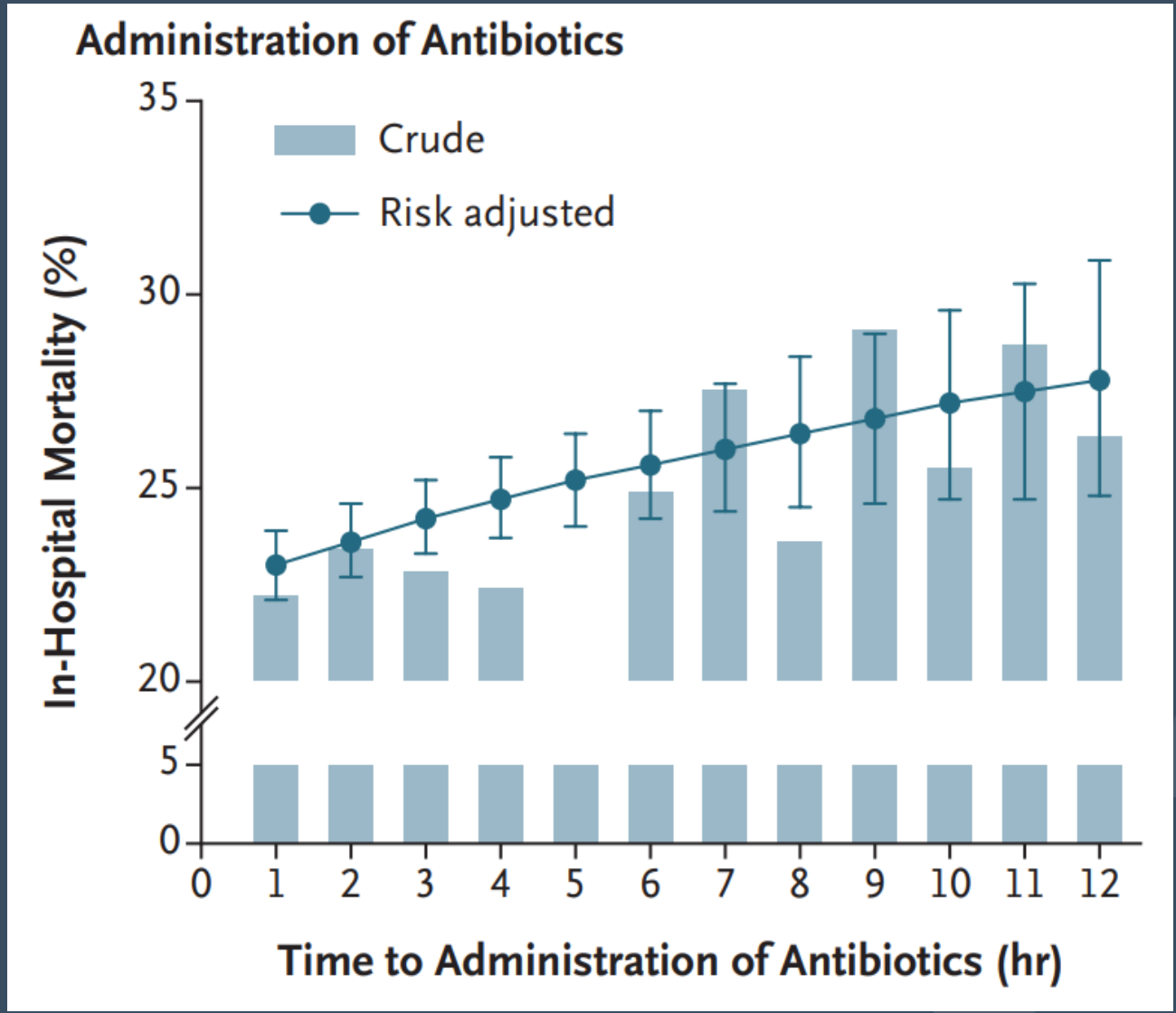
What is the goal?

https://medium.com/swlh/good-fast-or-cheap-pick-2-to-grow-your-business-7b37bf928a1

Time matters in sepsis & bacteremia

Every hour counts.

Quickly recognizing sepsis and treating bacteremia can improve survival.



DOI: 10.1056/NEJMoa1703058 N Engl J Med. 2017 Jun 8;376(23):2235-2244.

Time matters in sepsis & bacteremia

Using the RIGHT antibiotic is important for survival.
Antibiotic resistance kills.

TABLE 2. Variables Independently Associated With All-Cause Hospital Mortality

Variables	OR	95% CI	p
Age[a]	1.3	1.1–1.5	0.009
Acute Physiology and Chronic Health Evaluation score[a]	1.7	1.4–2.1	< 0.001
Duration of hospitalization prior to bacteremia[a]	1.3	1.1–1.6	0.002
Septic shock	2.3	1.9–2.8	< 0.001
Mechanical ventilation	1.5	1.2–1.8	< 0.001
Inappropriate antibiotics	3.4	2.8–4.1	< 0.001
Prior hospitalization[b]	1.4	1.2–1.6	< 0.001

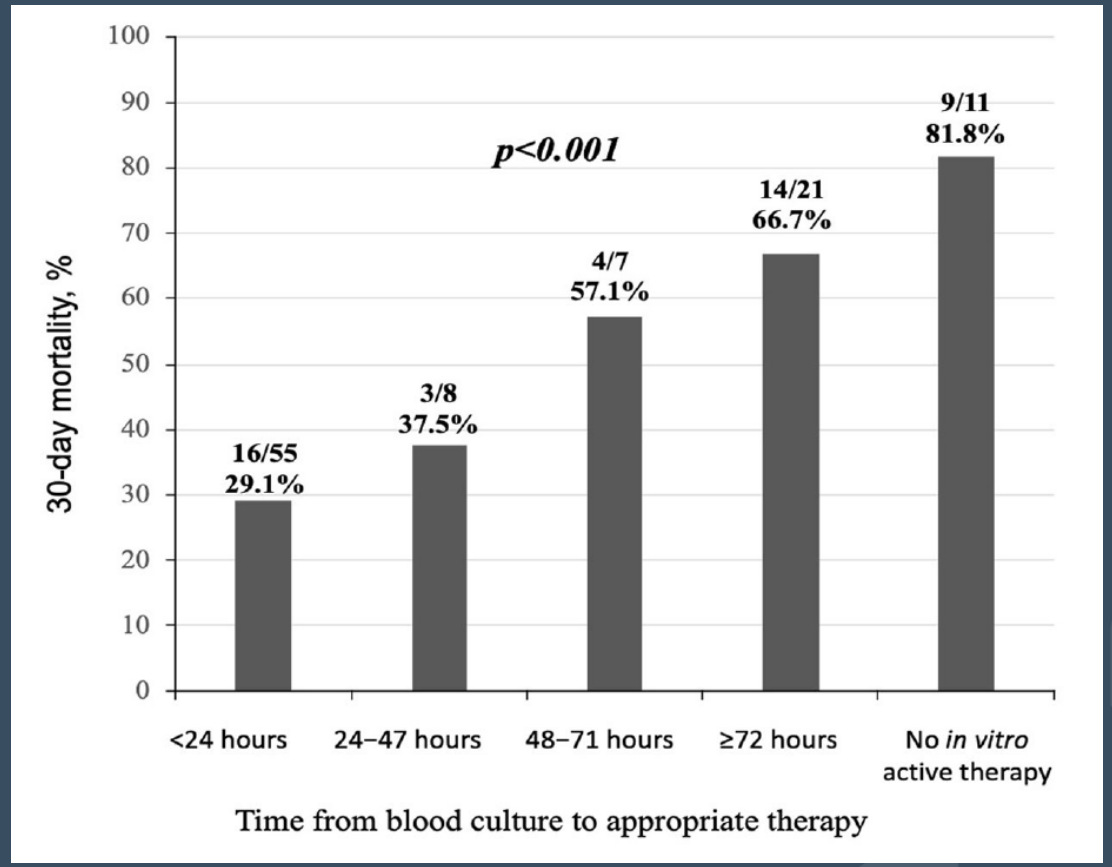
OR = odds ratio.

[a]Age, Acute Physiology and Chronic Health Evaluation score, and duration of hospitalization prior to bacteremia in days used as binary variables: ≤ 61, ≤ 16, ≤ 2 d.

[b]Within 90 d.

Goodness-of-fit by the Hosmer-Lemeshow test = 0.930.

DOI: 10.1097/CCM.0000000000000516 Crit Care Med. 2014 Nov;42(11):2342-9.



DOI: 10.1186/s13054-020-2742-9 Crit Care. 2020 Jan 30;24(1):29.

Time matters in sepsis & bacteremia

Post-analytical action is an important component of success:

"Rapid microarray testing on blood cultures combined with active antimicrobial stewardship intervention was associated with decreased time to antimicrobial switch, time to effective therapy, and hospital length of stay."

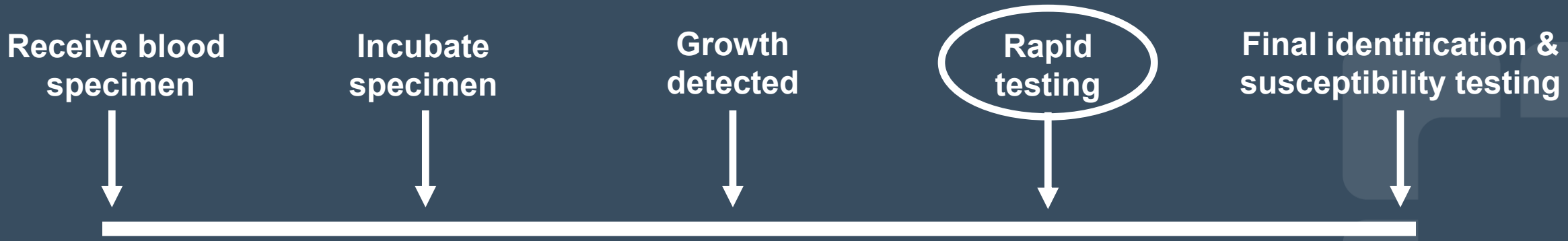
Rivard *et al*.
DOI: 10.1007/s10096-017-3008-6
Eur J Clin Microbiol Infect Dis. 2017 Oct;36(10):1879-1887.

"Integrating rapid diagnostics with antimicrobial stewardship improved time to optimal antibiotic therapy and effective antibiotic therapy. […] Mortality among patients during the intervention period was lower […]. Mean hospital costs for each inpatient survivor were reduced $26,298."

Perez *et al*.
DOI: 10.1016/j.jinf.2014.05.005
J Infect. 2014 Sep;69(3):216-25.

Time matters in sepsis & bacteremia

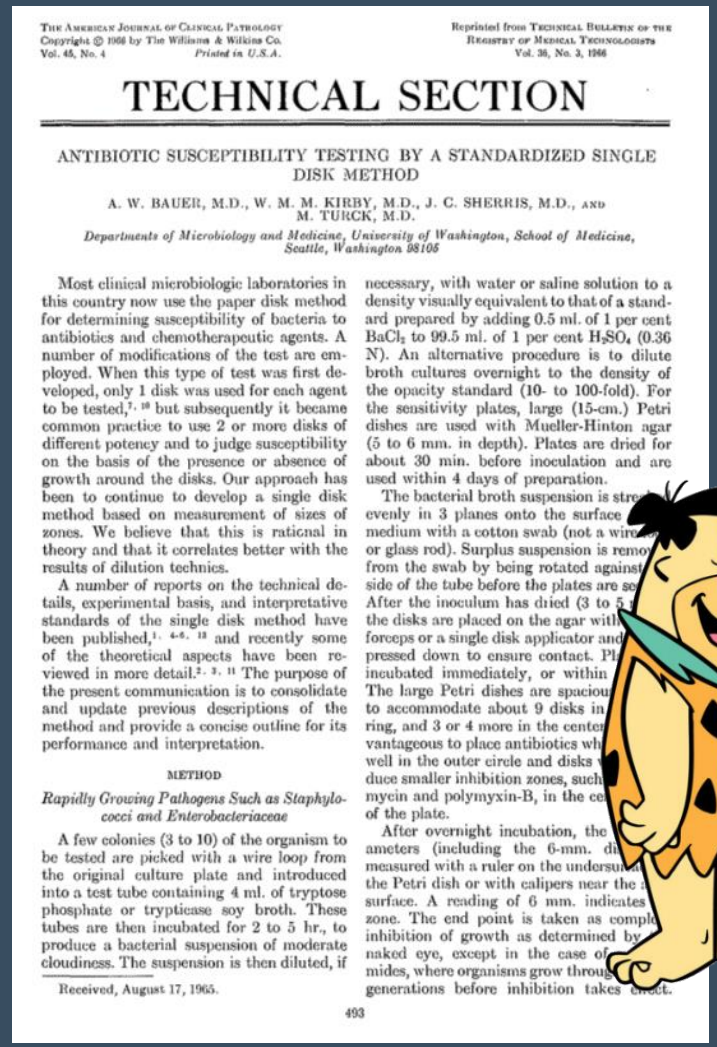
Lab testing:



Rapid testing for blood cultures

- Molecular detection of microbes & resistance genes
- Early MALDI
- Rapid antimicrobial susceptibility testing (AST)

In the beginning…



THE AMERICAN JOURNAL OF CLINICAL PATHOLOGY
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Vol. 45, No. 4 *Printed in U.S.A.*

Reprinted from TECHNICAL BULLETIN OF THE REGISTRY OF MEDICAL TECHNOLOGISTS
Vol. 36, No. 3, 1966

TECHNICAL SECTION

ANTIBIOTIC SUSCEPTIBILITY TESTING BY A STANDARDIZED SINGLE DISK METHOD

A. W. BAUER, M.D., W. M. M. KIRBY, M.D., J. C. SHERRIS, M.D., AND M. TURCK, M.D.

Departments of Microbiology and Medicine, University of Washington, School of Medicine, Seattle, Washington 98105

Most clinical microbiologic laboratories in this country now use the paper disk method for determining susceptibility of bacteria to antibiotics and chemotherapeutic agents. A number of modifications of the test are employed. When this type of test was first developed, only 1 disk was used for each agent to be tested,[7, 10] but subsequently it became common practice to use 2 or more disks of different potency and to judge susceptibility on the basis of the presence or absence of growth around the disks. Our approach has been to continue to develop a single disk method based on measurement of sizes of zones. We believe that this is rational in theory and that it correlates better with the results of dilution technics.

A number of reports on the technical details, experimental basis, and interpretative standards of the single disk method have been published,[1, 4-6, 12] and recently some of the theoretical aspects have been reviewed in more detail.[2, 3, 11] The purpose of the present communication is to consolidate and update previous descriptions of the method and provide a concise outline for its performance and interpretation.

METHOD

Rapidly Growing Pathogens Such as Staphylococci and Enterobacteriaceae

A few colonies (3 to 10) of the organism to be tested are picked with a wire loop from the original culture plate and introduced into a test tube containing 4 ml. of tryptose phosphate or trypticase soy broth. These tubes are then incubated for 2 to 5 hr., to produce a bacterial suspension of moderate cloudiness. The suspension is then diluted, if necessary, with water or saline solution to a density visually equivalent to that of a standard prepared by adding 0.5 ml. of 1 per cent $BaCl_2$ to 99.5 ml. of 1 per cent H_2SO_4 (0.36 N). An alternative procedure is to dilute broth cultures overnight to the density of the opacity standard (10- to 100-fold). For the sensitivity plates, large (15-cm.) Petri dishes are used with Mueller-Hinton agar (5 to 6 mm. in depth). Plates are dried for about 30 min. before inoculation and are used within 4 days of preparation.

The bacterial broth suspension is stre… evenly in 3 planes onto the surface … medium with a cotton swab (not a wire… or glass rod). Surplus suspension is remov… from the swab by being rotated against… side of the tube before the plates are se… After the inoculum has dried (3 to 5… the disks are placed on the agar with… forceps or a single disk applicator and… pressed down to ensure contact. Pl… incubated immediately, or within … The large Petri dishes are spaciou… to accommodate about 9 disks in … ring, and 3 or 4 more in the center… vantageous to place antibiotics wh… well in the outer circle and disks … duce smaller inhibition zones, such… mycin and polymyxin-B, in the ce… of the plate.

After overnight incubation, the … ameters (including the 6-mm. di… measured with a ruler on the undersur… the Petri dish or with calipers near the … surface. A reading of 6 mm. indicates … zone. The end point is taken as compl… inhibition of growth as determined by … naked eye, except in the case of … mides, where organisms grow throug… generations before inhibition takes effect.

Received, August 17, 1965.

April 1966 PMID: 5325707

7 years later (& 50 years ago)…

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Departments of Microbiology and Medicine, University of Washington, School of Medicine, Seattle, Washington 98105

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The bacterial broth suspension is streaked evenly in 3 planes onto the surface of the medium with a cotton swab (not a wire loop or glass rod). Surplus suspension is removed from the swab by being rotated against the side of the tube before the plates are seeded. After the inoculum has dried (3 to 5 min.), the disks are placed on the agar with flamed forceps or a single disk applicator and gently pressed down to ensure contact. Plates are incubated immediately, or within 30 min. The large Petri dishes are spacious enough to accommodate about 9 disks in an outer ring, and 3 or 4 more in the center. It is advantageous to place antibiotics which diffuse well in the outer circle and disks which produce smaller inhibition zones, such as vancomycin and polymyxin-B, in the central area of the plate.

After overnight incubation, the zone diameters (including the 6-mm. disk) are measured with a ruler on the undersurface of the Petri dish or with calipers near the agar surface. A reading of 6 mm. indicates no zone. The end point is taken as complete inhibition of growth as determined by the naked eye, except in the case of sulfonamides, where organisms grow through several generations before inhibition takes effect.

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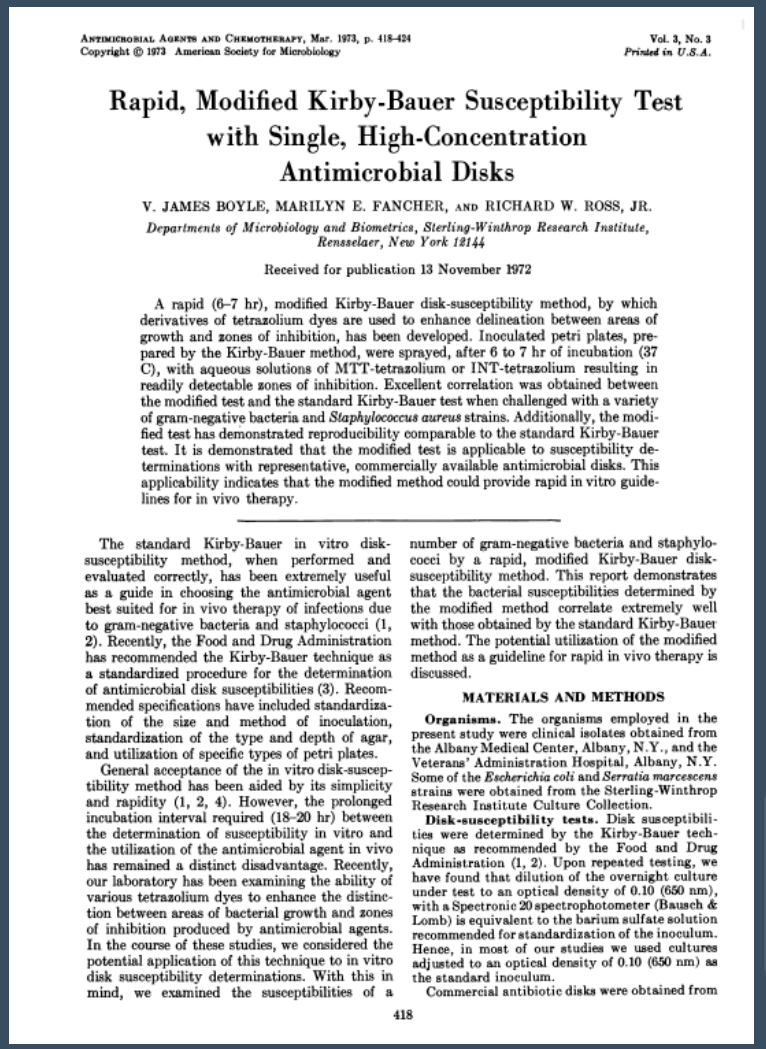

ANTIMICROBIAL AGENTS AND CHEMOTHERAPY, Mar. 1973, p. 418-424
Copyright © 1973 American Society for Microbiology
Vol. 3, No. 3
Printed in U.S.A.

Rapid, Modified Kirby-Bauer Susceptibility Test with Single, High-Concentration Antimicrobial Disks

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Received for publication 13 November 1972

A rapid (6–7 hr), modified Kirby-Bauer disk-susceptibility method, by which derivatives of tetrazolium dyes are used to enhance delineation between areas of growth and zones of inhibition, has been developed. Inoculated petri plates, prepared by the Kirby-Bauer method, were sprayed, after 6 to 7 hr of incubation (37 C), with aqueous solutions of MTT-tetrazolium or INT-tetrazolium resulting in readily detectable zones of inhibition. Excellent correlation was obtained between the modified test and the standard Kirby-Bauer test when challenged with a variety of gram-negative bacteria and *Staphylococcus aureus* strains. Additionally, the modified test has demonstrated reproducibility comparable to the standard Kirby-Bauer test. It is demonstrated that the modified test is applicable to susceptibility determinations with representative, commercially available antimicrobial disks. This applicability indicates that the modified method could provide rapid in vitro guidelines for in vivo therapy.

The standard Kirby-Bauer in vitro disk-susceptibility method, when performed and evaluated correctly, has been extremely useful as a guide in choosing the antimicrobial agent best suited for in vivo therapy of infections due to gram-negative bacteria and staphylococci (1, 2). Recently, the Food and Drug Administration has recommended the Kirby-Bauer technique as a standardized procedure for the determination of antimicrobial disk susceptibilities (3). Recommended specifications have included standardization of the size and method of inoculation, standardization of the type and depth of agar, and utilization of specific types of petri plates.

General acceptance of the in vitro disk-susceptibility method has been aided by its simplicity and rapidity (1, 2, 4). However, the prolonged incubation interval required (18–20 hr) between the determination of susceptibility in vitro and the utilization of the antimicrobial agent in vivo has remained a distinct disadvantage. Recently, our laboratory has been examining the ability of various tetrazolium dyes to enhance the distinction between areas of bacterial growth and zones of inhibition produced by antimicrobial agents. In the course of these studies, we considered the potential application of this technique to in vitro disk susceptibility determinations. With this in mind, we examined the susceptibilities of a number of gram-negative bacteria and staphylococci by a rapid, modified Kirby-Bauer disk-susceptibility method. This report demonstrates that the bacterial susceptibilities determined by the modified method correlate extremely well with those obtained by the standard Kirby-Bauer method. The potential utilization of the modified method as a guideline for rapid in vivo therapy is discussed.

MATERIALS AND METHODS

Organisms. The organisms employed in the present study were clinical isolates obtained from the Albany Medical Center, Albany, N.Y., and the Veterans' Administration Hospital, Albany, N.Y. Some of the *Escherichia coli* and *Serratia marcescens* strains were obtained from the Sterling-Winthrop Research Institute Culture Collection.

Disk-susceptibility tests. Disk susceptibilities were determined by the Kirby-Bauer technique as recommended by the Food and Drug Administration (1, 2). Upon repeated testing, we have found that dilution of the overnight culture under test to an optical density of 0.10 (650 nm), with a Spectronic 20 spectrophotometer (Bausch & Lomb) is equivalent to the barium sulfate solution recommended for standardization of the inoculum. Hence, in most of our studies we used cultures adjusted to an optical density of 0.10 (650 nm) as the standard inoculum.

Commercial antibiotic disks were obtained from

1973 PMID: 4790600

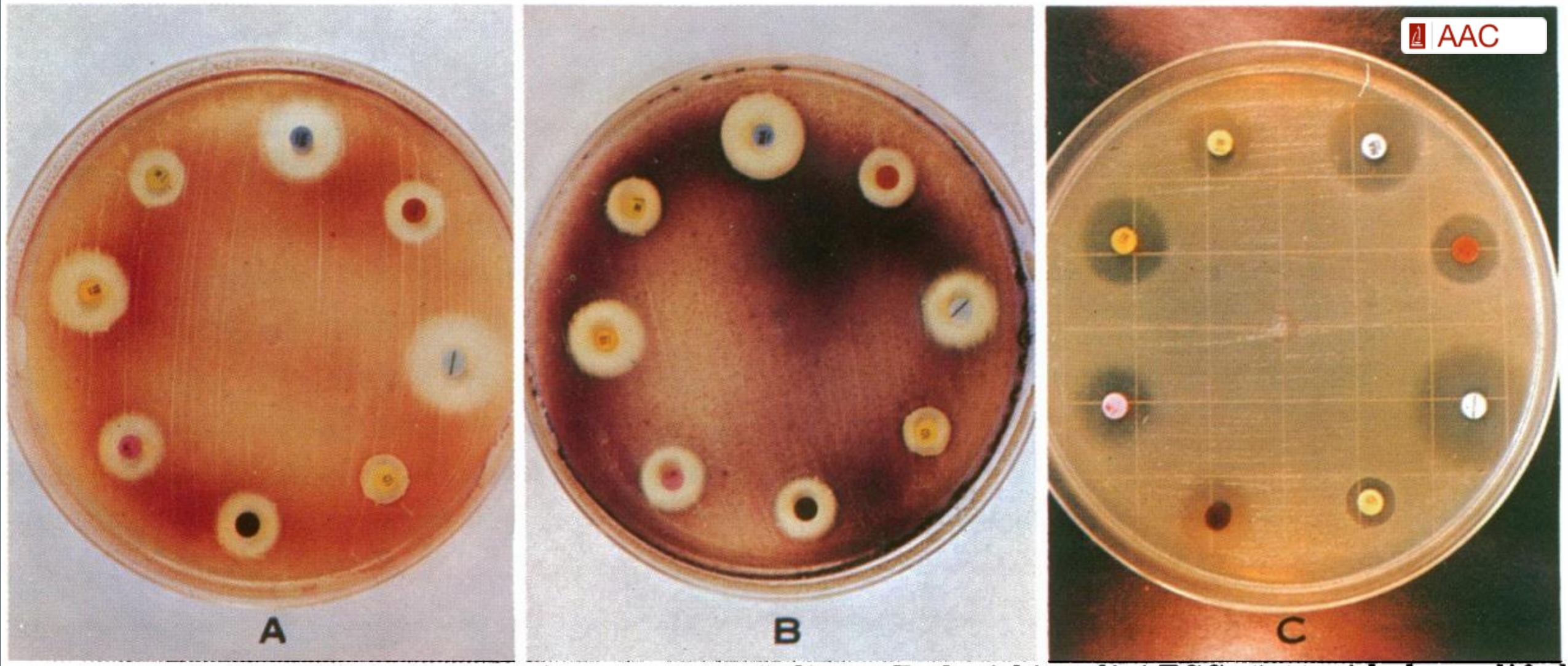

FIG. 1. *Comparative detection of the disk susceptibility of Escherichia coli ATCC 25922 with the modified Kirby-Bauer method and the standard Kirby-Bauer method. A, Modified Kirby-Bauer with 0.2% INT-tetrazolium; B, modified Kirby-Bauer with 0.5% MTT-tetrazolium; C, standard Kirby-Bauer method.*

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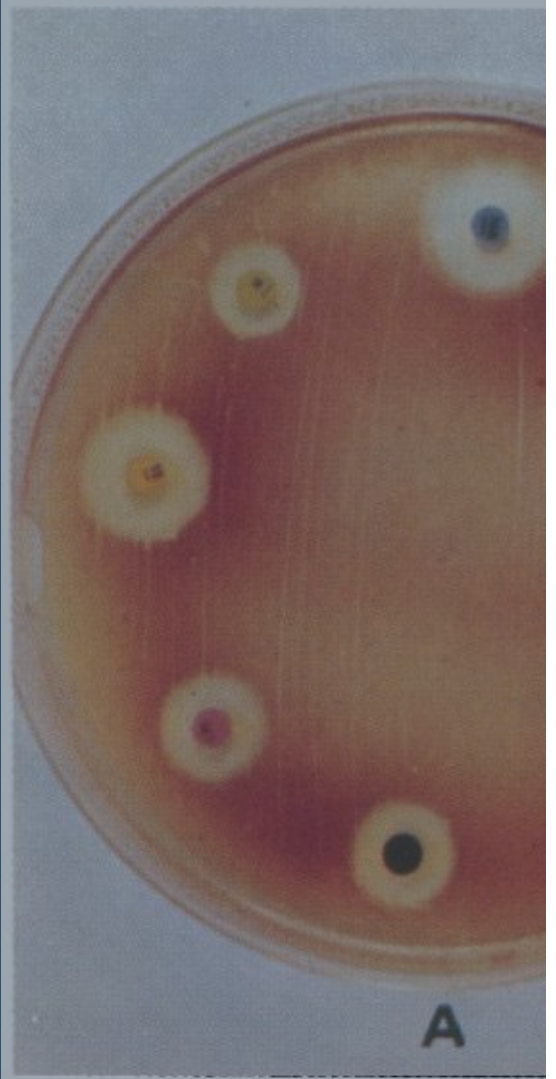
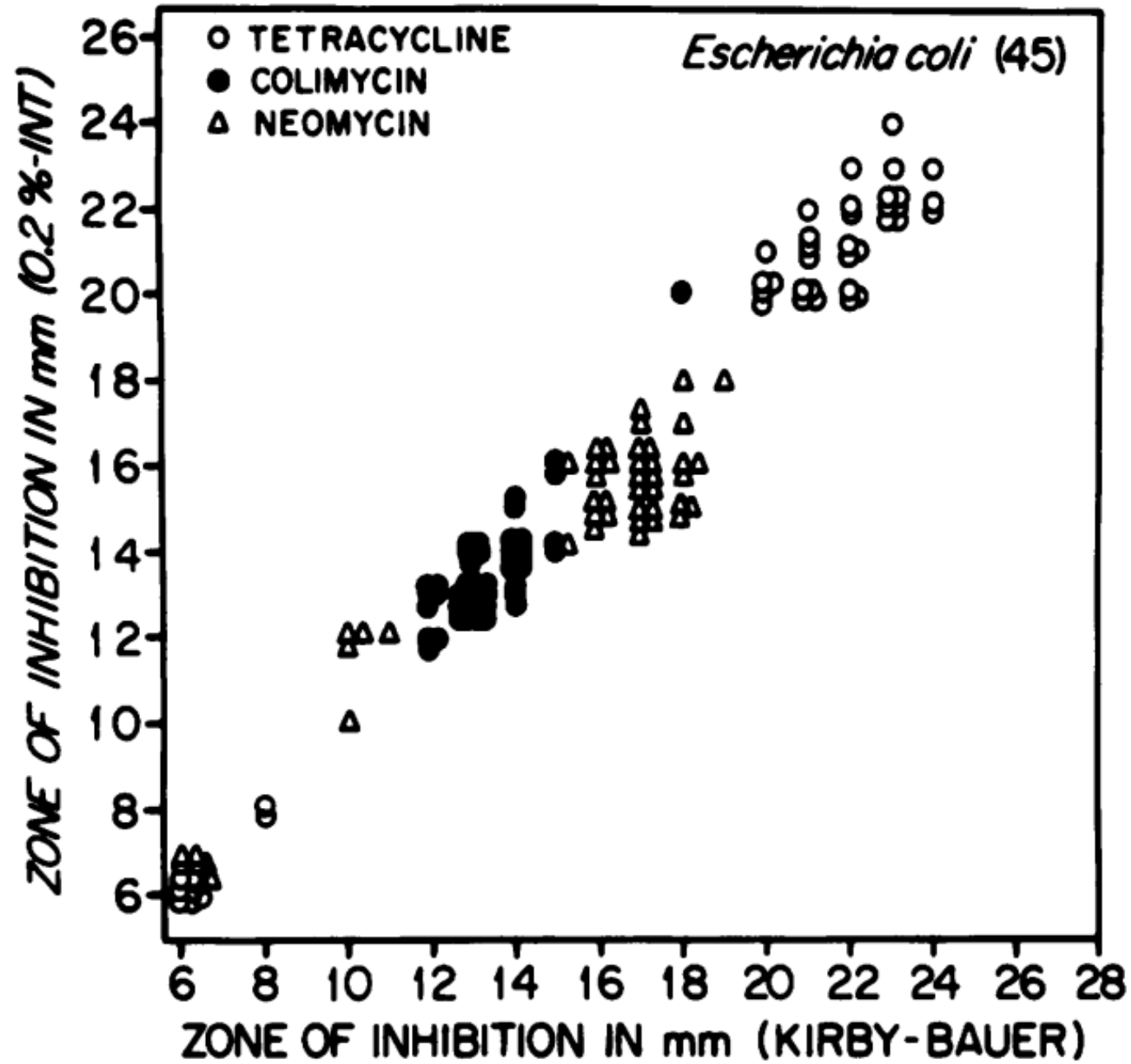
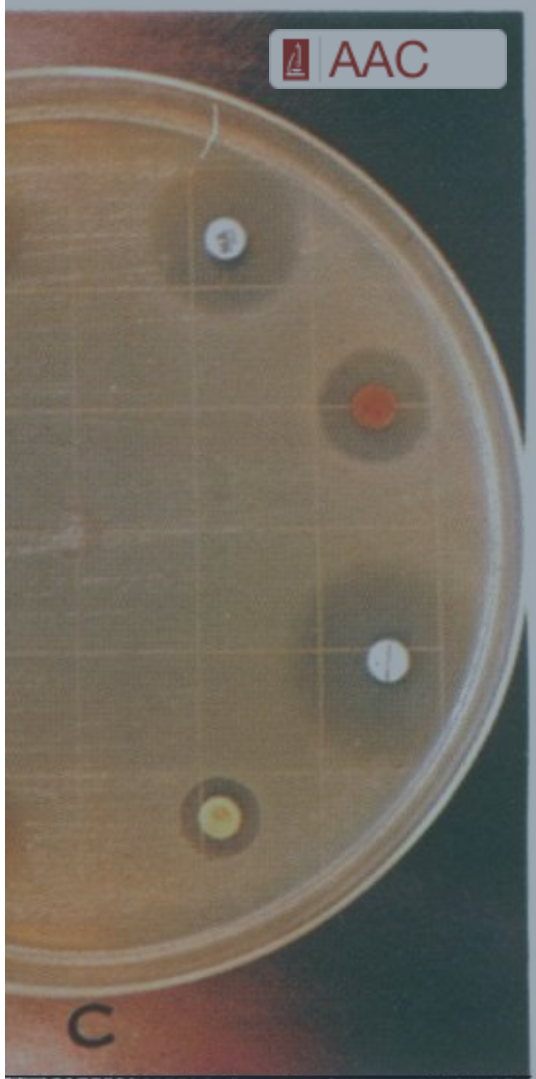


FIG. 1. *Comparativ*
Kirby-Bauer method
tetrazolium; B, modifi



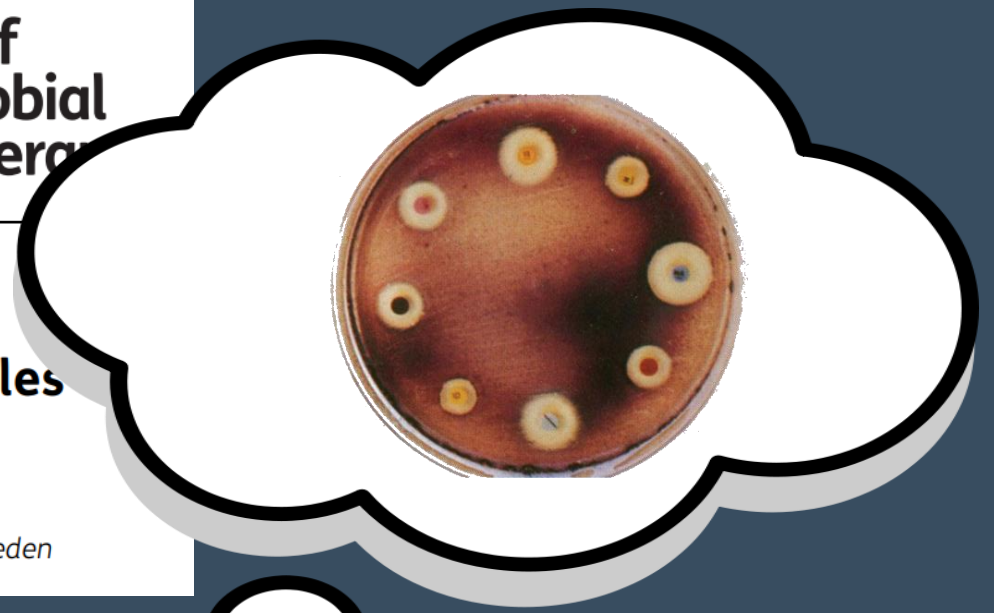


25922 with the modified
auer with 0.2% INT-
y-Bauer method.

PMID: 4790600

J Antimicrob Chemother 2020; **75**: 968–978
doi:10.1093/jac/dkz548 Advance Access publication 4 February 2020

Journal of Antimicrobial Chemothera



The EUCAST rapid disc diffusion method for antimicrobial susceptibility testing directly from positive blood culture bottles

Emma Jonasson[1]*, Erika Matuschek[2] and Gunnar Kahlmeter[1,2]

[1]Department of Clinical Microbiology, Central Hospital, Växjö, Sweden; [2]EUCAST Development Laboratory, Växjö, Sweden

2020 PMID: 32789506

Table 3F-1. Test for Performing Disk Diffusion Directly From Positive Blood Culture Broth

Test	Direct Disk Diffusion
Test method	Disk diffusion using positive blood culture broth
Organism group	Enterobacterales, *Pseudomonas aeruginosa*, and *Acinetobacter* spp.
Medium	MHA
Antimicrobial concentration	Standard disk contents for the antimicrobial agents are detailed in Table 3F-2 (Enterobacterales), Table 3F-3 (*P. aeruginosa*), and Table 3F-4 (*Acinetobacter* spp.).
Inoculum	Positive blood culture broth with gram-negative bacilli, used within 8 h of flagging positive by the blood culture system
Test procedure	1. Invert blood culture bottle 5–10 times to thoroughly mix. 2. Sterilize the top of the bottle with an alcohol wipe (allow to dry) and insert 20-gauge venting needle into the blood culture bottle. 3. Dispense 4 drops of blood culture broth onto an MHA plate. As a purity check, use an inoculated blood agar plate streaked for isolation. 4. Spread blood culture broth across the entire surface of the MHA plate using a sterile cotton swab. 5. Repeat this procedure by streaking twice more, rotating the plate approximately 60 degrees each time to ensure an even distribution of inoculum. 6. Leave the lid ajar for 3–5 minutes (ideally) but no more than 15 minutes. 7. Dispense antimicrobial disks onto the surface of the inoculated MHA plate. 8. Press each disk down to ensure complete contact with the agar surface. 9. Invert the plate and place in the incubator within 15 minutes of disks being applied.
Incubation conditions	35°C ± 2°C; ambient air
Incubation length	8–10 h or 16–18 h (refer to Tables 3F-2, 3F-3, and 3F-4 for antimicrobial agent–specific incubation lengths)

CLSI M100-Ed35

2018 PMID: 29305540

What is rapid?

JOURNAL OF CLINICAL MICROBIOLOGY, Aug. 2001, p. 2964–2966
0095-1137/01/$04.00+0 DOI: 10.1128/JCM.39.8.2964–2966.2001

JCM Vol. 39, No. 8

Evaluation of VITEK 2 Rapid Identification and Susceptibility Testing System against Gram-Negative Clinical Isolates

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Received 9 April 2001/Returned for modification 8 May 2001/Accepted 18 May 2001

A total of 281 strains of miscellaneous members of the family *Enterobacteriaceae*, *Pseudomonas aeruginosa*, n-negative bacteria were evaluated by use of identification tests with the VITEK 2 system (bio- n API identification system (bioMérieux). A total of 237 (95%) strains were correctly identified to the nly six (2.1%) strains were misidentified, and eight (2.8%) strains were not identified. Among 14 crepant identifications, 8 (57.1%) strains were nonfermenters. The susceptibilities of 228 strains to cluding amikacin, netilmicin, tobramycin, gentamicin, ciprofloxacin, imipenem, meropenem, ceftazi- piperacillin, and piperacillin in combination with tazobactam were tested with the VITEK 2 AST- by the broth microdilution (MB) method, according to NCCLS guidelines, as a reference. For sm-antibiotic combinations, the rates at which duplicate MICs correlated within ±1 dilution to 95.6%. Only 13 (0.5%) and 10 (0.4%) of the susceptibility tests gave major errors (resistant 2 system but sensitive by the MB method) and very major errors (sensitive with the VITEK 2 nt by the MB method), respectively. Both VITEK 2 ID-GNB (an identification system) and VITEK (a susceptibility testing system) card systems gave rapid, reliable, and highly reproducible results.

JOURNAL OF CLINICAL MICROBIOLOGY, Oct. 2003, p. 4705–4707
0095-1137/03/$08.00+0 DOI: 10.1128/JCM.41.10.4705–4707.2003

JCM Vol. 41, No. 10

Evaluation of the VITEK 2 System for Rapid Direct Identification and Susceptibility Testing of Gram-Negative Bacilli from Positive Blood Cultures

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Department of Microbiology, The Chinese University of Hong Kong, Prince of Wales Hospital, Hong Kong, Special Administrative Region, People's Republic of China

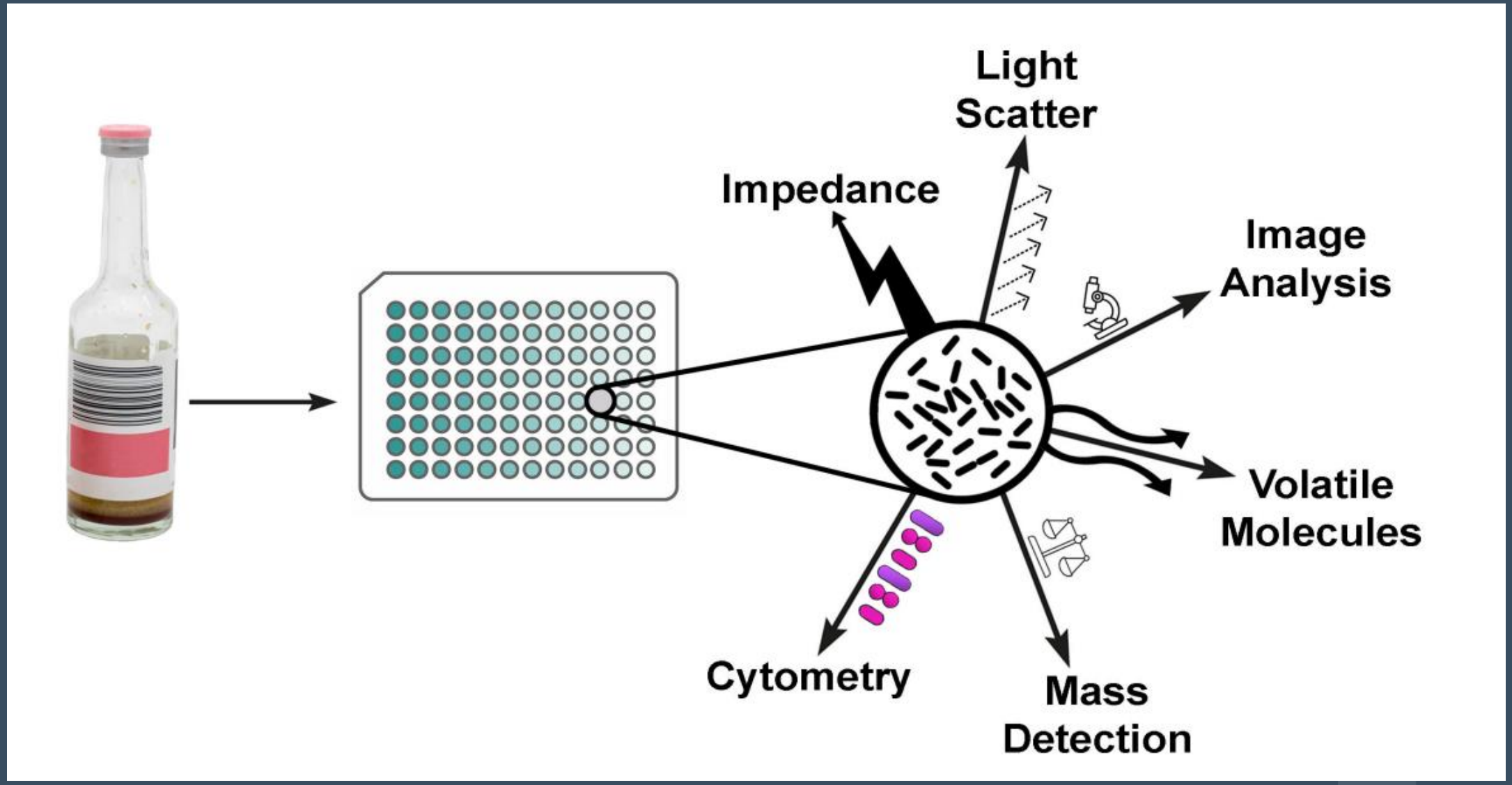
Received 29 April 2003/Returned for modification 9 July 2003/Accepted 29 July 2003

This study explores the possibility of combining the BacT/Alert Microbial Detection System with the VITEK 2 system to achieve rapid bacterial identification and susceptibility testing. Direct inoculation of bacterial suspension to the VITEK 2 ID-GNB card and AST-NO09 card was made by differential centrifugation of blood es of organisms with gram-negative enteric bacillus-like morphology. A total of 118 strains were inves- l; of these, 97 (82.2%) strains were correctly identified to the species level and 21 (17.8%) strains were ntified; by comparing the results with those of the reference method of API identification systems using culture, it was found that no strain had been misidentified. Among the 21 strains with no identification, .9%) strains were nonfermenters. The direct-identification reporting time of VITEK 2 was 3.3 h. Direct ; of susceptibility to 11 antibiotics, i.e., amikacin, cefepime, ceftazidime, ciprofloxacin, gentamicin, imi- meropenem, netilmicin, piperacillin, piperacillin-tazobactam, and tobramycin, was also performed by he broth microdilution (MB) method according to the NCCLS guidelines as a reference. After com- he MICs of the VITEK 2 system with those obtained by the MB method within ±twofold dilution, it rmined that the 1,067 organism-antibiotic combinations had an overall correct rate of 97.6% (1,041 tions). The rates of susceptibility to the 11 antibiotics ranged from 88.7 to 100%, respectively. Only two nd four (0.4%) combinations of the susceptibility tests gave very major errors (i.e., reported as tive by the VITEK 2 system but shown to be resistant by the MB method) and major errors (i.e., reported sistant by the VITEK 2 system but shown to be sensitive by the MB method), respectively. The reporting time for the direct testing of susceptibility against the 11 antibiotics for 97 blood culture isolates by the VITEK 2 system ranged from 3.3 to 17.5 h. Compared with conventional methods that require 1 or 2 days, this method can make same-day reporting possible and thus permit better patient management.

Our focus today

- “New” automated commercial solutions for rapid AST
- “Rapid” defined as 8 hours or fewer

Our focus today



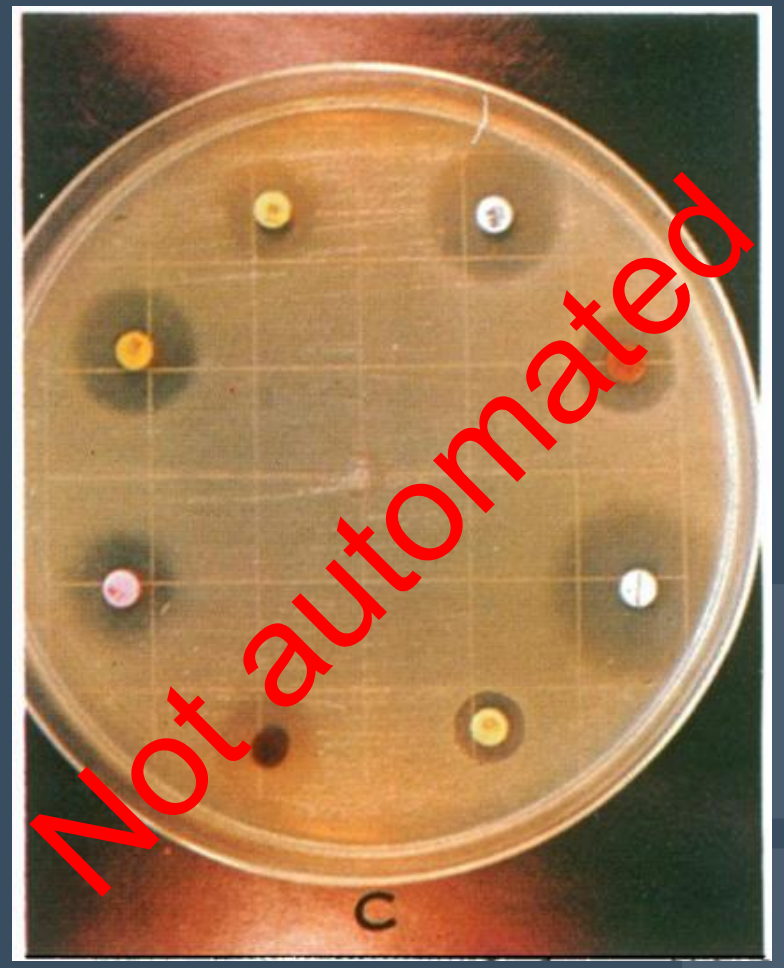
2025 PMID: 40899882

Our focus today

"New" automated commercial solutions for rapid AST

Our focus today

"New" automated commercial solutions for rapid AST



Our focus today

“New” automated commercial solutions for rapid AST

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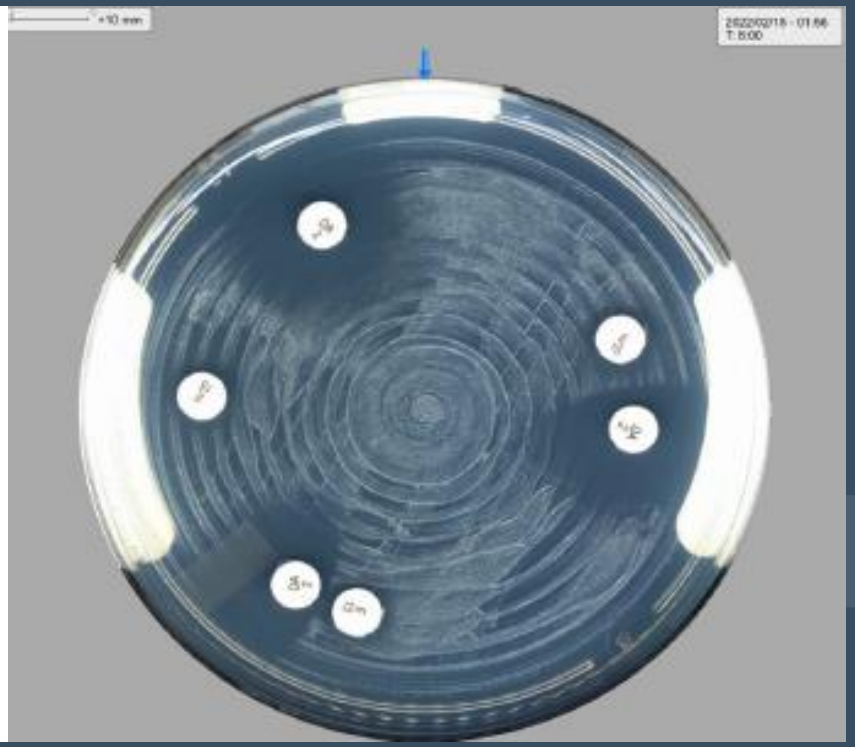
BACTERIOLOGY

Check for updates

Fully Automated EUCAST Rapid Antimicrobial Susceptibility Testing (RAST) from Positive Blood Cultures: Diagnostic Accuracy and Implementation

Abdessalam Cherkaoui,[a,b] Didier Schorderet,[a] Nouria Azam,[a] Luigi Crudeli,[a] José Fernandez,[a] Gesuele Renzi,[a] Adrien Fischer,[a] Jacques Schrenzel[a,c]

[a]Bacteriology Laboratory, Division of Laboratory Medicine, Department of Diagnostics, Geneva University Hospitals, Geneva, Switzerland
[b]Faculty of Medicine, Geneva, Switzerland
[c]Genomic Research Laboratory, Division of Infectious Diseases, Department of Medicine, Geneva University Hospitals and Faculty of Medicine, Geneva, Switzerland



2022 PMID: 36173195

① Copan Radian

Radian is on the market in the USA, but it has not yet been evaluated by the FDA.

https://www.copangroup.com/product-ranges/radian/ Accessed 6 May 2024

① Copan Radian

J Antimicrob Chemother
doi:10.1093/jac/dkx026

Journal of Antimicrobial Chemotherapy

Fully automated disc diffusion for rapid antibiotic susceptibility test results: a proof-of-principle study

Michael Hombach*†, Marion Jetter†, Nicolas Blöchliger, Natalia Kolesnik-Goldmann and Erik C. Böttger

2017 PMID: 28333189

1

	8 versus 18 h				
Species/drug	readability	categorical agreement	vMEs	MEs	mEs
E. coli, $n = 291$					
ampicillin	100	100	0.3	0.0	0.0
amoxicillin/clavulanate	100	89.0	0.7	**10.7**	0.0
piperacillin/tazobactam	100	96.6	0.3	0.0	3.4
cefuroxime	100	97.6	**2.8**	0.0	0.0
cefoxitin	100	95.2	**3.8**	**1.4**	0.0
cefpodoxime	100	97.2	**2.4**	0.7	0.0
ceftriaxone	100	100	0.0	0.0	0.3
cefepime	100	99.0	0.0	0.0	1.4
meropenem	100	100	0.0	0.0	0.3
norfloxacin	100	93.8	0.0	0.0	**6.6**
ciprofloxacin	100	97.6	0.0	0.0	2.8
levofloxacin	100	95.2	0.0	0.0	**5.2**
amikacin	100	97.6	0.0	0.0	2.8
gentamicin	100	99.3	0.0	0.0	1.0
tobramycin	100	90.0	0.0	0.0	**10.3**
tigecycline	100	99.3	0.0	0.0	1.0
nitrofurantoin	100	99.3	**1.0**	0.0	0.0
trimethoprim/sulfamethoxazole	100	91.4	**3.8**	0.0	**5.2**
average	100	96.6	0.8	0.7	2.2

2017 PMID: 28333189

2 FDA Accelerate Pheno

- Direct from positive blood culture in 7 hours
- Susceptibility determined using microscopic analysis
- Identification using nucleic acid probes
- Physically large consumables

	Identification	Ampicillin-Sulbactam	Piperacillin-Tazobactam	Cefepime	Ceftazidime	Ceftriaxone	Ertapenem	Meropenem	Amikacin	Gentamicin	Tobramycin	Ciprofloxacin	Aztreonam
E. coli	●	●	●	●	●	●	●	●	●	●	●	●	●
Klebsiella spp.	●	●	●	●	●	●	●	●	●	●	●	●	●
Enterobacter spp.	●		●	●	●	●	●	●	●	●	●	●	●
Proteus spp.	●	●	●	●	●	●	●	●	●	●	●	●	●
Citrobacter spp.	●		●	●	●	●	●	●	●	●	●	●	●
S. marcescens	●		●	●	●	●	●	●	●	●	●	●	●
P. aeruginosa	●		●	●	●			●	●	●	●	●	●
A. baumannii	●		●						●				

② FDA Accelerate Pheno

Rapid AST determined by “Morphokinetic Cellular Analysis”

2 FDA

Accelerate Pheno

Clinical Infectious Diseases

MAJOR ARTICLE

IDSA Infectious Diseases Society of America

hivma hiv medicine association

OXFORD

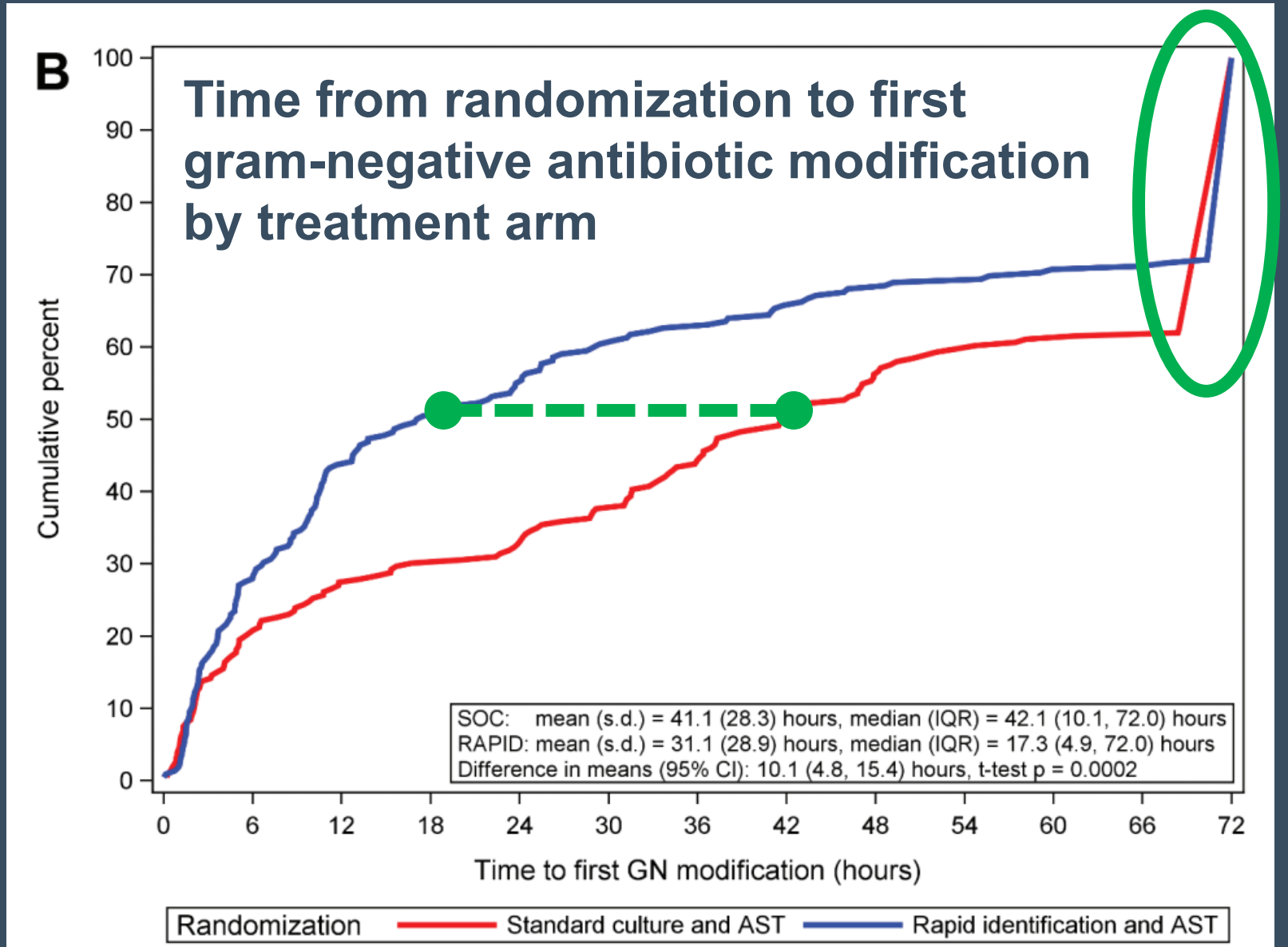
Randomized Trial Evaluating Clinical Impact of RAPid IDentification and Susceptibility Testing for Gram-negative Bacteremia: RAPIDS-GN

Ritu Banerjee,[1] Lauren Komarow,[2] Abinash Virk,[3] Nipunie Rajapakse,[3] Audrey N. Schuetz,[3] Brenda Dylla,[3] Michelle Earley,[2] Judith Lok,[4] Peggy Kohner,[3] Sherry Ihde,[3] Nicolynn Cole,[3] Lisa Hines,[3] Katelyn Reed,[3] Omai B. Garner,[5] Sukantha Chandrasekaran,[5] Annabelle de St. Maurice,[5] Meganne Kanatani,[5] Jennifer Curello,[5] Rubi Arias,[5] William Swearingen,[5] Sarah B. Doernberg,[6] and Robin Patel[3]; for the Antibacterial Resistance Leadership Group

PMID: 32374822

2

Accelerate Pheno



PMID: 32374822

2 FDA Accelerate Pheno

	Standard AST method (h)	Rapid AST method (h)
Standard of care cohort	**45 ± 12**	**--**
Rapid AST cohort	**50 ± 16**	**13.5 ± 56**

Fast

Accelerate PhenoTest® BC kit

–

Average time to results:

Antibiotic susceptibility in ~ 7 hours

Identification in ~ 2 hours

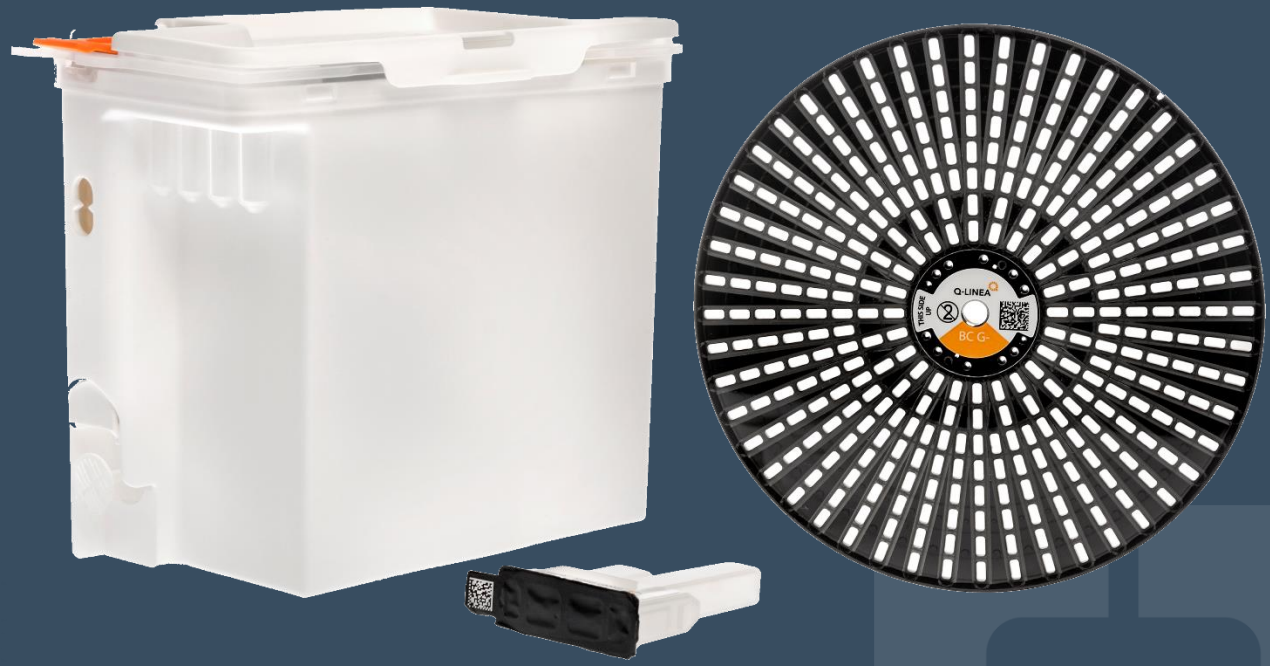
ymmv

PMID: 32374822

3

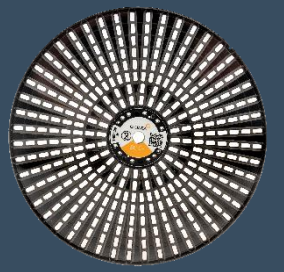
Q-Linea ASTar

- Direct from positive blood culture in 6 hours
- Susceptibility determined using microscopic analysis
- Random-access 12 samples per instrument



3

Q-Linea ASTar



- Direct from positive blood culture
- Susceptibility determined using microscopic analysis
- Random-access 12 samples per instrument

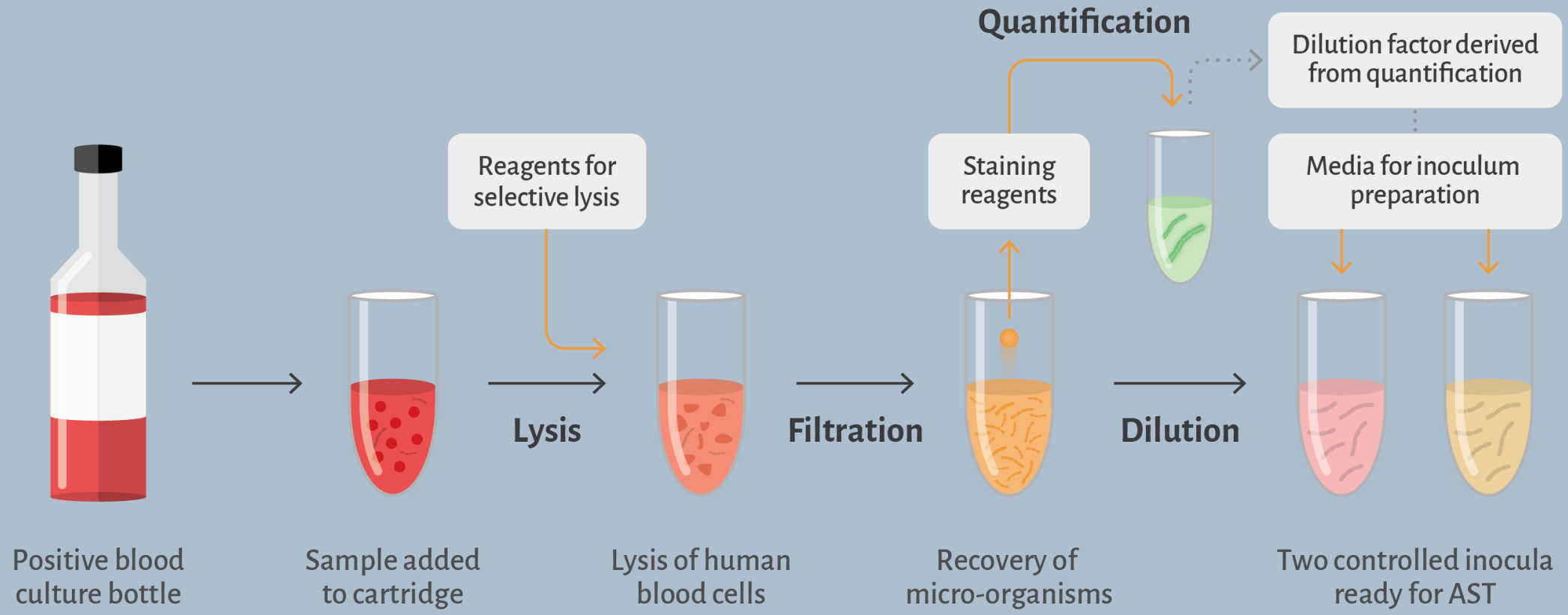


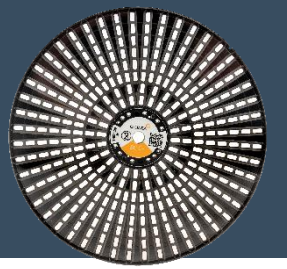
Table 1: ASTar BC G- Kit Product Panel

Antimicrobial class	Antimicrobial agent	*A. baumannii*	*C. freundii*	*C. koseri*	*E. cloacae* complex*	*E. coli*	*K. aerogenes*	*K. oxytoca*	*K. pneumoniae*	*P. aeruginosa*	*P. mirabilis*	*P. vulgaris*	*S. marcescens*
Penicillins	Ampicillin					●					●		
β-lactam combination agents	Ampicillin-sulbactam					●		●	●		●	●	
β-lactam combination agents	Ceftazidime-avibactam		●	●	●			●		●	●		●
β-lactam combination agents	Meropenem-vaborbactam		●	●	●	●	●	●	●		●		●
β-lactam combination agents	Piperacillin-tazobactam			●		●			●		●	●	●
Cephalosporin	Cefazolin								●				
Cephalosporin	Cefepime		●			●	●	●	●	●	●	●	●
Cephalosporin	Cefuroxime					●		●	●		●		
Cephalosporin	Ceftazidime				●	●		●	●		●	●	●
Monobactam	Aztreonam			●	●	●	●	●	●		●	●	●
Carbapenem	Meropenem	●	●	●		●				●	●	●	●
Aminoglycoside	Gentamicin		●	●				●	●	●	●	●	●
Aminoglycoside	Tobramycin		●	●	●	●			●		●		●
Aminoglycoside	Amikacin		●		●		●	●	●	●	●		●
Tetracycline	Tigecycline		●	●	●	●	●	●	●				●
Fluoroquinolone	Ciprofloxacin			●	●	●	●	●	●	●	●	●	●
Fluoroquinolone	Levofloxacin		●	●	●	●	●	●	●	●	●	●	●
Miscellaneous	Trimethoprim-sulfamethoxazole				●	●	●	●	●			●	

**Enterobacter cloacae* complex includes *E. cloacae*, *E. asburiae* and *E. hormaechei*.

3

Q-Linea ASTar



AMERICAN SOCIETY FOR MICROBIOLOGY | Journal of Clinical Microbiology

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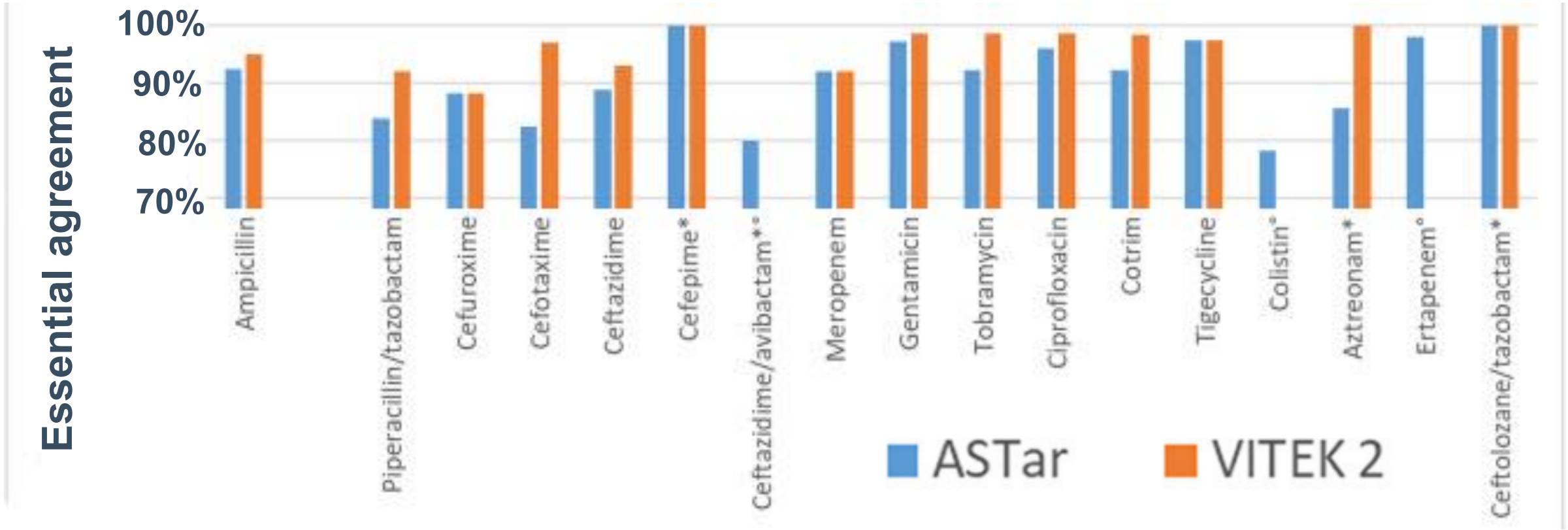
Clinical Microbiology | Full-Length Text

Rapid phenotypic antimicrobial susceptibility testing of Gram-negative rods directly from positive blood cultures using the novel Q-linea ASTar system

Jan Esse,[1] Johannes Träger,[1] Giuseppe Valenza,[1] Christian Bogdan,[1] Jürgen Held[1]

2023 PMID: 37819072

3 FDA Q-Linea ASTar



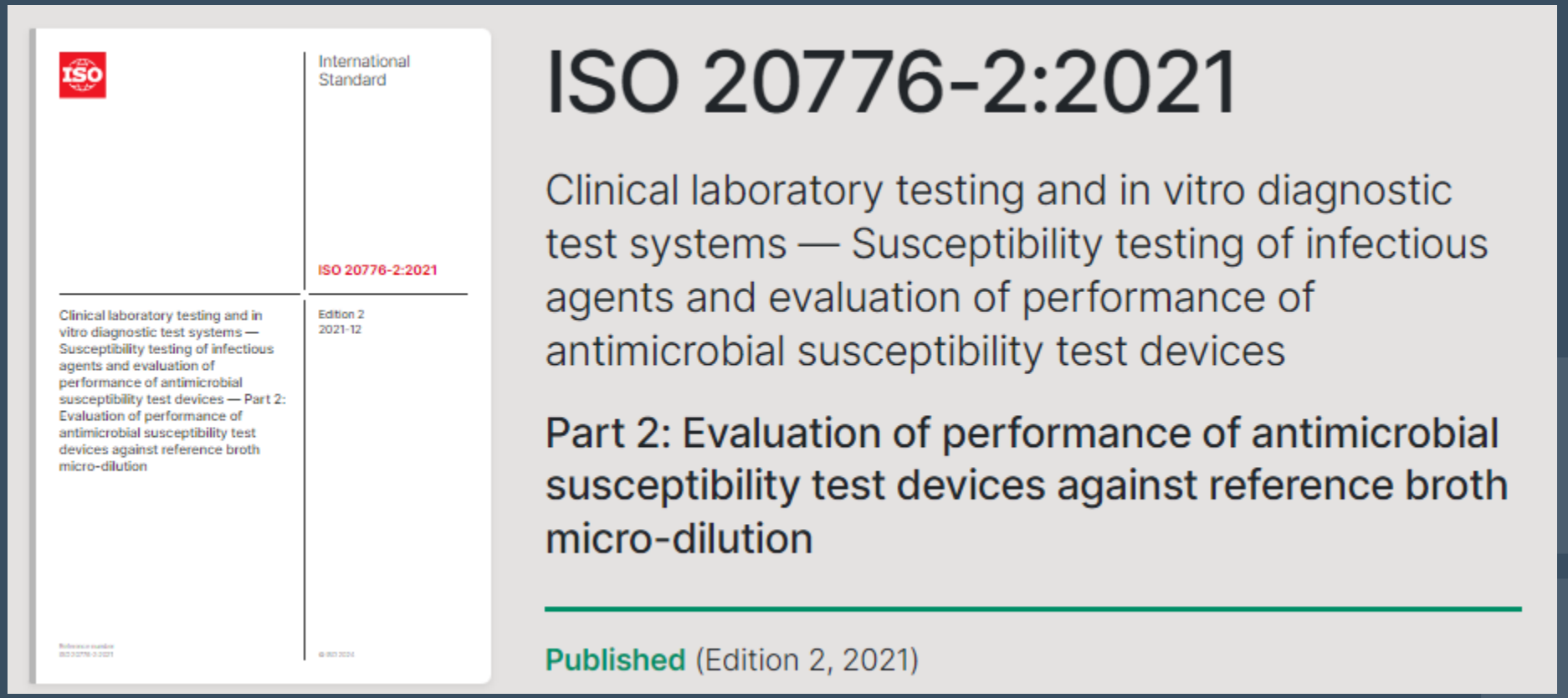
Comparison of essential agreement using ASTar and the lab's SOC rapid method (modified Vitek 2) was similar when Micronaut-S (Merlin; Germany) was used as the reference.

PMID: 37819072

ISO 20776-2:2021

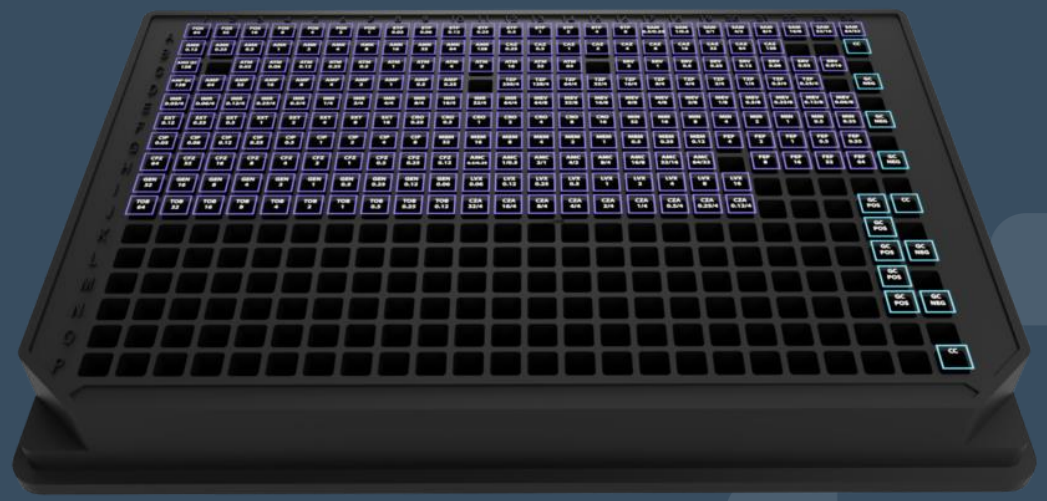
“MIC AST devices should always have both an overall EA of ≥ 90%
when compared to the reference method result(s) and less than ± 30% bias.”

“When making the comparison between any derivative test and that of the reference method, it is appropriate to apply measures of assay performance only and not result interpretation.”



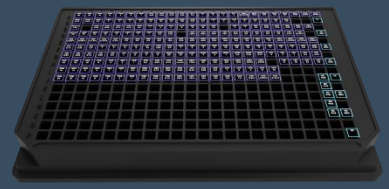
4 Selux Next-Gen Phenotyping

- Isolates or direct from positive blood culture in 6-7 hours
- Susceptibility determined by fluorescent growth indicators including a viability assay (resazurin) and a surface-binding assay (europium probe)
- Large antibiotic dilution series (384-well platform) & capacity for 86 panels
- 23 gram-negative drugs & 14 gram-positive drugs
- Large instrument

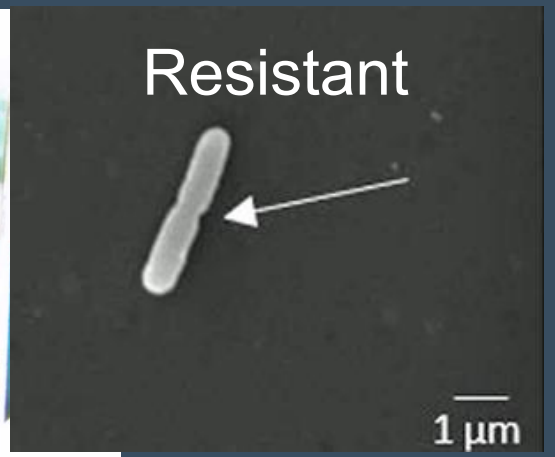


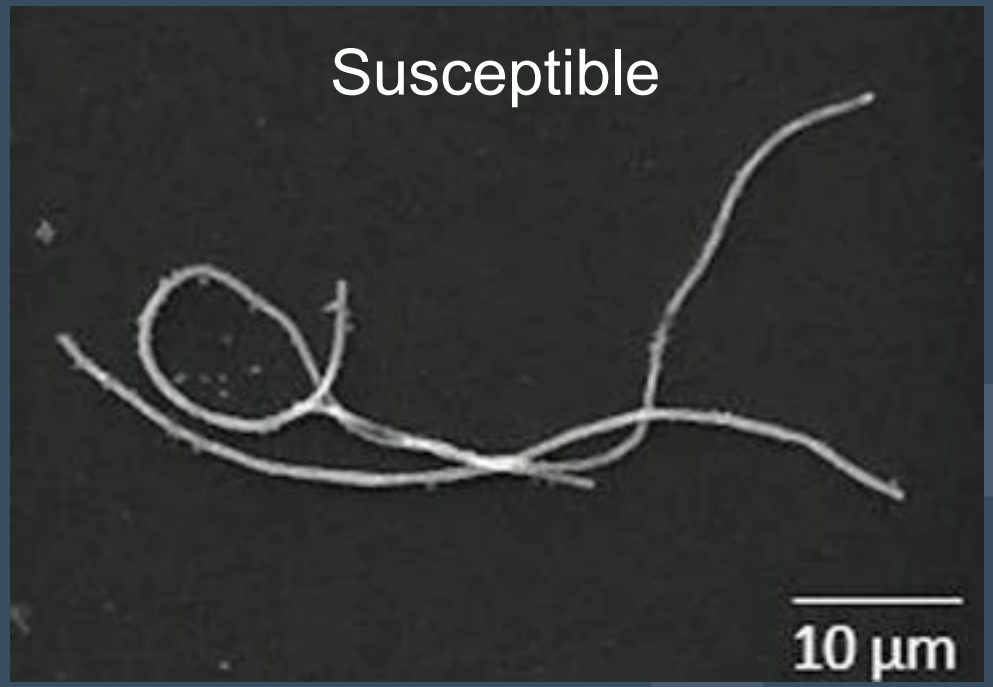
4

Selux NGP



- Isolates or direct from positive blood culture in 6-7 hours
- Susceptibility determined by fluorescent growth indicators including a viability assay (resazurin) and a surface-binding assay (europium probe)
- Large antibiotic dilution series (384-well platform) & capacity for 96 panels
- 23 gram-negative drugs & 14 gram-positive drugs





PMID: 30659207

4

Selux NGP

AMERICAN SOCIETY FOR MICROBIOLOGY | Journal of Clinical Microbiology

Check for updates

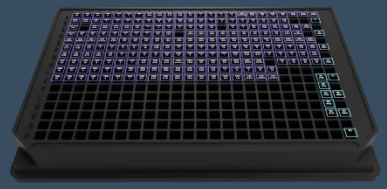
| Antimicrobial Chemotherapy | Full-Length Text

Multicenter evaluation of the Selux Next-Generation Phenotyping antimicrobial susceptibility testing system

Kristin R. Baker,[1] Kelly Flentie,[1] Benjamin R. Spears,[1] Sergey Mozharov,[1] Kristen Roberts,[1] Asmae El ganbour,[1] Mark Somers,[1] John Calkwood,[1] Jamie Liu,[1] Kayla DaPonte,[1] Nikitha Sam,[1] Gurleen Kaur,[1] Felicia Chen,[1] Jonathan Donato,[1] Alan Chao,[1] Autumn Lewis,[1] Jingzi Sherman,[1] Karen Mortimer,[1] Amanda T. Harrington,[2] Maria Traczewski,[3] Darcie Carpenter,[4] Dee Shortridge,[5] Jill Lindley,[5] Alexander Diep,[6] Emmet Norton,[6] Matt Green,[6] Joe Gajewski,[6] Rebecca Landrith,[6] Fatuma Nalubega,[6] Justin McCallum,[7] Melissa Beiswenger,[7] Brittany Dolan,[7] Kathleen Brennan,[7] Afton Carpenter,[7] Aleksandar Vacic,[1] Alec N. Flyer,[1] Virginia M. Pierce,[8] David C. Hooper,[9] James S. Lewis II,[10] Eric Stern[1]

2024 PMID: 38051069

4 FDA Selux NGP



Some species have longer turnaround times.

90% or better essential agreement obtained.

TABLE 3 Average TTR[a]

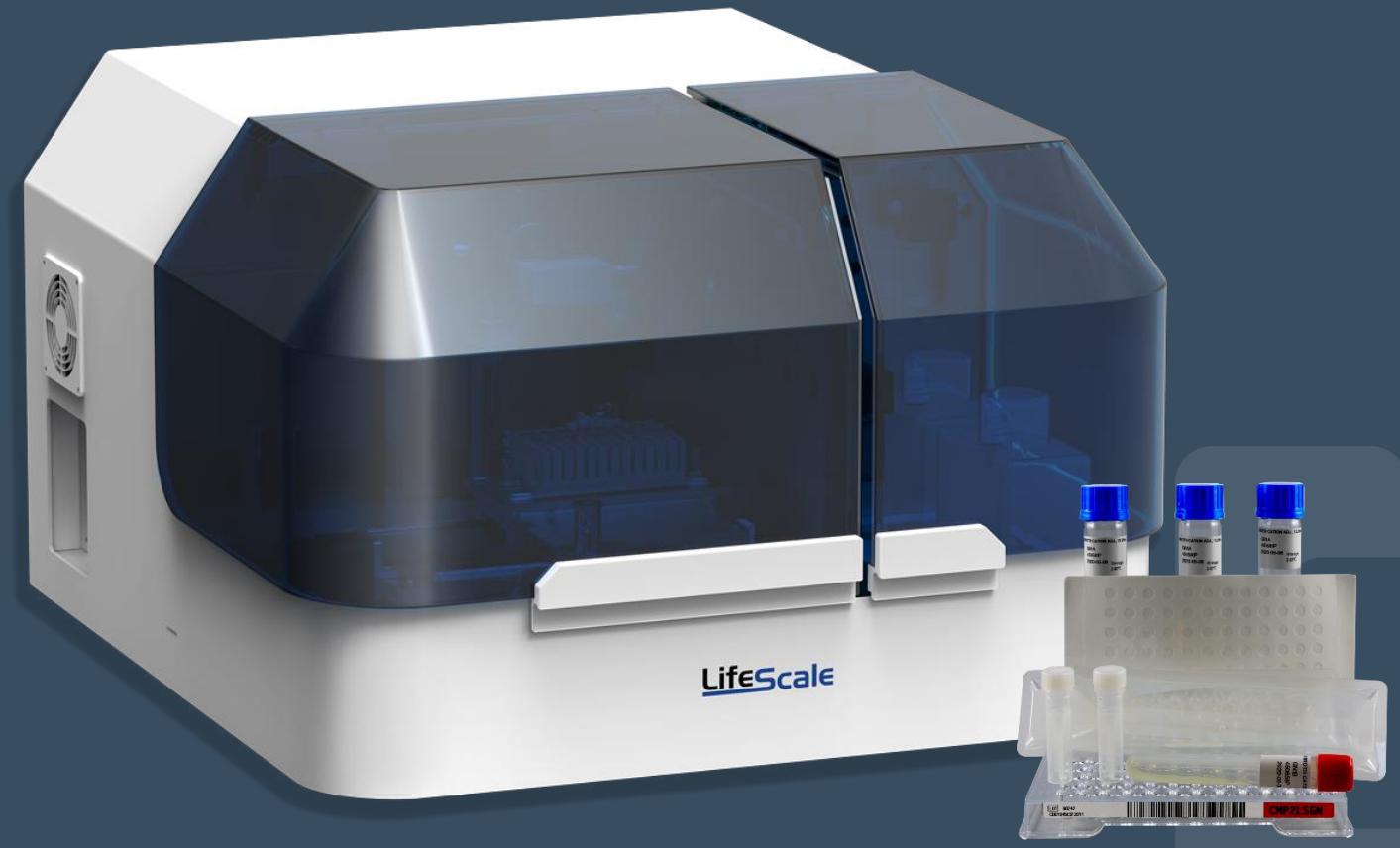
Organism group or species	Total tested	TTR (hour)		
		Mean	Min	Max
A. baumannii complex	120	5.66	5.18	7.73
Citrobacter freundii complex	64	5.59	5.20	7.27
Citrobacter koseri	60	5.66	5.22	7.36
Enterobacter cloacae complex	79	5.71	5.19	7.30
Escherichia coli	188	5.52	5.17	7.15
Klebsiella aerogenes	39	5.59	5.23	6.82
Klebsiella oxytoca	31	5.65	5.24	7.18
Klebsiella pneumoniae, variicola	141	5.59	5.18	7.15
Morganella morganii	63	5.48	5.21	6.74
Proteus mirabilis	62	5.53	5.14	6.19
Proteus vulgaris	58	5.53	5.20	7.23
P. aeruginosa	172	7.04	5.21	10.32
Serratia marcescens	63	5.66	5.22	7.30
Enterococcus faecalis	110	5.37	5.04	6.24
Enterococcus faecium	120	5.47	5.14	8.29
S. aureus	156	5.38	5.08	7.09
Coagulase-negative *Staphylococcus* spp.	100	5.63	5.08	8.49

[a]TTR defined as the time panels were placed on the analyzer (Selux NGP assay start) until MIC value was generated.

2024 PMID: 38051069

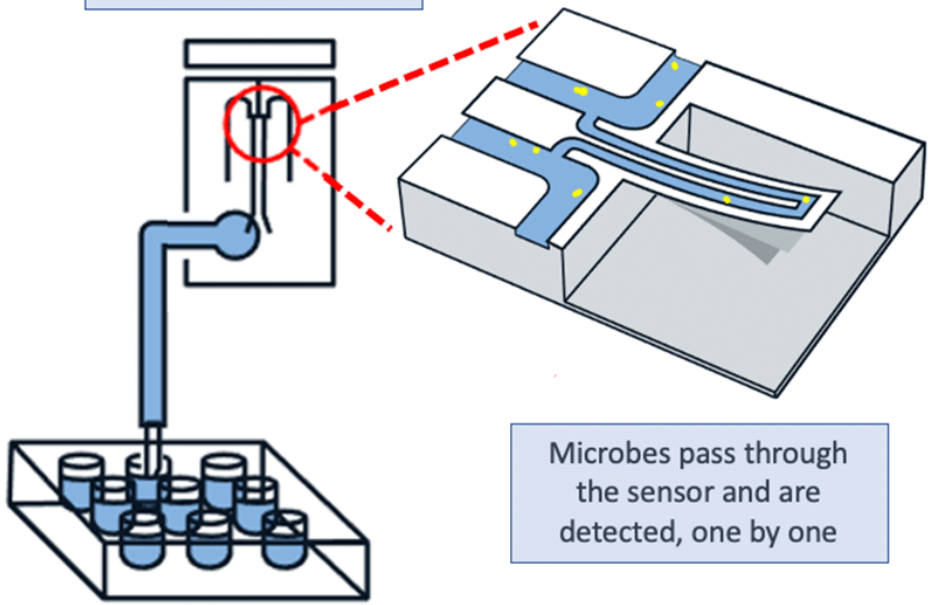
5 FDA Affinity Biosensors LifeScale AST

- Gram-negatives from positive blood cultures in 5 hours
- Susceptibility determined using a microfluidic sensor and resonant frequency to calculate organism concentration and/or mass distribution



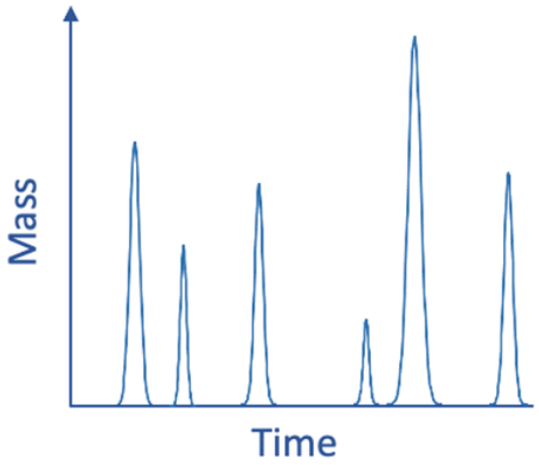
5 FDA LifeScale AST

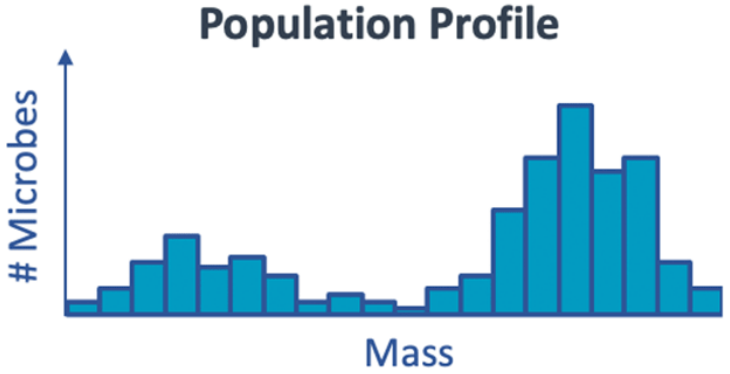
Each well is sampled, and a tiny aliquot ported to the sensor



Microbes pass through the sensor and are detected, one by one

Each peak is the sensor response (frequency shift) when a microbe passes through. The size of the peak indicates the mass of the microbe.

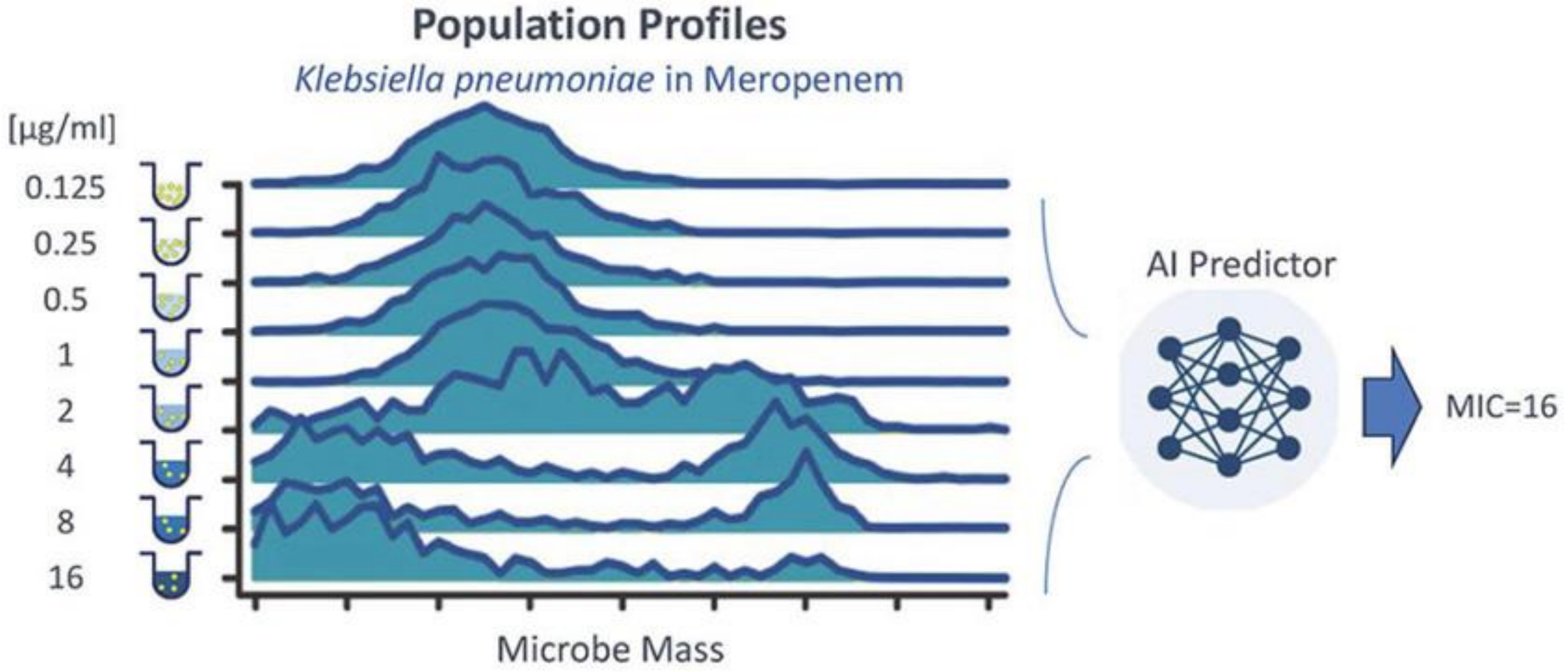




Many microbes are measured from each well, and the distribution of their masses is compiled. This the ***Population Profile*** for that well/culture.

5

LifeScale AST



5

LifeScale AST

December 2024 Volume 62 Issue 12

TABLE 4 Performance versus SOC

Antibiotic (abbr. reported organisms[a])	Number evaluated	Essential agreement (%)[b]	Categorical agreement (%)[b]
All	1,082	97.32 (1,053/1,082)	96.11 (1,039/1,081)
Amikacin (A, E, K.p., K.o., K.v., K.a., and P)	100	100.00 (100/100)	99.00 (99/100)
Ampicillin (E)	42	100.00 (42/42)	100.00 (42/42)
Aztreonam (E, K.p., K.o., and K.a.)	76	97.37 (74/76)	97.37 (74/76)
Cefazolin (E, K.p., and K.v)	67	88.06 (59/67)	86.96 (60/69)
Cefepime (E, K.p., K.o., and K.a.)	78	98.72 (77/78)	98.72 (77/78)
Ceftazidime (A, E, K.p., K.o., K.v., and K.a.)	96	96.88 (93/96)	94.79 (91/96)
Ceftazidime/avibactam (E, K.p., K.o., and K.a.)	76	100.00 (76/76)	100.00 (75/75)
Ertapenem (E, K.p., and K.a.)	76	100.00 (76/76)	100.00 (76/76)
Gentamicin (E, K.p., K.o, K.v., K.a., and P)	92	93.48 (86/92)	98.91 (91/92)
Levofloxacin (E, K.p., K.o, K.a., and P)	96	98.96 (95/96)	90.63 (87/96)
Meropenem (A, E, K.p., and P)	98	98.98 (97/98)	97.96 (96/98)
Mero/vaborbactam (E, K.p., K.o., and K.a.)	24	100.00 (24/24)	100.00 (24/24)
Piperacillin/tazobactam (A, E, K.p., K.a., and P)	85	94.12 (80/85)	86.75 (72/83)
Trimethoprim/sulfamethoxazole (E, K.p., K.o., K.v., and K.a.)	76	97.37 (74/76)	98.68 (75/76)

[a]A, *Acinetobacter* sp.; E, *Escherichia coli*; K.a., *Klebsiella aerogenes*; K.o., *Klebsiella oxytoca*; K.p., *Klebsiella pneumoniae*; K.v., *Klebsiella variicola*; P, *Pseudomonas*.
[b]Essential and categorical agreement, VMEs, and MEs after resolution by broth microdilution.

2024 PMID: 39480069

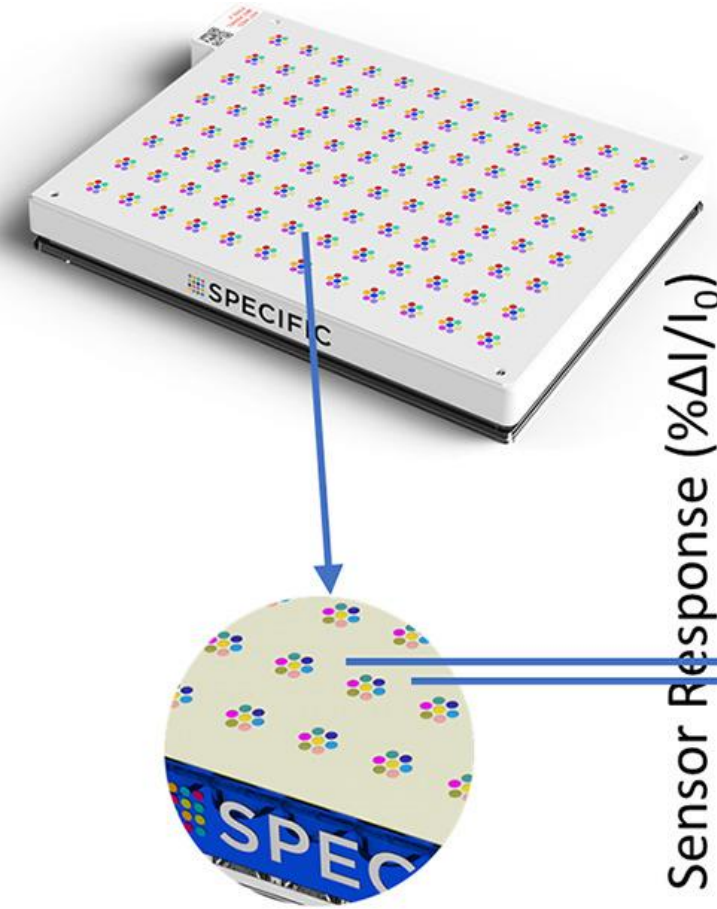
	E. coli	*Klebsiella spp.*	*P. aeruginosa*	*Acinetobacter spp.*
Ampicillin	X			
Cefazolin	X	X		
Ceftazidime	X	X	X	X
Cefepime	X	X	X	
Piperacillin-tazobactam	X	X	X	X
Aztreonam	X	X		
Ertapenem	X	X		
Meropenem	X	X	X	X
Ceftazidime-avibactam	X	X	X	
Meropenem-vaborbactam	X	X		
Gentamicin	X	X	X	
Amikacin	X	X	X	X
Trimethoprim-sulfamethoxazole	X	X		
Levofloxacin	X	X	X	

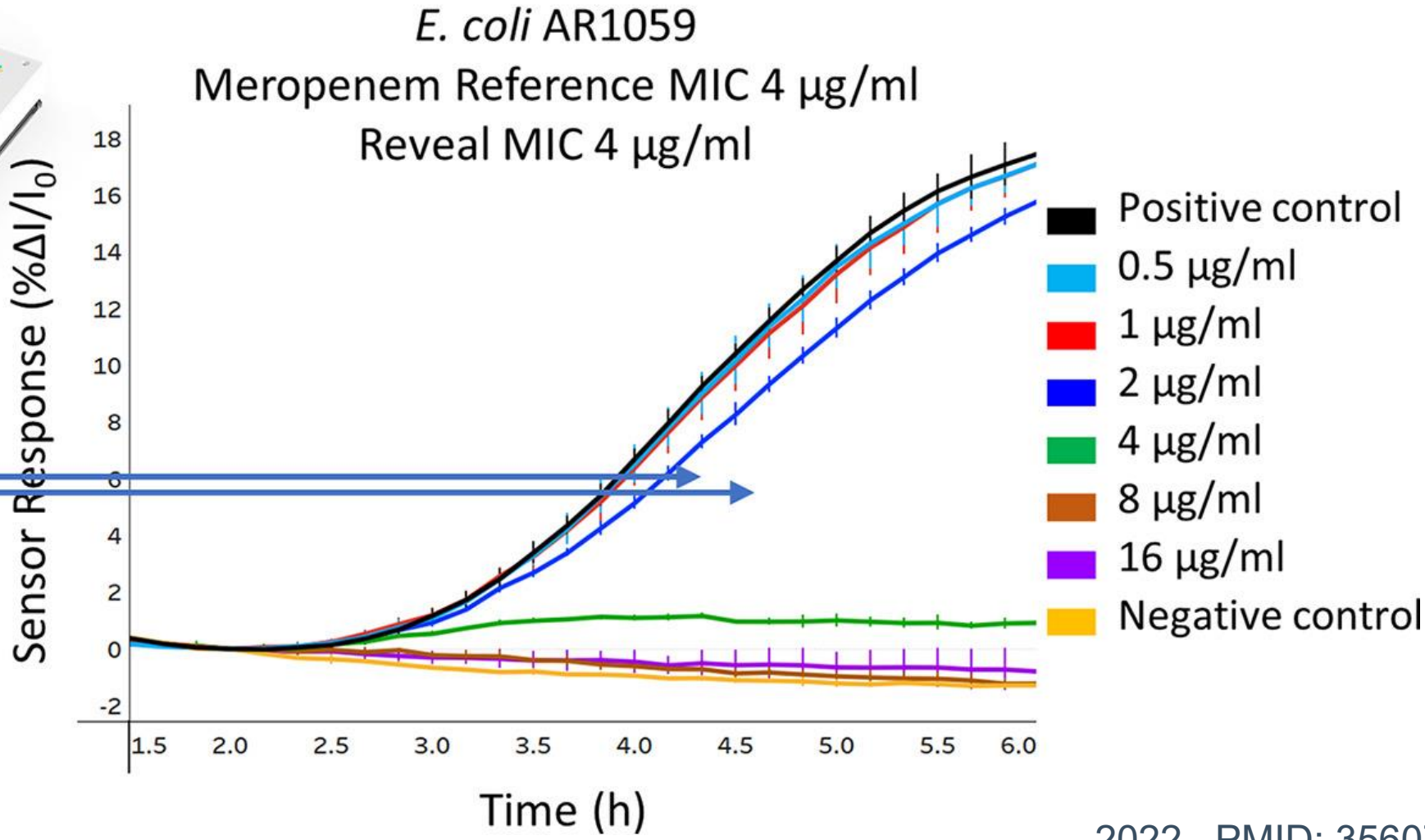
https://www.accessdata.fda.gov/cdrh_docs/pdf24/K241324.pdf

6 FDA bioMérieux Reveal

- Gram-negatives from positive blood cultures in 5 hours
- Susceptibility determined by monitoring the metabolism of each broth microdilution well using an array of colorimetric sensors that react to volatile organic compounds in the headspace

6 FDA bioMérieux Reveal





2022 PMID: 35607972

6

bioMérieux Reveal

AMERICAN SOCIETY FOR MICROBIOLOGY | Journal of Clinical Microbiology

Check for updates

Antimicrobial Chemotherapy | Full-Length Text

Performance evaluation of the Specific Reveal system for rapid antibiotic susceptibility testing from positive blood cultures containing Gram-negative pathogens

Greta Ostermann,[1] Barbara Körber-Irrgang,[1] Alexander Krüger,[1,2] Pragya Singh,[3] Kenny Vo,[4] Jörg Gielen,[2] Ute Aurbach,[1] Hilmar Wisplinghoff,[1,5] Nathalie Jazmati[1,2]

2024 PMID: 39545740

TABLE 2 AST results of the Reveal rapid AST system compared to the DxM MicroScan WalkAway test for 102 clinical Gram-negative strains and all drugs tested[g,h]

Species	Reveal average TTR (h)	No. of strains	No. of tested antibiotics per species	No. of AST results of the reference method						% (no.) agreement		% (no.) of errors		
				Total	Total used for EA calc.	Total used for CA and error calc.	S	I	R	EA[a,b]	CA	mE	ME	VME
Enterobacterales														
E. coli	5.4	73	20	1,460	1,453[c,d,e]	1,454[f]	1,229[f]	71	154	98.5 (1,431)	97.1 (1,412)	0.3 (5)	0.4 (5)	20.8 (32)
K. pneumoniae	5.3	18	20	360	355[c]	360	306	21	33	99.2 (352)	97.8 (352)	1.7 (6)	0 (0)	6.1 (2)
K. oxytoca	5.3	4	20	80	79[d]	80	70	6	4	98.7 (78)	96.3 (77)	2.5 (2)	1.4 (1)	0 (0)
E. cloacae	5.1	3	19	57	57	57	42	1	14	96.5 (55)	96.5 (55)	1.8 (1)	2.4 (1)	0 (0)
C. koseri	4.9	1	19	19	19	19	16	1	2	94.7 (18)	89.5 (17)	5.3 (1)	6.3 (1)	0 (0)
Non-fermentative GNB														
P. aeruginosa	6.0	2	12	24	21[c,e]	24	10	12	2	100.0 (21)	95.8 (23)	4.2 (1)	0 (0)	0 (0)
A. baumannii	4.2	1	8	8	7[c]	8	5	1	2	100.0 (7)	100.0 (8)	0 (0)	0 (0)	0 (0)
Overall	5.4	102	n.e.	2,008	1,991	2,002	1,678	113	211	98.5 (1,962)	97.1 (1,944)	0.8 (16)	0.5 (8)	16.1 (34)

2024 PMID: 39545740

TABLE 3 AST results of the Reveal rapid AST system compared to the DxM MicroScan WalkAway by drugs[g,h]

Drug	Reveal average TTR (h)	No. of strains with AST results of the reference method						% (no.) agreement		% (no.) of errors			ATU[c]
		Total	Total used for EA calc.	Total used for CA and error calc.	S	I	R	EA[a,b]	CA	mE	ME	VME	
Amikacin	3.9	102	102	102	98		4	99.0 (101)	96.1 (98)	n.a.	0 (0)	100.0 (4)	
Amoxicillin-clavulanic acid (EUCAST)	4.0	99	99	99	72		27	91.9 (91)	85.9 (85)	n.a.	0 (0)	51.9 (14)	
Ampicillin	3.6	99	99	99	44		55	99.0 (98)	99.0 (98)	n.a.	0 (0)	1.8 (1)	
Aztreonam	5.1	99	99	99	90	1	8	100.0 (99)	100.0 (99)	0 (0)	0 (0)	0 (0)	
Cefepime	5.9	101	101	101	93	3	5	99.0 (100)	98.0 (99)	2.0 (2)	0 (0)	0 (0)	
Cefotaxime	5.4	99	99	99	92		7	99.0 (98)	99.0 (98)	0 (0)	1.1 (1)	0 (0)	
Ceftazidime	5.3	101	101	101	93	2	6	97.0 (98)	98.0 (99)	1.0 (1)	0 (0)	16.7 (1)	
Ceftazidime-avibactam	6.1	101	101	101	101			99.0 (100)	99.0 (100)	n.a.	1.0 (1)	0 (0)	
Ceftolozane-tazobactam	6.4	101	101	101	99		2	98.0 (99)	98.0 (99)	n.a.	2.0 (2)	0 (0)	
Cefuroxime IV	5.1	95	95	95		88	7	98.9 (94)	96.8 (92)	3.2 (3)	0 (0)	0 (0)	
Ciprofloxacin	4.1	102	92[d]	96[c]	81[c]	3	12	96.7 (89)	97.9 (94)	1.0 (1)	1.2 (1)	0 (0)	5.9 (6)
Ertapenem	6.5	99	97[e]	99	98		1	100.0 (97)	100.0 (99)	n.a.	0 (0)	0 (0)	
Gentamicin	5.1	100	100	100	93		7	98.0 (98)	93.0 (93)	n.a.	1.1 (1)	85.7 (6)	
Imipenem	6.5	102	102	102	99	2	1	100.0 (102)	100.0 (102)	0 (0)	0 (0)	0 (0)	
Levofloxacin	4.3	102	102	102	89	3	10	100.0 (102)	99.0 (101)	1.0 (1)	0 (0)	0 (0)	
Meropenem	6.6	102	97[f]	102	101		1	100.0 (97)	100.0 (102)	0 (0)	0 (0)	0 (0)	
Piperacillin	5.0	101	101	101	62	7	32	100.0 (101)	94.1 (95)	5.9 (6)	0 (0)	0 (0)	
Piperacillin-tazobactam	7.3	101	101	101	92	3	6	97.0 (98)	96.0 (97)	1.0 (1)	0 (0)	50.0 (3)	
Tobramycin	4.1	102	102	102	95		7	99.0 (101)	94.1 (96)	n.a.	1.1 (1)	71.4 (5)	
Trimethoprim-sulfamethoxazole	4.0	100	100	100	86	1	13	99.0 (99)	98.0 (98)	1.0 (1)	1.2 (1)	0 (0)	

[a]Because of the limited concentration ranges for most antibiotics on the test plate MICs less or equal to the lowest concentration or greater than the highest concentration of a drug, were included in the calculation.
[b]Percentage (number) of strains for which the difference regarding all drugs tested was no more than ±1 log2 dilution.
[c]In Reveal testing 6 *E. coli* strains showed ciprofloxacin MIC values falling in the area of technical uncertainty (ATU) and were excluded for CA as well as for error calculation. All 6 strains were tested susceptible with the reference method or MTS.
[d]The concentration range of ciprofloxacin on the AST plate was ≤0.06 mg/l, 0.25-1 mg/l (the MIC of 0.125 mg/l was skipped). If a MIC of the Reveal system and/or reference method was 0.25 mg/l the respective strain was excluded from EA calculation. This was the case for 1 *A. baumannii* strain, 3 *E. coli* strains, 5 *K. pneumoniae* strains and 1 *P. aeruginosa* strain.
[e]The concentration range of ertapenem on the AST plate was ≤0.125 mg/l, 0.5-1 mg/l (the MIC 0.25 mg/l was skipped). If a MIC of the Reveal system and/or reference method was 0.5 mg/l the respective strain was excluded from EA calculation. This was the case for 1 *E. coli* strain and 1 *K. oxytoca* strain.
[f]The concentration range of meropenem on the AST plate was ≤0.125 mg/L, 1–32 mg/L (the MIC values 0.25 mg/L and 0.5 mg/L were skipped). If a MIC of the Reveal system and/or reference method was 1 mg/L, the respective strain was excluded from EA calculation. This was the case for 3 *E. coli* strains and 2 *P. aeruginosa* strains.
[g]TTR, time to result; calc., calculation; S, susceptible; I, susceptible increased dosage; R, resistant; EA, essential agreement; CA, category agreement; mE, minor error; ME, major error; VME, very major error; n.a., not applicable.
[h]In general, S, I, R categorization based on MIC results that were evaluated by the reference method or MTS (the latter was performed in case of discrepancies between Reveal and the reference method).

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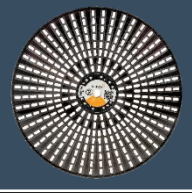
TABLE 5 Performance of Reveal AST with blood samples contrived with CDC AR Bank isolates

Parameter and study detail	Performance with spiked challenge strains
Parameter, % (no. positive/total no.)	
EA	97.7 (509/521)
CA	95.2 (496/521)
mE	4.0 (21/521)
ME	0 (0/122)
VME	1.0 (4/384)
Reveal avg TTR	4.4 h
Study set details	
No. of antibiotics	19
No. of species	6
No. of strains	33
No. of strain/antibiotic pairs	521
No. susceptible	122
No. intermediate	15
No. resistant	384
R (%)	73.7

2022 PMID: 35607972

ANTIMICROBIAL DRUG	MIC CALLING RANGE (µg/ml)	A. baumannii-calcoaceticus complex	C. freundii complex	C. koseri	E. cloacae complex	E. coli	K. aerogenes	K. oxytoca	K. pneumoniae group	P. mirabilis	P. vulgaris	P. aeruginosa	S. marcescens	
Amoxicillin / Clavulanate	4/2 - 16/8					✓		✓	✓	✓				4
Ampicillin / Sulbactam	2/1 - 64/32					✓		✓		✓				3
Cefepime	0.5 - 32			✓	✓	✓	✓	✓	✓			✓		7
Ceftazidime	0.12 - 32	✓		✓	✓	✓	✓	✓	✓					7
Ceftazidime / Avibactam	0.06/4 - 16/4		✓	✓	✓	✓	✓		✓	✓		✓		8
Ceftolozane / Tazobactam	0.12/4 - 32/4			✓	✓	✓	✓	✓		✓	✓	✓		8
Ceftriaxone	0.25 - 16				✓	✓	✓	✓	✓	✓				6
Ciprofloxacin	0.25 - 2		✓		✓	✓	✓	✓	✓		✓	✓	✓	9
Ertapenem	0.12 - 1					✓			✓	✓	✓			4
Imipenem	0.5 - 8	✓		✓	✓	✓		✓	✓			✓	✓	8
Levofloxacin	0.12 - 4		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	11
Meropenem	0.5 - 16	✓			✓	✓			✓	✓	✓	✓	✓	8
Meropenem / Vaborbactam	1/8 - 16/8		✓	✓	✓	✓	✓	✓	✓	✓				8
Piperacillin / Tazobactam	2/4 - 64/4			✓		✓			✓		✓			4
Tobramycin	0.5 - 8		✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	10
Trimethoprim / Sulfamethoxazole	2/38 - 4/76					✓	✓		✓					3
TOTAL		3	5	9	11	16	10	11	14	10	6	8	5	108

System reports interpretive categories (e.g., "S") for VITEK REVEAL BC GN02-AST according to FDA Susceptibility Test Interpretative Criteria (STIC).

	1	2	3	4	5	6
						
	Radian	**Pheno**	**ASTar**	**Selux**	**LifeScale**	**Reveal**
Regulatory		🇺🇸	🇺🇸	🇺🇸	🇺🇸	🇺🇸
Throughput	🦠	🦠	🦠	🦠	🦠	🦠
TAT (h)	**8**	**7**	**6**	**6-7**	**5**	**5**
Samples	🩸 🧫	🩸	🩸	🩸 🧫	🩸	🩸

Objectives

- Describe the potential clinical benefits of rapid antimicrobial susceptibility testing
- Recognize the diagnostic devices that currently on the market in the U.S. for rapid antimicrobial susceptibility testing.

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