How Culture Media Can Deliver Value to Your Lab

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Clinical Speaker



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Technology and the Microbiology Lab



Laboratory Section	Market Size	Year over Year Growth
Immunoassays	\$17.5 B	~6%
Point of Care	\$15.4 B	~8%
Chemistry	\$7.7 B	~6%
Molecular	\$7.2 B	~11%
Hematology	\$5.8 B	~2%
Microbiology	\$3.4 B	~6%



Projected ID and AST Format Changes Through 2025

	ID Forr	nat Changes			
	2014	2020	2025		
Manual	+	+	+		
Biochemical	++++	++	+		
Mass Spec	+++	++++	++++		
Molecular	+	+	++		
			AST For	mat	Chang
			2014		
		Dilution	+		
		Diffusion	++		

Average percent of specimens using that particular technology scale: 0-15 +, 16-30 ++, 31-45 +++, 46-60 ++++, 61-75 +++++

AST Format Changes					
	2014	2020	2025		
Dilution	+	+	+		
Diffusion	++	++	+		
E-strips	+	+	+		
Automated Instrument	+++++	+++++	++++		
Molecular	+	+	+		



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Media in Susceptibility Testing



Table 2

Essential and categorical agreements for colistin MIC tests for 75 Gram-negative bacteria with MICs on frozen broth microdilution panels as reference

	Organism	E coli and K pneumoniae (n=32)	P. aeruginosa (n-21)	Acinetobacter spp. (n-22)	All isolates (n-75)
	Colistin reference MIC range (mg/L)	0.25-32	0.25-128	0.5-32	0.25-128
% Essential agreement (EA)*	Sensititre custom plate ^b	96	100	91	96
	MICRONAUT-S	97	100	91	96
	MICRONAUT MIC-Strip	97	100	100	99
	SensiTest	96	93	71	88
	UMIC ^d	91	75	77	82
	Etest, Oxoid MH	84	62	59	71
	Etest, BBL MH	63	52	4.5	43
	Etest, MHE	75	43	9.1	47
	MTS, Oxoid MH	59	57	41	53
	MTS, BBL MH	75	57	59	65
Coloradial second (CAM		97	95	91	95
% Categorical agreement (CA)*	Sensititre custom plate				
	MICRONAUT-S	94	86	86	89
	MICRONAUT MIC-Strip	94	91	86	91
	SensiTest	94	91	82	89
	UMIC	94	91	91	92
	Etest, Oxoid MH	94	71	73	81
	Etest, BBL MH	94	67	68	79
	Etest, MHE	94	76	82	85
	MTS, Oxoid MH	81	71	82	79
	MTS, BBL MH	84	71	68	76
Number of major errors (ME)	Sensititre custom plate	1	1	2	4
5. B.S.S.	MICRONAUT-S	2	1	3	6
	MICRONAUT MIC-Strip	2	0	3	5
	SensiTest	2	1	4	7
	UMIC	2	1	0	3
	Etest, Oxoid MH	2	0	0	2
	Etest, BBL MH	1	0	0	1
	Etest, MHE	2	0	0	2
	MTS, Oxoid MH	0	0	0	0
		0	0	0	0
Number of super station over (DB/EV)	MTS, BBL MH	0	0	0	0
Number of very major errors (VME) [#]	Sensititre custom plate			(C)	
	MICRONAUT-S	0	2	0	2
	MICRONAUT MIC-Strip	0	2	0	2
	SensiTest	0	1	0	1
	UMIC	0	1	2	3
	Etest, Oxoid MH	0	6	6	12
	Etest, BBL MH	1	7	7	15
	Etest, MHE	0	5	4	9
	MTS, Oxoid MH	6	6	4	16
	MTS, BBL MH	5	6	7	18

* MICs being within ± 1 dilution of reference MICs.

* Because of truncations in the MIC dilutions, the total number of tests for calculation of EA was 28 for E. coli/K. pneumoniae and 19 for P. aeruginosa.

⁶ Because of truncations in the MIC dilutions, the total number of tests for calculation of EA was 26 for E. coli/K. pneumoniae, 15 for P. aeruginosa and 17 for Acinetobacter spp.

^d Because of truncations in the MIC dilutions, the total number of tests for calculation of EA was 20 for P. aeruginosa.

- * Test results with correct susceptibility categorization.
- f Resistant with test method, susceptible with reference method false resistant.

⁸ Susceptible with test method, resistant with reference method – false susceptible.

Essential AGREEMENT and CATEGORICAL AGREEMENT for Colistin* MICS

Matuschek et al. 2018. CMI. 24:865-870



*For Research Use Only. Not for diagnostic use

Table 1 – Comparison of interpretative results and MIC50 and MIC90 for antimicrobial agents and susceptibility testing methods.

Antimicrobial and method	N	° (%) of KPC-producing	g Enterobacter spp. isolates	MIC	(µg/mL)
	Susceptible	Intermediate	Resistant	50	90
Polymyxin B				100	
Broth microdilution*	36 (90)	1 (2.5)	3 (7.5)	0.5	1
Etest ^{® d}	NA	NA	NA	NA	NA
Vitek 2 [®] automated system ^d	NA	NA	NA	NA	NA
Disc diffusion ^e	39 (97.5)	0 (0)	1 (2.5)	NAd	NA
Figecycline					
Broth microdilution*	1 (2.5)	2 (5)	37 (92.5)	4	8
Etest [®]	8 (20)	26 (65)	6 (15)	1.5	4
Vitek 2 [®] automated system*	5 (12.5)	8 (20)	27 (67.5)	4	≥8
Disc diffusion*	11 (27.5)	25 (62.5)	4 (10)	NA ^d	NA
Grtapenem					
Broth microdilution*	0 (0)	1 (2.5)	39 (97.5)	32	256
Etest ^{® d}	NA	NA	NA	NA	NA
Vitek 2 [®] automated system*	0 (0)	1 (2.5)	39 (97.5)	≥8	≥8
Disc diffusion*	0 (0)	0 (0)	40 (100)	NAd	NA
mipenem					
Broth microdilution ^b	4 (10)	2 (5)	34 (85)	16	64
Etest ^{® d}	NA	NA	NA	NA	NA
Vitek 2 [®] automated system ^b	4 (10)	3 (7.5)	33 (82.5)	≥16	≥16
Disc diffusion ^b	0 (0)	2 (5)	38 (95)	NAd	NA
Meropenem					
Broth microdilution ^b	10 (25)	0 (0)	30 (75)	8	32
Etest [®] d	NA	NA	NA	NA	NA
Vitek 2 [®] automated system ^b	10 (25)	0 (0)	30 (75)	8	≥16
Disc diffusion ^h	0 (0)	2 (5)	38 (95)	NAd	NA

(ANVISA), in Technical Note Nº 01/2010.

* EUCAST breakpoints.

^b CLSI breakpoints.

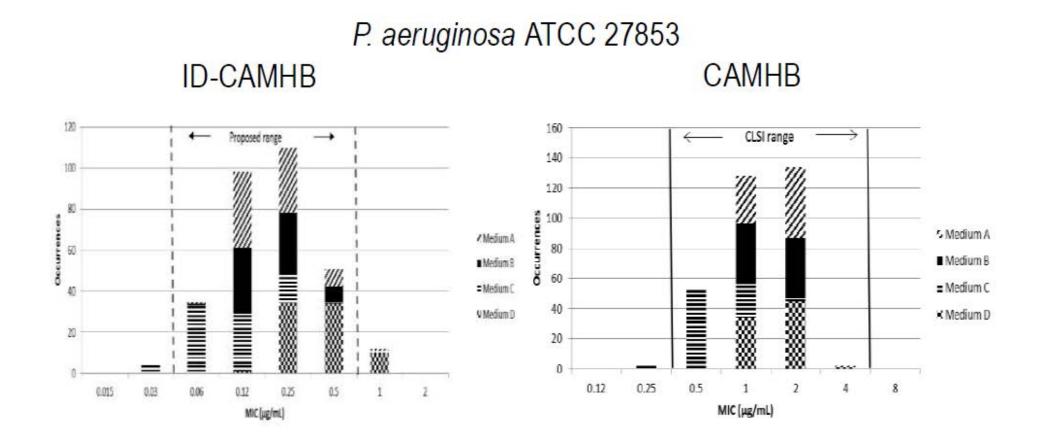
^c Breakpoints for Pseudomonas aeruginosa.

^d NA, not applicable.

TigeCycline and the Penems

Rechenchoski DZ et al. 2017. BJM. 509-514







Media and the Future



Media is critical to automation

Ideal results can be obtained when automation and media are paired

Partnering with your vendor and optimizing your media with your instrumentation is essential to automation success and can lead to gains in economic and clinical value

 Redeploy skilled personnel for optimal productivitythroughput capacity matches 2-3 FTE

When introducing a new dish into your automation system adjustments to the equipment are necessary to optimize functionality





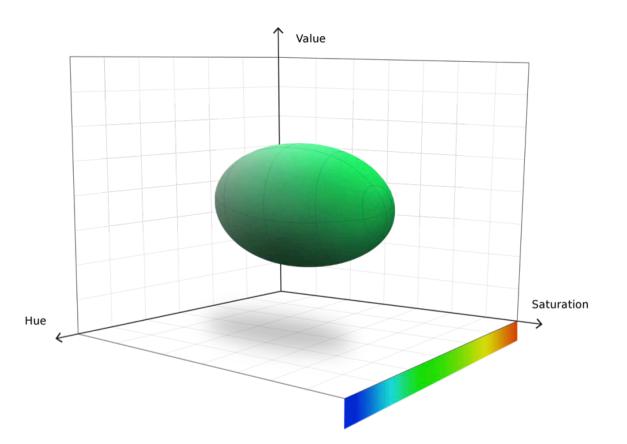
TABLE 2 Differences and percentages of change in the recovery of uropathogens reported in urine cultures pre- and post-TLA^{*a*}

	No. of time reported pe urine cultur	er 1,000			
Organism	Pre-TLA	Post-TLA	% change	P value	
Escherichia coli	79.4	101.2	+27	< 0.0001	
Klebsiella spp.	22.9	24.0	+5	0.24	
Streptococcus agalactiae	22.2	36.7	+66	< 0.0001	
Aerococcus urinae	2.2	4.4	+103	< 0.0001	
Staphylococcus saprophyticus	1.0	2.3	+126	< 0.0001	
Neisseria gonorrhoeae	0.2	1.0	+371	< 0.0001	
Actinotignum schaalii	0.1	0.13	+33	0.77	
Streptococcus pneumoniae	0.02	0.1	+312	0.27	
Alloscardovia omnicolens	0.0	0.06	NA	0.30	

^aTLA, total laboratory automation; NA, not applicable.









Discrepant analys	is of Manual Ne	gative/Auto	mation Posit	tive Plates
Discrepant Category	MN/AP ^a	Automation Positive 2 nd Manual Positive	Residual Matrix/Yeas t	Borderline Colors
Total number of plates	10,348	499	8,234	1,616
Colorex VRE	8996	432	7684	881
Remel VRE	1352	67	550	735
^a Manual Negative	Automation Po	sitive		



AI Can improve the sensitivity of culture

- 486 vaginal/rectal swabs
- All swabs were initially incubated in LIM for 18-24h at 35-37 degrees C
- Compared WASPLab segregation software to CLS read and BD MAX
- Chromogenic Strepto B agar w/AI Enhanced Image Analysis:
 - detected 6 additional positive cultures that were missed by technologist manual digital image culture reading

	Total Positive	True Positive	False Positive	False Negative	True Negative	Sensitivity	Specificity	PPPV	NPV
Tech Read	86	84	2	10	390	89.36%	99.49%	97.67%	97.50%
Software Read	221	90	131	4	261	95.74%	66.58%	40.72%	98.49%
BD MAX	94	90	4	4	388	95.74%	98.98%	95.74%	98.98%



Transitioning Media Vendors



My Lab Has Decided to Switch Vendors, What do I do now?

What are the key steps to a successful lab conversion?

1. Prepare your laboratory

- 1. Recognize impact of and involve the lab techs in the upcoming change
- 2. Validation procedures & Techniques
- 3. Check ordering systems

2. Train your staff

- 1. Colonies/hemolysis presentation differences in media
- 2. Conduct broad Verification study





My Lab Has Decided to Switch Vendors, What do I do now?

What are the key steps to a successful lab conversion?

- 1. Know what to expect with new media
 - 1. Evaluation & Validation
 - 2. Media differences
 - 3. Proper handling and storage
 - 4. Adjustments for automation





Hemolysis

- Plate formulation can have a significant impact on the hemolysis that you expect
- Users may see less dramatic effect, but that does not interfere with results or workflow
- Consequently, the ability to do follow up testing on discrete colonies could be improved





Streptococcus pyogenes ATCC 19614

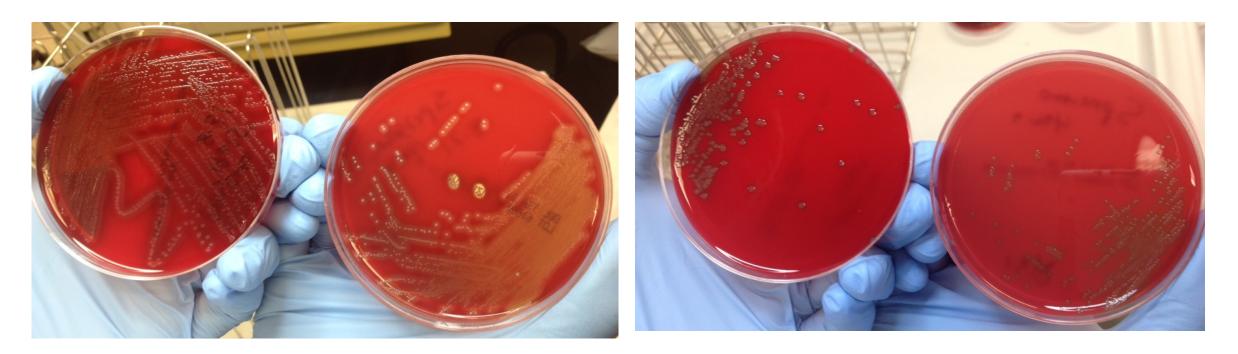
Thermo Scientific: flat gray, looks like BD: small, row water droplet

BD: small, round, whitish clear

Streptococcus pneumoniae ATCC 49619

Thermo Scientific: watery, alpha

BD: growth of S. pneumo.



Shared with permission from Poudre Valley Hospital, BD to Remel media comparison tests



Escherichia coli ATCC 25922

Remel: round, demarcated edges, isolated colonies

BD: Spready, fried egg appearance

E. coli lactose fermenter patient

Remel: Heavy growth

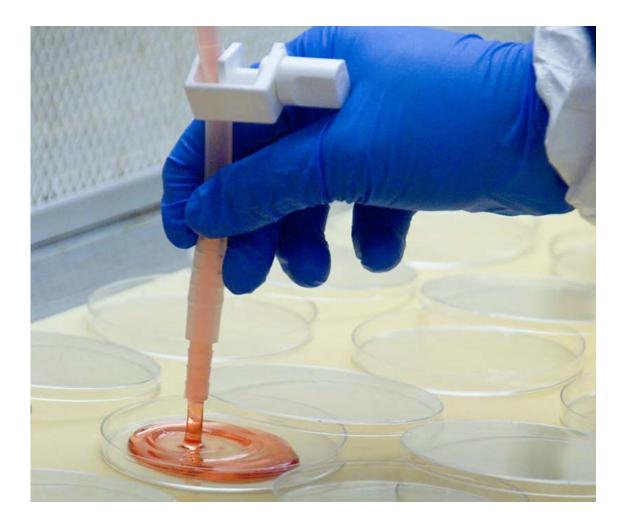
BD: Scant or "light" growth



Shared with permission from Poudre Valley Hospital, BD to Remel media comparison tests



While validation is not always needed, think IQCP. You'll need to reflect on your risk profile from you old vendor to your new vendor to ensure you're prepared for any inspections.







ThermoFisher SCIENTIFIC

How Cultural Media Can Deliver Value To Your Lab

Brittney Bunn, PhD. 16 March 20

The world leader in serving science

Technical support specialist

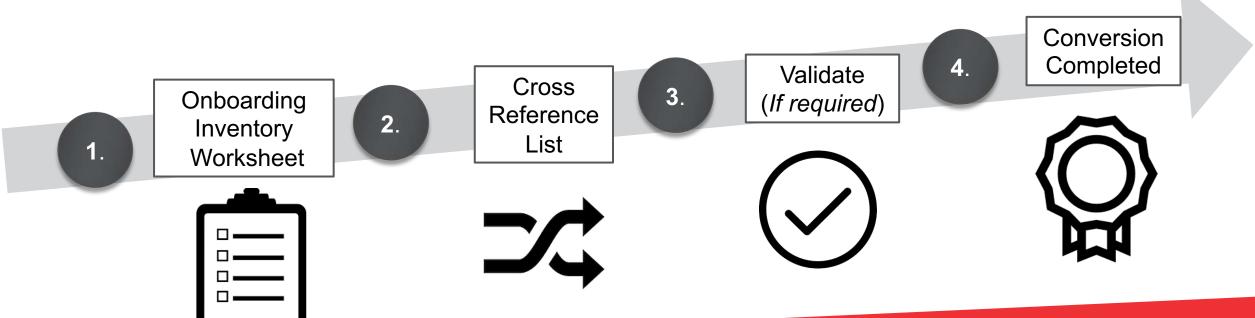


Dr. Brittney M. Bunn, PhD.

Dr. Brittney M. Bunn obtained her Ph. D. in chemistry from Case Western Reserve University. She currently serves as a Service Support supervisor for Thermo Fisher Scientific and has held other roles in the Technical Service department during her tenure of four years.



Simple Conversion Steps to Remel Media



Provide your Thermo Fisher Account Manager with a list of your annual media usage. Equivalent part numbers and descriptions and will submit your usage information to our planning department. Free of Charge Validation Media Pack will be shipped containing the media you have selected. Technical support will provide assistance and confirm successful validation. Your regular shipment date will be confirmed.

Preparation

Implementation



Ordering

ThermoFisher SCIENTIFIC

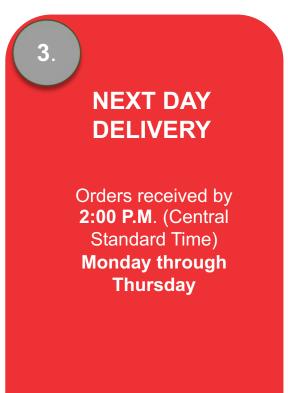
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Ordering process – Direct from the Thermo Fisher Scientific



2. Submit Product Information					
Thermo Fisher Part Number	Thermo Fisher Product Description	Thermo Fisher Pack Size			
R01202	Blood Agar, 5% Sheep Blood	100/PK			
R01302	Chocolate Agar	100/PK			

When you'll receive your order





What is the ordering process now that we've converted?

Cardinal Health and Fisher Healthcare customers order processes will remain the same



Orders are dropped shipped overnight to ensure our customers receive their orders as soon as possible



No changes to your current ordering process!



Managing Deliveries





Receiving your new media

Inspection

Laboratory personnel are responsible for inspecting media upon receipt and documenting the inspection



Packing List

The packing list provides the information required for quality control documentation



Documentation

REMEL has provided a section on the packing list for the customer to record this inspection when the media is unpacked

Orientation

Keep in mind REMEL plated media are shipped media side up. You will have to rotate the plates 180 degrees to a right side up position before using



Media Handling & Storage Guide

Maintaining Optimal Media Performance

- Most media have 10-12 week shelf life from date of manufacture
- Prepared Media shipments are validated at ambient temperature so avoid drying by leaving out for extended periods of time
- Different manufacturing processes determine the moisture levels and result in wetter or dryer media





Proper handling of your new media will ensure optimal performance

thermo scientific

Handling and Storage of Prepared Plate Media

Providing you with the highest quality media products is our goal. For optimal media performance, guidelines related to media handling and storage are listed below.



Expedite to laboratory

Ensure adherence to recommendations for storage and handling from the time media is received at your facility until it is used for patient testing.¹ cl.st. 2004. Dualty Convol for Commercially Prepared Microbiological Culture Media. 3rd ed. Approved Standard, M22-A2. Cl.SI, Wayne, PA.

Refrigerate upon arrival

Store media in the original packaging, with the media-filled side of the plate at the top, at 2-8°C up to the date of expiration. Storage temperature should be monitored daily. To avoid freezing, do not store media adjacent to the freezer compartment of the refrigerator.² CLSL 2004. Quality Control for Commercially Prepared Microbiological Culture Media. 3rd ed. Approved Standard, M22:4.3. CLSL Wayne, PA. Manufacturer's recommendation.

Store in the dark

Media should be stored in its original packaging; especially formulations containing dyes, indicators, and blood. Toxicity attributable to oxygen radicals and hydrogen peroxide resulting from prolonged light exposure may have a deleterious effect on performance and appearance.³ Bridson, E.Y. 2006. The Oxid Manual Bin ed. Oxid List. Basingsteix, U.K. Murray, P.R., E.J. Baron, J.H. Jargensen, M.A. Plater, and R.H. Yoken. 2003. Manual of Clinical Microbiology, Bin ed. ASM, Washington, D.C. Manufacurer's recommendation.

Avoid direct air flow

Minimize dehydration by storing and incubating media away from direct air flow, including fans. Additionally, media should not be stored in biological safety cabinets.⁴ Manufacurer's recommendation.

Incubate with humidity

Maximum growth and recovery of microorganisms is achieved when the humidity is 70% or higher. Use a humidified incubator or alternatively a basin of water placed in the incubator (change water frequently or add an antifungal agent to avoid contamination).⁵ Koneman, E.W., S.D. Alen, W.M. Janta, P.C. Schreckerberger, W.C. Wim, Jr. 1997. Color Alias and Textbook of Diagnostic Microbiology. Stitled. Lippincon, Williams & Wilkine, Philadelptia, PA. Iserberg, Henry D. 2004. Clirical Microbiology Procedures Handbook 2nd ed. ASM, Washington, D.C.

Utilize plate bags

Maintain media integrity by replacing unused plates in the original bag at the end of each day and returning them to the refrigerator. Bags should be closed, to reduce moisture loss. Stability may be adversely affected by a recurrent shift between room temperature and refrigeration.⁶ Koneran, EW., S.D. Aller, W.M. Janda, P.C. Schreckenberger, W.C. Winn, Jr. 1997. Color Alas and Textbook of Diagnostic Microbiology. Still ed. Upplicair, Williams & Wilkins, Philadepria, PA.



Technical Support





Technical Support

Our technical support team offers world class expertise at your demand

- Dedicated member resources readily available to assist with protocols, product transitions, troubleshooting and IQCP resources
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Questions



