Looking to the Future: How Automation will Grow the Value of Microbiology

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Outline

- Drivers of Automation
- The Necessities of Automation
- Is there a Benefit to Automation?
- Automation of Automation



What is the Future of Automation?



Drivers of Automation



Why Automate?

- Potential answer to shrinking workforce
 - Need to staff when plates are to be read, not just 9-5
- Answer to ergonomic realities

 Quality of life issues/cost to organization
- Labs are consolidating can do more potentially with less – but perhaps larger
- Better quality product consistent plating
- Pressure for decreased TAT from receipt to results
 - Pressure to be open 24/7
- Increased standardization of transport media ie liquid transport media (eSwab)



Why Automate ?

- Pre-analytical processing of specimens reduces time to incubation – increased quality, consistency in plating
- Digital Microbiology imaging analysis to aid the CLS
 - Useful for training/Documentation
 - Quality Assurance
 - Remote locations less skilled CLS



Automation is NOT as Simple as Installing New Hardware – Laboratory Workflow is Critical



Impact on productivity

Productivity Index = #samples / #FTEs worked

Productivity for hours worked	# FTE/d	Productivity Index
Current FTE	22	23.0
Future FTE	15	34.8

Productivity - Increased by 51%



Laboratory Process Current



We Practice What We Teach

Laboratory Process-Post Automation



Is There a True Benefit to Automation?



The future of diagnostic bacteriology

Productivity Increase



The Facts

Productivity Frimley: 2.5 times higher

- Productivity Lister: 2.7 times higher
- Productivity Bioscientia: 2.5 times higher

Dr lan Fry, Director of Pathology PPS Frimley Park:

"The efficiency of the system has been proven by far better management of samples both in terms of archiving and analysing. We had planned our staff reductions as we went through the procurement to full implementation and were successfully able to reduce our staff by 12 WT. This involved no compulsory redundancies as this was carefully planned part of our implementation. We did achieve what we set out to do in the Quick Scan. We were able to cope with 40% increase in workload and still make savings to the original staffing base. Much of this has been worked through using the Quick Scan approach"



Matthews S, et al. CMI, 2011.

Comparison of recovery rates of enteropathogens from stool cultures for a one-and two-year-period before and after introduction of automatic inoculation using Automation

	N (%) of recovery at each half-year period										
Organism		With manua	I inoculation			With Previ Isola				2 yr pre	
organishi	Aug 07-Jan 08 (n = 1,331)	Feb 08-Jul 08 (n = 1,238)	Aug 08-Jan 09 (n = 1,210)	Feb 09-Jul 09 (n = 1,361)	Aug 09-Jan 10 (n=1,369)	Feb 10-Jul 10 (n = 1,487)	Aug 10-Jan 11 (n = 1,432)	Feb 11-Jul 11 (n = 1,596)	vs. 1 yr after	vs. 2 yr after	
Salmonella	35 (2.6)	10 (0.8)	8 (0.7)	13 (1.0)	17 (1.2)	17 (1.1)	15 (1.0)	16 (1.0)	NS	NS	
Shigella	0	3 (0.2)	1 (0.1)	1 (0.1)	3 (0.2)	0	0	2 (0.1)	NS	NS	
Yersinia	2 (0.2)	0	1 (0.1)	0	0	0	2 (0.1)	0	NS	NS	
Campylobacter	13 (1.0)	6 (0.5)	6 (0.5)	4 (0.3)	17 (1.2)	15 (1.0)	19 (1.3)	13 (0.8)	0.002	0.003	
Total	50 (3.8)	19 (1.5)	16 (1.3)	18 (1.3)	37 (2.7)	32 (2.2)	36 (2.5)	31 (1.9)			



Mischnik A., et al. Annals of Laboratory Medicine, 2015

Comparison of sensitivities and specificities of manual/LS swab to WASP/ESwab for the recovery of *S. agalactiae*

	No. with	indicated test	result				
Method and swab type Direct plating	True positive	False positive	True negative	False negative	Total no.	Sensitivity (%)	Specificity (%)
Manual/LS swab	28	0	65	4ª	97	87.5	100.0
WASP/ESwab	30	0	65	2 <u>Þ</u>	97	93.8	100.0
Enrichment culture							
Manual/LS swab	29	0	65	3º	97	90.6	100.0
WASP/ESwab	31	0	65	1	97	96.9	100.0



Buchan B et al. 2014. JCM

VALIDATION OF URINE SPECIMENS

- 92 urine specimens were processed on the WASPLab, images were captured at 0, 18, and 24 hours. Plate images were initially viewed onscreen after 18 h incubation.
 - Negative cultures were automatically unloaded, negative result confirmed and discarded
 - Positive cultures designated as "pathogens requiring further workup", "fecal contaminated", "pathogens <10,000 cfu/mL", or "normal skin flora".
 - The plates were extracted from the WASPLab incubator and sent to the specified canister, manually read, and compared to the on-screen image.
- 76 of the 92 cultures were designated as positive
 - 100% concordance between manual read and WASPLab interpretation for 16 negative cultures
 - Of the 76 positive cultures, 78% concordance between manual interpretation and WASPLab. 17 cultures (22%) where the on-screen image and manual plate reading interpretations did not match.
 - 13 were due to overcalling a potential *Enterococcus* species on-screen, when the colony was actually a normal skin flora
 - Corrected through technologist education
 - 4 were due to missing a pathogen in heavily mixed cultures on the manual read
- Turnaround was reduced by ~18 hours



Performance of total laboratory automation combined with MS in clinical microbiology practice

- When full laboratory automation was combined with MALDI-ToF MS:
 - Pathogen identification using Kiestra TLA combined with MS resulted in a 30.6 h time gain per isolate compared to CM.
 - Pathogens were successfully identified in 98.4% (249/253) of all tested isolates. Early microbial identification without susceptibility testing led to an adjustment of antibiotic regimen in 12% (24/200) of patients.
- Did not evaluate the effect of automation alone on TAT or accuracy of identification



Mutters N et al. Annals of Laboratory Medicine. 2014;34:111-117

Streaking pattern details and resulting numbers of single colony counts



Quiblier C et al. 2016. JCM

Recovered Species

B Recovered species correlation

WASP 1 _μ l Manual	0	1	2	3	4	≥5
0	55	8	4			
1	1	33	6			
2		5	6			
3		1	1	1		
4						
≥5						

WASP 10µl Manual		1	2	3	4	≥5
0	161	35	5			
1	8	91	24	1		
2	4	9	30		1	
3		1	3	5		
4						
≥5				1		



Quiblier C et al. 2016. JCM

CFU Correlation between WASP and Manual Streaking

C CFU correlation

WASP 1 _µ l Manual		< 10 ^₄	10 ⁴	10 ⁵	10 ⁶	≥10 ⁶
n. g.	37	2				
< 1 0 ⁴	1	17	8		1	
10⁴		4	14	2		
10⁵			1	12	4	
10 ⁶				3	15	
≥10⁰						

WASP 10 _µ l Manual	n. g.	< 10 ^₄	10 ⁴	10 ⁵	10 ⁶	≥10 ⁶
n. g.	73	40	1			
< 10 ^₄		74	18	6	1	
1 04		11	30	19	7	
1 0⁵		2	1	22	30	
10 ⁶				4	40	
≥10 ⁶						



Quiblier C et al. 2016. JCM

Automated Interpretation of Chromogenic Media



The Algorithm





How it Works





Performance by Media Type

Chromogeni c mediaspecimens testedMP/APMN/ANMN/APMP/ANSensitivitySpecificityBio Rad466687994159942700100 (99-100)90.7 (90-91ChromID MRSA221716218981570100 (97-100)92.4 (91-93BD Chromagar880540676167830100 (99-100)90.7 (90-91	TABLE 2 Comparison of 3 Chromogenic Agars for the detection of MRSA No. of Results (no.) ^a Performance (% [95% Cl]) ^b									
chromID MRSA 2217 162 1898 157 0 100 (97-100) 92.4 (91-93 BD Chromagar 8805 406 7616 783 0 100 (99-100) 90.7 (90-91)	Chromogeni c media	•	MP/AP		, , ,	MP/AN			Specificity	
MRSA 2217 162 1898 157 0 100 (97-100) 92.4 (91-93) BD Chromagar 8805 406 7616 783 0 100 (99-100) 90.7 (90-91)	Bio Rad	46668	799	41599	4270	0		100 (99-100)	90.7 (90-91)	
Chromagar 8805 406 7616 783 0 100 (99-100) 90.7 (90-91)		2217	162	1898	157	0		100 (97-100)	92.4 (91-93)	
MRSA		8805	406	7616	783	0		100 (99-100)	90.7 (90-91)	

pos/automation Neg.

^b CI, confidence interval.









Manual Negative, Automation positive plates generated by WASPLab CDM software

> Automation Positive Naked Eye Negative showing a small colony not visually detected by manual examination but accurately identified as positive by the CDM (A1 and A2.). Residual Matrix on the plate showing lack of growth, but containing color due to the presence of specimen matrix (B.) and a Borderline Color plate demonstrating similar color colonies (C1 and C2).



Discrepant Analysis

TABLE 3 Discrepant analysis of Manual Negative/Automatio	n Positive Plates
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Discrepant Category	MN/AP ^a	Automation Positive Naked Eye Negative	Residual Matrix	Borderline Colors				
Number of plates	5210	153	1189	3868				
^a Manual Negative/Automation Positive								







Composite VRE Results

Comparison of 2 Chromogenic Agars for the detection of VRE using automated scoring

	No. of		Res	sults (no.)ª		Performance (% [95% CI]) ^b		
Chromo genic media	specime ns tested	MP/AP	MN/AN	MN/AP	MP/AN	Sensitivity	Specificity	
Colorex VRE	86,956	4,296	73,664	8,996	0	100 (99-100)	89.1 (89-89)	
Oxoid VRE	17,774	2,107	14,315	1,352	0	100 (99-100)	91.4 (91-92)	

^aMP/AP, manual Pos/automation Pos; MN/AN, manual Neg/automation Neg; MN/AP, manual Neg/automation Pos; MP/AN, manual Pos/automation Neg.

^b CI, confidence interval.



TABLE 2 Discrepant analysis of Manual Negative/Automation Positive Plates

Discrepant Category	MN/AP ^a	Automation Positive 2 nd Manual Positive	Residual Matrix/Yeast	Borderline Colors
Number of plates	10,348	498	8,234	1,616

^a Manual Negative/Automation Positive





^a. Shadel et al. Surveillance for vancomycin-resistant et We Practice What We Teach

implications.

Can it Quantitate?





Pre-Sorting of urine cultures – 1ul



0 CFU/ml 24 cultures per screen





10⁴ CFU/ml shows as approximately 10 colonies

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10⁵ CFU/ml shows as approximately 100 colonies or



Blood Plate Reading





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Plan Ahead

- Equipment Initial investment
 - Business case this is most difficult (important) part
 - WE NEED to prove ROI return on investment prior to purchase
 - What assurances are vendors giving us?
 - For a large lab could consume large % of system capital budget
 - It's own project with "special funding"

Change management

- What is change management-WORKFLOW ANALYSIS
 - Have we considered this concept fully in the laboratory before??
 - How will the automation impact the staffing??
- Information Technology needs has to be considered!
- Costs of remodel Facilities
 - Typically have to plan far enough in advance for most changes



Slide courtesy of S. Novak

The Key is Informatics





Daniel D. Rhoads et al. Clin. Microbiol. Rev. 2014;27:1025-1047