

# Microbiology of Today and Tomorrow, How Changes in Technology will Impact the Care We Deliver

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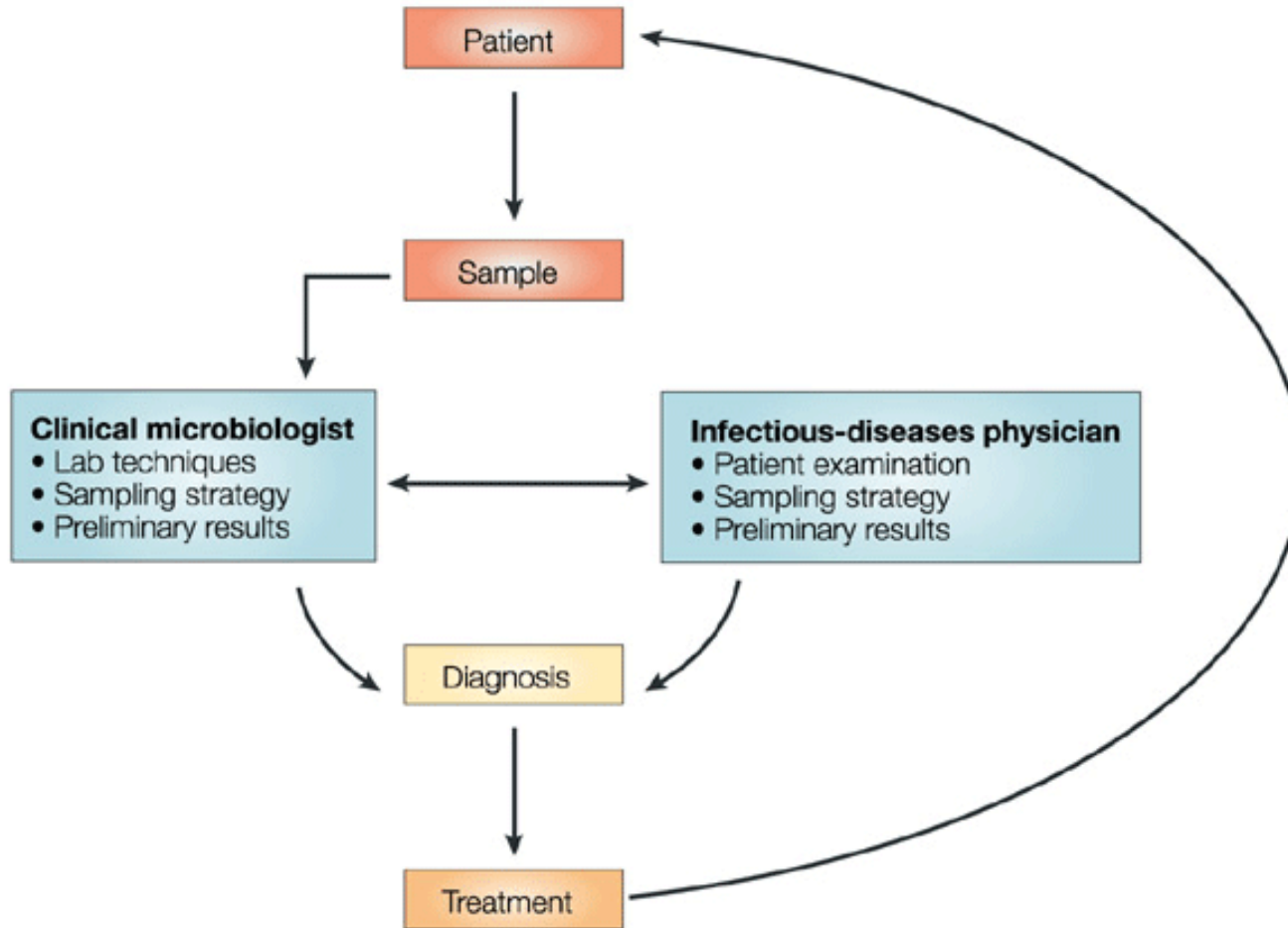
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  - Nanosphere
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  - iCubate
  - Copan Diagnostics
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  - Meridian, Quidel, IMDx, Cepheid, BD, bioMérieux, Bruker Daltonics, Nanosphere, Seegene, Life Technologies, Prodesse, Great Basin Corp, iCubate, Biohelix, BioRad
- Will discuss products that are not FDA approved

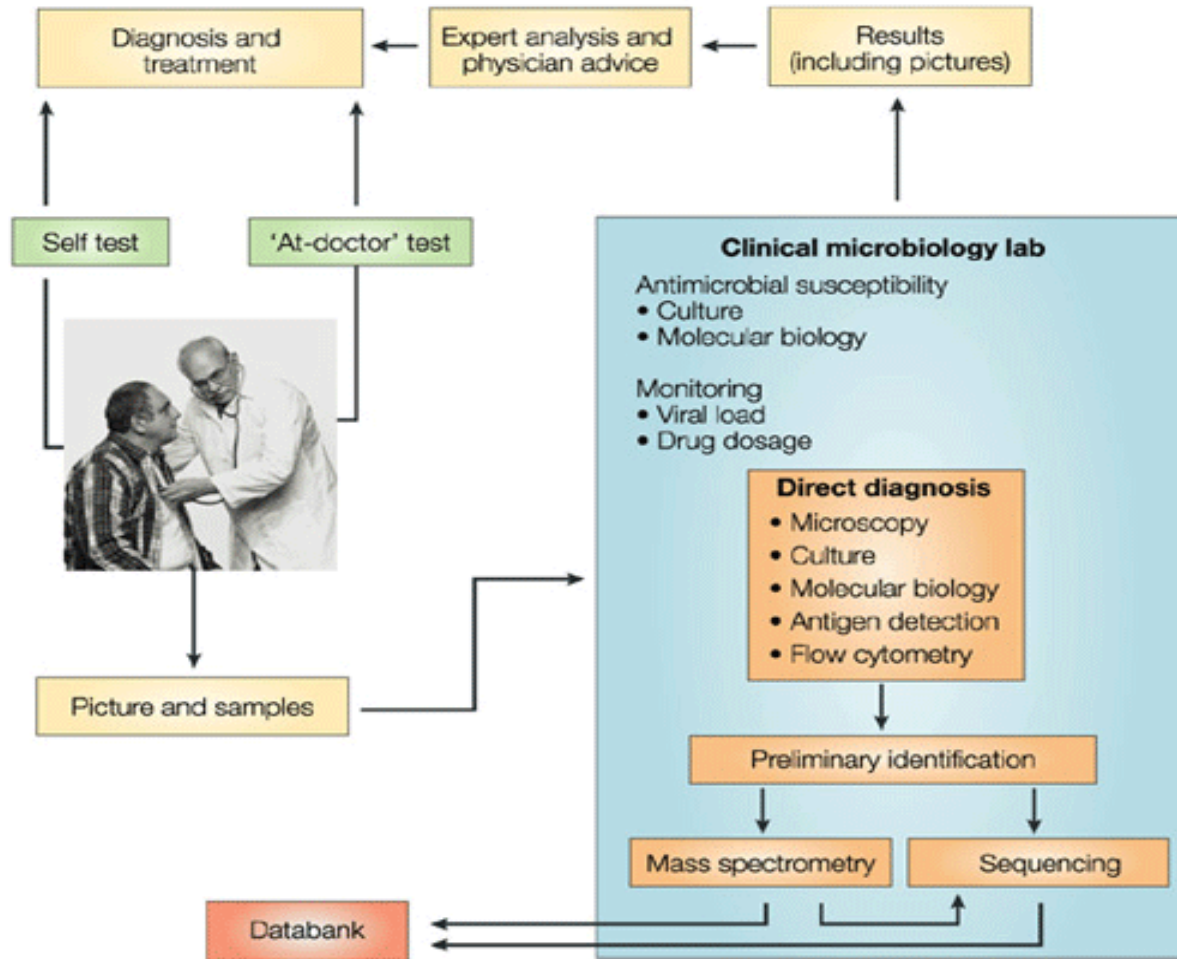
# Outline

- Drivers of Change
- Advances in Microbiology:
  - Culture
  - Mass Spectrometry
  - Molecular Microbiology
    - Sequencing
    - Panel Testing
  - Automation

# Current pathways of communication for the diagnosis and treatment of infectious diseases



# The future organization of clinical microbiology services – a Paradigm Shift



Clinical and Treatment-Related Outcomes

Outcome	Total		P Value
	Preintervention (n = 256)	Intervention (n = 245)	
<b>Clinical outcomes</b>			
30-day all-cause mortality	52 (20.3)	31 (12.7)	0.021
Time to microbiological clearance, d	3.3 ± 4.8	3.3 ± 5.7	0.928
Length of hospitalization, d	14.2 ± 20.6	11.4 ± 12.9	0.066
Length of ICU stay, d	14.9 ± 24.2	8.3 ± 9.0	0.014
Recurrence of same BSI	15 (5.9)	5 (2.0)	0.038
30-day readmission with same BSI	9 (3.5)	4 (1.6)	0.262
<b>Treatment-related outcomes</b>			
Time to effective therapy, h	30.1 ± 67.7	20.4 ± 20.7	0.021
Time to optimal therapy, h	90.3 ± 75.4	47.3 ± 121.5	<.001

# The Future of Bacterial Culture

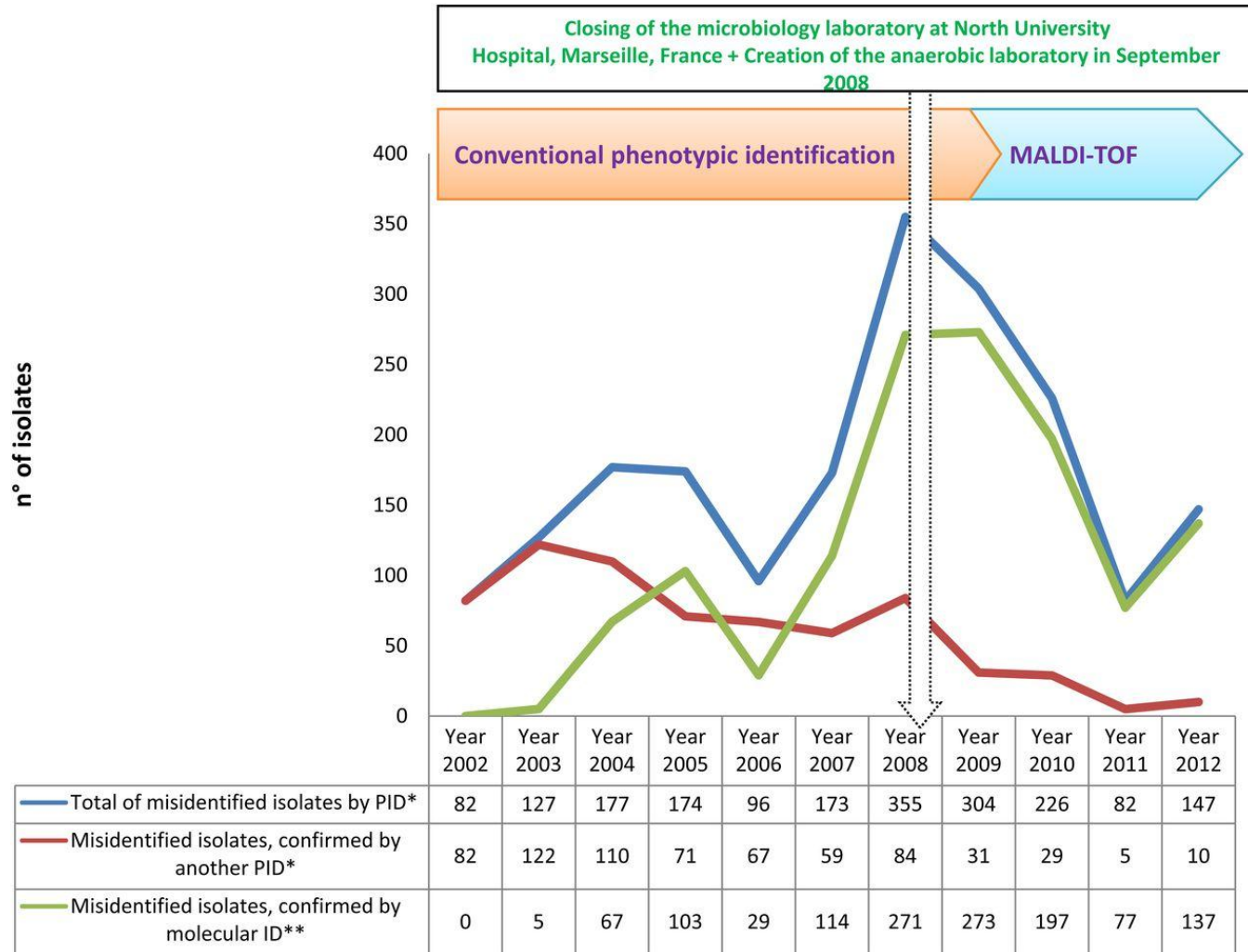
- Increased Consolidation
- Automation
- Culture will be used less as molecular will replace many applications
- Culture is not going away, we just need to become more efficient

# The Future of Mass Spectrometry

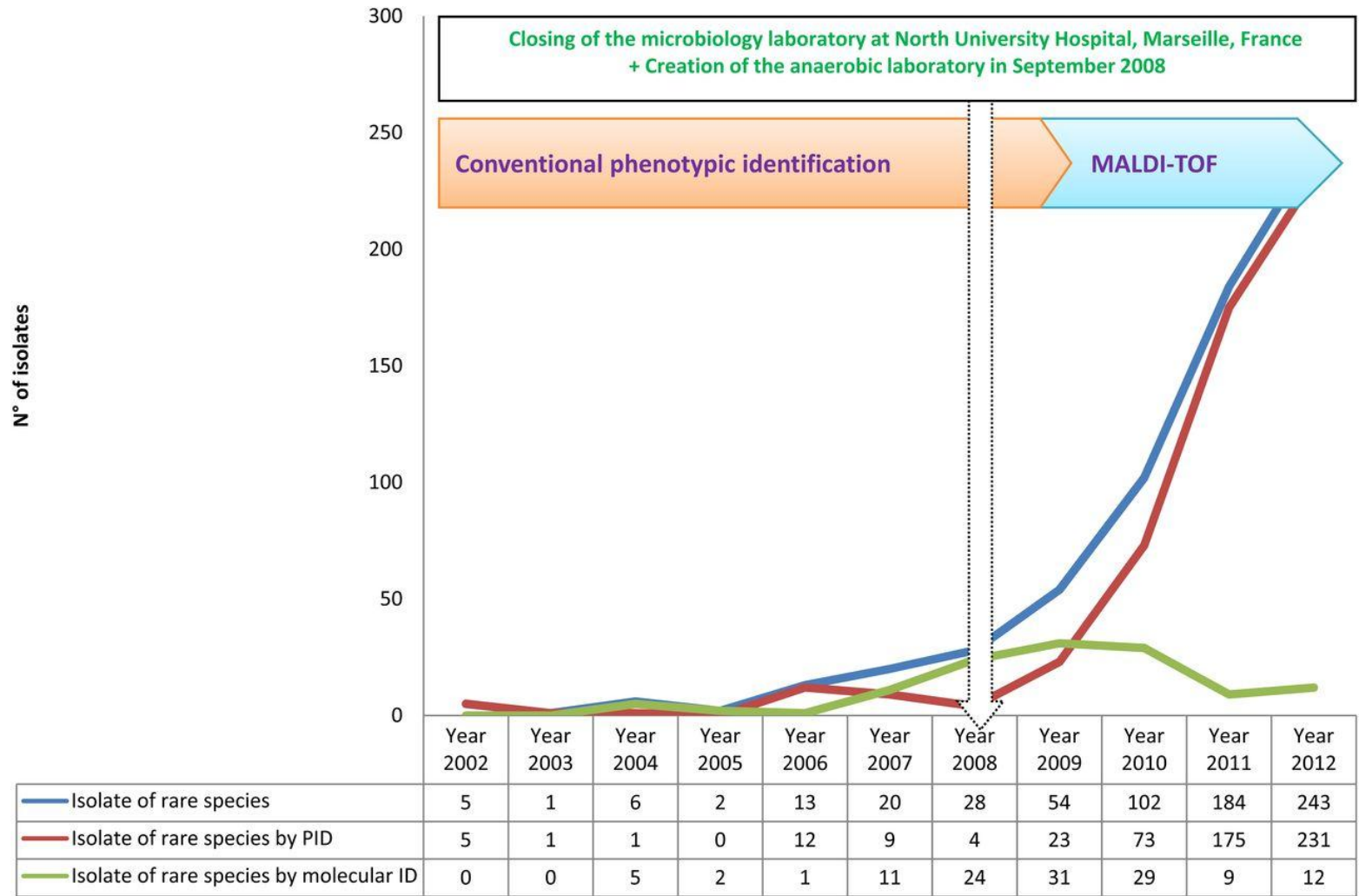
- Continued migration to mass spectrometry for microbial ID based on performance and cost
- Automation will simplify the set-up and further drive down costs
- Continued expansion of applications
- Limitations of MALDI-TOF will become apparent
  - Susceptibility testing



**Time course of the numbers of total isolates misidentified using phenotypic identification (PID\*), isolates confirmed by a second PID\* and isolates confirmed by molecular identification (ID\*\*) over 11 years of routine identification in our clinical laboratory.**



**Time course of the numbers of isolates of 128 rare species, 48 of which were identified using phenotypic identification (PID), and 75 of which were identified using molecular identification (ID).**



# The Future of Molecular Biology

- Migration away from singleplex PCR to disease state testing
  - Eg. stool pathogen panels, sepsis panels, pneumonia panels
- Moving testing closer to patient
- Increased competition based on menu
  - Menu will be king, less capital for boxes
- Increased competition based on price
- Increased need for clinical data supporting use of molecular tests
- Movement to FDA approved kits

# Enteritis

## Scope of problem-

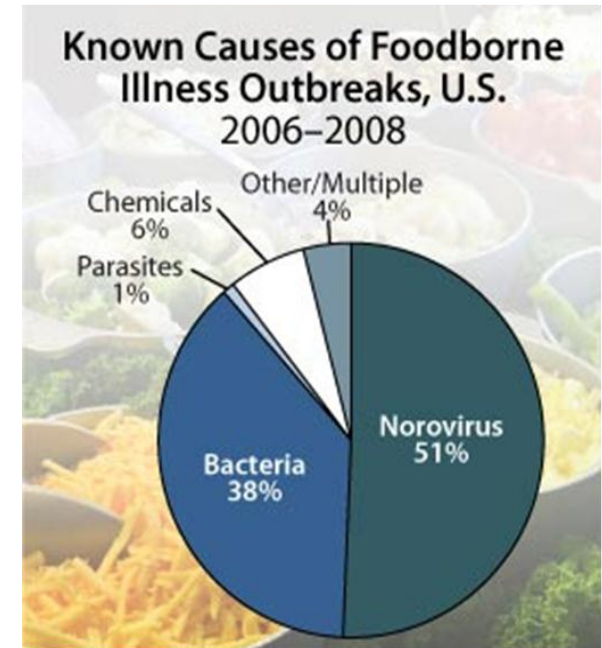
- ✓ Enteric illness affects millions yearly in US alone
- ✓ Mortality in infants and elderly

## Definition-

- ✓  $\geq 3$  unformed stools in 24 hr period

## Causes-

- ✓ Foodborne
  - ***Salmonella*, *Campylobacter*, *Y. enterocolitica*, *V. parahaemolyticus*, ETEC, EPEC**
- ✓ Environmental
  - *Cryptosporidium*, *Giardia*, *Isospora/Cyclospora*, *Aeromonas*, *Plesiomonas*
- ✓ Contagious
  - Rotavirus, Norovirus, *Shigella*, *V. cholerae*, *C. difficile*
- ✓ Toxin mediated
  - STEC, EHEC, *C. perfringens*, *B. cereus*, *S. aureus*



# Choices and Algorithms

## EHEC/STEC

*E. coli* containing *stx1* or *stx2*

Serotype o157 associated with *stx2* carriage

- HUS in 2-10% of infected peoples



*CDC recommendation (2009) and Joint Commission updated standard (2013) to culture for O157 and use EIA/NAAT for stx1/2*

TABLE 3. Cost of stool testing, Upstate Medical University Hospital

Test	Cost per test (\$) <sup>a</sup>	Cost per positive test (\$)
Stool culture	11.88	255.42
<i>C. difficile</i> PCR	52.80	333.77
Shiga toxin immunoassay	16.11	18,300.00

<sup>a</sup> Includes labor, reagents, and controls.

# Enteric pathogen “panels”

## ➤ Potential Benefits

- ✓ Higher sensitivity for detection/identification of enteric pathogens
  - ✓ More rapid TAT

## ➤ Considerations

- ✓ Cost of molecular testing
- ✓ Technologist expertise
  - Test complexity
  - ✓ Level of automation
- Sample – Result? Off line extractions or PCR
  - Volume!!!!
- ✓ Breadth of targets
  - All inclusive (viral, parasitic, bacterial, toxin)
  - Targeted (common causes of CA enteritis)

# PCR vs Culture?

Assay	No. positive							
	Stx1		Stx2		Stx1 and Stx2		Total	
	Specimens	Patients	Specimens	Patients	Specimens	Patients	Specimens	Patients
PCR	12	8	2	1	7	3	21	12
EIA Premier	3	2	0	0	3	2	6	4
ImmunoCard	3	2	0	0	1	1	4	3
SMAC	0	0	0	0	5	3	5	3

# ProGastro SSCS

Prospective study

- Preserved stools

## Comparison to reference culture method

	TP	TN	FP	FN	Total	Sens	Spec
<b><i>Campylobacter</i>*</b>	20	1106	13 <sup>a</sup>	0	1139	100.0%	98.8%
<b><i>Salmonella</i></b>	20	1108	10 <sup>b</sup>	1	1139	95.2%	99.1%
<b><i>Shigella</i></b>	15	1118	6 <sup>c</sup>	0	1139	100.0%	99.5%
<b><i>stx1/2</i></b>	9	1121	9 <sup>d</sup>	0	1139	100.0%	99.2%

\**C. coli* or *C. jejuni*

<sup>a</sup>6/13 positive by bi-directional sequencing

<sup>b</sup>10/10 positive by bi-directional sequencing

<sup>c</sup>6/6 positive by bi-directional sequencing

<sup>d</sup>9/9 positive for *stx1* or *2* by bi-directional sequencing



# ProGastro SSCS

Prospective study

- Preserved stools

## Culture sensitivity compared to ProGastro SSCS

	TP	TN	FP	FN	Total	Sens	Spec
<b><i>Campylobacter</i>*</b>	20	1113	0	6	1139	76.9%	100.0%
<b><i>Salmonella</i></b>	20	1108	1	10	1139	66.7%	99.9%
<b><i>Shigella</i></b>	15	1118	0	6	1139	71.4%	100.0%
<b><i>stx1/2 (EIA)</i></b>	9	1121	0	9	1139	50.0%	100.0%

\**C. coli* or *C. jejuni*

- Limited number of pathogens
- Requires nucleic acid extraction and two different master mix reactions
  - Manual pipetting, setup

# Enteric pathogen “panels”

## BD MAX Enteric Bacterial Panel (EBP)

- In FDA clinical trials
- Targets *Salmonella*, *Shigella*, *Campylobacter*, *stx1*, *stx2*

## Fully automated, sample to result

- Nucleic acid extraction , amplification , detection
  - Batch 1-24 samples
  - TAT 2-3 h



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# Clinical comparison of the BD MAX Enteric Bacterial Panel (EBP) with the ProGastro SSCS Assay for the detection of *Salmonella*, *Shigella*, *Campylobacter* and toxin encoding *stx1* and *stx2* genes in clinical stool specimens

- Preserved stool specimens were collected prospectively (n=210) or retrospectively (n=67) and tested using EBP and PG.
- For EBP, 10  $\mu$ L of specimen was transferred to a sample buffer tube, vortexed, and analyzed using the BD MAX.
- For PG, 100  $\mu$ L of a 1:10 dilution of specimen was extracted using the NucliSENS easyMAG system.
  - Extracted nucleic acid was combined with SSC (*Salmonella*, *Shigella*, *Campylobacter*) and STEC (*stx1*, *stx2*) PCR master mixes and run in parallel RT-PCR reactions.
  - Amplification and detection were performed using the Cepheid SmartCycler.
- Results from EBP and PG were compared to routine culture and *stx1/2* enzyme immunoassay as “gold standard”. Discrepancies were resolved using an alternative PCR and bi-directional sequencing.

# Comparison of MAX to PG

<b>BD (Combined)</b>	<b>TP</b>	<b>TN</b>	<b>FP</b>	<b>FN</b>	<b>total</b>	<b>sens</b>	<b>spec</b>
Salm	20	250	3	4	277	83.33%	98.81%
Shig	5	272	0	0	277	100.00%	100.00%
camp	21	244	8	4	277	84.00%	96.83%
stx	20	255	2	0	277	100.00%	99.22%
total	66	1021	13	8	278	89.19%	98.74%

<b>PG (Combined)</b>	<b>TP</b>	<b>TN</b>	<b>FP</b>	<b>FN</b>	<b>total</b>	<b>sens</b>	<b>spec</b>
Salm	19	250	3	5	277	79.17%	98.81%
Shig	5	272	0	0	277	100.00%	100.00%
camp	22	252	0	3	277	88.00%	100.00%
stx	20	255	2	0	277	100.00%	99.22%
total	66	1029	5	8	278	89.19%	99.52%

# Enteric pathogen “panels”

## xTAG GPP

- FDA-cleared
- Targets
  - Bacterial- *Salmonella*, *Shigella*, *Campylobacter*, *E. coli* 0157, ETEC (LS/ST), ***C. difficile***
  - Viral – Norovirus (GI/II), Rotavirus A
  - Parasites – *Giardia*, *Cryptosporidium*



45 min.



2.5 h



1 h



10 min

➤ Larger panel

- Requires nucleic acid extraction, PCR, hybridization/reading
- Manual pipetting, setup, open transfer of amplicon, equipment
  - 5 h TAT

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# GPP Performance

Organism(s)	% sensitivity (95% CI)	% specificity (95% CI)	% PPV (95% CI)	% NPV (95% CI)
Adenovirus 40/41	100 (60–100)	100 (98–100)	100 (60–100)	100 (98–100)
Vibrio cholerae	100 (31–100)	100 (98–100)	100 (31–100)	100 (98–100)
Yersinia enterocolytica	100 (31–100)	100 (98–100)	100 (31–100)	100 (98–100)
Salmonella spp.	92 (72–99)	100 (98–100)	100 (83–100)	99 (97–99)
Shigella spp.	93 (64–99)	100 (98–100)	100 (72–100)	99 (97–99)
Campylobacter jejuni	90 (67–98)	99 (97–99)	94 (72–99)	99 (97–99)
C. difficile A/B toxins	91 (69–98)	100 (98–100)	100 (80–100)	99 (97–99)
ETEC/STEC <sup>a</sup>	94 (79–99)	100 (98–100)	100 (87–100)	100 (87–100)
E. coli O157:H7	100 (55–100)	100 (95–100)	100 (55–100)	100 (95–100)
Rotavirus A	100 (63–100)	100 (98–100)	100 (63–100)	100 (98–100)
Giardia lamblia	95 (74–99)	99 (97–99)	95 (74–99)	99 (97–99)
Entamoeba histolytica	100 (46–100)	89 (84–93)	17 (06–36)	100 (98–100)
Cryptosporidium spp.	100 (73–100)	100 (98–100)	100 (73–100)	100 (98–100)
Norovirus GII	100 (46–100)	100 (95–100)	100 (46–100)	100 (95–100)
Norovirus GI	ND	100 (95–100)	ND	100 (95–100)
Total	94.5 (90–97)	99 (99–100)	87 (81–91)	99 (99–100)

# GPP Turnaround

Organism	Number (%) detected by GPP <sup>1</sup>	Mean, median age	% Male	Median day of request	Median LOS <sup>2</sup> (days)	Median isolation time (days)
<i>C. difficile</i>	57 (5.8)	47.6, 56	53	1	5	4
Norovirus	90 (9.1)	45.4, 41	48	1	3	3
Adenovirus	8 (0.8)	17.9, 3	50	1	1.5	1
Rotavirus	27 (2.7)	15.2, 1	63	1	2	2
<i>Campylobacter</i>	55 (5.6)	41.2, 41	65	0	3	2
<i>Salmonella</i>	30 (3.0)	25.5, 25	60	1	3	4
<i>Shigella</i>	13 (1.3)	39.4, 46	77	0.5	3	3
<i>E. coli O157</i>	3 (0.3)	16, 14	0	0	16	4
<i>Giardia</i>	14 (1.4)	31.2, 30	86	0	1.5	2
<i>E. histolytica</i>	6 (0.6)	22.5, 13.5	50	2	1	1
<i>Cryptosporidium</i>	6 (0.6)	56.3, 60.5	50	1	5.5	2
Any organism	282 (28.6)	40.3, 39	56	1	3	3
No organisms	704 (71.4)	47.3, 50	53	1	6	2
Any bacteria	157 (15.9)	40.1, 41	59	1	3	3
Any virus	124 (12.6)	37.5, 35	51	1	3	2.5
Any parasite	25 (2.5)	35.4, 30	68	0	5	1
Two or more organisms	27 (2.7)	20.7, 1	67	0	3	2.5
All samples	986	45.3, 48	54	1	5	3

<sup>1</sup> Gastrointestinal Pathogen Panel

<sup>2</sup> Length of stay

# Enteric pathogen “panels”

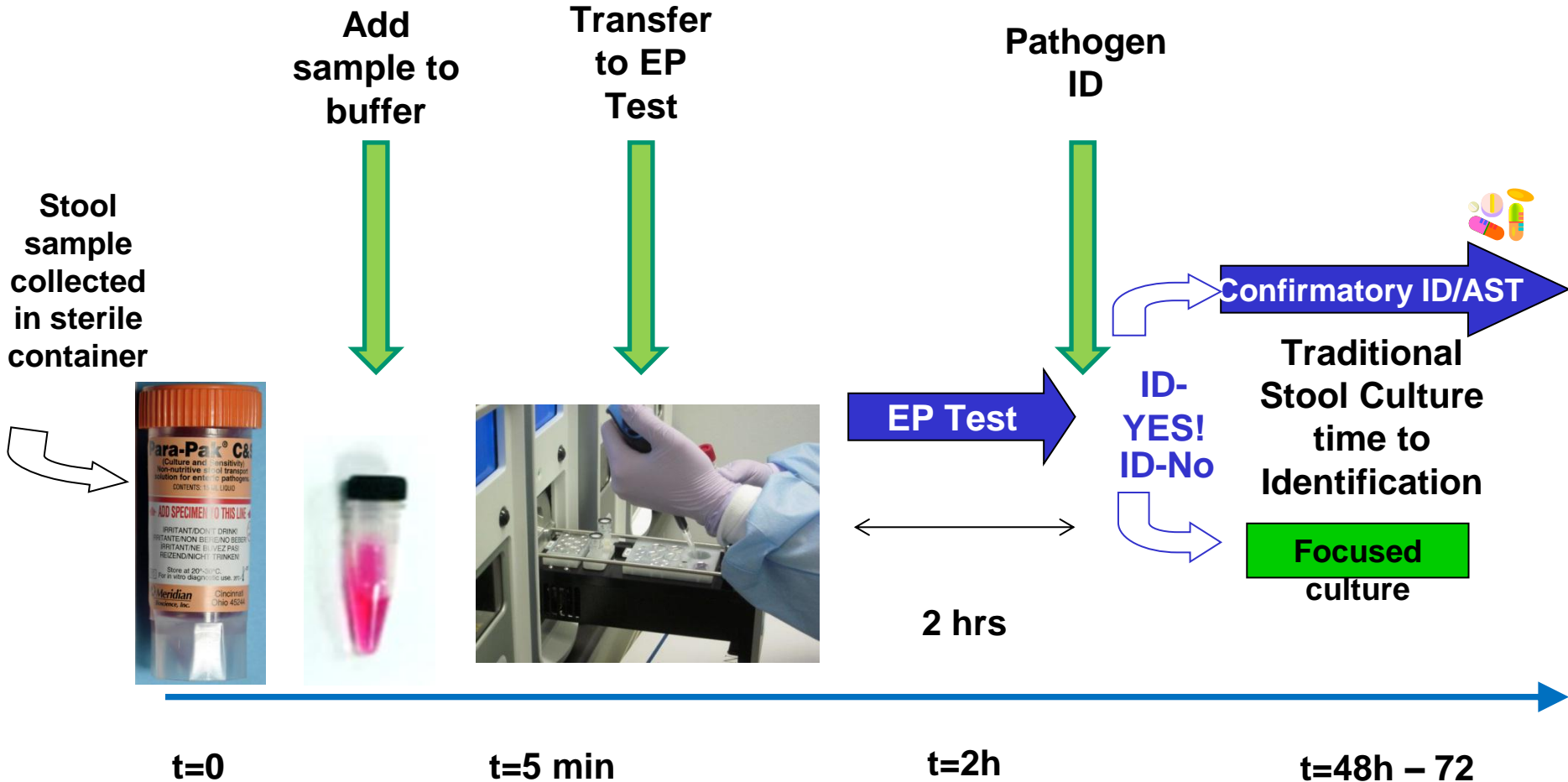
## BioFire FilmArray GI

- In development
  - *E. coli* – ETEC, EPEC, STEC/EHEC-O157:H7, EIEC, EAEC
  - Bacteria - *Aeromonas spp.*, *Salmonella spp.*, *Vibrio spp.*, *V. cholerae*, *Shigella spp.*, *S. dysenteriae*, *Campylobacter spp.*, *Y. enterocolitica*, ***C. difficile*****Nap1**, *P. s shigelloides*
  - Viruses - Norovirus (GI, GII, and GIV), Adenovirus F (40/41), Rotavirus (A, B, and C), Human Astrovirus, Sapovirus
  - Protozoa - *Cryptosporidium* group, *Giardia lamblia*, *Entamoeba histolytica*, *Cyclospora cayetanensis*
- Highly multiplexed, but is it suitable for high volume testing?
- \$/test
  - 1 test = 1 instrument





# Nanosphere Enteric Pathogen Panel - Workflow



# Preliminary results for bacterial targets –Verigene EP vs. Reference culture/Automated Phenotype Identification

## Stx 1 and Stx 2

<i>EP Target Analyte</i>	<i>Percent Agreement</i>	
	<i>Positive</i>	<i>Negative</i>
<i>Campylobacter</i>	96.7%	99.1%
<i>Salmonella</i>	96.6%	99.5%
<i>Shigella</i>	98.1%	99.0%
<i>Vibrio</i>	91.4%	100%
<i>Y. enterocolitica</i>	100%	100%
<i>Stx1</i>	100%	99.9%
<i>Stx2</i>	98.5%	99.9%

Study included 7 geographically distinct sites, n=1684

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# Molecular Enteric Pathogen Testing

## Advantages

- Rapid rule out for common CA pathogens (high NPV/sens)
  - Positive stools may not require further workup
  - Work-up of negative stools can be more focused (O&P, allergic, toxin)
- Antibiotic stewardship
  - Hold empiric therapy
  - *Salmonella*, EHEC, noro → may not require therapy; *Campylobacter*, *Shigella* → AST, treat
- Infection control
  - Identify outbreak or potential outbreak 48-72 h sooner → contain
  - Family members, school/daycare → isolate *Shigella*, Norovirus, possible source EHEC
- Cost neutral
  - Comparable to manual workup (labor not cheap, FNs etc.)
    - Full-automation “walk-away”
  - Compliance with CDC for stx1/2 at no “added” cost.

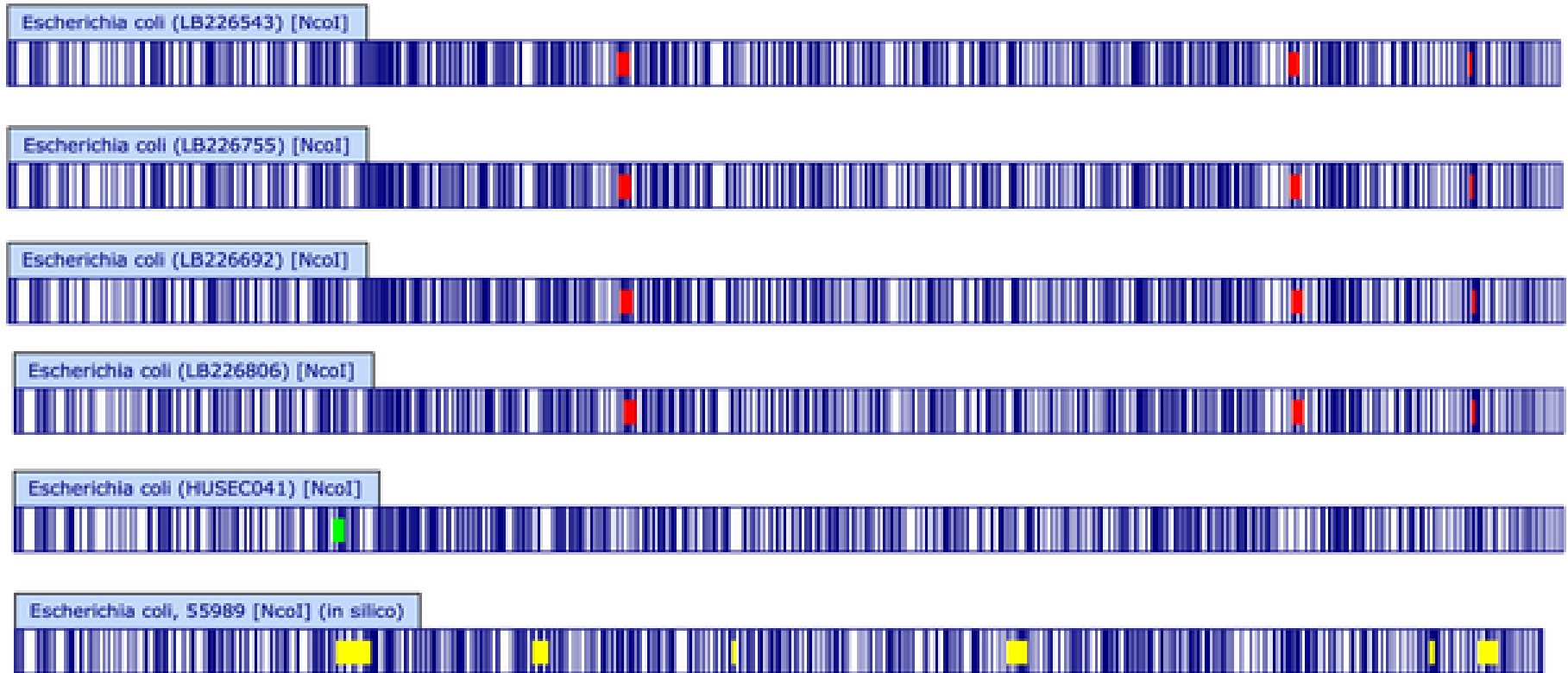
# Next Generation Sequencing

- Benefits
  - Detection of unculturable organisms
  - Interrogate genomes for novel and known resistance determinants
  - Direct from specimen identification
- Challenges
  - Need for clinically relevant databases
  - Cost
  - Turnaround

# Next Generation Sequencing

	Ion Torrent	454 Sequencing	Illumina
Sequencing Chemistry	Ion semiconductor sequencing	Pyrosequencing	Polymerase-based sequence-by-synthesis
Amplification approach	Emulsion PCR	Emulsion PCR	Bridge amplification
Mb per run	100	100	600,000
Time per run	1.5 hours	7 hours	9 days
Read length	200 bp	400 bp	2x100 bp
Cost per run	\$ 350 USD	\$ 8,438 USD	\$ 20,000 USD
Cost per Mb	\$ 5.00 USD	\$ 84.39 USD	\$ 0.03 USD
Cost per instrument	\$ 50,000 USD	\$ 500,000 USD	\$ 600,000 USD

## Whole chromosomal Optical Maps of the EHEC O104:H4 outbreak and related strains.



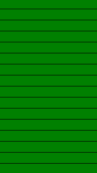
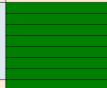
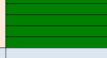

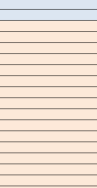

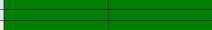











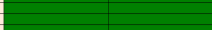











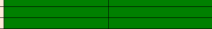












Mellmann A, Harmsen D, Cummings CA, Zentz EB, et al. (2011) Prospective Genomic Characterization of the German Enterohemorrhagic *Escherichia coli* O104:H4 Outbreak by Rapid Next Generation Sequencing Technology. PLoS ONE 6(7): e22751. doi:10.1371/journal.pone.0022751

<http://www.plosone.org/article/info:doi/10.1371/journal.pone.0022751>

# Specific species identification

Unique mapping  present  Not present  Not targeted

Members of CoNS

Sample \ amplicon	Members of CoNS															
	Enterococcus faecium, VanA	MRSA, Enterococcus faecalis, Staphylococcus epidermidis	Staphylococcus epidermidis	Staphylococcus epidermidis	Staphylococcus epidermidis	Staphylococcus epidermidis, MecA	Staphylococcus epidermidis	Staphylococcus epidermidis	Staphylococcus epidermidis	Staphylococcus epidermidis	Staphylococcus epidermidis, Corynebacterium spp.	Staphylococcus epidermidis, Corynebacterium spp.	Staphylococcus hominis	Staphylococcus capitis	CoNS Coagulase Negative Staphylococci	Viridans group Streptococci
AMPLE_faecalis																
AMPLE_faecium																
AMPLE_faecium_vanA																
AMPLvanB_Enterococcus																
AMPLMRSA-junction.104																
AMPLStaphylococcus_aureus																
AMPLStaphylococcus_aureus_spa																
AMPLStaphylococcus_aureus_erm																
AMPLEStaphylococcus_epidermidis																
AMPLEStaphylococcus_saprophyticus_coagulase_neg																
AMPLStreptococcus_pneumoniae																

S.epidermidis is a member of CoNS

Strep.pneumoniae is not a member of Viridans gr Strep. Non-specific hits.

# All mapping further identifies mecA resistance

All mapping

 present

 Not present

 Not targeted

Sample amplicon	Enterococcus faecium, VanA	MRSA, Enterococcus faecalis, Staphylococcus epidermidis	Staphylococcus epidermidis	Staphylococcus epidermidis	Staphylococcus epidermidis	Staphylococcus epidermidis, MecA	Staphylococcus epidermidis	Staphylococcus epidermidis	Staphylococcus epidermidis	Staphylococcus epidermidis, Corynebacteri um spp.	Staphylococcus epidermidis, Corynebacteri um spp.	Staphylococcus hominis	Staphylococcus capitis	Coagulase Negative Staphylococci	Viridans group Streptococci
AMPLStaphylococcus_aureus_mecA.26															
AMPLStaphylococcus_aureus_mecA.27															
AMPLStaphylococcus_aureus_mecA.28															
AMPLStaphylococcus_aureus_mecA.29															
AMPLStaphylococcus_epidermidis_mecA.38															
AMPLStaphylococcus_epidermidis_mecA.39															
AMPLStaphylococcus_epidermidis_mecA.40															
AMPLStaphylococcus_epidermidis_mecA.41															
AMPLStaphylococcus_epidermidis_mecA.42															
AMPLStaphylococcus_epidermidis_mecA.43															
AMPLStaphylococcus_epidermidis_mecA.44															
AMPLStaphylococcus_haemolyticus_coagulase_neg.24.a															
AMPLStaphylococcus_haemolyticus_coagulase_neg.24.b															
AMPLStaphylococcus_haemolyticus_coagulase_neg.24.c															
AMPLStaphylococcus_haemolyticus_coagulase_neg.25															

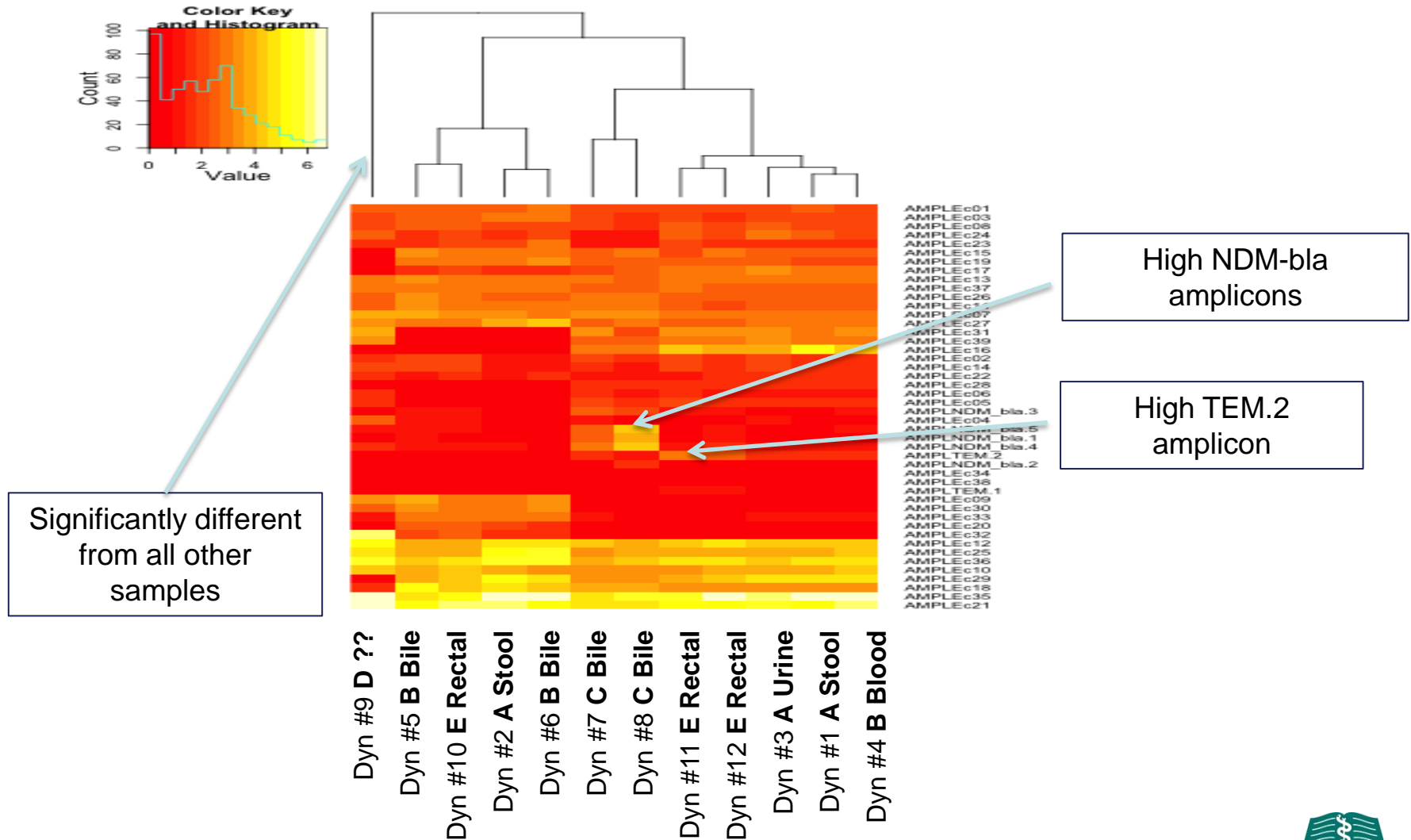
Some *S.epidermidis* samples have MecA some don't

Haemolyticus\_coagulase\_neg amplicons have many off-target hits and can not be used for identification purposes. .



		Provided by collaborator		Observed		Notes
Sample Name	Barcode	Bacteria	Resistance	Bacteria(Species)	Resistance gene(s)	
MCW-21	21	S. aureus	susceptible to all	S.aureus	Not detected	
MCW-22	22	S. epidermidis	Ery/Clinda/Tet/Doxy/Ox resistant	S.epidermidis	Erm, MecA	
MCW-23	23	Strep. Spp., Lactococcus, Leuconostoc	Not performed			No library
MCW-24	24	Strep. Sanguinis	Ceftri/vanc susceptible	Positive for 3 out of 7 Strep pneumoniae amplicons	Mef	
MCW-25	25	S. hominis	Not performed	Positive for 5 CoNS amplicons in unique mapping	Not detected	
MCW-26	26	spp	Not performed	Positive for 8 CoNS amplicons in unique mapping	TEM	
MCW-27	27	Lactobacillus	Not performed			No library
MCW-28	28	S. hominis	Not performed	Positive for 9 CoNS amplicons in unique mapping	TEM	
MCW-29	29	CoNS	Not performed	Positive for 5 CoNS amplicons in unique mapping	Not detected	
MCW-30	30	S. epidermidis	Not performed	S.epidermidis	Erm, MecA	
MCW-31	31	S. dysgalactiae	susceptible to all			No library
MCW-32	32	s. capitis	Not performed	Positive for 8 CoNS amplicons in unique mapping	Not detected	
MCW-33	33	S. epidermidis	Ery/Clinda/Ox Res, Tet/Doxy Sus	S.epidermidis	Erm, MecA	
MCW-34	34	S. epidermidis	Not performed	S.epidermidis	Erm, MecA	
MCW-35	35	Corynebacterium spp	Not performed			No library
MCW-36	36	S. epidermidis	Not performed	S.epidermidis	Erm, MecA	
MCW-37	37	Strep viridans gr.	susceptible to all	Positive for 4 out of 7 Strep pneumoniae amplicons	Not detected	
MCW-38	38	E. faecalis	Amp/Vanc susceptible	E.faecalis	Not detected	
MCW-39	39	atophobium rimae, E coli	Not performed (A. rimae)			No library
MCW-40	40	S. epidermidis	Not performed	S.epidermidis	Erm, MecA	
MCW-41	41	S. epidermidis	Not performed	S.epidermidis	MecA	
MCW-42	42	S. hominis	Not performed	Positive for 3 CoNS amplicons in unique mapping	Erm, MecA	
MCW-43	43	S. epidermidis	Not performed	S.epidermidis	Not detected	
MCW-44	44	S. dysgalactiae	susceptible to all			No library
MCW-45	45	E. coli, M. luteus				Very dirty library

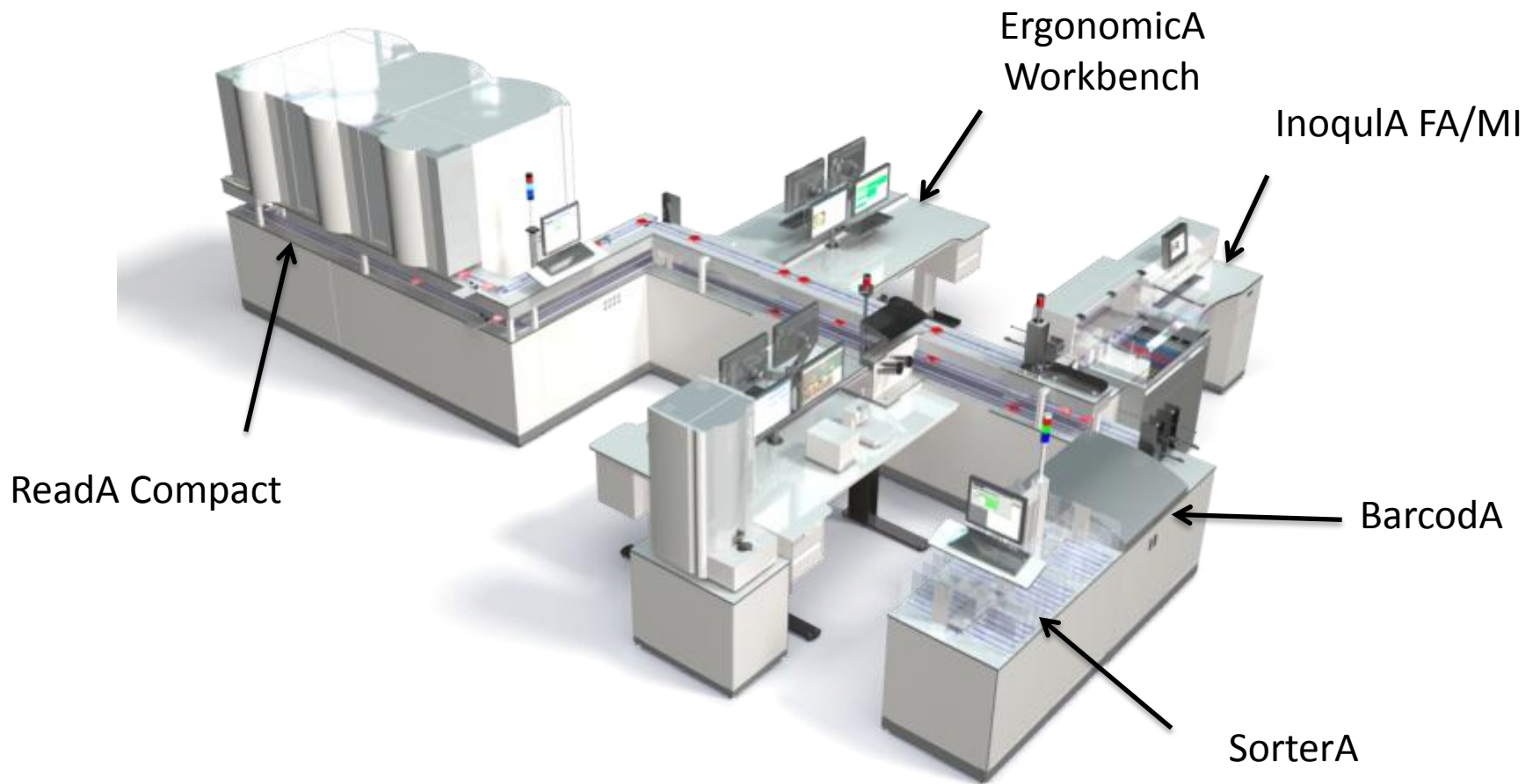
# Heat Map – Per Amplicon Coverage Metric as Estimated by Percentage of Uniquely Mapped Reads



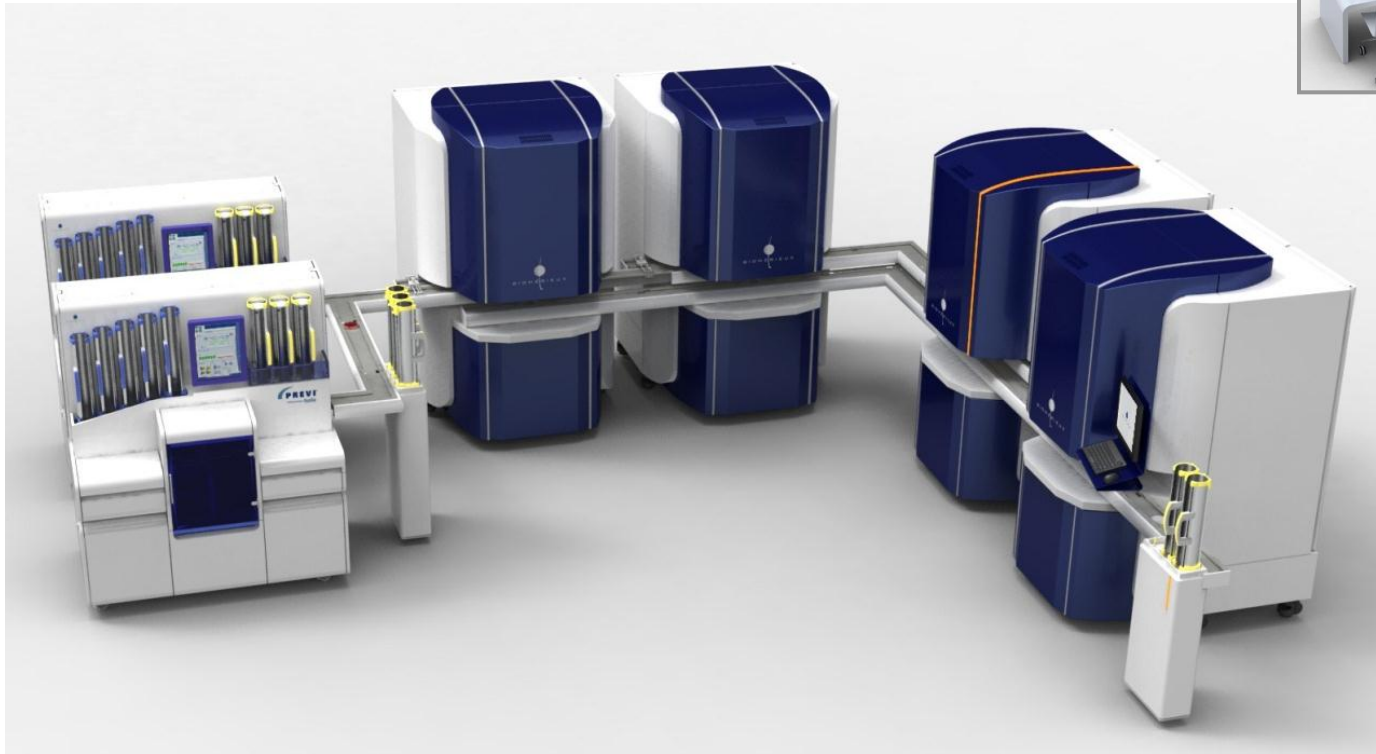
No automatic clustering by either tissue or patient type

# Trends to Automation?

- The Industry is Changing
  - Specimens increasing on average 10-15% per year
  - Laboratory consolidation
  - Reimbursement
- Workforce
  - Less students choose Medical Technology: reduction of 30-50%
  - Pay for technologists is substandard
- Quality
  - Physicians are demanding more services, in less time
  - Traceability



*We Practice What We Teach*

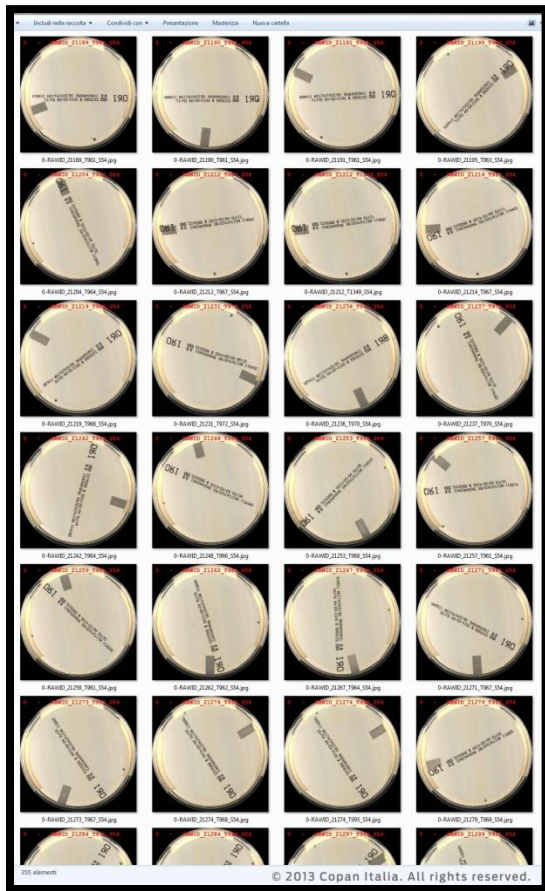


*We Practice What We Teach*

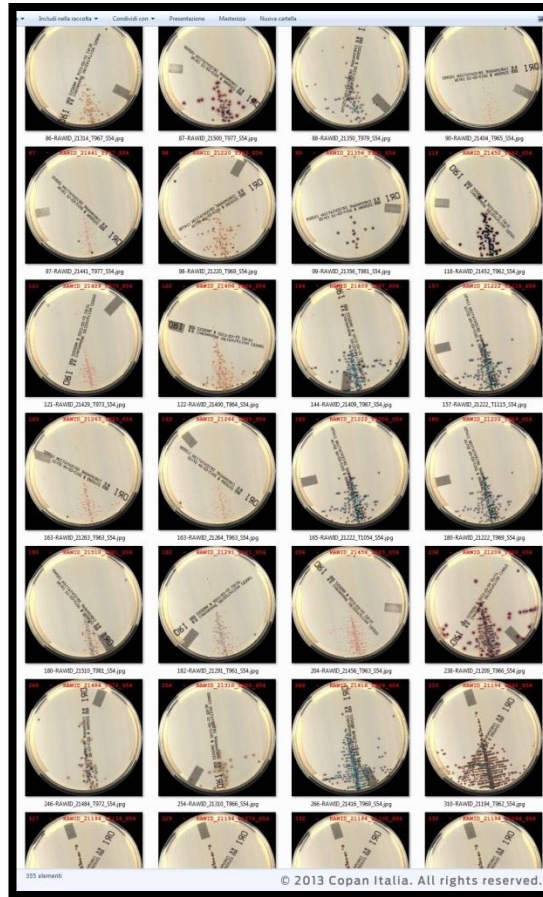


*We Practice What We Teach*

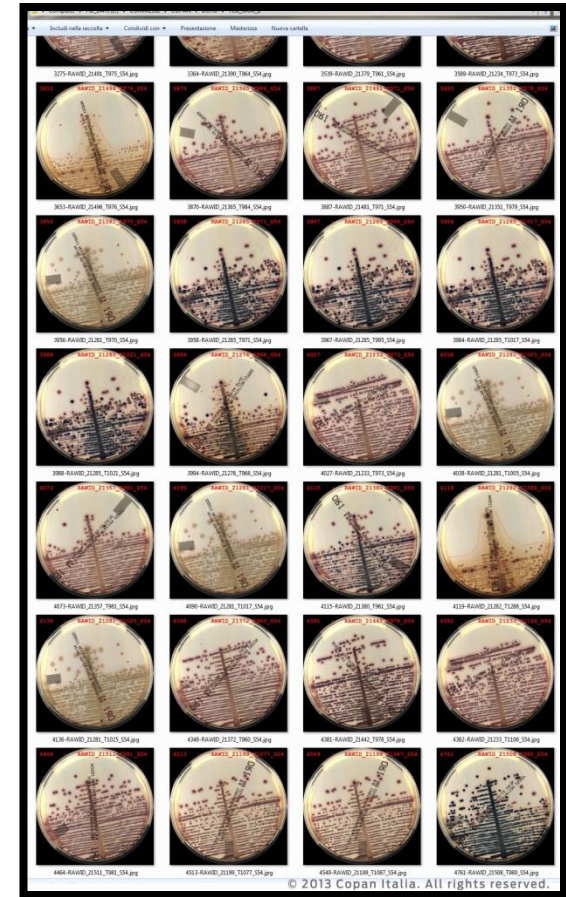
# Pre-Sorting of urine cultures – 1ul



0 CFU/ml  
24 cultures per screen



10<sup>4</sup> CFU/ml shows as  
approximately 10 colonies



10<sup>5</sup> CFU/ml  
shows as  
approximately  
100 colonies



*We Practice What We Teach*

# Costs



- 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 – is there a cost to this?
    - 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 hanges



# Considerations

- Change Management/ Staff acceptance
- LIS- Complex integration with automation
- Impact on other areas
- Integration of current systems
- Redundancy and backup for downtime
- Technology enhancements
- Impact of growth on staffing requirements after adoption of automation
- Impact on Safety

# So What's a Lab to Do? (Especially a Small one)

- Emerging technologies can be utilized in a variety of laboratory sizes
  - Companies are developing flexible solutions
  - MALDI-TOF can be cost-effective even for very low volume laboratories
  - Molecular solutions are scalable
    - Examples
      - Verigene, FilmArray, Xpert, GreatBasin
    - Convince the manufacturer to place an instrument
    - Consolidate testing to a minimum number of platforms to achieve volumes
- Size is not as important as before
  - Reimbursement changing to a quality basis, you will be paid for the value you bring
  - “Change the Message” – Demonstrate how lab testing can improve quality for the whole system
    - Cite the literature

# So What's a Lab to Do? (Especially a Small one)

- Who Can Help / Where can I get information without a travel budget?
  - Use your reference labs
  - JCM is available for free after 6 months
  - Attend regional meetings such as WSCLS, SCACM, etc
- Will new technologies prompt more consolidation?
  - Unknown, but potentially yes...
  - Recent Wall Street Journal article questions the benefits of large consolidated systems over smaller individual systems

# Questions?



“The patient in the next bed is highly infectious. Thank God for these curtains.”

*We Practice What We Teach*