A long time ago in a galaxy far, far away....

Rick Danforth, SM (ASCP)

Health & Environmental Testing Laboratory

Laboratory Program Advisor, Safety Officer, Quality Assurance, BT Coordinator,

Chief Test Tube Washer & Traditional Microbiologist

Tel: 207-287-5679

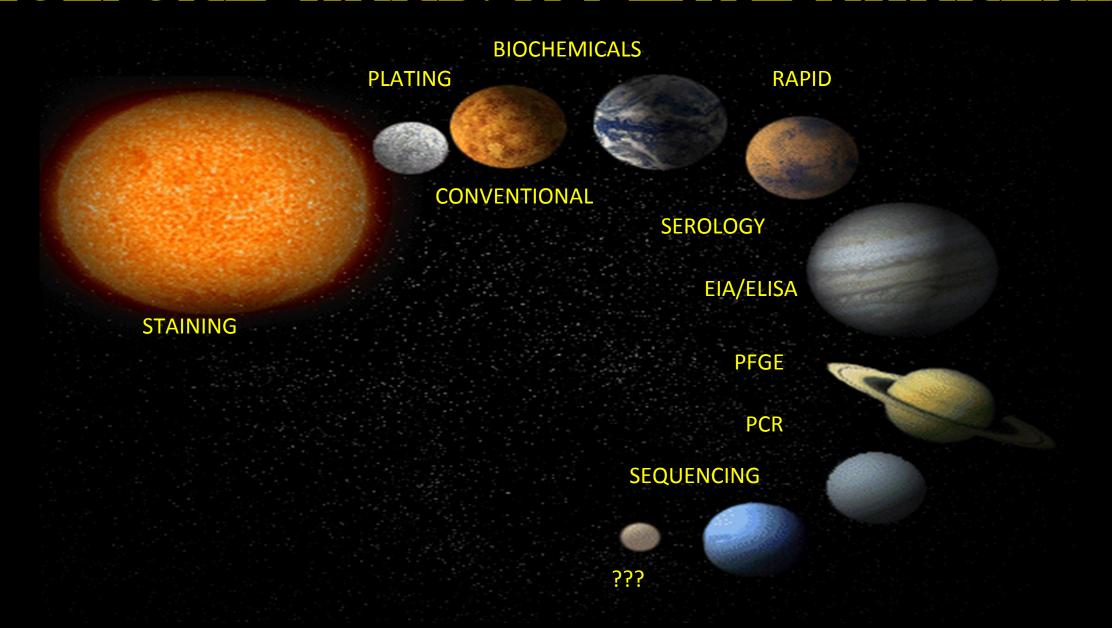
E-mail: richard.danforth@Maine.gov

A long time ago, far away, in a place called Micro Lab, cultures took 48 hours to complete. Availability of rapid tests has increased causing a revolutionary effect on the Galactic Healthcare Systems. Discussions now take place on how this impacted the planet called "Public Health." This presentation will examine how laboratories can use available forces needed in the crusade of controlling the spread of infectious diseases. Culture-Independent Diagnos Testing (CIDT) impacts many aspects of your clinical laboratory and has important implications for physicians, patients and public health surveillance. We will discuss the pros and cons of CIDTs for the new millennium and not to stray to deep into the dark side of the force.

GROUND



RULES





"There is more to life than simply increasing its speed"

Ghandi....not Yoda

Molecular Diagnostics

- Most rapidly growing area in clinical micro
 - Many methodologies available
- Will continue to change laboratory medicine
- May displace or complement traditional work
- Will continue to grow until the majority of tests are molecular



Why the quick acceleration of rapid tests?

- We can
- We must
- We have no time
- We asked for low cost
- Will save money

Continue...

- Growing Technology
- Superior performance
- Sample to result automation
- Availability to all labs and POC
- Simplification of complex procedures will happen much faster and in a cost effective manner

3ut......



HOW HAS THESE CHANGES IMPACTED THE GALAXY CALLED - EPIDEMIOLOGY?





An epidemic is described as an occurrence of a cluster of a disease caused by single pathogen in numbers in excess of what is expected for that time and place.

Council of State and Territorial Epidemiologists

CSTE

Case Classification – Updated Annually

Suspected: No definitive, presumptive or suggestive laboratory evidence

Probable: Clinically compatible illness that does not meet confirmed case definition, but meets one of the listed criteria for the disease. (e.g. PCR)

Confirmed: Clinically compatible illness with one of listed criteria for the disease. (e.g. Culture & ID)



Culture is still considered the "gold standard" for many infectious diseases

The increasing use of non-culture based diagnostic methods is concerning for a couple of reasons:

- ✓ Infections diagnosed in this manner do not meet the current laboratory criteria for case classification
- ✓ National-level efforts to monitor pathogenic enteric infections in order to identify and respond to multi-state outbreaks will be handicapped

A Microbe's Point of View

Modes of Transmission

Have learned to trick us by changing their antigens

Phenotype v. Genotype

The Evil Empire.....is seeking to require through legislation that laboratories perform culture testing on all specimens that are found to be positive by a cultureindependent diagnostic test.

We need rapid tests:

- Some pathogens do take time to grow
- Fastidious organisms

Non-culture based diagnostic testing methods

- Hospital and clinical labs are doing testing that makes sense from a business sense but present problems to health departments & CDC in terms of acceptability for case definitions.
- A workgroup has started with enterics, but this is certainly a wider issue that affects other pathogens. The workgroup can discuss how to adapt to the new realities of laboratory testing to come up with general principles about how this adaptation might take place.

Continue...

All states seem to be treating these cases differently and there is no standard.



Federal CDC Names Winner of the "No-Petri-Dish" Diagnostic Test Challenge

The developers of One Codex succeeded in demonstrating how their platform can rapidly identify STEC from complex clinical samples and provide meaningful information about its straintype and characteristics, even when the pathogens are present at levels too low to support assembly-based methods. Reference Genomics, Inc. and One Codex developers Nik Krumm, PhD and Nick Greenfield will receive the \$200,000 Challenge prize to continue development of their platform. A beta version of the One Codex platform is available on the web at www.onecodex.com



Growing Technology

These advances will have a greater impact on our understanding of infectious diseases and how to care for and manage those that are infected.....

COMING TO A LAB NEAR YOU

Culture Wars: Episode VIII Going Rogue

November 2018