

CULTURE WARS: A PLATE AWAKENS

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

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Culture Independent
Diagnostic Tests
General Overview

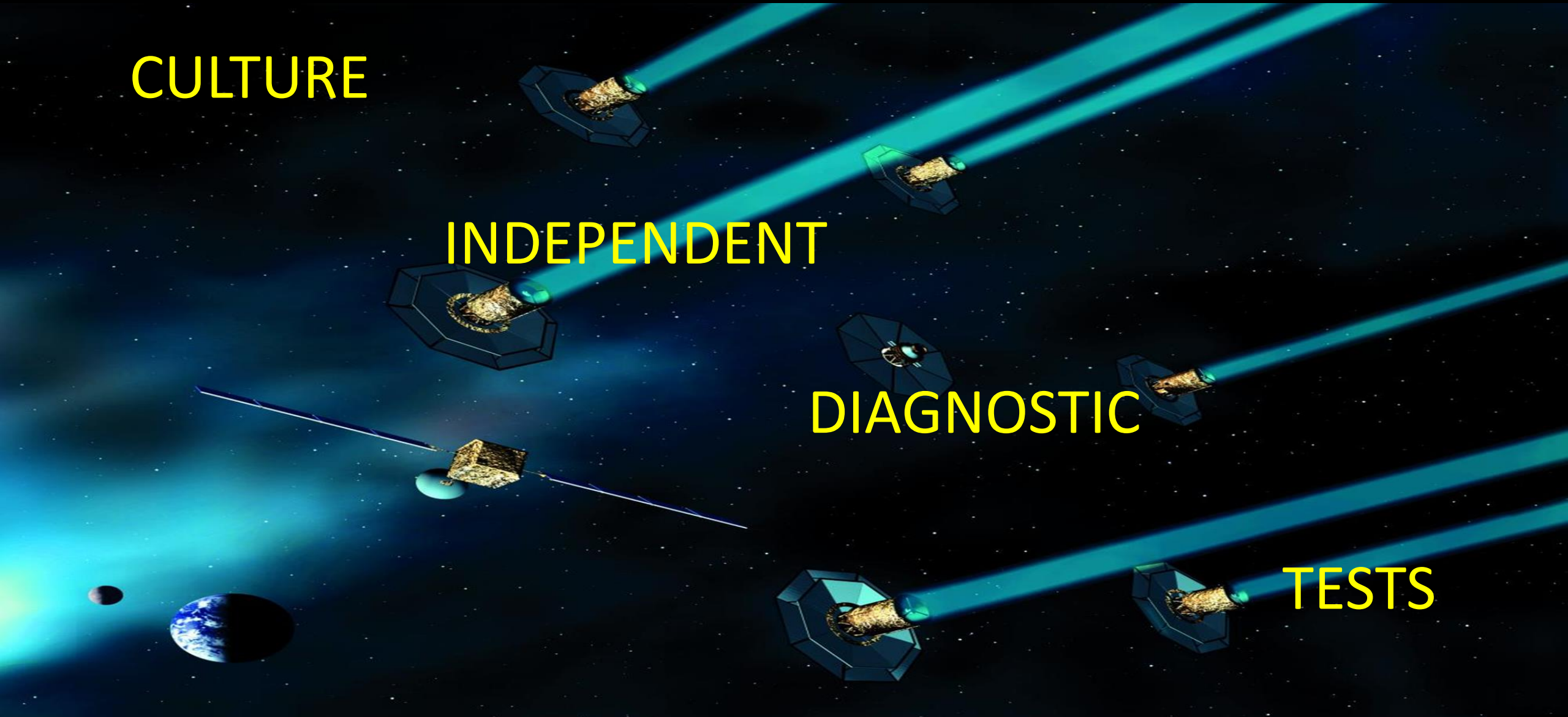
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CULTURE

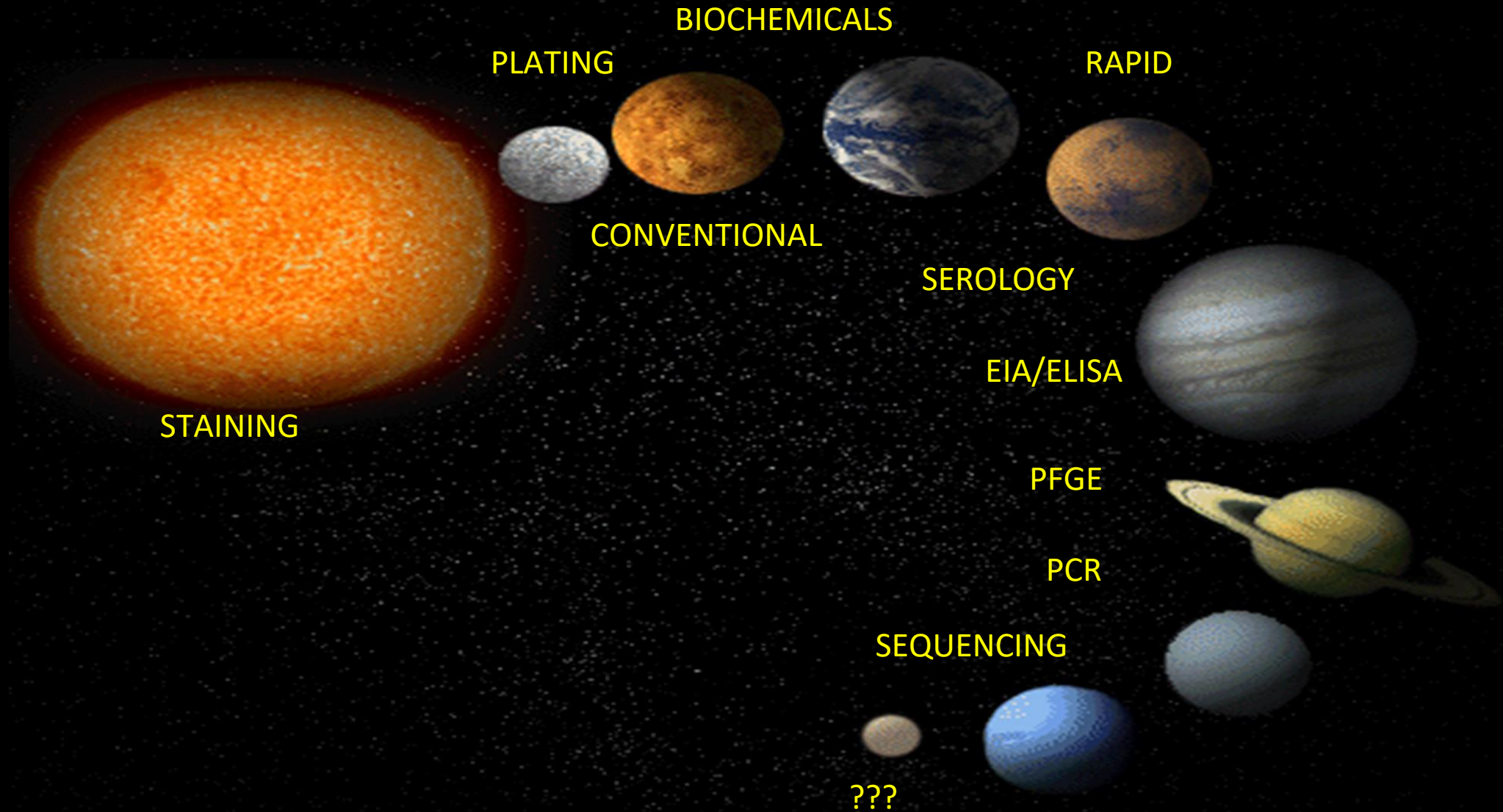
INDEPENDENT

DIAGNOSTIC

TESTS



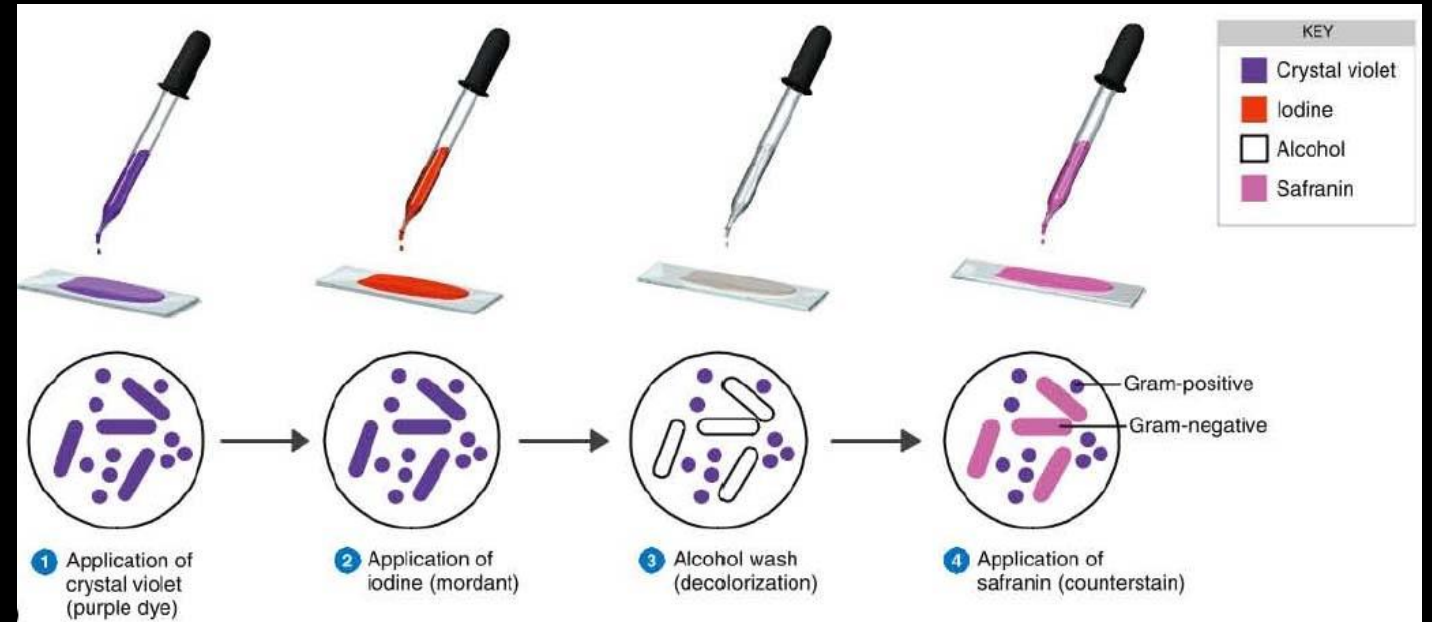
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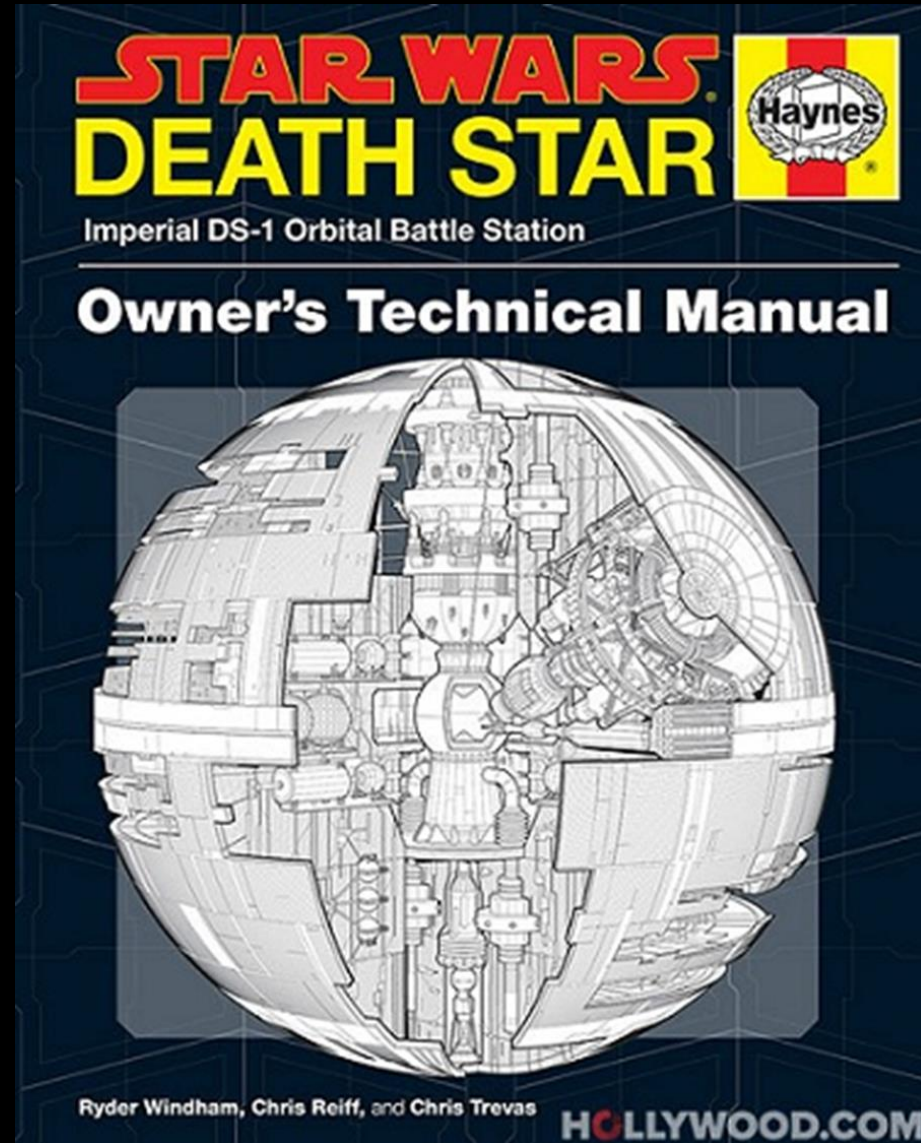
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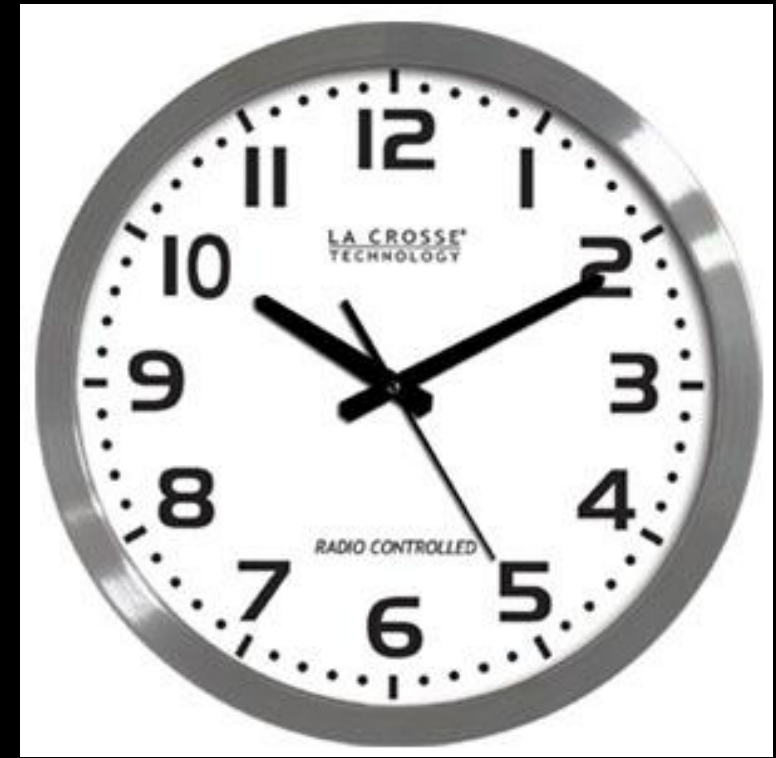
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“There is more to life than simply increasing its speed”

Ghandi.....not Yoda

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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

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Why the quick acceleration of rapid tests?

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

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- 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

But.....

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**HOW HAS THESE CHANGES IMPACTED THE
GALAXY CALLED - EPIDEMIOLOGY ?**



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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.

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Council of State and Territorial Epidemiologists

CSTE

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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)

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Culture is still considered the “gold standard”
for many infectious diseases

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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

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A Microbe's Point of View

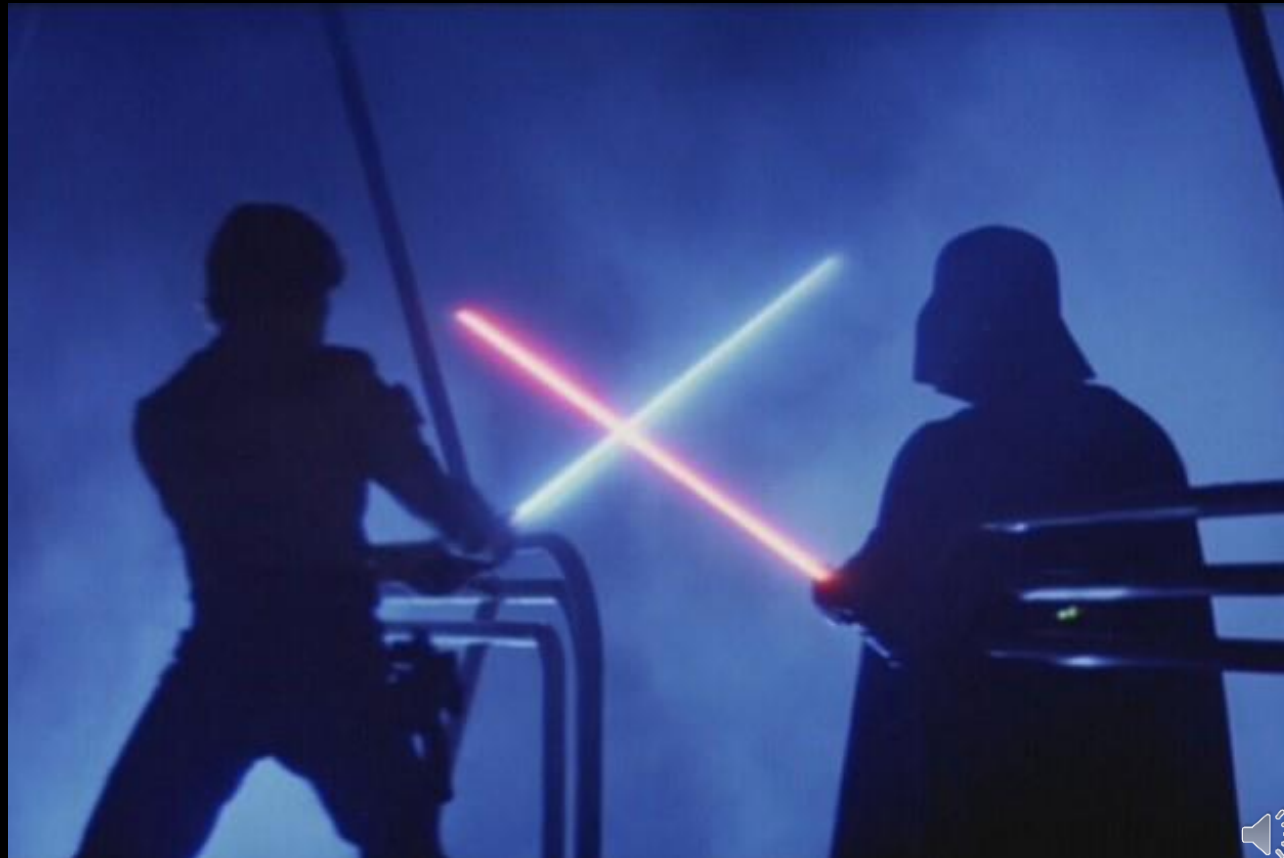
Modes of Transmission

Have learned to trick us by changing their antigens

Phenotype v. Genotype

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When cultures clash !!



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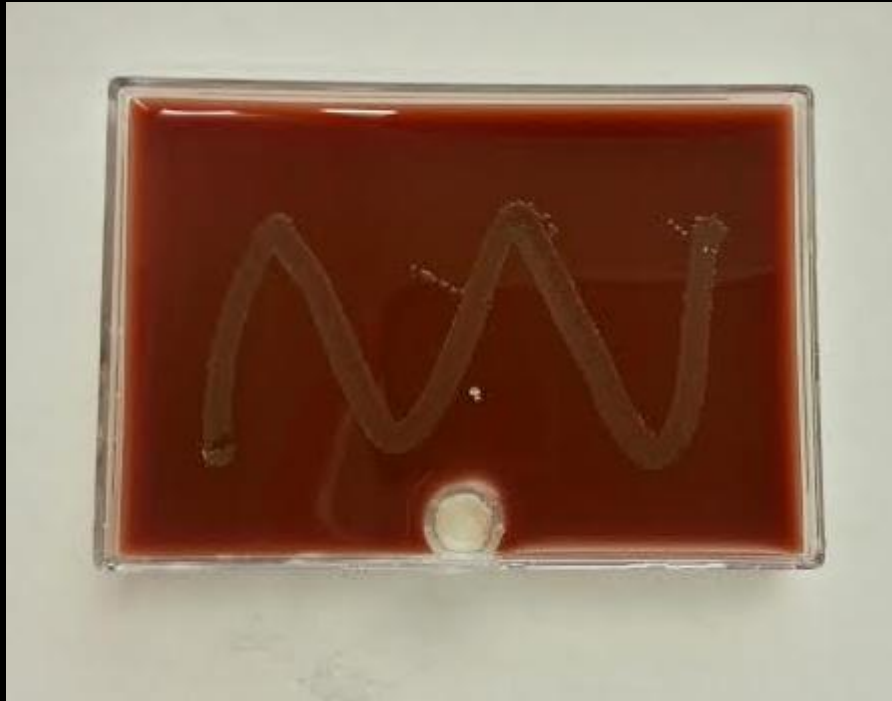
EXAMPLE

▣ Shiga Toxin Test	22.00
▣ Mac Broth	0.35
▣ Plate	0.55
▣ Send to PHL	2.50
▣ Total	25.40

Saving a more lives

PRICELESS

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The Empire State.....**NEW YORK**.....is seeking to require through legislation that laboratories perform culture testing on all specimens that are found to be positive by a culture-independent diagnostic test.

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We need rapid tests:

- ❖ Some pathogens do take time to grow
- ❖ Fastidious organisms

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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.

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Continue...

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

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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 strain type 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

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“Positive you believe,
Negative, you do not !!.... Yoda



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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.....