

WS2: MOLECULAR INFECTIOUS DISEASES TESTING

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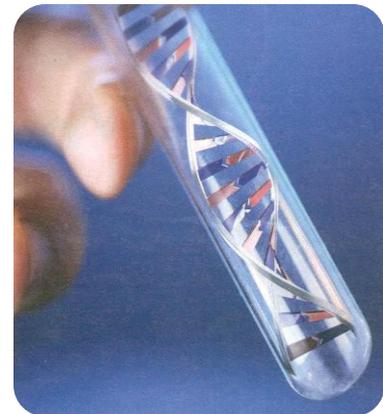
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Nucleic Acid Amplification Tests

- Have been around for sometime now
- Earliest application in clinical microbiology laboratory was for viruses
- Not totally unexpected
- Now method of choice for detecting or quantifying many viral pathogens
- Extensive literature exists

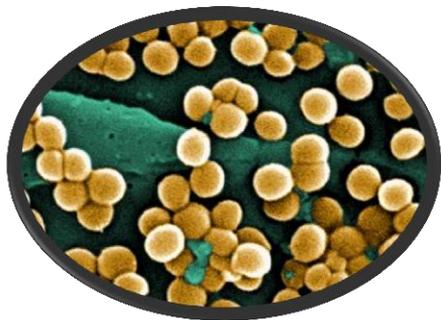


Other Areas of Clinical Microbiology

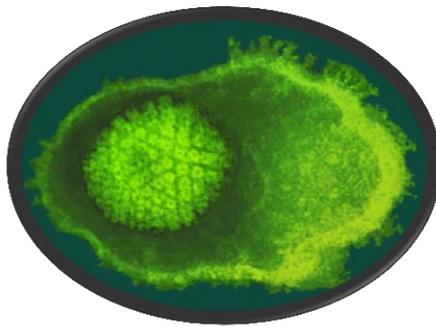
- Molecular assays have gradually infiltrated other areas of clinical microbiology
- Now being implemented for variety of reasons
- Number of areas being targeted
 - Infection control
 - Bloodstream infections
 - Mycobacteriology
 - Mycology
 - Parasitology
 - Pathogen ID
 - Detection of virulence factors and antimicrobial resistance determinants

Molecular Diagnostics

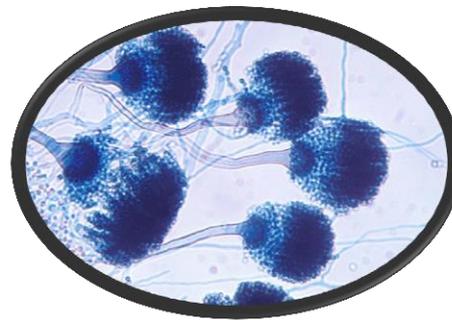
- Has rapidly evolved over the years
- Numerous technological advances
- Now the accepted standard for the diagnosis and monitoring of many microbial pathogens
- Significant clinical benefit being shown



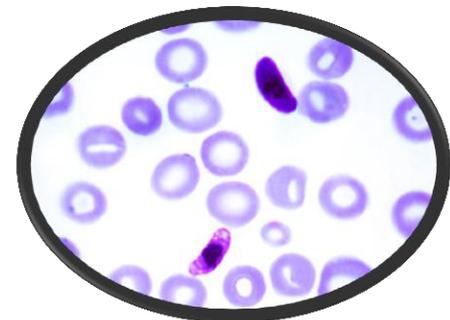
Bacteria



Viruses

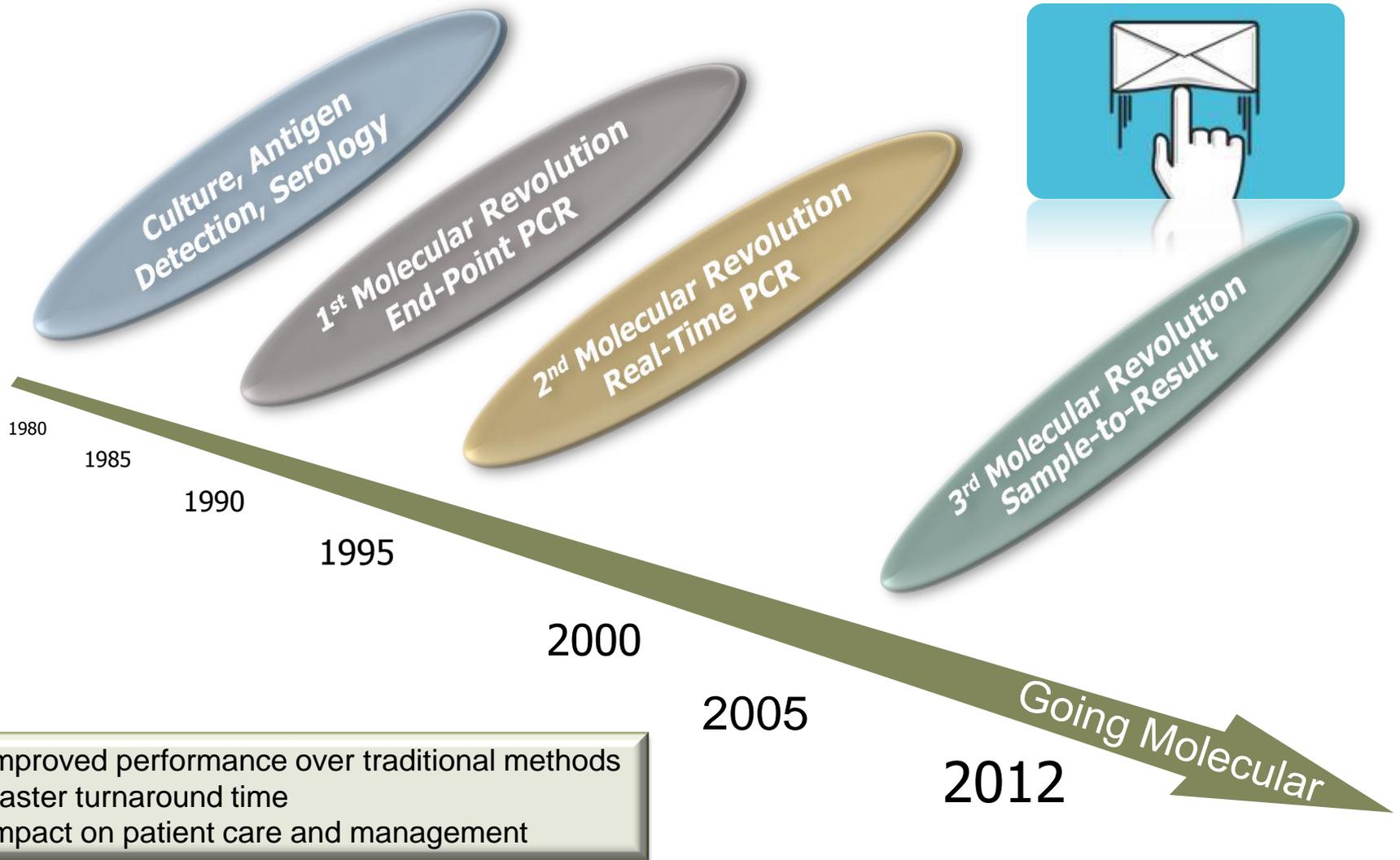


Fungi



Parasites

Molecular Diagnostic Technology Evolution



The New Era of Molecular Testing

- Our multiplex capabilities have greatly improved
- Multiple commercial platforms now licensed for U.S. and International markets
- Many targets from a single sample can be readily and simultaneously assessed
- Have great potential to:
 - Detect multiple agents from a single specimen
 - Can drive disease/syndrome-specific testing
 - Detect various genotypes/genetic variants
 - Detect agent and antimicrobial resistance genes

Value of Molecular Assays

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QUALITATIVE TESTS

- Early detection of infections
- ID new microorganisms
- Detect microbes that are:
 - Unculturable
 - Fastidious or slow-growing
 - Too dangerous to be amplified in culture
 - Nonviable or present in extremely low numbers or in small specimen volumes
- Molecular epidemiology

QUANTITATIVE TESTS

- Associate infection with disease
- Monitor efficacy of therapy
- Predict treatment failure; emergence of drug resistance
- Assess progression of disease
- Facilitate understanding of natural history and pathogenesis of organisms

Clinical Benefits of Rapid and Accurate Diagnosis



- Informing timely and effective antibiotic or antiviral therapy



- Preventing secondary spread of infection
- Shortening hospital stays



- Reducing costs of unnecessary tests

- Provide a specific diagnosis; early informed decision making
- Help manage high-risk patients (e.g., cancer, transplant, HIV, those in ICU, those with underlying co-morbidity)
- Education and clinical awareness
- Rapid outbreak ID at local, regional, national, and global levels

Today's Workshop Objectives

- Describe basic methods and instruments used for isolation and amplification of nucleic acids
- Discuss setup of molecular ID laboratory and application of best practices for QC/QA
- Compare/contrast technological advances in multiplex detection and specimen-to-result molecular platforms
- Recognize pros/cons of using molecular methods for diagnosis of infectious diseases
- Identify major applications of molecular testing in clinical microbiology and the impact on patient care and management