



MANAGING MICROBIAL RISK WITH NEW RAPID SCREENING TOOLS:

INTRODUCING EPRI™

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COMPANY OVERVIEW



Eurofins is the **global leader in biological testing** with an unrivaled reputation for unbiased analysis



200,000 reliable analytical methods for characterizing the safety, identity, purity, composition, authenticity, and origin of products



Our **diverse laboratories** navigate seamlessly through a dynamic and ever-changing global marketplace



50K+ EMPLOYEES



800+ LABORATORIES

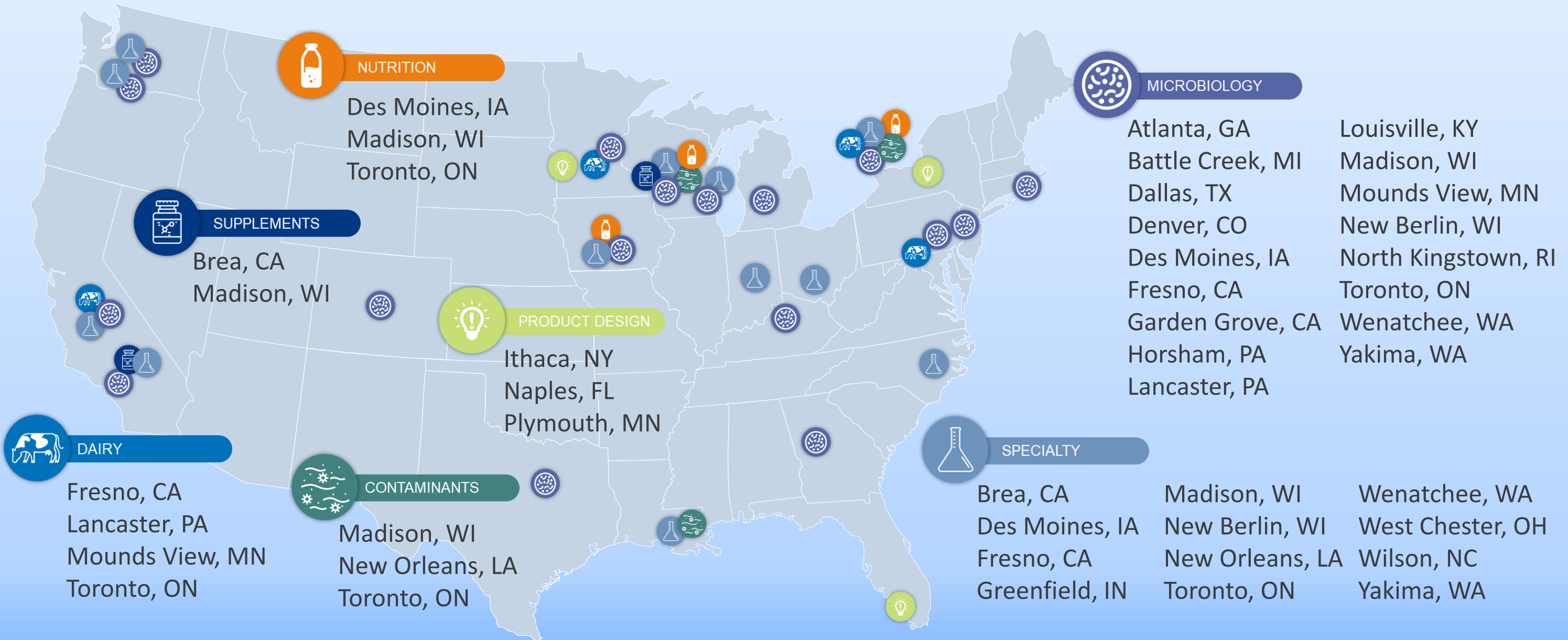


50 COUNTRIES



400M+ TESTS ANNUALLY

FOOD TESTING LABORATORIES



AGENDA

Microbial risk.

Building a testing program.

Risk screening tools.

EPRI™ Introduction.

MICROBIAL RISK

CDC estimates 1 in 6 Americans get sick from foodborne illness each year

- ***That's 48 million people***
- **128,000 are hospitalized**
- **3,000 people die**

Pathogens causing the most foodborne illnesses, hospitalizations, and deaths each year

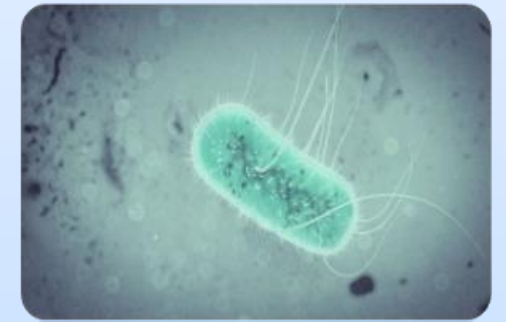
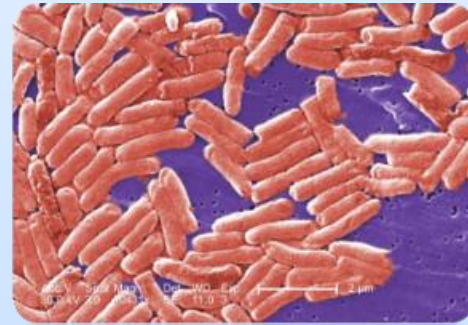
Top five pathogens contributing to domestically acquired foodborne illnesses

Pathogen	Estimated number of illnesses	90% credible interval	%
<u>Norovirus</u>	5,461,731	3,227,078–8,309,480	58
<u>Salmonella</u> , nontyphoidal	1,027,561	644,786–1,679,667	11
<u>Clostridium perfringens</u>	965,958	192,316–2,483,309	10
<u>Campylobacter spp.</u>	845,024	337,031–1,611,083	9
<u>Staphylococcus aureus</u>	241,148	72,341–529,417	3
Subtotal			91

Source: <https://www.cdc.gov/foodborneburden/2011-foodborne-estimates.html>

PATHOGENS OF CONCERN

- *Salmonella*
- *E.coli* O157:H7
- STEC
- *Campylobacter*
- *Listeria monocytogenes*
- *Staphylococcus aureus*
- *Cyclospora*
- *Norovirus* & *Hepatitis A*
- etc.



FOOD SAFETY PROFESSIONAL'S ROLE

- **Develop & manufacture products safe for consumption**
 - Account for inherent risk of a product
 - Identify introduced risk in the product
 - Manage risk in production environment (outside, or in a facility)

- **Derive Food Safety Programs that meet all:**
 - Federal regulations
 - State regulations
 - Local regulations
 - International regulations

FSMA RISK MANAGEMENT

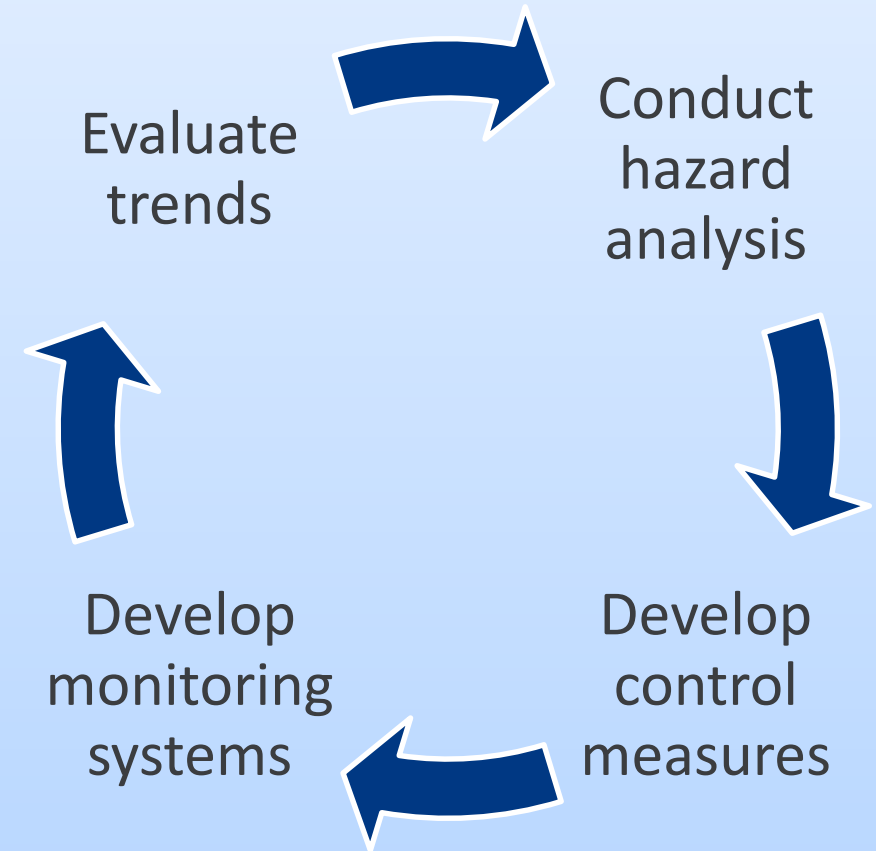
- Food Safety Plan

- **Hazard Analysis** - identify known/reasonably foreseeable biological, chemical & physical hazards
- **Preventative Controls** – must be written & implemented for any hazards identified to minimize/prevent the hazard
- **Management of preventative controls** – monitoring, corrections, corrective actions, verification
- **Supply Chain Program** - must implement a risk-based supply chain program if the hazard analysis identifies a hazard that (1) requires a preventive control and (2) the control will be applied in the facility's supply chain.
- **Recall Plan**

Source: <https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-preventive-controls-human-food>

HAZARD ANALYSIS & MANAGEMENT

- Identify Hazards & Risks associated with:
 - Supply chains
 - Ingredients
 - Processes
 - Environments
- Develop GMPs/GAPs/PCs to minimize risks & reinforce food safety culture
- Develop testing programs to identify risk, support mitigation steps, & augment management plans



BUILDING AN EFFECTIVE RISK MONITORING PROGRAM

TESTING AS A “TOOL”



Tests impart information.

Results of a test just convey info, it doesn't change anything.

Tests have limitations & can be broken.

Tests are just moments in time.

TESTING CONSIDERATIONS

“Testing is a measurement, not a mitigation”

- Role of testing is to tell us something, not control something.
- Effective testing allows us to make decisions.

WHAT'S THE PURPOSE

- **Be deliberate about your testing purpose.**
 - Surveillance, risk assessment, verification, investigation?
 - Look for the pathogen itself?
 - Monitor conditions favorable for the pathogen? (e.g. *Listeria* species testing, EB)
- **Testing doesn't make something safe, so “non-detect” testing can be of limited value.**
 - Value vs. Activity
 - Focus on finding value in your results; may mean a different approach

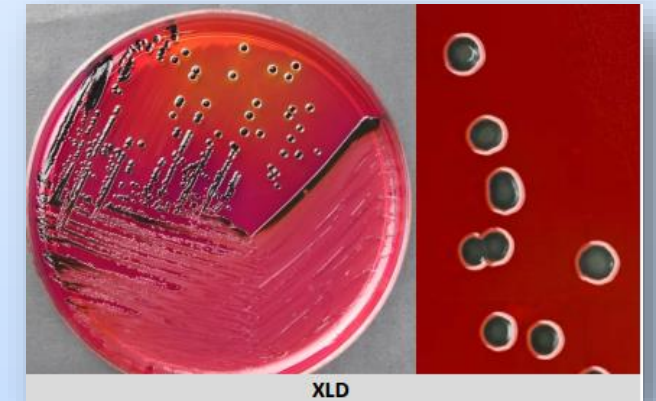
FINDING VALUE IN TESTING

- **What to test for?**
 - Direct pathogen tests
 - Indicator organisms
 - Indicators of biologic materials

- **Is your method fit for purpose?**
 - Sensitivity/Specificity
 - Reliable & Repeatable
 - Time to result
 - Output meets need & expectations
 - Price

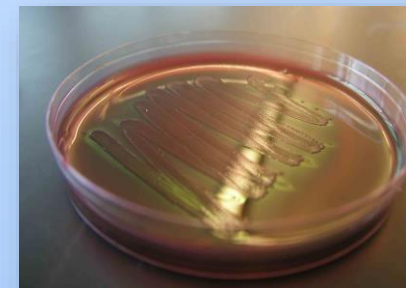
DIRECT PATHOGEN TESTING

- Pathogens can be screened for directly to monitor risk
- Pathogens are often at low prevalence
 - Means many tests may not find target, doesn't mean it isn't there
 - “Needle in Haystack” concept
- Quantitative methods based on culturing & biochemical appearances can be slow (days)
- Rapid methods offer faster testing, but can still be limited due to low prevalence
- Potential implications if a pathogen is found



INDICATOR TESTING BACKGROUND

- **Provide insight to the overall food safety or quality of a sample/product/process**
 - Highlight the potential for risk
 - Are not conclusive of a pathogen being present
 - Some indicators are tightly correlated to a pathogen, others less so
- **Indicator test use examples:**
 - Identifying trends of sanitation control
 - Assessing quality & pathogen risks of ingredients
 - Monitoring water quality, sanitation practices, etc.



INDICATOR TEST BACKGROUND

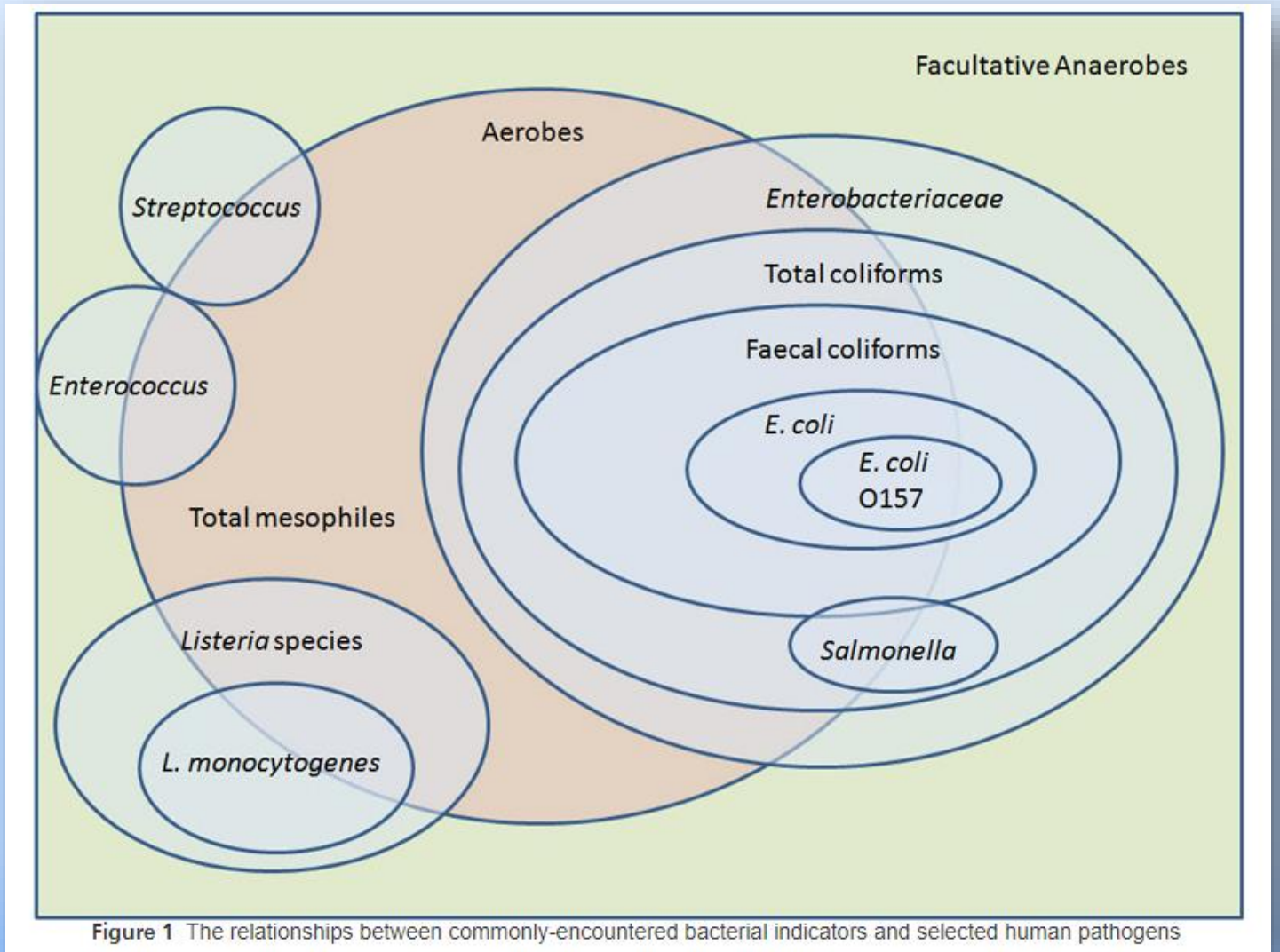
- **Indicator tests are often quantitative methods**
 - Provide information on the quantity of organisms in a sample
 - Generally, longer turnaround time than PCR/genomic based methods for pathogens
 - Indicators can be less informative of pathogen risk in certain circumstances
 - Normal microflora
 - Broad groups of organisms

Image source: <https://www.fda.gov/files/food/published/%3Ci%3ESalmonella%3C-i%3E-Flipbook.pdf>

INDICATOR EXAMPLES

Common indicator groups for the food industry:

- *Enterobacteriaceae* (EB)
- Generic *E.coli*
- Coliform
- Fecal coliform
- *Listeria* species
- Etc.



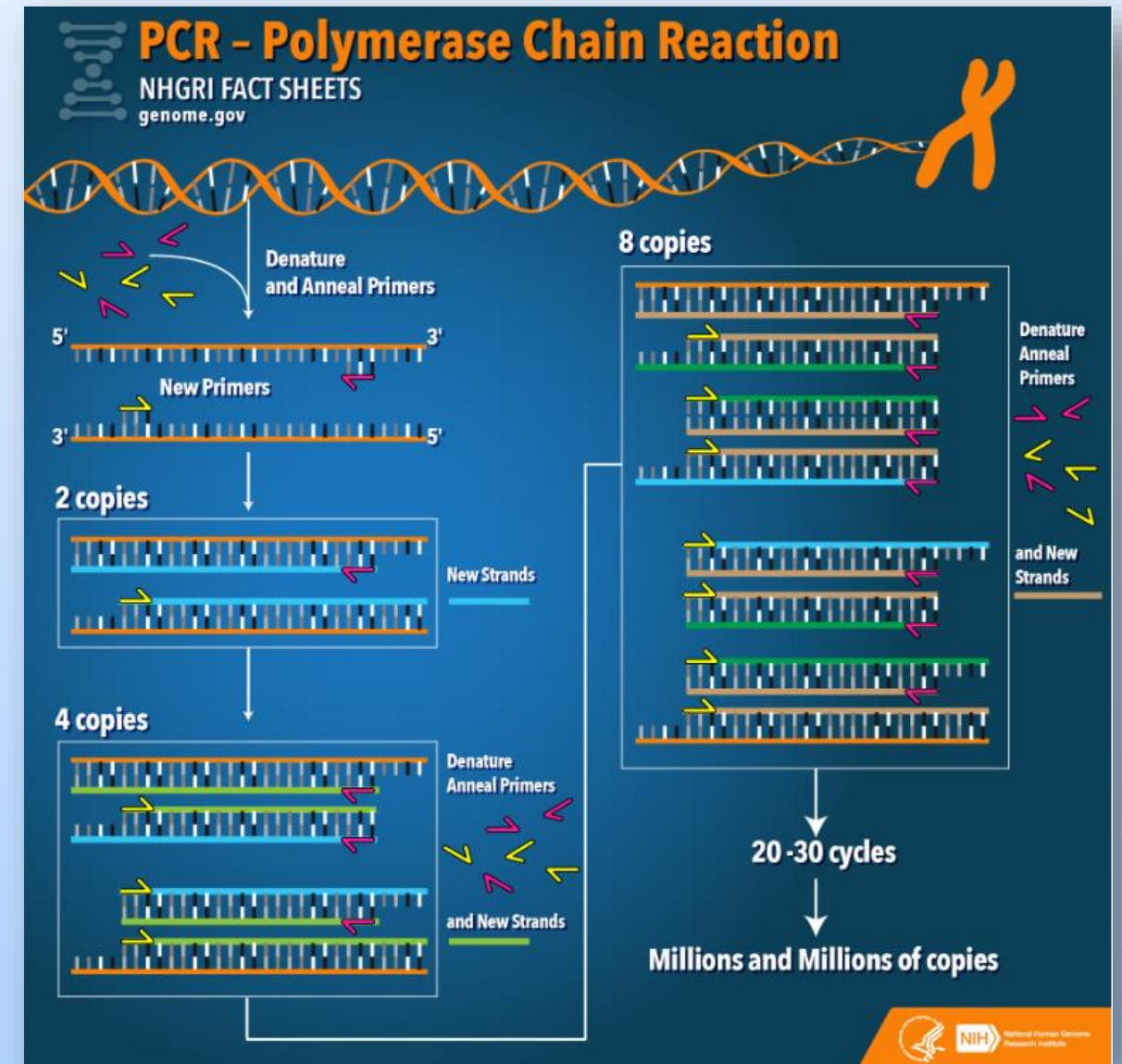
Quantitative methods vs. PCR

Quantitative Methods

- Methods designed to provide information on number of organisms present
- Based on biochemical properties to differentiate organisms
- Slower to results than many genomic methods

PCR

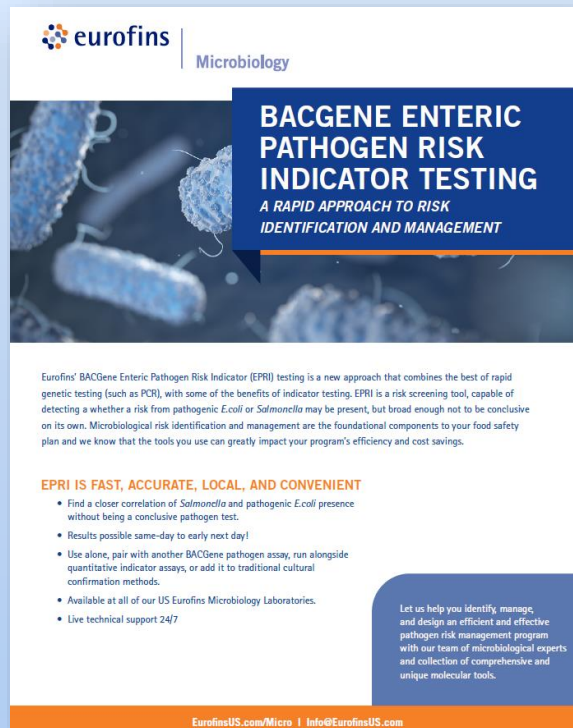
- Generally qualitative (yes/no)
- Amplification is specific for a certain gene target
- PCR is conducted following enrichment period
- Positives for PCR reactions means DNA is present



EPRI™ INTRODUCTION

Enteric Pathogen Risk Indicator (EPRI™)

- Qualitative method (presence/absence)
- **Screening*** tool for *Salmonella* & Shiga-Toxin producing *E.coli* (STEC)
- Not conclusive of a pathogen's presence
- Rapid PCR method
 - Based off of DNA for pathogens of interest
 - Includes gene targets not conclusive of pathogens
 - Rapid diagnostic tool for food companies' tool kits



*SCREENING TESTS

Screening tests are used to give insights, not necessarily conclusions

- Heart Rate & Blood pressure tests
- Blood panel tests
- Risks *may be* present, but further testing is needed to know for sure



EPRI™ VALIDATION

- Risk screening does NOT only detect pathogens
 - It has been validated to prove it will detect *Salmonella* & STEC pathogens, if present
- Validation completed by Eurofins Genescan to prove inclusivity of:
 - 120 *Salmonella enterica* strains
 - 50 STEC strains, including *E.coli* O157 & Top7 STEC
- Enrichment times of 10-24 hrs



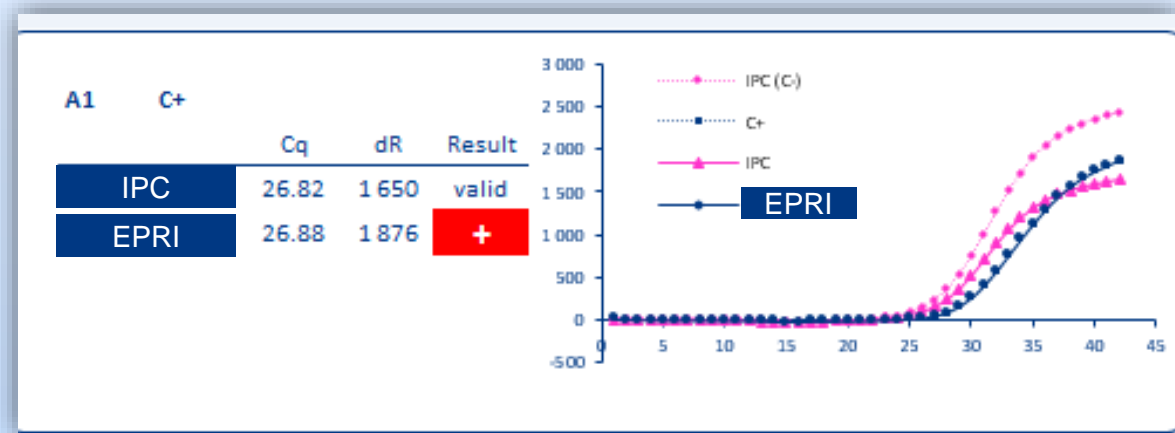
Pathogenic Risk Identification & Management

New Rapid Enteric Pathogen Risk Indicator (EPRI™) Testing



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EPRI™ REAL-TIME PCR



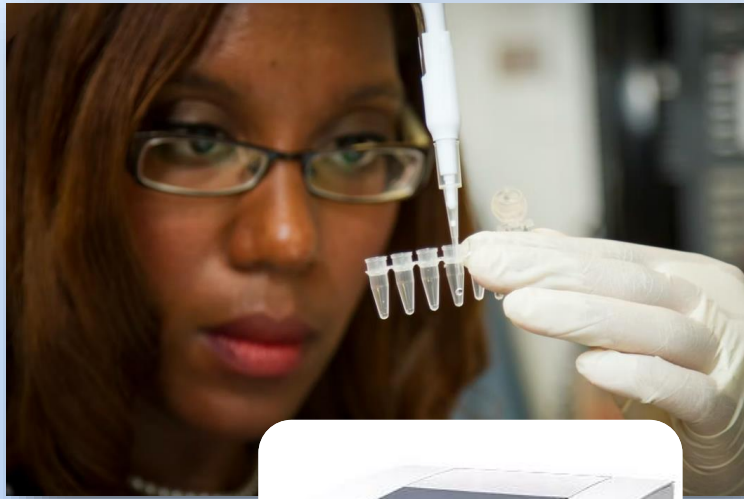
- **Real-time PCR**

- Monitors data throughout the PCR process
- Results determined by instrument analysis
- Consistency amongst labs & runs w/o human interpretation

- **EPRI detects genes from enteric pathogens & related, non-pathogenic organisms**

- **No data generated is able to differentiate signals; truly just a indicator of risk**

EPRI™ DETAILS



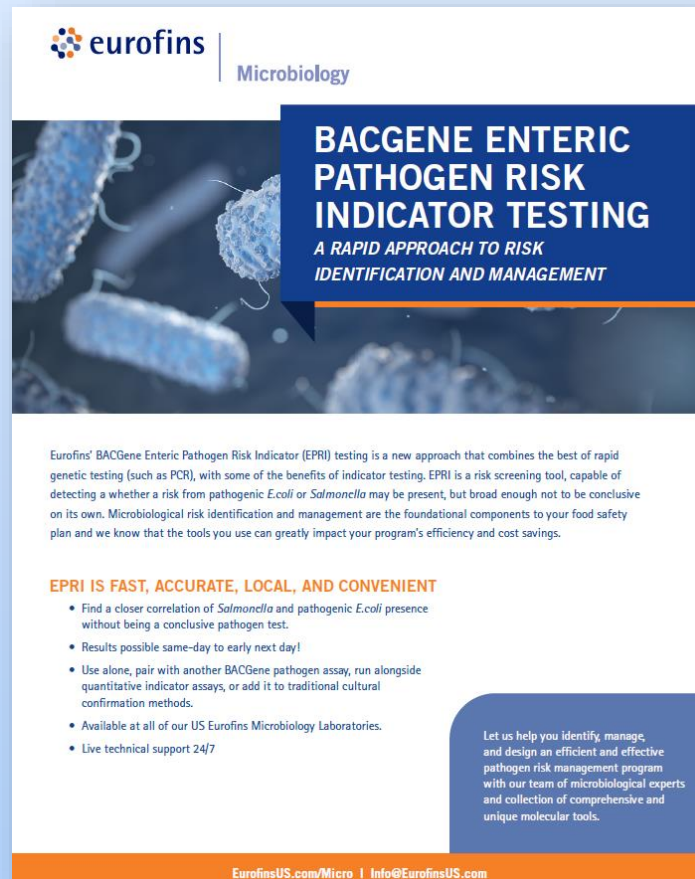
An “EPRI™ risk not detected” means:

- No gene targets are found
- Sample does not include STEC or *Salmonella*

An “EPRI™ risk detected” indicates a pathogen ***MAY BE*** present

- Gene targets are ***NOT CONCLUSIVE*** of *Salmonella* or STEC
- The assay will detect more than just STEC & *Salmonella*
- It’s a true screening test– its result alone is only a risk indicator

EPRI™ PROCESS FLOW



EPRI™ test

- Initial screening for risk
- Option to stop here with indication of risk
- Built off of AOAC & Genescan BACGene validation

Optional

AOAC Validated BACGene Sal & STEC & O157 kits

- Lysate prepared for EPRI™ can be run for pathogens of interest
- Presumptives follow regular BACGene process

Optional

FDA BAM cultural confirmation (Sal, O157)

- Gold standard if a pathogen is present, and living

EPRI™ METHOD



- Built off of existing AOAC BACGene kit methods
- You control how much you know about a risk, and when
- Detects risk of STEC and *Salmonella* in one reaction

EPRI™ – CONFIDENCE IN RESULTS

- **PREraser™ BACGene** treatment removes free DNA from samples
- Free DNA = DNA existing in a sample, but not bound within a *living* cell's membrane
- Effective tool to minimize detections from non-living organisms

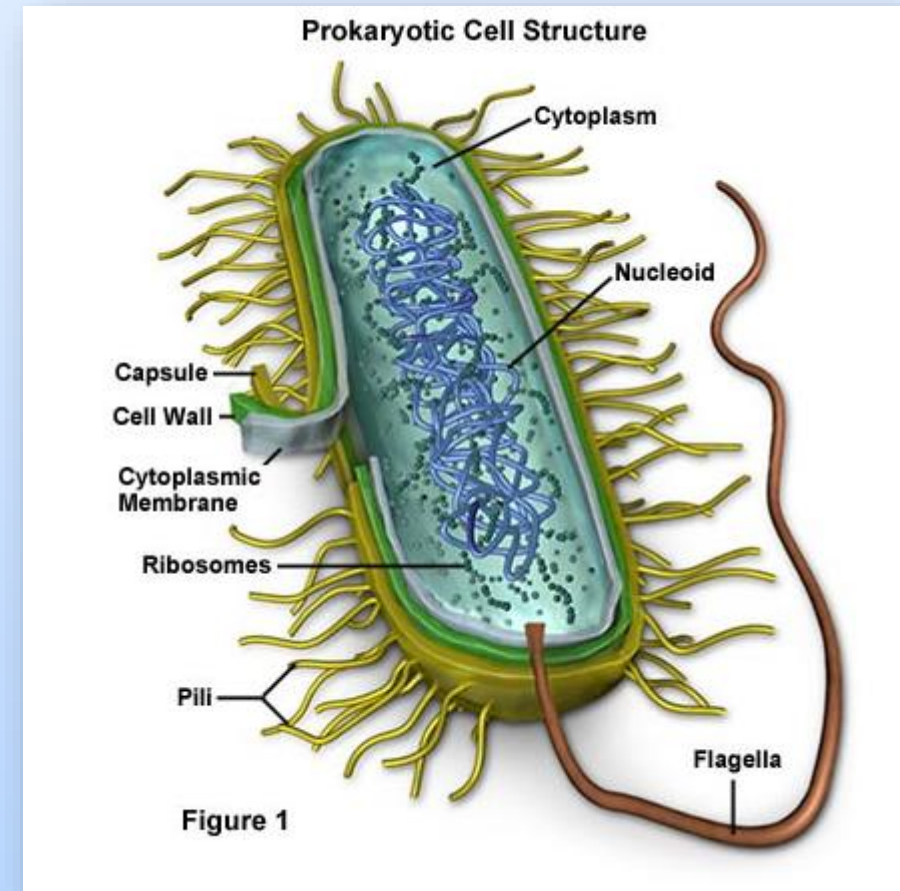
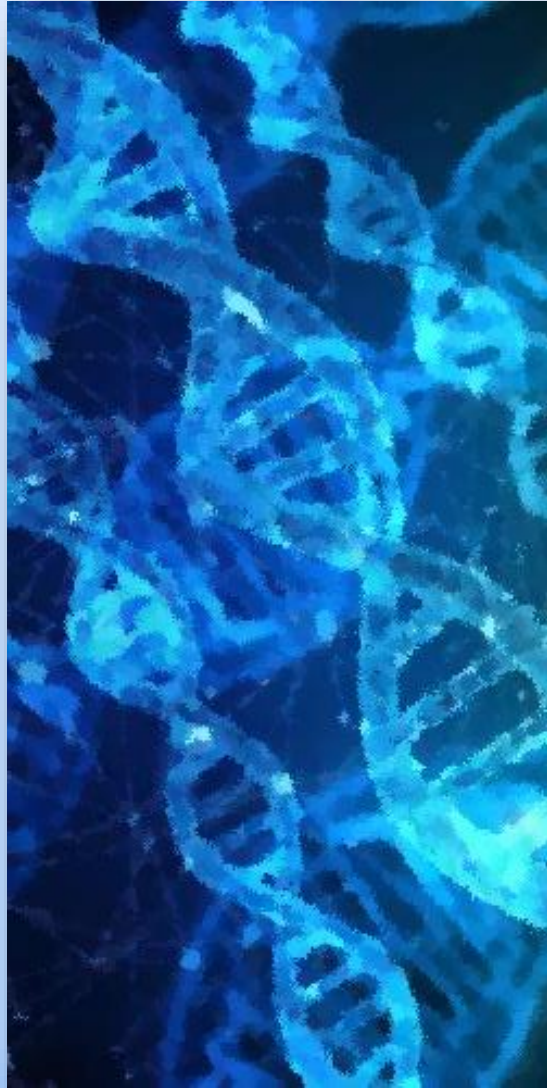


Image source:

<https://micro.magnet.fsu.edu/cells/bacteriacell.html#:~:text=Bacteria%20are%20prokaryotes%2C%20lacking%20well,flagellated%20rods%2C%20and%20filamentous%20chains.>

EPRI™ – CONFIDENCE IN RESULTS



UNG technology in every EPRI™ kit

- Uses Uracil instead of thymine in PCR reaction
 - Nucleotide (building block) for RNA vs. DNA
 - Can be interchanged with Thymine in DNA replication
- In beginning of every PCR run
 - Enzyme specifically degrades prior PCR product containing Uracil
 - Uracil will not exist in real DNA samples (DNA vs. RNA)
- ***Minimizes concerns of lab PCR contamination***

HOW TO USE THE EPRI™ TOOL?

- **Testing is a tool to:**

- Verify the efficacy of GMPs, GAPs, PCs
- Explore risks from certain items & suppliers
- Assess risks from sites, water sources, inputs, etc.
- Validate new procedures or mitigations
- Access sanitation practices & Environmental Monitoring trends

- **EPRI™ facilitates risk screening & assessment**

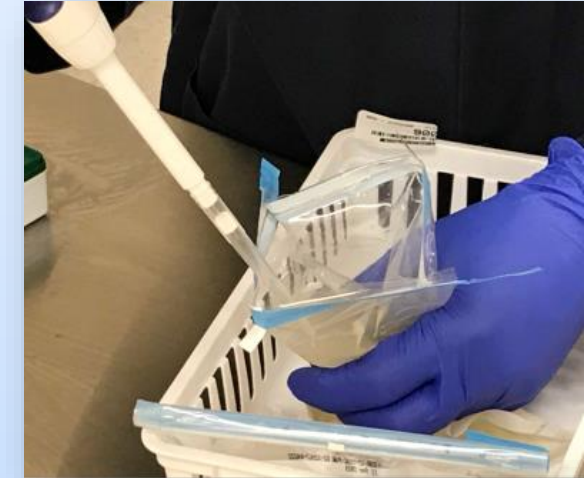
- Broader capture of risk than direct pathogen testing
- Faster & more focused testing than common indicator tests (ATP, EB, ECC)
- Initial screen can be paired with AOAC validated methods if a risk is found

EPRI™ testing is useful for:

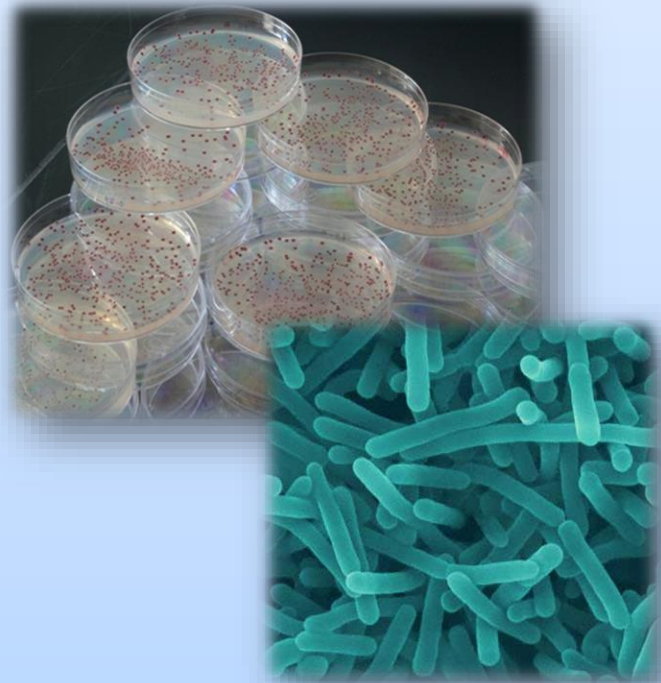
<i>Process verification studies</i>	<i>Environmental risk identification</i>
<i>Root-cause investigations</i>	<i>Supply chain risk surveillance testing</i>
<i>Environmental monitoring programs</i>	<i>Ingredient screening</i>
<i>Product risk surveillance programs</i>	

USING THE EPRI™ TOOL

- **EPRI™ can be paired with other indicator testing:**
 - *Listeria species*
 - *Enterobacteriaceae*
 - Generic *E.coli*
 - Coliform
- **Allows for Salmonella & STEC risk screening & more detailed trend analysis**
 - Facilitates indicator tool for facilities with high risk of *Salmonella* & pathogenic *E.coli*
 - Examples: dry facilities, facilities with products associated with these pathogens



EPRI™ ADVANTAGES



- **Risk screening**
 - Rapid testing
 - Control of information
 - Offers ability to do risk assessment w/ closer correlation to pathogens
- **Covers *Salmonella* & STEC risk in one reaction**
- **Allows for pathway back to an AOAC validated method within hours**

WHAT ARE YOU TRYING TO DO WITH YOUR TESTING?

- Testing is a tool to allow you to verify activities, identify risk & allow you to improve your food safety plan.
- Selecting the right tool for the activity you are trying to access
- Use your data to drive better programs
 - Reduce the risk in your supply chain
 - Allow you to visualize better the risk dynamic at various times of years
- Design your testing program with “fit for purpose”



EUROFINS IS HERE TO HELP

- **We pride ourselves in being partners for your testing & risk management needs.**
 - *“It’s our job to make your job easier”*
- **Provide data analysis tools for tracking & trending**
 - Online ordering & results viewing
 - Allow you to visualize better the risk dynamic at various times of years
- **Design your testing program with “fit for purpose”**
 - Make your testing dollars work more for you
 - Purpose is to reduce risk & control food safety for your products



THANK YOU