

BIOMÉRIEUX

# GENE-UP®

Confidence comes from results you can trust



PIONEERING DIAGNOSTICS

# Confidence comes from proven, reliable science

GENE-UP®, a real-time PCR pathogen detection system from the microbiology experts at bioMérieux. To protect your company and reputation, you need a fast, simple, and accurate method for detecting food-borne pathogens.

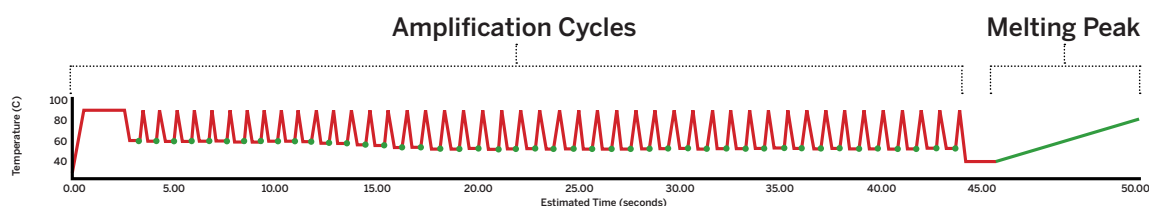
## Three Levels of Specificity:

- 1 Primers
- 2 FRET probes
- 3 Melt Peak

→ Melt Peak analysis offers an additional level of sensitivity valuable for detecting low level samples

## GENE-UP® DIFFERENTIATORS

Melt peak analysis is more sensitive than RT-PCR and is valuable for detecting low level samples. Melting temperature increases sensitivity and can also be used to differentiate between genetic variants in a species, adding another layer of specificity.



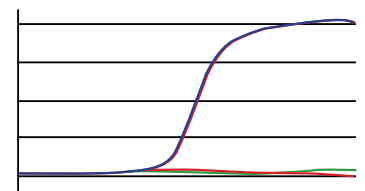
**High level of specificity** → Real-time PCR analysis coupled with endpoint melt peak analysis.

**Confidence in presumptive positives / low-level positives**

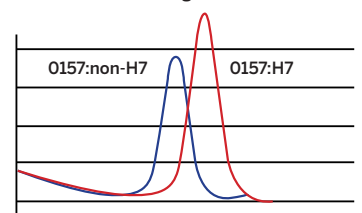
**Internal amplification control in each sample tube** → Confirms each sample works properly on platform, reducing errors from false negatives and inhibition.

**Mechanical lysis** → Less sample inhibition, reduction of indeterminate results. Ideal for PCR-challenging matrices.






Amplification Curves







Melting Peaks



# Reasons to select GENE-UP<sup>®</sup> above other PCR platforms

-  Approved and validated molecular confirmations
-  Continuous assay development and investment, keeping up with changing regulatory requirements & industry needs
-  Improved time to result
-  Real-time online instrument support and troubleshooting
-  Reduce indeterminates and low signal errors due to superior FRET chemistry and internal amplification controls

## Example of other molecular platform results:

-  Green (-) = Negative for target organism
-  Red (+) = Positive for target organism
-  Yellow (?) = Indeterminate result
-  Yellow (?) with red slash = Signal error (low signal)

## KNOW YOUR SALMONELLA

A comprehensive offering provides you risk assessment insight at every step of the production process.

- *Salmonella* spp.
- QUANT Salmonella - adopted by USDA FSIS and in MLG 4.13
  - o Protocols for both true enumeration of all levels of *Salmonella* spp. as well as 1 CFU / g breaded chicken regulatory requirement
- *Salmonella Enteritidis* / *Salmonella Typhimurium*



Pathogen  
Detection



Risk  
Assessment



Root Cause  
Investigations

# Innovation driven by collaboration

## xPRO™ CUSTOMIZATION



Our product pipelines are forged through **close partnerships** with industry leaders. Performance and project specifications are defined in partnership with clients to meet **unmet needs** in specific industries.



bioMérieux experts in our Philadelphia Predictive Diagnostics Innovation Center utilize **cutting-edge** microbiology, molecular diagnostics, whole genome sequencing, and data science to bring game changing assays to the market that ultimately **change the landscape of food safety testing.**

**With GENE-UP®, you are getting an intuitive real-time PCR solution for pathogen detection, and 60 years of microbiology leadership from a vigilant team that embraces the highest standards in microbiology safety.**

As a GENE-UP® customer you can expect:

→ **Dedicated Customer Support and expert Scientific Affairs teams**

## USDA EQUIVALENT METHOD

- USDA FSIS sets clear guidelines for how a laboratory can select a method for detection of relevant food-borne pathogens
- While FSIS provides a list of kits that have been validated, labs do not have to choose an MLG method
- List is intended to be informational and not an endorsement or approval of any specific test kit or method

\*Assuming proficient users, 1 thermocycler with 96 samples, based on E. coli O157:H7 assay, post incubation. Data on file, bioMérieux, Inc. Publication , IAFP 2020, Poster 0930.0.



**THE USDA AGREES:  
GENE-UP IS AN  
EQUIVALENT METHOD\***

GENE-UP has the lowest percentage of critical points related to time, temperature, and volume (TTV) compared to overall steps. TTV's are more prone to user, calibration, and non-traceable errors.

GENE-UP®	35% TTV
iQ-Check®	66% TTV
BAX® System	75% TTV
3M™ Molecular Detection System	92% TTV

## EFFICIENCY AND RELIABILITY WITH THE EHEC SOLUTION

Screen first with GENE-UP® Pathogenic *E. coli* (PEC) – unrivaled accuracy reduces unconfirmed positives.

→ Potentially reduces the number of false positive results

The EHEC Kit combines *stx* and *eae*, and the top 6 serogroups in one solution. And, using GENE-UP® in combination with VIDAS®, the EHEC solution provides unrivaled specificity.

## BACTIVIAB PMAxx™ - DECREASED RATE OF FALSE PRESUMPTIVES

An optional sample preparation to eliminate DNA signal from both free and dead nonviable cells, targeting only live cells for amplification and detection.

BACTIVIAB PMAxx is a photo-reactive dye that binds to DNA, separating live-cell DNA from free and dead cell DNA. This eliminates amplification and detection of DNA that does not originate from a living cell, thus reducing non-confirmed presumptive positives.

BACTIVIAB PMAxx is a superior alternative to Propidium Monoazide (PMA). PMA does not completely eliminate PCR products from dead cell DNA, potentially increasing non-confirmed presumptive positive results.

AOAC Research Institute Performance Tested Methods<sup>SM</sup> available: *Salmonella*, *Listeria* spp., *Listeria monocytogenes*, *Cronobacter*, ENVIROPRO, and Aspergillus PRO

## GENE-UP® OFFERS A PORTFOLIO OF SOLUTIONS FOR YOUR MOST PRESSING FOOD SAFETY CONCERNS

### CURRENT TEST KITS INCLUDE:

- *Salmonella* spp.
- *Cronobacter* spp.
- *Listeria* spp.
- *Listeria monocytogenes*
- *E. coli* O157:H7
- STEC-STX & EAE
- STEC-TOP 6 (O26, O45, O103, O111, O121, O145)
- Pathogenic *E. coli* (PEC)
- QUANT *Salmonella*
- *S. Enteritidis* / *S. Typhimurium*
- *Campylobacter*
- Norovirus GI
- Norovirus GII
- Norovirus GI & GII Duplex
- Hepatitis A
- Hepatitis E
- Adenovirus
- Cryptosporidium
- Enterovirus
- Giardia
- Rotavirus
- Sapovirus



## GENE-UP® ENVIROPRO™

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### Simultaneously Detect *Salmonella* and *Listeria*

GENE-UP® ENVIROPRO™ is the only assay of its kind to simultaneously detect both *Salmonella* and *Listeria* from environmental swabbing, including PCR confirmation.

It is an AOAC Performance Tested Method<sup>SM</sup> that helps provide:

- **Cost savings**
- **Laboratory waste reduction**
- **Streamlined workflow**
- **Empowering you to make rapid, effective quality decisions**

## VALIDATIONS

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- Large scope of matrices to fit most needs → 16 diverse food categories
- Multiple sample sizes to adapt easily → 15 different sample sizes (Environmentals, 1g, 10g, 25g, 30mL, 100g, 125g, 375g...)
- Extended validations to work in full confidence → various dilutions
- NPIP validations + AOAC PTM/OMA → >250 AOAC validated matrices
- Full access to bioMérieux Scientific Affairs Expertise to assist with future validations
- Updating GENE-UP® validations with PCR colony confirmation



**MICROVAL**

