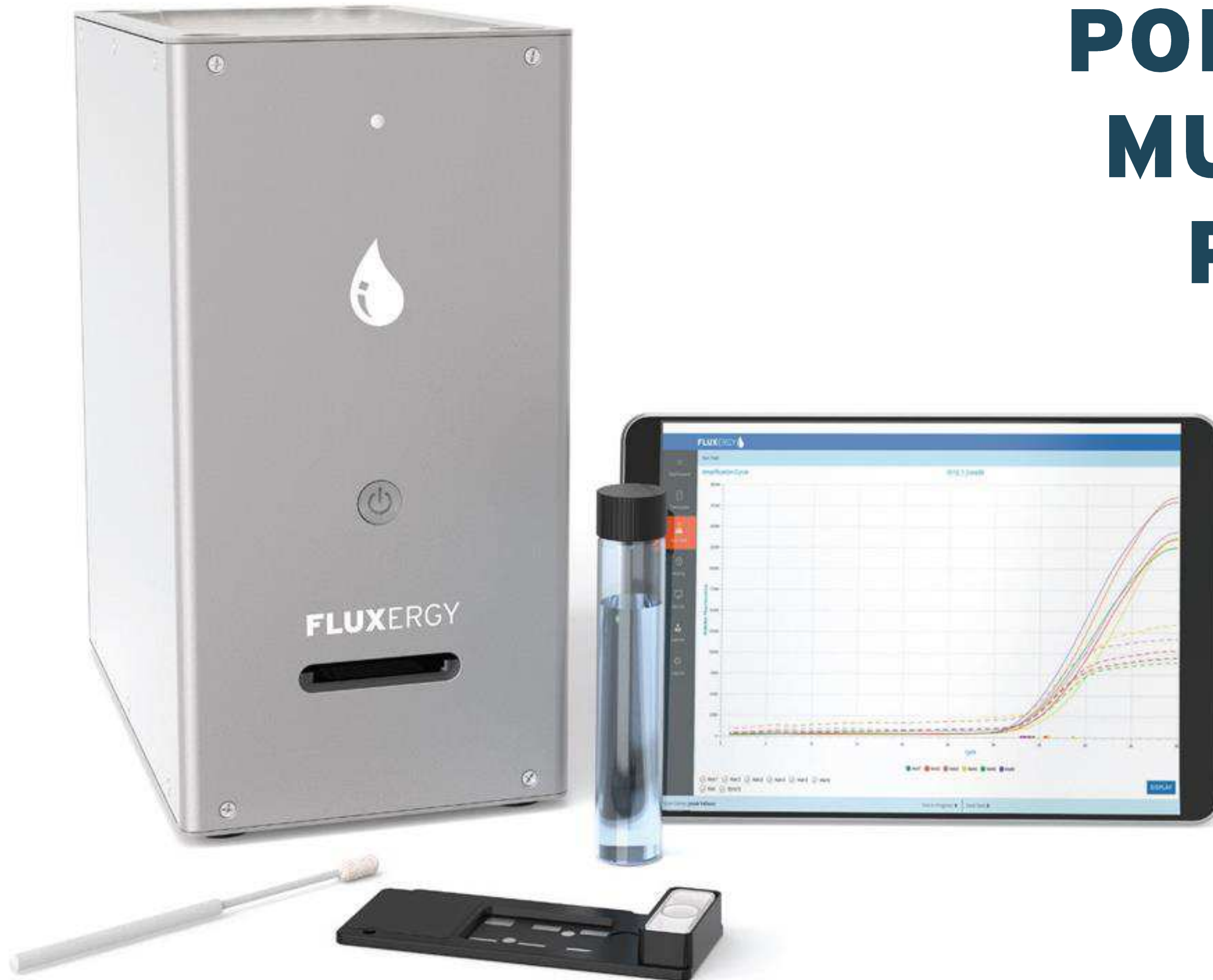


# POINT-OF-CARE MULTIMODAL & PCR TESTING

Building Better  
Biosecurity and  
Diagnostics to  
Improve Equine  
Health



**FLUXERGY** 

# REDEFINING EQUINE POINT-OF-CARE (POC) AND COMPETITION TESTING



"The first point-of-care PCR platform to be launched for equine medicine"

## Industry Activity



Confidential and Proprietary

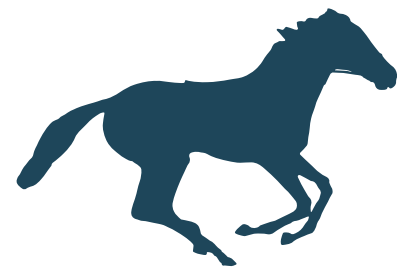


## Our POC platform simplifies PCR and more

- Built to run multiple test types and panels (Detect gene targets, proteins, cells, and chemical markers)
- Results within 15-60 minutes for any test
- Point-of-care (POC) platform simplifies workflow
- Microfluidic consumables
- Make testing consumables cost-effective with scalable manufacturing



# HURDLES IN THE EQUINE INDUSTRY



## LONG PCR WAIT TIMES

PCR results can take **3 days**, sometimes **one week**, depending on location. Logistics will always be a roadblock.



## ECONOMIC LOSS DUE TO OUTBREAKS

More than **100 outbreaks** in 2021 and 2022. Shutdowns across shows and barns result in **millions** of total **revenue loss** per week from primary stakeholders.



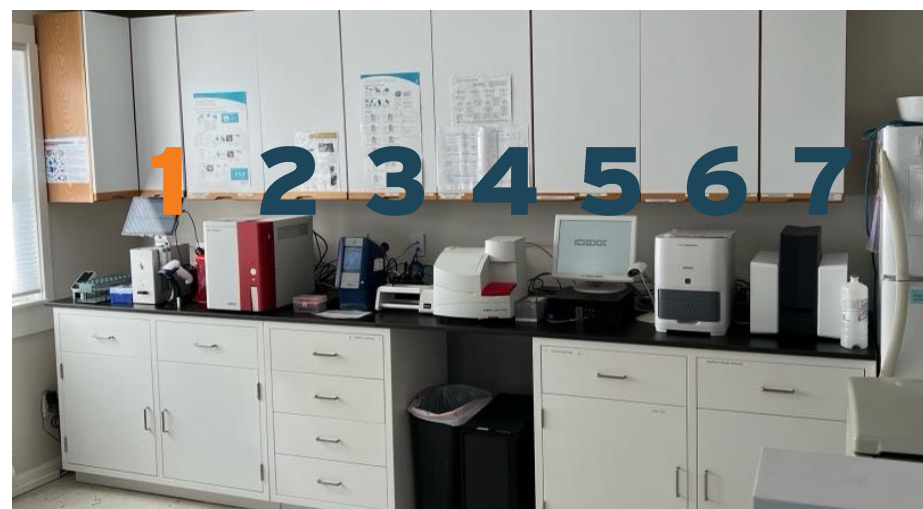
## LIMITED ON-SITE SPACE, TOO MANY DEVICES

Equine referral hospitals used an average of **6 different diagnostic systems**, limiting counter space and increasing overhead.

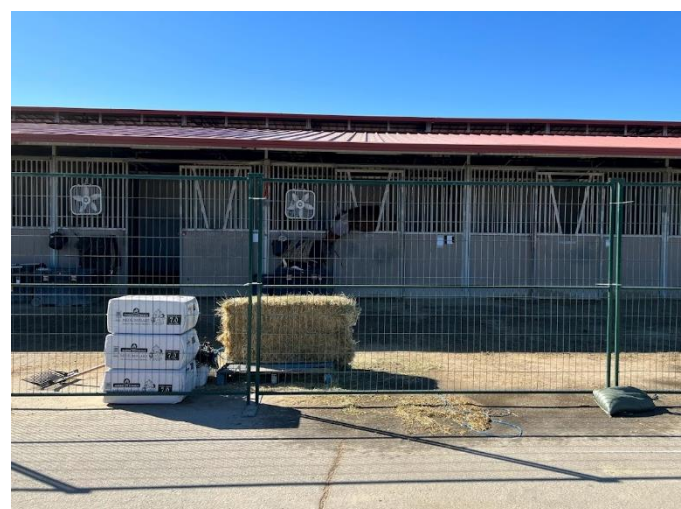


## LIMITED DIAGNOSTICS FOR MOBILE PRACTICES

**80%** of ambulatory veterinarians send out a majority of their laboratory tests.



Equine clinics are required to invest in capital equipment, maintenance, and personnel costs to operate several different instruments.



EHV-1 outbreaks have affected every state this year.  
(EDCC Disease Alerts)

## BETTER DIAGNOSTIC CARE



## RUN MULTIPLE TESTS ON ONE SYSTEM

The Fluxergy platform can read **molecular, immunochemistry, chemistry, PCR**, and **cytometry** assay types creating the capability to conduct a majority of routine and specialized laboratory tests. We aim to address:

- Biosecurity and outbreak management
- General wellness and performance
- Organ health
- Multiomic testing
- Mobile testing



# VALIDATED BY INDUSTRY LEADERS



**Dr. Nicola Pusterla, PhD, Dip  
ACVIM and AVDC-Equine**

"I've known Fluxergy for 5 years. Throughout their growth and development, Fluxergy has been unwavering in their commitment to equine. I knew this was something I wanted to support because of the effort and science they put behind it. The capability of a patient-side, reliable, sensitive, and cost-effective molecular detection instrument can be a tremendous improvement in the diagnostic field." "Having a tool where we test fever horses in an hour is a big step for our industry"



**Dr. Paul Wan DVM, Dip ACVS, CERT. VBM  
Owner at SoCal Equine Hospital**

"Fluxergy is at the forefront of diagnostic capabilities with PCR. The PCR run-time is quick and easy, which is critical for preventing environmental contamination. Education is a large part of our practice, and as we improve our care through newer technologies and diagnostics, such as Fluxergy, we are able to better educate our clients on what might be causing the problem."

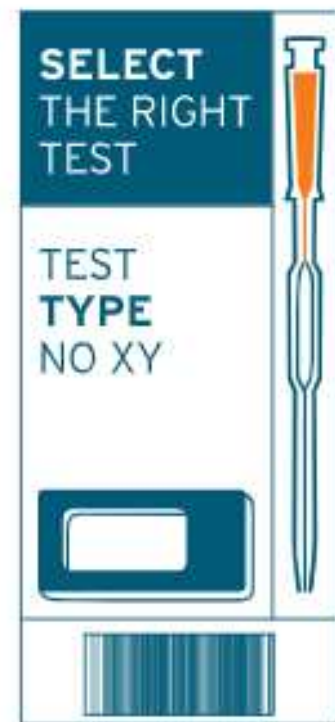


**Dr. Randolph Seidler, VMD, MBA**

"When I learned of Fluxergy's technology, I was impressed about the opportunity for a point-of-care multimodal testing platform. I am happy to be involved on Fluxergy's advisory board where I can bring my 20+ years of animal health and R&D experience. One of the big advantages of Fluxergy's technology is its quick process. When veterinarians see horses with high fevers, it's important that they can understand quickly what is going on."

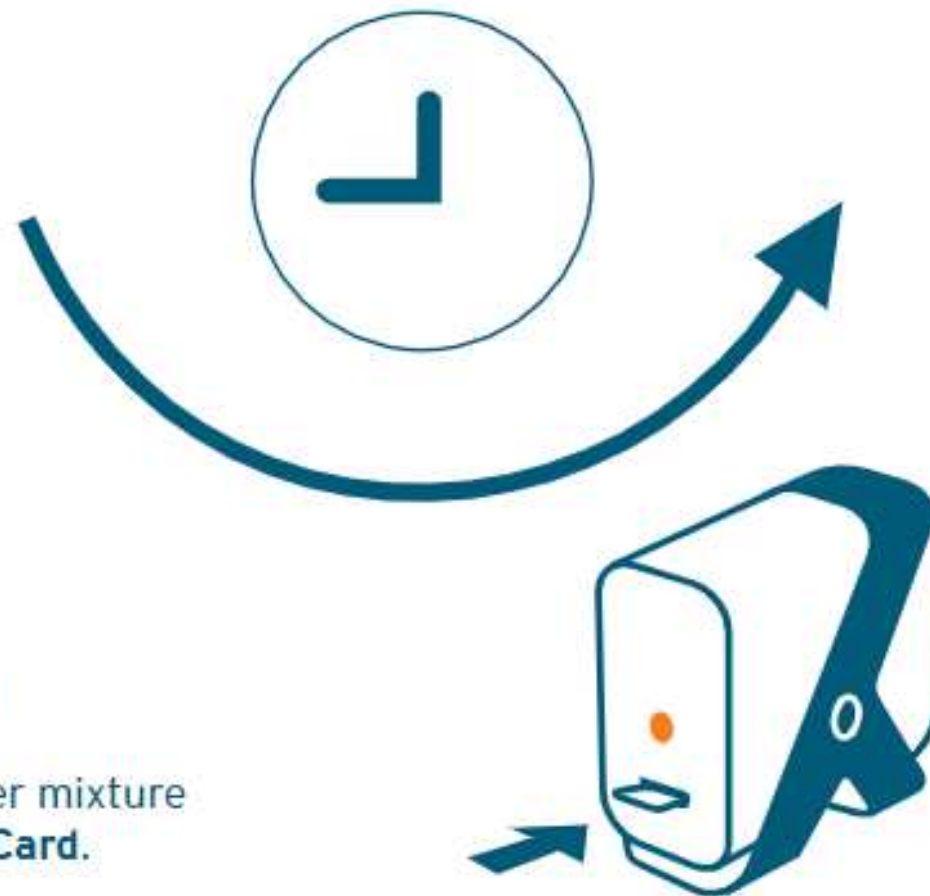
# LABORATORY TESTING SIMPLIFIED AT YOUR PRACTICE

Select a test, collect a sample and mix with supplied **FluxergyBuffer**.



Add sample and buffer mixture to selected **FluxergyCard**.

15 – 45 MIN



Insert **FluxergyCard** into the **FluxergyAnalyzer** and run the test.

Upload data, manage, store, analyze



**FluxergyWorks**

- Storage
- Services
- Big Data analytics
- Cloud connectivity



"The ability to offer PCR out of our laboratory opens up several new possibilities for our practice such as a one-hour test result time for infectious pathogens. "

**Dr. Laura H. Javiscas, VMD, Dip ACVIM**  
**Rhinebeck Equine L.L.P**

Fluxergy aims to provide simple and rapid workflows for every laboratory test to **bring the lab closer to the patient**



# WHY LOOK FOR EHV-1 (Equine Herpesvirus 1) & *Salmonella*



## BETTER RESPONSE TO OUTBREAK

High costs, loss of business & negative public perception, risk of transmission to animals & personnel



## BE AT THE FOREFRONT OF BIOSECURITY

Added security for every patient, verify performance of cleaning chemicals & procedures, clear stalls that may have had a suspect patient

## GIVE PEACE-OF-MIND TO HORSE OWNERS



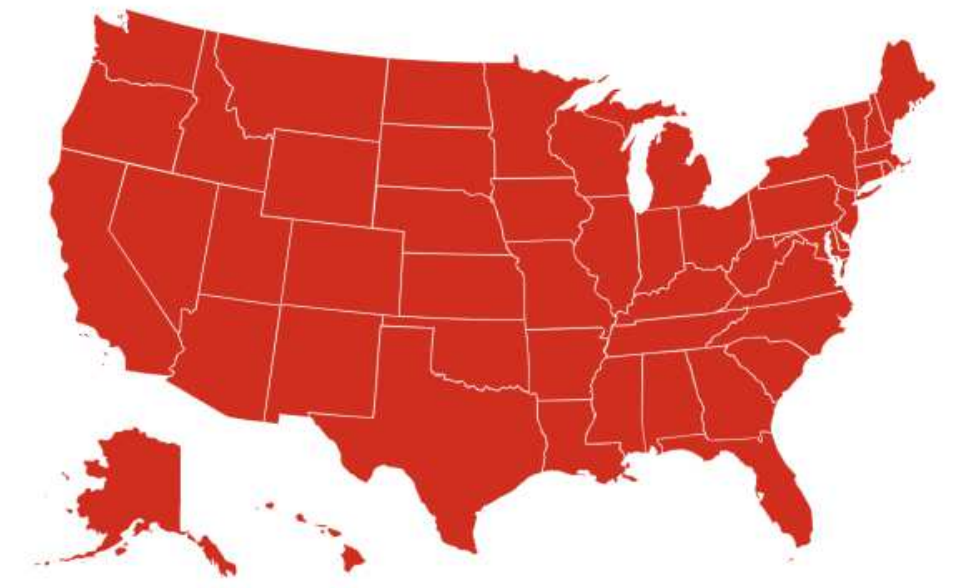
Ensure your horse is protected and reduce the spread of infectious diseases.

# THE NEED FOR ON-SITE, ACCURATE TESTING

## EHV-1 NEURO. OUTBREAKS IN 2020-2021 (PER EDCC)

Outbreaks reported to EDCC and limited to on-site show and racetrack grounds,  
excluding on-farm outbreaks post-showing:

1. Jan. 2020 - Remington Park Racetrack, Oklahoma County, OK, USA
2. May 2020 - Woodbine Racetrack - Woodbine, ON, Canada
3. February 2021 - Valencia, Spain & Europe
4. March 2021 - Laurel Park Racetrack, MD, USA
5. March 2021 - Blackwood Training Center, Woodford County, KY, USA
6. March 2021 - Pimlico Race Course, Baltimore, MD, USA
7. March 2021 - Bowie Training Center, Bowie, MD, USA
8. July 2021 - Saratoga Race Course, Saratoga, NY, USA
9. July 2021 - Sonoma and Sacramento Counties, CA, USA



EHV-1 outbreaks have affected every state this year. (EDCC Disease Alerts)

# LABORATORY TESTING FLUXERGY EHV-1 PCR WORKFLOW

1-hour results that has been validated against laboratory PCR



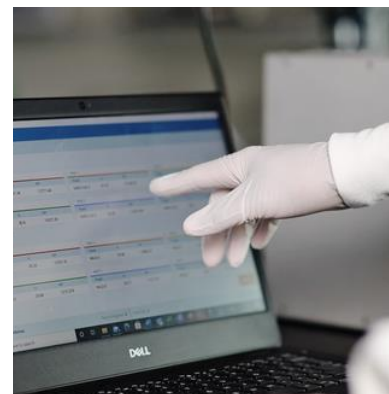
## Step 1

Place prepared sample  
into Fluxergy Card



## Step 2

Insert Card into Fluxergy  
Analyzer, run time <1 hour



## Step 3

View PCR Results in <1 Hour



**Sample-to-  
Answer**



**5 Minutes  
Hands on Time**

## Materials Provided in the Test Kit

Each Fluxergy Assay PCR EHV-1 Test Kit contains sufficient reagents and consumables.

- Fluxergy Reaction Mix EHV-1
- Fluxergy PCR Card
- Sample Collection Materials:
  - 80mm breakoff point nasopharyngeal swab
  - 3 mL of viral transport medium (VTM)



# LABORATORY TESTING ENVIRONMENTAL *SALMONELLA* PCR WORKFLOW

More reliable than conventional culture and faster than laboratory PCR



## Step 1

Swab stall or drain

## Step 2

Enrich sample overnight

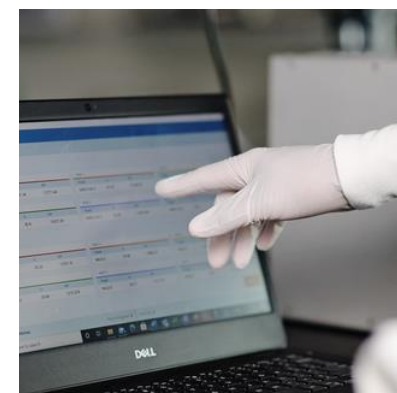
## Step 3

Place prepared sample  
into Fluxergy Card



## Step 4

Insert Card into Fluxergy  
Analyzer, run time <1 hour



## Step 5

View PCR Results in <1 Hour

## Materials Provided in the Test Kit

Each Fluxergy Assay PCR *Salmonella* Test Kit contains sufficient reagents and consumables.

- Fluxergy Reaction Mix *Salmonella*
- Fluxergy PCR Card
- Sample Collection Materials:
  - Sponge-Stick with 10mL Neutralizing Buffer
- Enrichment Media:
  - Selenite Cystine Broth

# EHV-1 & Salmonella

## Test Kit Specifications

	EHV-1	Salmonella
Sample Type	NP (polyester or nylon flocked swab) in 3mL VTM	Environmental Sponge in Selenite Broth post 16-hour enrichment
Assay Run Time	1 hour	55 minutes (post-enrichment)
Gene Targets	gB and gD	InvA
LOD	5000 cp/mL	1 CFU/mL
Sensitivity	97.5%	100%
Specificity	97.5%	100%
Validation Samples Tested	90	117
Validation Comparator	EHV-1 genesig Advanced Kit Cat #: Z-Path-EHV-1	Thermo Scientific SureTect Salmonella species PCR Assay
Instructions for Use (IFU)	<a href="#">Link to IFU</a>	<a href="#">Link to IFU</a>



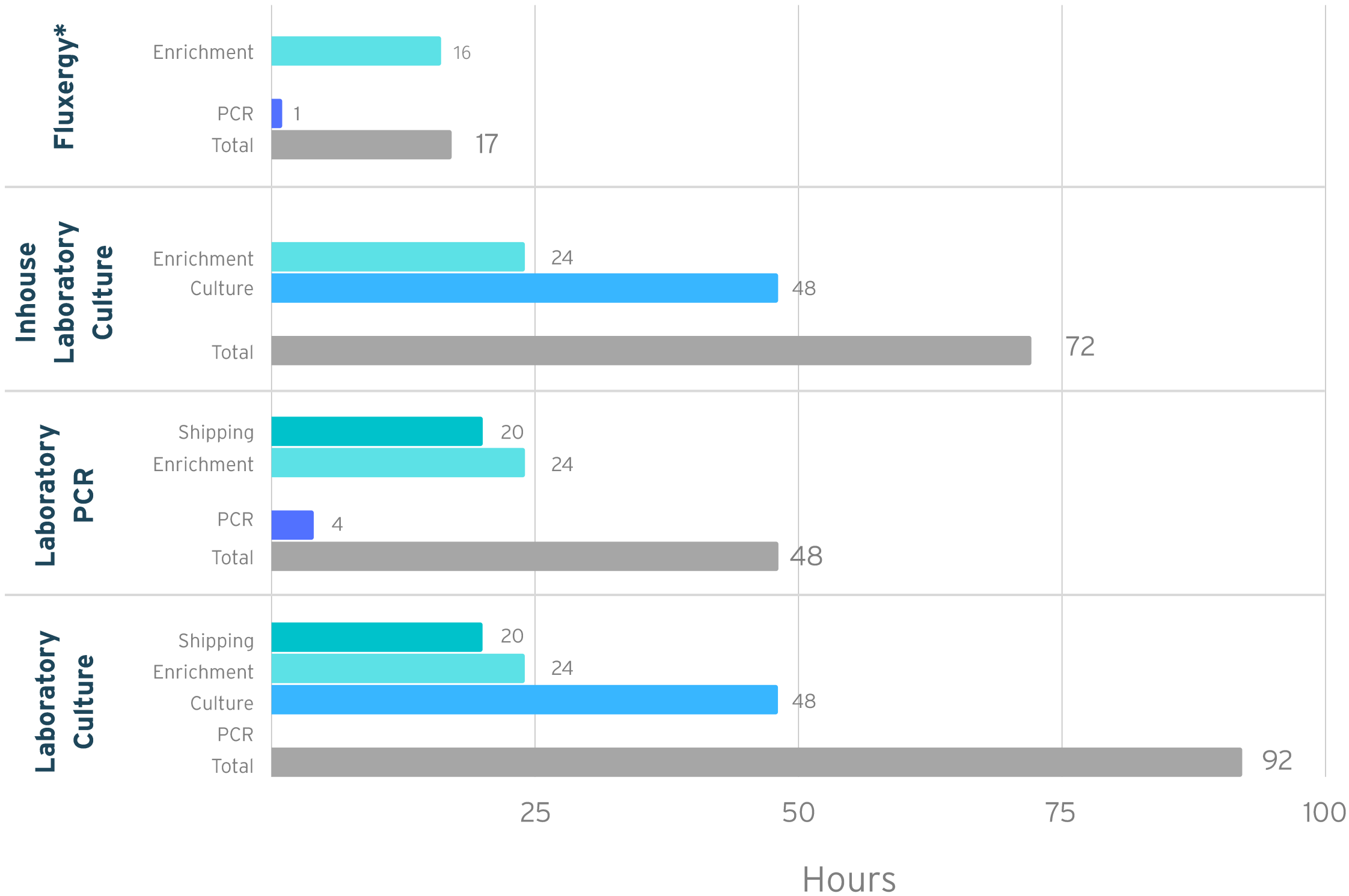
### Assay Performance Summary

\*Samples were tested within limit of detection of the platform

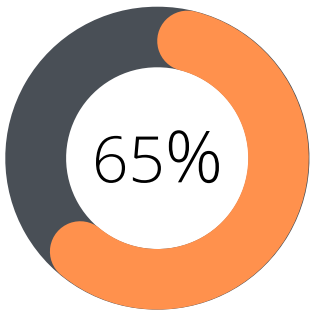
\*\* Validations were double blinded using real clinical samples. Spiked samples in clinical matrix were used when clinical samples were difficult to obtain

# CURRENT DIAGNOSTIC METHODS VS. FLUXERGY

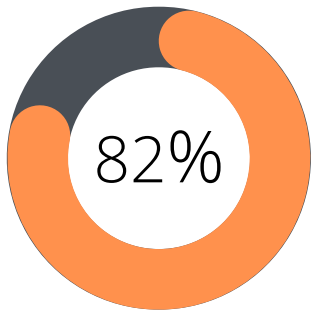
## TOTAL TIME IN HOURS



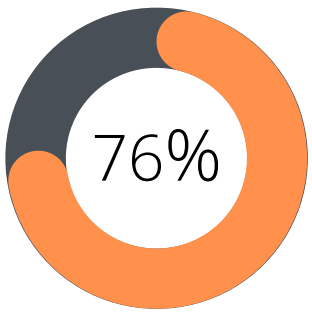
### TIME SAVED



Laboratory PCR



Laboratory Culture



Inhouse Laboratory Culture



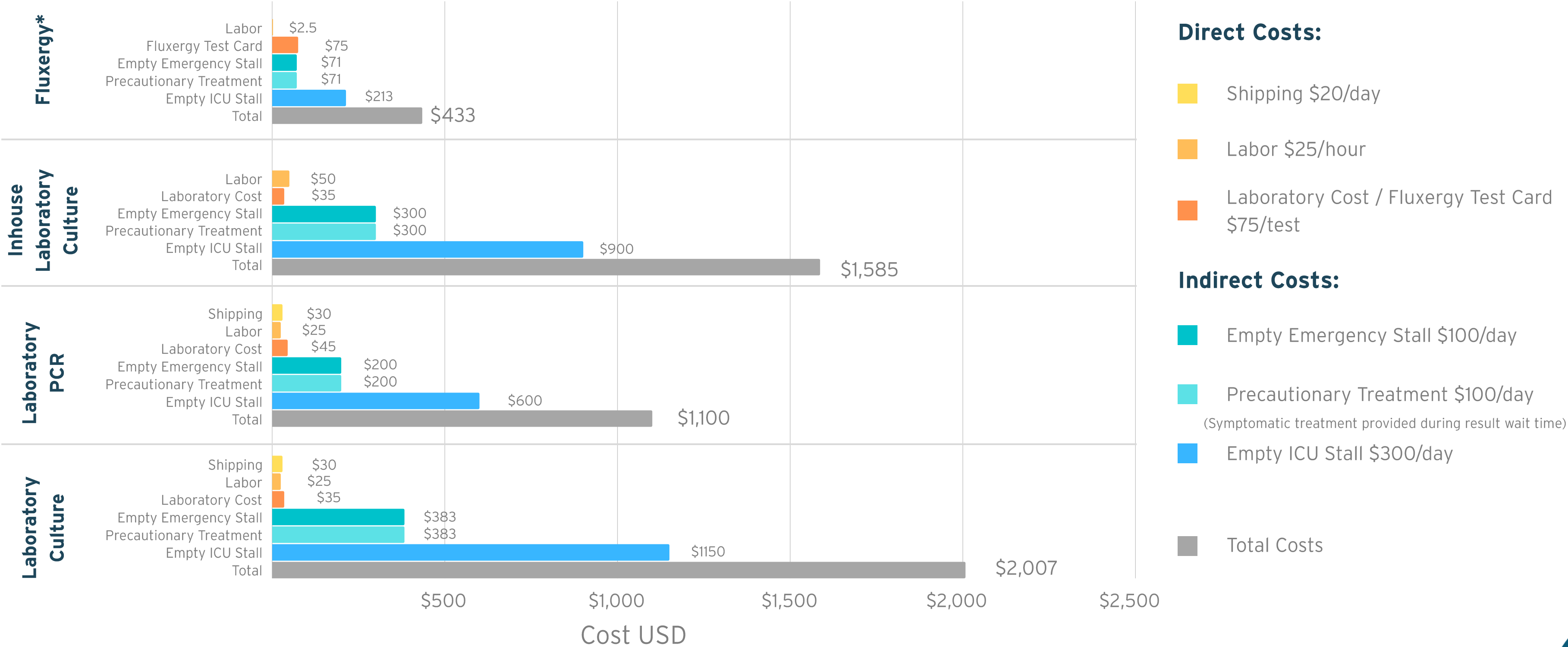
"The most exciting thing is that I can turn this around in 18 hours and feel very comfortable that my stall is clean and safe to put another horse in. Being able to get that answer quickly is beautiful."

**Dr. Ben Buchanan DVM, DACVIM, DACVECC**  
**Owner of Brazos Valley Equine Hospitals**



# CURRENT DIAGNOSTIC METHODS VS. FLUXERGY

## Total Direct and Indirect Costs x Time Per Method



# MULTIMODAL PRODUCT PIPELINE

## A TRANSFORMATIVE PORTFOLIO



PRODUCT	MODALITY	SAMPLE TYPE	AVAILABILITY
<i>Salmonella Spp.</i> Environmental	PCR	Environmental Swab	Available US/EU
Equine Herpesvirus 1 (EHV-1)	PCR	Nasal Swab	Available US RUO/EU Pending USDA Approval
<i>Streptococcus equi. Subsp. equi</i>	PCR	Nasal Swab, Guttural Pouch Lavage	Q3 2023
Equine Inflammation Panel (Saa)	Immunochemistry	Whole Blood, Plasma	In development
White Blood Cell Total Count (WBC)	Cytometry	Whole Blood	In development
Equine Respiratory Panel (EHV-1, <i>S. equi</i> <i>Ss equi</i> , EIV, EHV-4)	PCR	NP Swab	In development

# WHO WE WORK WITH IN THE EQUINE INDUSTRY

Our Fluxergy Analyzer is now located in over 30 multi-doctor equine practices and leading equine research groups in US, Canada, UK, and the EU.





# FREE TRIAL PROGRAM TO BUILD CONFIDENCE IN YOUR PLATFORM



60-day trial after in-person or virtual training



Delivery, lab equipment, installation, and support



Free PCR test kits for trial



Over \$2000 value to trial a game changing system



2022: One of the initial installations of Fluxergy's equine diagnostic platform\* and PCR tests at a referral hospital

# BIOSECURITY IS NOW FEASIBLE

## IMPROVED COST AND TURNAROUND TIME

### Article

#### Validation of a point-of-care polymerase chain reaction assay for detection of *Streptococcus equi* subspecies *equi* in rostral nasal swabs from horses with suspected strangles

Andrew T. Willis, Samantha Barnum, Nicola Pusterla

**Abstract** – This study aimed to validate a point-of-care polymerase chain reaction (PCR) assay for detection of *Streptococcus equi* subsp. *equi* (*S. equi*) in rostral nasal swabs from horses with suspected acute strangles and to compare the results against the molecular gold standard of quantitative polymerase chain reaction (qPCR). Two hundred thirty-two individual swabs of rostral nasal passages were characterized by qPCR as *S. equi* positive, *S. equi* subsp. *zooepidemicus* (*S. zooepidemicus*) positive, or *S. equi* and *S. zooepidemicus* negative. The specificity and sensitivity of the point-of-care PCR assay were 89% and 84%, respectively. The limits of detection of the qPCR assay and the point-of-care PCR analyzer were 3 and 277 *eqbE* target genes of *S. equi*, respectively. Overall agreement and short turnaround time make the point-of-care PCR assay a potential molecular diagnostic platform that will enhance the capability of equine veterinarians to timely support a diagnosis of strangles and institute proper biosecurity protocols.

**Résumé** – Validation d'une épreuve d'amplification en chaîne par la polymérase au point de service pour la détection de *Streptococcus equi* sous-espèce *equi* dans des écouvillons nasaux rostraux de chevaux suspects d'avoir la gourme. La présente étude visait à valider une épreuve d'amplification en chaîne par la polymérase (PCR) au point de service pour la détection de *Streptococcus equi* ssp. *equi* (*S. equi*) à partir d'écouvillons nasaux rostraux de chevaux suspects être atteints de gourme aiguë et de comparer les résultats à ceux de l'épreuve étalon de la réaction d'amplification en chaîne par la polymérase quantitative (qPCR). Deux cent trente-deux écouvillons individuels des voies nasales rostrales furent caractérisés par qPCR comme étant *S. equi* positif, *S. equi* ssp. *zooepidemicus* (*S. zooepidemicus*) positif ou *S. equi* et *S. zooepidemicus* négatifs. La spécificité et la sensibilité de l'épreuve PCR au point de service étaient de 89 % et 84 %, respectivement. Les limites de détection de l'épreuve par qPCR et de l'analyseur PCR au point de service étaient de 3 et 277 copies du gène cible *eqbE* de *S. equi*, respectivement. L'accord général et le court temps de réponse font du PCR au point de service une plate-forme de diagnostic moléculaire potentielle qui augmentera les capacités des vétérinaires équins à appuyer adéquatement un diagnostic de gourme et d'instituer les protocoles de biosécurité appropriés.

(Traduit par Dr Serge Messier)

Can Vet J 2021;62:51–54

#### Introduction

Strangles is a bacterial infection of the upper respiratory tract of equids, caused by *Streptococcus equi* subsp. *equi* (*S. equi*) (1). Clinical disease involves bacterial colonization of the patient's tonsils and pharynx resulting in upper respiratory catarrh and abscessation of the mandibular and retropharyn-

geal lymph nodes. The incubation period of strangles is up to 2 wk and signs will be evident within 1 to 2 d of the onset of fever. It is essential to isolate any horse with signs of strangles to prevent population outbreaks. Current diagnostic testing requires confirmation of the presence of *S. equi* detected by conventional bacterial culture and/or polymerase chain reaction

William R. Pritchard Veterinary Medical Teaching Hospital, School of Veterinary Medicine, University of California, 1 Garrod Drive, Davis, California, USA (Willis); Department of Medicine and Epidemiology, School of Veterinary Medicine, University of California, One Shields Avenue, Davis, California, USA (Barnum, Pusterla).

Address all correspondence to Dr. Nicola Pusterla; e-mail: npusterla@ucdavis.edu

None of the authors of this paper has a financial or personal relationship with other people or organizations that could inappropriately



**Dr. Nicola Pusterla, PhD, Dip ACVIM  
and AVDC-Equine, Professor,  
University of California Davis**

“ Is testing worth it even if only 1-5% cases will be positive? Absolutely, as shutting down your hospital and dealing with the negative financial, health, and PR related consequences from patient acquired nosocomial infection are worth avoiding.”



**Dr. Lucjan Witkowski, DVM, PhD, Professor,  
Epidemiology and Economics,  
Warsaw University of Life Sciences**

"Fluxergy's technology has a great potential to start a new era in the diagnostic field. Fluxergy's portable, user-friendly, and cost-effective PCR technology provides highly accurate results in less than an hour, which is needed to control the spread of infectious diseases."

**Validation of a point-of-care polymerase chain reaction assay  
for detection of *Streptococcus equi* subspecies *equi* in rostral  
nasal swabs from horses with suspected strangles**

Andrew T. Willis, Samantha Barnum, Nicola Pusterla



# FLUXERGY IS A DATA-DRIVEN TECHNOLOGY PROVIDER

## Multimodal Diagnostic Technology

Multiple Tests. Same Card. Same Time



Molecular  
Immunochemistry  
Chemistry  
Cytometry

## Certified Manufacturing



13485 : 2016



## Dedicated to Quality

**Fluxergy is a developing platform with multimodal detection technologies allowing for many laboratory tests to be run on a single card and analyzer**

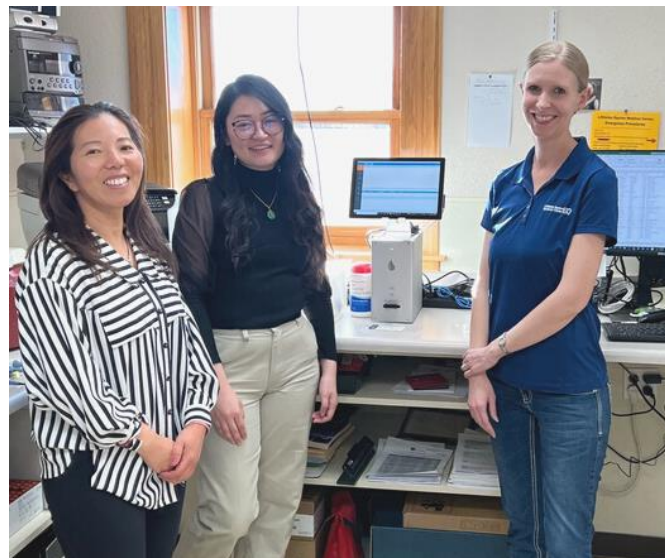
- Quality, real-time data collection, and end-to-end product traceability are core values that Fluxergy employs with its connected QMS, ERP, and shop-floor systems
- Fluxergy has grown to 100+ employees who share the common goal of providing accessible and affordable diagnostics technology
- Our state-of-the-art 70,000 SqFt manufacturing facility is currently producing 100,000 test kits per month with the ability to scale production up to 1,000,000 test kits per month



# SOLVING PROBLEMS WITH DATA: RESEARCH TO TRANSLATION



Conducting an EHV-1 study and implementing a surveillance program at a horse show



Fluxergy team installing at a referral equine practice



## Eric Mendonsa

Business Development | USA  
Background: Bioengineer, Fluxergy Principal

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## Lori Ackerman

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# INNOVATE WITH US