

# INSTRUCTIONS FOR USE

## FLUXERGY TEST KIT EHV-1

**REF** 7995 / 8008

For Use with the Fluxergy Analyzer CAT # 5506-NHU



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# 1. Intended Use

Fluxergy Assay PCR EHV-1 Test is a real-time polymerase chain reaction (RT-PCR) test. The EHV-1 primer and probe set are designed for the specific detection of equine herpesvirus 1 DNA in nasopharyngeal swab samples from horses with signs or symptoms of respiratory disease.

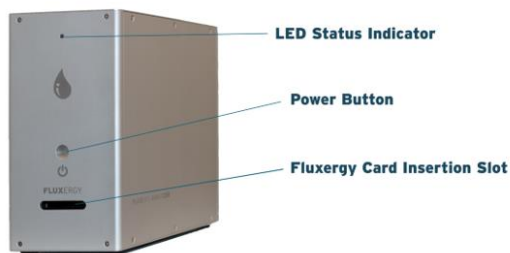
# 2. Explanation of the Test

The Fluxergy Assay PCR EHV-1 Test is a qualitative real-time reverse polymerase chain reaction (RT-PCR) test. The EHV-1 primer and probe sets are designed to detect DNA from EHV-1 in nasopharyngeal swab samples (NPS) from horses with signs and symptoms of respiratory disease. The test performance is monitored by a standardized internal control and provides results within 1 hour from when the test is initiated with a suspected sample.

# 3. Principles of the Procedure

## 3.1 Overview

The Fluxergy Assay PCR EHV-1 Test enables processing, amplification, and detection of EHV-1 DNA from infected nasopharyngeal swab samples. The assay consists of one Fluxergy Reaction Mix EHV-1 and one Fluxergy PCR Card. The assay is performed on the Fluxergy Analyzer instrument which is controlled by an external computer equipped with Fluxergy Works Software.



## 3.2 Fluxergy PCR Card

The Fluxergy PCR Card is a disposable card into which the PCR reagents mixed with test samples are manually pipetted. Each card contains a single sample/reagent input well and microfluidic channels that control the flow of liquid, and reaction wells. The Fluxergy PCR Card is self-contained to prevent cross-contamination between samples.

In the Fluxergy Assay PCR EHV-1 Test, fluorescent probes are used together with corresponding forward and reverse primers to amplify EHV-1 and exogenous internal control. Two well-conserved regions of the EHV-1 genome are targeted to identify EHV-1 DNA in the specimen. Internal control is used to detect PCR failure and/or inhibition in addition to monitoring adequate sample processing.

## 3.3 Fluxergy Analyzer

The Fluxergy Analyzer instrument is a real-time PCR (RT-PCR) thermocycler used for the identification of nucleic acid from biological specimens. The Fluxergy Analyzer performs amplification, detection, and analysis of fluorescent signals generated during PCR.

## 3.4 Process

In the Fluxergy Assay PCR EHV-1 Test, a NPS sample collected in viral transport media is mixed with ready-to-use Fluxergy Reaction Mix EHV-1 to prepare the complete test master mix. The master mix is then loaded onto the Fluxergy PCR Card. After loading the Fluxergy PCR Card into the Fluxergy Analyzer instrument, the test run is initiated. In approximately 1 hour, Fluxergy Works will complete the thermal cycling and analysis.

### 3.5 Primer and Probe Sets

Identification of the EHV-1 virus occurs using target specific primers and fluorescent-labeled probes that hybridize to the specific and conserved regions of the EHV-1 virus genome.

## 4. Reagents and Instruments



The Fluxergy Assay PCR EHV-1 Test is to be used with the following instrument, reagents, and supplies:

### 4.1 Materials Provided

The Fluxergy Assay PCR EHV-1 Test (single pack) contains sufficient reagents and consumables to test a single specimen or quality control sample. The Fluxergy Assay PCR EHV-1 Test contains the following and is available in packs of 10 (CAT #7080) or 100 (CAT #7075):

- Fluxergy Reaction Mix EHV-1
- Fluxergy PCR Card
- Sample Collection Materials:
  - Fisher Scientific Puritan HydraFlock Sterile Revised Ultrafine Flock Swab with 80mm breakoff point (catalog no. 22-029-698).
  - Microbrush Medical nylon 80mm breakoff point nasopharyngeal swab (part no. 292496).
  - 3 mL of viral transport medium (VTM): Puritan UniTranz-RT SKU #UT-300, or equivalent.

#### 4.1.1 Storage and Handling

- Store the Fluxergy PCR Card at 10 – 30°C 
- Do not open individual Fluxergy PCR Card packaging until you are ready to test
- Store the Fluxergy Reaction Mix EHV-1 at -30 to -10°C 
- Do not thaw or open Fluxergy Reaction Mix EHV-1 reagent until you are ready to test
- Freeze thaws of Fluxergy Reaction Mix EHV-1 will interfere with test results

### 4.2 Materials Required but Not Provided

- Fluxergy Analyzer (CAT #5506-NHU) sold separately.
- Barcode scanner
  - Light Source: 650 – 670nm
  - Scanner Type: Bi-directional
  - Host System Interfaces: USB
  - Indicators: LED & Buzzer
  - Supported Barcode Formats (minimum requirement):
    - 2D: Data Matrix, GS1 Data Matrix
  - Stand with hands-free operation capability.
- Laptop to install Fluxergy Works software.
  - Laptop Computer recommended requirements
    - Operating System, 64-bit
    - Windows 10 v1151 with Intel Core i5 2.5GHz processor or equivalent
    - RAM: 8GB DDR4
    - HDD: 250GB
    - Screen: 1080p
    - USB: 2x2.0 port (for scanner and mouse)
    - Networking: Ethernet port
- Minivortexer, FisherBrand Part Number 14-955-151 or equivalent
- Microcentrifuge, FisherBrand. Part Number 12-006-902 or equivalent
- Micropipettes (50 µL and 200 µL) and associated pipette tips
- -20° C manual defrost freezer
- Instructions and Documents
  - Instructions for Use, SDS, and additional resource documents can be found at [www.fluxergy.com/downloads](http://www.fluxergy.com/downloads)

## 5. Warnings and Precautions

### 5.1 General

- Positive results are indicative of the presence of EHV-1 DNA.
- Ensure that you save your sample in case follow up testing is needed.
- Authorized for use only with the equipment, materials, and supplies indicated in Section 4. Use with equipment, materials, and supplies other than those indicated above in Section 4 may cause errors and erroneous results.
- All biological specimens, including used Fluxergy PCR Cards, used sample collection materials, used sample transfer materials, and used reagents, should be handled as if infectious, using good laboratory procedures as outlined by your local or national authorities, for example: [Biosafety in Microbiological and Biomedical Laboratories – 6th Edition \(cdc.gov\)](#)<sup>1</sup> or [Laboratory Biosafety Manual – 4th Edition \(WHO\)](#)<sup>2</sup>.
- Follow safety procedures set by your institution for working with chemicals and handling biological specimens.
- Bleach introduced into a sample may damage DNA in that sample, which may lead to an erroneous result.
- Wear appropriate Personal Protective Equipment (PPE), including (but not limited to) disposable clean powder-free gloves. Protect skin, eyes, and mucous membranes. Change gloves often when handling equipment, reagents, or samples.<sup>3</sup>
- This product may contain components or chemicals that may cause cancer if ingested.
- Dispose of materials used in this assay, including reagents, samples, and used buffer tubes, according to local regulations.



### 5.2 Test/Reagent

- The Fluxergy Assay PCR EHV-1 Test is not compatible with cotton swabs. Residue found in cotton-tipped and calciumalginate swabs can inhibit PCR assays; therefore, these types of swabs should not be used.
- The Fluxergy Assay PCR EHV-1 Test including Fluxergy PCR Card and Fluxergy Reaction Mix EHV-1 are only compatible and for use only with the Fluxergy Analyzer.
- Do not handle samples or Fluxergy PCR Card in a biosafety cabinet which is used for EHV-1 culture or immunofluorescence testing.
- Do not use a test kit or components that are damaged.
- Each single-use Fluxergy PCR Card and single-use Fluxergy Reaction Mix are used to process one sample. Do not reuse processed Fluxergy PCR Card and Fluxergy Reaction Mix.
- Each pipette tip is used to transfer one sample.
- Do not reuse pipette tips for separate pipetting steps.
- Prior to processing samples, thoroughly clean both the work area with a suitable cleaner such as freshly prepared 10% bleach or a similar disinfectant.
- Fluxergy Reaction Mix, Fluxergy PCR Card, and samples should be handled and tested one-at-a-time.
- Always change gloves and clean the work area between using each Fluxergy PCR Card and Fluxergy Reaction Mix.
- Use clean gloves to remove materials from bulk packaging and reseal bulk-packaging when not in use (e.g. Fluxergy PCR Card bulk packaging).
- **Always check the expiration date on the Fluxergy PCR Cards and Fluxergy Reaction Mixes. Do not use kit components after the expiration date.**

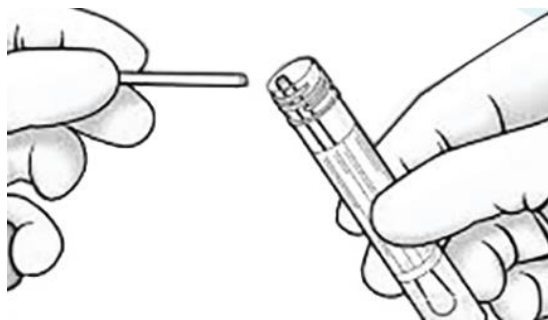


## 6. Sample Requirements

### 6.1 Sample Collection

Improperly collected, transported, or handled samples risk the potential for false positive, false negative or erroneous results. The detection of viral nucleic acid is dependent upon proper sample collection, handling, transportation, storage, and preparation. Follow instructions below to swab and collect equine sample:

1. Obtain swab from each nostril of a horse
2. Place the tip of the swab into the Fluxergy VTM tube provided and break the shaft at the red breakpoint



3. Close the tube

### 6.2 Transport and Storage

Samples should be processed and tested with the Fluxergy Assay PCR EHV-1 Test immediately after sample collection.

\* **Note:** Performance is not guaranteed if samples are not tested immediately. Extended heat and fluctuation of temperature will degrade sample and affect detection of nucleic acid.

## 7. Test Procedure

### 7.1 Setting up a Fluxergy Analyzer

Refer to the Fluxergy Analyzer IFU <sup>4</sup> for how to:

- Setup a Fluxergy Analyzer
- Manage devices on Fluxergy Works software
- When using multiple Fluxergy Analyzers, ensure that each device is labeled and uniquely named.
  - The Fluxergy Analyzer will not uniquely flash or prompt to identify itself.
- Add users on Fluxergy Works software

Prior to running a Fluxergy Assay PCR EHV-1 Test, make sure the Fluxergy Analyzer is on and connected to the Fluxergy Works software.

### 7.2 Test Features

Fluxergy Assay PCR EHV-1 Test Features	
Sample	Polyester or nylon-flocked nasopharyngeal swab (NPS) collected in 3 mL of viral transport medium (VTM)**
Reaction Mix Volume	98 $\mu$ L
Sample Volume	42 $\mu$ L
Test Card Loading Volume (Reaction Mix + Sample)	130 $\mu$ L
Duration of Test	Approximately 1 hour

### 7.3 Sample Collection

1. Refer to section 6.1 for patient sample collection.
2. **Do not discard sample after use in case follow-up testing is needed.**

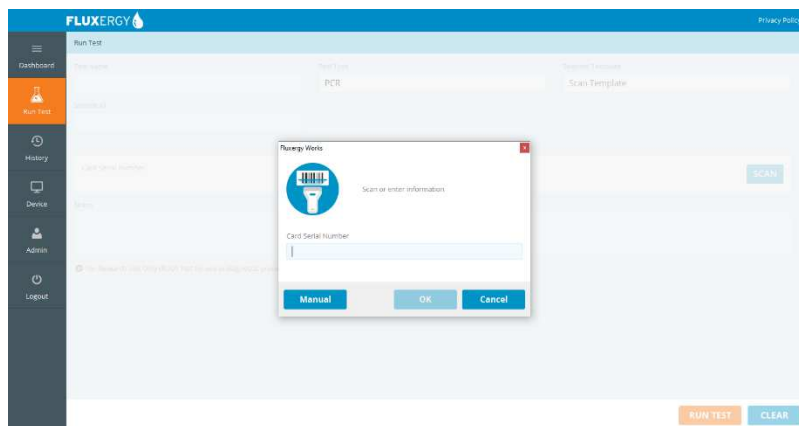
#### **IMPORTANT:**

- **Vortex the sample/VTM tube for 90 seconds. (Do not centrifuge the sample/VTM mix).**
- **Thaw Fluxergy Reaction Mix EHV-1 at room temperature before use (5-10 min). Ensure that the ReactionMix is completely thawed and use immediately. (Do not vortex the Reaction Mixes).**
- **Start the test within 4 minutes of adding the sample to the Fluxergy PCR Card.**

### 7.4 Set Up and Run Your Test on Fluxergy Works Software



1. Open Fluxergy Works on the laptop and log in using your user ID and password.

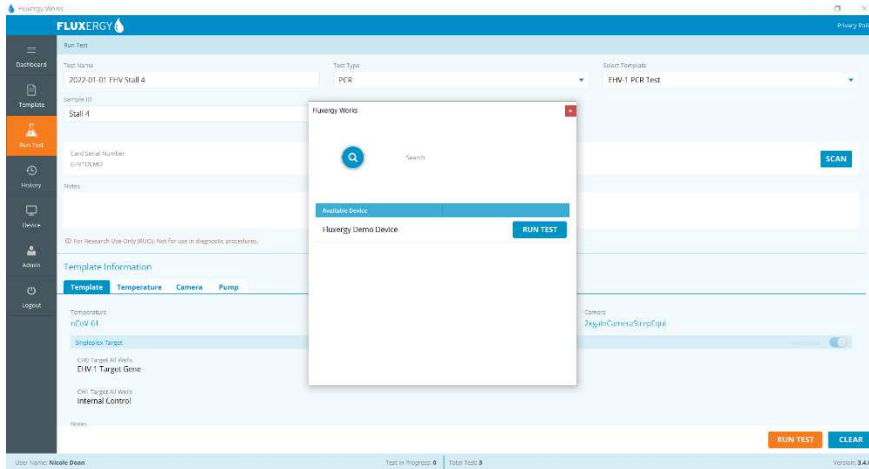
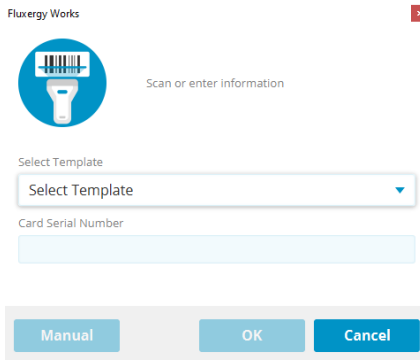


2. Click "Run Test" tab on the side-bar on the left side of the window.



3. Scan the barcode on the Fluxergy PCR Card Package.

*Note: For best results, ensure that the scanning surface is flat, and entire barcode can be captured.*



4. If the scan fails, click “Manual” and select the correct assay from the dropdown list.
5. Enter the serial number in the “Card Serial Number” section.
6. Type in “Test Name” and Sample specific information in the Notes section.
7. If a Test is a Retest, append the Test name with “\_Retest”.



8. Once the Reaction Mix is fully thawed, briefly spin down the Reaction Mix tube using a mini centrifuge.

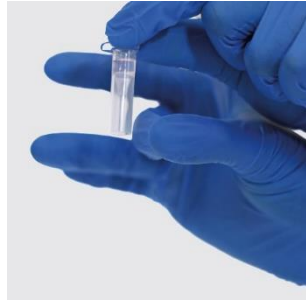


9. Vortex the swab sample in VTM for approximately 90 seconds to dislodge genetic material (If the sample sits before use, re-vortex for 3 seconds).





10. Pipette 42  $\mu\text{L}$  of (swab + VVTM) sample into the Reaction Mix tube.



11. Mix the sample and Reaction Mix by gently flicking the bottom of the tube 5 times.



12. Briefly spin down using a mini centrifuge to get residual fluid off cap and walls of the tube.

*Caution: DO NOT use pipette to mix sample and Reaction Mix!*



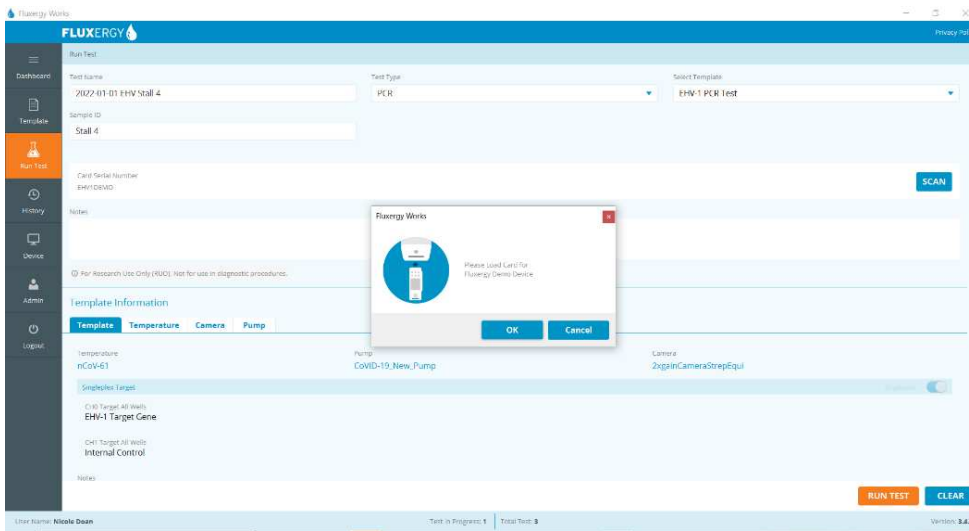
13. Place the Fluxergy PCR Card on a flat surface.

14. Carefully dispense 130  $\mu\text{L}$  into the loading port of the Fluxergy PCR Card.

*Caution: Pipette the sample mix directly onto the loading port. Avoid pipetting onto the loading port's wall.*



15. Press the plastic cap onto the loading port of the Fluxergy PCR Card.
16. Once the Fluxergy PCR Card is loaded and cap placed onto the loading port do not invert, shake, or drop the Fluxergy PCR Card.



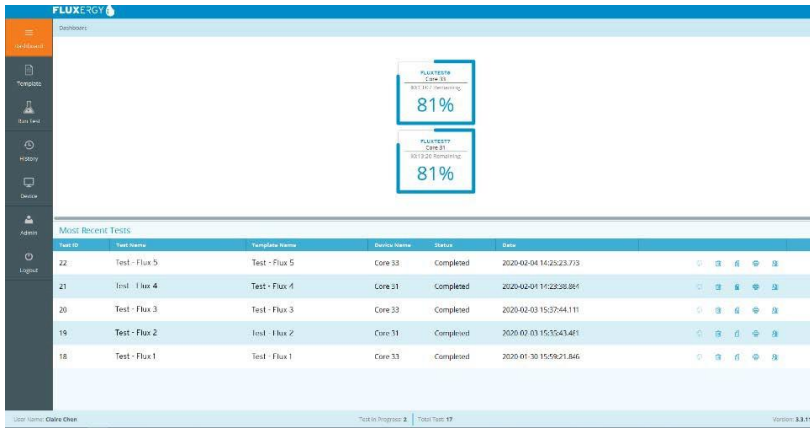
17. Click "RUN TEST" at the bottom right. Select a device from the list of available devices.  
*Note: Fluxergy Works automatically filters unavailable devices.*

18. Fluxergy Works will prompt you into insert a loaded Fluxergy PCR Card.

*Note: Immediately proceed to running a test, the user has 4 minutes to insert a Fluxergy PCR Card and run test.*

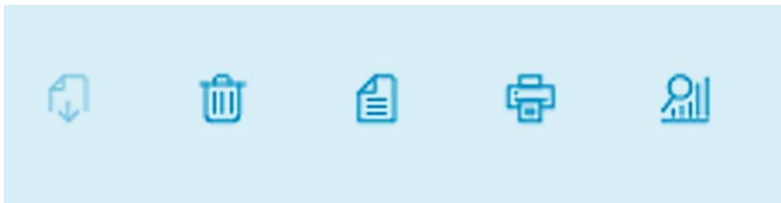


19. Insert the Fluxergy PCR Card with sample and Reaction Mix into Fluxergy Analyzer.
20. Click "OK" on Fluxergy Works to begin the test.

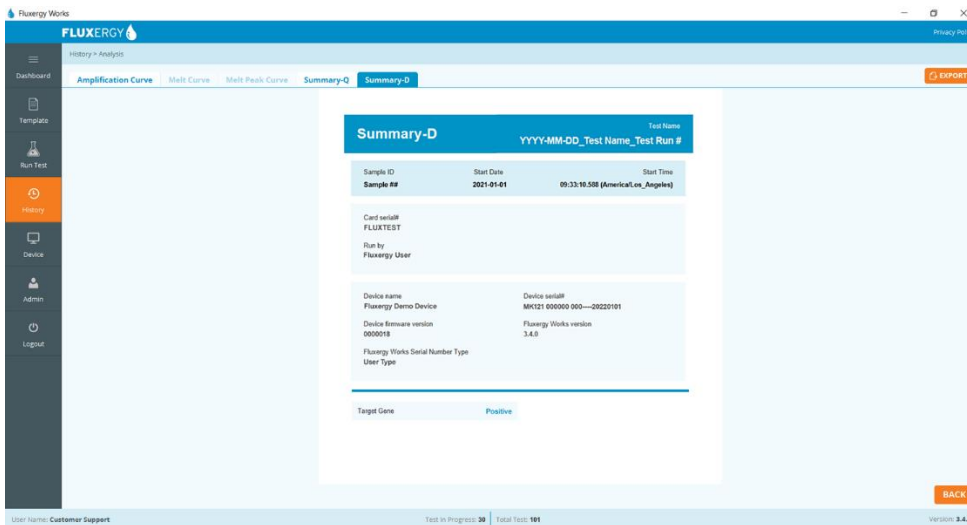


21. The test will be complete in about 1 hour. Tests in progress can be viewed on the Dashboard.

## 7.5 Accessing your Results



- Once you select “OK” to run the test, you will be redirected to the dashboard. Here, you can find your tests in progress, as well as a list of your most recent tests.
- To see all tests, select the “History” tab. On the right-hand side of the window, you can choose to delete, export, print, or view results for each test.
- Selecting the trash icon will delete test data permanently. Selecting the file icon will allow user to view template information for the test. Selecting the printer icon will enable you to print test summaries. Select the far-right option, the magnification glass and graph icon, to view and export your results.
- Summary D in each test will contain the qualitative test result.



\* For detailed instructions on how to view and print the results, see the *Fluxergy Analyzer IFU*.

## 8. Quality Control

### 8.1 Internal Control

An internal control, included as part of the Reaction Mix, is used in the background of every test to validate a true negative. Amplification must occur in the internal control channel for a negative to be qualified as a negative.

### 8.2 External Control

Fluxergy recommends including one positive and one negative control daily. Fluxergy does not supply external controls with Fluxergy Assay PCR EHV-1 Test. External controls can be requested with Fluxergy.

#### 8.2.1 Negative Control

- A “no template”, negative control is used when a new system is first set up, as well as for training or proficiency testing. The routine QC testing frequency will be based on the labs IQCP requirements.
- The negative control is added to Fluxergy Reaction Mix EHV-1 in the same way a patient sample would be (refer to section 7 of IFU for Test Procedure).
- Based on its internal validation, Fluxergy recommends using an approved viral transport medium as the negative control.

#### 8.2.2 Positive Control

- A positive template control is used when a new system is first set up, as well as for training or proficiency testing. The routine QC testing frequency will be based on the labs IQCP requirements.
- The positive control is added to Fluxergy Reaction Mix EHV-1 in the same way a patient sample would be (refer to section 7 of IFU for Test Procedure).
- A standard strain of EHV-1 or a previously tested/identified clinical sample (NPS) may be used as a positive control.
- Fluxergy EHV-1 PCR External Control (+) available in pack of 1 (CAT #7214) or packs of 10 (CAT #7217), sold separately.

## 9. Interpretation of Results

### 9.1 Test Outputs

Test Output	Interpretation	Action
Positive	EHV-1 DNA present	Report the result †
Negative	EHV-1 DNA not present	Report the result. †

† If the result is not consistent with clinical indications, seek confirmatory testing.

### 9.2 Error Codes

Error Codes	User Action on First Error	User Action on Second Error
600-625, 627-636	1. Restart Fluxergy Analyzer. 2. Retest sample with new card and mix.	Contact Customer Service
626	1. Dilute sample in 1:2 (e.g. 50 uL of sample with 50uL of diluent (e.g. VTM)). 2. Retest diluted sample with new card and mix.	Contact Customer Service
Network Error*	Click to retrieve Test Result.	Follow instructions above for any other errors.

\* This error can happen when analyzer loses connectivity with PC.

### 9.3 Retests

If an ERROR is shown as the result from the test, there is a strong likelihood that you need to retest the original sample. In cases where sample quality may have played a role, you may need to recollect the sample.

The procedure to retest is as follows:

1. If there is no sample recollection required, use the leftover sample from the original swab and transport media. If sample recollection is required, collect according to 7.3 and standard procedure.
2. Use a clean pair of gloves as if starting a new test. Vortex the sample for 90 seconds and follow steps 7.4 – 7.5.
3. Make sure to give a different name to test in Fluxergy Works (e.g. Original Test Name\_RETEST).
4. If an Error comes back for a second time, contact customer service, and seek confirmatory testing.

### 9.4 Restarting the Fluxergy Analyzer Device

*For instruction on how to Restart, Refer to the Fluxergy Analyzer IFU.*

## 10. Limitations

- For use for EHV-1 testing only.
- False negatives may occur if the number of viral genome copies in the specimen are below the test limit of detection (LoD).
- As with other tests, false positives may occur. Some settings may indicate the need for repeat testing or testing using a different system.
- The test cannot rule out disease or infection caused by other bacterial or viral pathogens. The tests only detect EHV-1 DNA.
- As with any molecular test, mutations within the target regions of EHV-1 could affect primer binding, resulting in failure to detect the presence of virus.
- The test was only validated against the following sample type: nasopharyngeal swabs (NPS) immersed in viral transport media.
- PCR only detects DNA and does not determine whether a virus is lytic or whether a patient is infectious. The PCR result must be interpreted by a health care provider along with clinical signs.
- Improperly collected, transported, or handled samples risk the potential for false positive, false negative or erroneous results. The detection of viral nucleic acid is dependent upon proper sample collection, handling, transportation, storage, and preparation.
- The internal control will not indicate whether nucleic acid has been lost due to inadequate collection, transport, or storage of samples.
- Because the test is a direct PCR, sample dilution into correct volume of transport media is important. Further, correct mixing of the sample is important for test function.

## 11. Conditions of Use for the Laboratory

Use of the Fluxergy Assay PCR EHV-1 Test must follow procedures outlined in the manufacturer's Instructions for Use and under the conditions set by the health authorities in your country.

- Laboratories using the Fluxergy Assay PCR EHV-1 Test will use the materials and equipment identified in the Instructions for Use. Deviations from the authorized procedures, including the authorized instruments, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use the Fluxergy Assay PCR EHV-1 Test are not permitted.
- All laboratory personnel using the Fluxergy Assay PCR EHV-1 Test must be appropriately trained in performing and interpreting the results of the Fluxergy Assay PCR EHV-1 Test, use appropriate personal protective equipment when handling this kit, and use the Fluxergy Assay PCR EHV-1 Test in accordance with the authorized labeling.
- Fluxergy, authorized distributors, and laboratories using the Fluxergy Assay PCR EHV-1 Test will ensure that records are maintained. Such records will be made available to their national authorities for inspection upon request.

## 12. Performance Evaluation

### 12.1 Assay Analytical Performance Evaluation

#### 12.1.1 Limit of Detection (LoD) – Analytical Sensitivity <sup>5</sup>

The LoD of the Fluxergy Assay PCR EHV-1 Test was conducted with serially diluted EHV-1 stock in negative pooled NB swab matrix. The EHV-1 stock was serially diluted and tested in triplicate and at the level where all triplicates were detected as positive, a confirmation testing was conducted using 20 replicates.

The EHV-1 stock was at 5000 copies/mL was confirmed to be the LoD as 20/20 replicates were detected at this dilution by the reaction mixture. The limit of detection for EHV-1 was defined as the lowest concentration at which each target is detected at least 95% of the time.

#### Confirmatory LoD of the Fluxergy Test Kit Salmonella PCR in pooled environmental swab matrix.

LoD Determination <i>Equine Herpesvirus 1 Virus</i> USDA strain (# 045-EDV)	
Concentration Tested	# Tested / # Detected (%)
5000 copies/mL	20/20 (100%)

#### 12.1.2 Cross Reactivity – Analytical Specificity

The cross-reactivity testing was conducted to validate the specificity of Fluxergy Assay PCR EHV-1 Test in the presence of other relevant microorganisms that could be present in the upper respiratory tract of horses. Qualified lots of Fluxergy's Assay PCR EHV-1 reaction mixture and test card were used to test the panel with a minimum of one operator.

Cross-reactivity of the Fluxergy Assay PCR EHV-1 Test was evaluated by wet-lab testing of organisms listed below. All cross-reactive microorganisms were extracted and diluted to a concentration of ~1E+5 copies/mL.

None of the organisms tested in the specificity study listed below were detected by the Fluxergy Assay PCR EHV-1 Test, thereby demonstrating the assay specificity.

Cross-Reactivity of Fluxergy Assay PCR EHV-1 Test Results		
Organism	Result	Results
Equine herpesvirus-4 (ATCC Strain: 405/76 (Cat #VR-2230; Lot#:63863763)	Neg (3/3)	No detection
Streptococcus equi sbsp. equi (ATCC Item # 33398)	Neg (3/3)	
Streptococcus equi sbsp. zoo (ATCC Item # 43079)	Neg (3/3)	
Equine influenza virus (EIV A-2 Alaska ,020-IDV)	Neg (3/3)	
Equine Rhinitis A virus (ERAV 060-EDV)	Neg (3/3)	
Equine Rhinitis B virus (ERBV 061-EDV)	Neg (3/3)	

### 12.1.3 Assay Reproducibility

The reproducibility testing was conducted to assess the Inter-assay precision (reproducibility) of Fluxergy Assay PCR EHV-1 Test to detect the presence of the virus EHV-1.

A standard strain of EHV-1 was serially diluted in negative pooled sample swab matrix down to 1x, 2x, and 3x LoD. Pooled NPS matrix was used as NTC. The study demonstrated 100% concordant calls for 1x and 2x LoD and negative samples and a 97.2% concordance for 3x LoD. The study found the assay to have low variability (<10% CV for observed FAM Ct values) as seen in the table below.

Assay Reproducibility Testing Per Card Run (Test)				
Sample	Replicates	Mean (FAM Ct)	Std Dev (FAM Ct)	% CV
1x LoD	36	33.5	1.06	3.16%
2x LoD	36	32.4	1.07	3.31%
3x LoD	36	31.9	1.36	4.27%

















### 12.1.4 Interference Study <sup>6</sup>

The assay interference from relevant microorganisms that could be present in the upper respiratory tract of horses were tested in this study. No interference was observed with any of the substances tested. The interfering substances were diluted to a concentration of ~1E+5 to 1E+7 copies/mL and spiked into 3x LoD EHV-1 strain. Testing was performed with the Fluxergy Assay PCR EHV-1 Test using the Fluxergy Analyzer and included triplicate testing per substance. A positive detection of test samples indicated lack of interference.



Potential Interfering Substance	Result	Results
Equine herpesvirus-4 (ATCC Strain: 405/76 (Cat #VR-2230; Lot#:63863763)	100% (3/ 3)	Positive
Streptococcus equi sbsp. equi (ATCC Item # 33398)	100% (3/ 3)	Positive
Streptococcus equi sbsp. zoo (ATCC Item # 43079)	100% (3/ 3)	Positive
Equine influenza virus (EIV A-2 Alaska ,020-IDV)	100% (3/ 3)	Positive
Equine Rhinitis A virus (ERAV 060-EDV)	100% (3/ 3)	Positive
Equine Rhinitis B virus (ERBV 061-EDV)	100% (3/ 3)	Positive

# 13. Symbols and Marking


## 13.1 Symbols on Packaging

Symbol	Meaning
 <a href="http://www.fluxergy.com/downloads">www.fluxergy.com/downloads</a>	The instructions for use are available for download electronically from the website shown.
	This symbol indicates the number of pieces in the package (10).
	This symbol indicates the number of pieces in the package (100).
	Indicates that the transport package shall be kept away from rain and in dry conditions.
 YYYY-MM-DD	Indicates the date after which the product is not to be used. The date format is YYYY- MM-DD where YYYY represents the four (4) digit year, MM is the two (2) digit month and DD is the two (2) digit day.
	Indicates the unique device identification data.
	Indicates the Fluxergy catalogue number so that the medical device can be identified.
	Indicates the Fluxergy serial number so that a specific medical device can be identified.
	Identifies the manufacturer's batch or lot code.
	Indicates the container's net volume in specific unit of measure.
	Indicates that the item is for single use only and must not be used more than once.
	Indicates the medical device manufacturer. This symbol is used to identify the name and address of company that manufactured the product.
	Indicates the temperature limits to which the product can be safely exposed and gives the maximum and minimum storage temperatures.
	Indicates that the user should not use the product without inspecting the contents of the package if the package is badly damaged.
	Indicates methods to contact customer support.
	Test Card Image



Symbol	Meaning
	Reaction Mix Image
 YYYY-MM-DD	Indicates the manufacturing date when the product is manufactured. The date format is YYYY-MM-DD where YYYY represents the four (4) digit year, MM is the two (2) digit month and DD is the two (2) digit day.

### 13.2 Symbols used in this IFU

Symbol	Meaning
	Indicates that there are potential biological risks associated with the medical device after use. This symbol is used to remind the user that the Fluxergy Assay PCR EHV-1 Test is considered hazardous waste after it has been used to perform a test. The used Fluxergy PCR Card should be disposed of as required by national authorities.

## 14. Contact and Legal Information

### 14.1 Fluxergy Headquarters Location



FLUXERGY  
30 Fairbanks, Suite 110  
Irvine, CA 92618, USA

### 14.2 Customer and Technical Support

#### 14.2.1 Contact us by Mail

Attn: Fluxergy Customer Support  
30 Fairbanks, Suite 110  
Irvine, CA 92618, USA

#### 14.2.2 Contact us by Email

[customersupport@fluxergy.com](mailto:customersupport@fluxergy.com)

#### 14.2.3 Contact us by Phone

+1 (949) 305-4201 US & International

## 15. References

<sup>1</sup> U.S. Department of Health and Human Services, *Biosafety in Microbiological and Biomedical Laboratories (BMBL)*, 6<sup>th</sup> Edition, HHS Publication No. (CDC) 300859, Revised June 2020.

<sup>2</sup> World Health Organization, *Laboratory Biosafety Manual*, 4<sup>th</sup> Edition, CC BY-NC-SA 3.0 IGO, 2020.

<sup>3</sup> Clinical And Laboratory Standards Institute. Protection Of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline - Fourth Edition. CLSI M29-A4.

<sup>4</sup> Fluxergy Inc, *IFU for the Fluxergy Analyzer System*, Current Revision

<sup>5</sup> CLSI. Protocols For Determination Of Limits Of Detection And Limits Of Quantitation; Approved Guideline. CLSI EP17-A.

<sup>6</sup> CLSI. Interference Testing In Clinical Chemistry - 3rd Edition. CLSI EP07-Ed3.