INSTRUCTIONS FOR USE

FLUXERGY HVRe Influenza/RSV/SARS-CoV-2

REF **8029 / 8032**

For Use with the Fluxergy Analyzer CAT # 5506-CE (or equivalent)

***In Vitro* Diagnostic Medical Device**

CE IVD

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TABLE OF CONTENTS

1. Intended Use 3
2. Explanation of the Test 3
3. Principles of the Procedure 3
   - 3.1 Overview 3
   - 3.2 Respiratory Specimen Collector 4
   - 3.3 Fluxergy HVRe Influenza/RSV/SARS-CoV-2 Multiplex PCR Card 4
   - 3.4 Fluxergy Analyzer 4
   - 3.5 Process 4
4. Reagents and Instruments 4
   - 4.1 Materials Provided 4
   - 4.2 Materials Required but Not Provided 5
5. Warnings and Precautions 6
   - 5.1 General 6
   - 5.2 Test/Reagent 6
6. Sample Requirements 7
   - 6.1 Sample Type and Sample Volume 7
   - 6.2 Transport and Storage 7
7. Test Procedure 7
   - 7.1 Setting up a Fluxergy Analyzer 7
   - 7.2 Test Features 8
   - 7.3 Sample Collection 8
   - 7.4 Set Up and Run Your Test on Fluxergy Works Software 8
   - 7.5 Accessing your Results 14
8. Quality Control 15
   - 8.1 Internal Control 15
   - 8.2 External Control 15
9. Interpretation of Results 15
   - 9.1 Test Outputs 15
   - 9.2 Error Codes 16
   - 9.3 Retests 16
   - 9.4 Restarting the Fluxergy Analyzer Device 16
10. Limitations 16
11. Conditions of Use for the Laboratory 17
12. Performance Evaluation 18
    - 12.1 Clinical Performance Evaluation 18
    - 12.2 Analytical Performance Evaluation 18
13. Symbols and Marking 25
    - 13.1 Symbols on Packaging 25
    - 13.2 Symbols used in this IFU 26
14. Contact and Legal Information 26
    - 14.1 Fluxergy Headquarter's Location 26
    - 14.2 Customer and Technical Support 26
    - 14.3 Authorized Representative 26
15. References 27

1. Intended Use

Fluxergy HVRe Influenza/RSV/SARS-CoV-2 is a multiplex real-time reverse transcriptase (rRT) polymerase chain reaction (RT-PCR) test intended for the simultaneous qualitative detection of nucleic acids from SARS-CoV-2, Influenza A/B viruses (undifferentiated), and Respiratory Syncytial Virus (RSV), in nasopharyngeal swab samples (NPS) from individuals showing symptoms of respiratory tract infection.

Results are for the identification of SARS-CoV-2, Influenza A/B viruses (undifferentiated), and Respiratory Syncytial Virus (RSV) nucleic acids. The RNA targets are generally detectable in upper respiratory specimens during the acute phase of infection.

Positive results are indicative of the presence of SARS-CoV-2, Influenza virus, and/or RSV; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses not tested. The agent detected may not be the definite cause of disease.

Laboratories may be required to report all positive SARS-CoV-2 results to the appropriate Competent Health Authorities. Laboratories may also be required to report negative SARS-CoV-2 results, positive and/or negative influenza results, and positive and/or negative RSV results to the appropriate Competent Health Authorities.

Negative results do not preclude SARS-CoV-2, influenza A/B, or RSV A/B infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

Fluxergy HVRe Influenza/RSV/SARS-CoV-2 is intended for use by qualified and trained clinical laboratory personnel specifically instructed and trained in the techniques of real-time PCR and in vitro diagnostic procedures.

2. Explanation of the Test

Fluxergy HVRe Influenza/RSV/SARS-CoV-2 is a qualitative multiplex real-time reverse transcriptase polymerase chain reaction (rRT-PCR) test. The primer and probe sets are designed to detect RNA from SARS-CoV-2, Influenza A/B viruses, or RSV in nasopharyngeal swab samples (NPS) from patients with signs and symptoms of respiratory viral infection. The test performance is monitored by standardized internal controls and provides results within 1 hour from when the test is initiated with a suspected sample.

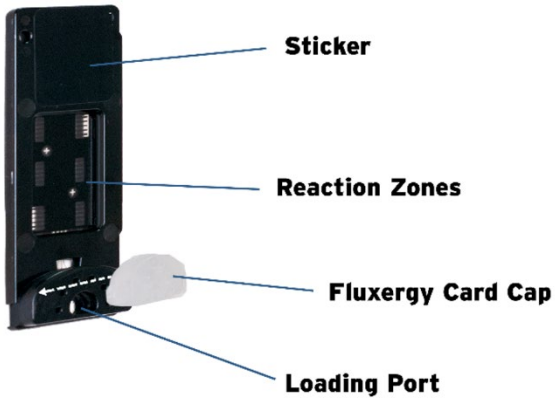
3. Principles of the Procedure

3.1 Overview

The Fluxergy HVRe Influenza/RSV/SARS-CoV-2 enables processing, amplification, and detection of SARS-CoV-2, Influenza A/B, and/or RSV RNA by real-time RT-PCR. Nasopharyngeal swabs samples are collected in approved viral transport medium. Using a transfer pipette, an aliquot of the sample medium is then transferred to the Fluxergy Respiratory Specimen Collector containing a diluent solution. The Fluxergy Respiratory Specimen Collector has a controlled dropper tip to allow precise loading of sample medium onto the Fluxergy HVRe Influenza/RSV/SARS-CoV-2 Multiplex PCR Card. The Fluxergy HVRe Influenza/RSV/SARS-CoV-2 Multiplex PCR Card is embedded with lyophilized reagent beads to target SARS-CoV-2, Influenza A/B, and RSV. The assay is performed on the Fluxergy Analyzer instrument which is controlled by an external computer equipped with Fluxergy Works Software. No operator intervention is necessary once the specimen is loaded onto the Fluxergy Analyzer.

3.2 Respiratory Specimen Collector

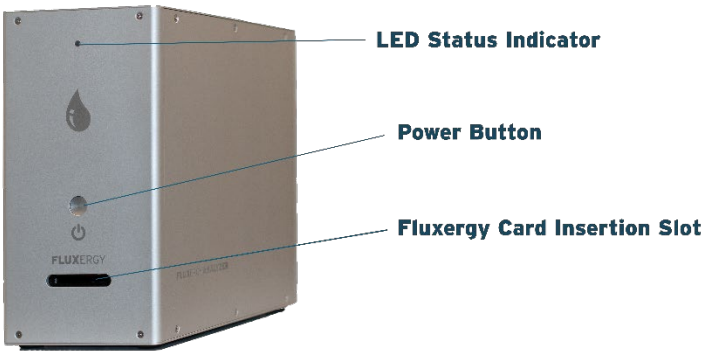
The Fluxergy Respiratory Specimen Collector will assist users with preparing, diluting, and storing samples for various assays. Using a transfer pipette, the user will transfer the NPS swab samples in viral transport medium to the dropper bottle containing a diluent solution for test preparation.



3.3 Fluxergy HVRe Influenza/RSV/SARS-CoV-2 Multiplex PCR Card

The Fluxergy HVRe Influenza/RSV/SARS-CoV-2 is a disposable Multiplex PCR Card containing a single sample loading port, microfluidic channels that control the flow of liquid, and reaction wells embedded with lyophilized reagent beads to target SARS-CoV-2, Influenza A/B, and RSV. In the lyophilized reagent beads, fluorescent probes are used together with corresponding forward and reverse primers to amplify SARS-CoV-2, Flu A/B, RSV RNA, and exogenous internal control. Internal control is used to detect PCR failure and/or inhibition in addition to monitoring adequate sample processing.

The Fluxergy HVRe Influenza/RSV/SARS-CoV-2 Multiplex PCR Card is self-contained to prevent cross-contamination between samples.



3.4 Fluxergy Analyzer

The Fluxergy Analyzer instrument is a rapid 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.

3.5 Process

In the Fluxergy HVRe Influenza/RSV/SARS-CoV-2, a NPS sample collected in viral transport medium is mixed with a diluent solution in the Respiratory Specimen Collector, and then loaded onto the Fluxergy Multiplex PCR Card embedded with lyophilized reagent beads that target influenza A/B, SARS-CoV-2 and RSV. After loading the Fluxergy Multiplex PCR Card into the Fluxergy Analyzer instrument, the run is initiated. Approximately in 1 hour, the Fluxergy Analyzer will complete the thermal cycling and analysis. Results are then downloaded to and displayed within Fluxergy Works.

4. Reagents and Instruments

The Fluxergy HVRe Influenza/RSV/SARS-CoV-2 is to be used with the following instrument, reagents, and supplies:

4.1 Materials Provided

The Fluxergy HVRe Influenza/RSV/SARS-CoV-2 (single pack) contains sufficient reagents and consumables to test a single specimen or quality control sample. The Fluxergy HVRe Influenza/RSV/SARS-CoV-2 is a consumable Multiplex PCR Card embedded with lyophilized reagent beads for influenza A/B, RSV, and SARS-CoV-2 and is packaged in packs of 10 (PN 8029) or 100 (PN 8032).

4.1.1 Storage and Handling

- Store the Fluxergy HVRe Influenza/RSV/SARS-CoV-2 Multiplex PCR Card at 15 to 25°C.
- Do not open individual Fluxergy HVRe Influenza/RSV/SARS-CoV-2 Multiplex PCR Card packaging until you are ready to test.

4.2 Materials Required but Not Provided

- Sample Collection Materials:
  - A rayon, polyester, or nylon-flocked swab with 80mm breakoff point (not cotton): Copan SKU #502CS01, or equivalent.
  - 3 mL of viral transport medium (VTM): Copan SKU #330C, Puritan SKU#UT-300, BD UVT SKU #220527/220528/220529/220531, or equivalent.

- Respiratory Specimen Collector which includes a set of dropper bottle filled with diluent solution and transfer pipette and is packaged in packs of 10 (PN 8041) or 100 (PN 8044). Store the Respiratory Specimen Collector at 15 – 30°C.
- Fluxergy Analyzer (CAT #5506-CE, or equivalent), sold separately.
- Barcode scanner
  - → 2D: Data Matrix, GS1 Data Matrix
  - → Stand with hands-free operation capability.
- PC or laptop to install Fluxergy Works software (v3.5.0 or higher)
  - → Operating System, 64-bit
  - → Windows 10 (build 1151 or later) 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
- Instructions and Documents
  - Instructions for Use, SDS, and additional resource documents can be found at www.fluxergy.com/downloads

5. Warnings and Precautions

5.1 General

- For *in vitro* diagnostic use.
- Positive results are indicative of the presence of SARS-CoV-2, Influenza A/B, and/or RSV RNA.
- Report all positive results to the appropriate health authorities as required.
- 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 outlinedby your local or national authorities, for example: Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID 19), https://www.cdc.gov/coronavirus/2019-ncov/lab/lab- biosafety-guidelines.html[1] or Laboratory Biosafety Manual – 4th Edition (WHO).[2]
- Follow safety procedures set by your institution for working with chemicals and handling biological specimens.
- Bleach introduced into a sample may damage DNA and RNA 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 mucus membranes. Change gloves often when handling equipment, reagents, or samples.[3]
- 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 HVRe Influenza/RSV/SARS-CoV-2 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 HVRe Influenza/RSV/SARS-CoV-2 is only compatible and for use only with the Fluxergy Analyzer.
- Do not handle samples or Fluxergy HVRe Influenza/RSV/SARS-CoV-2 Multiplex PCR Card in a biosafety cabinet which is used for SARS-CoV-2 culture orimmunofluorescence testing.
- Do not use a test kit or components that are damaged.
- Each single-use Fluxergy HVRe Influenza/RSV/SARS-CoV-2 Multiplex PCR Card and single-use Fluxergy Respiratory Specimen Collector are used to process one sample. Do not reuse processed Fluxergy HVRe Influenza/RSV/SARS-CoV-2 Multiplex PCR Card and Fluxergy Respiratory Specimen Collector.
- Prior to processing samples, thoroughly clean both the work area with a suitable cleaner such as freshly prepared10% bleach or a similar disinfectant.
- Fluxergy HVRe Influenza/RSV/SARS-CoV-2 Multiplex 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 HVRe Influenza/RSV/SARS-CoV-2 Multiplex PCR Card bulk packaging).
- **Always check the expiration date on the Fluxergy HVRe Influenza/RSV/SARS-CoV-2 Multiplex PCR Card. Do not use kitcomponents after the expiration date.**

6. Sample Requirements

6.1 Sample Type and Sample Volume

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 CDC's Interim Guidelines for Collecting and Handling of Clinical Specimens for COVID-19 Testing https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html[4] and Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19) https://www.cdc.gov/coronavirus/2019-ncov/lab/lab-biosafety-guidelines.html:

- Insert a swab into nostril parallel to the palate. Swab should reach depth equal to distance from nostrils to outer opening of the ear. Leave swab in place for several seconds to absorb secretions. Slowly remove swab while rotating it.
- Place swab into tube containing 3 mL of viral transport medium. Immediately break off swab tip at break line andcap sample collection tube tightly. Transport medium must be in 3 mL volume for expected performance.
- Acceptable specimen types include only nasopharyngeal swab (NPS)

6.2 Transport and Storage

Samples should be processed and tested with the Fluxergy HVRe Influenza/RSV/SARS-CoV-2 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. Follow CDC's Interim Guidelines for Collecting and Handling of Clinical Specimens for COVID-19 Testing https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines- clinical-specimens.html and Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19) https://www.cdc.gov/coronavirus/2019-ncov/lab/lab-biosafety-guidelines.html.

7. Test Procedure

7.1 Setting up a Fluxergy Analyzer

Refer to the Fluxergy Analyzer IFU[5] for how to:

- Setup a Fluxergy Analyzer
- Managing devices on Fluxergy Works software
- If 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.
- Adding users on Fluxergy Works software

Prior to running the Fluxergy HVRe Influenza/RSV/SARS-CoV-2, make sure the Fluxergy Analyzer is on and connected to the FluxergyWorks software.

7.2 Test Features

Fluxergy HVRe Influenza/RSV/SARS-CoV-2 Features	
Sample Type	Polyester, rayon, or nylon-flocked nasopharyngeal swab (NPS) collectedin 3 mL of viral transport medium
Minimum amount of sample required	300 µL
Duration of Test	Approximately 1 hour

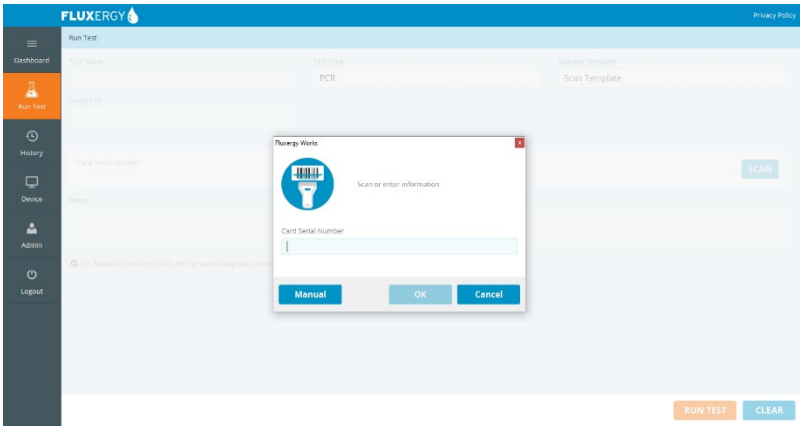
7.3 Sample Collection

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: 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

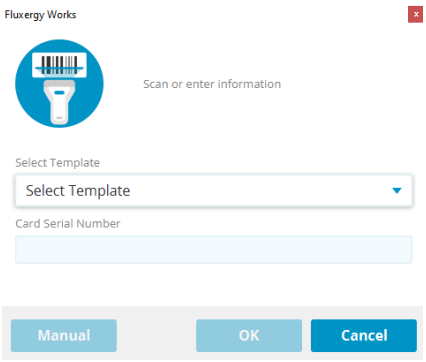
1. Open Fluxergy Works on the laptop and log in using your user ID and password.



2. Click the “Run Test” tab on the side-bar on the left side of your screen.

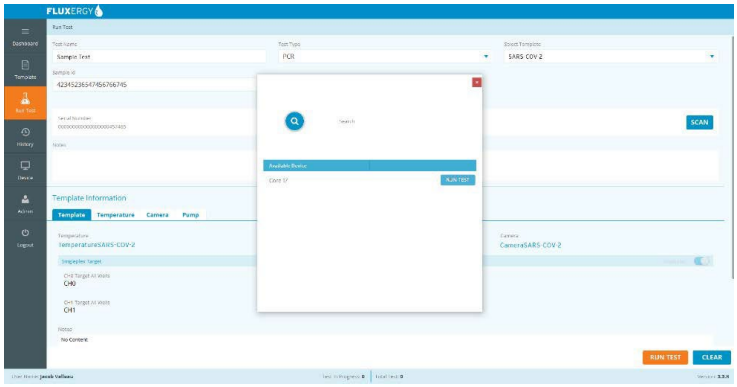
3. Scan the barcode on the Fluxergy HVRe Influenza/RSV/SARS-CoV-2 Multiplex PCR Card Package.

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



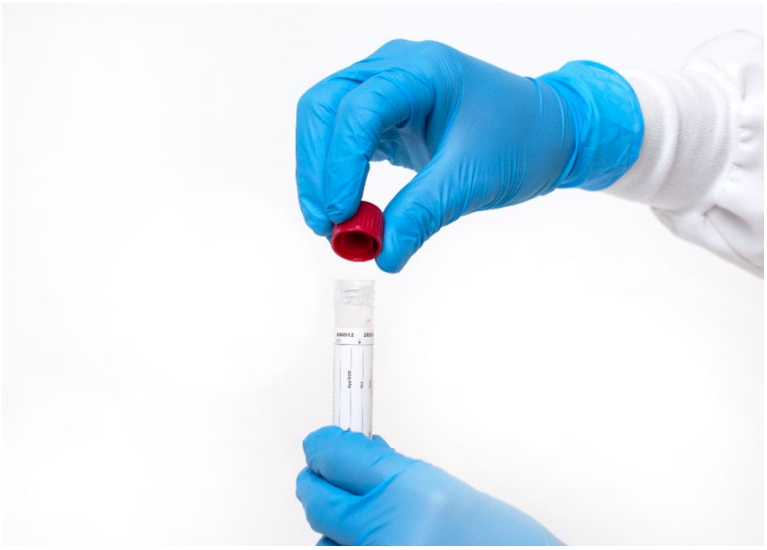
4. If the barcode cannot be scanned a prompt will appear, Click “Manual” and select the correct assay from the dropdown list.

5. Enter the serial number in the “Card Serial Number”, Click “OK”.



6. Type in “Test Name” and Sample ID. Sample specific information can also be included in the Notes section.

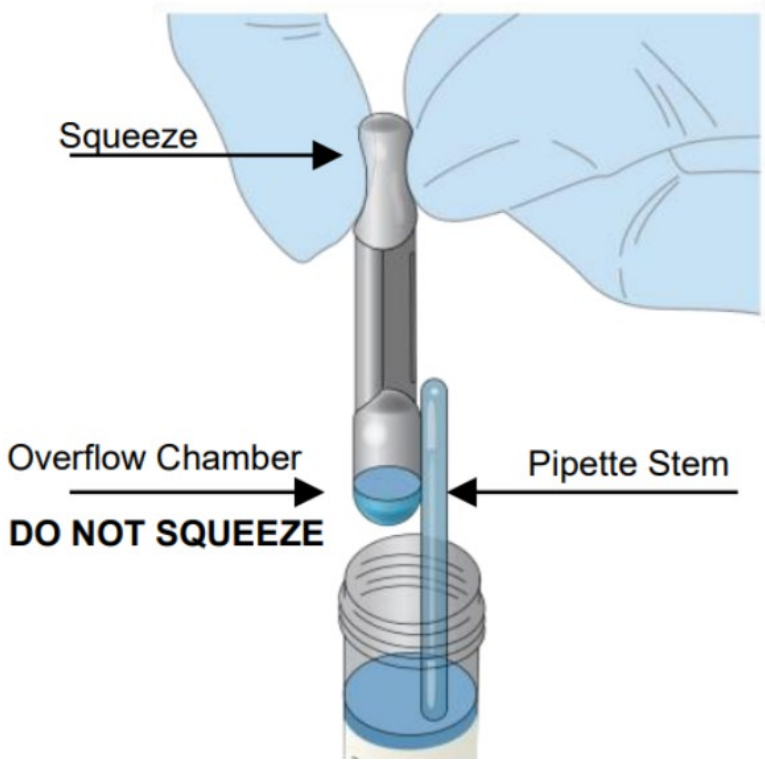
7. If a Test is a Retest, append the Test name with “_Retest”.



8. Shake the UTM tube containing patient sample for 15 seconds.

9. Uncap the UTM tube containing patient sample

10. Uncap the dropper bottle



11. Use the transfer pipette to draw the sample in UTM. Follow instructions below to draw the proper volume:

    - **Firmly** squeeze the **TOP** bulb of the pipette.
    - **While** continuing to squeeze the top bulb firmly, place the pipette tip well below the surface of the **liquid in the NPS/UTM sample tube**.
    - **Keep** the pipette tip well below the surface of the liquid.
    - **Slowly** release the top bulb to completely fill the pipette stem with sample. Some liquid may also be in the overflow chamber of the pipette.

    NOTE: Although excess liquid will enter the pipette's overflow chamber, only the liquid in the pipette stem will be dispensed.

12. Move the filled pipette over and into the dropper bottle.

    CAUTION: DO NOT squeeze any parts of the pipette during movement to avoid displacement of liquid.

13. **Firmly** squeeze the TOP bulb of the pipette to completely dispense the liquid in pipette stem into the dropper bottle.

14. Recap the dropper bottle.

15. Invert the dropper bottle at least five (5) times to mix the sample and diluent together.

16. Uncap the dropper bottles nozzle and dispose one (1) drop.

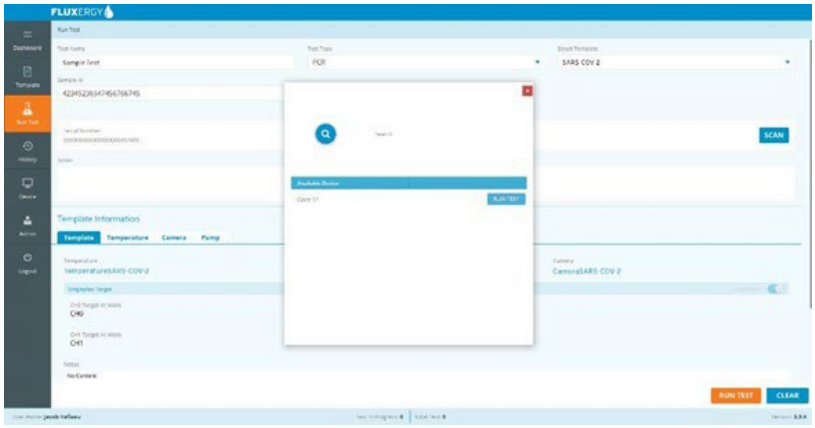
    WARNING: *Follow appropriate guidelines for laboratory biosafety protocols*[1,2,3,4]*!*

17. Squeeze the dropper bottle to dispense five (5) drops of sample solution into the loading port of the Fluxergy HVRe Influenza/RSV/SARS-CoV-2 Multiplex PCR Card.

    NOTE: Keep dropper bottle at **45°** angle to avoid over filling.

18. Place the plastic cap onto the loading port of the Fluxergy HVRe Influenza/RSV/SARS-CoV-2 Multiplex PCR Card immediately after loading the card, and press firmly to secure the cap.

19. Once the Fluxergy HVRe Influenza/RSV/SARS-CoV-2 Multiplex PCR Card is loaded and cap placed onto the loading port do not invert, shake, or drop the Fluxergy HVRe Influenza/RSV/SARS-CoV-2 Multiplex PCR Card.



20. Click “RUN TEST” at the right of the Fluxergy Works window. Select a device from the list of available devices.

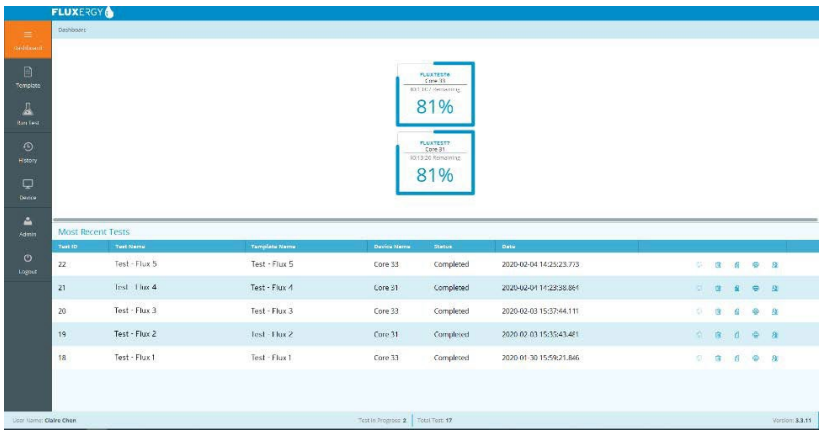
    Note: Fluxergy Works automatically filters unavailable devices.

21. Fluxergy Works will prompt you into insert a loaded Fluxergy HVRe Influenza/RSV/SARS-CoV-2 Multiplex PCR Card.

    NOTE: Immediately proceed to running a test, the user has 4 minutes to insert a Fluxergy HVRe Influenza/RSV/SARS-CoV-2 Multiplex PCR Card and run the test.

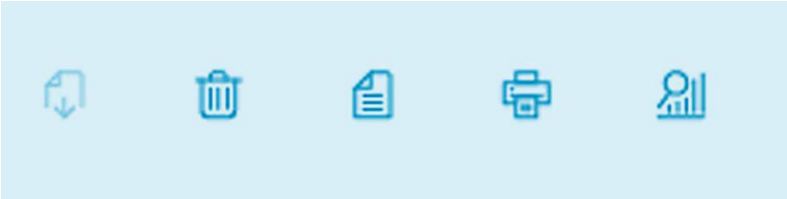
22. Insert the Fluxergy HVRe Influenza/RSV/SARS-CoV-2 Multiplex PCR Card loaded with sample solution into Fluxergy Analyzer.

23. Click “OK” on Fluxergy Works to begin the test.



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

7.5 Accessing your Results



1. 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.
2. 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 eachtest.
3. 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.
4. Summary D in each test will contain the qualitative test result.

Summary-D

Test Name
HRP_MC_VAL_063

Sample ID	Start Date	Start Time
HRPvFL.320	2022-05-18	14:00:00.085 (America/Los_Angeles)

Card serial#
9n000162

Run by
blab blab

Device name	Device serial#
Core 79	MK121 000079 003---- 20200507
Device firmware version	Fluxergy Works version
0000020	3.5.0

Fluxergy Works Serial Number Type
Human

CoVID-19	Positive	RSV	Negative
Flu A/B	Negative		

* 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 lyophilized reagent beads, 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 when clinical samples are tested. TheFluxergy HVRe Influenza/RSV/SARS-CoV-2 is not supplied with a Positive or Negative control.

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 proficiencytesting. The routine QC testing frequency will be based on the labs IQCP requirements.
- The negative control is added to Fluxergy HVRe Influenza/RSV/SARS-CoV-2 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 HVRe Influenza/RSV/SARS-CoV-2 in the same way a patient sample would be (referto section 7 of IFU for Test Procedure).
- Based on its internal validation, Fluxergy recommends using the following positive controls for SARS-CoV-2:
  - Heat-inactivated SARS-CoV-2 Culture Fluid (Zeptometrix Catalog # 0810587CFHI-0.5mL) at 2.7 $TCID_{50}$/mL, or
  - SARS-CoV-2 viral particles inactivated by heat treatment and gamma irradiation (SARS-CoV-2 Medium QControl 01, Qnostics Cat # SCV2MQC01-B) at 4000 copies/mL.
  - Fluxergy COVID-19 PCR External Controls (+) available in pack of 1 (CAT #7151) or pack of 10 (CAT #7154), sold separately.
- For Influenza A/B and RSV, any standard strains listed below can be used for positive controls:
  - Influenza A (H1N1 or H3N2 subtype) diluted to 250 TCID50/mL, or
  - Influenza B (Victoria or Yamagata lineages) diluted to 250 TCID50/mL, or
  - Respiratory Syncytial virus diluted to 50 TCID50/mL

9. Interpretation of Results

9.1 Test Outputs

Test Output	Interpretation	Action
Flu A/B POSITIVE	Influenza A or Influenza B RNA present	Report the result to appropriate public health authorities. †
RSV POSITIVE	RSV RNA present	Report the result to appropriate public health authorities. †
CoVID-19 POSITIVE	SARS-CoV-2 RNA present	Report the result to appropriate public health authorities. †
Flu A/B NEGATIVE	Influenza A or Influenza B RNA NOT present	Report the result. †
RSV NEGATIVE	RSV RNA NOT present	Report the result. †
CoVID-19 NEGATIVE	SARS-CoV-2 RNA NOT present	Report the result. †

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

9.2 Error Codes

Error Codes	Interpretation	User Action on First Error	User Action on Second Error
600-625, 627-636*	**NO** result	1. Restart Fluxergy Analyzer. 2. Retest sample with new card and mix.	Contact Customer Service
626**	**INVALID** result	1. Dilute sample. 2. Retest diluted sample with new card and mix. 3. Record new test output(s) for only the retest target(s) and use the original test result(s) for non-error test target(s).	Contact Customer Service
642**	**INCONCLUSIVE** result	1. Retest sample with new card and mix. 2. Record new test output(s) for all test targets.	Contact Customer Service
Network Error*	No connectivity between the analyzer and PC	Click to retrieve Test Result.	Follow instructions above for any other errors.

* *This is instrument error.*

** *This is test error and is specific to each test target.*

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. Ifsample 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 Instructions on how to Restart, Refer to the Fluxergy Analyzer IFU.

10. Limitations

- For use for Influenza A/B, RSV, and SARS-CoV-2 testing only.
- For *in vitro* diagnostic use.
- False negatives may occur if the number of viral genome copies in the specimen are below the test limit ofdetection (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 Influenza A/B, RSV, and SARS-CoV-2 RNA.
- As with any molecular test, mutations within the target regions of Influenza A/B, RSV, and SARS-CoV-2 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 RNA 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. Follow Interim Guidelines for Collecting, Handling, and Testing Clinical

Specimens from Persons for Coronavirus Disease 2019 (COVID-19) https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html and Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19) https://www.cdc.gov/coronavirus/2019-ncov/lab/lab-biosafety-guidelines.html.

- 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 HVRe Influenza/RSV/SARS-CoV-2 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 HVRe Influenza/RSV/SARS-CoV-2 will use the materials and equipment identified in the Instructions for Use. Deviations from the authorized procedures, including the authorized instruments, authorized extraction methods, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use the Fluxergy HVRe Influenza/RSV/SARS-CoV-2 are not permitted.
- Authorized laboratories that receive the Fluxergy HVRe Influenza/RSV/SARS-CoV-2 will notify the relevant public health authoritiesof their intent to run your product prior to initiating testing, as appropriate.
- Authorized laboratories using the Fluxergy HVRe Influenza/RSV/SARS-CoV-2 will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
- Laboratories will collect information on the performance of the Fluxergy HVRe Influenza/RSV/SARS-CoV-2 and report anysuspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of the Fluxergy HVRe Influenza/RSV/SARS-CoV-2 of which they become aware to the appropriate authorities and to Fluxergy (+1 949-305-4201 or customersupport@fluxergy.com).
- All laboratory personnel using the Fluxergy HVRe Influenza/RSV/SARS-CoV-2 must be appropriately trained in in performing and interpreting the results of the Fluxergy HVRe Influenza/RSV/SARS-CoV-2, use appropriate personal protective equipment when handling this kit, and use the Fluxergy HVRe Influenza/RSV/SARS-CoV-2 in accordance with the authorized labeling.
- Fluxergy, authorized distributors, and laboratories using the Fluxergy HVRe Influenza/RSV/SARS-CoV-2 will ensure that records are maintained. Such records will be made available to their national authorities for inspection upon request.

12. Performance Evaluation[6]

12.1 Clinical Performance Evaluation[7]

The clinical performance evaluation of the Fluxergy HVRe Influenza/RSV/SARS-CoV-2 was conducted with archived clinical nasopharyngeal swabs (NPS) in viral transport medium. A total of 240 nasopharyngeal swab (NPS) samples were collected from March 2020 to May 2022 during the COVID-19 pandemic in the United States. All samples had been confirmed as positive or negative for Influenza A/B, RSV, and SARS-CoV-2 by a CE-marked RT-PCR test.

The randomized and blinded samples were tested with the Fluxergy HVRe Influenza/RSV/SARS-CoV-2 using Fluxergy Analyzer to generate the Positive Percent Agreement (PPA) and Negative Percent Agreement (NPA) as an estimate for diagnostic accuracy. PPA and NPA were determined by comparing results of the Fluxergy HVRe Influenza/RSV/SARS-CoV-2 against the expected results. Results of these 240 archived clinical NPS samples are shown in the table below.

Clinical Performance Results of Fluxergy HVRe Influenza/RSV/SARS-CoV-2*

Target	# of NPS Samples	TP**	FN**	TN**	FP**	PPA (95% CI**)	NPA (95% CI**)
Influenza A/B (Combo)* **	180	86	33	57	4	**72.27%** (63.2% - 79.9%)	**93.44%** (83.3% - 97.9%)
Influenza A	*121*	*51*	*9*	*57*	*4*	*85.00% (73.0% - 92.5%)*	*93.44% (83.3% - 97.9%)*
Influenza B	*120*	*35*	*24*	*57*	*4*	*59.32% (45.8% - 71.7%)*	*93.44% (83.3% - 97.9%)*
RSV	180	50	10	118	2	**83.33%** (71.0% - 91.3%)	**98.33%** (93.5% - 99.7%)
SARS-CoV-2	240	48	12	175	5	**80.00%** (67.3% - 88.8%)	**97.22%** (93.3% - 99.0%)

* *During the study, any samples with errors were retested as instructed in IFU.*

** *TP: True Positive; FN: False Negative; TN: True Negative; FP: False Positive; CI: Confidence Interval.*

*** *The PPA and NPA of Influenza A/B (Combo) were calculated as averages from Influenza A and Influenza B.*

12.2 Analytical Performance Evaluation

12.2.1 Limit of Detection (LoD)[8] – Analytical Sensitivity

The LoD of the Fluxergy HVRe Influenza/RSV/SARS-CoV-2 was determined using standard strain for Influenza A, Influenza B, and RSV viruses, and heat-inactivated particles of SARS-Related Coronavirus 2 (SARS-CoV-2, Isolate: USA-WA1/2020). This SARS-CoV-2 virus was originally isolated from a patient with COVID-19 (GenBank MN985325). The cultivated virus titered by an infectious test and subsequently heat inactivated by the vendor (Zeptometrix Catalog # 0810587CFHI-0.5mL). Viral inactivation was verified by the absence of viral growth in tissue culture-based infectivity assays.

A preliminary LoD was determined by testing in triplicate 10-fold serial dilutions of the virus stocks spiked into pooled negative nasopharyngeal swab (NPS) matrix. NPS samples were collected in Puritan UniTranz-RT 3mL Universal Transport Solution (SKU#: UT-300). The collected NPS matrix samples were qualified as negatives by RT- PCR before using them for virus spiking. The limit of detection was defined as the lowest concentration at which each target is detected at least 95% of the time.

LoD of the Fluxergy HVRe Influenza/RSV/SARS-CoV-2 in pooled NPS matrix

Virus/Strain	LoD Concentration
Influenza A Virus, A/Netherlands/22/2003 (H3N2)	25 $TCID_{50}$/ mL
Influenza B Virus, B/Nevada/03/2011 (Victoria Lineage)	25 $TCID_{50}$/ mL
Human Respiratory Syncytial Virus, A2000/3-4	5 $TCID_{50}$/ mL
SARS-CoV-2 (Isolate: USA-WA1/2020) Culture Fluid (Heat Inactivated)	2.5 $TCID_{50}$/ mL

12.2.2 Inclusivity – Analytical Reactivity

The oligo designs for SARS-CoV-2 of the Fluxergy HVRe Influenza/RSV/SARS-CoV-2 is identical to the previously cleared CE-marked Fluxergy Test Kit COVID-19. See below for the previously reported analytical reactivity/inclusivity of SARS-CoV-2. Refer to the IFU of the Fluxergy Test Kit COVID-19[9] for a detailed report.

In-Silico Inclusivity Report (SARS-CoV-2)

Database	% Identity to N gene		% Identity to ORF1ab	
	Probe (% Match)	Primers (% Match)	Probe (% Match)	Primers (% Match)
NCBI	5049/5055*(99.88%)	5055/5055(100%)	4497/4541*(99.03%)	4507/4541*(99.25%)
GISAID	49073/49597*(98.95%)	49482/49597*(99.77%)	49512/49597*(99.83%)	49535/49597*(99.87%)

** The nucleotide mismatches have no predicted impact on the assay performance.*

The inclusivity of the Fluxergy HVRe Influenza/RSV/SARS-CoV-2 was evaluated using *in-silico* analysis of the assay primers and probes against 5,000 Influenza A sequences available in the National Center for Biotechnology Information (NCBI) databases for two gene targets, PB2 and PA.

The analysis demonstrated that the regions recognized by the Fluxergy HVRe Influenza/RSV/SARS-CoV-2's primers and probes have >= 99.20% homology with all available Influenza A sequences.

The nucleotide mismatches observed were predicted to have no impact on the assay performance. In addition, a two- target assay design mitigates the occurrence of false negative results due to failure to amplify the individual target sequences.

In-Silico Inclusivity Report (Influenza A)

Database	% Identity to PB2 gene		% Identity to PA gene	
	Probe (% Match)	Primers (% Match)	Probe (% Match)	Primers (% Match)
NCBI	4999/4999*(100%)	4960/5000 (99.20%)	4999/4999*(100%)	4970/4999*(99.42%)

** The nucleotide mismatches have no predicted impact on the assay performance.*

The inclusivity of the Fluxergy HVRe Influenza/RSV/SARS-CoV-2 was evaluated using *in-silico* analysis of the assay primers and probes against 5,000 Influenza B sequences available in the National Center for Biotechnology Information (NCBI) databases for the PA gene target.

The analysis demonstrated that the regions recognized by the Fluxergy HVRe Influenza/RSV/SARS-CoV-2's primers and probes have >= 99.90% homology with all available Influenza B sequences.

The nucleotide mismatches observed were predicted to have no impact on the assay performance.

In-Silico Inclusivity Report (Influenza B)

Database	% Identity to PA gene	
	Probe (% Match)	Primers (% Match)
NCBI	4998/5000*(99.96%)	4994/5000 (99.96%)

** The nucleotide mismatches have no predicted impact on the assay performance.*

The inclusivity of the Fluxergy HVRe Influenza/RSV/SARS-CoV-2 was evaluated using *in-silico* analysis of the assay primers and probes against 5,000 RSV sequences available in the National Center for Biotechnology Information (NCBI) databases for the M (matrix protein) gene.

The analysis demonstrated that the regions recognized by the Fluxergy HVRe Influenza/RSV/SARS-CoV-2's primers and probes have >= 98.80% homology with all available RSV sequences.

The nucleotide mismatches observed were predicted to have no impact on the assay performance.

In-Silico Inclusivity Report (RSV)

Database	% Identity to M (matrix protein) gene		
	Probe (% Match)	Forward Primers (% Match)	Reverse Primers (% Match)
NCBI	4231/4265*(99.20%)	4973/4999 (99.48%)	4134/4184*(98.80 %)

** The nucleotide mismatches have no predicted impact on the assay performance.*

12.2.3 Cross-Reactivity – Analytical Specificity

The oligo designs for SARS-CoV-2 of the Fluxergy HVRe Influenza/RSV/SARS-CoV-2 is identical to the previously cleared CE-marked Fluxergy Test Kit COVID-19. See below for the previously reported analytical reactivity/inclusivity of SARS-CoV-2. Refer to the IFU of the Fluxergy Test Kit COVID-19 for a detailed report.

Cross-Reactivity of Fluxergy HVRe Influenza/RSV/SARS-CoV-2
(Wet Lab Testing for SARS-CoV-2)

Organism	Strain	Cat # (BEI Resources)	Concentration
Bordetella holmesii	H785	NR-44175	2.04 x 10^8 copies/mL*
Candida albicans	23R	NR-29339	2.2 x 10^7 copies/mL*
Enterovirus D68	US/IL/14-18952	NR-49131	1.6 x 10^7 $TCID_{50}$/mL
Haemophilus haemolyticus	F0397	HM-469	7.5 x 10^7 /mL*
Human Coronavirus NL63	NL63	NR-470	5.5 x 10^5 $TCID_{50}$/mL
Human respiratory syncytial A	A2000/3-4	NR-28530	2.8 x 10^6 $TCID_{50}$/mL
Human respiratory syncytial B	B1	NR-4052	4.4 x 10^5 $TCID_{50}$/mL
Influenza A virus (H1N1)	A/Beijing/262/1995 (H1N1)	NR-12277	2.8 x 10^8 $CEID_{50}$/mL
Influenza A virus (H3N2)	A/Brisbane/10/2007 (H3N2)	NR-12283	2.2 x 10^8 $CEID_{50}$/mL
Influenza A Virus pdm09	A/NewYork/18/2009 (H1N1)pdm09	NR-49451	1.3 x 10^{10} copies/ mL*
Influenza B virus (Victoria)	B/Brisbane/60/2008	NR-42005	6.25 x 10^6 $CEID_{50}$/mL
MERS-Coronavirus	EMC/2012	NR-50549	8.9 x 10^5 $TCID_{50}$/mL
Pseudomonas aeruginosa	EnvKY1	NR-51329	1.4 x 10^7 copies/mL*
Rhinovirus 50	A2 #58	NR-51455	2 x 10^6 $TCID_{50}$/mL
SARS-CoV	Urbani strain	NR-9548	1 x 10^8 pfu/mL
Staphylococcus epidermidis	VCU013	NR-9548	8.5 x 10^5 copies/mL
Streptococcus pneumoniae	EMC23F	NR-51859	4.18 x 10^6 copies/mL*
Streptococcus pyogenes	ABC020063118	NR-48702	6.3 x 10^6 copies/mL*

* *copies/mL, calculated based on the total nucleic acid concentration of extracted stock material.*

Cross-Reactivity of Fluxergy HVRe Influenza/RSV/SARS-CoV-2
(*in silico* analysis for SARS-CoV-2)

Organism	In-Silico Analysis for % Identity*	
	nCoV- N gene	nCoV- orf1ab gene
Adenoviridae (taxid:10508)	No significant similarity found	No significant similarity found
Human metapneumovirus (taxid:162145)	No significant similarity found	No significant similarity found
Human parainfluenza virus 1 (taxid:12730)	No significant similarity found	No significant similarity found
Human parainfluenza virus 2 (taxid:1979160)	No significant similarity found	No significant similarity found
Human parainfluenza virus 3 (taxid:11216)	No significant similarity found	No significant similarity found
Human parainfluenza virus 4 (taxid:1979161)	No significant similarity found	No significant similarity found
Chlamydia pneumoniae (taxid:83558)	No significant similarity found	No significant similarity found
Haemophilus (taxid:724)	No significant similarity found	No significant similarity found
Streptococcus pneumoniae (taxid:1313)	No significant similarity found	No significant similarity found
Streptococcus pyogenes (taxid:1314)	No significant similarity found	No significant similarity found
Bordetella pertussis (taxid:520)	No significant similarity found	No significant similarity found
Bordetella holmesii (taxid:35814)	No significant similarity found	No significant similarity found
Mycoplasma pneumoniae (taxid:2104)	No significant similarity found	No significant similarity found
Pneumocystis jirovecii (taxid:42068)	No significant similarity found	No significant similarity found
Parechovirus (taxid:138954)	No significant similarity found	No significant similarity found
Candida albicans (taxid:5476)	No significant similarity found	No significant similarity found
Corynebacterium diphtheriae (taxid:1717)	No significant similarity found	No significant similarity found
Legionella (taxid:445)	No significant similarity found	No significant similarity found
Bacillus anthracis (taxid:1392)	No significant similarity found	No significant similarity found
Moraxella catarrhalis (taxid:480)	No significant similarity found	No significant similarity found
Neisseria elongata (taxid:495)	No significant similarity found	No significant similarity found
Neisseria meningitidis (taxid:487)	No significant similarity found	No significant similarity found
Pseudomonas aeruginosa group (taxid:136841)	No significant similarity found	No significant similarity found
Staphylococcus epidermidis (taxid:1282)	No significant similarity found	No significant similarity found
Leptospiraceae (taxid:170)	No significant similarity found	No significant similarity found
Chlamydia psittaci (taxid:83554)	No significant similarity found	No significant similarity found
Coxiella burnetii (taxid:777)	No significant similarity found	No significant similarity found
Staphylococcus aureus (taxid:1280)	No significant similarity found	No significant similarity found
Adenoviridae (taxid:10508)	No significant similarity found	No significant similarity found
Mycobacterium tuberculosis (taxid:1773)	No significant similarity found	No significant similarity found
Streptococcus salivarius (taxid:1304)	No significant similarity found	No significant similarity found
Human coronavirus 229E (taxid:11137)	No significant similarity found	No significant similarity found
Human coronavirus OC43 (taxid:31631)	No significant similarity found	No significant similarity found
Human coronavirus HKU1 (taxid:290028)	No significant similarity found	No significant similarity found

* *The amplicon sequences were blasted against low stringency filter [Somewhat similar sequences (blastn)].No alignment showed >70% homology and hence no potential for cross-reactivity.*

The in-silico cross-reactivity of Fluxergy HVRe Influenza/RSV/SARS-CoV-2 assays forward primers, reverse primers, and probe sequences (12 sequences – 6 for Influenza A, 3 for Influenza B, and 3 for RSV) were conducted by blasting sequences individually against the following 34 taxids, using low stringency filter (blastn).

Cross-Reactivity of Fluxergy HVRe Influenza/RSV/SARS-CoV-2
(*in silico* analysis for Influenza A, Influenza B, and RSV)

Organism	In-Silico Analysis for % Identity*			
	Influenza A (PB2 gene)	Influenza A (PA gene)	Influenza B (PA gene)	RSV (M gene)
Adenoviridae (taxid:10508)	No significant similarity found	No significant similarity found	No significant similarity found	No significant similarity found
Human metapneumovirus (taxid:162145)	No significant similarity found	No significant similarity found	No significant similarity found	No significant similarity found
Human parainfluenza virus (taxid:11216)	No significant similarity found	No significant similarity found	No significant similarity found	No significant similarity found
Human parainfluenza virus (taxid:12730)	No significant similarity found	No significant similarity found	No significant similarity found	No significant similarity found
Chlamydia pneumoniae (taxid:83558)	No significant similarity found	No significant similarity found	No significant similarity found	No significant similarity found
Haemophilus (taxid:724)	No significant similarity found	No significant similarity found	No significant similarity found	No significant similarity found
Streptococcus pneumoniae (taxid:1313)	No significant similarity found	No significant similarity found	No significant similarity found	No significant similarity found
Streptococcus pyogenes (taxid:1314)	No significant similarity found	No significant similarity found	No significant similarity found	No significant similarity found
Bordetella pertussis (taxid:520)	No significant similarity found	No significant similarity found	No significant similarity found	No significant similarity found
Bordetella holmesii (taxid:35814)	No significant similarity found	No significant similarity found	No significant similarity found	No significant similarity found
Mycoplasma pneumoniae (taxid:2104)	No significant similarity found	No significant similarity found	No significant similarity found	No significant similarity found
Pneumocystis jirovecii (taxid:42068)	No significant similarity found	No significant similarity found	No significant similarity found	No significant similarity found
Parechovirus (taxid:138954)	No significant similarity found	No significant similarity found	No significant similarity found	No significant similarity found
Candida albicans (taxid:5476)	No significant similarity found	No significant similarity found	No significant similarity found	No significant similarity found
Corynebacterium diphtheriae (taxid:1717)	No significant similarity found	No significant similarity found	No significant similarity found	No significant similarity found
Legionella (taxid:445)	No significant similarity found	No significant similarity found	No significant similarity found	No significant similarity found
Bacillus anthracis (taxid:1392)	No significant similarity found	No significant similarity found	No significant similarity found	No significant similarity found
Moraxella catarrhalis (taxid:480)	No significant similarity found	No significant similarity found	No significant similarity found	No significant similarity found
Neisseria elongata (taxid:495)	No significant similarity found	No significant similarity found	No significant similarity found	No significant similarity found
Neisseria meningitidis (taxid:487)	No significant similarity found	No significant similarity found	No significant similarity found	No significant similarity found
Pseudomonas aeruginosa group (taxid:136841)	No significant similarity found	No significant similarity found	No significant similarity found	No significant similarity found
Staphylococcus epidermidis (taxid:1282)	No significant similarity found	No significant similarity found	No significant similarity found	No significant similarity found
Leptospiraceae (taxid:170)	No significant similarity found	No significant similarity found	No significant similarity found	No significant similarity found
Chlamydia psittaci (taxid:83554)	No significant similarity found	No significant similarity found	No significant similarity found	No significant similarity found
Coxiella burnetii (taxid:777)	No significant similarity found	No significant similarity found	No significant similarity found	No significant similarity found
Staphylococcus aureus (taxid:1280)	No significant similarity found	No significant similarity found	No significant similarity found	No significant similarity found
Adenoviridae (taxid:10508)	No significant similarity found	No significant similarity found	No significant similarity found	No significant similarity found

Cross-Reactivity of Fluxergy HVRe Influenza/RSV/SARS-CoV-2
(*in silico* analysis for Influenza A, Influenza B, and RSV)

Organism	In-Silico Analysis for % Identity*			
	Influenza A (PB2 gene)	Influenza A (PA gene)	Influenza B (PA gene)	RSV (M gene)
Mycobacterium tuberculosis (taxid:1773)	No significant similarity found	No significant similarity found	No significant similarity found	No significant similarity found
Streptococcus salivarius (taxid:1304)	No significant similarity found	No significant similarity found	No significant similarity found	No significant similarity found
Human coronavirus 229E (taxid:11137)	No significant similarity found	No significant similarity found	No significant similarity found	No significant similarity found
Human coronavirus OC43 (taxid:31631)	No significant similarity found	No significant similarity found	No significant similarity found	No significant similarity found
Human coronavirus HKU1 (taxid:290028)	No significant similarity found	No significant similarity found	No significant similarity found	No significant similarity found
Candida albicans (taxid:5476)	No significant similarity found	No significant similarity found	No significant similarity found	No significant similarity found
Rhinoviruses (taxid:12059)	No significant similarity found	No significant similarity found	No significant similarity found	No significant similarity found

* *The amplicon sequences were blasted against low stringency filter [Somewhat similar sequences (blastn)].No alignment showed >70% homology and hence no potential for cross-reactivity.*

Based on the combined wet lab testing and in silico analysis, there is no potential unintended cross-reactivity with other organisms listed in the tables above.

12.2.4 Interference Study[10]

The oligo designs for SARS-CoV-2 of the Fluxergy HVRe Influenza/RSV/SARS-CoV-2 is identical to the previously cleared CE-marked Fluxergy Test Kit COVID-19. See below for the previously reported interference study of SARS-CoV-2. Refer to the IFU of the Fluxergy Test Kit COVID-19 for a detailed report.

Assay Interference Verification (Fluxergy Test Kit COVID-19)

Potential Interfering Substance	Active Ingredient	Concentration Tested	SARS-CoV-2 Detection (#Detected / #Tested)	IC % Detection (#Detected / #Tested)
Decongestant	Afrin Nasal Spray-Oxymetazoline	15% (v/v)	100% (3/ 3)	100% (3/ 3)
Antibacterial	Tobramycin	4 µg/mL	100% (3/ 3)	100% (3/ 3)
Antibiotic	Amoxicillin	0.5 mg/mL	100% (3/ 3)	100% (3/ 3)
Antibiotic	Cephalexin	0.04 mg/mL	100% (3/ 3)	100% (3/ 3)
Antibiotic	Clindamycin	0.03 mg/mL	100% (3/ 3)	100% (3/ 3)
Antibiotic	Erythromycin	1 mg/mL	100% (3/ 3)	100% (3/ 3)
Antibiotic	Mupirocin	6.6 mg/mL	100% (3/ 3)	100% (3/ 3)
Antibiotic	Penicillin	1200 U/mL	100% (3/ 3)	100% (3/ 3)
Antiviral Drug	Zanamivir	3.3 mg/mL	100% (3/ 3)	100% (3/ 3)
Aspirin	Aspirin	0.62 mg/mL	100% (3/ 3)	100% (3/ 3)
Benadryl	Diphenhydramine	10 µL/Rxn	100% (3/ 3)	100% (3/ 3)
Blood	N/A	2% (v/v)	100% (3/ 3)	100% (3/ 3)
Corticosterone	Corticosterone	4 mg/swab	100% (3/ 3)	100% (3/ 3)
Corticosterone	Fluticasone	5% (v/v)	100% (3/ 3)	100% (3/ 3)
Mucin Protein	Bovine	60 µg/mL	100% (3/ 3)	100% (3/ 3)

Assay Interference Verification (Fluxergy Test Kit COVID-19)

Potential Interfering Substance	Active Ingredient	Concentration Tested	SARS-CoV-2 Detection (#Detected / #Tested)	IC % Detection (#Detected / #Tested)
Neo-Synephrine	Phenylephrine HCl	0.16 mg/mL	100% (3/ 3)	100% (3/ 3)
Nyquil	Dextromethorphan; Hydrobromide; Doxylamine Succinate	1/200 Dilution	100% (3/ 3)	100% (3/ 3)
Pain Medication	Acetaminophen	1 mg/mL	100% (3/ 3)	100% (3/ 3)
Pain Medication	Nonsteroidal anti-inflammatory drug	1 mg/mL	100% (3/ 3)	100% (3/ 3)
Robitussin Cough	Dextromethorphan HBr; Guaifenesin	2.0 mg/mL	100% (3/ 3)	100% (3/ 3)
Tamiflu Antiviral Drug	Oseltamivir	1 µM	100% (3/ 3)	100% (3/ 3)
Nasal Spray	Saline	15% (v/v)	100% (3/ 3)	100% (3/ 3)
Sore Throat Lozenge	Menthol	1 mg/mL	100% (3/ 3)	100% (3/ 3)
Sore Throat Lozenge	Zinc GluconateGlycine	1 mg/mL	100% (3/ 3)	100% (3/ 3)
Zicam Nasal Gel	Oxymetazoline hydrochloride	5% (v/v)	100% (3/ 3)	100% (3/ 3)
NA	Non-spike Control	3x LoD	100% (3/ 3)	100% (3/ 3)

Potential interfering substances from upper respiratory specimens were tested using samples containing the virus stocks at 3x LoD in nuclease free water. Testing was performed with the Fluxergy HVRe Influenza/RSV/SARS-CoV-2 using the Fluxergy Analyzer and included triplicate testing per substance at the indicated levels.

Assay Interference Verification (Fluxergy HVRe Influenza/RSV/SARS-CoV-2)

Potential Interfering Substance	Active Ingredient	Concentration Tested	Viruses Tested	Influenza Detection (#Detected / #Tested)	RSV Detection (#Detected / #Tested)	SARS-CoV-2 Detection (#Detected / #Tested)
Decongestant	Afrin Nasal Spray-Oxymetazoline	15% (v/v)	Flu A + RSV	5/5	4/5*	0/5
Blood	N/A	2% (v/v)	Flu B + SARS-CoV2	4/5*	0/5	4/5*
Antiviral Drug	Zanamivir	3.3 mg/mL	RSV + SARS-CoV2	0/3	3/3	3/3
Zicam Nasal Gel	Oxymetazoline hydrochloride	5% (v/v)	RSV + SARS-CoV2	0/5	5/5	4/5*
Antibiotic	Penicillin	1200 U/mL	Flu A + RSV	5/5	4/5*	0/5
Aspirin	Aspirin	0.62 mg/mL	Flu A + SARS-CoV2	3/3	0/3	3/3
Benadryl	Diphenhydramine	0.025 mg/mL	Flu A + SARS-CoV2	3/3	0/3	3/3
Nyquil	Dextromethorphan, Hydrobromide; Doxylamine Succinate	1/400 Dilution	RSV + SARS-CoV2	0/5	5/5	4/5*
Pain Medication	Tylenol	1 mg/mL	Flu A + RSV	5/5	4/5*	0/5
Sore Throat Lozenge	Menthol	1 mg/mL	Flu B + SARS-CoV2	4/5*	0/5	3/5*

* *Additional runs were added, and the result was determined by the majority.*

13. Symbols and Marking

13.1 Symbols on Packaging

Symbol	Meaning
CE	The Fluxergy product conforms to DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 1998 on in vitro diagnostic medical devices.
IVD	This symbol indicates that the product is for In Vitro Diagnostic use.
www.fluxergy.com/downloads	The instructions for use are either included or available for download electronically from the website shown.
10	This symbol indicates the number of pieces in the package (10).
100	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. ISO 15223-1:2016 (5.3.4)
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.
UDI	Indicates the unique device identification data.
	Indicates methods to contact customer support.
REF	Indicates the Fluxergy catalogue number so that the medical device can be identified.
SN	Indicates the Fluxergy serial number so that a specific medical device can be identified.
LOT	Identifies the manufacturer's batch or lot code.
126 µl	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 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.

Symbol	Meaning
	Test Card image.
	Indicates the medical device manufacturer, as defined in EU Directive 98/79/EC. This symbol is used to identify the name and address of company that manufactured the product.
EC REP	Indicates the authorized representative in the European Community.
CH REP	Indicates the authorized representative in Switzerland.

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 HVRe Influenza/RSV/SARS-CoV-2 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 Headquarter's 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

14.2.3 Contact us by Phone

+1 (949) 305-4201 US & International

14.3 Authorized Representative

EC REP

CMC Medical Devices & Drugs S.L.
C/ Horacio Lengo N° 18
CP 29006 Málaga, Spain

CH REP

CMC Medical Devices GmbH
Bahnhofstrasse 32
CH- 6300 Zug, Switzerland

15. References

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[4] Centers for Disease Control and Prevention. Interim Guidelines for Collecting and Handling of Clinical Specimens for COVID-19 Testing https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical- specimens.html

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