INSTRUCTIONS FOR USE

FLUXERGY Repiratory Specimen Collector

REF **8041 / 8044 / 8074 / 8077**

In Vitro **Diagnostic Medical Device**

CE IVD

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Instructions For Use (PN: 7977A00)
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1. Intended Use

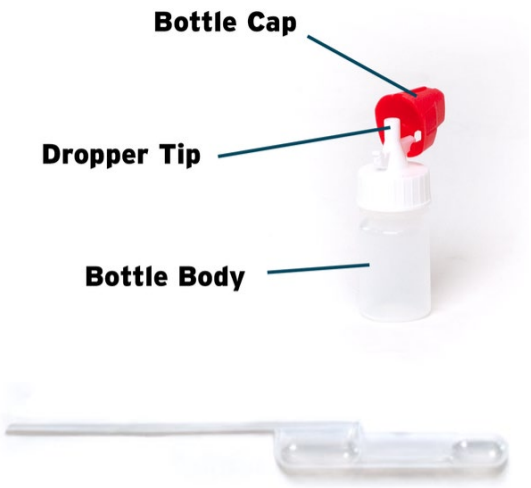
The Fluxergy Respiratory Specimen Collector is a sample collection device that is used to store a buffer solution to prepare clinical samples collected from various parts of the nasal cavity. The device is used to dilute, store, and prepare the samples for specific assays on test cartridges.

The Fluxergy Respiratory Specimen Collector is intended for low to moderate complexity laboratories with a CLIA waiver.

2. Principles of the Procedure

2.1 Overview (Dual-Step Workflow)

The Fluxergy Respiratory Specimen Collector will assist users with preparing, diluting, and storing samples for various assays. If sample preparation with a viral-transport-medium in a separate tube is required, the user will transfer the viral-transport-medium and sample mix to the dropper bottle using a transfer pipette. More detailed instructions can be found in section 6.



2.1.1 Dropper Bottle (5mL)

The 5mL dropper bottle is a disposable bottle in which the diluent solution mixed with test sample is manually dispensed into the assay-specific test cartridge.

2.1.2 Transfer Pipette (120µL)

The transfer pipette is a disposable pipette used to transfer diluent solution and/or sample into the dropper bottle.

2.1.3 Process

For assays where a viral-transport-medium is required, the tube containing the viral-transport-medium and sample will be mixed before a transfer pipette is used to transfer the liquid to the 5mL dropper bottle. Next, the user inverts the dropper bottle to mix followed by opening the dropper nozzle and dispensing into an assay-specific test cartridge.

2.2 Overview (Single-Step Workflow)

The Fluxergy Respiratory Specimen Collector will assist users with preparing, diluting, and storing samples for various assays. If the sample does not require prior preparation with viral-transport-medium in a separate tube, the user can directly insert the nasal swab into the dropper bottle. More detailed instructions can be found in section 6.

2.2.1 Dropper Bottle (50mL)

The 50mL dropper bottle is a disposable bottle in which the diluent solution mixed with test sample is manually dispensed into the assay-specific test cartridge.

2.2.2 Process

For assays where a viral-transport-medium is not required, a nasal swab will be placed into the 50mL dropper bottle with assay-specific` diluent solution. Once the bottle is capped, the user will shake to mix then squeeze the dropper bottle dispense the fluid (through the dropper tip) into an assay-specific test cartridge.

3. Materials and Instruments

The Fluxergy Respiratory Specimen Collector is to be used with the following instrument, reagents, and supplies:

3.1 Materials Provided

The Fluxergy Respiratory Specimen Collector contains sufficient reagents and consumables to test a single specimen.

3.1.1 Dual-Step Workflow

The Fluxergy Respiratory Specimen Collector is packaged and sold in 10pk and 100pk as kits:

- CAT #8041 (10-pack with 5mL dropper bottle containing diluent solution and 120µL transfer pipette)
- CAT #8044 (100-pack with 5mL dropper bottle containing diluent solution and 120µL transfer pipette)

3.1.2 Single-Step Workflow

The Fluxergy Respiratory Specimen Collector is packaged and sold in 10pk and 100pk as kits:

- CAT #8074 (10-pack with 50mL dropper bottle containing diluent solution)
- CAT #8077 (100-pack with 50mL dropper bottle containing diluent solution)

3.2 Storage and Handling

- Store the Respiratory Specimen Collector at 15 to 30°C.
- Do not open individual Respiratory Specimen Collector packaging until you are ready to test.

3.3 Materials Required but Not Provided

- Nasal Swab
  - Refer to assay-specific IFU for acceptable swab types.
- Viral transport medium
  - Refer to assay-specific IFU for acceptable viral transport medium types.
- Barcode scanner
  - Supported Barcode Formats (minimum requirement): 2D Data Matrix, 2D GS1 Data Matrix
- Instructions and Documents
  - Instructions for Use, SDS, and additional resource documents can be found at www.fluxergy.com/downloads

4. Warnings and Precautions

4.1 General

- For *in vitro* diagnostic use.
- Authorized for use only with the equipment, materials, and supplies indicated in Section 3. Use with equipment, materials, and supplies other than those indicated above in Section 3 may cause errors and erroneous results.
- All biological specimens, including 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 in Microbiological and Biomedical Laboratories – 6th Edition (cdc.gov) [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]
- Dispose of materials used with this device, including reagents, samples, and used buffer tubes, according to local regulations.

4.2 Test/Reagent

- Do not use components that are damaged.
- Each single-use Fluxergy Respiratory Specimen Collector is used to process one sample. Don't reuse processed dropper bottle or transfer pipette.
- Each transfer pipette is used to transfer one sample.
- Prior to processing samples, thoroughly clean both the work area with a suitable cleaner such as freshly prepared10% bleach or a similar disinfectant.
- Fluxergy Respiratory Specimen Collector, and samples should be handled and tested one-at-a-time.
- Use clean gloves to remove materials from bulk packaging and reseal bulk-packaging when not in use.
- **Always check the expiration date on the Respiratory Specimen Collector. Do not use kit components after the expiration date.**

5. Sample Requirements

5.1 Sample Type and Sample Volume

Assay-specific.

5.2 Transport and Storage

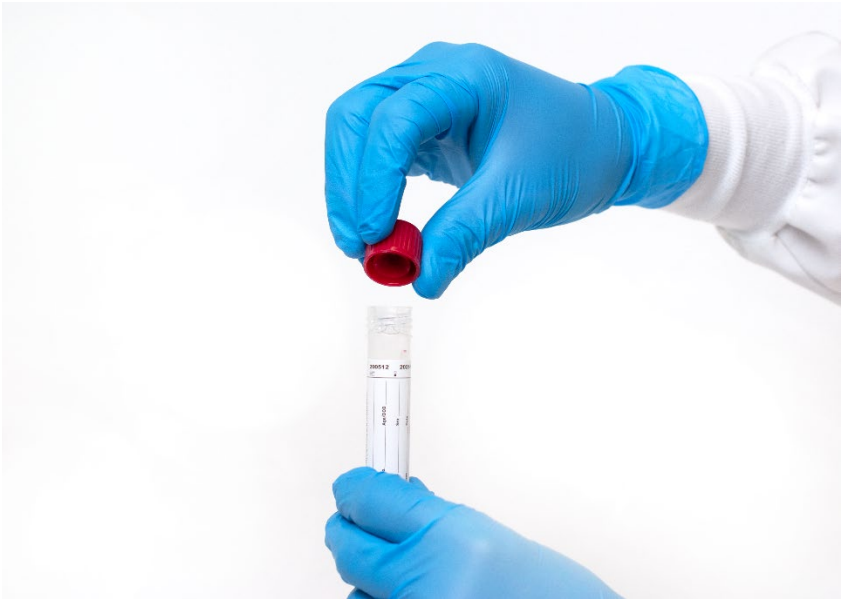
Assay-specific.

6. Test Procedure

6.1 Sample Collection

Refer to assay-specific IFU for patient sample collection.

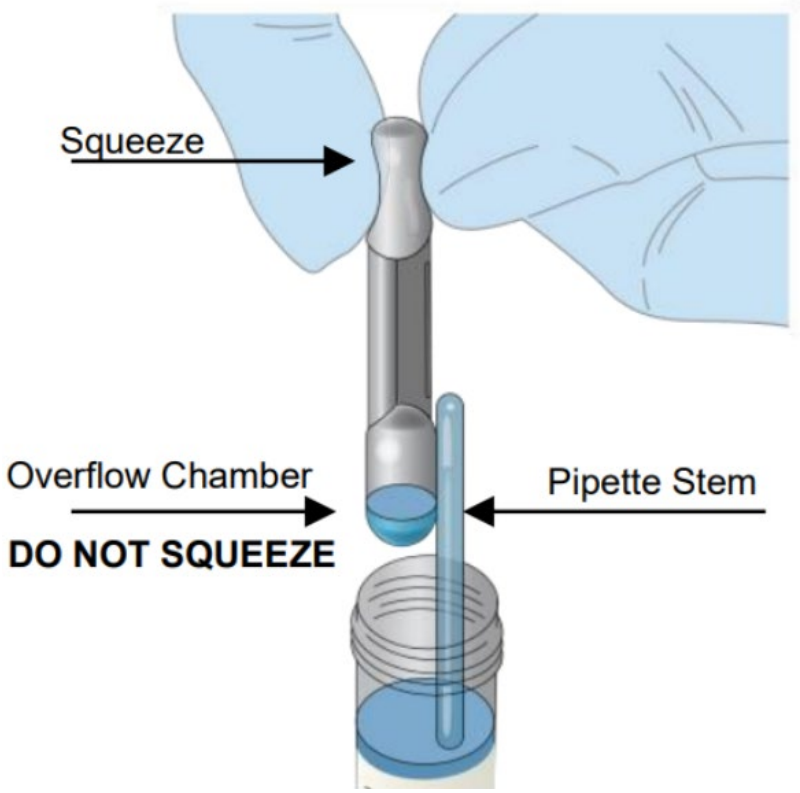
6.2 Dual-Step Workflow



1. Shake the viral-transport-medium tube containing patient sample for 15 seconds.

2. Uncap the viral-transport-medium tube containing patient sample

3. Uncap the dropper bottle



4. Use the transfer pipette to draw the sample in viral-transport-medium. 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/viral-transport-medium 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.

5. 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.

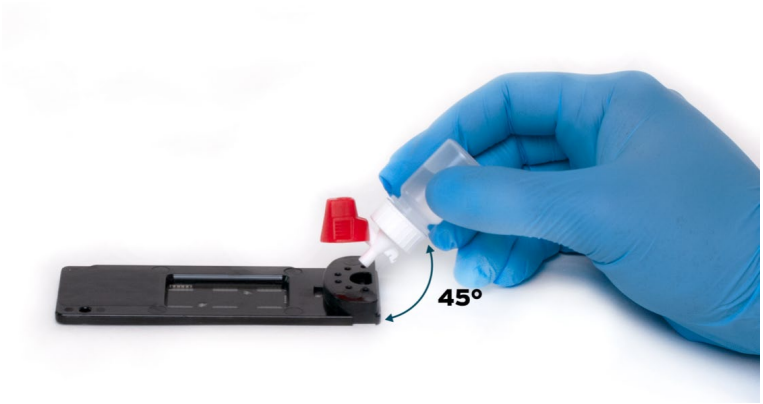
6. **Firmly** squeeze the TOP bulb of the pipette to completely dispense the liquid in pipette stem into the dropper bottle.

7. Recap the dropper bottle.

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

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

   WARNING: *Follow appropriate guidelines for laboratory biosafety protocols.* [1-2]



10. Squeeze the dropper bottle to dispense assay-specific* number of drops of fluid into the test cartridge.

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

    **See assay-specific IFU*

6.3 Single-Step Workflow

1. Collect patient sample via appropriate nasal swab.*

   **See assay-specific IFU for detailed instructions*

2. Uncap the dropper bottle.

3. Insert and snap off the nasal swab* into the dropper bottle.

   **See assay-specific IFU for swab type*

4. Recap the dropper bottle.

5. Vigorously shake the dropper bottle for 15 seconds to mix the sample and diluent together.

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

   WARNING: *Follow appropriate guidelines for laboratory biosafety protocols. 1 3*

7. Squeeze the dropper to dispense assay-specific* number of drops of fluid into the test cartridge.

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

**Refer to assay-specific IFU*

7. Quality Control

Not applicable.

8. Limitations

Not applicable.

9. Conditions of Use for the Laboratory

- For *in vitro* diagnostic use.
- 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.

10. Performance Evaluation

See initial validated performance in the Fluxergy HVRe Influenza/RSV/SARS-CoV-2 IFU.[4]

11. Symbols and Marking

11.1 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 available for download electronically from the websiteshown.
10	This symbol indicates the number of pieces in the package (10).
100	This symbol indicates the number of pieces in the package (100).
	Transfer Pipette Image.
	Dropper Bottle Image.

Symbol	Meaning
	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.
	Indicates that the transport package shall be kept away from rain and in dry conditions.
	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.
	Identifies the manufacturer's batch or lot code.
	Indicates the medical device manufacturer. This symbol is used to identify the name and address of company that manufactured the product.
	Indicates methods to contact customer support.
	Indicates the authorized representative in the European Community.
	Indicates the authorized representative in Switzerland.

11.2 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 PCR Card 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.

12. Contact and Legal Information

12.1 Fluxergy Headquarter's Location

FLUXERGY
30 Fairbanks, Suite 110 Irvine, CA 92618
USA

12.2 Customer and Technical Support

12.2.1 Contact us by Mail

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

12.2.2 Contact us by Email

customersupport@fluxergy.com

12.2.3 Contact us by Phone

+1 (949) 305-4201 US & International

12.3 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

13. References

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

[2] World Health Organization, *Laboratory Biosafety Manual*, 4th Edition, CC BY-NC-SA 3.0 IGO, 2020.

[3] Clinical And Laboratory Standards Institute. Protection Of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline - Fourth Edition. CLSI M29-A4.

[4] Fluxergy Inc, *Fluxergy HVRe Influenza/RSV/SARS-CoV-2 IFU*, Current Revision