INSTRUCTIONS FOR USE

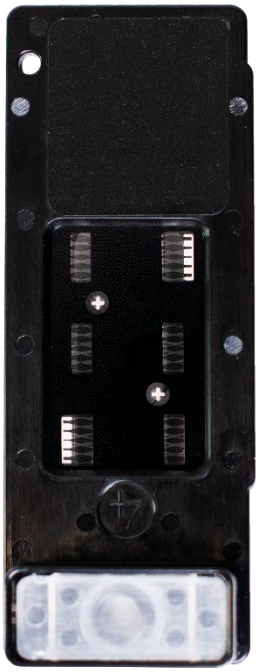
FLUXERGY PCR CARD

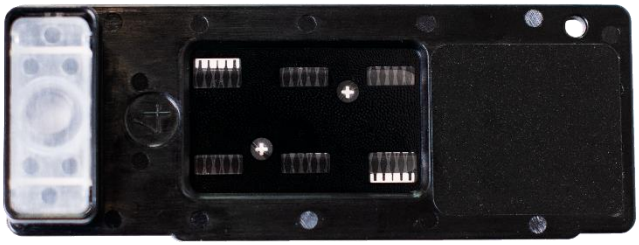
REF **5246-CE / 5527-CE / 5555 / 5558 / 8050 /8053**

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

***In Vitro* Diagnostic Medical Device**

CE IVD





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1. Intended Use

The Fluxergy PCR Card is a disposable card into which the PCR reagents mixed with test samples are manually pipetted in. 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. The Fluxergy PCR Card is used as an accessory with the Fluxergy Analyzer in real-time (RT) polymerase chain reaction (PCR). Testing should be performed by laboratories or in other qualified professional care settings that meet their local registration or licensing requirements for testing.

The Fluxergy PCR Card is intended for use by qualified and trained laboratory personnel specifically instructed and trained in the techniques of real-time PCR.

2. Principles of the Procedure

2.1 Overview

The Fluxergy PCR Card assists in the processing, amplification, and detection of assay-specific DNA or RNA from validated clinical samples from suspected patients. The assay consists of one assay-specific reagents 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.

2.2 Fluxergy PCR Card

The Fluxergy PCR Card is a disposable card into whichthe PCR reagents mixed with test samples are manually pipetted in. 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.

2.3 Fluxergy Analyzer (Sold Separately)

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.

2.4 Process

A sample indicated by Fluxergy is collected in a viral transport media and is mixed with ready-to-use assay-specific reagents to prepare the complete test master mix (see assay-specific IFU). The master mix is then loaded onto the Fluxergy PCR Card. After loading the Fluxergy PCR Card into the Fluxergy Analyzer instrument, the run is initiated. Approximately in 1 hour, Fluxergy Works will complete the thermal cycling and analysis.

3. Materials and Instruments

The Fluxergy PCR Card is to be used with the following instrument, reagents, and supplies:

3.1 Materials Provided

The Fluxergy PCR Card is available in packs of 10 (CAT #5246-CE, 5555, 8050, or equivalent) or 100 (CAT #5527-CE, 5558, 8053, or equivalent).

3.2 Storage and Handling

- Store the Fluxergy PCR Card at 10 – 30°C.
- Do not open individual Fluxergy Card packaging until you are ready to test.

3.3 Materials Required but Not Provided

- Fluxergy Analyzer (CAT #5506-CE, or equivalent), sold separately
- Instructions and Documents
  - Instructions for Use and additional resource documents can be found at www.fluxergy.com/downloads

4. Warnings and Precautions

4.1 General

- 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 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 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.
- 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]

4.2 Test/Reagent

- Fluxergy PCR Card is only compatible and for use only with the Fluxergy Analyzer.
- Do not use a Fluxergy PCR Card that is damaged.

- Each single-use Fluxergy PCR Card is used to process one sample. Do not reuse processed Fluxergy PCR Card.
- Prior to processing samples, thoroughly clean both the work area with a suitable cleaner such as freshly prepared10% bleach or a similar disinfectant.
- Use clean gloves to remove materials from bulk packaging and reseal bulk-packaging when not in use (e.g.,Fluxergy Card bulk packaging).

5. Test Procedure

5.1 Setting up a Fluxergy Analyzer

Refer to the Fluxergy Analyzer IFU[4] 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 an assay, make sure the Fluxergy Analyzer is on and connected to the Fluxergy Works software.

5.2 Test Features

See assay-specific IFU.

5.3 Sample Collection

See assay-specific IFU.

6. Quality Control

See assay-specific IFU.

7. Interpretation of Results

See assay-specific IFU.

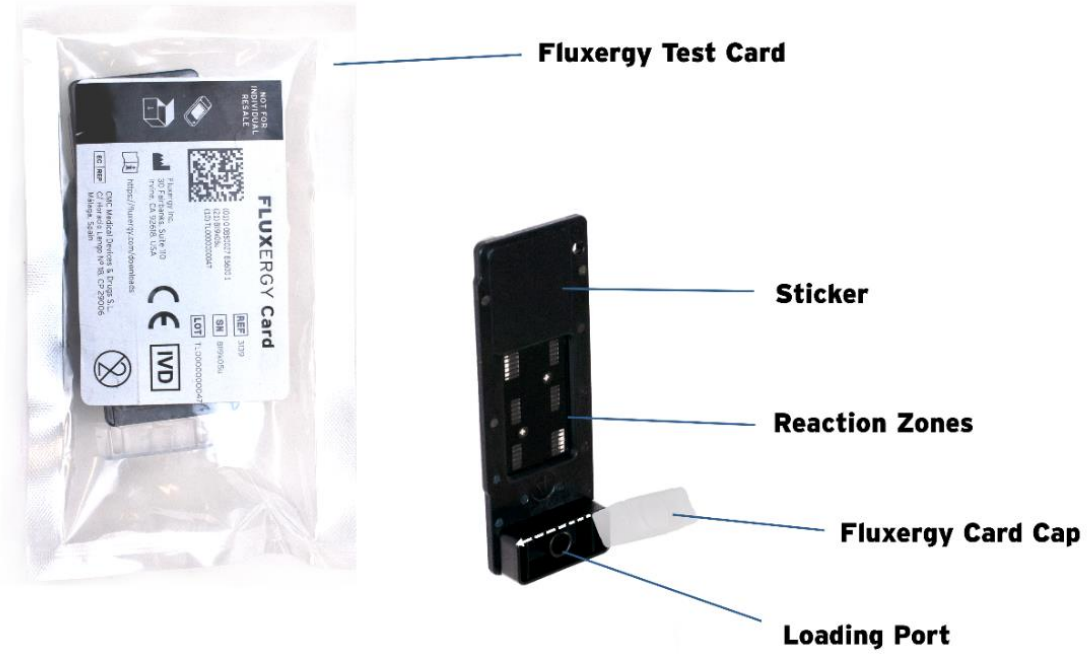
8. Conditions of Use for the Laboratory

See assay-specific IFU.

9. Performance Evaluation

See assay-specific IFU.

10. Test Card Overview



11. Symbols and Marking

11.1 Symbols on Packaging

Symbol	Meaning
	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.
	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.
	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.
	Indicates the authorized representative in the European Community.
	Indicates the authorized representative in Switzerland.
	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 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.

Symbol	Meaning
	Indicates methods to contact customer support.
	Test Card 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.

11.2 Symbols used in this manual

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, *IFU for the Fluxergy Analyzer System*, Current Revision