CEA FIA Rapid Test

(Serum/Plasma)

FIA-CEA-001

A rapid test for detecting Carcinoembryonic Antigen (CEA) in serum or plasma with the use of the Biopanda Fluorescence Immunoassay Analyser. For professional in vitro diagnostic use only.

INTENDED USE

The Biopanda CEA FIA Rapid Test is based on Fluorescence Immunoassay for the quantitative determination of Carcinoembryonic Antigen (CEA) in serum or plasma to aid in the monitoring of cancer patients.

SUMMARY

Carcinoembryonic Antigen (CEA) is a tumour associated antigen characterized as an oncofoetal glycoprotein.[1] CEA is expressed in a variety of malignancies, particularly pulmonary or gastrointestinal tumours (e.g. colon cancer, liver cancer and lung cancer). CEA normally occurs in foetal gut tissue with detectable serum levels essentially disappearing after birth.[2,3] Therefore, elevated levels of CEA can be of significant value in the diagnosis of primary carcinomas.

In addition to quantitative assessment, CEA testing plays an important role in the monitoring of cancer patients. Clinical evidence indicates that CEA levels can serve as predictive markers in both pre- and post-treatment of cancer. Progressive elevation of CEA may signal tumour recurrence 3-36 months before clinical evidence of metastasis. Persistent elevation of circulating CEA following treatment is strongly indicative of occult metastatic and residual diseases and deficient therapeutic response.[4]

PRINCIPLE

The CEA FIA Rapid Test Cassette detects CEA based on Fluorescence Immunoassay. The sample moves through the strip from sample pad to absorbent pad. If the specimen contains CEA, it attaches to the fluorescent microspheres-conjugated anti-CEA antibodies. Then the complex will be captured by the capture antibody coated on the nitrocellulose membrane. The concentration of CEA in the sample correlates with the fluorescence signal intensity captured on the T line. According to the fluorescence intensity of the test and product standard curve, the concentration of CEA in the sample can be calculated by the Biopanda Fluorescence Immunoassay Analyser to show CEA concentration in specimen.

REAGENTS

The test kit includes anti-CEA monoclonal antibody coated fluorophores and anti-CEA antibody coated on the membrane.

PRECAUTIONS

1. For professional *in vitro* diagnostic use only.
2. Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse.
3. Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
4. Do not eat, drink or smoke in the area where the specimens and tests are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
5. Do not interchange or mix reagents from different lots.
6. Humidity and temperature can adversely affect results.
7. Used testing materials should be discarded in accordance with local regulations.
8. Read the entire procedure carefully prior to any testing.
9. The Biopanda CEA FIA Rapid Test should only be used with the Biopanda Fluorescence Immunoassay Analyser by approved medical professionals.

STORAGE AND STABILITY

1. The kit should be stored at 4-30°C until the expiry date printed on the sealed pouch.
2. The test must remain in the sealed pouch until use.
3. Do not freeze.
4. Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

KIT COMPONENTS

- 10 x foil wrapped CEA test cassettes
- 10 x Specimen collection tubes with dilution buffer
- 1 x ID card (CEA)
- Package Insert

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer
- Centrifuge
- Pipette
- Biopanda Fluorescence Immunoassay Analyser

SPECIMEN COLLECTION AND PREPARATION

PREPARATION

1. Before performing the test, please make sure that all components are brought to room temperature (15-30^{o}C). Cold buffer solution or moisture condensation on the membrane can lead to invalid test results.
2. Take a tube with buffer solution out of the kit. Document patients name or ID on it. Open the screw cap.

BLOOD SAMPLE TAKING

1. Collect the specimen according to standard procedures.
2. Do not leave specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8 °C for up to 1 day, for long term storage, specimens should be kept below -20 °C.
3. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.
4. EDTA and Heparin sodium, can be used as the anticoagulant for collecting the specimen.

SAMPLE DILUTION / SAMPLE STABILITY

1. Transfer **50 µL of serum or plasma** to the buffer tube with a micro pipette.
2. Close the tube and shake the sample by hand vigorously for approximately **10 seconds** to mix the sample and dilution buffer.
3. Let the diluted sample homogenize for approximately 1 minute.
4. The diluted sample can then be used immediately or stored for up to 8 hours.

DIRECTIONS FOR USE

Refer to the Biopanda Fluorescence Immunoassay Analyser Operation Manual for the complete instructions on use of the Test. The test should be conducted at room temperature.

Allow the test, specimen, buffer and/or controls to reach room temperature (15-30°C) prior to testing.

1. Turn on the Analyser. Then according to the user requirement, select “Standard test” or “Quick test” mode.
2. Take out the ID card and insert it into the Analyser port.
3. **Serum/plasma**: Transfer 50 µl of serum/plasma into the buffer tube, mix the specimen and the buffer well.
4. **Add diluted specimen with a Pipette**: Pipette 75 µl of diluted specimen into the sample well of the test cassette. Start the timer at the same time.
5. There are two test modes for the Biopanda Fluorescence Immunoassay Analyser; Standard Test mode and Quick Test mode. Please refer to the user manual of the Biopanda Fluorescence Immunoassay Analyser for details.

“Quick test” mode: Insert the test cassette into the Analyser at 15 minutes after sample application and click "New Test", the Analyser will automatically give the test result after a few seconds.

“Standard test” mode: Insert the test cassette into the Analyser immediately after sample application, click "New test" at the same time, the Analyser will automatically count down the 15 minutes. After the countdown, the Analyser will give the result at once.

INTERPRETATION OF RESULTS

The result of tests for CEA is calculated by the Biopanda Fluorescence Immunoassay Analyser and displays the result on the screen. For additional information, please refer to the user manual of the Biopanda Fluorescence Immunoassay Analyser.

Linearity range of the Biopanda CEA FIA Rapid Test is 1-500 ng/ml.
Reference range: <4 ng/ml.

QUALITY CONTROL

Each Biopanda CEA FIA Rapid Test Cassette contains an internal control that satisfies routine quality control requirements. This internal control is performed each time a patient sample is tested. This control indicates that the test device was inserted and read properly by the Biopanda Fluorescence Immunoassay Analyser. An invalid result from the internal control causes an error message on the Biopanda Fluorescence Immunoassay Analyser indicating that the test should be repeated. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

LIMITATIONS

1. The Biopanda CEA FIA Rapid Test Cassette is for professional *in vitro* diagnostic use, and should only be used for the quantitative detection of CEA.
2. The Biopanda CEA FIA Rapid Test Cassette will only indicate the presence of CEA antigen in the specimen and should not be used as the sole criterion for the diagnosis of gastrointestinal tract tumours or other cancers.
3. As with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
4. The results of the Biopanda CEA FIA Rapid Tests are based on measuring the levels of CEA in a specimen. It should not be used as the sole criterion for treatment decisions. If the result is positive, other clinical findings and alternative test methods are recommended to reach proper medical treatments.

EXPECTED RESULTS

Concentrations	Clinical Reference
<4 ng/ml	Healthy
≥4 ng/ml	Risk of primary carcinomas

PERFORMANCE CHARACTERISTICS

1. **ACCURACY**: The test deviation is ≤±15%.
2. **DETECTION RANGE**: 1-500 ng/ml.
3. **LINEARITY RANGE**: 1-500 ng/ml, R≥0.990
4. **PRECISION**

INTRA-LOT PRECISION

Within-run precision has been determined by using 10 replicates of 2 specimens containing 4 ng/ml and 8 ng/ml of CEA. C.V. is ≤ 15%.

INTER-LOT PRECISION

Between-run precision has been determined by using 10 replicates for each of three lots using 2 specimens containing 4 ng/ml and 8 ng/ml of CEA. C.V. is ≤ 15%.

INTERFERING SUBSTANCES

The following substances do not interfere with the test results at the indicated concentrations: Ascorbic Acid at 200 mg/l, Hemoglobin at 10 g/l, Triglyceride at 30 g/l, Bilirubin at 1,000 mg/dl, Uric Acid at 200 mg/l.

METHOD COMPARISON

The assay was compared with Abbott CEA reagent kit with 100 samples. The correlation coefficient(r) is 0.976.

REFERENCES

1. Gold P and Freedman SO. Demonstration of Tumor-specific antigens in human colonic carcinomata by immunological tolerance and absorbtion. J. Exp. Med. 121:439, 1965.
2. Banjo C, Gold P, Freedman SO and Krupey J. Immunologically Active Heterosaccharides of the Carcinoembryonic Antigen (CEA) of the Human Digestive System, Nature, New Biol, 238,183, 1972.
3. Darcy DA, Turberville C, and Janes R. Immunological Study of Carcinoembryonic Antigen (CEA) and Related Glycoprotein, Br.J.Cancer, 28,147, 1973.
4. Phil Gold CC, and Goldenberg NA. The Carcinoembryonic Antigen (CEA): Past, Present, and Future. Perspectives in Colon and Rectal Surgery 9(2), 1996.

Index of Symbols

	Manufacturer		Tests per kit		Do not reuse test
IVD	*In vitro* diagnostic medical device		Expiration date	REF	Catalogue number
	Storage temperature	LOT	Lot Number		Consult instructions for use
	Do not use if package is damaged				

Thank you for purchasing Biopanda's CEA FIA Rapid Test. Please read this manual carefully before operating to ensure proper use.

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