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Tumor

AFIAS CEA

INTENDED USE

AFIAS CEA is a fluorescence Immunoassay (FIA) for the quantitative determination of CEA in human serum/plasma. It is useful as an aid in management and monitoring of cancer patients.

For *in vitro* diagnostic use only.

INTRODUCTION

CEA is an oncofetal glycoprotein, which is found at high levels in the fetal colon and at lower levels in the normal adult colonic epithelium. CEA occurs at abnormally high levels in several benign disorders and in some malignant tumors, including those of the stomach, small intestine, colon, rectum, pancreas, liver, breast, ovary, cervix, and lung[1]. CEA is a 180-kD glycoprotein that occurs at high levels in colon epithelial cells during embryonic development. Levels of CEA are significantly lower in colon tissue of adults, but can become elevated when inflammation or tumors' arise in any endodermal tissue, including in the gastrointestinal tract, respiratory tract, pancreas and breast[2]. CEA is also expressed by epithelial cells in several non-malignant disorders, including diverticulitis, pancreatitis, inflammatory bowel disease, cirrhosis, hepatitis, bronchitis and renal failure and also in individuals who smoke[3]. This fact has made it difficult to use serum CEA determination as a sensitive method for cancer screening. However, serum CEA levels have been useful in monitoring individuals for the recurrence of cancer[4]

PRINCIPLE

The test uses a sandwich immunodetection method; the detector antibody in buffer binds to antigen in sample, forming antigen-antibody complexes, and migrates onto nitrocellulose matrix to be captured by the other immobilized-antibody on test strip.

The more antigen in sample forms the more antigen-antibody complex and leads to stronger intensity of fluorescence signal on detector antibody, which is processed by the instrument for AFIAS tests to show CEA concentration in sample.

COMPONENTS

AFIAS CEA consists of 'Cartridge', 'Pipette tip', 'ID chip' and 'Instruction for use'.

- Each cartridge packaged in an aluminum pouch has two components, a detector part and cartridge part.
- Cartridge part contains a test strip, the membrane which has anti human CEA at the test line, while chicken IgY at the control line.
- Detector part contains anti human CEA-fluorescence conjugate, anti chicken IgY-fluorescence conjugate, bovine serum albumin (BSA) as a stabilizer and sodium azide in phosphate buffered saline (PBS) as a preservative.

WARNINGS AND PRECAUTIONS

- For in vitro diagnostic use only.
- Carefully follow the instructions and procedures described in this 'Instruction for use'.
- Use only fresh samples and avoid direct sunlight.
- Lot numbers of all the test components (cartridge and ID chip) must match each other.
- Do not interchange the test components between different lots or use the test components after the expiration date, either of which might yield misleading of test result(s).
- The cartridge should remain sealed in its aluminum pouch until use. Do not use the cartridge if that is damaged or already opened.
- For shipping, samples must be packed in accordance with the regulations. Sample with severe hemolytic and hyperlipidemia cannot be used and should be recollected.
- Just before use, allow the cartridge and sample to be at room temperature for approximately 30 minutes.
- **AFIAS CEA** as well as the instrument for AFIAS tests should be used away from vibration and/or magnetic field. During normal usage, it can be noted that the instrument for AFIAS tests may produce minor vibration.
- Used pipette tips, and cartridges should be handled carefully and disposed by an appropriate method in accordance with relevant local regulations.
- An exposure to larger quantities of sodium azide may cause certain health issues like convulsions, low blood pressure and heart rate, loss of consciousness, lung injury and respiratory failure.
- **AFIAS CEA** will provide accurate and reliable results subject to the following conditions.
  - Use **AFIAS CEA** should be used only in conjunction with the instrument for AFIAS tests.
  - Any anticoagulants other than **EDTA, heparin sodium, sodium citrate** should be avoided.

LIMITATIONS OF THE TEST SYSTEM

- The test may yield false positive result(s) due to the cross-reactions and/or non-specific adhesion of certain sample components to the capture/detector antibodies.
- The test may yield false negative result. The non-responsiveness of the antigen to the antibodies is most common where the epitope is masked by some unknown components, so as not to be detected or captured by the antibodies. The instability or degradation of the antigen with time and/or temperature may cause the false negative as it makes antigen unrecognizable by the antibodies.
- Other factors may interfere with the test and cause erroneous results, such as technical/procedural errors, degradation of the test components/reagents or presence of interfering substances in the test samples.
- Any clinical diagnosis based on the test result must be supported by a comprehensive judgment of the concerned physician including clinical symptoms and other relevant test results.

STORAGE AND STABILITY

- The cartridge is stable for 20 months (while sealed in an aluminum pouch) if stored at 2-8 °C.

MATERIALS SUPPLIED

REF SMFP-21

Components of **AFIAS CEA**

- Cartridge Box Contains
  - Cartridge 24
  - Pipette Tip (Zipperbag) 24
  - ID Chip 1
  - Instruction For Use 1

MATERIALS REQUIRED BUT SUPPLIED ON DEMAND

Following items can be purchased separately from **AFIAS CEA**.
Please contact our sales division for more information.

- **AFIAS-1** REF FPRR019
- **AFIAS-6** REF FPRR020
- **Boditech Tumor marker Control** REF CFPO-94
- **Boditech Tumor marker Calibrator** REF CFPO-106

SAMPLE COLLECTION AND PROCESSING

The sample type for **AFIAS CEA** is human serum/plasma.

- It is recommended to test the sample within 24 hours after collection.
- The serum or plasma should be separated from the clot by centrifugation within 3 hours after the collection of whole blood.
- Samples may be stored for up to a week at 2-8 °C prior to being tested. If testing will be delayed more than a week, serum or plasma sample should be frozen at -20 °C.
- Serum or plasma sample stored frozen at -20 °C for 2 months showed no performance difference.
- Once the sample was frozen, it should be thawed one time and only for test, because repeated freezing and thawing can result in the changed test values.

TEST SETUP

- Check the components of the **AFIAS CEA** as described below. : Cartridge, pipette tip, ID chip and instruction for use
- Keep the sealed cartridge (if stored in refrigerator) at room temperature for at least 30 minutes just prior to the test. Place the cartridge on a clean, dust-free and flat surface.
- Turn on the instrument for AFIAS tests.
- Empty the tip box.
- Insert the ID chip into the "ID chip port".
- Please refer to the instrument for AFIAS tests 'Operation Manual' for complete information and operating instructions.

TEST PROCEDURE

1) Take 200 µL of sample with a pipette and dispense it into the sample well on the cartridge.
2) Insert the cartridge into the cartridge holder
3) Insert a tip into the tip hole of the cartridge.
4) Tap the 'START' icon on the screen.
5) The test result will be displayed on the screen after 12 minutes.

※ Note: Refer to the instrument for AFIAS tests Operation Manual to select sample type.

INTERPRETATION OF TEST RESULT

- The instrument for AFIAS tests calculate the test result automatically and displays CEA concentration of the test sample in terms of ng/mL.
- Reference range
  - Non-Smoker 4 ng/mL
  - Smoker 5 ng/mL (95 % of healthy subjects)
- The working range of the **AFIAS CEA** is 1-500 ng/mL.

QUALITY CONTROL

- Quality control tests are a part of the good testing practice to confirm the expected results and validity of the assay and should be performed at regular intervals.
- The control tests should be performed immediately after opening a new test lot to ensure the test performance is not altered.
- Quality control tests should also be performed whenever there is any question concerning the validity of the test results.
- Control materials are not provided with **AFIAS CEA**. For more information regarding obtaining the control materials, contact Boditech Med Inc.'s Sales Division for assistance.
  (Please refer to the instruction for use of control material.)

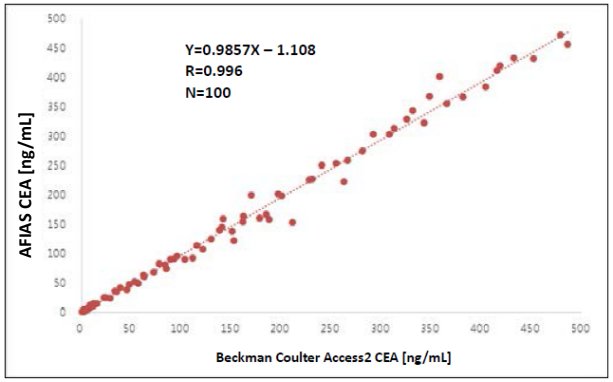
PERFORMANCE CHARACTERISTICS

- **Specificity**
  There, in test samples, are biomolecules such as bilirubin, lipid and hemoglobin for interference test, and disease related makers such as NCA in higher concentration than their normal physiological levels. But this doesn't interfere with the **AFIAS CEA** test measurements, nor occurs any significant cross-reactivity.

- **Precision**
  The intra-assay precision was calculated by one evaluator, who tested different concentration of control standard ten times each with three different lots of **AFIAS CEA**. The inter-assay precision was confirmed by 3 different evaluators with 3 different lots, testing five times each different concentration.

CEA [ng/mL]	Intra-assay		Inter-assay	
	Mean	CV (%)	Mean	CV (%)
6.5	6.86	8.66	6.81	7.76
65	68.54	3.81	67.13	4.49
130	131.67	5.12	129.23	5.60

- **Comparability**
  CEA concentrations of 100 clinical samples were quantified independently with **AFIAS CEA** and Beckman Coulter Access2 as per prescribed test procedures. Test results were compared and their comparability was investigated with linear regression and coefficient of correlation (R). Linear regression and coefficient of correlation between the two tests were Y=0.9857X – 1.108 and R = 0.996 respectively.



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2. Benchimol, S., A. Fuks, S. Jothy, N. Beauchemin, K. Shirota, and C.P. Stanners. 1989. Carcinoembryonic antigen, a human tumor marker, functions as an intercellular adhesion molecule. Cell 57:327-334.
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Note: Please refer to the table below to identify various symbols.

	Sufficient for <n> tests
	Read instruction for use
	Use by Date
LOT	Batch code
REF	Catalog number
	Caution
	Manufacturer
EC REP	Authorized representative of the European Community
IVD	In vitro diagnostic medical device
	Temperature limit
	Do not reuse
CE	This product fulfills the requirements of the Directive 98/79/EC on in vitro diagnostic medical devices

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