CEA

infinosis™

Carcinoembryonic Antigen (FIA)

REF: IN067707 Σ **25**

Intended use
The infinosis™ CEA is a fluorescence immunoassay (FIA) for the in vitro quantitative determination of carcinoembryonic antigen (CEA) in human serum or plasma. The assay is useful in the diagnosis of thyroid or pituitary disorders. For professional use only.

Summary
References[1-4]
CEA is a single chain glycoprotein containing 30 to 70 weight percent of carbonhydrate. CEA has a molecular weight of 2,000,000 Daltons.CEA level is elevated in many malignancies such as digestive tract cancers, breast cancer, lung cancer, metastatic diseases of the liver5, pancreatic carcinoma and medullar carcinoma of the thyroid. However, CEA level is also increased in nonmalignant disorders, for examples, liver diseases, active inflammatory bowel disease and aging. Heavy cigarette smokers have higher serum CEA than healthy non-smokers. CEA measurement provides an important tool for monitoring patients with known malignancy. The knowledge of CEA concentrations at pre- and post-treatment stages can help assess the efficacy of radiation or other treatments, monitor the recurrence after surgery, and predict the prognosis. It is recommended that the same CEA assay be used throughout the monitoring of each patient.

Test principle
Sandwich principle. Total duration of assay: **15 minutes**
Sample is added to the sample well of the test, then the fluorescence-labeled detector anti-CEA antibody binds to CEA antigen in blood specimen. As the sample mixture migrates on the nitrocellulose matrix of test strip by capillary action, the complexes of detector antibody and CEA are captured to anti-CEA antibody that has been immobilized on test strip.
More antigens in the sample will form more antigen-antibody complexes which lead to stronger fluorescence signal by detector antibodies, which is processed by instrument for infinosis™ tests to show CEA concentration in the sample.

Reagents
Materials provided
- **Test Cartridge**, 25 pcs, individually packaged
- **ID Chip** or **QR code of Calibration Curve**, 1 pcs
- **Sample Buffer,** 25 tubes
- **IFU**, 1 copy

Materials required (but not provided)
- infinosis™ FIA analyzer
- CEA control (DiaSino control is recommended)
- Transfer pipette set (100 µL size)
- Centrifuge (for plasma and serum only)
- Timer

Precautions and warnings
- For in vitro diagnostic use only.
- Carefully follow the instructions and procedures described in this instructions before testing.
- The test cartridge should remain in its original sealed pouch until ready to use. Do not use it if the pouch is damaged or the seal is broken.
- Do not use reagents beyond the labeled expiry date.
- Do not mix or use components from kits with different Lots.
- Don't use Test Cartridge if its Lot does not match with ID Chip that is inserted onto the instrument.
- The infinosis™ CEA should be used only in conjunction with the instrument for infinosis™ tests.
- The tests should be applied by professionally trained staff working in certified laboratories at some remove from the patient and clinic at which the sample is taken by qualified medical personnel.
- infinosis™ CEA assay is single use only. Do not reuse it.
- The Test Cartridge and instrument for infinosis™ tests should be used away from vibration and magnetic field. During normal usage, the Test Cartridge may generate slight vibration, which should be regarded as normal.
- Use separate clean pipette tips and buffer tubes for different specimens. The pipette tips and detector buffer tubes should be used for one specimen only.
- Do not smoke, eat, or drink in areas in which specimens or kit reagents are handled.
- Blood specimens, used test cartridges, pipette tips and sample buffer tubes are potentially infectious. Proper laboratory safety techniques, handing and disposal methods should be followed in accordance with standard procedures and relevant regulations observed by microbiological hazard materials.
- The results should be interpreted by the physician along with clinical findings and other laboratory test results.

Storage and stability
- Store the test kit at 2-30°C, the stability is up to the expiration date printed on package.
- Test cartridge and sample buffer should be used within 1 hour after opening the pack.

Specimen collection and preparation
- The test can be performed with either serum or plasma.
- Collect serum samples in accordance with correct medical practices.
- Using standard phlebotomy procedure, collect a venipuncture whole blood specimen using a blood collection tube. If collecting plasma use a blood collection tube containing suitable anticoagulant (EDTA recommended).
- Separate the serum/plasma from blood as soon as possible to avoid hemolysis.
- Test should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 3 days. For long-term storage, specimens should be kept below -20°C.

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 provided on demand with infinosis™ tests. For more information regarding obtaining the control materials, contact DiaSino Laboratories Co., Ltd for assistance.

Test setup
- Ensure that the lot number of the cartridge matches that of the sample buffer, and the ID Chip.
- If the sealed cartridge and sample buffer have been stored in refrigerator, place them at room temperature (18-25 °C) at least 30 minutes before measurement.
- Turn on the instrument for infinosis™ tests.
  Refer to the *'instrument for infinosis™ tests Operation Manual'* for the complete information and operating instructions.

Test procedure
1. Insert ID Chip into the instrument for infinosis™ tests or Scan the QR code to read the calibration curve.
2. Using a pipette to transfer **50 µL** of sample (Human plasma/serum) to the **sample buffer tube** provided in the kit.
3. Close the lid of the sample mixing tube and mix the sample thoroughly for **5-10 seconds** by tapping or inverting the tube.
4. Pipette out **100 µL** of **sample mixture** and load it onto the sample well on the cartridge.
5. Leave the sample-loaded cartridge at room temperature for **15 minutes.**
6. Insert the sample-loaded cartridge into the cartridge holder of instrument for infinosis™ tests.
   Ensure proper orientation of the cartridge before pushing it all the way inside the cartridge holder.
7. Press **"Test"** button on the instrument for infinosis™ tests.
8. Instrument for infinosis™ tests will start scanning the sample-loaded cartridge immediately.
9. Read the test result on the display screen of the instrument for infinosis™ tests.
10. Print out the testing results when press **"Print"** button on the instrument for infinosis™ tests.

Limitations - interference
- The assay is unaffected by icterus (bilirubin < 1129 µmol/L or < 66 mg/dL), hemolysis (Hb < 1.4 mmol/L or < 2.2 g/dL), lipemia (Intralipid < 1500 mg/dL) and biotin (< 491 nmol/L or < 120 ng/mL).
- Criterion: Recovery within ± 10 % of initial value.

IVD

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- Samples should not be taken from patients receiving therapy with high biotin doses (i.e. > 5 mg/day) until at least 8 hours following the last biotin administration.
- There is no high-dose hook effect at CEA concentrations up to 200000 ng/mL.
- For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

Calculation
The analyzer automatically calculates the analyte concentration of each sample either in IU/mL or ng/mL.

Conversion factor: IU/mL x 1.21 = ng/mL

Measuring range
0.5-200 ng/mL (defined by the lower detection limit and the maximum of the master curve). Values below the lower detection limit are reported as <0.5 ng/mL. Values above the measuring range are reported as >200 ng/mL.

Lower detection limit
0.5 ng/mL
The detection limit represents the lowest analyte level that can be distinguished from zero. It is calculated as the value lying two standard deviations above that of the lowest standard (master calibrator, standard 1+2 SD, repeatability study, n = 18).

Expected values
Studies with the Elecsys CEA assay were performed on 215 healthy subjects. The following results were obtained:

	All subjects		Non-smokers (past/never)		Smokers (current)	
Age (years)	20-69	40-69	20-69	40-69	20-69	40-69
95th percentile (ng/mL)	4.5	5.1	3.6	4.9	5.3	6.4
n	275	165	178	142	101	32

Each laboratory should investigate the transferability of the expected values to its own patient population and if necessary determine its own reference ranges.

Specific performance data
Representative performance data are given below. Results obtained in individual laboratories may differ.

Precision
Intra-assay
Determined by using 10 tests in the same batch to test with CEA control, CV ≤ 15%
Inter-assay
Determined by using 3 tests in 3 random and continuous batches to test with CEA control, CV ≤ 20%

Method comparison
A comparison of the Porrima CEA assay (y) with the Roche Elecsys CEA assay (x) using 108 clinical samples gave the following correlations:
Linear regression
y = 1.0017x + 0.0089
r = 0.9624
The sample concentrations were between approx. 3.0 and 560 ng/mL.

Functional sensitivity
1.0 ng/mL
The functional sensitivity is the lowest analyte concentration that can be reproducibly measured with an intermediate precision CV of ≤ 20 %.

References

1. Abeyounies, C.J. and Milgrom, F. Int. Arch. Allergy. Appl. Immunol. 43:30-38. 1972
2. Krupey, J., Wilson, T., Freedman, S.D. et al. Immunochemistry 9:617-622, 1972
3. Mansour, E.G. Cancer 51:1243-1248, 1983.
4. Vincent, R. and Chu. T.M. Journal of Thoracic and Cardiovascular Surgery. 66:320-328, 1973.

Symbols

IVD In vitro diagnostic medical device	30°C 2°C Temperature limit	Consult instructions for use	REF Catalog number
LOT Batch code	Date of manufacture	Use-by date	Σ Contains sufficient for <n> tests
Manufacturer	Do not re-use	Do not use if package is damaged and consult instructions for use	

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