# INSTRUCTIONS FOR USE

## SENSITIVE ONE STEP TEST

## Carcinoembryonic Antigen (CEA)

## Detection in Whole Blood/Serum/Plasma

Only for professional *in vitro* diagnostic use

**Product Code : TCEA01**

The Carcinoembryonic Antigen (CEA) Test Device detects tumor marker CEA in human whole blood, serum and plasma.

## BACKROUND INFORMATION

Carcinoembryonic Antigen (CEA) is a tumor-associated antigen characterized as an oncofetal glycoprotein. CEA is expressed in a variety of malignancies, particularly pulmonary or gastrointestinal tumors (e.g. colon cancer, liver cancer and lung cancer). CEA normally occurs in fetal gut tissue with detectable serum levels essentially disappearing after birth. Therefore, elevated levels of CEA can be of significant value in the diagnosis of primary carcinomas. In addition to qualitative 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 cancer. Progressive elevation of CEA may signal tumor 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.

## INTENDED USE

The Carcinoembryonic Antigen (CEA) Test Device is a rapid immunochromatographic assay for qualitative detection of CEA in human whole blood / serum / plasma to aid monitoring of cancer patients.

## REAGENTS

This test device contains anti-CEA antibody coated particles and anti-CEA antibodies immobilized on the membrane.

## METHOD

The Carcinoembryonic Antigen (CEA) Test Device is a rapid, qualitative, immunochromatographic assay for the detection of CEA in human whole blood / serum / plasma samples. Anti-CEA antibodies are immobilized on to "T" test area of the test. While performing the test; whole blood / serum / plasma sample dropped to the sample well reacts with the particles coated with anti-CEA antibodies. This complex migrates to the other end of the membrane by capillary action. If there is CEA in the sample, it binds to anti-CEA antibodies in the "T" test area and creates a visible, colored signal that means the test result is positive. If the sample does not contain CEA, colored line does not appear in the "T" test area. This means the test result is negative. The minimum detection level is 5 ng/mL As a procedural control, a colored line always appears in the "C" control area indicating that proper volume of sample has been introduced and membrane wicking has occurred.

## PRECAUTIONS AND LIMITATIONS

1. For professional and *in vitro* diagnostic use only.
2. Do not use test kit beyond expiry date. The test device is single use. Do not reuse.
3. The test device should remain in its original sealed pouch until usage. Do not use the test if the seal is broken or the pouch is damaged.
4. Wear disposable gloves while performing the test.
5. Use a new dropper for each sample.
6. All patient samples should be handled as taking capable of transmitting disease into consideration. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of samples.
7. The minimum detection level is 5 ng/mL If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of gastrointestinal tract tumors or other cancer.
8. This test will indicate only the presence or absence of CEA in the sample, and should not be used as the only basis for gastrointestinal tract tumors or other cancer. As with all diagnostic tests, it should be kept in mind that an identification diagnosis can't be based on a single test result. Diagnosis can only be reached by an expert after the evaluation of all clinical and laboratory findings.

## STORAGE

Test device should be kept away from direct sunlight, moisture, heat and radiation sources.
Store at 4 - 30°C (39 - 86°F). Do not freeze.
The test in the original packaging retains stable until expiry date at storage conditions. The test device should be used in maximum one hour after the foil is opened.

## SAMPLE COLLECTION AND PREPARATION

The test can be performed using whole blood, serum or plasma. To avoid hemolysis, serum or plasma should be separated from blood as soon as possible.

**For Whole Blood Samples:** Test should be performed immediately with whole blood samples. Otherwise, whole blood samples should be stored at 2 - 8 °C with anticoagulants (EDTA, heparin, citrate should be used) to avoid coagulation until they are being tested in a period of 2 days after collection.

**For Serum Samples:** Collect blood into a collection tube without anticoagulant, leave to settle for 30 minutes for blood coagulation and then centrifuge the blood. At the end of centrifuge period remaining supernatant is used as serum.

**For Plasma Samples:** Collect blood into a collection tube with anticoagulants (EDTA, heparin, citrate should be used) to avoid coagulation of blood sample and then centrifuge the blood. At the end of centrifuge period supernatant is used as plasma.

Do not use turbid, hemolyzed samples. If the sample cannot be tested on the day of collection, store the serum, plasma samples in a refrigerator or freezer. Do not freeze and thaw the serum, plasma samples repeatedly. **Do not freeze whole blood sample.** Bring the samples to room temperature before testing. Frozen samples must be completely thawed and mixed well prior to testing. Turbid test samples should be centrifuged. Using of frozen and thawed samples should be avoided whenever possible, due to the blocking of the membrane by the debris.

**Kit components:** Test devices, droppers, diluents and instructions for use.

**Additional materials required but not provided:** Sample collection tube, centrifuge and timer, lancet (for only fingerstick whole blood), heparinized dispensing bulbs and capillary tubes (for only fingerstick whole blood).

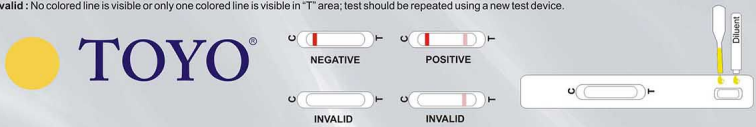
**Additional materials recommended but not provided:** Micropipettes to deliver mentioned amount of sample in the test procedure, negative and positive control materials.

## TEST PROCEDURE

1. Take the test device out of its pouch. Bring the tests and whole blood / serum /plasma samples to room temperature.
2. **For Whole Blood Samples:** Draw whole blood into dropper and put 2 drops (60 µl) into the sample well of the cassette. Immediately after, 1 drop (~40µL) of diluent is added into the sample well and allowed to soak in.
   **For Serum / Plasma Samples:** Draw serum / plasma into dropper and put 1 drop (30 µl) into the sample well of the cassette. Immediately after, 1 drop (~40µL) of diluent is added into the sample well and allowed to soak in. Avoid the formation of any air bubbles.
3. Depending on the CEA concentration in the sample, the test can react even in 5 minutes. Results should be read at 10 minutes as shown below. Results forming after 20 minutes should be regarded as invalid.

## INTERPRETATION OF RESULTS

**Negative :** Only one colored line is visible in "C" area, indicating that CEA does not exist.
**Positive:** Two colored lines are visible in "C" and "T" areas, indicating that CEA exists.
Low concentration of CEA may cause a faint line in "T" area. Even such a faint line in "T" area should be regarded as "positive".
**Invalid :** No colored line is visible or only one colored line is visible in "T" area; test should be repeated using a new test device.




## QUALITY CONTROL

Tests have built in procedural quality control features. When the test is complete, the user will see a colored line in the "C" area of the test on negative samples and a colored line in the "T" and "C" area on positive samples. The appearance of the control "C" line is considered as an internal procedural control. This line indicates that sufficient volume of sample was added as well as valid test result. It is recommended that a negative control and a positive control be used to verify proper test performance as an external control. Users should follow appropriate federal, state and local guidelines concerning the external quality controls.

## PERFORMANS EVALUATION

### Sensitivity and Specificity

TheCarcinoembryonic Antigen (CEA) Test Device has correctly identified a panel of specimens and has been compared to a leading commercial CEA EIA test using clinical specimens. The results are as below.

**CEA Test Device - EIA Test**

| Method | | EIA | | Total Results |
|---|---|---|---|---|
| | Results | Positive | Negative | |
| CEA Test Device | Positive | 147 | 2 | 149 |
| | Negative | 1 | 280 | 281 |
| Total Results | | 148 | 282 | 430 |

**Cut off:** 5 ng/ml CEA
**Sensitivity: 99,3 %** **Specificity: 99,3 %**
**+ Predictive V: 99,0 %** **- Predictive V: 99,6 %**

**Intra-Assay**
Within-run precision has been determined by using 15 replicates of three specimens: a negative, a low positive and a high positive. The negative, low positive and high positive values were correctly identified >99% of the time.

**Inter-Assay**
Between-run precision has been determined by 15 independent assays on the same three specimens: a negative, a low positive and a high positive. The Carcinoembryonic Antigen (CEA) Test Device have been tested using negative, low positive and high positive specimens. The specimens were correctly identified >99% of the time.

## CROSS REACTIVITY

Specimens positive for HCV, HBV, HIV, AFP and Rheumatoid factor (RF) have been tested. No crossreactivity was observed, indicating that the Carcinoembryonic Antigen (CEA) Test Device has a high degree of specificity for Carcinoembryonic Antigen.

## INTERFERING SUBSTANCES

The Carcinoembryonic Antigen (CEA) Test Device has been tested for possible interference from visibly hemolyzed and lipemic specimens. No interference was observed. In addition, no interference was observed in specimens containing up to 2.000 mg/dL Hemoglobin, 30 mg/dL Bilirubin, 700 mg/dL Triglycerides and 1.700 mg/dL Total Lipids.

## REFERANCES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4. Phil Gold CC, and Goldenberg NA. The Carcinoembryonic Antigen (CEA): Past, Present, and Future. Perspectives in Colon and Rectal Surgery 9(2), 1996.



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## SYMBOLS USED

CE

Manufacturer

EC REP Authorized European Representative

Attention, see instruction for use

Consult instruction for use

IVD *In vitro* diagnostic medical device

Σ n Number of test

For single use only

Storage temperature

LOT Lot number

REF Catalog number

Expiry date