

ELISURE

CA125 Rapid Test (Whole Blood/Serum/Plasma)

For professional use

IVD

REF

SIC-RDT-CA-202125

A rapid test for the qualitative detection of Cancer Antigen CA125 in human's whole blood, serum or plasma.

For professional *in vitro* diagnostic use only.

INTENDED USE

The CA125 Rapid Test (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of CA125 in human's whole blood, serum or plasma.

SUMMARY

CA-125 is the most frequently used prognostic biomarker for ovarian cancer detection.¹ Around 90% of women with advanced ovarian cancer have elevated levels of CA-125 in their blood serum, making CA-125 a useful tool for detecting ovarian cancer after the onset of symptoms.²

Monitoring CA-125 blood serum levels is also useful for determining how ovarian cancer is responding to treatment (with the duration of disease-free survival correlating with the rate of fall of CA-125)³ and for predicting a patient's prognosis after treatment.⁴ This is because the persistence of high levels of CA-125 during therapy is associated with poor survival rates in patients.⁴ Also, an increase in CA-125 levels within individuals in a remission is a strong predictor of the recurrence of ovarian cancer.⁵

PRINCIPLES

The CA125 Rapid Test (Whole Blood/Serum/Plasma) is a qualitative, lateral flow immunoassay for the detection of CA125 in whole blood, serum or plasma. The membrane is pre-coated with anti-CA125 on the test line region of the strip. During testing, the whole blood, serum or plasma specimen reacts with the particle coated with anti-CA125. The mixture migrates upward on the membrane by capillary action to react with anti-CA125 on the membrane and generate a colored line. The presence of this colored line in the test region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

MATERIALS

Materials provided

- Test cassettes
- Package insert
- Buffer
- Droppers

Materials required but not provided

- Specimen collection containers
- Centrifuge
- Timer
- Lancets (for fingerstick whole blood only)
- Heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only)

WARNINGS AND PRECAUTIONS

1. For professional *in vitro* diagnostic use only. Do not use after the expiration date.
2. Do not eat, drink or smoke in the area where the specimen or kits are handled.
3. Handle all the specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
4. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
5. Humidity and temperature can adversely affect results.

STORAGE AND STABILITY

Store as packaged at room temperature or refrigerated (2-30 °C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

- The CA125 Rapid Test (Whole Blood/Serum/Plasma) can be performed using whole blood, serum and plasma specimen.
- Both Fingerstick Whole Blood and Venipuncture Whole Blood can be used.
- To collect **Fingerstick Whole Blood specimens**:
 - Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
 - Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger
 - Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
 - Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
 - Add the Fingerstick Whole Blood specimen to the test by using a **capillary tube**:
 - Touch the end of the capillary tube to the blood until filled to approximately 75 μ L. Avoid air bubbles.
 - Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood to the specimen well of the test cassettes.
- Separate the serum or plasma from blood as soon as possible to avoid hemolysis. Only clear, non-hemolyzed specimens can be used.
- Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8 °C for up to 3 days. Whole blood collected by venipuncture should be stored at 2-8 °C if the test is to be run within 2 days of collection. For long term storage, specimens should be kept below -20 °C. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly for more than three times.
- If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.
- EDTA K2, Heparin sodium, Citrate sodium and Oxalate potassium can be used as anti-coagulants.

DIRECTIONS FOR USE

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

1. Remove the test cassettes from the foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Place the test cassette on a clean and level surface.

For **Serum or Plasma** specimens:

Hold the dropper vertically and **transfer 3 drops of serum or plasma** (approximately 75 μ L) to the specimen well (S) of the test cassettes, then start the timer. See illustration below.

For **Venipuncture Whole Blood** specimens:

Hold the dropper vertically and **transfer 3 drops of whole blood** (approximately 75 μ L) to the specimen well (S) of the test cassettes, and **add 1 drop of buffer** (approximately 40 μ L), then start the timer. See illustration below.

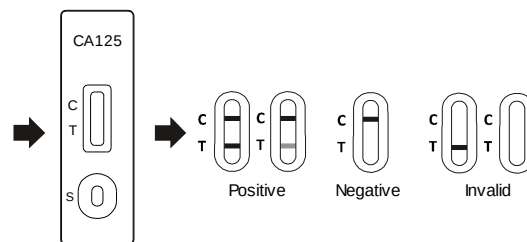
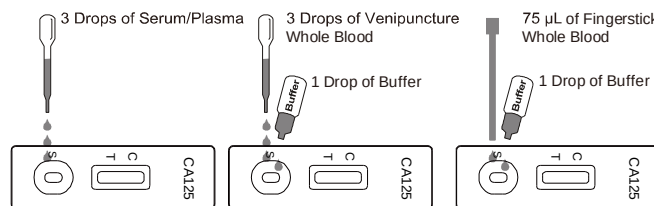
For **Fingerstick Whole Blood** specimens:

To use a capillary tube: Fill the capillary tube and **transfer approximately 75 μ L of fingerstick whole blood specimen** to the specimen well (S) of the test cassette, then **add 1 drop of buffer** (approximately 40 μ L) and start the timer. See illustration below.

3. Wait for the colored line is appeared. **The result should be read at 10 minutes.**

Do not interpret the result after 20 minutes.

Note: It is suggested not to use the buffer beyond 6 months after opening the vial.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

POSITIVE: * **Two colored lines appear.** One colored line should be in the control region (C) and another colored line should be in the test region (T).

***NOTE:** The intensity of the color in the test line region (T) will vary depending on the concentration of CA125 antigen present in the specimen. Therefore, any shade of color in the test region (T) should be considered positive.

NEGATIVE: **One colored line appears in the control region (C).** No apparent colored line appears in the test region (T).

INVALID: **Control line fails to appear.** Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

Internal procedural controls are included in the test. A colored line appearing in the control region (C) is an internal procedural control. It confirms sufficient specimen volume and correct procedural technique.

Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

1. The CA125 Rapid Test (Whole Blood/Serum/Plasma) is for *in vitro* diagnostic use only. This test should be used for detection of CA125 antigen in whole blood, serum or plasma specimens. Neither the quantitative value nor the rate of increase in the concentration of CA125 can be determined by this qualitative test.
2. The CA125 Rapid Test (Whole Blood/Serum/Plasma) will only indicate the presence of CA125 antigen in the specimen and should not be used as the sole criterion for the diagnosis/prognosis of Ovarian cancer.
3. As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
4. If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is suggested.
5. This CA125 Rapid Test is designed to work with hematocrit level between 25% and 65%. Performance of this test kit at a different hematocrit level can lead to erroneous results.

PERFORMANCE CHARACTERISTICS

Limitation of Detection

The CA125 Rapid Test (Whole Blood/Serum/Plasma) can detect CA125 antigen as low as 40 U/mL.

Sensitivity and Specificity

The CA125 Rapid Test (Whole Blood/Serum/Plasma) was compared with CA125 diagnostic kit (CMIA); the results indicate that CA125 Rapid Test (Whole Blood/Serum/Plasma) has a high sensitivity and specificity as follows.

Method	CMIA		Total Results
	Results		
	Positive	Negative	
CA125 Rapid Test (Whole Blood/Serum/Plasma)	55	5	60
	3	246	249
Total Results		58	251
		309	

Relative sensitivity: 94.8% (95%CI*: 85.6%–98.9%);

Relative specificity: 98.0% (95%CI*: 95.4%–99.4%);

Accuracy: 97.4% (95%CI*: 95.0%–98.9%).

*Confidence Intervals

Precision

Intra-Assay

Within-run precision has been determined by using 3 replicates of these specimens: negative, 40 U/mL CA125, 80 U/mL CA125 and 200 U/mL CA125. The negative, 40 U/mL CA125, 80 U/mL CA125 and 200 U/mL CA125 values were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by 3 independent assays on the same specimens: negative, 40 U/mL CA125, 80 U/mL CA125 and 200 U/mL CA125. Three different lots of the Cancer Marker CA125 Rapid Test (Whole Blood/Serum/Plasma) have been tested over a 3-days period using negative, 40 U/mL CA125, 80 U/mL CA125 and 200 U/mL CA125 positive specimens. The specimens were correctly identified >99% of the time.

Cross-reactivity

The CA125 Rapid Test (Whole Blood/Serum/Plasma) has been tested for HBsAg, anti-HIV, anti-HCV, anti-RF, anti-Spyhilis, anti-*H.pylori*, anti-Toxo IgG, anti-Rubella IgG, anti-CMV IgG positive specimens. The results showed no cross-reactivity.

Interfering Substances

The following compounds have also been tested using the CA125 Rapid Test (Whole Blood/Serum/Plasma) and no interference was observed.

Acetaminophen: 20 mg/dL	Caffeine: 20 mg/dL
Acetylsalicylic Acid: 20 mg/dL	Gentisic Acid: 20 mg/dL
Ascorbic Acid: 2 g/dL	Albumin: 2 g/dL
Creatin: 200 mg/dL	Hemoglobin: 1,000 mg/dL
Bilirubin: 1 g/dL	Oxalic Acid: 60 mg/dL

BIBLIOGRAPHY

1. Suh KS, Park SW, Castro A, Patel H, Blake P, Liang M, Goy A (Nov 2010). "Ovarian cancer biomarkers for molecular biosensors and translational medicine". Expert Review of Molecular Diagnostics. 10 (8): 1069–83.
2. Gupta D, Lis CG (2010). "Pretreatment serum albumin as a predictor of cancer survival: a systematic review of the epidemiological literature". Nutrition Journal. 9: 69.
3. Bast RC, Klug TL, St John E, Jenison E, Niloff JM, Lazarus H, Berkowitz RS, Leavitt T, Griffiths CT, Parker L, Zurawski VR, Knapp RC (Oct 1983). "A radioimmunoassay using a monoclonal antibody to monitor the course of epithelial ovarian cancer". The New England Journal of Medicine. 309 (15): 883–7.
4. Göcze P, Vahrson H (Apr 1993). "[Ovarian carcinoma antigen (CA 125) and ovarian cancer (clinical follow-up and prognostic studies)]". Orvosi Hetilap (in Hungarian). 134 (17): 915–8.
5. Santillan A, Garg R, Zahurak ML, Gardner GJ, Giuntoli RL, Armstrong DK, Bristow RE (Dec 2005). "Risk of epithelial ovarian cancer recurrence in patients with rising serum CA-125 levels within the normal range". Journal of Clinical Oncology. 23 (36): 9338–43.

INDEX OF SYMBOLS

	Consult instructions for use		Contains sufficient for <n> tests
	<i>In vitro</i> diagnostic medical device		Use-by date
	Temperature limit		Batch code
	Do not use if package is damaged		Manufacturer
	Catalogue number		Do not re-use



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