

CORTEZ DIAGNOSTICS, INC.

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IVD



See external label



2°C-30°C



Σ=25 or 50 tests

REF

Cat. #13061-1

OneStep

CEA

RapiDip™ InstaTest

Cat # 13061-1

INTRODUCTION

Cortez Diagnostics, Inc. OneStep CEA RapiDip™ InstaTest is a, direct binding test for the detection of Carcinoma Embryonic Antigen (CEA) in serum. It is used as an aid in the diagnosis of colorectal, breast, lung and pancreas cancers. The test is based on the principle of sandwich immunoassay for determination of CEA in serum. Monoclonal and polyclonal antibodies are employed to identify CEA specifically. This one step test is very sensitive and only takes 10-20 minutes. The sensitivity of the test can reach to 5µg/L.

SPECIMEN COLLECTION & PREPARATION

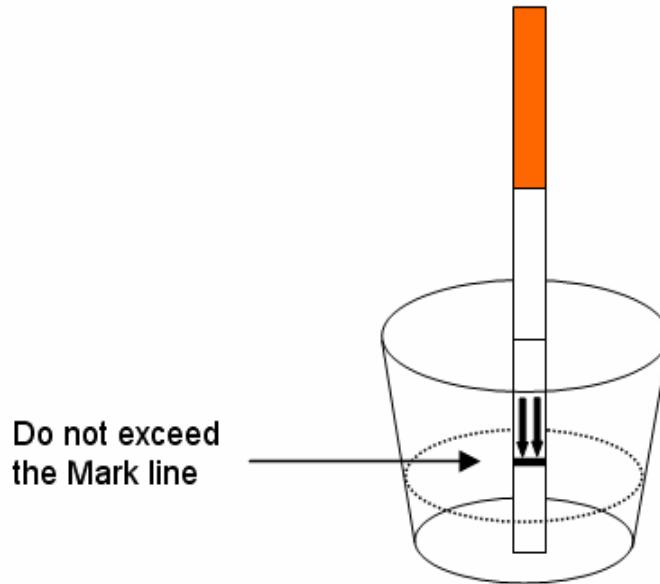
For serum, collect blood into a container without anticoagulant. Allow the blood to clot and separate the serum from the clot. Use the serum for testing.

If the specimen cannot be tested on the day of collection, store the serum specimen in a refrigerator or freezer. Stir and bring the specimens to room temperature before testing. Do not freeze and thaw the specimen repeatedly.

TEST PROCEDURE

1. When you are ready to begin testing, open the sealed pouch by tearing along the notch. Remove

- the test kit from the pouch and use it as soon as possible.
2. Following the illustration, dip the test strip with the arrow side pointing down into the vessel of serum for about 10 seconds. Do not immerse past the marker line. Take the strip out and lay it flat on a clean, dry and non-absorbent surface.
 3. Wait for 10 minutes and read results. It is important that the background is clear before the result is read. Wait for 10 minutes and read results. Do not read results after more than 30 minutes.

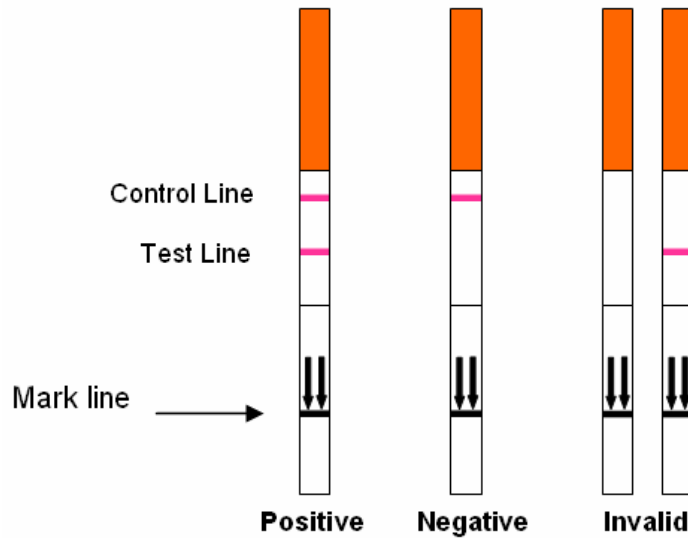


PRECAUTION

1. For in vitro diagnostic use only.
2. Do not use test kit beyond expiry date.
3. The test device should not be reused.

INTERPRETATION OF RESULTS

- **Negative:** Only one colored band appears on the control region. No apparent band on the test region.
- **Positive:** Distinct color bands appear on the control and test regions. Both test line and control line indicate a positive CEA result. Color intensity of the test bands may vary.
- **Invalid:** A total absence of color in both (C) and (T) regions or no colored band appears on the control (C) region is an indication of procedure error and/or the test reagent has deteriorated. Repeat with a new test kit. If the problem persists, discontinue using the test kit immediately and contact your local distributor.



STORAGE AND STABILITY

The test kit can be stored at temperatures between 2 to 30°C in the sealed pouch to the date of expiration. The test kit should be kept away from direct sunlight, moisture and heat.

LIMITATIONS

1. As with all Cortez tests, all results must be considered with other clinical information available to the physician. A definite clinical diagnosis should only be made by the physician after all clinical and laboratory findings have been evaluated.
2. Reliable and reproducible results will be obtained when the assay procedure is carried out with a complete understanding of the package insert instructions and with adherence to good laboratory practice.
3. Heterophilic antibodies such as human anti-mouse antibodies (HAMA) are frequently found in the serum of human subjects. Those antibodies can cause severe interference in many immunodiagnostic procedures. This assay has been designed to minimize that kinds of interference. Nevertheless, complete elimination of this interference from all patient specimens cannot be guaranteed. A test result that is inconsistent with the clinical picture and patient history should be interpreted with caution.

Date Adopted	Reference No.
2003-10-06	DA-CEA-2009



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