



CORTEZ DIAGNOSTICS, INC.

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IVD



See external label



2°C-30°C



$\Sigma=25$ or 50 tests

REF

Cat # 13041-1

OneStep

AFP

RapiDip™ InstaTest

Cat # 13041-1

INTRODUCTION

Cortez Diagnostics, Inc. OneStep AFP RapiDip™ InstaTest is a, direct binding test for the detection of Alpha Fetoprotein in serum. It is used as an aid in the diagnosis of primary hepatocellular carcinomas, testicular teratocarcinomas and neural tube defects. The test is based on the principle of sandwich immunoassay. Monoclonal and polyclonal antibodies are employed to identify AFP specifically. This test takes only 10-20 minutes to detected 25 ng/mL AFP in serum.

SPECIMEN COLLECTION & PREPARATION

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

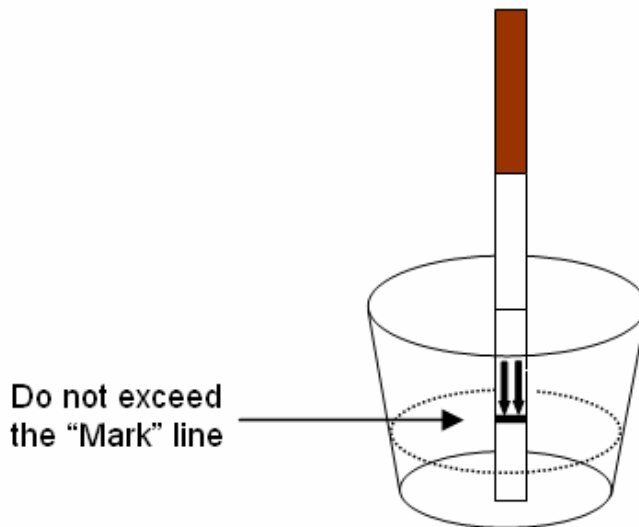
If the specimen cannot be tested on the day of collection, store the test specimen in a refrigerator or freezer. Stir and bring the specimen to room temperature before testing. Do not freeze and thaw the specimen repeatedly.

TEST PROCEDURE

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.

Following the illustration, dip the strip with arrow pointing down into the vessel of serum for about 10 seconds. Do not immerse past the “Mark” line. Take the strip out and lay it flat on a clean, dry and non-absorbent surface.

Wait 10-20 minutes and read result. It is important that the background is clear before the result is read. Do not read results after 30 minutes.



PRECAUTION

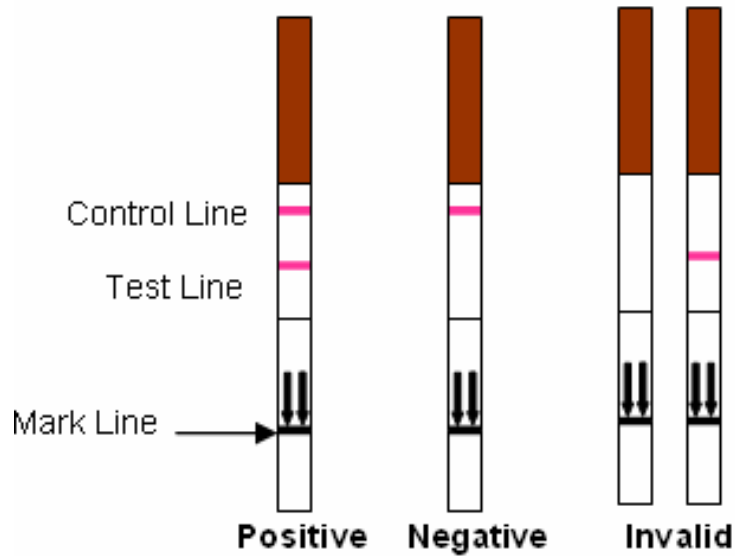
1. For in vitro diagnostic use only.
2. Do not use test kit beyond expiry date.
3. The test device should not be reused.

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.

INTERPRETATION OF RESULTS

- **Negative:** Only one colored band appears on the control region. No apparent band on the test region. AFP level is below 20 ng/mL.
- **Positive:** In addition to a pink colored control band, a distinct pink colored band will also appear in the test region. This indicates that the AFP concentration is more than 25 ng/mL. If the test band is equal to or darker than the control band, it indicates that the AFP concentration of specimen had reached to or greater than 400 ng/mL. Please consult your physician to perform a much more detailed exam.
- **Invalid:** A total absence of color band in both (T) and (C) regions or no colored band appears on the control (C) region is an indication of procedure error and/or that 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.



LIMITATIONS

1. This test provides a presumptive diagnosis for primary hepatocellular carcinomas, testicular teratocarcinomas and neural tube defects. A detailed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
2. This test is limited to the detection AFP in human serum only.
3. Although the test is very accurate in detecting elevated AFP levels, a low incidence of false results may occur.

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



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