

HEALTH-CHEM DIAGNOSTICS, LLC

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ONE STEP ALPHAFETOPROTEIN TEST™

For Down's Syndrome (DS- α -FP) in Second Trimester

INTENDED USE

The HCD **One Step Alphafetoprotein Test™** for Down's syndrome (DS- α -FP) is a rapid immunoassay designed for the semiquantitative determination of human α -FP in serum/plasma. It is intended for professional use as an aid in diagnosis of Down's syndrome in the second trimester.

SUMMARY AND EXPLANATION

Down's syndrome (DS), trisomy 21 is the most common congenital cause of severe mental retardation, with an incidence at birth of about 1.3 per 1,000. Prenatal diagnosis of DS is performed by chorionic villus sampling (CVS) or amniocentesis (AC), but these invasive procedures carry a risk of 0.5-1.5% of inducing spontaneous abortion.

Screening programs that the combination of measurements of maternal serum hCG and α -FP, with or without Estriol unconjugated, in the second trimester are routinely carried out in many countries and this approach detects ~65-75% of Down-affected pregnancies, with a false-positive rate of ~5%. With both biochemical markers, hCG and α -FP, a rapid One Step semi-quantitative test is possible.

PRINCIPLES OF THE PROCEDURE

The membrane in the device was pre-coated with an anti- α -FP capture antibody on the Test zone and goat anti-mouse antibody on the Control zone. During the testing, the serum sample is added to the sample well with the aid of a dropper and allowed to flow out through the device by capillary action. The α -FP in the sample reacts with a colored conjugate of a monoclonal α -FP antibody, which was pre-dried on the strip, and an antibody-antigen complex is formed when α -FP is present in the sample. The mixture then moves upward and the color band will be seen in the Test zone. Inversely, a color band will always appear in the Control zone, indicating the device is functioning correctly. The control band also serves as a reference of the color intensity of the approximate level design of α -FP. Comparing the intensity of the test band and control band, the range of concentration of α -FP can be determined.

Median MoM levels in DS 2nd Trimester

α -FP: normal value x 0.77

KIT CONTENTS

Device for detection of DS- α -FP

Series No.	apply to age of gestation
14	14 weeks
15	15 weeks
16	16 weeks
17	17 weeks

Each sealed foil pouch includes:

- 1 Test Cassette
- 1 Dropper
- 1 Desiccant

SPECIMEN COLLECTION AND STORAGE

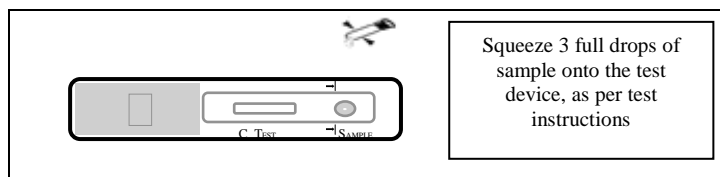
If specimens are not immediately tested, they should be refrigerated at 2-8°C. For storage period more than 3 days, freezing is recommended.

KIT STORAGE CONDITIONS

The HCD **One Step Alphafetoprotein Test™** kit may be stored at room temperature (15-28°C) for up to 18 months.

ASSAY PROCEDURE

Prior to use, bring all test components and patient samples to room temperature.



1. Remove the cassette from the foil pouch and place it on a clean, dry, level surface.
2. Hold the disposable dropper in a vertical position and add 3 drops of sample (one by one) into the sample well of the test device. Allow each drop to soak in before adding the next one.
3. As soon as the sample reaches the view window, start timing.

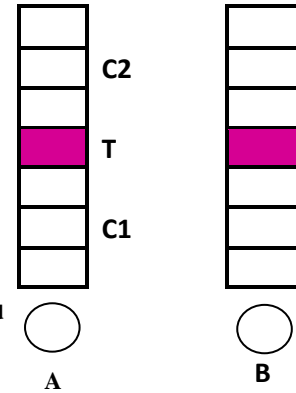
4. Because this test is based on color intensity, it is important to read the results within the time specified, after addition of the sample.

Exact reading time varies from lot to lot and is specified on the Certificate of Analysis provided with each lot.

INTERPRETATION OF RESULTS

To determine the result, compare the color intensity, i.e., shade of color, lightness or darkness or color of the Test band “T” to the Control band “C”.

Positive. If the Test band is of equal or greater intensity (equal or darker) than the Control band, this indicates the concentration of antigen of the sample is above the value represented by the Control band.



Add Sample and Buffer (S) → → →

CLINICAL INDICATION

If the test results show: $T \leq C$

A high risk of DS is indicated. Further investigation should be done.

QUALITY CONTROL

The daily use of a control is recommended to verify proper kit performance. Quality control samples should be tested according to quality control requirements established by the testing laboratory.

WARNINGS AND PRECAUTIONS

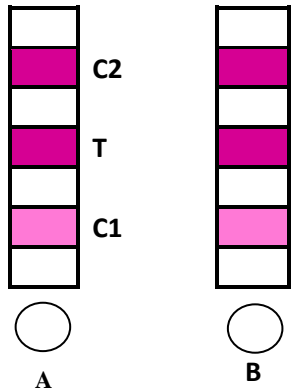
1. For *in-vitro* diagnostic use only.
2. **Avoid splashing or aerosol formation while adding the specimens.**
3. Do not use beyond the expiration date indicated on the label.
4. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single result, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

PERFORMANCE CHARACTERISTICS

1. **Precision.** Inter assay and intra assay precision tests were run using five samples with the concentration $<C$, five samples with the concentration $>C$ positive serum samples with 100% correct identification.
2. **Accuracy.** A study was performed using 87 serum samples, including 35 of level $<C$, 42 of level $>C$. They were assayed using DS- α -FP One Step test and a commercially available quantitative ELISA test. The correlation was 98%.

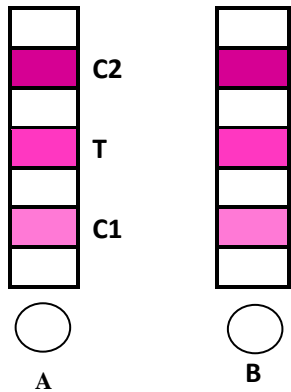
3. **Specificity.** None of the substances showed interference or cross reactivity with the test:

1,000	mIU/ml	FSH
200,000	mIU/ml	hCG
1,000	mIU/ml	LH
1,000	mIU/ml	TSH



Add Sample and Buffer (S) → → →

Negative. If the Test band is of lesser intensity (lighter) than the Control band, this means the level of antigen in the sample is less than the value represented by the Control band.



Add Sample and Buffer (S) → → →

Invalid. If no Control band appears within ten minutes, the result is Invalid and should be ignored. A visible Control band is needed in all cases to confirm proper test operation. No Control band indicates either the test procedures were not followed correctly, or the test reagents failed.

$T \leq C^*$ $\leq 0.77 \times \text{MoM}$
 $T > C$ $> \text{MoM}$

*High Risk of DS

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Manufactured in the USA by:

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