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PI-8001
Version 3.1

ADEXUSDx®

hCG TEST

Product Family No. 8001 | For *in vitro* diagnostic use only

Rx Only

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INTENDED USE

The **ADEXUSDx**® hCG Test is an immunoassay used for the qualitative detection of human chorionic gonadotropin in human whole blood (capillary or heparinized venous), plasma, or serum and is indicated as an aid for healthcare professionals in the diagnosis of early pregnancy.

FEATURES

- Clinical relevant cutoff: 10 mIU/ml
- Small sample volume test (about 40 µL)
- Simple one-step device
- Human whole blood (capillary or heparinized venous), plasma, or serum test

BENEFITS

- Quickly analyze patients after 10 minutes
- Easy-to-use
- Accurate results (correlates with laboratory method)

SUMMARY & EXPLANATION

Pregnancy tests are based on the detection of human chorionic gonadotropin (hCG), a hormone produced by the placenta around the fourth day after conception. hCG levels rise rapidly and double approximately every two days. The **ADEXUSDx®** hCG Test can detect hCG in a single drop of whole blood, serum, or plasma without additional reagents or materials.

PRINCIPLE OF THE PROCEDURE

The **ADEXUSDx®** hCG Test is a rapid chromatographic immunoassay. A sample is dispensed at the Sample Application Point to fill the Sample Application Zone. When enough sample is in the Sample Application Zone, the sample flows into a dry porous test strip composed of a plasma-separating membrane and an analytical membrane. The sample first passes through the plasma-separating

PRINCIPLE OF THE PROCEDURE (CONT.)

membrane containing detector monoclonal mouse anti-hCG antibodies labeled with color. The detector antibodies bind to hCG in the sample to form soluble colored hCG complexes which then move to the analytical membrane. The colored hCG complexes are captured by polygonal goat anti-hCG antibodies that are immobilized at the test band position of the analytical membrane. The appearance of a visible band indicates the sample contains a detectable level of hCG.

Excess detector antibodies will flow past the test band region and bind to immobilized polyclonal goat anti-mouse antibodies at the control band position of the analytical membrane. A visible control band with an absent test band assures that the negative result was not due to improper procedure.

STORAGE & STABILITY

The **ADEXUSDx**® hCG Test is stable unopened at 4°C-30°C (39°F–86°F) until the expiration date.

DIRECTIONS FOR USE

Warnings and Precautionary Statements:

- For *in vitro* diagnostic use only.
- Dispose of expired tests and completed tests as biohazardous material.
- Do not use expired tests.
- Do not use if the pouch seal is compromised.
- Single use only.

CAUTION: The device contains material of human or animal origin and should be handled as a potential carrier and transmitter of disease.

MATERIALS

MATERIAL PROVIDED:

- The **ADEXUSDx**® hCG Test is packaged in individually sealed pouches.

MATERIAL REQUIRED BUT NOT PROVIDED:

Capillary Blood Test

- Commercially available lancet for obtaining blood from a finger puncture
- Alcohol prep pads
- Timer

Venous Blood, Plasma, and Serum Test

- Heparinized sample collection container for venous blood
- Appropriate sample collection container and equipment for obtaining plasma or serum
- Sample transfer device
- Timer

SAMPLE COLLECTION & HANDLING

Capillary Blood Test

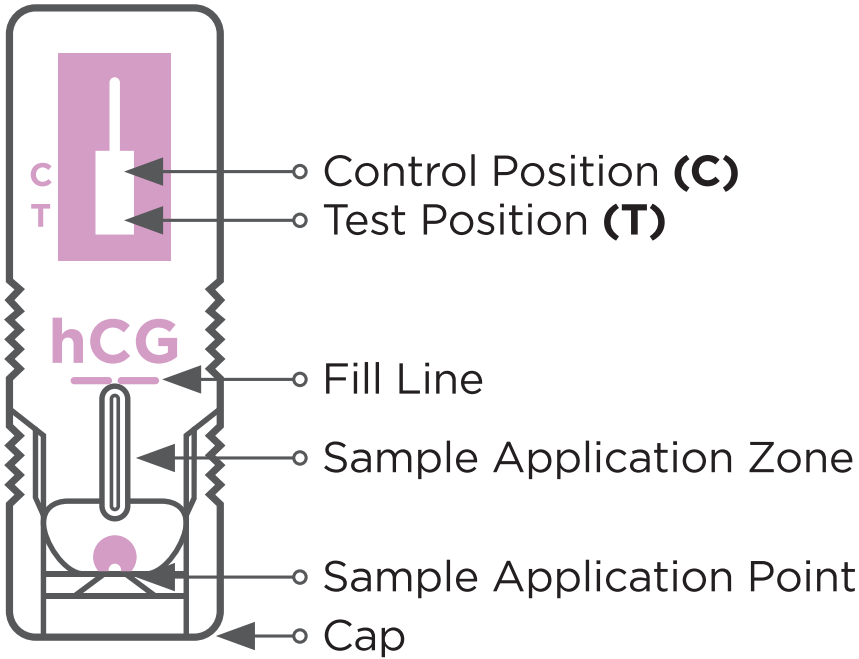
- A blood sample from a finger puncture should be obtained immediately before application to the test.

Venous Blood, Plasma, and Serum Test

- For venous blood or plasma tests, obtain blood by venipuncture in a heparinized container. If necessary, process the blood to obtain plasma.
- For serum tests, obtain blood by venipuncture in an appropriate container. Process the blood to obtain serum.

Venous blood samples may be stored at room temperature 15°C-25°C (59°F–77°F) for up to 4 hours prior to testing. Plasma and serum samples may be stored for 72 hours at 2°C–8°C (36°F–46°F) prior to testing. Allow samples to reach room temperature prior to testing.

TEST METHOD



Finger Puncture Site

For Capillary Whole Blood Samples

1. Remove the **ADEXUSDx**® hCG Test from the foil pouch and discard the desiccant and packaging.
2. Remove the cap.
3. To promote blood flow to the fingertips, ask the person to lower the hand to be punctured and massage the fingers toward the tips of the fingers.
4. Choose either the “ring” or “middle” finger for the test site and select the side of the finger closest to the pinky (as shown on page 10). Wipe the fingertip with an alcohol prep pad and allow the finger to thoroughly air-dry.
5. Prepare the lancet following the manufacturer’s instructions.
6. Select the fingertip test site. Do not use the center or top of the finger, since these are the most sensitive areas of the finger.
7. Squeeze the center of the finger (with one hand) at the same time as pressing firmly on the test site with the lancet (with the other hand).

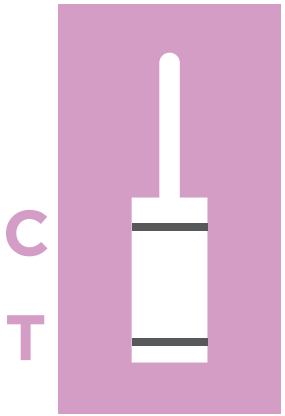
8. Release the lancet following the manufacturer's instructions.
9. Gently massage the fingertip toward the puncture site to obtain a full drop of blood. Keep test parallel to the ground. Do not tilt.
10. Touch the puncture site with the Sample Application Point of the **ADEXUSDx**® hCG Test.
11. Wait until all blood sample is drawn into the **ADEXUSDx**® hCG Test. If the blood sample has not reached the Fill Line, continue to massage the finger until the Sample Application Zone is filled.
12. Once the Sample Application Zone is full, tap the test on the table firmly twice with the Sample Application Point facing up. Lay the test on a flat surface.
13. Start the timer.
14. After 10 minutes, observe the appearance of bands in the Test Window at the Control Position (C) and the Test Position (T). See Interpretation of Results. Do not interpret the results of the test after 30 minutes.

For Venous Blood, Plasma, or Serum Samples

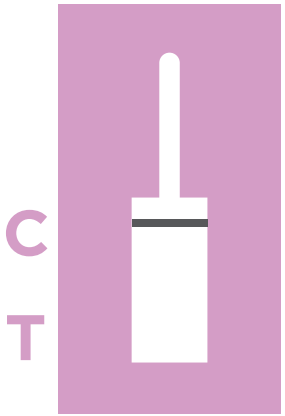
1. Remove the **ADEXUSDx**® hCG Test from the foil pouch and discard the desiccant and packaging.
2. Apply the sample to the **ADEXUSDx**® hCG Test Sample Application Point using a liquid transfer device (not supplied) until the sample reaches the Fill Line (about 40 µL).
3. Once the Sample Application Zone is full, tap the test on the table firmly twice with the capped end facing up. Lay the test on a flat surface.
4. Start the timer.
5. After 10 minutes, observe the appearance of bands in the Test Window at the Control Position (C) and the Test Position (T). See Interpretation of Results. Do not interpret the results of the test after 30 minutes.

INTERPRETATION OF RESULTS

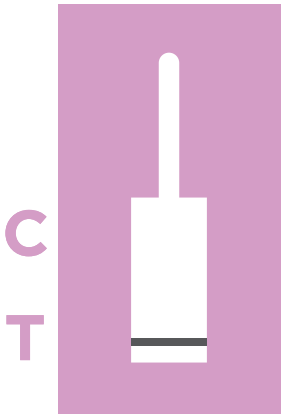
A band of any signal intensity appearing at the Test Position (T) is considered positive for hCG.



Positive Result



Negative Result



Invalid Result

Invalid Result

INTERPRETATION OF RESULTS (CONT.)

Notes:

- The control band and the test band may vary in color intensity.
- The intensity of the test band will vary depending on the concentration of hCG present in the specimen. However, the quantitative value of hCG cannot be determined by this qualitative test.
- The color intensity of the bands will increase slowly with time as a result of sample evaporation. Therefore, do not read the test after 30 minutes.

MedWatch

MedWatch is FDA's safety information and adverse event reporting program. It is a voluntary reporting system for health professionals and consumers to report product-related safety, adverse events, and quality issues. Reports to the MedWatch program can be made by:

Phone: 1-800-FDA-1088
Fax: 1-800-FDA-0178
Website: www.fda.gov/medwatch

QUALITY CONTROL

The **ADEXUSDx**® hCG Test is an internal quality control band. In cases where the test band is absent, the appearance of the control band assures that the sample was applied correctly and that proper chromatography in the test occured.

It is recommended that external quality control materials be used to verify the performance of the **ADEXUSDx**® hCG Test. A negative hCG control (< 5 mIU hCG/mL) and a positive hCG control (> 10 mIU hCG/mL) should be used. It is suggested that federal, state, and local guidelines be followed.

EXPECTED RESULTS

hCG in nonpregnant women is normally not detected by the **ADEXUSDx**® hCG Test. hCG concentrations are generally between 5 and 50 mIU/mL within 1 week of gestational age or 3 weeks after the last menstrual period (LMP). hCG levels rise rapidly, doubling about every two days and peak to greater than 100,000 mIU/mL in the latter part of the first trimester of pregnancy. If a test result is negative and pregnancy is suspected, repeat the test after 2 days or more.

A faintly positive test can be confirmed by repeating the test after 2 days or more.

LIMITATIONS

- Other clinical conditions that produce hCG include trophoblastic diseases and germ cell tumors.
- Pregnancy tests such as the **ADEXUSDx**® hCG Test may detect pregnancies ending in an early pregnancy loss, which occurs in about one out of every four pregnancies. Results should be used in conjunction with other clinical and laboratory data.
- Very strong positive samples may cause the control band to become faint. A high dose hook effect was not evident at 150,000 mIU hCG/mL.
- As with any other assay using mouse antibodies, the possibilities exists for interference by human anti-mouse antibodies (HAMA) or other interferring substances in the sample.

DISPOSAL

Disposal of the expired tests and completed tests as biohazardous material.

PERFORMANCE CHARACTERISTICS

Sensitivity:

The test band was designed to be visible when a specimen containing an hCG concentration of approximately 10 mIU/mL is analyzed by the test. The test was calibrated with the Abbott Architect for total β-hCG which is calibrated with material referenced to WHO, 3rd International Standard 75/537.

Assay Precision Near the Cutoff

Three hCG positive patient serum pools were prepared to have concentrations near 20, 10, and 5 mIU hCG/mL. Twenty (20) replicates of each pool for a total of 60 samples were tested with the **ADEXUSDx**® hCG Test. The **ADEXUSDx**® hCG Test identified the 40 positive samples (20 and 10 mIU hCG/mL) and the 20 negative samples (5 mIU hCG/mL).

Method Comparison:

A comparison study between the **ADEXUSDx**® hCG Test and another commercially available serum hCG assay was performed. Fifty-nine (59) and 57 female serum samples with hCG concentrations above and below 10 mIU/mL, respectively, were tested.

		ADEXUSDx® hCG Test	
		Positive	Negative
Other Assay	Positive	59	4
	Negative	0	53

For hCG-positive serum samples (10-200 mIU/mL), there was 100% agreement between the two assays. For normal serum samples, there were four discrepancies in which the other assay gave positive results and the **ADEXUSDx**® hCG Test gave negative results. The discrepant samples had hCG concentrations in the range of 2-6 mIU/mL, and were correctly reported as negative results by the **ADEXUSDx**®

hCG Test based on the 10 mIU hCG/mL cutoff value. There was 100% agreement of the **ADEXUSDx**® hCG Test with the other assay for the remaining normal samples.

Proficiency Testing:

Three samples of normal human whole blood were spiked with hCG to attain concentrations less than or above the cutoff value of 10 mIU/mL. Three different hospital laboratories and a sponsor lab, for a total of 4 sites, were provided with 5 replicates of each sample. The replicates were sent as blind samples with a unique label for each of the 15 tubes. There was complete agreement of the results between sites.

Site	Number of Positive Results/Total			Agreement within Run
	Below cutoff (not spiked)	3x cutoff	6x cutoff	
1	0/5	5/5	5/5	100%
2	0/5	5/5	5/5	100%
3	0/5	5/5	5/5	100%
On-site	0/5	5/5	5/5	100%
Agreement Between Sites	100%	100%	100%	

Dilution Study:

Three serial two-fold dilutions of hCG-positive plasma were made. Five replicates of each sample were applied to the **ADEXUSDx**® hCG Test. Samples with hCG concentartions above 10 mIU/mL all showed positive results. Samples below 10 mIU/mL all showed negative results.

hCG conc. (mIU/mL)	Number of Positive/Total
24.8	5/5
12.4	5/5
6.2	0/5
3.1	0/5

Correlation Between Whole Blood Plasma:

Heparinized whole blood from a non-pregnant female was spiked with hCG.

Plasma recovered from the spiked samples was quantified and contained <1.2, 4, 9, and 19 mIU hCG/ml. Both blood and the corresponding plasma samples, for a total of 4 sets of samples, were tested with the **ADEXUSDx**® hCG Test. Each set was tested 5 times.

Results from the blood and plasma test were correlated.

		Whole Blood	
		Positive	Negative
Plasma	Positive	10	0
	Negative	2	8

The agreement between between whole blood and plasma is 100% for hCG values greater than or equal to 9 mIU hCG/mL. Two tests gave a weak positive signal at 4 mIU hCG/mL for whole blood.

Hook Effect:

Normal human serum was spiked with hCG to attain a concentration of 150,000 mIU hCG/mL. Five (5) replicates were tested with the **ADEXUSDx**® hCG Test. In all cases the test band signal was very strong.

Capillary Blood Study:

I. Normal Female Samples Capillary blood samples from 10 non-pregnant female donors were taken using commercially available lancets to puncture fingers. The samples were applied to the **ADEXUSDx**® hCG Test and examined after 10 minutes. For all the tests, the control band was present, the red blood cell front was below the test window, the plasma front reached the top end of the test strip, and hemolysis did not occur. The test band was absent in all the tests indicating negative results.

II. Clinical Samples Clinical personnel obtained 40 capillary blood samples from female patients and tested the samples using the **ADEXUSDx**® hCG Test. Diagnosis was based on patient history and the results of either ultrasound or quantitative testing of serum.

There were no discrepancies between the **ADEXUSDx**® hCG Test results and patient diagnosis. The **ADEXUSDx**® hCG Test correctly identified the 26 patients who were pregnant with a positive result and the 14 patients who were not pregnant with a negative result. Of the 26 pregnant patients, 8 were tested within -1 and +9 days of the missed menstrual period. The other 18 pregnant patients were tested 2 weeks to 17 weeks after the missed menstrual period.

Specificity and Interfering Substances: The following related hormones were added to human negative control serum: hTSH 1000 µIU/mL, hLH 500 mIU/mL, and hFSH 1000 mIU/mL. Negative results were obtained at the given concentrations. The following potentially interfering substances were added to serum samples containing 0 to 10 mIU hCG/mL: Protein 14 g/dL, Hemoglobin 250 mg/dL, Triglycerides 2000 mg/dL, and Bilirubin 15 mg/dL. None of the substances at the concentrations tested interfered with the ADEXUSDx® hCG Test.

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4. Braunstein GD, Rasor J, Danzer H, Adler D, Wade ME. Serum human chorionic gonadotropin levels throughout normal pregnancy. Am. J. Obstet. Gynecol. 1976; 126(6):678-681.

Simple test

Perform in-office
No outside lab required

Fast and
accurate results

ADEXUSDx® is reinventing how diagnostics are performed. Our patented approach allows physicians to easily and accurately receive results quickly by using the tiniest blood sample. The focus of our rapid format for the laboratory and point-of-care diagnostics is to meet the needs of today's healthcare professionals and improve patient care.