PULSE SCIENTIFIC INC.
Unit 18, 5100 South Service Road
Burlington, Ont. Canada L7L 6A5
Tel: (905) 333-8188
Fax: (905) 333-0500
Toll Free: 1-800-363-7907

Pulse Serum/Urine Pregnancy Card Test

INTENDED USE
The PULSE Serum/Urine Pregnancy Test (SU PREG TEST) is intended to be used for the qualitative determination of human chorionic gonadotropin (hCG) in urine and serum in the early detection of pregnancy.

SUMMARY & PRINCIPLE [1,2]
Human chorionic gonadotropin (hCG) is a glycoprotein hormone secreted by the developing placenta shortly after fertilization. During normal pregnancy, hCG can be detected as early as 6 days following conception, doubling every 1.3 to 2 days. The detection of hCG is an excellent marker for confirming pregnancy.
HCG consists of an alpha and a beta sub-unit. The alpha sub-unit is shared by other glycoprotein hormones, e.g., luteinizing hormone (LH), follicle stimulating hormone (FSH), and thyroid stimulating hormone (TSH). The beta sub-units of these molecules differ and confer biological specificity to each hormone. The PULSE SU PREG TEST detects the intact hCG molecule in serum or urine.
The PULSE SU PREG TEST is a qualitative immunoassay for the detection of human chorionic gonadotropin (hCG) in serum or urine. The test utilizes a combination of monoclonal and polyclonal antibody reagents to selectively detect elevated levels of hCG. The assay is conducted by the addition of specimen into the sample well and observing for the formation of colored lines in the result area. The specimen migrates via capillary action along the membrane and reacts with the antibody-dye conjugate. Positive hCG specimens react with the specific antibody-hCG-colored conjugate and form a colored line in the Specimen Zone (S) portion of the membrane. Absence of this colored line suggests a negative result. To serve as a positive procedural control, a colored line in the Control Zone (C) will always appear regardless of the presence or absence of hCG.

MATERIALS SUPPLIED
Each test kit contains material to perform 25, 50 or 100 tests. Each test requires:
1. Sealed foil pouch containing: One (1) Test Device, comprised of colored dye coated with polyclonal antibodies specific for hCG, immobilized antibodies against hCG and monoclonal anti-mouse IgG antibodies.
2. Disposable pipette for the transfer of the specimens.

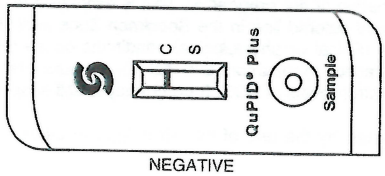
STORAGE & STABILITY
The PULSE SU PREG TEST is to be stored at a temperature range of 2° to 30°C. Individual tests are stored in the sealed pouch. **DO NOT FREEZE** the test kit. The test kit is stable until the date indicated on the box label.

PRECAUTIONS
This product is for In Vitro Diagnostic and Professional Use Only. Read instructions carefully before using this product. Do not use test kit beyond expiry date. For single use only, do not reuse. Handle all specimens for testing as if they are potentially hazadarous.

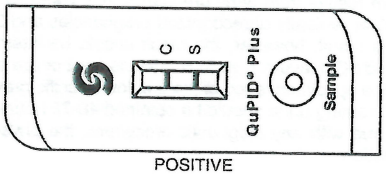
SPECIMEN COLLECTION [3]
Urine: Specimens must be collected in a clean, dry container, either plastic or glass, without preservatives. Specimens collected at any time may be used. However, the first morning urine generally contains the highest concentration of hCG and is therefore the most suitable. If testing is to be delayed for more than a few hours, urine can be stored at 2°C to 8°C for up to 72 hours or frozen (-20°C) for 3 months, but must be brought to room temperature prior to testing.
Serum: Specimens should be collected under standard laboratory conditions; avoid hemolysis. Specimens should be tested within 48 hours after collection and stored at 2°C to 8°C until ready to assay. Specimens can be kept frozen (-20°C) if testing is delayed for more than 48 hours. Bring to 15°C - 30°C and mix well prior to testing. Do Not Refreeze.

PROCEDURE:
1. Allow specimens and the PULSE SU PREG TEST to reach room temperature prior to testing.
2. Remove the test device from the protective pouch and place it on a flat surface. Label the device with patient or control identifications.
3. Holding the disposable dropper vertically, dispense **2 FULL DROPS** (approximately 0.12ml) of serum or urine into the round sample well.
4. Read results at **3 MINUTES** for urine.
5. Read results at **5 MINUTES** for serum.

READING TEST RESULTS
1. **Negative Results:** The test is negative if only a line appears at the Control Zone (C) in the result area.
2. **Positive Results:** The test is positive if two (2) colored lines appear. One (1) colored line will appear at the Specimen Zone (S) and one (1) at the Control Zone (C). The appearance of any pink to red colored line in the Specimen Zone (S) along with a line in the Control Zone (C) should be considered positive. Intensity of colored lines is not an indication of the concentration of hCG in the sample.
3. **Invalid Results:** The test is invalid if no line appears at the Control Zone (C) even if a colored line appears at the Specimen Zone (S). In this case, the test should be repeated.



NEGATIVE



POSITIVE

QUALITY CONTROL
A positive procedural control (Control Zone "C") is built into the PULSE SU PREG TEST. This control line will always appear if the test is performed correctly and if the device is working properly. An absence of this control line indicates incorrect procedure or deterioration of reagents. If background color appears in the result area, which interferes with the ability to read the test results, the result may be invalid. If the control line fails to appear with a repeat assay, do not report patient results.

EXPECTED VALUES [8]
Healthy men and non-pregnant women do not have hCG levels detectable by the PULSE SU PREG TEST. In normal pregnancy, levels of 20 mIU/mL hCG can be reached 2 to 3 days before the first missed menstrual period. HCG levels peak about 8 weeks after the last menstrual period and then decline to lower values during the remainder of the pregnancy. Following delivery, hCG levels rapidly decrease and usually return to normal within days after parturition.

PERFORMANCE CHARACTERISTICS

Accuracy

A study was performed using a total of (150) positive and (150) negative urine specimens. These specimens were assayed with the PULSE SU PREG TEST and the Abbott TestPack™ Plus urine test according to their package inserts, and yielded the following results:

		Abott TestPack™ Plus	
PULSE SU PREG TEST		(+)	(-)
	(+)	150	0
	(-)	0	150

The accuracy study was also performed by determining the qualitative recovery of known amounts of hCG added to a negative urine pool.

	Conc. hCG Added (mIU/ml)	Expected	Observed
Urine Pool	0	Negative	Negative
	20	Positive	Positive
	50	Positive	Positive
	100	Positive	Positive

A multi-center clinical evaluation was performed comparing the PULSE SU PREG TEST and the Abbott TestPack Plus™. The study was performed using a total of 72 positive and negative serum specimens:

		Abott TestPack™ Plus	
PULSE SU PREG TEST		(+)	(-)
	(+)	21	0
	(-)	0	51

Specificity

1. Cross Reactivity
   A study was performed using positive and negative urine specimens spiked with 500 mIU/mL, 1000 mIU/mL hTSH, and 1000 mIU/mL hFSH. No cross-reactivity was observed.
2. Interfering Substances
   High urine hCG levels may occur in patients suffering from chorionic epithelioma or hydatid mole. In these cases a false positive may occur. Excretion of hCG is often decreased in extra uterine pregnancy, toxemia of pregnancy or threatened abortion. Such circumstances can yield false negative results.
   Potentially interfering substances were added to urine, which had hCG levels of 0 and 20 mIU/mL. In all cases, no interference with the expected results were observed.

Acetaminophen	20 mg/dl	Cannabidiol	10 mg/dl
Acetylsalicylic acid	20 mg/dl	Cannabinol	10 mg/dl
Ampicillin	20 mg/dl	Gentisic Acid	20 mg/dl
Ascorbic Acid	20 mg/dl	Glucose	2 mg/dl
Atropine	20 mg/dl	Hemoglobin	1 mg/dl
Benzolecgonine	20 mg/dl	Tetracycline	20 mg/dl
Caffeine	20 mg/dl	Uric Acid	20 mg/dl

Standardization

The PULSE SU PREG TEST is standardized in accordance with the WHO 3rd I.S. for human chorionic gonadotropin

Clinical Studies

An evaluation of the PULSE SU PREG TEST was conducted at three clinics using patient samples. Testing was performed by clinic personnel with diverse educational backgrounds and work experience. The results obtained at each site had 100 % agreement with the expected results.

Precision & Sensitivity

Within run precision was determined by using 12 replicates of three specimens containing 0, 20 and 100 mIU/mL of hCG. The negative and positive values were correctly identified 100% of the time. Between run precision was determined by using the same three specimens, 0, 20 and 100 mIU/mL of hCG, in 11 different assays, using three different lots of test devices over a six (6) month period. Again, the negative and positive values were correctly identified 100% of the time.

The PULSE SU PREG TEST for Pregnancy detects hCG concentrations of 20 mIU/mL and greater in serum or urine specimens in accordance with the WHO 3rd I.S. Specimens containing high levels of hCG (1,000,000 mIU/mL), when tested, consistently gave positive results.

LIMITATIONS OF THE TEST [4,5,6,7]

1. A specimen with a low level of hCG may show color development over time.
2. The contents of this kit are for use in the qualitative detection of hCG.
3. A number of conditions (see Interfering Substances section) other than pregnancy, including trophoblastic disease and certain non-trophoblastic neoplasms, cause elevated levels of hCG. These diagnoses should be confirmed by other tests methods.
4. Normal pregnancy cannot be distinguished from an ectopic pregnancy based on hCG levels alone. Spontaneous miscarriage may also cause confusion in interpreting assay results.
5. Specimens from patients who have received preparations of mouse monoclonal antibodies for diagnosis or therapy may contain human anti-mouse antibodies (HAMA). These specimens may demonstrate either false positive or false negative results when tested with assays, which employ mouse monoclonal antibodies.
6. HCG levels may remain detectable for several weeks after normal delivery, delivery by caesarean section, spontaneous abortion, therapeutic abortion or hCG injections.
7. Do not use test devices which have become wet or which have been left out of the foil pouch for more than 24 hours.
8. Positive results from early pregnancy may later prove negative due to natural termination of the pregnancy. This is estimated to occur in 22% of clinically unrecognized pregnancies and 31% of pregnancies overall. A faint colored line in the Specimen Zone indicates a positive result, however, the result should be interpreted in the context of possible clinical or physiological conditions cause slightly elevated hCG levels. If such conditions exist or are suspected, it is good laboratory practice to resample and test 48-72 hours later.
9. If a urine specimen is too dilute (i.e. low specific gravity) it may not contain representative levels of hCG. If pregnancy is still suspected, a first morning urine should be obtained 48-72 hours later and retested.
10. As is true with any diagnostic procedure, the physician should evaluate data obtained by the use of this kit in light of other clinical information.

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Burlington, Ontario, Canada