CLIAwaived™ Inc.

Pregnancy Urine Test (Cassette)

One-Step Assay With Rapid Visual Results CE

For Qualitative *In Vitro* Diagnostic Use.

INTENDED USE

The CLIAwaived, Inc. Pregnancy Urine Test (Cassette) is a qualitative immunoassay for the detection of human chorionic gonadotropin (hCG) in human urine for the early detection of pregnancy. It is for health care professional use only and not for self testing.

SUMMARY AND EXPLANATION OF THE TEST

This pregnancy test is based on the detection of the human chorionic gonadotropin (hCG) in urine. HCG is a hormone produced by the placenta. In normal subjects, hCG in urine and provides an early indication of pregnancy. The CLIAwaived, Inc. Pregnancy Urine Test (Cassette) uses a monoclonal antibody specific to hCG in a one-step lateral flow chromatographic immunoassay to accurately detect hCG at the level close to or greater than 25 mIU/ml (WHO 3rd IS 75/537).

PRINCIPLE OF THE PROCEDURE

This assay is a one-step lateral flow chromatographic immunoassay. The test strip in the device includes: 1) a conjugate pad containing mouse monoclonal anti-hCG antibody conjugated to colloidal gold, and 2) nitrocellulose membrane containing a test line (T line) and a control line (C line).

When an adequate amount of specimen is applied to the sample pad of the device, hCG in the specimen binds to sites on the anti-hCG antibody-gold conjugate in the conjugate pad to form a complex and migrates along the membrane strip. If the specimen contains hCG at a level close to or greater than 25 mIU/ml, the complex will bind to the capture antibody coated on the T line to develop a burgundy-colored band. If the specimen does not contain hCG or the hCG level is below the detectable level, the T line will not develop.

The C line is coated with goat anti-mouse antibody, which should bind to the gold-antibody conjugate and forms a burgundy colored line regardless of the presence of hCG.

REAGENTS AND MATERIALS SUPPLIED

- 25 test devices, each sealed in a foil pouch with a dropper pipette and a desiccant
- 1 package insert (Instructions for Use)

MATERIALS REQUIRED BUT NOT SUPPLIED

- Specimen collection containers
- Timer
- External Controls (positive and negative)

STORAGE & STABILITY

Store the kit at room temperature 15-30°C (59-86°F). Each device may be used until the expiration date printed on the label if it remains sealed in its foil pouch.

NOTE: Do not freeze and/or expose the kit to temperatures over 30°C (86°F).

SPECIMEN COLLECTION

1. Each urine specimen must be collected in a clean container.
2. Specimens may be kept at 15-30°C (59-86°F) for 8 hours, at 2-8°C for up to 3 days and at -20°C or lower for prolonged storage. Do not mix specimens.

PRECAUTION

1. The instructions must be followed exactly to obtain accurate results.
2. This test is for professional in vitro diagnostic use only.
3. Do not open the sealed pouch, unless ready to conduct the assay.
4. Do not use expired devices.
5. Dispose of all specimens and used assay materials as potentially biohazardous.

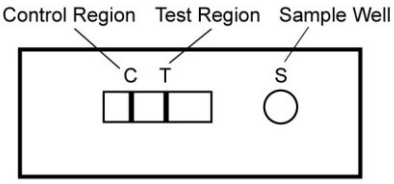
ASSAY PROCEDURE

1. Refrigerated specimens and other test materials including devices, **must be equilibrated to room temperature before testing.**
2. Remove the test device from its pouch and place it on a flat surface.
3. Holding the dropper vertically, add four drops of the specimen to the sample well.
4. Strong positive results may be observed in 2-3 minutes. Weak positive results may take longer time, up to 5 minutes to develop.

LIMITATIONS

1. This kit is not intended for any use other than early detection of pregnancy.
2. HCG may be detectable in some conditions other than normal pregnancy, that should be ruled out when diagnosing pregnancy.
   - Low titer elevations of hCG can occur in normal, non-pregnant subjects.
   - Ectopic pregnancy cannot be distinguished from normal pregnancy from hCG measurements alone.
   - Positive hCG levels may be detectable for several weeks following delivery or abortion.
3. The results must be evaluated with other data by a physician before diagnosing pregnancy.

INTERPRETATION OF RESULTS



POSITIVE

POSITIVE: If the C line and T line appear in the viewing window, the test indicates that hCG is present in the specimen at the level close to or higher than 25 mIU/ml.

NEGATIVE

NEGATIVE: If only the C line appears, the test indicates that the hCG level in the specimen is not detectable and the result is negative. **If pregnancy is suspected, repeat the test after 2 to 3 days with a new device and fresh sample.**

INVALID

INVALID: If C line is visible in the control region within 5 minutes, repeat the assay with a new test device.

IMPORTANT: Do not interpret the results after 7 minutes. The T Line should always be interpreted independently of the C Line.

QUALITY CONTROL

- **BUILT-IN CONTROL FEATURES:** The CLIAwaived, Inc. Pregnancy Urine Test (Cassette) contains a built-in control feature, the C line. The appearance of the burgundy C line indicates that the test has been performed correctly; specifically an adequate volume of specimen has been absorbed and capillary flow has occurred. The C line should always appear regardless of the presence of hCG. If the C line does not develop within 5 minutes, review the procedure and repeat test with a new device.

- **EXTERNAL QUALITY CONTROL:** External controls (positive and negative) should be run to determine if tests are working properly with each new lot received, each new shipment even if it is the same lot received previously, and each new operator (or operator who has not performed the test recently). External controls also should be run monthly, as a check on storage conditions, when problems (storage, operator, instrument, or other) are suspected or identified, and if otherwise required by your laboratory's standard QC procedures.

EXPECTED VALUES

This test is capable of detecting hCG at the level as low as 25 mIU/ml (WHO 3rd IS 75/537) or the first day of a missed period and no sooner. In normal subjects, hCG in urine and provides an early indication of pregnancy. In a 28 day cycle with ovulation occurring at day 14, hCG can be detected in urine and in minute quantities around day 23, or 5 days before the expected menstruation. The hormone concentration doubles approximately every 2 days and peaks between 7-12 weeks after the first day of the last menstrual period with a mean concentration of 50,000 mIU/ml. Concentrations as high as 100,000 mIU/mL have been reported in normal pregnancies during the first trimester.

PERFORMANCE CHARACTERISTICS

1. **Sensitivity.** The CLIAwaived, Inc. Pregnancy Urine Test (Cassette) will display positive results with specimens containing hCG at the level close to or greater than 25 mIU/ml. The test is standardized to the WHO 3rd IS 75/537.
2. **Accuracy.**
   - **Samples Studied**
     Pooled urine specimens from forty healthy non-pregnant humans were spiked with hCG to concentrations of 0, 15, 20, 25, 30, 35, 50, 100 mIU/ml with 5 replicates each. All specimens were blind labeled.
   - **Comparison Studies**
     Comparison studies on the CLIAwaived, Inc. Pregnancy Urine Test (Cassette) with a legally marketed device were performed in-house and in a clinical reference laboratory. Positive and negative results were compared and the correlation was 100%.
   - **Physician's Office Laboratory (POL) Studies**
     The CLIAwaived, Inc. Pregnancy Urine Test (Cassette) was evaluated at three POL sites by persons with diverse educational backgrounds and work experiences. The results from all three POL sites agreed 100%.
3. **Specificity.** The α subunit of hTSH, hLH, and hFSH is similar to that of hCG, which may cause cross reactivity between those hormones. High physiological concentrations of hTSH (up to 1,000 µIU/ml), hLH (up to 300 mIU/ml), and hFSH (up to 1,000 mIU/ml) spiked in hCG positive (spiked to 25mIU/ml) and negative specimens were tested, separately, in the CLIAwaived, Inc. Pregnancy Urine Test (Cassette), and did not affect the expected results in that study.
4. **Interefering Substances.** The following analytes spiked in urine pools containing 0, or 25mIU/ml hCG (WHO 3rd IS) were tested, separately, in the CLIAwaived, Inc. Pregnancy Urine Test (Cassette), and did not affect the expected results in that study.

CHEMICAL ANALYTES

Description	Concentration
Acetoacetic Acid	*2,000 mg/dL*
Acetaminophen	*20 mg/dL*
Acetylsalicylic Acid	*20 mg/dL*
Ascorbic Acid	*20 mg/dL*
Benzoylecgonine	*10 mg/dL*
Caffeine	*20 mg/dL*
Cannabinol	*10 mg/dL*
DMSO	*5%*
EDTA	*80 mg/dL*
Ephedrine	*20 mg/dL*
Ethanol	*1%*
Gentisic Acid	*20 mg/dL*
Methadone	*10 mg/dL*
Methanol	*10%*
Phenothiazine	*20 mg/dL*
Phenylpropanolamine	*20 mg/dL*
Salicylic Acid	*20 mg/dL*
β-Hydroxybutyrate	*2,000 mg/dL*
Uric Acid	*20 mg/dL*

BIOLOGICAL ANALYTES

Description	Concentration
Albumin(serum)	*2,000 mg/dL*
Bilirubin	*1,000 µg/dL*
Hemoglobin	*1,000 µg/dL*
Glucose	*2,000 mg/dL*
pH	*5-9*

BACTERIA

Description	Concentration
E. Coli	*10^8 CFU/mL*
Group B streptococcus	*2.5×10^8 CFU/mL*
Chlamydia trachomatis	*10^4 IFU/mL*

REFERENCES

- Braunstein GD, Grodin JM, Vaitukaitis J and Ross GT. Secretory rates of human chorionic gonadotropin by normal trophoblast. American Journal of Obstetrics and Gynecology, 115:447-50, 1973.
- Brody S and Carlstrom G. Immunoassay of human chorionic gonadotropin in normal and pathologic pregnancy. Journal of Clinical Endocrinology and Metabolism, 22:564, 1962.
- Borkowski A and Muquardt C. Human chorionic gonadotropin in the plasma of normal, nonpregnant subjects. N Engl J Med. 1979, 301: 298-302.
- Ross GT. Clinical relevance of research on the structure of human chorionic gonadotropin. American Journal of Obstetrics and Gynecology 1977; 129:795.

Legend

Do not reuse		Use by YYY-MM-DD or YYYY-MM	
LOT	Batch Code	SN	Serial number
	Caution, consult accompanying documents	REF	Catalog number
	Manufacturer		Temperature limitation
	Contains sufficient for <n> tests		Keep away from sunlight
IVD	*In vitro* diagnostic medical device		Keep away from moisture
	Consult instructions for use	CE	CE Mark
	Recycle	EC REP	Authorized representative in the European Community

CLIA*waived*™ Inc.

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EC REP

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