137 x 218 mm

CE

clue® HCG

ONE STEP PREGNANCY TEST

DEVICE

INTRODUCTION

clue® one step pregnancy test is a rapid, qualitative, two site sandwich immunoassay for the determination of human chorionic gonadotropin (hCG), a marker for pregnancy, in urine specimens.

SUMMARY

Human chorionic gonadotropin (hCG), a glycoprotein hormone secreted by viable placental tissue during pregnancy, is excreted in urine approximately 20 days after the last menstrual period. The levels of hCG rise rapidly reaching peak levels after 60 - 80 days.The appearance of hCG in urine soon after conception and its rapid rise in concentration makes it an ideal marker for the early detection and confirmation of pregnancy. However elevated hCG levels are frequently associated with trophoblastic and non-trophoblastic neoplasms and hence these conditions should be considered before a diagnosis of pregnancy can be made. **clue**® one step pregnancy test detects the presence of hCG in urine specimens, qualitatively, at concentrations as low as 10 mIU/ml in less than five minutes.

PRINCIPLE

clue® one step pregnancy test utilizes the principle of agglutination of antibodies/ antisera with respective antigen in immuno-chromatography format along with use of nano gold particles as agglutination revealing agent. As the test sample flows through the membrane assembly within the test device, the colored Agglutinating sera for hCG-colloidal gold conjugate complexes with the hCG in the sample. This complex moves further on the membrane to the test region where it is immobilized by the Agglutinating sera for hCG coated on the membrane leading to formation of a colored band which confirms a positive test result. Absence of this colored band in the test region indicates a negative test result. The unreacted conjugate and unbound complex if any move further on the membrane and are subsequently immobilized by the Agglutinating sera for rabbit globulin coated on the membrane at the control region, forming a colored band. This control band serves to validate the test results. The control band formation is based on the 'Rabbit globulin / Agglutinating Sera for Rabbit globulin' system. Since it is completely independent of the analyte detection system, it facilitates formation of consistent control band signal independent of the analyte concentration. This control band serves to validate the test performance.

REAGENTS AND MATERIALS SUPPLIED

A. Each individual pouch contains :

1. DEVICE : Contains membrane assembly predispensed with Agglutinating sera for hCG-colloidal gold conjugate, rabbit globulin-colloidal gold conjugate, Agglutinating sera for hCG and Agglutinating sera for rabbit globulin at the respective regions.
2. PIPETTE : Disposable plastic sample applicator.
3. Desiccant pouch.

B. Package Insert

REF	301010001	301010010	301010025	301010050	301010100
Σ	1	10	25	50	100

STORAGE AND STABILITY

The sealed pouches in the test kit may be stored between 4°C To 30°C till the duration of the shelf life as indicated on the pouch/ carton. DO NOT FREEZE.

NOTE

(1). For in vitro diagnostic use only. NOT FOR MEDICINAL USE. For professional use. (2).Do not use beyond expiry date. (3). Read the instructions carefully before performing the test. (4). Handle all specimens as potentially infectious. (5). Follow standard biosafety guidelines for handling and disposal of potentially infective material. (6). Contact with the contents of desiccant pouch containing, among other substances, cobalt chloride (CAS# 7646-79-9) should be kept to a minimum. Inhalation / swallowing may cause harm.

SPECIMEN COLLECTION AND PREPARATION

Though random urine specimens can be used, first morning urine specimen is preferable as it contains the highest concentration of hCG. Specimens should be collected in clean glass or plastic containers. If testing is not immediate, the urine specimens may be stored at 2°C To 8°C for upto 72 hours. Turbid specimens should be centrifuged or allowed to settle and only the clear supernatant should be used for testing.

TEST PROCEDURE AND INTERPRETATION OF RESULTS

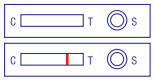
1. Bring the sealed pouches to room temperature. Open the pouch and remove the device, applicator and desiccant.

Check the color of the desiccant. It should be blue. If it has turned colorless or pink discard the device and use another device. Once opened, the device must be used immediately.

2. Dispense two drops of urine specimen into the sample well 'S' using the applicator provided. Refrigerated specimens must be brought to room temperature prior to testing.
3. At the end of five minutes read the results as follows:

NEGATIVE : A colored band appears on the control region 'C'.

POSITIVE : In addition to the control band, a colored band also appears on the test region 'T'.



INVALID : The test should be considered invalid if no colored band appears on the device. The test should also be considered invalid if a colored band appears only at the test region 'T' and not at the control region 'C'. In such cases, repeat the test with a new device ensuring that the test procedure has been followed accurately .

4. Although, depending on the concentration of hCG in the specimen, positive results may start appearing as early as 30 seconds, negative results must be confirmed only at the end of five minutes.

PERFORMANCE CHARACTERISTICS

1. **Sensitivity:** **clue**® one step pregnancy test detects the presence of hCG in urine specimens, qualitatively, at concentrations as low as 10 mIU/ml. Concentrations of about 100 mIU/ml of hCG are reached by the first day of the missed menstrual period in normal pregnancy. Thus **clue**® one step pregnancy test is able to detect pregnancy at very early stages.
2. **Specificity:** Healthy men and healthy non-pregnant women do not have detectable levels of hCG by **clue**® one step pregnancy test. Homologous hormones and other potentially interfering substances spiked beyond peak physiological concentrations did not cross react with **clue**® one step pregnancy test.
3. **Accuracy:** The results obtained by **clue**® one step pregnancy test correlated very well when run in parallel with other commercially available tests for pregnancy, using known positive and negative specimens.

LIMITATIONS OF THE TEST

(1). A number of conditions other than pregnancy including trophoblastic and non-trophoblastic neoplasms such as hydatidiform mole, choriocarcinoma etc. cause elevated levels of hCG. Such clinical conditions must be ruled out before a diagnosis of pregnancy can be made. (2). Highly dilute urine specimens and specimens from very early pregnancy may not contain representative levels of hCG. If pregnancy is still suspected, repeat the test with first morning urine after 48-72 hours.(3).As with all diagnostic tests, the results must be correlated with clinical findings.

WARRANTY

This product is designed to perform as described on the label and package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

BIBLIOGRAPHY

(1). Batzer. F. R., Hormonal evaluation of early pregnancy, Fertility and Sterility, (July 1980),34. 1. (2).Thompson, R. J., Jackson, A. P., Langlois, N. 1986, Circulating antibodies to mouse monoclonal immunoglobulins in Normal subjects-incidence, species, specificity and effects on a two-site assay for creatinekinase-MB isoenzyme, Clin. Chem. 32, 476-481. (3). Data on file : Orchid Biomedical Systems.

SYMBOL KEYS

	Temperature Limitation		Manufacturer	DEVICE	Device	Σ	Contains sufficient for <n> tests
	Use by		Consult Instructions for use	PIPETTE	Disposable Plastic Sample Applicator		
	Date of Manufacture	REF	Catalogue Number		This side up		Do not reuse
LOT	Batch Number / Lot Number	IVD	In vitro Diagnostic Medical Device	EC REP	Authorised Representative in the European Community		

Manufactured by:
Orchid Biomedical Systems
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EC REP
CMC Medical Devices & Drugs S.L., Spain.

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