

## Datasheet for ABIN504780 hCG CLIA Kit



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### Overview

Quantity:	96 tests
Target:	hCG
Reactivity:	Human
Method Type:	Sandwich ELISA
Application:	ELISA

### Product Details

Purpose:	Immunoenzymometric assay: The essential reagents required for an immunoenzymometric assay include high affinity and specificity antibodies (enzyme and immobilized), with different and distinct epitope recognition, in excess, and native antigen. In this procedure, the immobilization takes place during the assay at the surface of a microplate well through the interaction of streptavidin coated on the well and exogenously added biotinylated monoclonal anti-hCG antibody. Upon mixing monoclonal biotinylated antibody, the enzyme-labeled antibody and a serum containing the native antigen, reaction results between the native antigen and the antibodies, without competition or steric hindrance, to form a soluble sandwich complex.
Analytical Method:	Quantitative
Detection Method:	Chemiluminescent
Characteristics:	The Quantitative Determination of Chorionic Gonadotropin Concentration in Human Serum by a Microplate Chemiluminescence Assay (CLIA)

### Target Details

Target:	hCG
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## Target Details

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Abstract: [hCG Products](#)

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Target Type: Hormone

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Background: Human chorionic gonadotropin (hCG) concentration increases dramatically in blood and urine during normal pregnancy. hCG is secreted by placental tissue, beginning with the primitive trophoblast, almost from the time of implantation, and serves to support the corpus luteum during the early weeks of pregnancy. hCG or hCG similar glycoproteins can also be produced by a wide variety of trophoblastic and nontrophoblastic tumors. The measurement of hCG, by assay systems with suitable sensitivity and specificity has proven great value in the detection of pregnancy and the diagnosis of early pregnancy disorders. According to the literature, hCG is detectable as early as 10 days after ovulation, reaching 100 mIU/ml by the first missed period. At the time for the next ovulation, the hCG level is 200 mIU/ml (approximately 28 days after conception) (1). A peak of 50,000 or even 100,000 mIU/ml is attained by the third month, then a gradual decline is observed (2, 3). In this method, hCG calibrator, patient specimen or control is first added to a streptavidin coated well. Biotinylated monoclonal and enzyme labeled antibodies (directed against distinct and different epitopes of hCG) are added and the reactants mixed. Reaction between the various hCG antibodies and native hCG forms a sandwich complex that binds with the streptavidin coated to the well. After the completion of the required incubation period, the enzyme-Chorionic Gonadotropin antibody bound conjugate is separated from the unbound enzyme-Chorionic Gonadotropin conjugate by aspiration or decantation. The activity of the enzyme present on the surface of the well is quantitated by reaction with a suitable substrate to produce light. The employment of several serum references of known Chorionic Gonadotropin levels permits construction of a dose response curve of activity and concentration. From comparison to the dose response curve, an unknown specimen's activity can be correlated with Chorionic Gonadotropin concentration.

## Application Details

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Application Notes: All products that contain human serum have been found to be non-reactive for Hepatitis B Surface Antigen, HIV 1&2 and HCV Antibodies by FDA required tests. Since no known test can offer complete assurance that infectious agents are absent, all human serum products should be handled as potentially hazardous and capable of transmitting disease. Good laboratory procedures for handling blood products can be found in the Center for Disease Control / National Institute of Health, "Biosafety in Microbiological and Biomedical Laboratories," 2nd Edition, 1988, HHS Publication No. (CDC) 88-8395.

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Plate: Pre-coated

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Protocol:

### **Specimen Collection and Preparation:**

The specimens shall be blood, serum in type and the usual precautions in the collection of venipuncture samples should be observed. For accurate comparison to established normal values, a fasting morning serum sample should be obtained. The blood should be collected in a plain redtop venipuncture tube without additives or anti-coagulants. Allow the blood to clot. Centrifuge the specimen to separate the serum from the cells. Samples may be refrigerated at 2-8(C for a maximum period of five (5) days. If the specimen(s) cannot be assayed within this time, the sample(s) may be stored at temperatures of -20(C for up to 30 days. Avoid repetitive freezing and thawing. When assayed in duplicate, 0.050ml of the specimen is required

### **Reagent Preparation:**

1. Wash Buffer Dilute contents of Wash Concentrate to 1000ml with distilled or deionized water in a suitable storage container. Store diluted buffer at room temperature 20-27(C. 2. Working Signal Reagent Solution - Store at 2 - 8(C. Determine the amount of reagent needed and prepare by mixing equal portions of Signal Reagent A and Signal Reagent B in a clean container. For example, add 1 ml of A and 1ml of B per two (2) eight well strips (A slight excess of solution is made). Discard the unused portion if not used within 36 hours after mixing. If complete utilization of the reagents is anticipated, within the above time constraint, pour the contents of Signal Reagent B into Signal Reagent A and label accordingly.

### **Test Procedure:**

Before proceeding with the assay, bring all reagents, serum references and controls to room temperature (20-27(C). 1. Format the microplate wells for each serum reference, control and patient specimen to be assayed in duplicate. Replace any unused microwell strips back into the aluminum bag, seal and store at 2-8(C. 2. Pipette 0.025 ml (25l) of the appropriate serum reference, control or specimen into the assigned well. Add 0.100 ml (100l) of hCG Tracer Reagent to all wells. 4. Swirl the microplate gently for 20-30 seconds to mix and cover. 5. Incubate 45 minutes at room temperature. 6. Discard the contents of the microplate by decantation or aspiration. If decanting, blot the plate dry with absorbent paper. 7. Add 350l of wash buffer (see Reagent Preparation Section), decant (tap and blot) or aspirate. Repeat four (4) additional times for a total of five (5) washes. An automatic or manual plate washer can be used. Follow the manufacturers instruction for proper usage. If a squeeze bottle is employed, fill each well by depressing the container (avoiding air bubbles) to dispense the wash. Decant the wash and repeat four (4) additional times. Add 0.100 ml (100l) of working signal reagent to all wells (see Reagent Preparation Section). Always add reagents in the same order to minimize reaction time differences between wells Incubate at room temperature in the dark for five (5) minutes. 10. Read the relative light units in each well with a chemiluminescence microplate

## Application Details

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reader for 0.5-1.0 seconds. The results should be read within 30 minutes after adding substrate.

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Restrictions: For Research Use only