SHD
SCIENCE HEALTH DIAGNOSTICS

8 683981 707254 100 T
8 683981 707278 200 T
8 683981 707292 400 T

Total Human Chorionic Gonadotropin (Total hCG)
(Magnetic Particle Based Chemiluminescence Immunoassay)

INTENDED USE

Total Human Chorionic Gonadotropin Test Kit (Chemiluminescence Immunoassay) is a quantitative test for use on Innoviqure Spectrum Chemiluminescence Immunoassay Analyzer and Innoviqure Nexus Chemiluminescence Immunoassay Analyzer for the determination of Total hCG in human serum and plasma. Total hCG plays a critical role in the diagnosis of pregnancy.

PACKAGING SPECIFICATIONS

100T/200T/400T

SUMMARY AND EXPLANATION

hCG consists of two subunits alpha-hCG and β-hCG. In early pregnancy, hCG plays a role in stimulating progesterone production within the corpus luteum. It is also commonly administered via injection to induce ovulation in assisted reproductive treatments (ART). In biological fluids, hCG can be found in its intact form, as free subunits, or in degraded forms. Measuring these variations is crucial for diagnosing and monitoring pregnancy, pregnancy-related conditions, and certain types of cancer (Stenman et al., 2006). The molecular weight of hCG is about 36,000, with 25-41% of it attributed to sugar side chains (25-30% in regular hCG and 35-41% in hyperglycosylated hCG). During pregnancy, hCG levels follow a distinct pattern. They rise rapidly and exponentially in the early stages, peak during the late first trimester, and then gradually decrease until stabilizing at consistent levels throughout the second and third trimesters (Korevaar et al., 2015). The β-subunit of hCG, though somewhat structurally similar to the β-subunit of LH, distinguishes hCG, hyperglycosylated hCG, and pituitary hCG from other molecules. Both hCG and LH act through the shared hCG/LH receptor. A key difference between LH and hCG is their circulating half-lives: LH (pI 8.0) has a half-life of 25-30 minutes, whereas hCG (pI 3.5) has a significantly longer half-life of approximately 37 hours—about 80 times longer than LH. While LH, FSH, and TSH are synthesized in the anterior pituitary, hCG is produced by fused and differentiated placental syncytiotrophoblast cells (Cole, 2010). In conclusion, β-hCG is a critical hormone during pregnancy, supporting the early stages by stimulating progesterone production, promoting placental development, and modulating the immune system. Its levels rise rapidly in early pregnancy, peak in the first trimester, and then stabilize during the second and third trimesters. Clinically, β-hCG is essential for confirming pregnancy, monitoring its progress, and detecting potential complications. Abnormal levels can indicate conditions such as ectopic pregnancy, chromosomal abnormalities, or trophoblastic diseases, highlighting its importance in prenatal care and diagnostics.

SHD
SCIENCE HEALTH DIAGNOSTICS

PRINCIPLE OF TESTING

The Total hCG test utilizing Magnetic Particle-Based Chemiluminescence Immunoassay (CLIA) combines the sensitivity of chemiluminescence with the specificity of magnetic particles to capture and detect Total hCG in samples.

1.Sample Introduction and Pre-Coated Magnetic Particles

A solid phase consisting of magnetic particles is pre-coated with monoclonal antibodies specific to human hCG (Antibody I). When the sample is added, if hCG is present, it binds to these antibodies on the magnetic particles, forming an immune complex.

2.Addition of Chemiluminescent-Labeled Antibody

A second reagent containing chemiluminescent-labeled monoclonal antibodies specific to hCG (Antibody II) is introduced into the reaction mixture. These labeled antibodies bind to the hCG already captured on the magnetic particles, forming a sandwich immunocomplex.

3.Magnetic Separation and Washing

The magnetic particles are then separated from the solution using a magnet, allowing for the removal of any unbound substances or reagents. The particles are then washed to ensure that only the immune complexes bound to the hCG are retained.

4.Chemiluminescent Reaction

A chemiluminescent substrate is added to the reaction mixture. The chemiluminescent-labeled antibody conjugates catalyze a reaction that emits light in proportion to the amount of Total hCG present in the sample.

5.Detection and Quantification

The emitted light is measured by a chemiluminescence analyzer. The intensity of the light produced is directly correlated with the concentration of Total hCG in the sample. A standard curve, created using known concentrations of Total hCG, allows for the quantitative determination of Total hCG levels.

6.Result Interpretation

The Total hCG concentration in the sample is calculated based on the measured light intensity, providing diagnostic information for detecting pregnancy.

MAIN COMPONENTS

This reagent kit consists of Reagent Ra, Reagent Rd, calibrators (optional) and controls (optional).

Characteristics of Reagents

Reagent	For 100 T	Component
Ra	10,50 mL	Magnetic particles coated with recombinant Total hCG
Rd	10,50 mL	Acridinium ester conjugated to recombinant Total hCG antibody

Characteristics of Calibrators

Calibrator	mL/vial	Component
6 point	1,0 mL	Recombinant Total hCG antigen

Characteristics of Controls

Control	mL/vial	Component
2 point	5,0 mL	Recombinant Total hCG antigen (Lyophilized)

STORAGE CONDITIONS AND PERIOD OF VALID

The period of validity of the test kit is 18 months while the package is sealed and stored at 2-8 °C.

APPLICABLE INSTRUMENTS

Innoviqure Spectrum Chemiluminescence Immunoassay Analyzer and Innoviqure Nexus Chemiluminescence Immunoassay Analyzer manufactured by Deniz Biyokimya Urunleri Dis. Tic. A.S.

THE REQUIREMENTS OF SAMPLE

This kit is suitable for Serum / Plasma samples.
Serum / Plasma Collection: The serum or plasma should be separated for analysis immediately after blood collection to avoid hemolysis. Use within 8 hours if the sample is stored at room temperature; use within 48 hours if the sample is stored at 2-8 °C; use within 3 months if the sample is stored at -20°C with one cycle of freeze and thaw.

The sample must reach the equilibrium status at room temperature (20~30°C) before use.

TEST METHOD

- When loading Reagent Ra into the instrument for the first time, mix the reagent thoroughly in its bottle to resuspend any magnetic particles that may have settled during transportation.
- Check the sample volume in the sample tube before each test to ensure that the sample volume in the sample tube is always greater than 110 µL.
- If necessary, perform the calibration procedure. Refer to the manual of the device used for information on how to carry out the calibration procedure.
- Gently swirl the calibrator or control bottle 5-10 times to mix thoroughly before use.
- Sample Loading: Refer to the manual of the instrument used for information on sample loading.
- Press the “Run” button to perform the test.
- Dilution is required if the sample concentration is greater than 10,000 mIU/mL.

CONFIDENCE INTERVAL

The serum and plasma samples of non-pregnant donors (n=224) were tested using Total hCG Test Kit. The results showed that the 99% percentile of Total hCG was less than 5 mIU/mL. The above reference values are for reference only. Due to the differences in geography, race, gender and age, it is recommended that each laboratory establish its own reference values (reference range) according to the actual situation.

INTERPRETATION OF TEST RESULTS

The test results of this test kits are only for reference in clinical and cannot be used as the sole indicator for the diagnosis or exclusion of disease. The clinical diagnosis and treatment of patients should be considered in combination with their symptoms, medical history, and other laboratory tests result and treatment reactions.

LIMITATIONS OF TEST RESULTS

1. The kit can be used for the determination of serum or plasma, and the reliability for the concentration determination of Total hCG needs further confirmation.
2. Plasma samples in this kit are recommended to use EDTA, sodium heparin or sodium citrate as anticoagulants. If other anticoagulants are selected, the effect needs to be further confirmed.
3. The concentrations of Total hCG obtained from other methods are not directly comparable with the results obtained from this kit.
4. If the test results of this kit are inconsistent with the clinical evaluations, further examination is required.
5. Operation must be carried out strictly in accordance with operating manual, please operate carefully for getting more accurate results, any modification of the operating manual may affect the results.
6. In the case of false positive results, some non-specific components in the sample with similar antigen-determining clusters might participate in the reaction. In case of false negative results, some unknown components might the antigen-determining cluster and disturb the immune recognition reaction. The detection of Total hCG might be unsuccessful if the sample has been taken for too long time or the environmental temperature is causing the degradation of analytes.
7. Other factors may also cause inaccuracy in Total hCG test results, including technical problems, inappropriate operation or sample factors, such as wrong sample collection process, preservation and handling.
8. The test results are for reference only and should not be taken as the only indicator for clinical diagnosis.

PRODUCT PERFORMANCE REQUIREMENTS

1. Linear Range: within the range of 0.50 to 10,000.00 mIU/mL , the correlation coefficient R value should be greater than or equal to 0,990.
2. Precision:
2.1 Intra-batch precision: the coefficient of variation CV should not be greater than 8.0 %.
2.2 Inter-batch precision: the coefficient of variation CV should not be greater than 15.0 %.
3. Accuracy: The relative deviation should not be greater than 10.0 %.
4. The Limit of Detection: The limit of detection of this kit is no higher than 0.50 mIU/mL .

PRECAUTIONS

1. This kit is only used for in vitro diagnosis and should not be used for other purposes.
2. The kit is only for use by laboratory medicine professionals.
3. This product is disposable and cannot be reused.
4. Do not use the contaminated or spoiled samples or expired products for testing.
5. Fresh samples are recommended. Hyperlipidemia, jaundice and hemolysis are not recommended.
6. Do not use for detection if the package is not intact.
7. When using the test kit for detection, the environment temperature should not be too high or too low.
8. During the test, the analyzer should avoid strong electromagnetic environment.
9. All wastes shall be disposed in accordance with infectious materials.
10. The test result of this kit is not the only indicator for disease. Judgement should be made by doctors while considering all relevant indications and clinical symptoms.
11. It is recommended to wear gloves without talcum powder, because the powder may lead to wrong results.
12. If you have any questions or suggestions about this reagent, please contact the manufacturer.
13. The longest transportation period for the test kit must not exceed 12 days under 2-8 °C.

SHD
SCIENCE HEALTH DIAGNOSTICS

CALIBRATIONS

Use the relevant reagents and calibrators to perform the calibration. Recalibration is required in the following cases:
(1) Reagents with a different lot number;
(2) Reagents with the same lot number have been used in the analyzer for more than 28 days;
(3) The quality control value is outside the allowable range.

QUALITY CONTROL

The controls are used for quality control. If the results are outside the range, the reagents may have deteriorated or there may be technical problems. In this case the results may be invalid and the materials need to be retested. If necessary, perform the calibration again. For information on troubleshooting, refer to the manual of the instrument used.

ASSAY SPECIFICATIONS (Table 1)

Sample Type	Serum, Plasma
Sample Volume	110 µL
Assay Range	0.50 –10,000.00 mIU/mL
Time to First Result	15 minutes
LoB	0.20 mIU/mL
LoD (10 % CV)	0. 50 mIU/mL

REFERANCES

Stenman, U.-H., Tiitinen, A., Alfthan, H., & Valmu, L. (2006). The classification, functions and clinical use of different isoforms of HCG. Human Reproduction Update, 12(6), 769–784. https://doi.org/10.1093/humupd/dml029

Cole, L. A. (2010). Biological functions of hcg and HCG-related molecules. Reproductive Biology and Endocrinology, 8(1), 102. https://doi.org/10.1186/1477-7827-8-102

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Deniz Biyokimya

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Index or Symbols

	Attention, see instructions for use	Σ 1	Tests per Kit		Manufacturer
IVD	For *in vitro*		Use by		Do NOT Use Damaged Box
	Store between 2 - 30°C	LOT	Lot Number	REF	Catalogue Number

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