βhCG

Beta-Human Chorionic Gonadotropin (FIA)

infinosis™

REF: IN027702 Σ 25

Intended use
The Infinosis™ βhCG is a fluorescence immunoassay (FIA) for the in vitro quantitative determination of the human chorionic gonadotropin (hCG) plus the hCG β−subunit in Human whole blood, serum or plasma. For professional use only.

Summary
References[1,2]
Similarly to LH (Luteinizing hormone), FSH (Follicle-stimulating hormone) and TSH (Thyroid-stimulating hormone), human chorionic gonadotropin (hCG) is a member of the glycoprotein family and consists of 2 subunits (α-1 and β-chains) which are associated to form the intact hormone. The α-chains in all four of these glycoprotein hormones are virtually identical, whereas the β-chains have greatly differing structures and are responsible for the respective specific hormonal functions. Specific assays for beta-hCG permit the early detection of pregnancy.

Test principle
Sandwich principle. Total duration of assay: **15 minutes**
Sample is added to the sample well of the test, then the fluorescence-labeled detector anti-βhCG antibody binds to βhCG antigen in blood specimen. As the sample mixture migrates on the nitrocellulose matrix of test strip by capillary action, the complexes of detector antibody and βhCG are captured to anti-βhCG antibody that has been immobilized on test strip.
The more βhCG antigen is in blood specimen, the more complexes are accumulated on test strip. Signal intensity of fluorescence of detector antibody reflects amount of βhCG captured and the instrument for infinosis™ tests shows βhCG concentrations in blood specimen.

Reagents
Materials provided
- **Test Cartridge**, 25 pcs, individually packaged
- **ID chip**, 1 pcs
- **Sample Buffer,** 25 tubes
- **IFU**, 1 copy

Materials required (but not provided)
- infinosis™ 2020 FIA analyzer
- βhCG control (DiaSino control is recommended)
- Transfer pipette set (100 μL size)
- Centrifuge (for plasma and serum only)
- Timer

Precautions and warnings
- For in vitro diagnostic use only.
- Carefully follow the instructions and procedures described in this instructions before testing.
- The test cartridge should remain in its original sealed pouch until ready to use. Do not use it if the pouch is damaged or the seal is broken.
- Do not use reagents beyond the labeled expiry date.
- Do not mix or use components from kits with different Lots.
- Don't use Test Cartridge if its Lot does not match with ID Chip that is inserted onto the instrument.
- The infinosis™ βhCG should be used only in conjunction with the instrument for infinosis™ tests.
- The tests should be applied by professionally trained staff working in certified laboratories at some remove from the patient and clinic at which the sample is taken by qualified medical personnel.
- infinosis™ βhCG assay is single use only. Do not reuse it.
- The Test Cartridge and instrument for infinosis™ tests should be used away from vibration and magnetic field. During normal usage, the Test Cartridge may generate slight vibration, which should be regarded as normal.
- Use separate clean pipette tips and buffer tubes for different specimens. The pipette tips and detector buffer tubes should be used for one specimen only.
- Do not smoke, eat, or drink in areas in which specimens or kit reagents are handled.
- Blood specimens, used test cartridges, pipette tips and sample buffer tubes are potentially infectious. Proper laboratory safety techniques, handing and disposal methods should be followed in accordance with standard procedures and relevant regulations observed by microbiological hazard materials.
- The results should be interpreted by the physician along with clinical findings and other laboratory test results.

Incident report
Any suspected serious incidents related to this assay shall be immediately reported to DiaSino, DiaSino's Authorized Representative in the EU, and the national competent authorities of the Member States where the users and/or patients are located.

Storage and stability
- Store the test kit at 2-30℃, the stability is up to the expiration date printed on package.
- Test cartridge and sample buffer should be used within 1 hour after opening the pack.

Specimen collection and preparation
- The test can be performed with either whole blood, serum or plasma.
- Collect serum samples in accordance with correct medical practices.
- Using standard phlebotomy procedure, collect a venipuncture whole blood specimen using a blood collection tube. If collecting plasma use a blood collection tube containing suitable anticoagulant (EDTA recommended).
- Separate the serum/plasma from blood as soon as possible to avoid hemolysis.
- Test should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8℃ for up to 3 days. For long-term storage, specimens should be kept below -20℃.

Quality control
- Quality control tests are a part of the good testing practice to confirm the expected results and validity of the assay and should be performed at regular intervals.
- The control tests should be performed immediately after opening a new test lot to ensure the test performance is not altered.
- Quality control tests should also be performed whenever there is any question concerning the validity of the test results.
- Control materials are provided on demand with infinosis™ tests. For more information regarding obtaining the control materials, contact DiaSino Laboratories Co., Ltd for assistance.

Test setup
- Ensure that the lot number of the cartridge matches that of the sample buffer, and the ID Chip.
- If the sealed cartridge and sample buffer have been stored in refrigerator, place them at room temperature (18-25 ℃) at least 30 minutes before measurement.
- Turn on the instrument for infinosis™ tests.
  Refer to the *'instrument for infinosis™ tests Operation Manual'* for the complete information and operating instructions.

Test procedure
1. Insert ID Chip into the instrument for infinosis™ tests and read ID chip information.
2. Using a pipette to transfer **20 μL** of sample (Human whole blood/plasma/serum) to the **sample buffer tube** provided in the kit.
3. Close the lid of the sample mixing tube and mix the sample thoroughly for **5-10 seconds** by tapping or inverting the tube.
4. Pipette out **100 μL** of **sample mixture** and load it onto the sample well on the cartridge.
5. Leave the sample-loaded cartridge at room temperature for **15 minutes.**
6. Insert the sample-loaded cartridge into the cartridge holder of instrument for infinosis™ tests.
   Ensure proper orientation of the cartridge before pushing it all the way inside the cartridge holder.
7. Press **"Test"** button on the instrument for infinosis™ tests.
8. Instrument for infinosis™ tests will start scanning the sample-loaded cartridge immediately.
9. Read the test result on the display screen of the instrument for infinosis™ tests.
10. Print out the testing results when press **"Print"** button on the instrument for infinosis™ tests.

Limitations - interference
- The assay is unaffected by icterus (bilirubin < 410 μmol/L or < 24 mg/dL), hemolysis (Hb < 0.621 mmol/L or < 1.0 g/dL), lipemia (Intralipid < 1400 mg/dL) and biotin (< 327 nmol/L or < 80 ng/mL).
- Criterion: Recovery within ± 10 % of initial value.

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- No interference was observed from rheumatoid factors up to a concentration of 3400 IU/mL and samples from dialysis patients.
- For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

Measuring range
0.1–10000 mIU/mL (defined by the lower detection limit and the maximum of the master curve). Values below the lower detection limit are reported as < 0.1 mIU/mL. Values above the measuring range are reported as > 10000 mIU/mL.

Lower detection limit
0.1 mIU/mL
The detection limit represents the lowest analyte level that can be distinguished from zero. It is calculated as the value lying two standard deviations above that of the lowest standard (master calibrator, standard 1+2 SD, repeatability study, n = 21).

Expected values
0-5.0 mIU/mL
Results from a multicenter study in clinical centers are listed below.
- 0-3 mIU/mL hCG for 97.5 % of the values obtained from 126 healthy, non–pregnant premenopausal women. The corresponding upper 95 % confidence limit ranges up to 5.5 mIU/mL.
- 0-7 mIU/mL hCG for 97.5 % of the values obtained from 113 healthy, postmenopausal women. The corresponding upper 95 % confidence limit ranges up to 8.5 mIU/mL.
- 0-2.5 mIU/mL hCG for 97.5 % of the values obtained from 129 men. The corresponding upper 95 % confidence limit ranges up to 3.0 mIU/mL.
- During pregnancy (weeks of pregnancy - defined as completed weeks of pregnancy beginning with the start of the last menstruation phase), the following values have been determined.

Data are given only for the weeks of gestation for which the case numbers (n) were greater than 10.

Weeks of gestation	N	hCG mIU/mL	
		Median	5-95th percentile
3	17	16.8	6.6-58.3
4	57	158	11.4-692
5	41	1477	198-8009
6	39	3899	265->20000
7	25	>20000	3787->20000
8-12	17	>20000	>20000

Median values and the 5th and 95th percentile were calculated for the completed gestational weeks - see within the table above.

The results from patients are summarized data from measurements with the infinosis™ βhCG assay in the table below.

Cencentration mIU/mL	N	Percent (%)				
Healthy subjects	788	≤ 4	>4 - ≤ 8	>8 - ≤ 100	>100	>1000
Males	369	98.92	1.08			
Females Premenopause	286	98.60	1.40			
Females Postmenopause	133	66.17	33.08	0.75		
Others	364	51.65	9.90	11.54	12.36	14.55

Each laboratory should investigate the transferability of the expected values to its own patient population and if necessary determine its own reference ranges.

Specific performance data
Representative performance data are given below. Results obtained in individual laboratories may differ.

Precision
Intra-assay
Determined by using 10 tests in the same batch to test with TSH control, CV ≤ 15%
Inter-assay
Determined by using 3 tests in 3 random and continuous batches to test with TSH control, CV ≤ 20%

Method comparison
A comparison of the infinosis™ βhCG assay (y) with the Roche Elecsys hCG+β (x) using clinical samples gave the following correlations:
Number of samples measured: 98

Linear regression
y = 1.036x - 1.095
r = 0.9882

The sample concentrations were between approx. 1 and 10000 mIU/mL.

Analytical specificity
For the monoclonal antibodies used, the following cross-reactivities were found: TSH: not detectable, LH 0.12 %, FSH < 0.1 %.

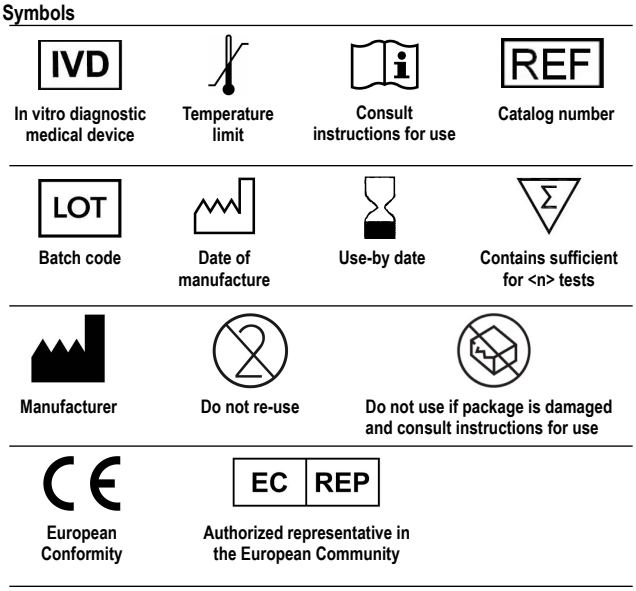
Functional sensitivity
0.18 mIU/mL
The functional sensitivity is the lowest analyte concentration that can be reproducibly measured with an intermediate precision CV of 20 %.

Hook effect
There is no high-dose hook effect at hCG concentrations up to 1000000 mIU/mL.

References

1. Schwarz S, Berger P, Wick G. The Antigenic Surface of Human Chorionic Gonadotropin as Mapped by Murine Monoclonal Antibodies. Endocrinology 1986;118(1):189-197.
2. Sturgeon CM, McAllister EJ. Analysis of hCG: clinical applications and assay requirements. Ann Clin Biochem 1998;35:460-491.

Symbols



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