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. In the event of performance changes or product malfunction, please contact manufacturer.

BIBLIOGRAPHY

1. Kuang qingmei, zhang wenhui, Chen wenying, li yinfang. The value of serum human chorionic gonadotropin and serum lipid in early pregnancy in predicting pregnancy hypertension[J]. Clinical medicine engineering, 2015, 22(10): 1349-1350+1353.
2. Xue wJ, wang w, wang xl, huang hj. Experimental evaluation of determination of human chorionic gonadotropin beta in urine by Access chemiluminescence[J]. Shanghai Journal of Medical Laboratory Science, 2003(02): 105-106. (in Chinese with English abstract)
3. Xu LAN, Chen zhuqin. Diagnostic value of human chorionic gonadotropin measurement of betaemia in abdominal cavity for ectopic pregnancy[J]. Journal of the Third Military Medical University, 1994(02): 155.
4. Li w, Du wj. Value of serum beta human chorionic gonadotropin, progesterone, oncoantigen 125 and endometrial thickness in the diagnosis of early ectopic pregnancy [J]. Chinese Journal of Obstetrics and Gynecology, 2010, 26(10): 759-762.

SYMBOL KEYS

Temperature Limitation	Consult Instructions for use	Date of Manufacture	Do not reuse
Manufacturer	IVD *In vitro* Diagnostic Medical Device	This side up	Use by
Contains sufficient for <n> tests	REF Catalogue Number	LOT Batch Number / Lot Number	DEVICE Device

Manufactured by:

Zephyr Biomedicals

A Division of Tulip Diagnostics (P) Ltd.

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0223/VER-01

FIAcheck™

β-hCG

Fluorescence Immunoassay for Quantitative determination of Beta-hCG in Human Serum and Plasma

DEVICE

FOR IN VITRO DIAGNOSTIC USE ONLY

Store at 4°C to 30°C

INTENDED USE

FIAcheck™ β-hCG Fluorescence Immunoassay is intended for the in-vitro quantitative measurement of Beta-Human Chorionic Gonadotropin (β-hCG) in human serum and plasma.

INTRODUCTION

Human Chorionic Gonadotropin (hCG) is a sialoglycoprotein. hCG is initially secreted by the trophoblastic cells of the placenta shortly after implantation of the fertilized ovum into the uterine wall. The rapid rise in hCG serum levels after conception makes it an excellent marker for early confirmation and monitoring of pregnancy. Physiologically, hCG appears to maintain the corpus luteum, thereby allowing synthesis of progesterone and estrogens that support the endometrium. As uncomplicated pregnancies progress, the placenta assumes the production of these hormones. The serum hCG levels increase to a peak concentration, then decrease and plateau. hCG circulates as the intact molecule in the serum of normal women who have an uncomplicated pregnancy. The subunits are cleared rapidly and excreted by the kidney. The placental hormone, hCG, is similar to luteinizing hormone (LH), follicle stimulating hormone (FSH) and thyroid stimulating hormone (TSH). All are glycoproteins consisting of two non-covalently bound dissimilar subunits, designated alpha and beta, with attached carbohydrate sidechains. The alpha subunits of these glycoproteins are very similar. In contrast, the beta subunit portions determine the biological and immunochemical specificities. The beta subunits of hCG and LH exhibit considerable homology in amino acid content. Amino acid residues specific for the beta subunit of hCG confer the immuno-chemical specificity. With the availability of sensitive quantitative assays for the measurement of serum β-hCG, it has been shown that hCG levels can be useful in predicting spontaneous abortions, aiding in the detection of ectopic pregnancy and multiple gestation. Elevated levels of hCG have also been detected in serum from patients with abnormal physiological conditions not related to pregnancy.

PRINCIPLE OF THE TEST

FIAcheck™ β-hCG is based on principle of agglutination of antibodies/anti-sera with respective antigen in immuno-chromatographic format using fluorophores as signal generators. The **FIAcheck™ β-hCG** test device is coated with immobilized β-hCG mouse monoclonal antibody 1 on the test line, sheep anti chicken IgY in control line and a mixture of β-hCG murine monoclonal antibody 2 and Chicken IgY labeled with fluorescent microspheres on the binding pad.

β-hCG in sample binds to the β-hCG murine monoclonal antibody 2 labeled with fluorescent microspheres in the binding pad.

The fluorescent labeled Ag-Ab complex moves forward due to capillary action and is captured by the immobilized β-hCG mouse monoclonal antibody 1 forming a double antibody sandwich and produces the test line. Chicken IgY labelled with fluorescent microspheres binds with sheep anti chicken IgY to produce the control line. When the **FIAcheck™** test device is inserted in the **FIAcheck™** analyzer, it scans both the test line and control line. The ratio of the two fluorescence values is used to calculate the concentration of the analyte present in the sample.

MATERIALS AND COMPONENTS

Materials provided with the test kits:

- **FIAcheck™ β-hCG** test device in a sealed pouch with desiccant.
- QR Code card for calibration.
- Sample Diluent. Ready to use.
- Empty vials for sample dilution.

Materials required but not provided

- Precision pipettes: 100-1000µl
- Disposable pipette tips
- Disposable Gloves
- **FIAcheck™** Analyzer (Time Resolved Fluorescence Immunoassay Analyzer)
- Digital Thermometer
- Stopwatch

STORAGE AND STABILITY

1. **FIAcheck™ β-hCG** kit is stable at 4°C to 30°C upto expiry date printed on the label. DO NOT FREEZE.

2. **FIAcheck**™ Test device should be used within 30 minutes once the foil pouch is opened.
3. If the colour of the desiccant has changed from blue to pink or colourless at the time of opening the pouch, kindly discard the device and use another device.
4. Once opened, the sample diluent can be stored between 4°C to 30°C for remaining duration of shelf life.

SAMPLE COLLECTION

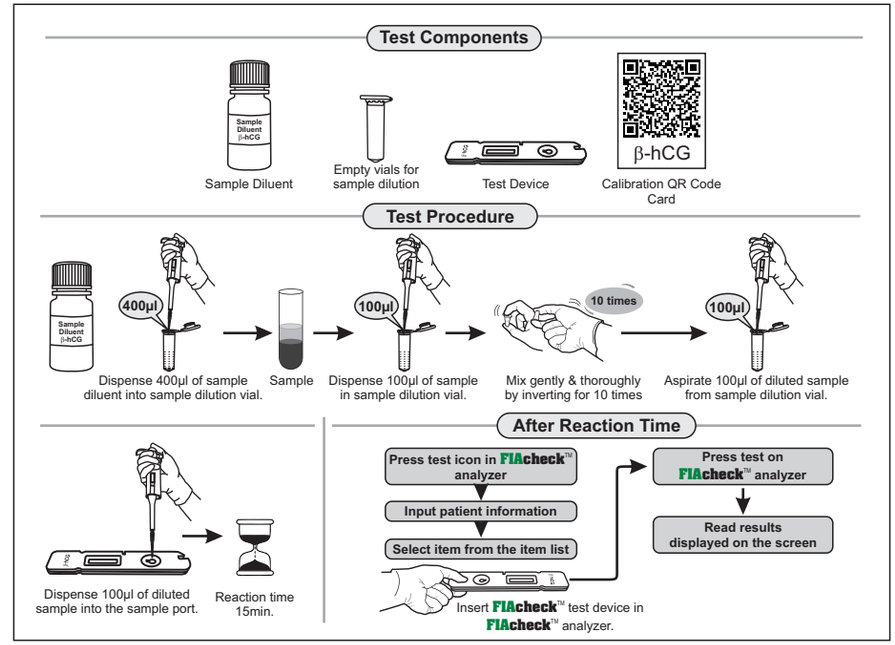
1. Only human Serum and Plasma sample should be used. Other bodily fluids and samples may not give accurate result.
2. Plasma can be anti-coagulated with Heparin and Sodium citrate or Tri sodium citrate under aseptic conditions.
3. The test should be performed within 4 hours after the sample collection at room temperature.
4. Avoid grossly hemolytic, lipemic or turbid samples.
5. Preferably use fresh samples. However, samples can be stored for 3 days at 2°C to 8°C and if more than 3 days, they should be stored at -20°C.
6. The sample should be recovered to room temperature (18°C to 30°C) before testing. Avoid repeated freezing and thawing of samples as it can affect test values.
7. Samples containing precipitate or particulate matter should be clarified by centrifugation prior to use.
8. Samples should be free from particulate matter and microbial contamination.

PRECAUTIONS

1. Only for In vitro diagnostic use.
2. Bring all reagents and samples to room temperature before use.
3. After the test device is removed from the sealed pouch, it should be used immediately or within 30 minutes of opening the pouch.
4. Do not reuse the tested **FIAcheck**™ device. Do not use sample dilution vial for more than one sample.
5. Do not use damaged **FIAcheck**™ test device or pouch.
6. All samples should be considered potentially infectious and discarded appropriately as per Standard Bio-Safety guidelines.
7. Do not use kit after the expiry date.
8. Do not mix components of one kit with another.
9. Always use new tip for each sample and reagent.
10. Scan QR code card specific to the lot you are using.
11. Ambient temperature of testing environment directly impacts the accuracy of results. Ideal working temperature is 18°C to 30°C.
12. It is highly recommended to mix the sample diluent and sample mixture thoroughly by gently inverting the vial 10 times. (Refer pictorial presentation.)
13. It is not recommended to use the sample diluent and sample mixture beyond specified time.
14. The **FIAcheck**™ test device should be read immediately after the specified reaction time. Delay in reading might affect the accuracy of results.
15. The **FIAcheck**™ test device should be used only in conjunction with **FIAcheck**™ analyzer for accurate and reliable results.

TEST PROCEDURE

1. To calibrate the **FIAcheck**™ **β-hCG** kit, scan the QR code card provided with the kit.
2. Dispense **400** µl of sample diluent into the empty sample dilution vial.
3. Add **100**µl of the sample into the sample diluent and mix thoroughly by rinsing the tip 3 times.
4. Close the lid of the sample dilution vial, label with sample identity and mix the content of the vial by gently inverting it for 10 times. (See pictorial representation)
5. Remove **FIAcheck**™ **β-hCG** test device from sealed pouch and place it horizontally on a clean table, label the device with sample identity.
6. Dispense 100 µl of the above mixture on the sample port in the **FIAcheck**™ **β-hCG** test device.
7. Incubate at room temperature (18°C to 30°C) for **15 minutes**.
8. After 15 minutes, insert the test device immediately into the **FIAcheck**™ analyzer and read results.



Expected Range
Cut-Off Value: 5.0mIU/mL
The cut-off value for β-hCG was determined by testing samples from 200 apparently healthy individuals. The 95th percentile of the concentration for β-hCG is 5.0mIU/mL.
It is recommended that each laboratory establish its own reference range for the population it serves.

PERFORMANCE CHARACTERISTICS

1. Measuring Range: 2.0-20000mIU/mL.
2. Lower Detection Limit: ≤2.0mIU/mL.
3. Upper Detection Limit: ≥20000mIU/mL
4. Accuracy: Based on comparison experiments, the relative standard deviation of ≤15%, and the correlation coefficient of r≥0.990 was observed.
5. Within-Run Precision: ≤15%.
6. Between-Run Precision: ≤15%.
7. Hook Test: No hook effect with high concentration sample. Hook test was conducted with reference material exceeding the upper limit of measuring range, and the detection result was greater than the upper limit of detection.
8. In an internal Study, **FIAcheck**™ **β-hCG** was evaluated against commercially available licensed kit with 100 random clinical samples and **FIAcheck**™ **β-hCG** has demonstrated 100% clinical correlation with the commercially available licensed kit.

β-hCG Levels	No. of samples	FIAcheck™ β-hCG	EIA β-hCG
Normal	80	80	80
Low	8	8	8
High	12	12	12

9. In an external Study, **FIAcheck**™ **β-hCG** has been evaluated by a NABL accredited lab against their reference method. In this evaluation **FIAcheck**™ **β-hCG** has demonstrated 100% correlation with the reference method.
*Data file: Zephyr Biomedicals (A Division of Tulip Diagnostics (P) Ltd).

LIMITATIONS OF THE ASSAY

1. As with all diagnostic tests, a definite clinical diagnosis should not be based on the results of a single test but should only be made by the physician after all clinical and laboratory findings have been evaluated.
2. This kit is only for human serum and plasma.