Hipro Biotechnology Co.,Ltd

EN
ENGLISH

HCG

Human Chorionic Gonadotropin Test Kit
(Immune Fluorescence Detection Method)

Instructions for Use

Version: A/3

REF HP-HCG-25

Manufacturer

Shijiazhuang Hipro Biotechnology Co.,Ltd.
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Product Name

General Name：Human Chorionic Gonadotropin Test Kit
(Immune Fluorescence Detection Method)

Specification

Package Specification

25 Tests/ Kit.

Intended Use

This product is used to determine the content of human Chorionic gonadotophin (HCG) in human serum, it is mainly used for the auxiliary diagnosis of ectopic pregnancy and early pregnancy.

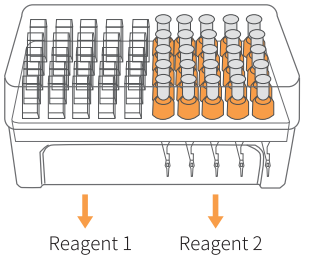
Test Principle

The human chorionic gonadotophin in the sample and the monoclonal antibody in reagent 1 become to immune complexes. The antigenic determinant-DNA coupling template in Reagent 2 binds to the remaining monoclonal antibodies, and the unbound antigenic determinant-DNA coupling template and dNTPs are used to synthesize double-stranded DNA products under the action of polymerase. This product binds to fluorescent dyes and will produce fluorescence which is proportional to the intensity of fluorescence and samples ofhuman chorionic gonadotophin levels. Using specific protein analyzer to measure the intensity of fluorescence, the concentration of HCG is determined by comparing the fluorescence intensity of samples to the standard concentration.

Component

The Hipro HCG test kit consists of two reagents R1 and R2, as shown on figure 1.

Figure 1



Name	Content	Quantity
Reagent 1 (R1)	Tris buffer	1mol/L
	Anti human chorionic gonadotropin antibody	>70mg/L
	Deoxyribonucleic acid (DNA) polymerase.	>10U
	Triphosphate deoxyribonucleic acid (dNTP)	10mM
	DNA dye	Appropriate
Reagent 2 (R2)	Tris buffer	1mol/L
	Monoclonal antibody specific binding to determinant-DNA coupling template	>70mg/L
IC card (optional)	/	1

Note:
Do not misuse Reagent 1 and Reagent 2 with different lots.

Storage&stability

Store the test kit at 2°C-8°C until the expiration date indicated on the label. The test kit is stable for one year when unopened.

Use up the test kit within one month after opening the package.

Do not freeze the test kit.

Do not mix different lots of the test kit.

Special Instrument Requirements

HP-083/4-II POCT Immunoassay System,

HP-AFS/1 Automatic Immunoassay System,

HP-AFS/3 Automatic Immunoassay System.

Specimen type

Serum, avoid hemolysis. Fasting blood collection and separation of serum as soon as possible. The sample store at 2-8°C for 3 days, -20°C for 1 month. Avoid repeated freezing. Before test, ensure fully mixed.

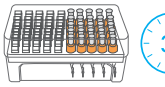
Procedures

HP-083/4-II POCT Immunoassay System

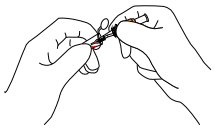
Note:

- Please read user manual of HP-083/4-II before use;
- The analyzer will finish self check after start-up;
- Insert the IC card of HCG test kit to let analyzer read the parameter;
- The analyzer calibration can be done with app. It is recommended that analyzer calibration should be done for each new lot of test kit.

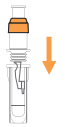
Step 1 Sample Preparation



1a Allow the test kit back to room temperature for 30 minutes before use.



1b Use the R2 with quantitative capillary to collect sample.

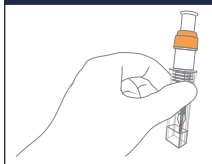


1c Insert the R2 into R1.

Note:

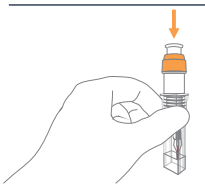
- The parameter is built in the IC card.
- Please insert the corresponding IC card into analyzer to let the analyzer read the parameter before each assay test.
- The capillary of the R2 should be fully filled.

Step 2 Testing



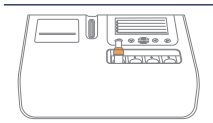
2a Hold the narrow side of R1 and shake from left to right for 12 times to let the sample completely mix with R1.

Note: Do not hold the wide sides of R1.



2b Press the piston on R2.

2c Hold the narrow sides of R1 and shake for 3-5 seconds to let R1 and R2 mix well.

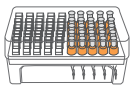


2d Insert the R1 into test channel of HP-083/4-II and the analyzer will finish the test and print out results automatically.

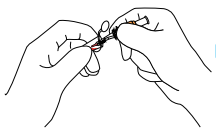
HP-AFS/1&HP-AFS/3 Automatic Immunoassay System

- Please read user manual of HP-AFS/1 and HP-AFS/3 before use;
- The analyzer will finish the self check after start-up;
- It is recommend to do analyzer calibration monthly and for each new lot of test kit.

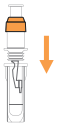
Step 1 Sample Preparation



3a Allow the test kit back to room temperature for 30 minutes before use



3b Use the R2 with quantitative capillary to collect sample.

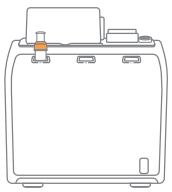


3c Insert the R2 into R1.

Note:

- Please update the standard curve with the barcode on the R1 cuvette if a new lot test kit is to be used.
- The capillary of the R2 should be fully filled.

Step 2 Testing



4a Insert the R1 into test channel of analyzer.

4b The analyzer will mix the sample from R2 capillary with R1 automatically.

4c The analyzer will mix the R2 and R1 automatically.

4d The analyzer will test and print the results automatically.

Calibration

The calibration values for the different lots of the kits are stored on the calibration IC card or the two-dimensional code on the cuvette. Before test the new lot of kits, read the calibration card parameters first. Or the instrument automatically scan the two-dimensional code on the cup to obtain the corresponding calibration curve during testing.

Quality control

3- level calibration system guarantee the results' reliability for each lot of test kits, including the instrument calibration, remote reagent calibration and the third party calibration.

The third party calibration applicable for:

1. The daily indoor quality control test.
2. New lots of reagent.
3. New operator training.
4. The results can not match the clinical symptoms.
5. The first use of the reagent.

If still can not be calibrated, contact the manufacture for further technical support.

Reference Value

＜10 IU/L

Recommended that each laboratory establish its own reference range.

Interpretation

Gestation Age (weeks)	HCG levels (IU/L)	Gestation Age (weeks)	HCG levels (IU/L)
0.2-1	10-50	4-5	1000-50000
1-2	50-500	5-6	10000-100000
2-3	100-5000	6-8	15000-200000
3-4	500-10000	8-12	10000-100000

All laboratory tests depend on random errors. If the test results are in doubt, or if they do not match the clinical symptoms, re-test the sample or confirm the results with other methods.

Limitations

1. This test is used to detect early pregnancy.
2. The samples concentration of 5000-200000IU / mL , the sample should be diluted.
3. Bilirubin > 10mg / dL, triglyceride> 1800mg / dL, hemoglobin of hemolysis samples > 500mg / dL, the test results will be affected.

Performance Characteristics

1. **Linearity range:** 2.5 IU/L ～ 5000 IU/L.
2. **Detection limit:** ≤2.0 IU/L.

   The limit of detection means the lowest detectable analyte level that can distinguish the concentration. Calculate based on the minimum standard above the two standard deviation of the data (Blank table, 1+2SD, within-run precision, n=21).
3. **Precision**

   Test the control material by human chorionic gonadotophin Test Kit（Immune Fluorescence Detection Method） 2 times per day for 20 days (n=80) according to EP5-A2 of CLSI.

The data as below:

a.

HP-083/4-II POCT Immunoassay System					
Sample	Mean IU/L	Within-Run		Between-Run	
		S.D.	%C.V.	S.D.	%C.V.
Control 1	8.2	0.47	5.7	0.53	6.5
Control 2	232.3	12.55	5.4	12.92	5.6
Control 2	3302.0	133.22	4.0	138.70	4.2

b.

HP-AFS/3 Automatic Immunoassay System					
Sample	Mean IU/L	Within-Run		Between-Run	
		S.D.	%C.V.	S.D.	%C.V.
Control 1	8.2	0.49	6.0	0.51	6.2
Control 2	232.3	12.07	5.2	12.65	5.4
Control 2	3304.0	134.58	4.1	134.90	4.1

c.

HP-AFS/1 POCT Immunoassay Analyer					
Sample	Mean IU/L	Within-Run		Between-Run	
		S.D.	%C.V.	S.D.	%C.V.
Control 1	8.0	0.58	7.2	0.61	7.6
Control 2	235.1	12.69	5.4	12.95	5.5
Control 2	3309.0	136.35	4.1	137.90	4.2

4.Methodology comparison

Compared to HCG by test the same serum sample, the relative data as below:

HP-AFS/3 POCT Immunoassay Analyer				
Site No.	Sample Type	No.of Assays	Regression Line	Coefficient correlation
1	Serum	50	Y= 0.93X+0.83	0.94

The concentration of sample is about 2.5 IU/L ～ 5000 IU/L.

Precautions

⚠ Attention:

Only for in vitro diagnostic.

Only for professional use.

All samples and reactive wastes are treated as sources of infection.

Do not use the kits beyond shelf life.

Do not mix different batches of reagents.

⚠ Warning:

To avoid error, do not forced to take out the cuvette from the device. Follow the device operation manual strictly, If the problem cannot be solved, contact the manufacturer for further technical support.

SYMBOLS USED ON LABELS

Symbol	Usage	Symbol	Usage
	Use-By date		Do not freeze
LOT	Batch code		Biological risks
	Manufacturer		Do Not Reuse
	Temperature Limit		
	Contains sufficient for <n> tests		
	Do not use if package is damaged		
	Consult Instructions for use		
	Keep Away from Sunlight		
IVD	In Vitro Diagnostic Medical device		
EC REP	Authorized Representative in the European Community		

References

1.Xu Xiaocha , Lv Shiming .Forms of in vivo human chorionic gonadotropin and its clinical application[J] .Foreign Med Sci (Sect Clin Biochem Lab Med Sci), 2005, 26(11):815-818.
2.Peng Shiwei, Tan Buzhen.Advances in diagnosis of the pregnancy-related diseases by detecting human chorionic gonadotropin[J] .Prog Obstet Gynecol, 2007, 16(12):934-935. Chinese .
3.Stenman U H, Alfthan H , Hotakainen K .Human chorionic gonadotropin in cancer[J] .Clin Biochem, 2004, 37(7):549-561.

Approval Date&Revision Date

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Revision Date：Nov. 1, 2022
Revision Date：Jan 1, 2023
Revision Date: Dec 22,2023

CE IVD

尺寸：24*25cm展开尺寸，横向三折页再垂直方向两次对折