PATHKITS

PregAtHome Pregnancy Kit

Product Code: **PKRK0016**
Kit Contents: **3,25, 50, 100 Kits**
Shelf Life: **24 Months**

Kit Components	Quantity
Test Cassette	3,25, 50, 100
Sample Dropper	25, 50, 100
IFU	1

Introduction

Human chorionic gonadotropin (hCG) is a glycoprotein hormone secreted by the developing placenta shortly after fertilization. During pregnancy, the human body will start producing a special pregnancy hormone known as hCG. hCG can be detected in both urine and serum or plasma as early as 7 to 10 days after conception and its rapid rise in concentration make it an excellent marker for confirmation of pregnancy. This test will detect the presence of hCG in urine as early as the first day of a missed period. hCG levels continue to rise very rapidly, frequently exceeding 100 mIU/mL by the first missed menstrual period and peaking in the 100,000-200,000 mIU/mL range about 10-12 weeks into pregnancy. The rapid increase in concentration of hCG in both urine and serum or plasma shortly after conception, as well as its subsequent rapid rise in concentration during early gestational development, render it an excellent marker for early pregnancy identification. With a sensitivity of 25 mIU/mL, PregAtHome Pregnancy Kit detects the presence of hCG in urine, serum, or plasma specimens qualitatively. The procedure detects elevated levels of hCG in urine, serum, or plasma using a blend of monoclonal and polyclonal antibodies.

Intended Use

PregAtHome Pregnancy Kit determines the presence of hCG (Human Chorionic Gonadotropin) in urine samples. The presence of hCG in urine appears shortly after pregnancy, followed by a rapid increase in concentration during early gestational development. This test is used to obtain a visual, qualitative result for the early detection of pregnancy. The kit is not intended for quantitative results and it only offers preliminary analytical data. A more precise alternate clinical method must be used to obtain a validated analytical result for a final diagnosis of pregnancy.

Test Principle

PregAtHome Pregnancy Kit is a rapid chromatographic immunoassay. The test uses two lines to indicate results. To detect elevated levels of hCG, the test uses a variety of antibodies, including a monoclonal hCG antibody. The control line is made up of colloidal gold particles and goat polyclonal antibodies. The assay is carried out by immersing the test cassette in a urine sample and monitoring for colored lines to appear. The specimen migrates along the membrane through capillary action to react with the colored conjugate. Positive samples form a colored line at the test line region of the membrane when they react with the unique antibody-hCG-colored conjugate. A negative result is indicated by the absence of this colored line. A colored line will often appear in the control line region as a procedural control, indicating that the appropriate volume of specimen has been applied and membrane wicking has occurred.

Warnings and Precautions

- For professional in vitro diagnostic use only. Do not use it after the expiration date.
- Before starting the test, make sure to read the entire package insert. If the instructions are not followed, the test results would be incorrect.
- In areas where specimens or kit reagents are handled, do not smoke, drink, or eat.
- Bring all reagents to room temperature (15°C-30°C) before use.
- Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
- Do not open the sealed pouch, unless ready to conduct the assay.
- Do not use the components in any other type of test kit as a substitute for the components in this kit.
- Dispose of all specimens and materials used to perform the test as bio-hazardous waste.
- Handle the negative and positive controls in the same manner as the patient specimens.
- Do not reuse the test device.
- Use separate sample dropper or pipette tips for each sample in order to avoid cross contamination of samples which could cause erroneous results.

Sample collection and Storage Instructions

- All products with a human origin should be treated as infectious and handled according to standard biosafety procedures.
- The urine sample must be collected in a dry, clean container, such as plastic or glass, that is free of preservatives.
- Specimens may be obtained at any time, but the first morning urine usually has the highest hormone concentration.
- The sample specimen should be refrigerated (2°C-8°C) if the test is not performed immediately after collection but within 48 hours.
- The sample can be stored for up to 8 hours at room temperature (25±5 °C) and for up to 4 days at 2°C-8°C.

Materials Required but not provided

- Timer or Stopwatch.
- Other consumables for collection and disposal of samples.

Mfg By: PathKits Healthcare Pvt Ltd, Plot 28, 29 Sector 18(P), Gurgaon -122001, India Customer care No.: +91-7303429198
Email: info@pathkits.com

PATHKITS

PregAtHome Pregnancy Kit

Storage and Stability

This kit can be stored between 2-40 ℃. Do not freeze the kit. The kit is stable upto expiration date as printed on the pouch. Do not use it beyond the expiry date.

Limitations

- As with all the diagnostic tests, the interpretation of assay results must always be correlated with clinical findings.
- Any modifications to the given procedure or use of other reagents will invalidate the test procedure.
- It is intended for screening use only, not for use in diagnostic procedures.
- hCG levels are elevated in some cases, such as trophoblastic diseases and non-trophoblastic neoplasms, and are comparable to normal pregnancy. Clinical evidence should be used to make the diagnosis.
- As with all diagnostic tests, the test result should not be based on the results obtained by a single test, but should only be made by the physician after all clinical and laboratory findings have been assessed.
- Although the PregAtHome Pregnancy Kit is very effective in detecting pregnancy, there is a small chance of getting false results.
- If you get unexpected or contradictory test results, talk to your doctor.
- Oral contraception, pain relievers, antibiotics, and other common medications have little effect on the test's outcome.

Test Procedure

- Bring the kit components and specimens to be tested to room temperature before testing.
- Open the test card and desiccant from the pouch prior to use and place it on a flat and dry surface. Check the color of the desiccant, it should be blue. Note: Do not use the card if desiccant is pink in color.
- The test should be performed immediately after removing the test card from the pouch.
- Place the Card on a flat surface, fill the urine dropper with specimen, and dispense 2-3 drops (50-75 µl) into the sample well without air bubbles.
- Observe the result within 2 to 5 minutes.

Note: Sample should be taken as per the marking and sample taken below or above the mark is wrong and will lead to erratic results.

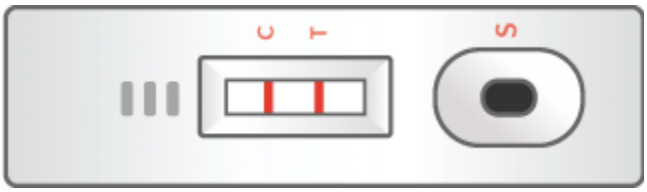
- Observe the results in 5 minutes. Do not read the result after 5 minutes. Reading beyond prescribed time may give false results.
- Discard the test card immediately after reading results.

Interpretation of results

Positive Results

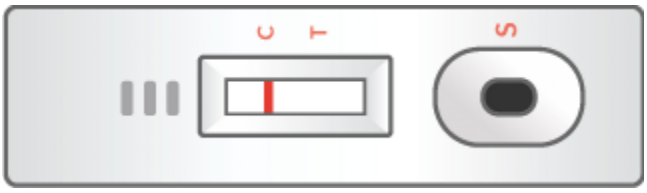
Appearance of two coloured lines, one each test (T) & Control region (C) indicates the presence of HCG in the specimen. The result is positive and it indicates that you are pregnant. Since various stages of pregnancy have different hCG hormone concentrations, the color intensity of the test bands can vary.

Consider a faint test line also as a positive result.



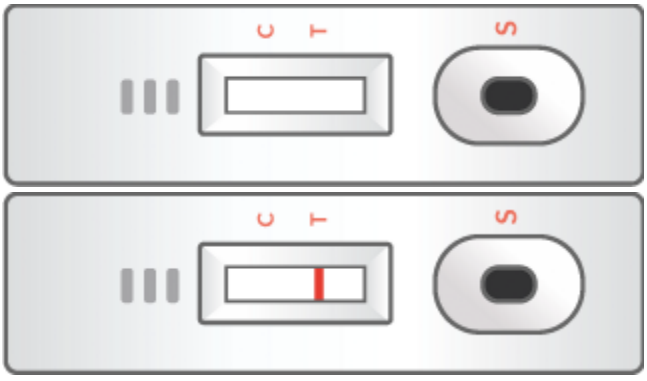
Negative Result

Appearance of only one coloured line at Control (C) region indicates that no detectable HCG is present in the specimen. The result is negative and it indicates that you are not pregnant.



Invalid Results

Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.



Technical Assistance

For customer support, please contact our Technical Support:

PathKits Healthcare Pvt Ltd, Plot 28, 29 Sector 18(P), Gurgaon -122001, India Customer care No.: +91-7303429198

Email: info@pathkits.com

Mfg By: PathKits Healthcare Pvt Ltd, Plot 28, 29 Sector 18(P), Gurgaon -122001, India Customer care No.: +91-7303429198

Email: info@pathkits.com

From

State Drugs Controller-cum-Licensing Authority
Food and Drugs Administration, Haryana,
SCO-94, Sector-5, Panchkula.

To

M/s Pathkits Healthcare Pvt. Ltd.,
Plot no. 28-29,Electronic City, Sec-18,
District- Gurgaon-122001 (Haryana)

Dated: 30-12-2021

Subject: Regarding additional items.

With reference to your application no. MFG/MD/2021/48941 dated 26.10.2021 on the subject cited above.

Find enclosed herewith copy of Form MD-5 Endorsement -2.

Enclosed:- As above.

State Drugs Controller
Food & Drugs Administration, Haryana

State Drugs Controller-cum-Controlling & Licensing Authority
Food & Drugs Administration, Haryana

सत्यमेव जयते

FORM MD-5

[See sub-rule (4) of rule 20 and sub-rule (6) of rule 20]

Licence to Manufacture for Sale or for Distribution of Class A or Class B medical device

Licence Number: MFG/IVD/2021/000069

Endorsement No. 2

1. M/s PATHKITS HEALTHCARE PRIVATE LIMITED, Plot No-28-29, Sector-18Gurgaon, Gurgaon, Haryana (India) - 122001 Telephone No.: 8802872273 FAX: 8802872273 has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at M/s PATHKITS HEALTHCARE PRIVATE LIMITED, 28, 29 Electronic City, Sector -18, Gurgaon, Haryana (India) - 122001 Telephone No.: 8588869343 FAX: 8588869343

2. Details of medical device(s) [Annexed]

3. This licence is subject to the provisions of the Medical Devices Rules, 2017 and conditions prescribed therein.

ANNEXURE

S.No.	Details Of Device(s)
1	Generic Name:Human Chorionic Gonadotropin (hCG) test kit Model No.:PKRK0016 - NA Intended Use:It determines the presence of hCG (Human Chorionic Gonadotropin) in urine samples. Class of medical device:Class B Material of construction:NA Dimension(if any):NA Shelflife:24 Months Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):PregAtHome Pregnancy Kit; PregAtHome Pregnancy Mini Kit
2	Generic Name:Human Chorionic Gonadotropin (hCG) Strip Model No.:PKUR001 - NA Intended Use:It determines the presence of hCG (Human Chorionic Gonadotropin) in urine samples. Class of medical device:Class B Material of construction:NA Dimension(if any):NA Shelflife:24 Months Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):PregAtHome Pregnancy Strip

3	Generic Name:Luteinizing Hormone (LH) Test kit Model No.:PKRK019 - NA Intended Use:It is a rapid visual immunoassay for the qualitative, presumptive detection of luteinizing hormone in human urine specimens. This kit is for use as an aid in the detection of ovulation. Class of medical device:Class B Material of construction:NA Dimension(if any):NA Shelflife:24 Months Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):PregAtHome Ovulation Kit

Place:

Date30-Dec-21

Approved vide No.....to.....
Except Sr. No.....
State Licensing Authority

(Manmohan Taneja)
State Drugs Controller-cum-Controlling &
Licensing Authority
Food & Drugs Administration, Haryana