Follicle-Stimulating Hormone (FSH) Menopause Test Kit

Instructions For Use

Format: Cassette
Specimen: Urine
Catalog Number: A01-04-122

CE

* Please read the instructions carefully before use

INTENDED USE

Artron One-Step Follicle-stimulating hormone (FSH) Test is a rapid and convenient immunochromatographic assay used for the qualitative detection of FSH in urine at or above the 25 mIU/ml level for early diagnosis of menopause. The device is designed for professional and over the counter use. The test provides a visual, qualitative result. Clinical expertise and professional judgment should be sought to further evaluate the result of the test.

SUMMARY AND PRINCIPLE OF THE ASSAY

Follicle-stimulating hormone is a glycoprotein hormone weighing approximately 30,000 Da. It is composed of two polypeptide chains: the alpha and beta subunits. In response to Gonadotropin-releasing hormone (GnRH) produced by the hypothalamus, the basophilic cells of the anterior pituitary secrete FSH and Luteinizing Hormone (LH). Both of these hormones control gonadal development and maintenance. FSH controls the development of the ovarian follicles in females and spermatogenesis in males. Both LH and FSH act in a negative feedback effect on the hypothalamus, thus regulating the circulatory levels of both hormones. As women get close to perimenopause, the number of small antral follicles recruited in each cycle diminishes and consequently insufficient Inhibin B is produced to fully lower FSH and the serum level of FSH begins to rise.

The most common reason for high serum FSH concentration is when the women is undergoing or has recently undergone menopause. High levels of FSH indicate that the normal restricting feedback from the gonad is absent, leading to an unrestricted pituitary FSH production. If high FSH levels occur during the reproductive years, it is abnormal. Conditions with high FSH levels include: Premature menopause also known as Premature Ovarian Failure, poor ovarian reserve also known as premature ovarian aging, gonadal dysgenesis, Turner syndrome castration, testicular failure, Klinefelter syndrome, etc. Most of these conditions are associated with subfertility and/or infertility.

Artron One-Step FSH Test is an antigen-capture immunochromatographic assay, which detects the presence of FSH in human urine samples. Monoclonal antibodies specifically against FSH are 1) conjugated with colloidal gold and deposited on the conjugate pad and 2) immobilized on the test line of the nitrocellulose membrane. When the urine sample is added the gold-antibody conjugate is rehydrated and the FSH, if any in samples, interacts with the gold conjugated antibodies. The antigen-antibody-gold complex will migrate towards the test window until the Test Zone (T) where it will be captured by immobilized antibodies, forming a visible pink line (Test band), indicating a positive result. If FSH are absent in the sample, no pink line will appear in the Test Zone (T), indicating a negative result.

To serve as an internal process control, a control line should always appear at Control Zone (C) after the test is completed. Absence of a pink control line in the Control Zone is an indication of an invalid result.

The detection limit for the Artron One-Step FSH Menopause Test Device is 25 mIU/ml FSH. Urine samples equal to or greater than 25 mIU/ml will be tested positive.

PACKAGE CONTENTS

- Pouch contents: Test cassette, Sample dropper, Desiccant.
- Test instructions

MATERIALS REQUIRED (BUT NOT PROVIDED)

- Clean, dry urine specimen collection container (plastic or glass).
- Clock or timer

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use only. Do not reuse.
- Do not use if the product seal or its packaging is compromised.
- Do not use after the expiration date shown on the pouch.
- Do not mix and interchange different specimens.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Clean up spills thoroughly with appropriate disinfectants.

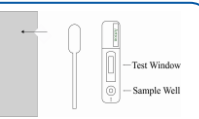
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing procedures.
- Dispose of all specimens and used devices in a proper bio-hazard container. The handling and disposal of the hazardous materials should follow local, national or regional regulations.
- Keep out of children's reach.

SPECIMEN PREPARATION

- Collect urine sample in a clean, dry container without preservatives. If specimen cannot be assayed immediately, they can be stored at 2-8°C for up to 72 hours prior to testing or frozen at – 20ºC for longer period of time.
- Equilibrate specimens to room temperature before testing if they were refrigerated or frozen.
- Urine specimens exhibiting visible precipitates should be filtered, centrifuged, or allowed to settle so that clear aliquots can be obtained for testing

TEST PROCEDURES

1. Remove the testing device from the sealed pouch by tearing at the notch and place the testing device on a leveled surface.



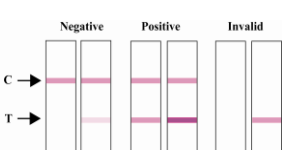
2. Hold the sample dropper vertically. Add three full drops (130 µl) of specimen without air bubbles into the sample well that is marked with an arrow on the testing device.

3. Read the result in 10 minutes. Read results as shown under interpretation of results.

NOTE: Strong positive specimen may produce positive result in as little as 1 minute. Confirm negative result in 10-20 minutes.

DO NOT INTERPRET RESULTS AFTER 30 MINUTES

RESULT INTERPRETATIONS



Negative
Only one pink colored band appears at the control region (C), or the test band (T) is lighter than the control band (C); indicating a negative test result where FSH level is lower than 25 mIU/ml

Positive
Distinct pink colored bands appear at the control and test regions, and the test band (T) is equal to or darker than the control band (C); indicating a positive result where FSH level is at or above 25 mIU/ml.

Invalid
No visible band appears at the control region. Repeat with a new test device. If the test still fails, please contact the distributor with the lot number.

QUALITY CONTROL

Although the testing device contains an internal quality control (pink colored band in the control region), good laboratory practice recommends the daily use of an outside control to ensure proper testing device performance. Quality control samples should be tested according to the standard quality control requirements established by your laboratory.

STORAGE AND STABILITY

- Test device in the sealed pouch can be stored at 2-30ºC up to the expiration date.
- Do not freeze the test device.
- The test device should be kept away from direct sunlight, moisture and heat.

LIMITATIONS

- Humidity and temperature can adversely affect results.
- The instructions for the use of the test should be followed during testing procedures.
- There is always a possibility that false results will occur due to the presence of interfering substances in the specimen or factors beyond the control of the manufacturer, such as technical or procedural errors associated with the testing.
- Although the test demonstrates superior accuracy in detecting FSH, a low incidence of false results can occur. Therefore, other clinically available tests are required in case of questionable results. As with all diagnostic tests, a definitive 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.

MANUFACTURER CONTACT INFORMATION

Artron Laboratories Inc.
3938 North Fraser Way
Burnaby, BC
V5J 5H6 Canada

Ph: 604.415.9757
Fax: 604.415.9795
www.artronlab.com
info@artronlab.com

EC REP

Wellkang Ltd
Suite B
29 Harley Street LONDON,
W1G 9QR
United Kingdom

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