# AMH Rapid Test (Whole Blood/Serum/Plasma) For professional use

ELISURE

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*A rapid test for the semi-quantitative detection of the anti-Mullerian Hormone (AMH) in whole blood, serum or plasma.*
*For professional in vitro diagnostic use only.*

## INTENDED USE

The AMH Rapid Test (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for the semi-quantitative detection of the anti-Mullerian Hormone in whole blood, serum or plasma to aid in the diagnosis of ovarian functions.

## SUMMARY

Anti-Mullerian hormone (AMH) has become the 'molecule of the moment' in the field of reproductive endocrinology. Serum AMH concentrations show a progressive decline with female ageing. Indeed, it is valuable as a means of increasing understanding of ovarian pathophysiology and for guiding clinical management across a broad range of conditions.[1] AMH is an effective measure of ovarian reserve and it can predict ovarian response to controlled stimulation for women. The clinical pregnancy rate tends to increase as AMH increases.[2] The serum AMH level is an accurate marker of the ovarian early antral follicle number and offers a good diagnostic potency. In situations where accurate ultrasonographic data are not available, AMH could thus be used instead of the follicle count as a diagnostic criterionandin corporated as such in the Rotterdam definition of PCOS.[3]

## PRINCIPLES

The AMH Rapid Test (Whole Blood/Serum/Plasma) is a semi-quantitative membrane based immunoassay for the detection of anti-Mullerian Hormone in whole blood, serum or plasma. In this test procedure, anti-AMH antibodies is immobilized in the test line region of the test. After specimen is added to the specimen well of the cassette, if AMH is present, it reacts with anti-AMH antibody coated colloid gold particles in the test. This mixture migrates chromatographically along the length of the test and interacts with the immobilized anti-AMH antibodies. If the specimen contains AMH, a colored line will appear in the test line region indicating a positive result. If the specimen does not contain AMH, a colored line will not appear in this region indicating a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

## MATERIALS

**Materials provided**

- Test cassettes
- Package insert
- Droppers
- Buffer
- Color Card

**Materials required but not provided**

- Timer
- Specimen collection containers
- Centrifuge

For fingerstick whole blood

- Heparinized capillary tubes and dispensing bulb
- Lancets

## WARNINGS AND PRECAUTIONS

1. For professional *in vitro* diagnostic use only. Do not use after the expiration date.
2. Do not eat, drink or smoke in the area where the specimens or kits are handled.
3. Do not use test if pouch is damaged.
4. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
5. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
6. The used test should be discarded according to local regulations.
7. Humidity and temperature can adversely affect results.

## STORAGE AND STABILITY

Store as packaged in the sealed pouch at room temperature or refrigerated (2-30 °C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE**. Do not use beyond the expiration date.

## SPECIMEN COLLECTION AND PREPARATION

- The AMH Rapid Test (Whole Blood/Serum/Plasma) can be performed using whole blood (from venipuncture or fingerstick) , serum or plasma.
- To collect **Fingerstick Whole Blood** specimens:
  - Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
  - Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
  - Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
  - Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
  - Add the Fingerstick Whole Blood specimen to the test by using **a capillary tube:**
    - Touch the end of the capillary tube to the blood until filled to approximately 75 μL. Avoid air bubbles.
    - Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood to the specimen well of the test cassette.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear non-hemolyzed specimens.
- Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8 °C for up to 3 days. For long term storage, specimens should be kept below -20 °C. Whole blood collected by venipuncture should be stored at 2-8 °C if the test is to be run within 1 day of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
- If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.
- EDTA K2, Heparin sodium, Citrate sodium and Potassium Oxalate can be used as the anticoagulant for collecting the specimen.

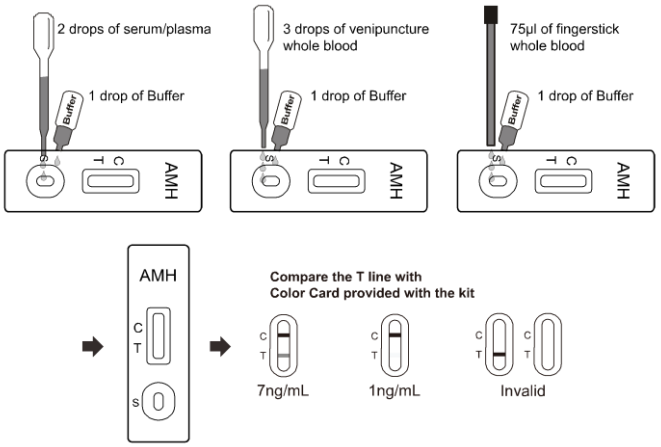
## DIRECTIONS FOR USE

**Allow the test, specimen, buffer and/or controls to reach room temperature (15-30 °C) prior to testing.**

1. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it as soon as possible.
2. Place the cassette on a clean and level surface.
   For **Serum or Plasma** specimen:
   - Hold the dropper vertically and transfer **2 drops of serum or plasma** (approximately 50 μL) to the specimen well (S), then add **1 drop of buffer** (approximately 40 μL), and start the timer. See illustration below.

   For **Venipuncture Whole Blood** specimen:
   - Hold the dropper vertically and transfer **3 drops of whole blood** (approximately 75 μL) to the specimen well (S), then add **1 drop of buffer** (approximately 40 μL), and start the timer. See illustration below.

   For **Fingerstick Whole Blood** specimen:
   - To use a capillary tube: Fill the capillary tube and **transfer approximately 75 μL of fingerstick whole blood** specimen to the specimen well (S) of test cassette, then add **1 drop of buffer** (approximately 40 μL) and start the timer. See illustration below.
3. Wait for the colored line(s) to appear. **Read results at 10 minutes by comparing the T line intensity with provided color card.** Do not interpret the result after 20 minutes.
   **Note:** It is suggested not to use the buffer beyond 6 months after opening the vial.




## INTERPRETATION OF RESULTS

**(Please refer to the illustration and compare the T line intensity with "AMH Color Card" provided with the kit.)**

| AMH Level | | Reference Range (ng/mL) |
|---|---|---|
| Normal | | 1-7 |
| Abnormal | Indicative of lower ovarian reserve | <1 |
| | Indicative of PCOS | >7 |

**Normal: Two colored lines appear.** One is in the control region (C) and another should be in the test region (T). **The line intensity in the test region (T) is darker than the 1 ng/mL line and lighter than 7 ng/mL line depicted on Color card provided with the kit.**

**Abnormal:**

**Indicative of lower ovarian reserve: One colored line appears in the control region (C).** No colored line appears in the test region (T).

**Indicative of PCOS: Two colored lines appear,** one is in the control region (C) and another should be in the test region (T). **The line intensity in region (T) is darker than the 7 ng/mL line depicted on the Color card.**

**Note:** Always compare the T line intensity with **"AMH Color Card"** and interpret results accordingly.

**INVALID: 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 cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

## QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

## LIMITATIONS

1. The AMH Rapid Test (Whole Blood/Serum/Plasma) is for in vitro diagnostic use only. This test should be used for the detection of AMH in whole blood, serum or plasma specimen.
2. The AMH Rapid Test (Whole Blood/Serum/Plasma) will only indicate the semi-quantitative level of AMH in the specimen and should not be used as the sole criteria for the diagnosis of ovarian functions.
3. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
4. Physicians should diagnosis Polycystic ovary syndrome (PCOS) by combining a detailed history and the diagnostic critiria of the Rotterdam ESHRE/ASRM consensus for PCOS.

## PERFORMANCE CHARACTERISTICS

**Accuracy**

The AMH Rapid Test (Whole Blood/Serum/Plasma) has been compared with CLIA. The following results are tablulated:

**Precision**

| Method | | CLIA | | | Total Results |
|---|---|---|---|---|---|
| AMH Rapid Test | Results | Lower (<1 ng/mL) | Normal (1-7 ng/mL) | PCOS (>7 ng/mL) | |
| | Lower (<1 ng/mL) | 32 | 3 | 0 | 35 |
| | Normal (1-7 ng/mL) | 2 | 149 | 1 | 152 |
| | PCOS (>7 ng/mL) | 0 | 0 | 18 | 18 |
| Total Results | | 34 | 152 | 19 | 205 |
| Accuracy | | 94.1% | 98.0% | 94.7% | 97.1% |

**Limitation of Detection**

The minimum detection level is between 1-7 ng/ml for AMH positive specimen.

**Intra-Assay**

Within-run precision has been determined by using 3 replicates of three specimens: 1

ng/mL, 7 ng/mL and 10 ng/mL positive. The specimens were correctly identified >99% of the time.

**Inter-Assay**

Between-run precision has been determined by 3 independent assays on the same three specimens: 1 ng/mL, 7 ng/mL and 10 ng/mL positive. Three different lots of the AMH Rapid Test (Whole Blood/Serum/Plasma) have been tested using 1 ng/mL, 7 ng/mL and 10 ng/mL positive specimens. The specimens were correctly identified >99% of the time.

**Cross-reactivity**

The AMH Rapid Test (Whole Blood/Serum/Plasma) has been tested by inhibin-A, activin-A, LH, FSH, TGFβ-1 positive specimens. The results showed no cross-reactivity.

**Interfering Substance**

The AMH Rapid Test (Whole Blood/Serum/Plasma) has been tested for possible interference specimens. No interference was observed.
In addition, no interference was observed in specimens containing up to 300 mg/dL Hemoglobin, 170 μmol/L ascorbic acid, 20 mg/dL acetaminophen, 65 mg/dL acetylsalicylic acid, 12 g/dL human serum Albumin and 1.4 mmol/L Uric Acid.

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**INDEX OF SYMBOLS**

| | | | |
|---|---|---|---|
|  | Consult instructions for use |  | Contains sufficient for <n> tests |
| IVD | *In vitro* diagnostic medical device |  | Use-by date |
|  | Temperature limit | LOT | Batch code |
|  | Do not use if package is damaged |  | Manufacturer |
| REF | Catalogue number |  | Do not re-use |


Sicuro Bioengineering Ltd
Address: 19 East West Road,
Port Harcourt - Nigeria
Email: info@sicurobio.com
Website: www.sicurobio.com

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