One Step MAU Microalbuminuria Test

Instructions For Use

Format: Cassette
Catalog Number: A08-01-122

* Please carefully read the instructions before use

INTENDED USE

The one-step Urinary Albumin Cassette Test is a chromatographic immunoassay for semi-quantitative determination of human serum albumin (HSA) in urine. This test is designed for laboratory use for the early detection of microalbuminuria before overt symptoms of renal disease.

SUMMARY AND PRINCIPLE OF THE ASSAY

Human serum albumin is the most abundant protein in human blood plasma. Under physiological circumstances, the protein is not present in urine due to glomerular barrier. When there is an abnormally high permeability for albumin in the renal glomerulus, small amounts of albumin are filtered into the urine, resulting in a situation referred to as microalbuminuria. Microalbuminuria is frequently seen in patients with established diabetes, hypertension, heart failure, cirrhosis and systemic lupus erythematosus (SLE). Thus, the measurement of albumin in urine is an indicator of renal function in such diseases.

Artron one-step Urinary Albumin Cassette Test is a lateral flow test to semi-quantitatively determine the concentration of albumin in urine. The mouse anti-albumin antibody conjugated with colloidal gold are deposited onto the conjugate pad and albumin-BSA complex on test region. The control line of reaction membranes is coated with goat anti-mouse IgG antibodies. When urine samples are tested, the albumin, if any, binds to the gold conjugated anti-albumin antibody and move toward test window by capillary diffusion. The unbound gold-antibody complex will be immobilized in test line coated with human albumin (A visible red line will appear), while bound gold-antibodies complex will continue to move until being captured by the non-specific antibody in the control zone. The concentration of albumin in urine is inversely proportional to signal intensity of test line. To serve as an internal process control, a control band was designed to indicate that the test is performed properly. This control line should always be seen after test is complete. Absence of a colored control line in the control region is an indication of an invalid result.

PACKAGE CONTENTS

- Pouch Contents: Cassette, Sample Dropper, Desiccant
- Test instruction.

MATERIALS REQUIRED BUT NOT PROVIDED

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

PRECAUTIONS

- For *in vitro* diagnostic use only.
- Do not reuse.
- Test device should remain sealed until use.
- Do not use after the expiration date shown on the pouch.
- Keep out of children’s reach.

SPECIMEN PREPARATION

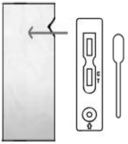
Two urine samples (50-60ml) should to be collected in provided containers at an interval of 1-2 hours in the morning.

Note:
1) The urine specimens can be stored at 4°C for up to 14 days (do not freeze).
2) Urine specimens exhibiting visible precipitates should be filtered, centrifuged, or allowed to settle so that clear aliquots can be obtained for testing.
3) If the testing results of the two urine samples are not in agreement, a third urine sample should be tested.

TEST PROCEDURES

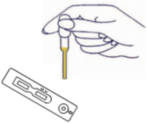
1

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



2

Hold the Sample dropper vertically, adds four full drops (0.2ml) of specimen without air bubbles into the sample well that is marked with an arrow on the testing device.

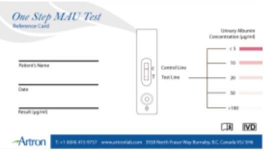


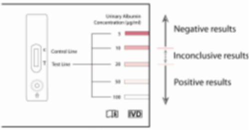
3

Read the test result in 10 minutes. Ensure that the background of the test area is white before interpreting the result.

DO NOT INTERPRET RESULTS AFTER 30 MINUTES

RESULT INTERPRETATIONS





Positive results (+): The color intensity of the test band is less than the one of the color block corresponding to 20µg/ml on the Reference Card.

Inconclusive results (+/-): The test bands are visible and the color intensity of the test band falls within range between the ones of the color blocks corresponding to 10 and 20µg/ml on the Reference Card.

Negative results (-): The test bands are visible and the color intensity of the test band is greater than the ones of the color block corresponding to 10µg/ml on the Reference Card.

Invalid results: No band in control zone is visible. Please repeat the test with a new test device and if test still fails, please contact the distributor with the lot number

Note: The Artron one-step urinary albumin cassette test is a semi-quantitative assay to determine human serum albumin (HSA) concentration in urine. To make diagnosis of microalbuminuria, clinical expertise and professional judgment should be sought to further evaluate the test results.

QUALITY CONTROL

Good laboratory practice recommends the use of control materials to ensure proper kit performance. Quality control specimens are available from commercial sources. When testing the positive and negative controls, use the same assay procedure as with a urine specimen.

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

- This product is designed for in vitro use only.
- There is always a possibility that false results will occur due to the presence of interfering substances or factors beyond the control of the manufacturer, such as technical or procedural errors associated with the testing.
- As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test.

MANUFACTURER CONTACT INFORMATION

Artron

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

REVISION: May, 2012