Chemtrue®

One-Step Microalbuminuria Test

For in vitro Diagnostic Use CE
Product Code: 5001C31-5

INTENDED USE

The Chemtrue® One-Step Microalbuminuria Test is a simple，One-Step immunochromatographic assay for the rapid detection of microalbuminuria (MAU) in urine. This product is used to obtain visual semi-quantitative result and is intended for professional in vitro use.

This assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result.

SUMMARY

MAU, the presence of low but abnormal levels （＞30mg/day）of albumin in the urine，is considered as an early marker of renal failure and cardiovascular complications in insulin-dependent diabetes mellitus（IDDM）and non-insulin-dependent diabetes mellitus（NIDM）. In healthy individuals, urinary albumin excretion ranges from 0-30mg/day. Persistent increase in urine albumin excretion rate between 30-300mg/day or 20-200mg/liter is the earliest clinically identifiable sign of risk of diabetic nephropathy and other vascular complications In approximately 17% per year. The American Diabetes Association has recommended that annual screening of MAU be performed on patients with insulin-dependent diabetes.

Conventional urinary dipstick-type assays for albumin were only capable of detecting urinary albumin concentrations representative of albumin excretion of approximately 300mg/day. It is important to measure urinary albumin in the concentration range of importance for MAU enables the physician to regularly check patients albumin status of the urine.

Chemtrue® One-Step Microalbuminuria Test is based on the principle of the highly specific immunochemical reactions of antigens and antibodies that are used to detect albumin in urine. It is a simple, visual, one-step immunoassay for rapid semi-quantitative measurement of MAU in urine.

PRINCIPLE

The Chemtrue® One-Step Microalbuminuria Test is based on the principle of competitive immunochemical reaction between the albumin in the urine sample and albumin immobilized on the membrane for the limited antibody sites. The test strip contains a nitrocellulose membrane strip and a colored anti-human albumin monoclonal antibody-colloidal gold conjugate pad. The nitrocellulose membrane is pre-coated with human albumin on the test region and a secondary antibody on the control region. The anti-albumin antibody-colloidal gold conjugate pad is placed at the bottom of the membrane strip. During the test, the urine sample is allowed to migrate upward and dehydrating the anti-albumin antibody-colloidal gold conjugate. The mixture then migrates along the membrane chromatographically by the capillary action to the immobilized albumin zone on the test region. When albumin is absent in the urine, the colored anti-albumin antibody-colloidal gold conjugate and immobilized albumin bind specifically to form a visible line as the antibody complexes with the albumin. When albumin is present in the urine, the urine albumin competes with albumin immobilized on the test region for the limited antibody sites on the anti-albumin antibody-colloidal gold conjugate. The test line will become less intense with increasing urine albumin concentration

A control line generated by a different antigen/antibody reaction is also present at control region of the test strip. The control line should always appear regardless the presence of albumin in the urine sample. Since test line intensity decreases with increasing albumin concentration and the control line intensity is independent of the albumin concentration level in the sample. The presence of control line also serves as a build-in control, which demonstrates that the test is performed properly.

REAGENTS AND MATERIALS SUPPLIED

- The test devices. Test devices contains human albumin immobilized on the test region, secondary antibody on the control region and anti-human albumin monoclonal labeled with colloidal gold.
- Disposable transfer pipette
- The test instruction

MATERIALS REQUIRED BUT NOT SUPPLIED

- Specimen collection container
- Timer

STORAGE AND STABILITY

The test kit should be stored at room temperature in the original sealed pouch for the duration of the shelf-life.

PRECAUTIONS

- *For IN VITRO DIAGNOSTIC USE*
- For professional use only.
- Do not use test after the expiration date.
- Urine specimens have the potential to be infectious. Proper handling and disposal methods should be established.
- Avoid cross-contamination of urine samples by using a new specimen container for each urine sample.

SPECIMEN COLLECTION AND STORAGE

The Chemtrue® One-Step Microalbuminuria Test is

formulated for use with urine specimen. First morning urine specimen is preferably to be used for test, and the urine does not require any special handling or pretreatment. Three samples are acceptable: 24-hour urine collection and 12-hour urine collection and overnight urine collection. The specimen may be refrigerated at 2-8℃ up to 3 days. Specimens that have been refrigerated must be equilibrated to room temperature, and mixed thoroughly prior to testing.

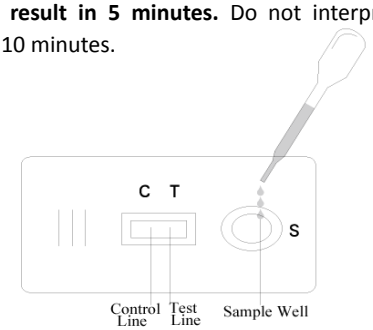
TEST PROCEDURE

Preparation

- Review the test instruction carefully.
- If specimen，control, or test devices have been stored at refrigerated temperatures, allow them to warm to room temperature before testing.
- Do not open test device pouch until ready to perform the test.

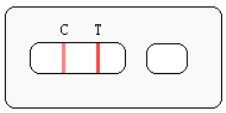
Testing

- Remove test device from the sealed pouch.
- Use the pipette to withdraw urine from the specimen collection container and dispense 2～3 drops in a vertical position into sample well.
- **Read result in 5 minutes.** Do not interpret result after 10 minutes.

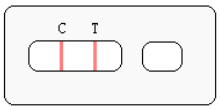


INTERPRETATION OF RESULTS

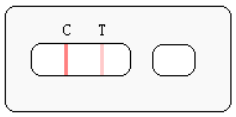
The test results are interpreted by comparing the relative intensity of test line **(T)** and control line **(C)**. The sample can be classified into one of three categories: **Negative (＜15mg/l), Cut-off (15-20mg/l), and positive (＞20mg/l).**



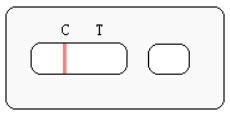
Negative (＜15 mg/l):
The test line is stronger than Control line



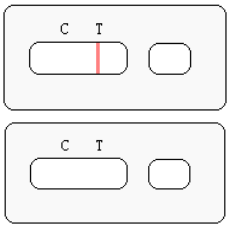
Cut-off (15-20mg/l):
The intensities of Test line and Control line are approximately equal.



Positive (＞20mg/l):
The test line is weaker than Control line.



Dose-hook effect (＞200mg/l)：
The test line will disappear.



Invalid:
No control line appears in the section of the detection window.

Note: If there is no test line or a very faint Test line, this indicates that the concentration of the albumin is above 200mg/l. To determine the albumin concentration, add one part of the urine sample with four parts of the water and repeat the test and multiply the result by 5.

LIMITATION OF PROCEDURE

- The assay is designed for use with human urine only
- Dose-hook effect (＞200mg/l)：The test line will disappear.
- There is a possibility that technical or procedural errors may interfere with the test and cause false results. If questionable results are obtained or abnormal level of MAU is suspected, the test should be repeated using a fresh urine specimen.
- Several clinical conditions, such as urinary tract infection, acute febrile illnesses, and heart failure, may transiently increase urinary albumin excretion. Screening of MAU should be postponed in these situations.

QUALITY CONTROL

Good laboratory practice should be followed including proper specimen collection and handling, and the use of quality control materials to ensure proper assay performance. Quality control specimens can be purchased from commercial sources. When testing the positive and negative controls, the same assay procedure should be followed.

PEREORMANCE CHARACTERISIICS

Seventy-five men and seventy-five women were selected via advertisements in Shanghai. All the selected users represent different age, and represent different background and education, but none of them had

educational and occupational background of medicine and clinical examination. Each person supplied only one urine sample which was immediately assessed by Diagnostic chemicals, LTD. ImmunoDip™ Urinary Albumin Screen. Meanwhile, each person was randomly given one type of the Chemtrue® One-Step Microalbuminuria Test, and was asked to perform the assay according to the test instruction without others help. After performing the assay, the user should answer a questionnaire, which includes the information of the feedback on the test and ease of use, and clarity and readability of the test results. The selected samples were then to evaluate the test results.

Test method		Diagnostic chemicals, LTD. ImmunoDip™ Urinary Albumin Screen		Total
		Positive	Negative	
Chemtrue® One-Step MAU Test	positive	25	1	26
	negative	0	124	124
Total		25	125	150

In the selected one hundred and fifty users, twenty-six were clinical assessed as positive and one hundred and twenty-four were clinical assessed as negative.
Relative Sensitivity: 25 / 26=96.2%
Relative Specificity: 124 / 124=100.0%
Relative Accuracy: (25+124) / 150=99.3%
There was a false negative result according to our test. The concentration of MAU in the sample was at the cut-off level. Although the educational levels of the uses were different, they all could correctly perform the assay according to the test instruction insert, and the test results reach a high accuracy comparing with the Diagnostic chemicals, LTD. ImmunoDip™ Urinary Albumin Screen.

Interference testing

Potentially interference of common medications and various human proteins, and other substances that are likely to be present in urine was studied. All substances were spiked into negative and positive controls and tested with Chemtrue® One-Step Microalbuminuria Test. No interference was observed at substance concentrations listed below:

Substances	Concentration (mg/l)
Acetaminophen	20
Acetylsalicylic acid	20
Ascorbic acid	20
Atropine	20
Caffeine	20
Glucose	2
Hemoglobin	500
Vitamin C	20

REFERENCE

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