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Singclean® Quickclean®

Quality you can count on. Results you can trust.

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Singclean®

Multi-drug One Step Test Kit

Singclean Urine Drug Test Applications

The test is used to obtain visual qualitative result and is intended for health care professionals use including professionals at point of care sites to assist in the determination of drug compliance

Ideal for:

Intended Use

Singclean Multi-Drug One Step Test Kit is used to qualitatively detect whether there are drugs or drug metabolites in the urine of target people, and conduct preliminary screening for target drug users with colloidal gold method.

It is for the detection of 23 drugs like COC、AMP、MOP、THC、MET、OPI、BAR、BZO、MTD、MDMA、TCA、OXY、BUP、PCP、EDDP.



- 1.Pre-employment drug screening
- 2.Random drug testing
- 3. Medical clinic drug testing
- **4.**Reasonable suspicion drug tests
- **5.** Substance abuse screening in hospitals



Singclean Advantages

Accurate results:

More than 99% accurate, according to international drug abuse monitoring standards;

Good specificity:

Select monoclonal antibody with high specificity to minimize possible crossover;

Easy to operate:

Do not need any equipment and additional testing; Samples are easy to collect and can be tested on site;

Fast detection:

5 minutes to interpret the results, saving time;

Joint testing:

Multiple drugs can be screened at once.

When is the best time to collect a sample?

There is no special requirement for choosing time to collect urine sample, but it's recommended to detect urine sample as soon as possible after suspected drug use.

Specification

Storage: store between

2°C and 30°C

Shelf life: 2 years

Format: cassette, panel, and cup

cassette format: Customized, up to 6 panels

panel format: up to 16 panels
cup format: up to 18 panels



How much sample do I need?

Cassette format: need 3 drops of urine sample (about 100µL).

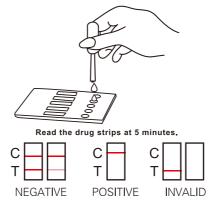
Panel format: Immerse the test panel vertically into the urine specimen for at least 10-15 seconds or until migration occurs. Immerse the strip(s) at least the level of the wavy lines, but not above the arrow(s) on the test card.

Cup format: fill the Drug Test Cup with urine to at least the minimum fill level line. Customization is available. Special format for testing special types of drugs according to clients' requirement can be provided.

Certificate

CE ISO13485

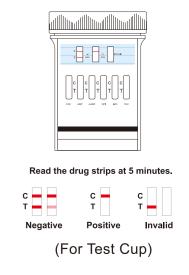
Test Procedure



(For Test Cassette)



(For Test Panel)



Procedure

For Test Cassette

- Place the Test Cassette on a clean and level surface. Hold the dropper vertically and transfer 3 full drops of urine (approx,100L) to the specimen well (s). Avoid trapping air bubbles in the specimen well (S).
- Start the time and wait for the colored line to appear.
- Read the test results at 5 minutes. Do not read the results after 10minutes.

For Test Panel

- Remove the cap from the end of the test card. With arrows pointing toward the urine specimen, immerse the test panel vertically into the urine specimen for at least 10-15 seconds or until migration occurs. Immerse the strip(s) at least the level of the wavy lines, but not above the arrow(s) on the test card.
- Place the test panel on a flat dry surface, start the time and wait for the colored line(s) to appear.
- Read the test results at 5 minutes. Do not read the results after10minutes.

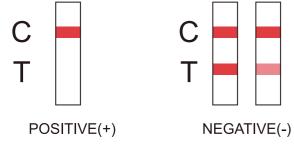
For Test Cup

- Collect specimen in the cup and secure the cap tightly.
- If the temperature strip is included with Drug Test Cup, please read urine temperature between 2-4 minutes after voiding to verify the temperature ranges between 32-38°C.

INVALID

- Place the cup on a flat surface.
- Date and initial the security seal, and place the security seal on the cap.
- Peel off the label on the cup to view the results.
- Read the test results at 5 minutes. Do not read the results after 10 minutes.

Interpretation of Results:





Only one colored band appears in the control region (C). No apparent colored band appears in the test region (T). The absence of a line in the test region (T) indicates a positive result. The positive result indicates that the drug concentration in the urine specimen is above the designated cut-off level for that specific drug.

Note: The samples with positive results should be confirmed with more specific method.

NEGATIVE

Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T). The negative result indicates that the drug concentration in the urine specimen is below the designated cut-off level for that specific drug.

INVALID

Control band fails to appear. Results from any test which has not produced a control band at the specified reading time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

Test

Limitations:

- 1. Failure to use this kit as directed may result in an insufficient sample or an inaccurate screening result.
- **2.** The possibility exists that substances and factors not described in this instruction may interfere with the test, causing false results (e.g. technical or procedural error).
- **3.** This test provides a screening result. It is not designed to determine the actual concentration of a drug or the level of intoxication.







Intended Use

The human chorionic gonadotropin (HCG) pregnancy test kit is a rapid, one-step lateral flow immunoassay for the qualitaive detection of human chorionic gonadotropin (HCG) in urine to aid in the detection of pregnancy.

Characteristic:

- ♦ Over 99% Accurate
- ◆ Early detection of pregnancy
- ♦ Simple to use
- ◆ A variety of design specifications
- ♦ Fast, results in 3 minutes

Singclean®

HCG

Early Home Detection Pregnancy Test Kit

When to take the HCG test?

You can have a test if you have the following symptoms













Frequent Urination

You can test your urine as early as the first day you miss your period by detecting HCG levels as low as 25 mIU/mI. You can perform the test anytime of the day, however, the most pregnancy hormone would be contained in the first morning urine.

Principle

The human chorionic gonadotropin (HCG) pregnancy test kit utilizes a combination of antibodies including a monoclonal HCG antibody to selectively detect elevated levels of HCG in urine to aid in the early detection. of pregnancy for self-testing.

Product specifications

Strip: 1 test/box, 5 tests/box, 25 tests/box,

100 tests/box:

Cassette: 1 test/box, 5 tests/box, 40 tests/box;

Midstream: 1 test/box. 20 tests/box.

Test Procedure

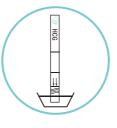
Read the instruction carefully.

Sampling: first morning urine is recommended.

Tear the packaging aluminum bag and take out the reagent.

Perform urine testing by type.

Read the result at 3 minutes. It is judged nvalid after 10 minutes.



Strip



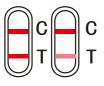
Cassette



Midstream

Human Chorionic Gonadotropin (HCG) Early Home Detection Pregnancy Test Kit

Result Interpretation







Pregnant

Not Pregnant

Invalid

PREGNANT

Two distinct colored lines appear. One is located in the test line region (T), the other is in control line region (C). And the line in test line region (T) is the same as or darker than the one in the control line region (C).

It means that your urine contains HCG and you are probably pregnant. See your doctor to confirm that you are pregnant and to discuss the steps you should take.

NOT PREGNANT

One colored line appears in the control line region (C). No line appears in the test line region (T). It means that no HCG has been detected in your urine and probably you are not pregnant. If you do not start your period within a week of its due date, repeat the test with a new test. If you receive the same result after repeating the test and you still do not get your period, you should see your doctor.

INVALID

The result is invalid if no colored line appears in the control line region (C) even if a line appears in the test line region (T). You should repeat the test with a new test kit.

Precautions

- 1. Please refer to the instruction for use before performing the test.,
- **2.** Please use the morning urine test as much as possible. Avoid drinking a lot of water before the test. The urine concentration is higher and the result is more obvious.
- **3.** If a very light color is detected, it is recommended to use the morning urine test again 48 hours later. The color of the T line will be darkened and the pink parallel bars can be confirmed.
- 4. This product is a single-use in vitro diagnostic reagent, please do not reuse it.

FAQ:

Q: How does the test work?

A: The HCG pregnancy test kit detects a hormone in your urine that your body produces during pregnancy (HCG-human chorionic gonadotropin). The amount of pregnancy hormone increases as pregnancy progresses.

Q: What should I do if the result shows that I am pregnant?

A: It means that your urine contains HCG and you are probably pregnant. See your doctor to confirm that you are pregnant and to discuss the steps you should take.

Q: What should I do if the result shows that I am not pregnant?

A: It means that no HCG has been detected in your urine and probably you are not pregnant. If you do not start your period within a week of its due date, repeat the test with a new test strip. If you receive the same result after repeating the test and you still do not get your period, you should see your doctor.

Q: What is the difference between pregnancy test midstream and strip?

A: The midstream format is more convenient than the strip format. You won't be afraid of getting your hands dirty because there is no need to collect urine with a disposable cup. You can directly urinate towards the sample well of the midstream, which make it suitable during a trip or at office.

Q: Is it important to use the first urine of the day?

A: Although you can test at any time of the day, your first morning urine is usually the most concentrated of the day and would have the most HCG in it.





Singclean FSH

Self-test Ovarian Function

FOR:

- Women of childbearing age who are preparing for pregnancy, to provide useful information
- Women after childbirth or under high pressure, help you predict premature ovarian failure
- Women who are close to 50 years old, help you predict whether menopause is coming



Intended Use

It is intend for qualitative determination of FSH levels in women urine, provides useful information for women who will prepare for pregnancy or focus on ovarian health, functions and fertility, also assists the diagnosis and treatment of pituitary and gonadal dysfunction.

Product Specifications

Strip: 1 test/box, 5 tests/box, 25 tests/box, 100 tests/box;

Cassette: 1 test/box, 5 tests/box, 40 tests/box;

Midstream: 1 test/box, 20 tests/box

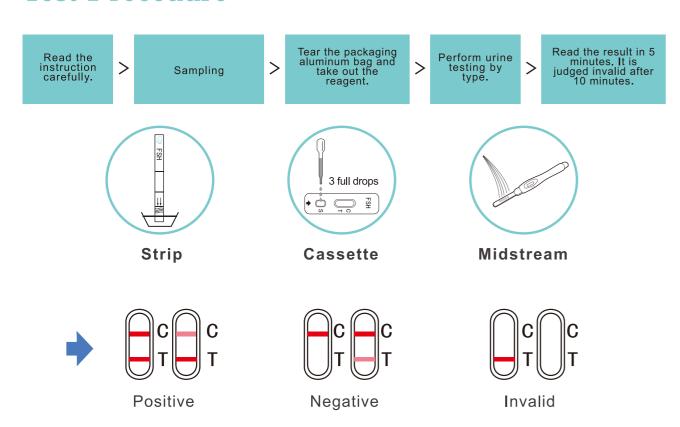
Principle



Follicle Stimulating Hormone (FSH)
Test Kit (Colloidal Gold) is based on
the principle of colloidal gold labeling
technique and immune chromatography
of double-antibody sandwich method.

Follicle-stimulating Hormone (FSH) For Self-Testing Specimens: Urine

Test Procedure



Result Interpretation

POSITIVE: Two red lines are visible. One is located in the test line region (T), the other is in control line region (C). And the line region (T) is the same as or darker than the one in the control line region (C). A positive result indicates ovary tend to menopause.

NEGATIVE: One or two red lines are visible. One is located in the test region (T), the other is in control region (C). And T line is lighter than the C line, or there was no T line. A negative result indicates that no FSH surge has been detected.

INVALID: There is no red line in control region (C). Insufficient specimen volume or incorrect techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, stop using the test kit immediately and contact your local distributor.



What does the result mean if it is positive?

If the test result is positive, it means that the ovarian function is declining, which affects the chance of pregnancy. It is recommended to collect urine at approximately the same time every 5-7 days for re-examination. It is recommended to follow up for more than 3 times in the same cycle. If there are more than 2 positive results in a row, it indicates that there may be ovarian function defects. You should get tested in an authoritative organization.

Product precautions

- 1. This reagent is only used for single use in vitro diagnosis, and the subject cannot be pregnant or have entered menopause.
- 2. Never use frozen, expired, damaged aluminum foil bags, damp products and contaminated urine samples.
- **3.** "One person, one sample, one tube" to avoid cross-contamination and avoid direct hand touching the observation window area.
- **4.** This test paper cannot be used to determine ovulation or early pregnancy. A positive result of this test paper indicates that the FSH concentration in the urine sample is not less than 25mIU/mI, which may be affected by other factors. The final diagnosis should be made by the doctor after comprehensively checking the indicators and clinical symptoms.



- Predict peak ovulation period
- Instruct women of childbearing age to choose the best time to get pregnant
- Instruct women to prevent pregnancy during the safe period.





Intended Use

It is intend for qualitative determination of

LH levels in women urine to predict ovulation time, so as to guide reproductive women to choose the optimal conception time or safe period contraception.



When do you start using ovulation tests?

First, confim the menstrual cycle length, that means how many days from the first day of the period (menstrual bleeding) to the next period starts, Please recall recent average days of the menstrual cycle. Then reference to the following table to determine test interval.

Menstrual cycle	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38
Interval days	6	6	7	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21

Last, determine the day to start testing. Starting from and including the first day of the last period, count ahead the number of interval days. Generally, it is recommended to conduct the test once a day for 5 days.



For example: menstrual cycle is 28 days, the Interval days is 11 days according to Table 1. If the last period is on 3, Wednesday, the day to start testing is on 13, Saturday. Conduct the test once a day until 17, Wednesday.

Luteinizing Hormone (LH) Ovulation Test Kit

Principle

Luteinizing Hormone(LH) Ovulation
Test Kit based on the principle of
colloidal gold labeling technique and
immune chromatography of
double-antibody sandwich method.

Product specifications

Strip: 1 test/box, 5 tests/box,

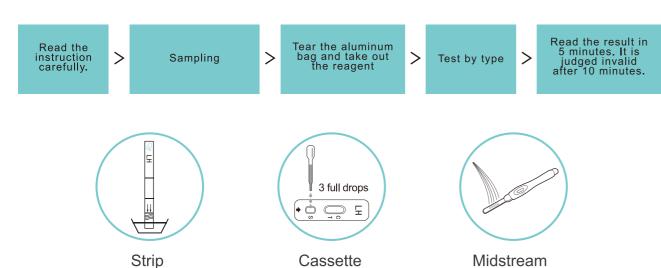
25 tests/box, 100 tests/box;

Cassette: 1 test/box, 5 tests/box,

40 tests/box;

Midstream: 1 test/box, 20 tests/box

Test Procedure:



NOTE: Sampling:



Do not drink water 2 hours before the test

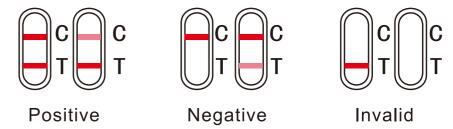


Do not use the morning urine test



Better test from 10am to 8pm

Result interpretation



Positive (+): Two red lines are visible. One is located in the test line region (T), the other is in control line region (C). And the line in test line region (T) is the same as or darker than the one in the control line region (C). It indicates probable ovulation in 24-48 hours.

Negative (-): One or two red lines are visible. One is located in the test region (T), the other is in control region (C). And T line is lighter than the C line, or there was no T line. It indicates that no LH surge has been detected.

Invalid: There is no red line in control region (C). Incorrect operation or the product has been damaged are the most likely reasons. Please repeat the test with a new test. If the problem still exists, should stop using the product immediately and contact with local suppliers.

Product precautions

- 1. This reagent is only for single use
- 2. Never use frozen, expired, aluminum foil bags, damp products and contaminated urine samples.
- **3.** "One person, one sample, one tube" to avoid cross-contamination and avoid direct hand touching the observation window area.





Application

Used for the preliminary screening of influenza patients, but the final confirmation should be based on dinical observation and professional doctors' decision.



Product Introduction

Influenza viruses (Flu) are the pathogens that cause influenza. The seasonal flu epidemics are caused by two main types of influenza viruses, A and B. About 10% of the population are being affected every year.

The symptoms of influenza are similar with corona and other viral respiratory infections including fever, cough, stuffy nose, body aches, etc. Clinically it is hard to differentiate these from each other and Singclean Flu A&B Antigen Test Kit can be used to screen for influenza, help with the early diagnosis and treatment.

Intended Use

Singclean Flu A/B Antigen Test Kit is an in vitro qualitative detection that uses colloidal gold immunochromatography to test influenza A/B antigen in nasopharyngeal swab samples obtained from patients with signs and symptoms of respiratory infection in just 15 minutes. It is designed to give rapid and reliable test results on the spot without any laboratory equipment. This allows early start of treatment, which helps reduce the duration and severity of the disease. Besides, detection of influenza reduces unnecessary use of antibiotics and aids in limiting the spread of the infection.

Certificate

CE Approved



Specification

Singclean FLU A/B Antigen Test Kit					
Sample type	Nasopharyngeal swab				
Format	1 Test/Box; 20 Tests/Box				
Material s supplied	Sampling Cotton Swabs; Antigen Extraction Buffer; Antigen Extraction Tube; Paper Workbench; Instruction for Use				
Time to results	15 minutes				
Storage	Store between 4-30 °C				
Shelf life	2 years				



Advantages

- a. Easy to operate: All components include in kit, no additional equipment or laboratory resources required;
- b. Fast detection: 15 minutes to interpret the result after collecting specimen;
- C. Joint testing: Influenza A and B can both be tested in one reagent;
- e. Accurate, Rapid, Sensitive

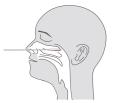
High quality CE marked and approved for sale in Europe

Performance Characteristics

A total of 406 samples were tested in this study. The results of test reagent and control reagent both were 215 negative specimens, 92 Flu A positive specimens and 99 Flu B positive specimens.

			Reference Reagent Results					
M	ethod	FLU A Positive	FLU B Positive	Negative	Total			
Test Reagent	Positive	89	97	2	188			
Results	Negative	3	2	213	218			
Total		92	99	215	406			
FLU A Sensitivity		96.74%	90.85%~98.88%		% ~ 98.88%			
FLU B Sensitivity		97.98%	95%	92.93%	%~99.44%			
Specificity		99.07%	confidence interval	96.67%	%~99.74%			
Accuracy		98.28%	intol val	96.48%~99.16%				

Test Procedure



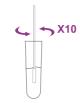
1. Insert a sterile swab into the nostril of the patient, reaching the surface of the posterior nasopharynx.



2. Swab over the surface of the



3. Withdraw the sterile swab



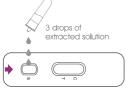
4. Insert the swab into an extraction buffer tube pre-added with 6 drops of extraction buffer, rotate the swab about 10 times. while pressing the swab head against the tube wall to release



5. Leave the swab in the extraction tube for 1 minute. Remove the swab while squeezing the tip of the swab to extract the liquid from the swab.



6. Press the dropper tip tightly onto the tube, and let it stand for 1 minute



7. Apply 3 drops of extracted solution to the specimen well of the

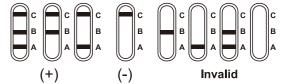


8. Read the test result

Interpretation of Results

Positive:

Positive influenza A and B: Line C, Line A and Line B all appeared. A positive result in the influenza A region and



influenza B region indicates that both Influenza A and be antigen were detected in the sample.

Influenza A Positive:

Line C and Line A both appeared. A positive result in the Influenza A region indicates that Influenza A antigen was detected in the sample.

Influenza B Positive:

Line C and line B both appeared. A positive result in the Influenza B region indicates that Influenza B antigen was detected in the sample.

Negative:

Only Line C appeared, the absence of any burgundy color in the T band, the result indicates that no Flu A/B antigens are detected in the specimen.

Invalid:

Control line fails to appear.

Limitations

- 1. Use fresh samples whenever possible.
- **2.** Optimal assay performance requires strictly adherence to the assay procedure described in Instruction for use. Deviations may lead to aberrant results.
- **3.** A negative result for an individual subject indicates absence of detectable Flu A/B antigen. However, a negative test result does not preclude the possibility of exposure to or infection with Flu A/B
- **4.** A negative result can occur if the quantity of the Flu A/B antigen present in the specimen is below the detection limits of the assay, or failed to collect the Flu A/B antigen in the nasal cavity of the patient.
- **5.** As with all diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

06.

Bacterial Vaginosis Diagnostic Strip Sets

(Dry Chemical Enzymatic Detection)



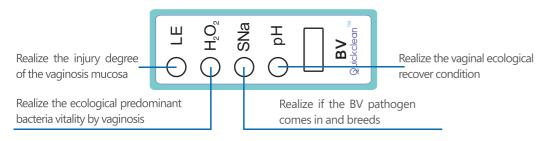
1 Introduction



Product introduction

Bacterial vaginosis diagnostic strip sets(dry chemical enzymatic detection), is an in vitro diagnostic reagents products to test female bacterial vaginosis. Through testing the H_2O_2 , pH value, SNa and LE, the four indicators of female vaginal discharge, evaluate comprehensively, and get the result, it has certain guiding significance for the clinical diagnosis.

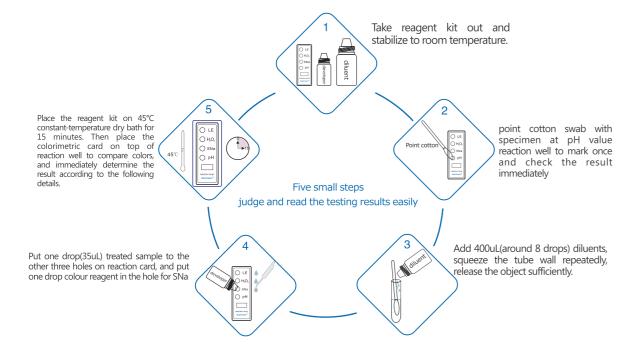






Used to assist the diagnostic of bacterial vaginosis, evaluate the micro ecological balance in genital tract, and so to prevent the repeat disease of vaginosis.

2 Test Procedure



3 Result judgement



Clinical judgement standard

H ₂ O ₂	H ₂ O ₂ SNa LE		
red/light red negative (prompt normal)	no color change negative (prompt normal)	no color change negative (prompt normal)	yellow/yellow-green negative
no color change positive (prompt possible dysbacteriosis)	purplegray/gray/black positive (prompt possible infection of bacterial vaginosis)	blue-green/blue positive (prompt different level of the inflammation)	dark green/blue– green/blue positive

Clinical result judgement list

	Test	ing result (- means neg)	Clinical significance	
No.	H ₂ O ₂	SNa	LE pH		
1	-	-	-	-	normal
2	-	_	_	+	Vaginal micro ecological balance is broken
3	+	-	-	-	Vaginal micro ecological balance is broken
4	-	_	+	-/+	Vaginitis or cervicitis
5	+	-	+	-/+	Vaginitis or cervicitis
6	_	+	_	-/+	BV early phase
7	-	+	+	-/+	BV early phase, might be with vaginitis, cervicitis etc.
8	+	+	_	-/+	BV
9	+	+	+	-/+	BV, poor prognosis

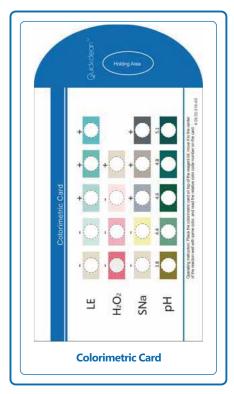
4 Announcements

Storage and Shelf Life

Store below $2^{\circ}\text{C} \sim 8^{\circ}\text{C}$. It expires after 12 months. , The product must be used within 8 hours after the aluminum foil bag for reaction strip is unpacked.



- 1. Rotate cotton swab at vaginal fornix for 10-20 sec. Try to collect more vaginal discharge from patient until discharge is clearly visible on the cotton swab, assay the specimen after collection.
- 2. Don't acquire specimen during menstrual period. Don't acquire specimen if patient had sex, bath, vaginal irrigation or applied local medication within 24hours.
- 3. Keep it below 2°C ~ 8°C for assay latter in the day.
- 4. This product only can be used as assistant for in vitro diagnosis. Test results should be combined with other validated equivalent methods and clinical symptoms before comprehensive diagnosis.
- 5. Components from different batches of the reagent kits shall not be
- 6. Please read instructions for use carefully. Compare to the standard colorimetric card to determine the color result.





Microalbuminuria (MAU) Rapid Test Kit (Colloidal Gold)



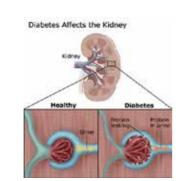
Intended Use

This kit is a rapid visual immuno-assay for the qualitative, pr esumptive detection of microalbumin in urine. The test used as an supplementary method in the diagnosis of diabetic ne phropathy and other renal damage. MAU occurs when the kidney leaks small amounts of albumin into the urine.

- The first indicator of a renal dysfunction, especially for diabetic patients.
- Independent risk indicator to evaluate the progression of chronic kidney disease (CKD).

Specification

High sensitivity	20mg/L
Small sample size	two drops urine
Shelf life	24 months





Testing Procedure

Read IFU

- Bring the test pouch t room temperature (20-30°C)
- Remove the test from the pouch
- perform urine testing by type
- Read the result at 3-5 mins

Do not read results after 10mins







Interpretation of Results

Negative



Two red lines are visible. One is located in the test line region (T), the other is in control line region (C). A negative result with the test indicates the albumin in urine is less then cut off value.

Positive (+)



One colored line appears in the control line region (C). No line appears in the test line region (T). A positive result with the test indicates the albumin in urine is more then cut off value.

Invalid



There is no red line in control region(C). Incorrect operation or the product has been damaged are the most likely reasons. Please repeat the test with a new test. If the problem still exists, should stop using this batch of product immediately and contact with local suppliers.

Neutrophil Gelatinase-Associated Lipocalin Rapid Test Kit (Colloidal Gold)

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Intended Use

NGAL Rapid Test Kit applies colloidal gold Immunol Chromatography, for the qualitative detection of Neutrophils Gelatinase Associated Lipocalin (NGAL) in urine. The test is used as an aid in the early diagnosis of acute kidney injury, risk classification and treatment monitoring.

Acute kidney injury (AKI) is where your kidneys suddenly stop working properly. It can range from minor loss of kidney function to complete kidney failure.

Symptoms of acute kidney injury:

feeling sick or being sick diarrhoea dehydration peeing less than usual confusion

confusion drowsiness

It's essential that AKI is detected early and treated promptly. If the kidneys shut down completely, this may require temporary support from a dialysis machine, or lead to death.



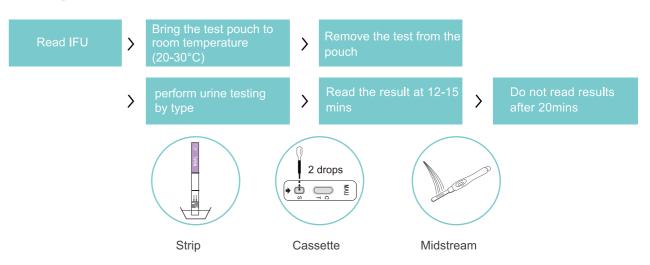
Specification

High sensitivity	20ng/mL
Small sample size	two drops urine
Shelf life	24 months



■ The optimal biomarker for early diagnosis of acute kidney injury (AKI).

Testing Procedure



Interpretation of Results

Positive (+)



Two colored lines are visible. One is located in the test line region (T), the other is in control line region (C). A positive result with the test indicates the NGAL in urine is more than cut off value.

Negative (-)



One colored line appears in the control line region (C). No line appears in the test line region (T). A negative result with the test indicates the NGAL in urine is less than cut off value.

Invalid



There is no colored line in control region (C). Incorrect operation or the product has been damaged are the most likely reasons. Please repeat the test with a new test. If the problem still exists, should stop using this batch of product immediately and contact with local suppliers.







- **23** Invention Patents
- 4 Quality Management Systems, Environmental Management Systems Approved
- 1 National High-tech Enterprise
- 3 Product National Standards Or Industry Standards Set Or Modify
- 1 Industry Certification Of Company—made In **Zhejiang**
- 23 Utility Model Patents



Strong R&D Team
EU Certification
Standardized Shipping Warehouse
Fast and Reliable Logistics
Professional Service
OEM/ODM Customized

As a result of continuous R&D breakthroughs, Singclean Medical established in 2002, has become one of the key players in the fields of absorbable biomaterials. Our innovative products are now exported to more than 70 countries around the world, such as Italy, Russia, Turkey, Brazil and Chile.



Singclean aims to improve

people's health

and well-being worldwide

using our industry

expertise, our global

partnerships and our

problem solving product.

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