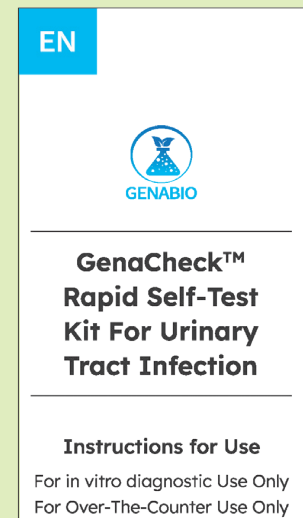
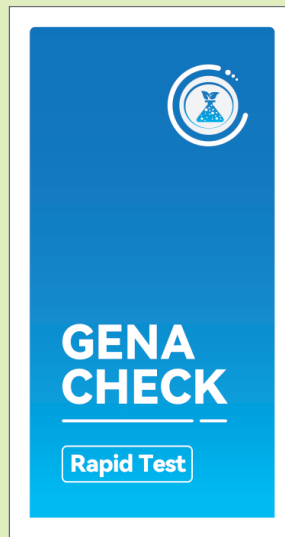
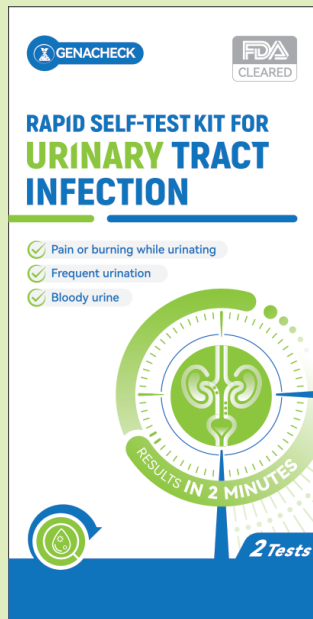




# RAPID SELF-TEST KIT FOR URINARY TRACT INFECTION

- ✓ FDA Cleared for At-Home Use
- ✓ Private and Convenient
- ✓ Results in 2 Minutes
- ✓ Easy-to-Use





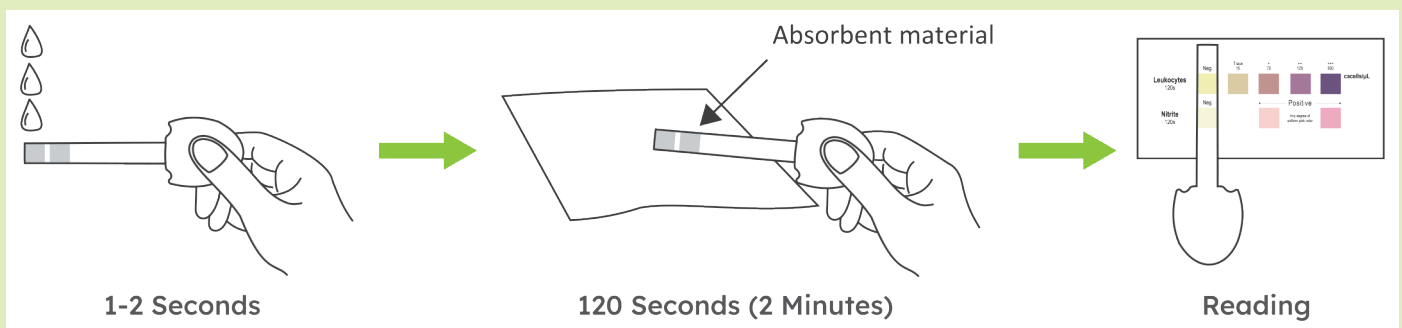
## PRODUCT FEATURES

Dual Detection: Leukocytes (White Blood Cell) and Nitrite in urine

Quick Test Time: 2 Minutes

Highly Sensitive: 15 cells/uL for Leukocytes, 0.05 mg/mL for Nitrite

Intuitive Design: Grip handle





## ORDER INFORMATION

Name		Item No.		Package	
GenaCheck™ Rapid Self-Test Kit for Urinary Tract Infection		RA9-E01801		2 Tests per Box	
	Dimension	Pack Size	Gross Weight	Quantity	
Carton	L: 37cm w: 25cm H: 33cm	102 (boxes per carton)	4kg	204 (tests per carton)	
Pallet	L: 112cm w: 100cm H: 111cm	36 (cartons per pallet)	184kg	7344 (tests per pallet)	



## PERFORMANCE CHARACTERISTICS

### Detection time and Range

Item	Sensitivity	Reportable Range	Read Time
Nitrite	0.05 mg/mL	Negative or Positive	2 Minutes
Leukocytes	15 cells/uL	Negative to 500 cells/uL	2 Minutes

Test Results Explanation

Leukocyte Result (Top Pad)	Nitrite Result (Bottom Pad)	Recommendation
Negative	Negative	No UTI detected
Negative	Positive	Signs of a UTI are present. Repeat the test the next time you urinate. Seek medical advice if the results remain the same or turn positive.
Trace	Negative	Unclear results. Repeat the test the next day. Seek medical advice if the results remain the same or if you continue to experience symptoms.
Trace	Positive	Results suggest the possibility of a UTI. Stay hydrated and consult with your doctor for further guidance.
Positive	Negative	
Positive	Positive	





## Establishment Registration & Device Listing

➤ [FDA Home](#) ➤ [Medical Devices](#) ➤ [Databases](#)



[New Search](#)

[Back To Search Results](#)

<b>Proprietary Name:</b>	GenaCheck Rapid Self-Test Kit for Urinary Tract Infection
<b>Classification Name:</b>	TEST, URINE LEUKOCYTE
<b>Product Code:</b>	<a href="#">LJX</a>
<b>Device Class:</b>	1
<b>Regulation Number:</b>	<a href="#">864.7675</a>
<b>Medical Specialty:</b>	Hematology
<b>Registered Establishment Name:</b>	<a href="#">GENABIO DIAGNOSTICS INC</a>
<b>Registered Establishment Number:</b>	3016609999
<b>Premarket Submission Number:</b>	<a href="#">K231045</a>
<b>Owner/Operator:</b>	<a href="#">Genabio Diagnostics Inc.</a>
<b>Owner/Operator Number:</b>	10063095
<b>Establishment Operations:</b>	Repackager/Relabeler; Complaint File Establishment



## GenaCheck™ Rapid Self-Test Kit For Urinary Tract Infection

### Instructions For Use

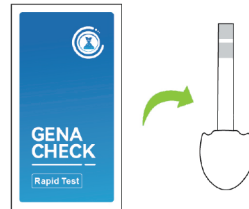
For in vitro diagnostic Use Only  
For Over-The-Counter Use Only

### Step By Step Instructions

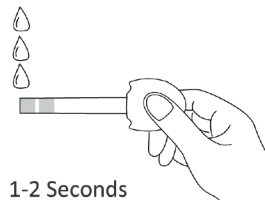
#### 1 Test Procedure

Remove the test strip from the foil pouch. Retain the foil pouch to use the color chart on the outside to interpret the results. Do not use the test strip if the pouch is torn or damaged.

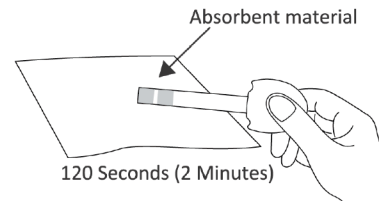
Immediately bring the edge of the test strip into contact with an absorbent material (e.g. paper towel) to remove excess urine. Lay the test strip with the test pads facing upwards and begin timing.



Hold the end of the test strip and begin urinating. After 1 or 2 seconds of passing urine, hold the strip downward with the test pads pointing into the urine stream for 1-2 seconds. Make sure the test pads are completely wet.

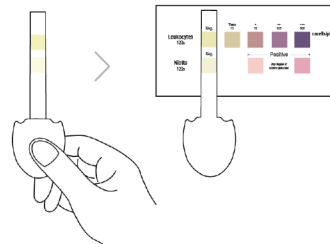


1-2 Seconds



Interpret results at 120 seconds (2 minutes). Compare the test pads to the color blocks on the foil pouch. Hold the test strip close to the color blocks and carefully match each test pad to the color chart for that test.

**Note: Do not read results after 180 seconds (3 minutes).**



Match Color

#### 2 Result Interpretation

Interpret the results by comparing the test pads to the color blocks on the foil pouch. Match the color of the test pad to the closest color block on the foil pouch.

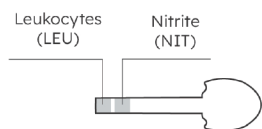
TEST STRIP RESULTS Leukocytes (LEU) Nitrite (NIT)		RECOMMENDATIONS
Negative	Negative	No sign of UTI detected. However, if you still have symptoms, consult with your physician; there are some cases of UTI that are not detectable.
Trace	Negative	Results suggest that additional testing is required. Test again the following day with a new strip. If you have symptoms or if you get another trace leukocyte result, consult with your physician.
Negative or Trace	Positive	Results suggest a sign of a UTI. Consult with your physician immediately.
Positive +, ++, +++	Positive	Results suggest a sign of a UTI. Consult with your physician immediately.
Positive +, ++, +++	Negative	Results suggest a sign of a UTI. Repeat the test next time you urinate using a new test strip. Make sure to wash the genital area first. If LEU is still positive, consult with your physician.

## Intended Use

The GenaCheck™ Rapid Self-Test Kit for Urinary Tract Infection is for the qualitative detection of leukocytes (white blood cells) and nitrite in urine as an aid in the screening of a Urinary Tract Infection (UTI). It is intended for over-the-counter use only.

## Test Principle

The test is a firm plastic strip onto which Leukocyte and Nitrite test pads are attached. If the test is positive, the test pad should be a uniform purple or pink color.



## Detection Time/Range

Item	Sensitivity	Reportable range	Read time
Nitrite (mg/dL)	0.05	Negative - Positive	120 seconds
Leukocytes (cells/ $\mu$ L)	15	Negative - 500 cells/ $\mu$ L	120 seconds

## Reactive Ingredients

(Based On Dry Weight At Impregnation Time)

Leukocytes	<ul style="list-style-type: none"><li>• 4.3% w/w pyrrole amino acid ester</li><li>• 0.4% w/w diazonium salt</li><li>• 92.6% w/w buffer</li><li>• 2.7% w/w nonreactive ingredients.</li></ul>
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Nitrite

- 1.3% w/w p-aminobenzene sulfonamide
- 0.9% 1, 2, 3, 4-tetrahydro-benzo(h)quino lin-3-phenol
- 89.6% w/w buffer
- 8.2% w/w nonreactive ingredients.

## Materials

### Materials Provided

- a) Test strips
- b) Instructions for Use

### Materials Required But Not Provided

- a) Timer, clock, or watch
- b) Absorbent material (e.g., paper towel)
- c) Specimen collection container

## Warnings And Precautions

Please read ALL the information in this Instructions for Use before performing the test.

- For invitro diagnostic use only. Not to be taken internally.
- For human urine testing only. Do not use for blood testing.
- Do not use after the expiration date.
- Keep out of the reach of children.
- Do not open the test strip package until ready to use. The opened strip should be used immediately.
- Used strip should be discarded according to local regulations.
- Analyze results in bright, natural light. Do not analyze under a colored light source to avoid color deviation.
- Do not interpret the results before

- 60 seconds (1 minute) or past 180 seconds (3 minutes).
- Individuals with color-impaired vision may not be able to adequately interpret test results.
- Diagnosis and treatment should not be based on a single test.

## Storage And Handling

- Store in a dry place at temperatures between 2-30°C (36-86°F).
- Do not refrigerate.
- Keep out of direct sunlight.
- The test strip should remain in the foil pouch with the drying packet until use.
- Do not touch the test pads of the strip.
- Any unused test strip with discolored test pads should be considered damaged or defective and should be discarded.
- Every strip can be used only once.

## Limitations

There is the possibility that this test may produce false results. The test may be affected by medication or dietary supplement that may change urine color. Do not use test strips if you observe abnormal urine colors (such as bright yellow or green). Do not use test strips while taking antibiotics. Consult with your physician before making any medical decision.

### Note:

1. Leukocytes: High glucose ( $\geq 1000$ mg/dL) or high Vitamin C ( $\geq 150$ mg/dL) in urine may cause test results to be low. Urine with a pH $\geq 8.0$  may cause a false positive leukocyte reading. Dehydration may cause false negative leukocyte reading.
2. Nitrite: High Vitamin C ( $\geq 150$ mg/dL) in urine may cause a false negative

nitrite reading. Any degree of uniform pink color should be read as a positive result. You may get a negative result if you have UTI caused by bacteria that do not change nitrate to nitrite, when urine has not been held in the bladder for more than 4 hours, when taking antibiotics, or when your diet does not include nitrates.

## Performance Characteristics

The performance characteristics of the test strips are based on both laboratory and clinical tests. The sensitivity of the test depends upon several factors, such as the variability of color perception, the presence or absence of inhibitory factors, and the lighting conditions under which the test strip is interpreted.

## Frequently Asked Questions

**Q: What are the common symptoms of UTI?**

**A:** The common symptoms of UTI include burning or pain during urination, frequent urination, fever, and back or groin pain.

**Q: Can I have UTI without symptoms?**

**A:** Yes, UTI can occur without symptoms in young children, pregnant women, and the elderly.

**Q: Do I have to test with my First-Morning Urine?**

**A:** Although you can test at any time of day, your First-Morning Urine would contain the most bacteria if UTI is present. Avoid testing during your menstrual period.

**Q: Will common foods, alcohol, or medications affect my test results?**

**A:** Generally, no. Most substances will not interfere with the test. Consult your physician if you are taking antibiotics. However, some medications can affect the color of your urine, making it difficult to match your results with the color chart on the foil pouch. Large quantities of Vitamin C may cause false negative results.

**Q: I received an abnormal result; What should I do now?**

**A:** We recommend you contact your physician or healthcare professional.

## Index Of Symbols

	Do Not Re-use		Consult Instructions For Use
	Test Per Kit		Store At 2-30°C (36-86°F)
	Batch Number		Catalog #
	Unique Device Identifier		For in vitro diagnostic Use Only
	Expiration Date		Keep Away From Sunlight
	Keep Dry		

## Assistance

For questions or comments please call Genabio Customer Service at 1-800-614-3365 (9:00 - 17:00 EST).

## Manufactured For Genabio Diagnostics Inc.

Address: 19 Crosby Dr., Ste 220, Bedford, MA 01730, USA  
Phone: 1-800-614-3365  
Hours of Operation: 9:00-17:00 EST  
Email: info@genabio.com  
Website: www.genabio.com  
Document No.: RA9-U01802  
Rev.01  
Effective Date: February 9, 2024





## COMPANY INTRODUCTION

Genabio is a global leader in the production of over-the-counter self-testing products, with an impressive sales record of over \$100 million in the past three years. Our extensive customer base spans across the USA, Canada, the UK, Japan and India.

A significant aspect of our product range is the FDA approval, including the COVID-19 Rapid Self-Test Kit. These sought-after products can be found in thousands of locations, including renowned pharmacy chains like Walgreens, leading hospitals such as NYU Langone Health, accredited laboratories like SV Diagnostics Labs and Molecular Testing Labs, and various government departments.

In 2023, Genabio marked a pivotal moment in initiating our listing and financing efforts in Hong Kong. Simultaneously, we are focused on enhancing our brand identity and emphasizing clinical research within the United States. This commitment to research and development aligns with our expansion plans, which encompass increasing our production capacity in both the United States and China.

Our overarching vision is to be the world's foremost provider of self-testing solutions, offering precise, user-friendly, and cost-effective health diagnostics for individuals worldwide.

Our mission is to enhance global health awareness and accessibility, by delivering quality, FDA-approved self-test kits, by driving innovation, and by expanding our reach to ensure individual scan monitor their health with precision and convenience.

