

# HEALTH-CHEM DIAGNOSTICS, LLC

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## URI-TEST GLUCOSE IN URINE

FOR IN VITRO DIAGNOSTIC USE ONLY. FOR USE OUTSIDE THE BODY

*Please read the entire insert before performing the test.*

*If you have any questions, call 1-800-482-2907 for technical assistance*

### ABOUT THE TEST:

The URI-TEST Glucose in Urine detects glucose in urine. It is extremely sensitive and will register small amounts of glucose (100 mg/dl). Glucose in urine is associated with early stages of diabetes and other carbohydrate metabolic diseases. By performing the test yourself at home, you can detect the presence of glucose in your urine. Normally you should have no glucose in urine. If a positive reaction is observed, you must notify your physician as soon as possible.

The detection of glucose is based on the glucose oxidase peroxidase-chromogen reaction. Apart from glucose, no other substance in urine is known to cause a positive reaction. A green to brown color that develops on the sensor pad indicates a positive reaction and means that you have glucose in your urine. If the test is positive you should immediately consult your physician. The clinical symptoms of diabetes include fatigue, excessive thirst and a need to urinate frequently. If you have these symptoms and your test is POSITIVE you should contact your physician immediately. If you have any of these symptoms and your Test Strip is negative - consult your physician immediately.

### CONTENTS OF THE KIT

Glucose Reagent Test Strips  
Plastic Collection Cups  
Performance Cup  
Color Chart  
Product Instructions

Test Strips are individually wrapped in foil pouches and ready to use from the package. They are completely disposable after use.

The Sensor Pad located on the Test Strip is impregnated with 4% w/w glucose oxidase, <1% w/w peroxidase, 5% w/w Color reagent, 80% w/w buffer and 10% w/w non-reactive components. The Test Strips are stable when stored at room temperature until the expiration date stated on the package.

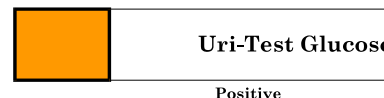
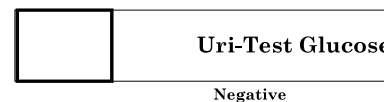
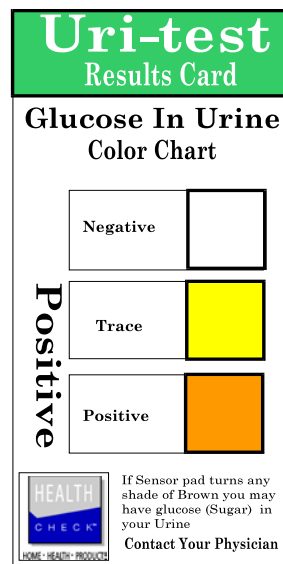
### PROPER USE AND STORAGE

Do not open the package in a steamy bathroom  
Open the foil package and remove the Glucose Test Strip. Do not open until ready to use  
Do not touch the Sensor Pad  
Use Test Strip immediately after opening  
Do not let the Test Strip come in contact with any liquid prior to use  
Store kit in a dry place below 86°F (30°C). Do not store in the refrigerator  
Do not re-use Test Strip

PIN# 425012

Discard Test Strip after use

### READING THE RESULT



**NORMAL/NEGATIVE:** if after 90 SECONDS of wetting the Test Strip the Sensor Pad is still a very pale green color (compare to color chart) the test result is negative. No color change indicates that there is no detectable glucose (sugar) in your urine. **NEGATIVE RESULT**

**ABNORMAL/POSITIVE:** If after 90 SECONDS of wetting the Test Strip, the Sensor Pad becomes a progressively darker color (compare to color chart) the test is positive. Write down results and call your physician. Any color change is considered a positive reaction. Call your physician. A positive result indicates that you have glucose in your urine.

**CALL YOUR PHYSICIAN IF YOU GET ANY COLOR CHANGE ON THE SENSOR PAD. THIS IS CONSIDERED A POSITIVE TEST FOR GLUCOSE. GLUCOSE IN URINE IS ASSOCIATED WITH DIABETES AND OTHER CARBOHYDRATE METABOLIC DISEASES. IT IS IMPORTANT TO SEE YOUR PHYSICIAN IF YOU GET A POSITIVE TEST RESULTS.**

**IF THE TEST IS NEGATIVE AND YOU CONTINUE TO EXPERIENCE ANY ABNORMAL SYMPTOMS, CONTACT YOUR PHYSICIAN**

## DIRECTIONS FOR USE

Ideally, you should perform the test about two hours after your last substantial meal.

1. Collect fresh urine in a clean plastic cup (included). Collected urine should be tested as soon as possible. If sample is not tested immediately, Urine can be stored in the refrigerator (2-8°C) for up to 8 hours. If you store your urine, before testing, let the urine stand at room temperature for 15-20 minutes.
2. DO NOT OPEN IN A STEAMY BATHROOM. Remove the Glucose Test Strip from the individual foil package.
3. Examine the Test Strip prior to use. The sensor pad should be a pale green color, discard if sensor is damaged or discolored.
4. Completely immerse the test area of the Test Strip in fresh urine until sensor pad is wet.
5. After wetting the Test Strip with urine, tap the Test Strip against the side of the container and place in the holder provided.
6. Wait 90 seconds. Compare the color of the Test Sensor Pad to the Color chart provided.

WHEN READING, HOLD THE TEST STRIP CLOSE TO COLOR BLOCKS AND MATCH COLOR CAREFULLY.

**IMPORTANT NOTE: IGNORE COLOR CHANGES THAT OCCUR AFTER THREE MINUTES**

## GUIDELINES FOR USE

The onset of diabetes can be rapid (within six days), gradual (one week to two months) or indefinite. Diabetes can occur during pregnancy.

After the age of 40, when diabetes and other carbohydrate metabolic diseases are most prevalent, testing for sugar (glucose) in the urine several times a year using the URI-TEST Glucose in Urine Test is advisable. Individuals with a family history of diabetes, overweight individuals or pregnant women may consider performing the test more often.

## EXPECTED VALUES

Normally, there is no detectable glucose in urine. Possible pathological glucose concentration are indicated by a color change from pale green to brown. A pale green test result should be considered negative - normal.

Any color change to darker green-brown should be considered a positive result.

After testing, write down your test results so that you can discuss them with your physician

If you have a negative test result and you continue to have symptoms of diabetes contact your physician immediately

## LIMITATIONS

1. URI-TEST Glucose in Urine is not a conclusive test for diabetes. Positive results **must** be confirmed by your physician.
2. Large amounts of Vitamin C or fruit juices (Ascorbic Acid) and/or antibiotic therapy can lead to lower or false negative results
3. False positives can be produced by a residue of peroxide-containing agents (household bleach).
4. The test is specific for glucose. No substance excreted in urine other than glucose is known to give a positive result. Other sugars including Lactose, galactose, fructose nor any other metabolic reducing agent (e.g. salicylates) do not interfere with the test reaction.
5. Substances that cause abnormal urine color, such as drugs containing azo dyes (ex. Pyridium, AZO Gantrisin, AZO Grantanol), nitrofurantoin and riboflavin, may affect the readability of the URI-TEST Glucose in Urine test result. The color development on the reagent pad may be masked or a color reaction may be produced on the pad that could be misinterpreted. If urine appears to be discolored, do not perform the test.
6. Blood in urine may affect the final color reaction

## PRODUCT PERFORMANCE

STUDIES HAVE BEEN DONE TO CONFIRM THE PERFORMANCE OF THE URI-TEST - GLUCOSE IN URINE TO ANOTHER COMPARABLE PRODUCT. THE DATA CONFIRM THE SENSITIVITY, SPECIFICITY AND ACCURACY OF THE URI-TEST GLUCOSE IN URINE.

THE FOLLOWING IS A SUMMARY OF THE PERFORMANCE

	COMPETITIVE PRODUCT (+)	COMPETITIVE PRODUCT (-)	TOTAL
URI-TEST +	38	1	39
URI-TEST -	0	66	66
TOTAL	38	67	105

DATA.

Sensitivity = >99% Specificity = 98.5% Accuracy = 99%  
The test is specific for glucose. No substance excreted in urine other than glucose is known to give a positive result.

**Manufactured in the US by:**

**HEALTH-CHEM DIAGNOSTICS LLC**

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CUSTOMER HOT-LINE - CALL 1-800-482-2907

**Certified ISO/CMDCAS 13485:2003**



**FM77504 - Quality Award**  
**FDA Establishment Registration No: 1048532**