

# HEALTH-CHEM DIAGNOSTICS, LLC

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## HEALTHCHECK®

### Protein In Urine

## Kidney and Bladder Screening Test

FOR IN VITRO DIAGNOSTIC USE ONLY

FOR USE OUTSIDE THE BODY

Please read the entire insert before doing the test. If you have any questions, call the HealthCheck® Help Line at 1-800-482-2907 for help.

#### ABOUT THE TEST

The HealthCheck® Protein in Urine Test is a screening test for protein in urine.

Protein in urine may be an indication of renal and/or bladder disorders. Renal or bladder disorders may be a complication of diabetes mellitus.

By testing yourself at home, you can screen for protein in your urine. Normally, you should have no protein in your urine. If the HealthCheck® Protein in Urine Test is positive, you should contact your doctor as soon as possible.

Some symptoms of renal and/or bladder disorders include frequent, painful or bloody urination, fever, back and groin pain, puffiness of the face and general weakness. If you have any of these symptoms **EVEN IF YOUR SCREENING TEST FOR PROTEIN IS NEGATIVE**, you should call your doctor right away.

#### PRECAUTIONS

This product screens for protein in the urine. Screening for protein in your urine will alert you and your doctor to the possible need for additional testing. Protein may be present in the urine if you have a renal and/or bladder disorder. There are certain conditions when protein is found in the urine of normal people. Additional testing is necessary to determine the reason why you have protein in your urine. This test by itself cannot be used to diagnose a medical condition or determine treatment.

**THIS TEST IS ONLY A SCREENING TEST FOR PROTEIN IN URINE.**

#### CONTENTS OF THE KIT

**HEALTHCHECK® PROTEIN IN URINE SCREENING TEST INCLUDES:**

Three individually wrapped Test Strips - Strips are ready to use from the package and are disposable.

- Plastic collection cups

- Color chart
- Product Instructions

#### PROPER USE AND STORAGE

The test strips should be stored at room temperature. When stored at room temperature, the Test Strips can be used until the expiration date printed on the package. Do not use test strips beyond the expiration date.

#### DO NOT OPEN THE TEST STRIPS IN A STEAMY BATHROOM.

- Do not open until you are ready to use.
- Do not touch the Test Pad.
- Do not let the Strip come in contact with any liquid prior to use.
- Do not re-use Test Strip. Discard Test Strip after use.

#### DIRECTIONS FOR USE:

1. Collect fresh urine in a clean plastic cup (included).
2. Remove one Protein Test Strip from the individual foil package.
3. Examine the Test Strip prior to use. The Test Pad should be a yellow color. If the Test Pad is any other color or appears damaged, throw away that Test Strip. Call the HealthCheck® HelpLine for assistance at 1-800-482-2907.
4. Dip the Test Strip into the urine, being sure that you wet the Test Pad completely.
5. After wetting the strip with urine, run the test strip against the side of the cup to remove excess urine.
6. Wait 60 seconds. Compare the color of the TEST PAD to the Color Chart enclosed.

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

**IMPORTANT NOTE: IGNORE COLOR CHANGES THAT APPEAR AFTER 90 SECONDS.**

- Please Note: Chemical Composition and technical references are available upon request. Please call the HealthCheck® HelpLine at 800-482-2907.

**READING THE RESULT**

**NORMAL/NEGATIVE:**

After 60 SECONDS, compare the Test Pad to the Color Chart provided. If the Test Pad remains a yellow color, the TEST RESULT is NEGATIVE. No green color means that there is no detectable protein in your urine and that the test is negative.

**IF THE TEST IS NEGATIVE AND YOU CONTINUE TO HAVE ANY ABNORMAL SYMPTOMS, YOU SHOULD SEE YOUR DOCTOR.**

**ABNORMAL/POSITIVE**

After 60 SECONDS, compare the TEST PAD to the color chart. If the TEST PAD turns a green color, the TEST RESULT is POSITIVE. Call your doctor if you see any shade of green on the Test Pad. This is considered a positive result. A positive result means that you may have protein in your urine.

**CALL YOUR DOCTOR IF YOU GET ANY GREEN COLOR ON THE SENSOR PAD. THIS IS CONSIDERED A POSITIVE TEST FOR PROTEIN.** If you see a color other than green, this may be associated with certain medication or dyes in your urine. **CALL YOUR DOCTOR.**

If you have any questions concerning your test results call the HealthCheck® HelpLine at 1-800-482-2907.

**LIMITATIONS:**

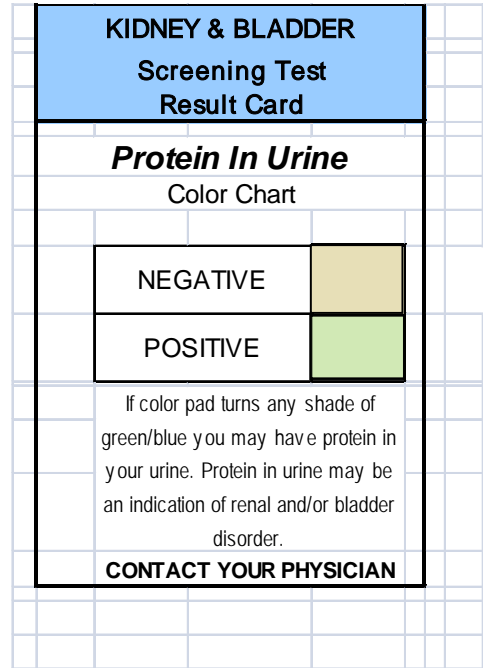
- 1) False positive results are possible in highly alkaline urine samples (pH 8.5).
- 2) Certain medication containing quinine may produce false positive reactions.
- 3) The protein color change may be masked by the presence of certain dyes that may be present in your urine (e.g. methylene blue or beetroot pigments).
- 4) The presence of blood in your urine may mask the color change on the Test Pad.
- 5) HealthCheck® Protein in Urine Test is not equally sensitive to all proteins.
- 6) False negatives could be related to frequent urination, which can occur with increased fluid intake.

**PRODUCT PERFORMANCE**

Studies have been done to confirm the performance of the HealthCheck® Protein in Urine Test. 170 specimens were tested by both a Laboratory Technician and Consumers. The HealthCheck® Protein in Urine Test was compared to another product used for the detection of protein. Consumer data was collected and confirms that the HealthCheck® Protein in Urine Test is sensitive enough to detect 15 mg/dL of protein in urine.

Accuracy of the HealthCheck® Protein in Urine Test results based on the consumer data when the test results are compared to a similar product.

**Consumer Accuracy: 98% Laboratory Accuracy: 97%**



*(Color Chart Illustration: not for clinical use)*

Manufactured in the USA by:  
**HEALTH-CHEM DIAGNOSTICS LLC**  
**US FDA & ISO Certified Facility**  
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 Certified ISO CMDCAS 13485:2003



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