



User Manual

# How to use your Minuteful – Kidney Test

---

## STEP 1

Download the 'Minuteful – Kidney Test' app: [www.minuteful.com/uk/kidney/download](http://www.minuteful.com/uk/kidney/download) OR scan the QR-code:



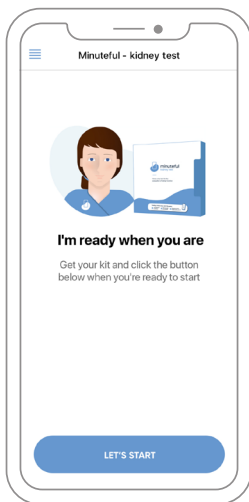
Download on the  
App Store



GET IT ON  
Google Play

## STEP 2

Open the 'MinuteFul - Kidney Test' app and follow the app instructions. It will guide you through the test process.



## STEP 3

Once you complete the test, results will be securely sent to your healthcare professional for further care.

## **Minuteful - Kidney Test**

Healthy.io Ltd.

8 Yitzhak Sadeh St., Tel Aviv 6777508, Israel

### **Intended Use**

The Minuteful - Kidney Test system is a urine analysis test system intended for home-use, in vitro analysis. The kit includes the standard equipment required to perform the test: a single-wrapped ACR reagent strip, a Colour-Board, a biocompatible urine collection cup, and an absorbing pad. The kit allows for standard semi-quantitative detection of albumin and creatinine, as well as the qualitative measurement of the ratio between them.

### **Indications for Use**

System measurements can be used to guide patient management and care, and aid in the diagnosis and monitoring of metabolic or systemic diseases that affect kidney function. Clinician interpretation of the results should be made in conjunction with the patient's other clinical information to determine if further confirmatory tests or consultations are necessary.

### **Summary**

The device is a mobile application that in conjunction with the Minuteful - Kidney Test kit effectively turns a smartphone into an Albumin-Creatinine urine analysis test system. The smartphone application provides a step-by-step instructional guide

to the user throughout the testing procedure, performs the scan and securely delivers the analysed test results to the patient's Health care provider for further care.

## **Precautions**

- For in vitro use only.
- The ACR Reagent Strip ("Dipstick") can only be read by the application.
- Do not touch the reagent area of the dipstick.
- The used dipstick should be discarded according to local regulations after testing.
- Wash your hands before and after performing the test.
- The cup, dipstick and the Colour-Board are for single - use only.
- Do not use the cup or the absorbing pad if it is contaminated by dirt or foreign substances.
- Dip the stick so that all patches are fully immersed in the urine.
- Keep the dipstick and Colour-Board in the original packaging until you are ready to use them.
- Do not use a kit that is past the expiration date or one that shows signs of visible damage.
- Only use the dipstick that is provided with the kit.
- Do not use a soiled dipstick or Colour-Board.
- Do not use a bent or broken dipstick or Colour-Board.
- Make sure the smartphone camera is

working before performing a urine test.

- Make sure the lens of the smartphone camera is clean before use.
- Make sure that your smartphone battery is at least 10% charged. If the smartphone battery is below this level, the test may not complete successfully.
- Make sure that the smartphone is connected to the Internet before performing the test.
- Make sure you have at least 50MB of available disk space on your smartphone before performing the test.

### **Storage and Stability**

- Store at room temperature.
- Keep out of direct sunlight.
- The dipstick is stable through the expiration date.
- Do not use beyond the expiration date.
- Do not freeze.
- Stability may be reduced if stored outside of the recommended storage temperatures.

### **Specimen Collection and Preparation**

- Wash your hands thoroughly.
- Extract the cup, remove its lid, and extend it all the way.
- Collect midstream urine - after 1 or 2 seconds of passing urine, place the cup underneath the urine stream and begin collecting urine, until you reach the 'FULL' marked line. It is recommended to use the first urine of the day.

- Place the cup back in the designated cup holder.
- Perform the test at room temperature.
- Follow the app instructions.

### **Phone and Operating System Limitations**

Please visit [www.minuteful.com/uk/kidney/download](http://www.minuteful.com/uk/kidney/download) to verify that your smartphone is compatible with the 'Minuteful - Kidney Test' application.

### **Materials Provided**

- Cup and lid
- Colour-Board
- ACR Test dipstick and a desiccant
- Absorbing pad
- User manual

For Self-Testing

### **Directions for Use**

Before starting the test, download the 'Minuteful - Kidney Test' application. The application includes a dedicated instructional flow, which will guide you through the test process step by step. Extract the cup, remove its lid, and extend it all the way. Fill it with midstream urine up to the full marked line. According to the app instructions, immerse the dipstick fully for about one second, then gently blot the dipstick by touching the edge of the dipstick on the designated absorbing pad for one second to remove any excess urine and then place it at the centre of the Colour-Board. Wait for 75 seconds and then

use the in-app scanner to scan the Colour-Board. Your test results will be securely sent to your clinician for further care.

## **Test Principles**

**Albumin:** The test is based on dye binding using a sulfonephthalein dye. At a constant pH, albumin binds sulfonephthalein dye to develop any blue colour. Results range in colour from pale green to aqua blue. The albumin patch is traceable to the CRM 475 from IFCC.

**Creatinine:** The peroxidase-like activity of copper creatinine complex that catalyzes the reaction of cummen hydroperoxide and 3,3',5,5'-tetramethylbenzidine to produce a resulting colour range from yellow through green to blue. The creatinine patch is traceable to SRM 914a from NIST.

## **Calibration and Maintenance**

No calibration or maintenance is required.



## Reported Values

### Minuteful - Kidney ACR Test Dipstick Parameter Table

Parameter Name (Abbreviation)	Conventional	SI Units
Albumin (ALB)	10 mg/L 30 mg/L 80 mg/L 150 mg/L	10 mg/L 30 mg/L 80 mg/L 150 mg/L
Creatinine (CRE)	10 mg/dL 50 mg/dL 100 mg/dL 200 mg/dL 300 mg/dL	0.9 mmol/L 4.4 mmol/L 8.8 mmol/L 17.7 mmol/L 26.5 mmol/L
Albumin-Creatinine Ratio (ACR)	Normal (<30 mg/g) Abnormal (30-300 mg/g) High abnormal (>300 mg/g)	Normal (<3mg/mmol) Abnormal (3-30 mg/mmol) High abnormal (>30 mg/mmol)

\*The reported parameters may vary by partner

## Performance Characteristics of the Minuteful - Kidney Test

The performance characteristics of the Minuteful - Kidney Test have been determined in both laboratory and clinical tests. Outlined below short summaries of the main studies performed.

## Accuracy

The Minuteful - Kidney Test system was tested during multi-site clinical trials, in which the test was performed by over 250 lay users, with a variety of health conditions. Each sample was also tested using a commercially-marketed comparator device and the results were compared.

Minuteful - Kidney Test System Reading vs. Predicate Device Reading			
Analyte Name (Abbreviation)	% Exact Match Agreement	% $\pm 1$ colour block Agreement	95% Confidence Interval
Albumin (ALB)	84.6%	99.8%	81%-87%
Creatinine (CRE)	84.6%	99.8%	81%-87%
Albumin-Creatinine ratio (ACR)	92.6%	100%	90%-95%

## Precision

A within-run repeatability and a between-run reproducibility studies were conducted to assess the performance of the Minuteful - Kidney Test. These studies were conducted with spike urine samples that were validated using another commercially-marketed comparator device.

Analyte Name (Abbreviation)	Repeatability % Exact Match Agreement (95% Confidence Interval)	Reproducibility % Exact Match Agreement (95% Confidence Interval)
Albumin (ALB)	100% (99%-100%)	99.8% (99.5%-99.9%)
Creatinine (CRE)	100% (99%-100%)	99.9% (99.7%-100%)
Albumin-Creatinine Ratio (ACR)	100% (99%-100%)	99.9% (99.6%-100%)

## Sensitivity

### Albumin:

The test detects urinary albumin levels as low as 22 mg/L.

### Creatinine:

The test detects urinary creatinine levels as low as 34 mg/dL; .

## Factors That May Interfere With The Test Results

Note: The test dipstick may be affected by substances that cause abnormal urine colour, such as drugs containing azo dyes (e.g. Pyridium<sup>®</sup>, Azo Gantrisin<sup>®</sup>, Azo Gantanol<sup>®</sup>), nitrofurantoin (Macrochantin<sup>®</sup>, Furadantin<sup>®</sup>). Urinary albumin excretions can be elevated by exercise, urinary tract infection, and acute illness with fever. It is recommended that individuals avoid strenuous exercise prior to testing.

The following table shows the substances which interfere with either one or both of the analytes.

**Albumin:** All positive results for albumin including low concentrations of albumin should be confirmed with quantitative test methods.

Interferent	Lowest tested concentration causing an interference	Affect on Results
Hemoglobin	5.1 mg/dL	Falsely elevated
Blood	0.045%	Falsely elevated
Sodium Bicarbonate	1,305 mg/dL	Falsely elevated

**Creatinine:**

Interferent	Lowest tested concentration causing an interference	Affect on Results
Ascorbic Acid	330 mg/dL	Falsely decreased
Blood	0.06%	Falsely elevated
Mesna	380 mg/dL	Falsely decreased

## Troubleshooting

Error Message	Description	Patient Instructions
No Internet connection	The system checks for stable Internet connection and notifies the user about the status.	Make sure your device is connected to the Internet during the test.
Device / operating system is not supported	The system checks if the user is using a compatible device / operating system and alerts the user if the system is incompatible.	Only supported devices and operating systems are valid for use. Please visit: <a href="http://www.minute.com/uk/kidney/download">www.minute.com/uk/kidney/download</a> to verify that your smartphone is compatible with the Minute-ful - Kidney Test.
Disk space	The system checks if there is enough disk space on the smartphone to perform the test.	Try to delete some data from your smartphone.
Low battery	The system checks if there is enough battery to perform the test.	Charge your smartphone above 10%.
Bad lighting conditions	Lighting conditions do not enable accurate scanning.	Enhance the light or find a different room to perform the test.
Shadow on Colour-Board	Key parts of the Colour-Board are shaded. Such conditions preclude accurate scanning.	Remove any objects that stand between the main light source and the Colour-Board. Make sure there is no strong shade covering the Colour-Board.
Picture is blurry	The scanning sequence took place while the patient move the phone.	Retry the scanning sequence and hold the phone still while the scanning sequence is starting.

Mis-placed dipstick	The dipstick was not placed in its designated location at the centre of the Colour-Board.	Make sure that the dipstick is placed in the designated area in the middle gap on the Colour-Board and retry the scanning sequence.
General	General problem.	Follow the app instructions and retry.
Image upload taking too long	The system recognises that the upload process is taking too long, or stuck due to bandwidth issues.	Keep the app running, the scan will be uploaded as soon as the bandwidth allows it and will notify accordingly.
Dipstick is no longer valid	The dipstick is valid for analysis between 75–180 seconds after it was dipped. The system measures the time and allows the user to scan only during this range.	Follow the app instructions and restart the test with a new kit.

## Data Security and Privacy

We take your data very seriously and have implemented mechanisms to protect it. We recommend that you use the following security measures to protect your smartphone from unauthorized access:

- Setup your device with a screen lock. Biometrics locks (Touch ID, Face ID, etc.) are recommended.
- Turn on your device's auto-lock feature.
- Keep your device's operating system up to date.
- Connect to secure Wi-Fi networks and avoid public networks.
- Beware of downloads from unauthorized

sources.

- Do not jailbreak or root your device.
- Activate your device encryption.
- Install anti-virus software.
- Download the Minuteful - Kidney Test application only from either the App Store or Google Play.
- Keep the Minuteful - Kidney Test application up to date.

The device is composed of several software components, and is dependent on a few well-known public services: the mobile application stores - Google Play and Apple AppStore - and the Google Cloud Platform.

In the unlikely event of any service disruption or cybersecurity incident involving these providers, there is a possibility that the service may become temporarily unavailable, and this measure is taken to safeguard your data. Should this occur, the app will promptly notify you of the issue, and we suggest that you retry the service after a reasonable period of time.

### **Further Assistance**

For further assistance please contact:  
[support-uk@minuteful-kidney.com](mailto:support-uk@minuteful-kidney.com)

### **Patent Markings**

For more information about Healthy.io's patents visit: [www.healthy.io/patents](http://www.healthy.io/patents)

## **Bibliography**











1. Zhang QL and Rothenbacher D. Prevalence of chronic kidney disease in population-based studies : systematic review. *BMJ public Health*: 8-117; 2008.
2. Keane WF and Eknoyan G. Proteinuria, albuminuria, risk, assessment, detection, elimination (PARADE): A position paper of the National Kidney Foundation. *Am J Kidney Dis* 33:1004-10; 1999.
3. Sacks DB, Arnold M, Bakris GL, Bruns DE, Horvath AR, Kirkman MS, et al. Position statement executive summary: guidelines and recommendations for laboratory analysis in the diagnosis and management of diabetes mellitus. *Diabetes Care* 34:1419-23; 2011.
4. Mogensen, C.E. et al: Prevention of Diabetic Renal Disease with Special Reference to Microalbuminuria. *Lancet* 346:1080-1084; 1995
5. Hishi S, Tochikubo O, Miyajima E, Ishi M, Circadian variation of urinary microalbumin excretion and ambulatory blood pressure in patients with essential hypertension. *J Hypertens*: 16:2101-8; 1998.
6. Levey AS, Eckardt KU, Tsukamoto Y, Levin A, Coresh J, Rossert J, et al. Definition and classification of chronic kidney disease: a position statement from Kidney Disease: Improving Global Outcomes (KDIGO). *Kidney Int*: 67:2089-100; 2005.
7. Wilde HM, Banks D, Larsen CL, Connors G, Wallace D, Lyon ME. Evaluation of the Bayer microalbumin/creatinine urinalysis



- dipstick. *Clinica Chimica Acta* 393:110-3; 2008.
8. Guy M, Newall R, Borzomato J, Kalra PA, Price C. Diagnostic accuracy of the urinary albumin:creatinine ratio determined by the CLINTEK Microalbumin and DCA 2000+ for the rule-out of albuminuria in chronic kidney disease. *Clin Chim Acta*; 399:54-8; 2009
  9. Position Statement: Diabetic Nephropathy. *Diabetes Care* 20: S24-S27; 1997.
  10. McTaggart MP, Price CP, Pinnock RG, Stevens PE, Newall RG, Lamb EJ. The diagnostic accuracy of a urine albumin-creatinine ratio point-of-care test for detection of albuminuria in primary care. *AM J Kidney Dis* 60:787-94; 2012.
  11. Burtis C.A.; and Ashwood ER.: *Tietz Textbook of Clinical Chemistry* 3rd ed. Philadelphia: Saunders; 1999; pp. 483-484.
  12. Mangili, R. et al.: Prevalence of Hypertension and Microalbuminuria in Adult Type 1 (Insulin-Dependent) Diabetic patients Without Renal Failure in Italy-Validation of Screening Techniques to Detect Microalbuminuria. *Acta Diabetol.* 29: 156-166; 1992.
  13. American Diabetes Association, *Clinical Practice Recommendations, Diabetes Care*, Vol. 31, Suppl. 1, January 2008.
  14. B. Berg, K. Hellsing, R. Jagenburg & A. Kallner. Guidelines for evaluation of reagent strips. *Scand. J. Clin. Lab. Invest* :49:689-199; 1989.
  15. Omoruyi FO, Mustafa GM, Okorodudu

AO, Petersen JR. Evaluation of the performance of urine albumin, creatinine and albumin-creatinine ratio assay on two POCT analyzers relative to a central laboratory method. Clin Chim Acta: 413:625-9; 2012.

16. NCCLS (National Committee For Clinical Laboratory Standard) GP 16 - A / Routine urinalysis and collection, transportation and preservation of urine specimens ; approved guidelines No. 15.1995.

	Do not reuse
	Store between 15°- 30°C
	Keep dry
	Use by date
	Keep away from sunlight
	In vitro diagnostic medical device
	Consult instruction for use
	Manufactured by
	Do not use if package is damaged
	Caution

EC REP

CEpartner4U BV,  
 Esdoornlaan 13, 3951 DB  
 Maarn. The Netherlands  
[www.CEpartner4U.com](http://www.CEpartner4U.com)



Healthy.io Ltd  
 8 Yitzhak Sadeh  
 St., Tel Aviv  
 6777508, Israel

Effective Date: May 2023  
 Rev 7.0 | MNT KDN-UML-EN-GEN

 0483

