minuteful kidney test

User Manual

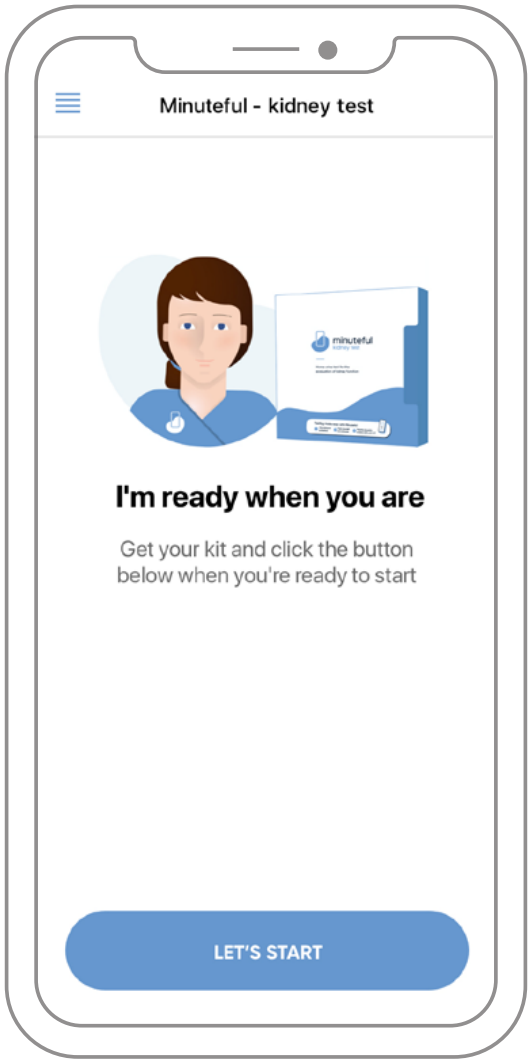
How to use your Minuteful – kidney test

STEP 1

Download the 'Minuteful – kidney test' app by clicking the link inside the text message received from your healthcare provider.

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
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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.healthy.io/download/minuteful-kidney-uk 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 using the text message received from your healthcare provider. 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 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	% ± 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®, Azo Gantrisin®, Azo Gantanol®), nitrofurantoin (Macrodantin®, Furadantin®). 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: www.healthy.io/download/minuteful-kidney-uk to verify that your smartphone is compatible with the Minuteful - 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.
Misplaced 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.

Further Assistance

For further assistance please contact:
support-uk@minuteful-kidney.com

Patent Markings

For more information about Healthy.io's patents visit: www.healthy.io/patents

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	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

EC REP

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