



User Manual

How to use your Minuteful – kidney test

STEP 1

Download the 'Minuteful – kidney test' app: www.healthy.io/download/minuteful-kidney OR scan the QR-code:



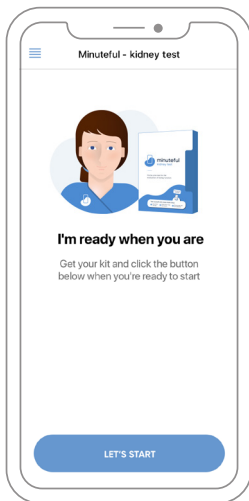
Download on the
App Store



GET IT ON
Google Play

STEP 2

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



STEP 3

Once you complete the test, results will be securely sent to your doctor/ prescribing physician for further care.

Minuteful - kidney test

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Indications for Use

The Minuteful - kidney test is an in-vitro diagnostic, home-use urine analysis test system for the semi-quantitative measurement of albumin and creatinine in urine, as well as the presentation of their ratio, the albumin-creatinine ratio (ACR). The system consists of a smartphone application, proprietary Color-Board and an ACR Reagent Strip. The system is available for prescription-use only and is intended for people at risk of kidney disease. Results are intended to be used in conjunction with clinical evaluation as an aid in the assessment of kidney health.

Summary

The device is a mobile application that in conjunction with the Minuteful - kidney test kit effectively turns your smartphone into an ACR urine analysis test system. The smartphone application provides a step-by-step instructional guide throughout the testing procedure, which facilitates the scan and securely delivers the analyzed test results to your doctor/prescribing physician 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 color patches of the dipstick.
- Wash your hands before and after performing the test.
- The kit and its components (cup, absorbing pad, ACR Test Dipstick, Color-Board) are for single-use only.
- Do not perform the test if any of the kit's components are missing.
- Do not use the kit if one of its components is contaminated by dirt or foreign substances.
- Dip the stick so that all patches are fully immersed in the urine.
- Keep the dipstick in the original packaging until you are ready to use it.
- 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 bent or broken dipstick or Color-Board.
- Do not use the device in the case of a discolored urine specimen. If the color of your urine is different than yellow or clear, do not use this test and consult with your healthcare professional.

- Do not make any decisions of medical relevance or make any changes to your treatment based on your results without first consulting your healthcare professional.
- Make sure the smartphone camera is working before performing the 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.
- The kit's components should be discarded according to local regulations after testing.
- It is recommended to avoid testing after exercise, when experiencing a fever or when having a urinary tract infection, due to a potential temporary increase in urine protein (albumin).

Storage and Stability

- Store at 59°–86°F (15°–30°C) .
- Stability may be reduced if stored outside of recommended storage temperatures.
- Keep out of direct sunlight.
- The dipstick is stable through the

expiration date.

- Do not freeze.

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' line. It is recommended to use the first urine of the day.
- Place the cup back in the designated cup holder.
- The test should be performed within 15 minutes of urine collection.
- Perform the test at room temperature.
- Follow the in-app instructions.

Technical Requirements - Supported Devices

Please visit www.healthy.io/download/minute-ful-kidney to verify that your smartphone is compatible with the 'Minute-ful - kidney test' application.

Materials Provided

- Cup and lid
- Color-Board
- ACR Test Dipstick
- 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. The instructions will explain how to extract the cup, remove its lid, extend it all the way, and then fill it with midstream urine up to the 'FULL' 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 in the center of the Color-Board. Wait for 75 seconds and then use the in-app scanner to scan the Color-Board. Upon completion, your test results will be securely sent to your doctor/prescribing physician for further care.

Reported Values:

Result	Concentration (mg/g)
Normal	<30
Abnormal	30-300
High abnormal	>300

Meaning of Results

ACR	Meaning of your results
Normal	<p>Albumin was NOT detected in your urine at an elevated level at this time.</p> <p>It is recommended to share your results with your primary care physician at your next visit.</p>
Abnormal or High abnormal	<p>Your test result shows there's an elevated level of albumin in your urine at this time. Persistent elevation of albumin in your urine can be an early sign of kidney damage. When detected early, kidney damage can be managed to stop its progression.</p> <p>It is recommended that you see your primary care physician to discuss your test results.</p>

Performance Characteristics

The performance characteristics of the Minuteful – kidney test have been determined in both laboratory and clinical tests.

Assistance Using the Device

- Elderly people or those who require aid may be assisted when operating the device.

- The use of the device for children below the age of 18 years old should be guided by an adult.

Troubleshooting

Error Message	Description	Patient Instructions
Preparations		
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 it is incompatible.	Only supported devices and operating systems are valid for use. Please visit: www.healthy.io/download/minute-ful-kidney to verify that your smartphone is compatible with the Minute-ful - kidney test app.
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%.
Connectivity issue	The system depends on a cloud system, and is checking for proper connectivity.	Wait a few minutes and retry. If the problem persists, please contact customer support.
Scanning process		
Bad lighting conditions	Lighting conditions do not enable accurate scanning.	Enhance the light or find a different room to perform the test.
Shadow on Color-Board	Strong shadow on the Color-Board does not enable accurate scanning.	Remove any objects that stand between the main light source and the Color-Board. Make sure there is no strong shadow covering the Color-Board.
Picture is blurry	The acquired images were not sharp enough.	Make sure your camera lens is clean and retry the scanning sequence. Try to hold the phone still.

Misplaced dipstick	The dipstick was not placed in its designated location in the center of the Color-Board.	Make sure that the dipstick is placed in the designated area in the middle gap on the Color-Board and retry the scanning sequence.
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. Failing to follow the app instructions can lead to inaccurate results.
Image upload taking too long	The system recognizes that the upload process is taking too long, or is stuck due to bandwidth issues.	Keep the app running, the scan will be uploaded as soon as the bandwidth allows and will notify you accordingly.

Factors That May Interfere With The Test Results

Some substances (i.e, medications and vitamins) at high concentrations may change the color of urine and interfere with the reactions on the dipstick, making the test results unreliable.

The substances that have been shown to interfere include: Ascorbic acid (Vitamin C), mesna (MESNEX), sodium bicarbonate and hydroxychloroquine sulfate (PLAQUENIL®). If you are taking these medications or supplements, please inform your physician.

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 event of any downtime or cybersecurity incident with these providers, there is a chance that the service will not be available, and this will be for the protection of your data.

In the event of a suspected cybersecurity incident in our systems or our providers' systems, we may suspend some of the security components that operate the device. In this case, the app will notify you that there is a problem with the system, and we recommend that you retry after a period of time.

Further Assistance











For further assistance please contact:

Phone number: | Email:

(844) 688-5055 | support-us@minuteful-kidney.com

Patent Markings

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

	Prescription only
	Do not reuse
	Store between 59°– 86°F (15° – 30°C)
	Keep dry
	Use by date
	Keep away from sunlight
	In vitro diagnostic medical device
	Consult instruction for use
	Manufactured by
	Caution



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