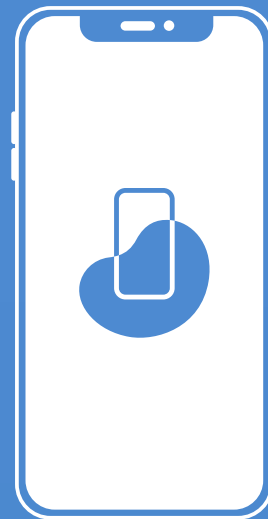
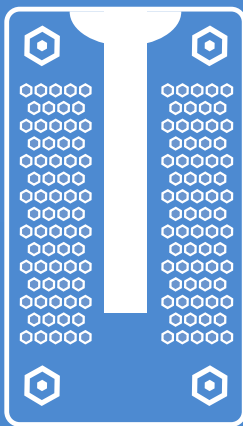


Physician Compendium for Minuteful – kidney test



Minuteful – kidney test

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Intended Use

See indication for use below.

Indication 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 a smartphone into an ACR urine analysis test system. The smartphone application provides a step-by-step instructional guide to the user throughout the testing procedure, which facilitates the scan and securely delivers the analyzed test results to the patient's doctor / prescribing physician for further care.

For Self-Testing

Test's Precautions

- For in vitro use only.
- The ACR Reagent Strip ("dipstick") can only be read by the Minuteful – kidney test application.
- The color patches of the dipstick should not be touched.
- Patient shall wash his 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.
- The test shall not be performed if any of the kit's components are missing.
- The kit shall not be used if one of its components is contaminated by dirt or foreign substances.
- While dipping the stick, all patches shall be immersed in urine.
- The dipstick shall be kept in its original packaging until used.
- A kit that has passed the expiration date or shows signs of visible damage should not be used.
- The kit should only be used with the dipstick provided.
- A bent or broken dipstick or Color-Board should not be used.

- The device should not be used in the case of a discolored urine specimen. If the color of the patient's urine is different than yellow or clear, do not use this test and consult with your healthcare professional.
- A quantitative follow-up test is recommended.
- Patients should consult with their healthcare professional regarding their results and any questions they may have.
- Patients should not make any decisions of medical relevance or make any changes to their treatment based on their results, without first consulting their healthcare professional.
- Patients shall make sure the smartphone camera is working before performing the test.
- Patients shall make sure the lens of the smartphone camera is clean before use.
- Patients shall make sure the smartphone battery is at least 10% charged. If the smartphone battery is below this level, the test may not be completed.
- Patients shall make sure that the smartphone is connected to the internet before performing the test.
- Patients shall make sure they have at least 50MB of available disk space on the smartphone before performing the test.
- The kit's components should be discarded according to local regulations after testing.
- It is recommended that patients avoid testing after exercise, when experiencing a fever or when having a urinary tract infection, due to a potential temporary increase in urine albumin.

Storage and Stability

- The kit shall be stored at 59°–86°F (15°–30°C).
- Stability may be reduced if stored outside of recommended storage temperatures.
- The kit shall be kept out of direct sunlight.
- The dipstick is stable through the expiration date.
- The kit shall not be frozen.

Specimen Collection and Preparation

When collecting the specimen, the patient should:

- Wash their hands thoroughly.
- Extract the cup, remove its lid and extend it all the way.
- Fill the cup to the marked line with midstream urine.
- Place the cup in its designated cup holder.
- Perform the test within 15 minutes of urine collection.
- Perform the test at room temperature.
- Follow the in-app instructions.

Technical Requirements – Supported Devices

Instruct the patient to visit www.healthy.io/download/minute-ful-kidney to verify that their smartphone is compatible with the 'Minute-ful – kidney test' application.

Materials Provided

- Cup and lid
- Color-Board
- ACR Test Dipstick
- Absorbing pad
- User manual

Directions for Use

Before starting the test, the patient shall download and install the 'Minuteful-kidney test' application using the "QR code" provided with the kit. The application includes a dedicated instructional flow, which will guide the patient through the test process, step by step. The patient shall extract the cup, remove the lid, extend it all the way, and then fill it with midstream urine up to the 'FULL' line. Following the app instructions, the patient shall immerse the dipstick in the urine for about one second, then gently blot the dipstick by touching the edge of the dipstick on the designated absorbing pad to remove any excess urine. Then, the patient shall place it in the center of the Color-Board. After waiting 75 seconds, the patient shall use the in-app scanner to scan the Color-Board. When completed, the test results will be securely sent to a healthcare professional for further care.

Principles and Expected Values

Albumin

The test for albumin is based on the dye binding reaction using a sulfonephthalein dye. At constant pH, albumin binds sulfonephthalein. The resulting color ranges from pale green to aqua blue.

Creatinine

The test is based on the peroxidase-like activity of copper creatinine complex that catalyzes the reaction of cumene hydroperoxide and 3,3',5,5'-tetramethylbenzidine. The resulting color ranges from yellow through green to blue.

Calibration and Maintenance

No calibration or maintenance is required.

Performance Characteristics of the Minuteful – kidney test

The performance characteristics of the Minuteful – kidney test have been determined in both laboratory and clinical tests. The following table indicates performance characteristics for each parameter.

Reported Values

ACR Reagent Strip Parameter Table

Parameter Name (Abbreviation)	Conventional
Albumin (ALB)	10 mg/L
	30-80 mg/L
	150 mg/L
Creatinine (CRE)	10 mg/dL
	50 mg/dL
	100 mg/dL
	200-300 mg/dL
Albumin-Creatinine Ratio (ACR)	Normal (<30 mg/g)
	Abnormal (30-300 mg/g)
	High abnormal (>300 mg/g)

Sensitivity

Reagent	Sensitivity - Minuteful - kidney test reading
Albumin	Detects albumin as low as 24 mg/L
Creatinine	Detects creatinine as low 36 mg/dL

Accuracy

The MinuteFul – kidney test system was evaluated during extensive clinical trials to evaluate the agreement levels with another commercially-marketed, semi-quantitative urine analyzer. These trials included 466 patients, specifically selected to best represent the intended population of the device. The study results are presented in the table below:

ACR	Comparator device				
MinuteFul Kidney test	Reported block	Normal	Abnormal	High Abnormal	Total
	Normal	254 92.0%	5 3%	-	259
	Abnormal	22 8%	158 94.0%	2 9.1%	182
	High Abnormal	-	5 3%	20 90.9%	25
	Total	276	168	22	466
	Exact match	92%	94%	90.9%	92.7%
	±1 Color block	100%	100%	100%	100%

Factors That May Interfere With the Test Results

The test strip may be affected by substances that cause abnormal urine color, such as drugs containing azo dyes (e.g. Pyridium®, Azo Gantrisin®, Azo Gantanol®), nitrofurantoin (Macrochantin®, Furadantin®). Urinary albumin excretions can be elevated by vigorous exercise, urinary tract infection, and acute illness with fever. It is recommended that individuals avoid strenuous exercise prior to testing. In addition, the ACR result may be falsely elevated in patients taking sodium bicarbonate and/or hydroxychloroquine in high concentrations, as presented in the table below:

Analyte	Interferent	Lowest tested concentration causing an interference	Affect on results
Albumin	Sodium bicarbonate	1,300 mg/dL	Falsely increased
	Hydroxychloroquine	6 mg/dL	
Creatinine	Ascorbic acid	330 mg/dL	Falsely decreased
	Mesna	380 mg/dL	
	Sodium bicarbonate	1,300 mg/dL	
ACR	Sodium bicarbonate	1,300 mg/dL	Falsely increased
	Hydroxychloroquine	6 mg/dL	

Further Assistance

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

Bibliography

Zhang QL and Rothenbacher D. Prevalence of chronic kidney disease in population-based studies: systematic review. *BMJ public Health*: 8-117; 2008.

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.

Mogensen, C.E. et al: Prevention of Diabetic Renal Disease with Special Reference to Microalbuminuria. *Lancet* 346:1080-1084; 1995

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

Position Statement: Diabetic Nephropathy. *Diabetes Care* 20: S24-S27; 1997.

American Diabetes Association, Clinical Practice Recommendations, *Diabetes Care*, Vol. 31, Suppl. 1, January 2008



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 instructions for use



Manufactured by



Caution



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