

# Healthy.io test for home testing of urine albumin to creatinine ratio

Medtech innovation briefing

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[www.nice.org.uk/guidance/mib221](https://www.nice.org.uk/guidance/mib221)

## Summary

- The **technology** described in this briefing is an albumin to creatinine ratio (ACR) home test using smartphone technology. It is for screening of ACR for people at risk of chronic kidney disease.
- The **innovative aspects** are that it allows non-clinical users to take semi-quantitative ACR measurements with a smartphone. They can do this in their own home and digitally share results with a clinician through existing electronic medical records (EMR).
- The intended **place in therapy** would be instead of, or alongside, existing tests to detect microalbuminuria in people with diabetes or high blood pressure who are at risk of kidney disease.

- The **main points from the evidence** summarised in this briefing are from a single-arm observational study involving 2,196 people with diabetes who were previously non-compliant with standard ACR testing. It shows that the technology can help improve ACR test compliance and that most people prefer home testing.
- **Key uncertainties** around the evidence or technology are that there is currently limited long-term follow-up data evaluating the effect of the technology on kidney and cardiovascular outcomes. Available published data only report on patient satisfaction and uptake of the test during a 1-month follow-up period.
- The **cost** of the technology is estimated at £12.10 per person (excluding VAT). This includes the cost of the test kit, handling and shipping, and integration into EMRs. The estimated unit cost of standard quantitative urine testing is £6.

## The technology

The albumin to creatinine ratio (ACR) product (Healthy.io) is a smartphone-based diagnostic test for home use. It is used for semi-quantitative detection of microalbumin and creatinine, and the qualitative measurement of the ratio between them. The test is for people with diabetes, high blood pressure or other risk factors for chronic kidney disease (CKD). The ACR results help identify possible kidney disease and guide patient management and care. The technology consists of an ACR test kit and a mobile application containing image recognition software. This allows a smartphone to act as an ACR urine strip analyser.

The ACR test kit is sent to the patient in the post and contains all single-use equipment needed for in vitro ACR testing (testing outside the body). It includes:

- a urine collection cup
- an individually wrapped ACR urine reagent strip
- an absorbent pad to remove excess liquid from the reagent strip
- a colour-board to enable image recognition.

The patient also receives a text message from their healthcare provider inviting them to download the ACR app. The app can be installed on Android and iOS smartphones that meet the minimum hardware criteria. The app guides the patient through each step of the testing process using video, audio and text guidance. To do the test the user collects a

urine sample using the urine collection cup. They then dip the reagent strip into the sample for 1 second, remove any excess liquid with the absorbent pad and place it on the colour-board. The user then waits 60 seconds before scanning the colour-board. The software algorithm analyses the scanned image. Once the test is complete, the app automatically and securely sends the analysed results to the referring clinician through the patient's electronic medical record (EMR). Healthy.io's ACR testing system is integrated into EMIS and SystmOne EMR providers. In addition, all ACR test results are automatically uploaded to a secure online portal where healthcare professionals can also view them.

This briefing focuses on Healthy.io's ACR product. Further home-use urine tests using smartphone technology are also available from the company. These include a multiparameter urinalysis test (Dip.io).

## Innovations

The innovative aspects are that it allows non-clinical users to do semi-quantitative ACR testing with a smartphone in their own home. Results can be shared with a clinician through EMR. This allows real-time results to be reviewed and followed up. Current standard of care for ACR urine testing involves asking the patient to collect a urine sample at home. They have to bring this back to the healthcare provider who then sends it to the lab for analysis.

## Current care pathway

ACR testing is recommended for adults at risk of CKD. This includes people with diabetes, hypertension and other risk factors including acute kidney injury, cardiovascular disease, structural renal tract disease, recurrent renal calculi or prostatic hypertrophy, multisystem diseases with potential kidney involvement, family history of end-stage kidney disease, opportunistic detection of haematuria, and prescribed drugs that have an effect on kidney function.

ACR testing should be done in people with diabetes and those without diabetes with a glomerular filtration rate (GFR) of less than 60 ml/min/1.73 m<sup>2</sup>. The presence of protein in the urine should be tested for by measuring ACR and testing for blood in the urine using a reagent strip. Current standard of care for urine ACR testing involves asking the patient to collect a urine sample at home which they bring back to the healthcare provider for lab analysis. If the first ACR reading is between 3 mg/mmol and 70 mg/mmol, it is

recommended that a repeat test be done using another early morning sample. If the first ACR reading is 70 mg/mmol or more, a repeat sample does not need to be tested. A confirmed ACR reading of 3 mg/mmol or above should be seen as clinically important. Reagent strips are not recommended unless they can specifically measure albumin at low concentrations and express the results as an ACR. The strips used in Healthy.io's ACR home test enables this measurement.

The following publications have been identified as relevant to this care pathway:

- [NICE guideline on chronic kidney disease in adults: assessment and management](#)
- [NICE quality standard on chronic kidney disease in adults](#)
- [NICE guideline on hypertension in adults: diagnosis and management](#)

## Population, setting and intended user

The product is used for ACR screening in people at risk of CKD, such as those with diabetes and hypertension. The technology is for home testing of ACR and is done by patients. The app has simple explanations and videos with steps in real time for the patient to follow.

There are an estimated 3.9 million people diagnosed with diabetes in the UK ([Diabetes UK's diabetes prevalence, 2019](#)), and 13.9 million people over the age of 16 with hypertension in England ([Public Health England's hypertension prevalence estimates for local populations, 2017](#)). Despite guidance on ACR testing, the [National CKD Audit \(2017\)](#) found that only 54% of people with diabetes have relevant annual urinary ACR tests. For other groups (such as those with hypertension), ACR rates are below 30%.

The company states that the technology is currently being used for ACR home testing by 4 NHS centres. The technology is also in the NHS Innovation Accelerator and is part of the Greater Manchester Digital Health Accelerator.

## Costs

### Technology costs

The cost of home ACR testing was provided by the company. Currently, the estimated cost per person is £12.10 (excluding VAT), this includes:

- £4.50, cost of diagnostic test
- £2.10 for handling and shipping of test kits to a patient's home
- £5.50 for patient engagement; follow up and EMR integration.

The estimate of £12.10 includes total costs associated with the technology. There are no additional upfront costs to the NHS for setting up the technology digitally and integrating it with usual care.

### Costs of standard care

According to [Shore et al. \(2019\)](#), the estimated unit cost of standard quantitative urine testing is £6. This includes the cost for all components needed for in-clinic urinalysis, as well as the unit costs of an ACR test. The cost of standard care testing was based on [economic considerations for Delphi in NICE's guideline on routine preoperative tests for elective surgery \(appendix M\)](#).

The unit cost of a urine ACR test was estimated by some of the experts to be between £0.45 and £2.08.

## Resource consequences

The technology costs more per test than standard urine ACR testing but could be resource releasing if it results in an increase in the number of CKD diagnoses and reduced cases of subsequent end-stage renal disease and cardiovascular disease.

Economic modelling by Shore et al. (2019) claimed that, in people with diabetes who are non-compliant with standard ACR testing, the technology is associated with cost saving of around £2,000 per person over a lifetime. In this study, the cost of the technology was provided by the company. This included shipping and service charges which covered

outreach, customer support and integration work. The claimed cost saving was driven by an estimated increase in the CKD diagnoses and reduced progression to end-stage renal failure.

## Regulatory information

The ACR product is CE marked as an in vitro diagnostic (IVD) for self-testing.

## Equality considerations

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

The ACR product is only available to people who have access to and can use a smartphone device. The company states that the app is compatible with a wide range of smartphones. The ACR product may be unsuitable for people with visual or cognitive impairment, problems with manual dexterity or learning disabilities. The company states that the app uses a combination of spoken word, text, and video set at a reading age of 9 years. Some people with diabetes and hypertension will be classified as having a disability under the Equality Act. Disability is a protected characteristic under the Equality Act.

## Clinical and technical evidence

A literature search was carried out for this briefing in accordance with the [interim process and methods statement](#). This briefing includes the most relevant or best available published evidence relating to the clinical effectiveness of the technology. Further information about how the evidence for this briefing was selected is available on request by contacting [mibs@nice.org.uk](mailto:mibs@nice.org.uk).

## Published evidence

The evidence for Healthy.io's albumin to creatinine ratio (ACR) product is from 1 single-arm observational study of 2,196 people with diabetes.

One randomised controlled trial (Leddy et al. 2019) and 1 conference abstract ([Burke et al. 2019](#)) with data on Healthy.io smartphone urine testing were also found. However, these studies were not included because they did not assess the ACR product specifically. Also, the abstracts involved indications which were outside the focus of this briefing (routine prenatal care and self-testing for urinary tract infections).

The clinical evidence and its strengths and limitations is summarised in the overall assessment of the evidence.

## Overall assessment of the evidence

The evidence for the ACR product is from a single-armed observational study in people with diabetes done in an NHS setting. It suggests that home-based ACR testing using the technology can help improve ACR screening compliance (compliance with home-based testing was shown to be over 70%). It also found that most people find the test easy to use and prefer ACR home testing to standard care. Study outcomes suggests that the technology is likely to be cost saving (around £2,000 per person over a patient's lifetime). This is when it is used for people with diabetes who have previously been non-compliant with standard ACR testing. Cost savings in the study were driven by an estimated increase in the number of chronic kidney disease (CKD) diagnoses and a reduction in end-stage renal disease cases.

There is no published evidence on the sensitivity and specificity of the test compared with standard care. However, [the company have provided evidence to the US Food and Drugs Administration \(from bench and clinical studies\), collected during regulatory approval](#). This describes diagnostic accuracy compared with standard semi-quantitative testing. Published data from Shore et al. (2019) only reports on patient satisfaction and uptake of the test during a 1-month follow-up period. There is limited clinical evidence with long-term patient follow up evaluating the effect of the test on clinical outcomes. These outcomes could include time to diagnosis and treatment, and subsequent kidney and cardiovascular outcomes (such as the incidence of end-stage kidney failure, kidney dialysis and transplant, and cardiovascular events). The evidence base involves patients with diabetes who were previously non-compliant with standard ACR testing. There is limited published evidence for the ACR home test in other patient populations when ACR testing is also recommended.

## Shore et al. (2019)

### Study size, design and location

Single-arm observational study of 2,196 people with diabetes who had not had an ACR measurement reported in the last 18 months. Results from the clinical evaluation were used for economic modelling to assess the cost consequence of home urinalysis. Study was done in the UK.

### Intervention and comparator(s)

Intervention: Healthy.io's ACR product.

No comparator.

### Key outcomes

Of the 2,196 people contacted, 695 (32%) agreed to be sent a home urinalysis test kit. Of these, 72% completed and returned the test, within the 1-month follow up. Of the 170 people who completed a usability survey, 92% said they found the test easy or very easy to use and only 3% said they preferred testing at the surgery compared with home testing. The study's cost modelling showed a cost saving with home urinalysis of £2,008 per person over a lifetime time horizon. This was because of increased CKD diagnosis and reduced progression to end-stage renal failure.

### Strengths and limitations

The study provides real-world evidence for the use of home-based ACR testing within the NHS, and results are likely to be generalisable. It was a single-arm observational study and results are subject to confounding. No published diagnostic accuracy data was available, so diagnostic accuracy estimates were assumed to be the same as standard care semi-quantitative testing (based on unpublished data collected during regulatory approval). The cost of home ACR testing used in this study was £11, which differed slightly from the current cost of the test (£12.10). The company provided financial support for the manuscript. Uptake was measured as newly reported ACR results 1 month after the test kits were sent out. The study stated that patient follow up was started based on ACR results, but further details of this follow up were not reported.



## Sustainability

The company states that the materials of the test kit are all recyclable and that the test could decrease patients' carbon emissions because of reduced travel time. There is no published evidence to support these claims.

## Recent and ongoing studies

- [Patient information sheet on testing new technology to improve uptake of the urine ACR test](#). Indication: people with diabetes needing an ACR check for their annual diabetes review. Device: Healthy.io ACR app. Country: UK.
- [Pharmiweb press release, Healthy.io conducts first large-scale population screening for chronic kidney disease through smartphone-based health technology](#). Indication: population screening study on CKD. Devices: Healthy.io ACR product compared with standard ACR laboratory testing. Country: The Netherlands.

## Expert comments

Comments on this technology were invited from clinical experts working in the field and relevant patient organisations. The comments received are individual opinions and do not represent NICE's view.

There were 3 out of 4 experts who were familiar with or had used this technology before.

## Level of innovation

Healthy.io's albumin to creatinine ratio (ACR) urinalysis test was found to be novel by most of the experts for the semi-quantitative detection of albumin and creatinine. One of the experts said that smartphone cameras have not been used as medical grade devices before. Three of the experts noted that electronically communicating urinalysis results to healthcare professionals was novel. Another expert felt that the concept of self-testing of urine at a time and venue that is more convenient for patients was an innovative aspect of the technology. Two of the experts felt that the technology could replace standard care for some patients. Because of the cost of the technology, an expert did not think it would replace urine ACR testing for patients attending healthcare services. Also, they felt that people using the technology at home would be in addition to standard urine ACR testing

done in clinics. One of the experts said that without more diagnostic accuracy data, this technology could not substitute laboratory ACR testing. None of the experts were aware of any competing or alternative technologies available in the NHS.

## Potential patient impact

Some of the main potential benefits identified by experts were the ease of use and convenience of taking the test at home, the reduced need to attend the GP during opening hours and reduced patient costs related to travel and parking. Other benefits identified included giving timely reassurance to some patients and the potential reduction in risk of developing long-term complications from hypertension and diabetes. One of the experts said that it was unclear whether any clinical benefits would be realised as there is limited information on the diagnostic accuracy of this test. One expert said that people who had kidney transplants and those at high risk of chronic kidney disease (CKD) would benefit from the test. Other people who the experts thought would benefit from home ACR testing included people living in remote areas, people who have difficulty physically accessing their primary healthcare team, and those who find it difficult to attend appointments in opening times without taking time off work. One of the experts noted that, despite the importance of ACR testing for people at risk of CKD, it is the least frequently completed care process in the National Diabetes Audit. All of the experts felt that the technology could change the current care pathway in some way. This could be through increasing the number of urine ACR tests done, leading to increased awareness of early-stage kidney disease and improving convenience for patients. One expert stated that if people can be treated remotely then they will not have to wait as long for treatment, which may lead to improved outcomes.

## Potential system impact

The experts identified potential system benefits including improved CKD detection rates through increased uptake of ACR screening and reduction in unnecessary clinic visits for some patients, leading to more effective use of resources. Other potential system impacts included a reduction in time, staff and resource costs for sending appointment reminders to patients and posting urine sample bottles, improving equity when accessing treatment and a possible reduction in the workload for pathology laboratories. One expert said that if treatment changes happened through recommendations in NICE guidelines, the technology could reduce cardiovascular disease (in particular, stroke) which has a huge financial cost to the NHS. They also said that a possible reduction in end-stage renal

failure may help reduce the need for renal replacement therapy. One expert said that the cost per test is greater than standard care but may have an overall cost benefit to NHS if rates of end-stage renal failure are reduced. One expert felt that the technology would be cost neutral or slightly more costly than standard care but could be cost saving in patients who are hard to reach. One expert said that without further evidence on the accuracy of the test, it is not possible to determine whether the technology is cost saving. They also added that it is unclear what the care pathway would look like and whether laboratory confirmation of test results would be needed. One expert stated that using the technology would cost less than the current standard of care if clinician and hospital time was reduced. Most of the experts did not think that changes to facilities or infrastructure, or any specific training, would be needed to use the technology. None of the experts were aware of any safety concerns or regulatory issues around the technology.

## General comments

One of the experts had used the technology in their clinical practice and said that they found it easy to adopt and that it was well liked by patients. One of the experts noted that use of the technology needs a link to the app to be texted to the patient, which they said can be easily done from primary care electronic records. Experts highlighted that the technology needs people to have access to and be able to use a smartphone device. One expert felt the step-by-step guide within the app could be followed by people with a mild learning disability or early dementia if they were familiar with using a smartphone device. Experts said that it may be difficult for patients with visual impairment or impaired manual dexterity to use the test. One of the experts said that any data supporting patient and clinical criteria would be helpful to ensure the technology is offered to people who would benefit from it.

## Patient organisation comments

Key benefits for patients identified by patient organisations include convenience, speed of diagnosis and improved uptake of albumin to creatinine ratio (ACR) urine testing. Both organisations highlighted the inadequate uptake of urine kidney testing. One organisation commented that testing is often not completed because it can be impractical for patients. Another organisation noted that currently 25% of people with type 1 diabetes and 39% of people with type 2 diabetes were not accessing urine kidney testing. Patient organisations noted that those who could particularly benefit from the technology included people with type 1 diabetes who do not access the urine kidney function test, young people who are

less engaged with their local diabetes service and people with chronic kidney disease or at risk of it from diabetes or high blood pressure. Also, people with kidney transplants who need to travel to transplant units to give a urine samples could particularly benefit. One of the organisations highlighted that people who are having dialysis do not pass urine and would not be able to use this test. They also noted that people who do not have smartphone devices or internet access would not be able to use the technology. This may particularly apply to older people. Digital literacy was highlighted by one of the organisations as a potential barrier to adoption. The organisation felt that because of this, the test should not replace in-clinic ACR testing entirely. However, people with diabetes could have more choice in their care by having 2 testing options. The cost of the test was highlighted as a possible barrier to adoption by both organisations.

## Expert commentators

The following clinicians contributed to this briefing:

- Deborah Livesey, GP partner, AWC Division of Modality Partnership, co-author on Shore et al. (2019) publication which was included in this briefing; won HSJ Award 2019 (November 2019) and is nominated for the British Medical Journal Diagnostics Team of the Year 2020 for this published study.
- Hugh Gallagher, consultant nephrologist, Epsom and St Helier University Hospitals NHS Trust, did not declare any interests.
- Jonathan Stephen Murray, consultant nephrologist, South Tees Hospitals NHS Foundation Trust and Academic Health Science Network for the North East and North Cumbria, chief investigator for the STOK (Self Testing Own Kidneys) study, ISRCTN registration number 68116915. Healthy.io provided 50 Dip.io urine test kits and applications, and provided technology set up and training free of charge for this study only.
- Donal O'Donoghue, professor of renal medicine, University of Manchester, Salford Royal Foundation Trust, Registrar, Royal College of Physicians.

Representatives from the following patient organisations contributed to this briefing:

- Diabetes UK
- Kidney Care UK.

# Development of this briefing

This briefing was developed by NICE. The [interim process and methods statement](#) sets out the process NICE uses to select topics, and how the briefings are developed, quality-assured and approved for publication.

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