

PARTICIPANT INFORMATION SHEET – Healthy Volunteers

Study Title: Asthma-Dx: A platform for investigating novel diagnostic techniques to improve asthma diagnosis in primary care (pilot)

Chief Investigator: Dr Helen Ashdown, University of Oxford

If you need a larger print version of this document, or a different language, please contact the study team: asthma-dx@phc.ox.ac.uk or [phone]

We would like to invite you to take part in our study

This Participant Information Sheet (PIS) explains why we are doing this study and what it will involve for you if you decide to take part. Please read it carefully before deciding whether you would be happy to take part and discuss it with others if you wish. If you have any questions, please get in touch with us using the contact information at the end of this document.

Why have I been invited to take part in this study?

You are being invited to take part in this study as a member of our healthy volunteer cohort. This means that you **do not** have any symptoms that suggest you may have asthma, but you are willing to try tests that could help improve asthma diagnosis in the future.

At this stage of the research study we are inviting 100 people with suspected asthma to take part and 50 healthy volunteers to act as a 'control' to check on the new tests.

What is the purpose of the study?

Asthma is a lung condition which causes the airways to become narrow and inflamed. This causes coughing, breathlessness, and wheezing which vary over time. There is no single test that can say whether someone has asthma or not. The diagnosis is made using a combination of symptoms and breathing tests.

The problem is that as asthma symptoms vary, the results may be normal at the time the tests are done. We know from previous studies that patients find it very frustrating to have lots of tests, none of which provide a final answer. Over-diagnosed asthma results in unnecessary treatment which could have side effects, while undiagnosed asthma can cause long-term lung damage.

We want to look at whether we can detect asthma more accurately, using new techniques and tests to see how they compare to current methods.

Who can take part in the study?

For the healthy control part of the study, you can take part if you are aged 18 to 59 and do not have any current lung symptoms or suspicion of asthma or other chronic respiratory disease.

Certain factors, such as smoking, other breathing conditions, or medications that affect your breathing and immune system, may make you ineligible for this study. Our study team will go through all of these with you when discussing your eligibility.

What will happen if I don't want to carry on with the study?

It is up to you to decide whether to take part. You can withdraw from the research, without giving a reason and at any time.

If you do withdraw from the study any data that has already been collected will be kept. It will be de-identified so we will not be able to identify your data as coming from you. If we already have a blood sample this will be destroyed.

If you do decide to take part, you will be given a copy of this PIS to keep and asked to sign a consent form.

What will happen if I take part in the research?

If you decide to take part in this study we will ask you to complete the following steps:

Express Interest

- Please complete our Expression of Interest Form on our website (<https://www.phctrials.ox.ac.uk/recruiting-trials/asthma-dx>) to let us know that you are interested in taking part, or you can e-mail asthma-dx@phc.ox.ac.uk.
- The Expression of Interest form is hosted on our study research platform (TrialDeck) and you will receive an e-mail link to register – you should register for this if you do want to take part, but you can just ignore it if you decide not to take part.

Screening

- Within about one week, we will arrange a telephone or video call with you so we can make sure you understand the research and check that you are eligible to take part. This will take 5 minutes.
- Following this, we will ask you to complete an Informed Consent Form, provide contact details, and arrange the study appointment. This will take about 15 minutes.

Baseline

- We will send you a link to an online form which you can do at home. It will take about 20 minutes. This will ask questions about yourself, your symptoms, and your medical history. It also includes some standard questionnaires about asthma and other lung conditions.

Appointment

- Attend a face-to-face appointment with our research nurses at one of the University of Oxford buildings, to have a series of tests. We can usually arrange parking if you need assistance.
- Take the current standard asthma diagnosis tests. You can find about details of these tests in **Appendix A – Standard Tests** at the end of this information sheet.
- Take some new tests that we are looking at to better understand how asthma affects the lungs and see if they might be better at diagnosing asthma. You can find details about these in **Appendix B – Novel Tests** at the end of this information sheet
- This visit will take about 2.5 hours, and you will be able to take a break between the tests if you need to. **Table 1** summarises the different tests that we will ask you to do at this appointment.
- At this appointment we may also ask you to complete some questionnaires, and to rate the different tests in terms of how easy-to-use and comfortable they are.

What tests will I have to do?

We will carry out standard tests for asthma diagnosis including FeNo, Spirometry, blood tests and home peak flow measurements. Asthma tests are usually carried out before and after taking a medicine to widen the airways (which we will provide), to record whether there is any difference. This is usually through a salbutamol inhaler (often coloured blue) which is very commonly used. It is very safe but can sometimes make you feel a bit jittery or shaky for a short time. You can find about details of the standard tests in **Appendix A – Standard Tests** at the end of this information sheet.

You can also read more about these here:

<https://www.asthmaandlung.org.uk/conditions/asthma/diagnosing-asthma>

In addition, we will ask you to try some novel tests, including breathing and a blood test. All of the breathing tests will look at your breathing in various ways. For example, some of the novel tests use handheld equipment that you breathe into, others will use an app on a mobile phone. The blood test will be taken at the same time as the standard care blood test and take about 20mls. You can find details about these in **Appendix B – Novel Tests** at the end of this information sheet and each one will be explained to you before you use it.

What are the possible disadvantages and risks in taking part?

The disadvantage of taking part in research as a healthy volunteer is the time burden. These are tests that you would not normally need to take.

Are there any benefits in taking part?

There are not necessarily immediate benefits for you participating in this study. We also hope that this study will lead to those who have suspected asthma in the future being able to receive a clearer diagnosis, with less delay.

Will my taking part be kept confidential?

Yes. All study records and samples will be identified only by a code. We will only use names, date of birth, NHS numbers where this is necessary to contact you. Information that can identify you will only be held securely by University of Oxford for the purposes of the study.

Your data will be stored on secure, password protected servers at the University of Oxford. Only the research team, and relevant members of the University of Oxford will have access to the research data. Identifiable data (including consent forms) will be stored separately from your research data, and this identifiable data will be destroyed within three months after the end of the research study, unless you give us permission to keep this information longer to contact you about other research projects. The other research data will be stored for five years after the end of the research.

Responsible members of the University of Oxford and regulatory authorities and your GP practice may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

We would like to use this data in future studies, and to share this with other researchers (e.g. in online databases). If this does happen it will be completely anonymous and it will not be able to be possible to identify you from the data.

Data storage and sharing in relation to novel tests may be different and where relevant this is detailed in the **Appendix B – Novel Tests** to this Information Sheet.

Will I be reimbursed for taking part?

When you have completed your participation in the main study you will receive a £30 voucher as a token of our thanks. If you participate in the research interviews as well you will receive another £30 voucher. In addition, if you incur any travel expenses for attending the face to face appointment these will be reimbursed. Please keep any receipts to help with this.

What will happen to the samples I give?

As part of the study we will collect a blood sample. These samples will be stored and analysed within the University of Oxford. We will be looking for markers in the blood that may indicate asthma. Any samples remaining at the end of the study will be destroyed. If you withdraw from the

study we will keep the samples already collected up to the point of withdrawal. Standard care samples will be ordered by your GP as usual, but collected during the study visit. Any blood samples required for a novel test will also be collected during the study visit but will be labelled with your study ID instead of your identifiable information.

What will happen to my data?

Data protection legislation requires that we, the University of Oxford (whose legal name is The Chancellor Masters and Scholars of the University of Oxford), state the legal basis for processing information about you. In the case of research, this is a 'task in the public interest'. The University of Oxford is the sponsor for this study and is responsible for looking after your information and using it properly.

We will need to use information from your medical records and your GP for this research project. We will share your information related to this research project with the following types of organisations:

- Researchers at the University of Oxford involved in this study
- NHS organisations involved in your care, including hospitals and GP practices
- Laboratories or companies analysing study samples or test results on behalf of the research team
- Regulatory authorities and oversight organisations who check that research is carried out safely and correctly
- Ethics committees and study monitors who review how the research is conducted
- Trusted data service providers who securely store or manage research data for the study sponsor
- Parties that have developed the novel tests

We may use third party service providers or subcontractors to help with some of the research activities we carry out (e.g. IT provision, survey provision, transcription services etc.). We may therefore share your personal data with these providers when it is necessary to do so to allow them to carry out the services we require them to provide. However, we require all our third-party providers to have appropriate security measures in place to protect your data and we only allow them to process your data for the specific purposes we have stated in our instructions.

This information will include your NHS number, name, and contact details. People will use this information to do the research or to check your records to make sure that the research is being done properly. Responsible members of the University of Oxford, and regulatory authorities may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

International Transfers

We may share data about you outside the UK for research related purposes to:

- Share information with the parties that have developed the novel tests which are based outside the UK.

If this happens, we will only share the data that is needed. We will also make sure you can't be identified from the data that is shared where possible. This may not be possible under certain circumstances - for instance, if you have a rare illness, it may still be possible to identify you.

If your data is shared outside the UK, it will be with the following sorts of organisations:

- The parties that have developed the novel tests which are based outside the UK.

We will make sure your data is protected. Anyone who accesses your data outside the UK must do what we tell them so that your data has a similar level of protection as it does under UK law. We will make sure your data is safe outside the UK by doing the following:

- The countries your data will be shared with have an adequacy decision in place. This means that we know their laws offer a similar level of protection to data protection laws in the UK
- We use specific contracts approved for use in the UK which give personal data the same level of protection it has in the UK. For further details visit the Information Commissioner's Office (ICO) website: <https://ico.org.uk/for-organisations/uk-gdpr-guidance-and-resources/international-transfers/>
- We do not allow those who access your data outside the UK to use it for anything other than what our written contract with them says
- We need other organisations to have appropriate security measures to protect your data which are consistent with the data security and confidentiality obligations we have. This includes having appropriate measures to protect your data against accidental loss and unauthorised access, use, changes or sharing
- We have procedures in place to deal with any suspected personal data breach. We will tell you and applicable regulators when there has been a breach of your personal data when this is legally required. For further details about UK breach reporting rules visit the Information Commissioner's Office (ICO) website: <https://ico.org.uk/for-organisations/report-a-breach>

How will we use information about you after the study ends?

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

After the study ends, the retention period (this means the length of time we keep your data for) will begin and we will keep your data for a minimum of 5 years in line University Policy on Management of Data. Once the retention period has finished, the study data will be kept in a way that does not identify you.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. You have the right to ask us to remove, change or delete data we hold about you for the purposes of the study. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.

Where can you find out more about how your information is used?

You can find out more about how we use your information, including the specific mechanism used by us when transferring your personal data out of the UK:

- asking one of the research team asthma-dx@phc.ox.ac.uk
- contacting the University's Data Protection Officer data.protection@admin.ox.ac.uk
- looking at the University's privacy notice available at: [How we use your personal data for research purposes | Compliance](#)

If you would like to find out more about the use of confidential data in research, the HRA has developed a general information leaflet which is available at: Patient data and research leaflet - Health Research Authority.

What if we find something unexpected?

If the study finds anything unexpected and medically important, we will share this information with you so that you can follow this up with your GP.

What will happen to the results of the study?

The results will be published in scientific journals and on our website <https://www.phctrials.ox.ac.uk/recruiting-trials/asthma-dx> for you to read. You will not be identifiable in any reports or publications that result from this research.

Who is organising and funding the research?

This research is being funded by the charity Asthma and Lung UK, NIHR School for Primary Care Research, and NIHR HealthTech Research Centre in Community Healthcare.

The Chief Investigator and lead of this study is Dr Helen Ashdown, a researcher at Nuffield Department of Primary Care Health Sciences, University of Oxford and NHS GP.

Who has reviewed this research?

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee (REC). The REC is there to protect your safety, rights, wellbeing and dignity. This research has been reviewed and given favourable opinion by London - Riverside Research Ethics Committee. The Ethics reference is 26/LO/0110.

Who do I contact if there is a problem?

The investigators recognise the important contribution that volunteers make to medical research, and will make every effort to ensure your safety and wellbeing. The University of Oxford has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this study. If something does go wrong, you are harmed during the research, and this is due to someone's negligence, then you may have grounds for a legal action for compensation. While the Sponsor will cooperate with any claim, you may wish to seek independent legal advice to ensure that you are properly represented in pursuing any complaint.

If you wish to complain about any aspect of the way in which you have been approached or treated during this study, you should contact the research team whose details are given below. Alternatively, you may contact the University of Oxford Research Governance, Ethics & Assurance (RGEA) office by email rgea.complaints@admin.ox.ac.uk .

Further information and contact details

If you would like to discuss the research with someone before making a decision about taking part or you have any other questions, please contact us:

Email: asthma-dx@phc.ox.ac.uk

Table 1 – Summary of Tests

Standard Care		
Test	Time	Location
Fractional Exhaled Nitric Oxide (FeNO) Test	5–10 minutes	Study Visit
Spirometry*	30mins	Study Visit
Blood Sample	5–10 minutes	Study Visit
Peak Flow Measurement*	5–10 minutes	Study Visit
Novel Tests		
Test	Time	Location
N-Tidal Capture by TidalSense*	Less than 5 minutes	Study Visit
Eupnoos by Eupnoos Ltd.	Less than 5 minutes	Study Visit
Tremoflo C2 by Thorasys*	Less than 5 minutes	Study Visit
Exhale-DX by Breath Predict Ltd.*	Less than 5 minutes	Study Visit
ArtiQ.Spiro by ArtiQ*	No additional time, software add-on to standard care spirometry	Study Visit
Lung Test Using Laser Gas Analysis	12-15mins	Study Visit
Blood and Breath metabolomics	Less than 10 minutes	Study Visit

* Tests that are performed before and after using a bronchodilator inhaler

Summary of Tests

Standard Care Tests (Appendix A)				
Test (device) name	Brief description	Time taken to perform the test	Location	See more details
Fractional Exhaled Nitric Oxide (FeNO) Test	This test checks the level of nitric oxide in your breath. You'll take a deep breath in, then slowly blow out into a mouthpiece for about 10 seconds.	5 – 10 mins	Study visit	Page 13
Peak Flow Measurement	This test checks how quickly you can blow air out of your lungs. You will be asked to take a deep breath in, then blow out as hard and fast as you can into a small handheld device.	5 – 10 mins	study visit	Page 14
Spirometry	This test checks how much air you can breathe in and out, how fast, and whether your lungs work better with asthma medication. You will be asked to blow forcefully into a small machine using a mouthpiece while wearing a nose clip.	30 mins	Study visit	Page 15
Blood Sample	A blood sample will be taken from a vein in your arm to check for signs of inflammation or allergies linked to asthma.	5 – 10 mins	Study visit	Page 16

Novel Tests (Appendix B)				
N-Tidal Capture by TidalSense	This device measures your breathing pattern and the level of carbon dioxide (CO ₂) in your breath. You will be asked to simply breathe in and out normally into the device.	Up to 2 mins	Study visit	Page 17
Eupnoos by Eupnoos Ltd.	This test is done using a smartphone app that analyses your breathing and voice. You'll be asked to blow into the phone's microphone and make sounds like "ah" and "oo." After the first test, you'll take a few puffs from an inhaler, and the test will be repeated about 20 minutes later.	Up to 5 mins	Study visit	Page 18
Tremoflo C2 oscillometry by Thorasys	This test checks how well air moves through the small airways in your lungs using gentle vibrations. You'll breathe normally into a mouthpiece for 20 - 30 seconds while the device sends soft vibrations through it.	Up to 10 mins	Study visit	Page 19
Exhale-Dx by Breath Predict Ltd.	This test is done using a handheld device that analyses tiny chemicals in your breath that may be linked to asthma. You'll be asked to breathe normally into the device, following simple guidance on your clinician's smartphone screen to help you do the test correctly and comfortably.	Up to 5 mins	Study visit	Page 20

<p>Computer Cardiopulmonography (CCP) using Laser Gas Analysis (LGA)</p>	<p>This test measures how evenly your lungs fill with air and how much air remains after you exhale. You will be asked to breathe through a mouthpiece while wearing a nose clip. You'll breathe normal air for about 7 minutes, then 100% oxygen for 5 minutes. Small, safe amounts of other gases may be used. Your oxygen level and heart rate will be monitored with a small clip on your finger.</p>	<p>12-15 mins</p>	<p>Study visit</p>	<p>Page 21</p>
<p>NMR-Based Breath Metabolomics Test for Asthma Diagnosis</p>	<p>This test looks for chemical patterns in your breath linked to asthma to analyse small molecules (metabolites). You'll sit comfortably and breathe normally through a mouthpiece while condensed breath collects in a small sterile tube.</p>	<p>6-8 mins</p>	<p>Study visit</p>	<p>Page 22</p>
<p>NMR-Based Blood Metabolomics Test for Asthma Diagnosis</p>	<p>Like breath metabolomics, this test uses NMR spectroscopy to look for chemical patterns in your blood linked to asthma. A small blood sample will be taken from your arm and analysed in a research lab.</p>	<p>No additional time</p>	<p>Study visit</p>	<p>Page 23</p>
<p>ArtiQ.PFT (ArtiQ.Spiro) by ArtiQ</p>	<p>This is a computer program that uses artificial intelligence to check the quality of your spirometry test and help interpret the results. You'll complete the spirometry test as normal, and the software built into the machine will generate a report.</p>	<p>No additional time</p>	<p>Study visit</p>	<p>Page 24</p>

Appendix A – Standard Tests

Fractional Exhaled Nitric Oxide (FeNO) Test

What does it do?

This test measures the level of nitric oxide in your breath. Raised levels can indicate airway inflammation, which is common in asthma.

Where do I take the test?

At the clinic with a trained clinician.

How do I use it?

You will breathe in deeply through a mouthpiece attached to a monitor, then breathe out slowly and steadily over about 10 seconds.



How long does it take?

The test takes around 5–10 minutes. It may take a few tries to get the hang of the breathing technique.

How often do I use it?

Once during your appointment at the clinic.

What information do I need to provide?

No additional patient information is needed for this test.

What happens to my data?

The results will be used by your clinician to help with diagnosis and will be handled according to clinic privacy policies.

Are there associated risks with this test?

There are no associated risks; the test is completely safe.

See <https://www.asthmaandlung.org.uk/symptoms-tests-treatments/tests/feno-test> for further details.

Peak Flow Measurement

What does it do?

This test measures how fast you can blow air out of your lungs and helps assess how well your lungs are working.

Where do I take the test?

At the clinic and at home.

How do I use it?

Take a deep breath in and then blow out as hard and fast as possible into a hand-held device called a peak flow meter.



How long does it take?

Each set of measurements takes around 5–10 minutes.

How often do I use it?

At your clinic appointment and twice daily (morning and evening) for two weeks at home. Also use it if you develop symptoms or after using a reliever inhaler (if given by your GP).

What information do I need to provide?

You'll record your best result of three readings in a diary, along with the time and any symptoms or inhaler use.

What happens to my data?

Your recordings will help your clinician assess patterns in your breathing. Data is managed according to clinic privacy protocols.

Are there associated risks with this test?

There are no associated risks; it is a simple and safe test.

See <https://www.asthmaandlung.org.uk/symptoms-tests-treatments/tests/peak-flow> for further details.

Spirometry with Bronchodilator Reversibility

What does it do?

This test measures how much air you can breathe in and out, and how quickly, to assess lung function and see if it improves with asthma medication.

Where do I take the test?

At a clinic with a trained clinician.

How do I use it?

You'll be asked to blow into a small machine through a mouthpiece while wearing a nose clip. After the initial set of tests, you'll take some puffs from an inhaler. The test is repeated about 20 minutes later.



How long does it take?

About 30 minutes in total.

How often do I use it?

Once during your clinic appointment.

What information do I need to provide?

Your age, sex, height, and weight will be recorded to interpret results accurately.

What happens to my data?

Results are used to support diagnosis and stored in accordance with clinic privacy policies.

Are there associated risks with this test?

The test is safe for most people. Because it increases pressure in the head, chest, stomach and eyes, it may not be suitable for you if you have certain conditions, but the clinicians will check this first. Some people can feel some brief discomfort, feel a bit tired or dizzy from the effort, or the forced blows can make them cough, but this usually passes quickly.

See <https://www.asthmaandlung.org.uk/symptoms-tests-treatments/tests/spirometry> for further details.

Blood Sample

What does it do?

A blood test is used to assess markers related to asthma, such as inflammation or allergies, via standard full blood count and other clinical tests.

Where do I take the test?

At a clinic with a trained healthcare professional.

How do I use it?

A blood sample will be taken from a vein in your arm.

How long does it take?

5–10 minutes.

How often do I use it?

Once during your appointment.

What information do I need to provide?

No additional information is required other than basic clinical details.

What happens to my data?

Samples are analysed and destroyed after testing. They will not be stored beyond this point.

Are there associated risks with this test?

Minimal risks, such as slight bruising or discomfort at the needle site.

Appendix B – Novel Tests

N-Tidal Capture by TidalSense

What does it do?

N-Tidal Capture measures the levels of carbon dioxide (CO₂) gas present in your breath. Powered by artificial intelligence, the device analyses your breathing pattern, and changes in the level of CO₂ to tell how likely you are to have asthma.

Where do I take the test?

At a clinic with a trained clinician.

How do I use it?

You will be asked to breathe normally in and out of the device.

How long does it take?

The process takes less than five minutes.

How often do I use it?

Twice during your appointment at the clinic (before and after asthma medication to see if there is any improvement)

What information do I need to provide?

No additional patient information is required for the test.

What happens to my data?

The data is used by the clinician to support diagnosis and is handled according to clinic privacy policies.

Are there associated risks with this test?

There are no associated risks with using this device.



Eupnoos by Eupnoos Ltd.

What does it do?

Eupnoos is a smartphone-based tool that assesses lung health by analysing breath and vocal sounds to detect airway obstruction and asthma symptoms.

Where do I take the test?

At a clinic with a trained clinician.

How do I use it?

The Eupnoos app will guide you through three breathing exercises, where you blow into your clinician's phone microphone and make vowel sounds like /a/ and /u/. The app then analyses breath, and voice sounds and provides a score indicating the likelihood of any lung issues related to asthma.

How long does it take?

The test takes less than five minutes.

How often do I use it?

Twice during your appointment at the clinic (before and after asthma medication to see if there is any improvement)

What information do I need to provide?

No additional patient information is required for the test.

What happens to my data?

The data is used by the clinician to support diagnosis and is handled according to clinic privacy policies.

Are there associated risks with this test?

There are no associated risks with using this device.



Tremoflo C2 by Thorasys

What does it do?

Tremoflo C2 assesses lung function by measuring how air moves through the small airways using gentle vibrations (test called oscillometry).

Where do I take the test?

At a clinic with a trained clinician.

How do I use it?

You will be asked to breathe normally into the device's mouthpiece for 20-30 seconds while the device applies a gentle vibration to the mouthpiece.

How long does it take?

The test takes just a few minutes.

How often do I use it?

Twice during your appointment at the clinic (before and after asthma medication to see if there is any improvement) . **What information do I need to provide?**

No additional patient information is required for the test.

What happens to my data?

The data is used by the clinician to support diagnosis and is handled according to clinic privacy policies.

Are there associated risks with this test?

There are no associated risks with using this device.



Exhale-DX by Breath Predict Ltd.

What does it do?

Exhale-DX is a hand-held device that uses artificial intelligence software to capture and analyse volatile organic compounds (VOCs) in your breath. These VOCs form a unique pattern that could indicate the presence of asthma, even at an early stage.

Where do I take the test?

At a clinic with a trained clinician.

How do I use it?

You will be asked to breathe normally into a lightweight, handheld device. Your breathing will be guided by a visual display on your clinician's smartphone, ensuring the test is done accurately and comfortably.

How long does it take?

The test takes only a few minutes.

How often do I use it?

Twice during your appointment at the clinic (before and after asthma medication to see if there is any improvement)

What information do I need to provide?

Basic demographic information such as age, sex and smoking status to allow the software to calculate your risk of asthma.

What happens to my data?

All data is stored securely in the cloud and is only accessible by you and your clinician.

Are there associated risks with this test?

There are no associated risks with using this device.



Lung Test Using Laser Gas Analysis

What does it do?

This test assesses how well your lungs function by analysing the gases you breathe in and out. It helps us understand aspects of your lung performance, such as how evenly your lungs expand and how much air remains in your lungs after breathing out.

Where do I take the test?

At a clinic with trained staff.



How do I use it?

You will be asked to breathe through a plastic mouthpiece while wearing a soft nose clip to ensure all breathing is through your mouth. During the test, the composition of the air you breathe will vary. You will start by breathing normal air for 7 minutes, followed by 5 minutes of 100% oxygen. In some parts of the test, the air you breathe may also include very small amounts of safe gases, including oxygen (up to 100%); Carbon dioxide (no more than 8%); Acetylene, methane, and carbon monoxide (each less than 1%). The levels are carefully controlled to ensure safety and comfort. Your oxygen levels and heart rate will also be monitored throughout using a simple finger clip called a pulse oximeter.

How long does it take?

The total time for these tests is around 12 to 15 minutes

How often do I use it?

Twice during your appointment at the clinic **What information do I need to provide?**

No additional personal information is required.

What happens to my data?

The gases you breathe in and out will be continuously measured and recorded. A small sample of your expired air may be kept for up to 12 months for analysis related to this study only. No genetic material will be stored. The results are analysed using a mathematical model to estimate different aspects of lung function.

Are there associated risks with this test?

There are no known risks. All gases are used at safe concentrations, and your vital signs will be monitored throughout.

Breath metabolomics

What does it do?

This test looks for chemical patterns in your breath that may be linked to asthma. It uses a method called NMR spectroscopy to measure small molecules (called metabolites) in condensed water collected from your breath, which may help researchers understand whether you are more or less likely to have asthma.



Where do I take the test?

At a clinic with a trained clinician.

How do I use it?

You will sit comfortably and breathe normally through a mouthpiece. As you breathe out, water vapour from your breath cools and collects into a small sterile tube. About 1 mL is collected.

How long does it take?

Around 6 - 8 minutes of normal breathing

How often do I use it?

Just once during your clinic appointment.

What information do I need to provide?

No additional information is needed beyond what you already provide for your study visit.

What happens to my data?

Your sample will be processed without your name or identifying details. The data is securely stored at the University of Oxford and only shared under strict ethical approvals.

Are there associated risks with this test?

The procedure is non-invasive and poses no risk beyond normal breathing.

Blood metabolomics

What does it do?

Similarly to breath metabolomics, this test looks for chemical patterns in your blood that may be linked to asthma using NMR spectroscopy.

Where do I take the test?

At a clinic with a trained clinician.

How do I use it?

A small sample of your blood will be taken from your arm, along with blood taken for the standard tests. The blood is then processed and analysed in a research lab. **How long does it take?**

No additional time as the blood gets collected during standard blood test.

How often do I use it?

Just once during your clinic appointment.

What information do I need to provide?

No additional information is needed beyond what you already provide for your study visit.

What happens to my data?

Your sample will be processed without your name or identifying details. The data is securely stored at the University of Oxford and only shared under strict ethical approvals.

Are there associated risks with this test?

The only risk is minor discomfort or bruising from the blood sample, which is the same as with any routine blood test.

ArtiQ.Spiro by ArtiQ

What does it do?

ArtiQ.Spiro is an artificial intelligence (AI) software which has been developed to help with assessing quality and interpretation of spirometry. This software has previously been tested and is currently used successfully in UK and European hospitals and primary care practices. AI uses pattern recognition with the results from the breathing tests to provide a report for your GP.

Where do I take the test?

The software is used as part of spirometry testing in a clinic.

How do I use it?

You just complete standard the spirometry testing, but with ArtiQ.Spiro directly integrated into the unit.

How long does it take?

No additional time as it is used while you are completing spirometry testing compared to spirometry.

How often do I use it?

Once during your appointment at the clinic.

What information do I need to provide?

Basic demographic information such as age, sex and smoking status to allow for spirometry calculations.

What happens to my data?

The spirometry test results, and basic demographic information will be shared with ArtiQ to produce a report. No personal identifiable information is shared.

Are there associated risks with this test?

There are no associated risks with using this device.

ARTIQ

FOR DEMONSTRATIVE PURPOSES ONLY

Analyzed: 2024-05-16 13:36

Report ID: DEMO

Age: 64

Gender: Female

Current Smoker: Yes

Pack-Years: 34

Interpretation of lung function tests

Moderate obstructive spirometry.
Bronchodilator response test is not performed.

Disease probability



Conclusions and suggestions

Highest disease probability based on lung function: COPD

Consider referring to specialist and/or further testing as appropriate:
Careful auscultation on all lung areas for presence of rhonchi. Repeat spirometry with bronchodilator test. Perform screening laboratory (including eosinophilia). Perform X-ray of the thorax. Consider bronchodilator therapy to evaluate the effect.

Warnings

No warnings.