PARTICIPANT INFORMATION SHEET - Suspected Asthma Cohort

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 have been invited to take part in this study because you have been in touch with your GP about symptoms that could suggest asthma. As part of standard NHS care you would have more tests to find out if you have asthma.

In this study, we will be doing the standard tests and also ask you to do some new tests as well. Only the results of the standard care tests will be given to your GP. We are inviting you to take part before you start any treatments, as this can affect the results.

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?

You can take part in the study if you are aged 18 to 59 years and have symptoms which might be caused by asthma. These include coughing, breathlessness, or wheezing and your GP would like further tests to look for potential asthma.

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. This will not have any effect on your diagnosis, the healthcare you receive or your legal rights.

If this is the case, it is important that you let your GP know that you no longer taking part in this study so that they can arrange the standard tests for asthma diagnosis via the normal NHS routes.

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

- Your GP may have already completed a referral form if you gave permission for your contact details to be shared with our research team. If so, we will contact you within 1-3 working days. Please use this time to consider the study information and note that you are still free to decide whether or not to take part. We will aim to arrange appointments quite quickly so that you don't have to wait too long for investigation of your symptoms, but please do let the research team know if you would like longer to decide whether you want to take part.

- If your GP didn't complete a referral or you aren't sure, please contact the study team to let us know you are interested in taking part asthma-dx@phc.ox.ac.uk you by visiting our website https://www.phctrials.ox.ac.uk/recruiting-trials/asthma-dx where you can complete an Expression of Interest form.
- Both the GP referral form and Expression of Interest form are 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

- We will contact your GP if we need to check any of the information provided.
- Within about one working day of referral, 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 40 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.
- Take part in an audio-recorded telephone or video consultation with one of our research clinicians. This is for you to explain your symptoms and ask questions about the study. The research clinician may ask you questions about your health or asthma symptoms. This consultation will take about 10-15 minutes. The research clinician will not be able to give you advice about your symptoms or diagnosis but they will pass the summary notes of the consultation back to your own GP.

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 which your GP might have requested anyway. The results of these will be passed back to your GP to help in their diagnosis of your symptoms and any treatment needed. 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. The results of these new tests will not be given to your GP as we don't yet know if they are useful for 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.

At Home

- Monitor your symptoms and breathing at home for about two weeks using a peak flow meter. We will provide this for you and you can keep it after the study ends. This is something which is commonly done as part of standard assessment of possible asthma.
- Monitoring your symptoms and breathing at home using a new test which uses a phone app. You will be asked to download an app to your phone and confirm that you are happy to take part. They will also check that you are happy with how they are using and storing your data. For more details about how each at home test uses and stores data please see **Appendix B – Novel Tests** at the end of this document.
- Finally, we will ask your permission to check your GP or hospital records. We might also talk to your GP to confirm any test results, previous medical history, diagnosis and treatments you have been given. That is the end of your part in the main study. There are other ways that you could help us with further research if you are happy to.

After the home monitoring

- After the two weeks of monitoring with the app we will send you an online questionnaire that asks you about how you found the experience of home monitoring and taking part in the study in general.
- At the end of home monitoring, you can keep all the home monitoring tools.

Optional Follow-ups

- Allow us to contact you again, if needed, up to three more times over the following two years, to find out about your diagnosis and treatment.
- Participate in an interview about how you found the experience of completing all these tests and the process of having your symptoms diagnosed (further information and a separate consent form would be completed for this).
- Allow us to contact you in future in case there are other studies we are involved in that you might be able to take part in.

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 as 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?

In order to work out why you are experiencing your symptoms you would need to go through some or all of the standard of care tests listed above (approximately 1.5 hours of tests, potentially across several appointments/locations; plus two-week home monitoring of peak flow), but we are asking you to complete some more tests which will take more time. The additional time burden linked to the study is about 1-1.5 hours (including the time for the symptom questionnaires and telephone/video consultation) and using an additional test as part of the two-week home monitoring. There is no change to your ongoing treatment, which will be managed in the usual way by your GP practice.

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 General Practitioner (GP) be informed of my participation?

Yes, your GP will be informed about your participation in the study. Your GP will only receive the results of the standard care tests not the outcome of the research procedures.

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 requested 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.

Audio-Recordings

The consultation video call with one of our research clinicians will be audio-recorded so that we can have an accurate record of the conversation and it will be saved and transcribed using automatic recording software e.g. Microsoft Teams and/or a Dictaphone. Any personal information will be removed from the recording. We will also ask for your consent to share this audio recording and transcription, with no link to your personal information (completely anonymised), for use in another research study which is developing a new technology to diagnose lung problems earlier using information in consultations – but this is optional. Otherwise, the audio recording will be deleted once the transcription has been checked.

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 novels 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 novels 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 and 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 (twice a day for two week and with symptoms)	At Home
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
MIR†	5–10 minutes (twice a day for two week and with symptoms)	At Home
Smart Peak Flow by Smart Respiratory †	5–10 minutes (twice a day for two week and with symptoms)	At Home

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

† **For these tests, you will only use one or the other**, not both**. Y**ou will be told at **the first telephone call** which one you will use

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 16
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	At home and study visit	Page 17
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 18
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 19

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 20
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 21
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 22
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 23

Computer Cardiopulmonography (CCP) using Laser Gas Analysis (LGA)	This test measures how evenly your lungs fill with air and how much air remains after you exhale. You will be aksed 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.	12-15 mins	Study visit	Page 24
Smart Peak Flow meter	This device checks how fast you can blow air out to monitor your lung health and help spot early signs of flare-ups. You will blow into the device three times, and the highest reading is automatically saved in the app. The app will guide you to make sure you do it correctly.	2-3 mins	At home	Page 25
SpiroBank Smart by MIR	This device measures how much air you can breathe in and out, and how fast. You will take a deep breath in and blow out as hard and fast as possible into the device. The test is repeated three times, and the highest result is automatically saved in the app, which provides step-by-step guidance.	2-5 mins	At home	Page 26
NMR-Based Breath Metabolomics Test for Asthma Diagnosis	This test looks for chemical patterns in your breath linked to asthma to analyse small molecules (metabolites). You'll sit comfortably and breathe	6-8 mins	Study visit	Page 27

	normally through a mouthpiece while condensed breath collects in a small sterile tube.			
NMR-Based Blood Metabolomics Test for Asthma Diagnosis	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.	**No additional time**	Study visit	Page 28
ArtiQ.PFT (ArtiQ.Spiro) by ArtiQ	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.	**No additional time**	Study visit	Page 29

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 (CO_2) gas present in your breath. Powered by artificial intelligence, the device analyses your breathing pattern, and changes in the level of CO_2 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.

Smart Peak Flow by SmartRespiratory

What does it do?

Smart Peak Flow measures how fast you can breathe out to track lung health and predict flare-ups.

Where do I take the test?

At home using a handheld device and a smartphone app.

How do I use it?

You will be asked to blow into the device three times in one session, and the highest result is saved automatically in the app.
The app will provide guidance for accurate measurements. See test demonstration here: https://youtu.be/y9-yPG9I3GE?si=pJiyc3LK98jRjTRd

How long does it take?

The test takes about one minute to complete.

How often do I use it?

Twice daily (morning and evening) for two weeks or if you experience symptoms.

What information do I need to provide?

Name, email, password, year of birth, height, and symptom control information.

What happens to my data?

Your data is stored securely in the app and can be shared with your doctor.

Are there associated risks with this test?

There are no associated risks with using this device.

SpiroBank Smart by MIR

What does it do?

SpiroBank Smart is a portable spirometer for at-home use to measure how much air you can breathe out and how fast you can exhale. It records key lung function measurements to help monitor lung health and detect changes over time.

Where do I take the test?

At home using a handheld spirometer connected to the MIR Spirobank smartphone app via Bluetooth.

How do I use it?

You will be asked to take a deep breath in and then blow out as hard and as fast as possible into the device. You will usually repeat the test three times in one session, and the best result will be automatically saved in the app. The app provides step-by-step guidance to ensure accurate measurements.

How long does it take?

The test takes approximately 2 – 5 minutes to complete.

How often do I use it?

Twice daily (morning and evening) for two weeks, or if you experience worsening symptoms.

What information do I need to provide?

Name, email address, password, year of birth, height, sex, and symptoms information if required.

What happens to my data?

Your lung function results are stored securely within the MIR Spirobank app on your smartphone. You will be asked to download your results in PDF or CVS format at the end of home-monitoring period and share it with the research team for analysis.

Are there associated risks with this test?

Spirometry is generally safe. Some people may feel briefly light-headed or dizzy after blowing forcefully. If this happens, you should stop the test and rest. There are no significant risks associated with using this device when used as instructed.

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.


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

COPD
80.2%

Asthma
COPD
Normal
ILD
Unidentified

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.

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.