Transforming respiratory diagnostics: the urgent need in primary care

A blueprint for a simple lung test to drive innovation

LifeArc | ASTHMA+ LUNG UK | NIHR | HealthTech Research Centre Diagnostic and technology evaluation

Contents

A note on terminology

We use the term ‘chronic lung disease’ when talking generally about a persistent disruption to the structure or function of the respiratory system, whereas we use the term ‘chronic lung condition’ to describe a named diagnosis with a specific set of symptoms or traits.

We use the term ‘primary care’ to cover the GP practice and other community settings including pharmacies. We specify the type of primary care setting where relevant. For example, our target product profile included in this report was developed specifically for new tests that fit in a GP practice, with additional utility in other settings.

Foreword

At LifeArc, we are committed to improving the lives of people living with chronic and rare respiratory diseases.

Our mission is to bring about transformative change to the diagnosis of respiratory disease by supporting diagnostic developers to drive innovation and bring new technologies to the clinic. We want to dramatically shorten the long diagnostic journey experienced by many, and ensure new innovations improve the path to diagnosis for those with rare respiratory diseases as well as the more common.

In November 2023, LifeArc and Asthma + Lung UK held a joint workshop to explore how diagnostic innovation could better support people living with chronic breathlessness and cough. One of the key outcomes was the recognition of an urgent need for improved diagnostic tools in the primary care setting. To drive innovation that delivers against this unmet need, we have developed a set of instructions for new test developers – a target product profile (TPP) on page 20-23 of this report.

To ensure the TPP reflects real world needs we engaged a broad range of stakeholders including patients, clinicians and others in the HealthTech innovation ecosystem to capture lived experience, clinical insight and market realities. This inclusive approach helps ensure that future diagnostic tools meet the needs of end-users and healthcare systems. Our TPP is modality-agnostic describing the types of solutions that could address the unmet need. It is intended to both guide the direction of projects already in development, and to catalyse creativity that could bring new thinking to long-standing challenges and signal demand for more funding in this area.

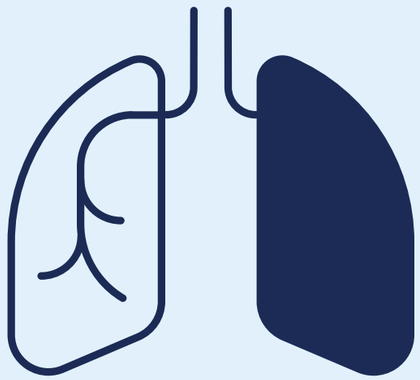
This report is intended as a guidance document for developers, highlighting the significant unmet need and providing key information that should accelerate their development path. It is an exciting time for diagnostic innovation, with advances in artificial intelligence and machine learning, wearable technologies and innovative use of biomarkers. We invite developers to rise to our challenge to develop new products or repurpose existing ones to deliver diagnostic solutions that could identify underlying lung conditions in primary care.

With innovation, we have the opportunity to transform a diagnostic pathway that currently fails patients due to long delays. By reimagining how we detect lung disease, we can accelerate diagnosis, improve outcomes, and ensure that timely care becomes the norm.

Heather McKinnon PhD,
Head of Chronic and Rare Respiratory Disease

Chronic lung conditions are a leading cause of death worldwide

Despite taking some 7.5 million breaths each year most of us rarely stop to consider our lungs and their intricate and intimate connection with our overall health. It's often only when our lungs fail us that their importance is brought into focus.



For people with a chronic lung condition, the constant threat of breathlessness can make even simple activities daunting. This sustained, severe breathing discomfort and shortness of breath can make people avoid basic activities such as walking, shopping or cooking, leading to frailty and social isolation. Persistent symptoms can permanently damage the lungs, making them far more difficult to treat, and sudden worsening of symptoms known as exacerbations drive further lung damage, causing hospitalisation and even death.

> "I feel as if I'm always struggling"
>
> **individual with a chronic lung condition**

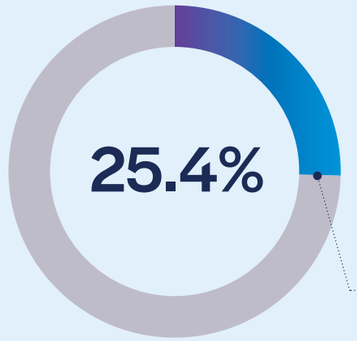
This is the reality for

1 in 5 people in the UK[1]

> "I don't have a diagnosis. And I've been in and out of hospital since I was a baby, struggling to breathe"
>
> **Person with severe respiratory symptoms from childhood, diagnosed with asthma but undergoing further investigations**

For many, the underlying cause of their breathlessness is poorly understood. It can take years to be matched with the right treatment, by which time the lungs are likely irreversibly damaged. The path to diagnosis is often fraught with delays and misdiagnoses, hindered by tests that are difficult to perform and inaccessible to patients and their healthcare teams. Patients may experience countless appointments before a diagnosis is reached, through repeat visits to their GP, multiple test appointments or emergency care due to worsening symptoms. Clinicians may be less likely to suspect rarer conditions, which can result in patients not being referred for the specialist referrals needed for diagnosis. Early and accurate diagnosis is critical to timely, life-changing treatment and care and preventing the risk of dangerous exacerbations.

55.2m people with chronic respiratory disease worldwide in 2021[2]



of people with bronchiectasis reported having symptoms for **over 10 years** before diagnosis[3]

> "On a couple of occasions my breathing was so severe that I couldn't leave the home at all for several months at a time"
>
> **Person with undiagnosed breathlessness who has experienced symptoms for over 10 years**

Lung related deaths are

7x higher in the poorest parts of the country[4]

Total economic cost of lung conditions in the UK was

£188bn

in 2019[5]

A long, convoluted diagnostic journey

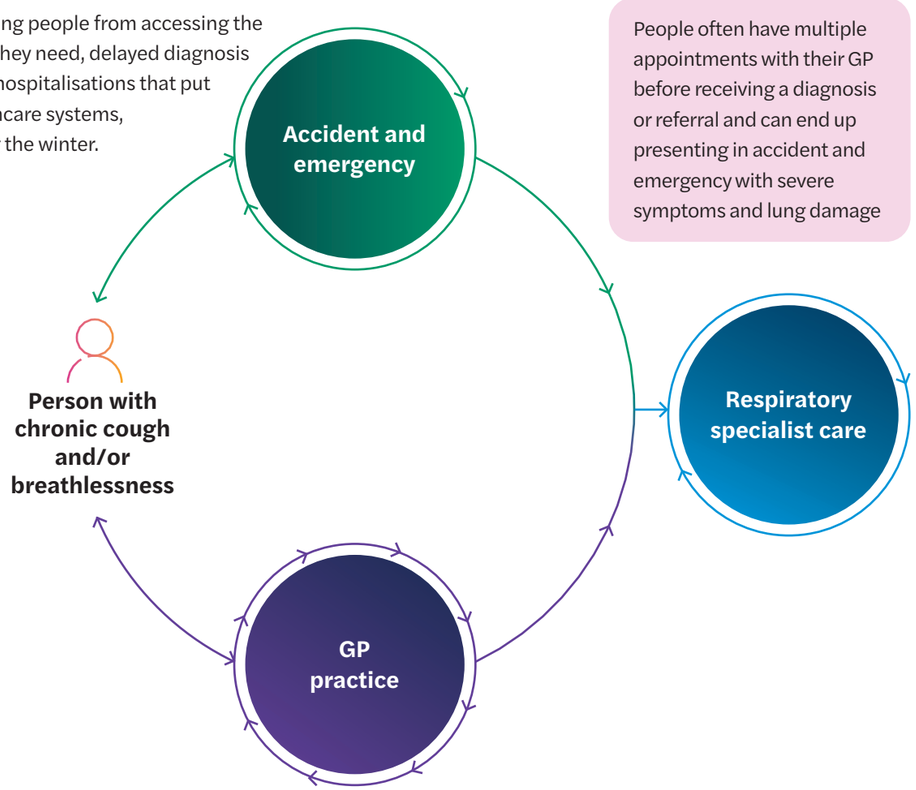
For many people with a chronic cough and/or breathlessness, their first step towards a diagnosis will be to visit their GP practice.

Clinical guidelines suggest GPs should have access to diagnostic tests to make an initial assessment or diagnosis of the causes of their symptoms.

In reality, however, people with symptoms of chronic lung conditions get stuck in a loop of repeated visits to their primary care provider or might first present in accident and emergency (A&E). They often wait years for a diagnosis, navigating a complex pathway that is hindered by long waiting times and inconclusive tests with poor accessibility. The lack of good definitive diagnostic tests means definitive data on diagnostic delays is lacking.

> “I think a quick diagnosis can help prevent further escalations of exacerbations. In my case, I’m pretty sure that I would have less lung damage had I been diagnosed much faster”
>
> **Person with bronchiectasis**

As well as preventing people from accessing the care and support they need, delayed diagnosis causes increased hospitalisations that put pressure on healthcare systems, particularly during the winter.



People often have multiple appointments with their GP before receiving a diagnosis or referral and can end up presenting in accident and emergency with severe symptoms and lung damage

Current diagnostic tests present a range of challenges

Diagnosis revolves around spirometry, but in primary care this test has limitations and is inaccessible to many

Poor access to tests drive long waiting times for patients. Those who are most sick may be unable to travel to where the test is available

Patient experience a reliance on forced exhalation - a six second forced blow into a machine - can be difficult and distressing for people with reduced lung capacity

Error-prone tests, reliant on technique, lead to inconclusive results and misdiagnoses for patients

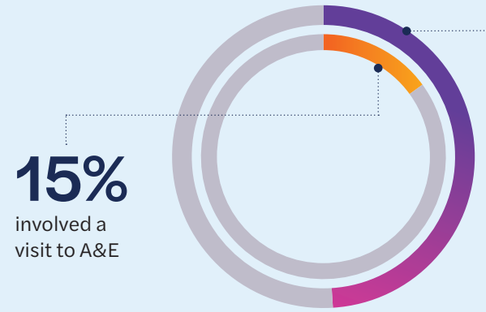
Highly trained personnel are required for delivery and interpretation of results, with the accuracy of the conclusion dependent on their expertise

Health inequalities are driven by a range of factors, including regional variations in availability, commissioning and capacity

Cost and reimbursement model can be a barrier to widespread adoption of some tests

Rarer conditions may not be suspected by GPs and other healthcare professionals

We asked people living with chronic lung conditions about their journey to a diagnosis



71% had more than 3 diagnostic tests performed

Results from a LifeArc online survey completed by 87 people with lived experience of chronic lung disease in September-October 2025

Chronic lung conditions and the challenge of accurate diagnosis

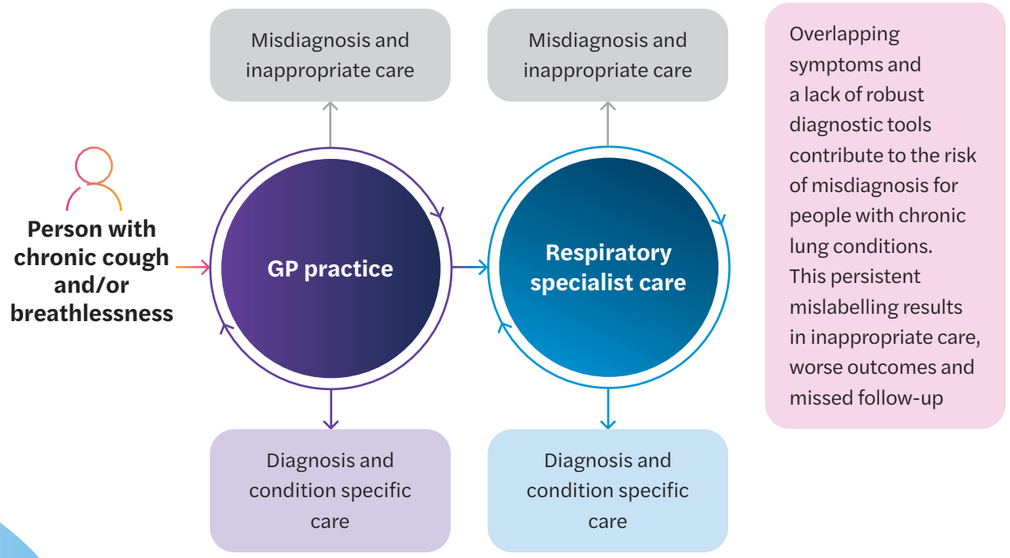
Asthma and chronic obstructive pulmonary disease (COPD) are the most common types of chronic lung disease. Bronchiectasis and interstitial lung disease (ILD) are comparatively rarer.

Due to diverse and overlapping symptoms, these conditions are commonly misdiagnosed. There is no single test that can diagnose and differentiate these four conditions. Misdiagnosis can lead to patients receiving treatment that is at best unnecessary and at worst harmful or remaining untreated as their condition deteriorates.

All these conditions share an urgent need for accurate diagnosis at an earlier stage, when intervention with appropriate treatment can have the best chance of slowing their progression and protecting lung health.

> “I’ve got too many horror stories of patients seeing multiple clinicians for ongoing breathlessness. Tried on huge amounts of therapy and 18 months later get sent to me and I literally put a stethoscope on them and do an urgent referral”
>
> **Advanced respiratory specialist working in primary care**

Chronic lung conditions are frequently misdiagnosed



Asthma

Asthma is a lifelong, heterogenous condition characterised by inflammation and tightening of the airways. This makes it difficult to breathe and, in some cases, leads to life-threatening asthma attacks.

In 2024, 7.2 million, or 1 in 9, people in the UK were living with asthma (including 2 million, or 1 in 8, children)[6]

Up to **750,000** people in England are incorrectly diagnosed with asthma.

This costs the NHS **£132m** each year.[7]

Chronic obstructive pulmonary disease (COPD)

COPD is characterised by irreversible lung damage that narrows the airways and makes it difficult to breathe. Symptoms usually get progressively worse without treatment, and people may experience sudden periods of exacerbation.

In 2023, 1.7 million people were living with COPD in the UK (around 600,000 undiagnosed)[8]

Around 1 in 4 people with COPD wait more than five years for a diagnosis, with 1 in 8 waiting more than a decade[9]

Bronchiectasis

Bronchiectasis is a long-term condition where the airways become permanently damaged and widened, leading to a buildup of sputum that increases the risk of lung infections. Each new infection can further damage the airways.

In 2019 there were estimated to be around 212,000 people in the UK living with bronchiectasis[10]

25.4% of people with bronchiectasis reported having symptoms for over 10 years before diagnosis[11]

25.7% of people with bronchiectasis reported being misdiagnosed with another disease first, the most common misdiagnosis was asthma[12]

Interstitial lung disease (ILD)

Interstitial lung diseases (ILDs) are a group of rare conditions that cause inflammation and progressive thickening of lung tissue, making it harder for the lungs to expand. There are more than 200 types of ILD, with the most common type being idiopathic pulmonary fibrosis.

In 2021 there were estimated to be 102,500 people living with ILD in the UK[13]

36.7% of individuals experienced symptoms for over 2 years before their first specialist[14]

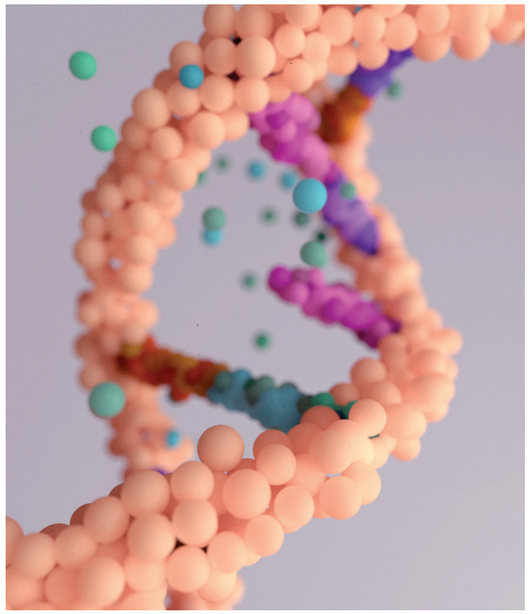
Idiopathic pulmonary fibrosis has a reported survival of: 3 to 5 years post-diagnosis[15]

Common symptoms, complex subtypes

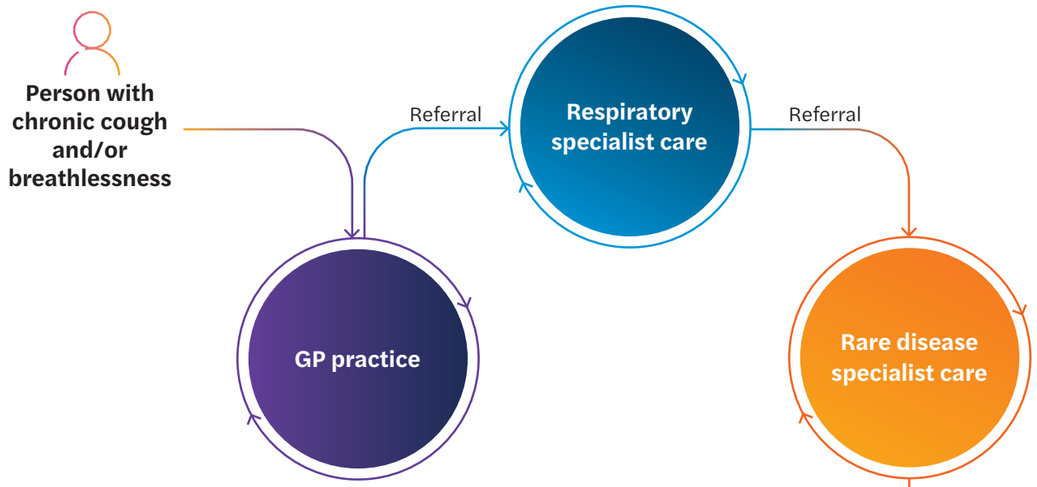
While asthma, COPD, bronchiectasis and ILD are characterised by specific symptoms and pathophysiologies, they comprise a heterogenous collection of diseases with diverse underlying causes.

Some of these are rare and underpinned by distinct mechanisms requiring different treatment and management. For example, COPD can be caused by environmental exposures or the rarer genetic condition alpha-1 antitrypsin deficiency (AATD). Bronchiectasis can be a consequence of genetic conditions including AATD and primary ciliary dyskinesia (PCD) and can arise after pulmonary infections such as those caused by mycobacteria.

Diagnosing the underlying cause of the disease can only be achieved with referral to the right specialist and is essential for matching patients to appropriate treatment, management and clinical trials.



The journey to underlying rare disease diagnosis



The path to a rare disease diagnosis requires multiple referral decisions which adds further opportunities for delays

A shared vision

At Asthma + Lung UK, we routinely hear from people at a moment of fear: being breathless and not knowing what's wrong with them.

For the 12 million people in the UK at risk of developing a lung disease, their journey to find answers will begin in primary care.

Samantha Walker PhD
Director of Research + Innovation
Asthma + Lung UK

Yet current diagnostic tests are difficult for patients and clinicians to perform, inaccurate and require extensive training. The outcome is that a formal diagnosis of major respiratory conditions can take many years.

This delayed diagnosis of respiratory diseases – common or rare – leads to lives spent struggling with breathlessness, severely limiting daily life and impacting productivity at work. Persistent symptoms cause lung damage that is often irreversible.

To address this disturbing and costly reality, LifeArc and Asthma + Lung UK have worked together to improve the state of respiratory diagnostics. Our joint report from 2023 forms the basis of a 10-year Diagnostics Grand Challenge and explicitly calls for a simple, accurate low-cost diagnostic tool that can be adopted at scale in primary care.

This report accelerates our efforts to transform respiratory diagnostics.

The Target product profile outlined here fills a vital gap for innovators – defining a blueprint for new respiratory diagnostics tools that meets the needs of patients, clinicians and the NHS. Through a carefully designed process, the perspectives of people with lung disease were incorporated from the outset, strengthening the prospect of patient acceptability.

Innovation that can satisfy the TPP's criteria will therefore not only meet the needs of key stakeholders but will be better positioned for widespread adoption in GP surgeries across the UK.

Using this rigorously developed blueprint to improve respiratory diagnostics will also support the wider shifts within the NHS to prioritise prevention, community-based care and the use of digital technologies. Policy initiatives announced in the 10 Year Health Plan and Life Sciences Sector Plan will therefore provide an opportunity for the pioneers of tomorrow's diagnostics to use the TPP to apply their excellence to the challenge of diagnosing respiratory diseases.

By rising to this challenge, we can begin to envision a world in which the diagnosis respiratory conditions occurs in a matter of minutes not years, fast-tracking effective management in the community, reducing emergency admissions and supporting further research.

We have identified the need for a transformative diagnostic tool

We are encouraging the development of a tool that could be used in primary care to diagnose asthma and COPD and expedite referral for suspected bronchiectasis and ILD.

Such a test would contribute to wider efforts to tackle breathlessness and its underlying conditions, a priority for the World Health Assembly, the NHS Long Term Plan, the UK Government's Life Sciences Sector Plan and other global initiatives[16].

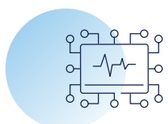
Our vision is that this document serves as a catalyst, inspiring developers to generate novel solutions that meet the needs of those struggling with persistent symptoms of cough and breathlessness

We encourage the adaptation or repurposing of promising development projects or existing specialist diagnostics to address the unmet need. For example:

Breath analysis and acoustic technologies both present opportunities for non-invasive analysis of complex signatures with the potential for early disease detection

Digital technology, including wearables, may offer non-invasive and remote testing across a broad range of biomarkers, with the potential ability to detect fluctuating and subtle disease signs

Artificial intelligence (AI) and machine learning could enhance result analysis of current tests without extensive processing or specialist involvement



AI technologies could be used to probe health records for disease patterns, providing prompts that encourage clinicians to consider rarer conditions they may not have previously encountered

Developing a diagnostic tool to drive impact

Transform patient outcomes

Earlier diagnosis of chronic lung conditions enables earlier, more effective intervention – improving quality of life, preventing permanent lung damage, reducing emergency hospitalisation and lost productivity from illness, caregiving and premature death.

Reduce healthcare inequalities and inequities

Chronic lung disease disproportionately affects people from poorer backgrounds who may be less likely to access NHS care and less likely to be referred to a specialist.

Support diagnosis of rarer disease

With better decision support tools, primary care clinicians may be more likely to recognise rare disease and refer patients for specialist care.

Contribute to a growing global market

The respiratory diagnostics market was $6.17 billion in 2024 and is estimated to rise to $9 billion by 2030[17]. The development of cutting-edge respiratory diagnostics could also help to drive the development of new personalised treatments in a global respiratory therapeutics market, which was valued at $143 billion in 2021 is expected to double by 2028[18].

Our approach: developing a TPP rooted in lived experience and clinical insight

To direct innovation, we developed a target product profile (TPP) - a structured set of specifications, or user requirements, describing the necessary features and performance criteria for an acceptable and effective diagnostic test that meets the clinical need.

Our goal is for the TPP to serve as a strategic springboard for developers to create solutions that are both clinically relevant and operationally feasible, within the primary care setting.

From the outset, a lived experience panel reviewed our focus group questions and survey design, and we received extensive input through stakeholder surveys. Project oversight was provided by an advisory group with expertise spanning respiratory disease management, diagnostic innovation, and lived experience, ensuring a balanced and informed development process.

This inclusive approach ensures the TPP both aligns with clinical and technological landscapes and is responsive to the real needs of patients – increasing the likelihood of future products succeeding in clinical settings and delivering meaningful impact.

> “We made a deliberate effort to embed lived experience throughout: too often, the patient voice is absent from the early stages of research and development.”

A convening workshop identifying the need: LifeArc and Asthma + Lung UK held a workshop with clinicians, academics, innovators and people with lived experience to understand unmet needs in respiratory diagnostics – identifying the need for a simple, accurate low-cost diagnostic tool.

Extensive stakeholder engagement to co-develop the TPP

- **113 people with lived experience** of asthma, COPD, bronchiectasis or ILD, or undiagnosed breathlessness.
- **38 healthcare professionals** involved in the diagnosis of chronic lung disease, with a focus on primary care.
- **23 innovation ecosystem members** including researchers, diagnostic developers and decision makers involved in bringing new HealthTech to the clinic.

1. Defining the scope of the TPP
Through a series of focus groups and a review of clinical guidelines, we sought to understand the unmet needs of patients and healthcare professionals and their priority characteristics for future diagnostics

9 | 12

Expert advisory group input
1 | 4 | 2

Expert advisory group input
1 | 4 | 2

3. Achieving consensus
We surveyed the chronic lung disease and diagnostic development community to finalise the TPP. We also surveyed people living with chronic lung conditions to understand their priorities

87 | 21 | 14

Expert advisory group input
1 | 4 | 2

PPIE input
Lived experience panel advised on focus group format and questions
8

2. Refining the TPP
We drafted the scope, key characteristics and value proposition of the TPP. This was refined through extensive stakeholder discussions
9 | 13

PPIE input
Lived experience panel advised on focus group format and questions
8

Expert advisory group input
1 | 4 | 2

Simple lung test TPP and guidance document

Full methodology will be published and available via the simple lung test website

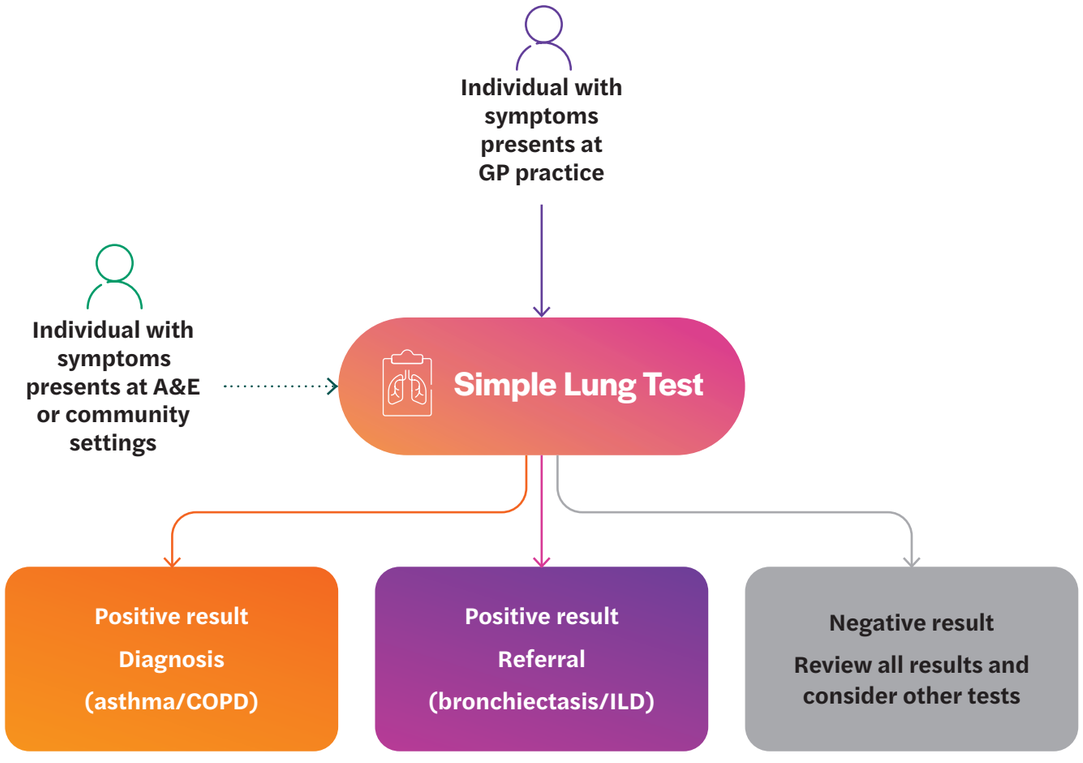
Defining the simple lung test

We have identified a strong demand for a “simple lung test” that can be delivered within a single appointment in a GP practice, upon patients presenting with symptoms of respiratory disease.

Such a tool would enhance referral precision, reduce diagnostic delays and help avoid unnecessary and costly hospital visits. It must be user-friendly for both patients and healthcare professionals, deliver reproducible results and provide clear, actionable outputs. We have kept the concept intentionally broad. It could range from direct measures of lung function to more innovative approaches using digital biomarkers and AI.

We encourage developers to aim high and meet the TPP criteria, with the ultimate, ambitious goal of transforming the diagnostic journey for people living with breathlessness. In the shorter term, we acknowledge that incremental progress is also valuable, and that the unmet need might be more realistically addressed with multiple complementary tests.

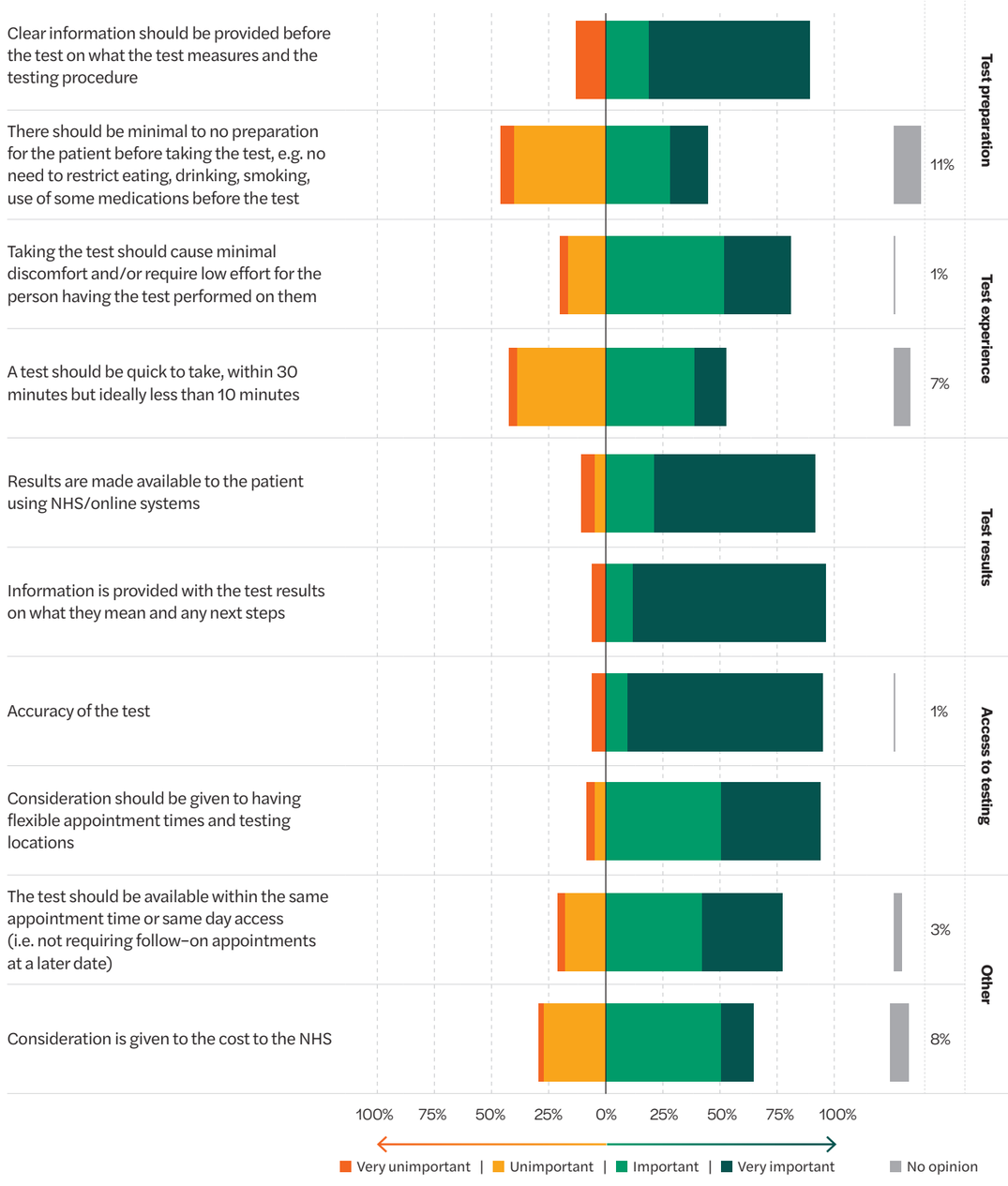
The ideal test would integrate smoothly into routine practice – enabling accurate diagnosis of asthma and COPD and supporting referrals for suspected bronchiectasis and ILD



Test priorities for people living with chronic lung disease

People living with chronic lung conditions ranked test accuracy and communication of results as the most important priorities for a simple lung test. Pre-test preparation and time to take the test were ranked as least important.

Results from a LifeArc online survey completed by 87 people with lived experience of chronic lung disease in September-October 2025



The need for respiratory diagnostics for children

We heard from healthcare professionals that there is a clear need for improved diagnostic tests that are specifically designed and validated for use in children.

Chronic lung conditions often present differently in children compared to adults, and the biomarkers of disease may not be the same. It can be harder to spot underlying chronic lung conditions, because children often get acute chest infections. Additionally, some chronic lung conditions that are common in adults are rare in children, so doctors may not always recognise the signs.

Children with respiratory conditions need:

- effective diagnostic tools to prevent misdiagnosis and ensure children are rapidly matched to the most appropriate treatment for their condition
- simple and accessible testing within primary care as very young children may be unable to perform standard lung function tests
- tests that are underpinned by robust evidence and reference values, which is currently lacking

> “We’ve had kids who’ve had three or four courses of steroids in the last 12 months without a diagnosis”
>
> **Respiratory consultant**

Opportunities for development include:

- a predictive scoring or screening tool that could be used within primary care to search patient history for key data, including frequency of respiratory infections or early respiratory distress to assist, in diagnosis or referral decisions
- supporting healthcare professionals to recognise the difference between a dry and wet cough to help differentiate the underlying cause

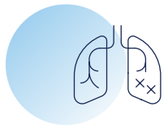
Asthma is the most common long-term condition in children worldwide[19]

Up to
735 in 100k[20]
children are predicted to have bronchiectasis – but it’s not often suspected

The future of diagnostics for chronic lung disease

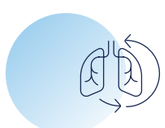
Chronic lung disease represents a global burden, comprising rare and common conditions that collectively add up to the third leading cause of death worldwide – yet it remains woefully overlooked and underfunded.

A simple lung test that enables earlier diagnosis and timely intervention, before lasting lung damage becomes problematic, could be transformative for patients and society. While our current focus is on solutions aligned with current care pathways, we recognise the potential for even greater advancements through more ambitious, innovative approaches in the future.



Asymptomatic detection of disease
The onset of symptoms, such as breathlessness, often signals irreversible lung damage. Developing a diagnostic tool capable of identifying lung disease at its earliest, asymptomatic stages could empower patients to take pre-emptive steps to protect their lung health. This approach may also help to identify patients suitable for clinical trials testing new treatments that target the early stages of lung disease.

Expanding testing locations
We recognise there is value in bringing a simple lung test to additional community, emergency and social care settings. Meeting optimal characteristics, such as portability and calibration, may support this applicability. Bringing diagnostic services closer to where people live and work – such as in pharmacies and libraries – may further reduce barriers for patients and reach demographics who may face challenges in accessing healthcare.



Integration with existing screening initiatives
There may be potential to embed a simple lung test within established lung screening programmes, such as the UK NHS Lung Cancer Screening Programme, which invites people at high risk of lung cancer to discuss their history and, where relevant, undergo a CT scan. This may enable targeted support and earlier diagnosis of high-risk individuals, particularly underserved populations who may be less likely to interact with healthcare services.

Living with a chronic lung condition means facing each day with quiet strength — with every breath a battle.

To help win the war on chronic lung disease, we need better diagnostic tools. This TPP reflects a need to lay the groundwork to fill a huge gap in diagnostics for people affected by and suffering with chronic lung disease. Testing that can improve speed and accuracy of diagnosis is imperative to improve efficiency in respiratory healthcare and, ultimately, quality of life and health outcomes for those living with a lung condition.

Target product profile for a simple lung test

Value proposition of the simple lung test:

- to speed up diagnosis of chronic lung conditions (asthma, bronchiectasis, COPD and ILD) by providing testing in the GP practice, and reducing the number of appointments before a patient receives a diagnosis
- to provide a reproducible and minimally invasive measure of chronic lung disease appropriate for the primary care setting
- to reduce unnecessary specialist referral of those that could be diagnosed in the GP practice
- to enable equitable access to diagnostic testing for patients and healthcare workers

Over the following pages, tables present priority characteristics, with minimally acceptable and optimal features that should be met for a new product that fits the intended use in the intended setting.

Category: Scope

Characteristic	Minimal	Optimal
Intended use	To support detection and differentiation of chronic lung diseases. Specifically, to **support diagnosis** of asthma and COPD and to identify suspected bronchiectasis and ILD for specialist referral.	To support detection and differentiation of chronic lung diseases. Specifically, to **diagnose** asthma and COPD and to identify suspected bronchiectasis and ILD for specialist referral.
Description of test/ device	Minimally invasive and minimal effort measure of chronic lung disease, proportional to the value of the output (i.e. if providing a quick and definitive diagnosis, a more invasive test may be tolerated).	As minimal and enables clinical decision making (diagnosis or referral) from a single simple lung test result by incorporating multiple measures and/or utilising novel biomarkers.
Target patient population	Children (5+), young people and adults with clinical features suggestive of chronic lung disease, e.g. breathlessness and/or chronic cough.	
Target setting	GP practice.	
Target end user - the individual delivering the test	Any healthcare professional with the appropriate training (see training requirements) can deliver the test in the target setting.	

Category: Design

Characteristic	Minimal	Optimal
Target biomarker - what is being measured	Clinically validated measures of chronic lung disease, which could include direct measures of lung function and a range of biomarkers from breath to digital.	As minimal and the target biomarker validated to detect chronic lung disease even when other respiratory conditions are present (such as active infection or an exacerbation).
Validity of biomarker	Target biomarker is validated to cover the effect of gender, body size, age, ethnicity, and factors relevant to respiratory health e.g. smoking status, air pollution. Should be demonstrated to be effective in across different socioeconomic backgrounds.	
Sample collection	Minimally invasive and minimally uncomfortable sample collection, proportional to the value of the output and whether repeat testing is required. Sample type and volume dependent on test/biomarker type. Consideration should be given to minimising aerosol generation during sample collection.	
Patient acceptability	Demonstrated evidence of patient acceptability in the target setting. Acceptability should be equal or superior to existing tests in the target setting.	
Design considerations	Small footprint and portable within GP practice. Consider consumable needs and minimise specific high-cost consumables.	As minimal and fully portable solution that can be transported into settings closer to the patient e.g. at home or pop-up clinics.
Calibration	Self-calibration for day to day use – consideration given to impact of moving device on calibration.	No calibration required once delivered or automatic operator-independent calibration.
Servicing	Fixed service schedule, preference for service by time period e.g. yearly rather than for a fixed number of tests. Calibration checked during annual servicing or built into a disposable single-use/limited use aspect of the machine.	
Test capacity - number of tests per day	Suitable for both low capacity and infrequent testing and high capacity and frequent testing situations (or concurrent testing, e.g. if it is a single use device).	
Reproducibility and repeatability of results	Reproducibility and repeatability of results should be tested during the product development. This should be within expected limits for the biomarker for all age groups. Consideration should be given to the effect of active respiratory symptoms on the results.	
Technical failure rate and quality control	Low technical failure rate. Result quality should be easily assessed by the operator without additional training requirement. Live feedback from device on result quality or failure and clear guidance should be available on what do.	As minimal and automation of quality control integrated with test by design as a pre-requisite of generating a test output.
Safety	Test should conform to relevant chemical, electrical and biosafety standards for medical devices. Normal use of the test should not confer any additional hazards to the user when following expected procedure. Minimal or no adverse device effects. Minimise generation of aerosols and no/low risk of bodily fluid exposure, using correct infection control procedures.	
Sustainability	Considerations to sustainability in the product design e.g. minimising the use of single use plastics. Minimal carbon footprint.	

Category: Performance

Characteristic	Minimal	Optimal
Diagnostic sensitivity	High sensitivity to identify individuals with chronic lung disease and provide confidence that a negative result rules out a diagnosis.	Very high sensitivity (>95%) for diagnosis of asthma and COPD. High sensitivity prioritised over specificity to provide confidence that all suspected bronchiectasis and ILD cases are identified for specialist referral.
Diagnostic specificity	High specificity to provide confidence that a positive result confirms presence of chronic lung disease.	Very high specificity (>95%) for diagnosis of asthma and COPD.
Time required to administer test	Less than 30 minutes, within extended appointment times. Consideration given to staff resource needed for test delivery (see target end user).	Less than 10 minutes.
Time to results	The time to results should be appropriate for the chosen test modality, the accuracy of the test and the clinical value of the result.	Minutes (less than 10 minutes end-to-end, test-to-results), results available within the same appointment.
Results output	Local printout/LIMS upload permissible only as part of a stepwise approach to EHR integration.	As minimal and EHR/NHS App integration.
Results interpretation	Results outputted in a way which is easy to understand by healthcare professionals with minimal training. Options for both simple and detailed displays depending on the user's expertise. Interpretation should be clear, standardised, and compliant. For AI/machine learning outputs must be transparent (“explainable AI”).	

Category: Product registration, access and cost

Characteristic	Minimal	Optimal
Product registration - substantiation of product claim to regulatory body	CE marking (IVDR), UKCA (or approval by other regional regulatory equivalent authority). Country-level registration as required.	
Equity of access	Equally accessible to all relevant target populations, with considerations given to different demographics and languages - to minimise regional disparity and healthcare inequality. Consider digital inclusion (older patients, low-literacy groups), and accessibility for underserved/remote communities to address health inequalities.	
Pricing	Cost envelope should account for total cost of delivery (including consumables, practitioner time, training, servicing and interpretation) rather than just the unit cost.	
Cost effectiveness	Implementation deemed "cost effective" compared to current practice, in accordance with local policies. Note that improved accuracy of specialist referral will have cost benefits, but these may be at a systems level rather than in the target test setting.	Implementation deemed "cost saving" compared to current practice, in accordance with local policies. Demonstrated decrease in time and cost to diagnosis, and impact on QALYs.

Category: Operational

Characteristic	Minimal	Optimal
Training requirements	Any healthcare professional could deliver test with minimal training and no specialist certification, noting that decision-making would require appropriate training. Online and on-demand training preferred. Language-appropriate training materials, results guide, and aids should be made available.	
Ease of use	Clear instructions for use, should include diagram of method and results interpretation.	Minimal user steps with clear instructions for use including diagram of method and results interpretation.
Device stability and storage	Validated lifespan (typically 3–5 years) with servicing. Suitable for use across reasonable range of temperatures and humidities. No additional equipment required to maintain operating conditions. No impact of frequent ethanol wipes and other standard disinfection on device stability, using medical-grade materials where necessary.	
Reagent and/or consumables stability and storage	Stable for a minimum of 1 year when stored under refrigeration (typically 2-8°C), avoiding cold storage where possible.	Stable for minimum of 1 year at room temperature.
Connectivity - internet and power requirements	USB/offline with delayed upload. Compatible with cybersecurity requirements (e.g. ISO/IEC 27001, GDPR). Device should be able to work independent of computer/Wi-Fi/mobile connectivity. Battery capacity should be sufficient to deliver a full day of testing in a high throughput setting without requiring charging.	As minimal with additional HL7/FHIR integration with NHS systems.
Labels	ISO 15223-1 (symbols), ISO 18113 (IVD IFUs), IEC 62366 (usability), and UDI requirements. Labelling should be in line with country-level legislation.	
Instructions for use	Simple instructions for use and result interpretation - instruction provided to sit alongside device. Clear guidance on what to do if the tests fails and clear warnings of limitations for use including expected performance characteristic. Consider eIFU where permitted. Instructions for use should be in line with country-level legislation.	
Waste streams & disposal requirements	Does not include materials that cannot be disposed of in normal clinical waste streams.	As minimal and where possible focuses on minimising clinical waste and focuses on recycle and reuse.
Infection control	Test should be compatible with PPE used in GP practices and existing NHS guidance and procedures. Consideration should be given to infection control and not involve any onerous cleaning regimes. Equipment should be compatible with standard disinfection procedures used in target setting.	

Key considerations for developers

The path to successful development and adoption of new diagnostic tests involves many steps. In addition to understanding the patient and clinical need, developers should consider the regulatory, healthcare and policy landscape[21]. Some key considerations relevant for new tests meeting the simple lung test TPP requirements are outlined below.

Clinical utility

- The test should not add another layer to an already complex diagnostic pathway, but must overcome issues with current diagnostic tests, including lack of access, patient acceptability, and staff training requirements.
- To increase accuracy of diagnosis or referral, the simple lung test could incorporate key patient history data that is already collected (e.g. occupation, frequent infections, early life respiratory distress) and physical examination results (e.g. chest sounds).
- Although bronchiectasis and ILD are diagnosed in secondary care, in line with clinical guidelines, a lack of awareness and/or access to appropriate triage tests in primary care can delay referral. Identifying suspected cases earlier could expedite referral and subsequent diagnosis.
- Diagnosing individuals despite confounding factors is important. There is a need to differentiate chronic lung diseases with overlapping symptoms. Additionally, people may have more than one chronic lung disease and other common co-morbidities that affect lung function and test results. Diagnostics should be validated across these varied contexts.
- There would be clinical value in being able to diagnose people with chronic lung disease both in the presence of an active infection and/or exacerbation and in the absence of any symptoms.
- In addition to diagnosis, there is a strong clinical need for tests that inform treatment decisions, for example through identifying disease subtypes that respond to specific therapies.

Diagnostic development

- Developers should design appropriate analytical validity and performance studies to demonstrate safety and efficacy, as well as ensuring end-user acceptability.
- Developers should outline their regulatory strategy early in the development process, including the applicable regulatory requirements in the target region(s) and compliance to relevant quality standards, such as ISO 13485.
- Clinical study design should be considered when validating the test, including how the target biomarker may vary across demographics, to ensure the test is applicable across diverse patient groups.
- Developers should seek insights from people living with chronic lung disease from the initiation of a new innovation project and throughout development, to ensure the product meets the needs and priorities of end-users.

Integration within the healthcare system

- HealthTech assessments evaluate whether a new test should enter clinical use by considering clinical, economic, and practical factors, such as effectiveness, evidence quality, regulatory standards, and accessibility. Developers should engage with the process relevant to their target setting and understand the requirements from an early stage.
- Health economic impact and cost effectiveness will need to be determined within the specific setting where the test will be used (‘real-world' evidence). System-wide savings are difficult to calculate but should consider cost and resources associated with specialist referrals and emergency care admissions. Developers should consider who holds the budgets for any costs associated with implementation of the test and the practicalities associated with single outlays vs ongoing costs (e.g. consumables).
- The simple lung test TPP describes a test to be used in a GP practice but there is clear potential clinical utility in other settings. We invite developers to consider the test’s applicability to additional entry points, including emergency care and community settings, such as pharmacies, community diagnostic centres, and potentially screening programmes. Some of the required test characteristics will need to be re-defined for these settings.
- Training costs are frequently underestimated, particularly with high staff turnover. Developers should consider the level of training required for the test; empowering and training healthcare professionals in different roles to deliver and interpret the test may provide a more efficient and cost-effective option.
- It is critical that test results are easily communicated between different parts of the healthcare system. Developers should ensure the test design does not preclude sharing of clinical data across the healthcare system.
- The simple lung test must be universally accessible within the target region. It should be robustly assessed with both healthcare professionals and people with experience of lung conditions. It should be validated across a diverse population (age, gender, ethnicity) and made available through the healthcare system without geographic restrictions.

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Key terms

Person with lived experience of a condition
This includes patients, parents, carers and loved ones.

HealthTech
Innovations directed at solving healthcare problems, including devices, digital solutions, medicines and vaccines.

Healthcare professionals
A term that encompasses a range of roles that deliver health care service, including doctors, nurses and allied health workers.

Care settings
Primary care refers to the first contact point with the healthcare system e.g. GP practice, pharmacy. Secondary care refers to care in a hospital setting. Tertiary care refers to specialist centres. We use 'respiratory specialist care' to refer to specialised care in a hospital setting.

Artificial intelligence and machine learning
Artificial intelligence refers to the use of computers to perform tasks that require human intelligence e.g. learning, problem solving and decision making. Machine learning is type of artificial intelligence that involves enabling systems to learn from data and improve performance.

Pathophysiology
The functional changes that occur in the body as the result of disease.

Lung function testing
A series of tests that are carried out in hospital to measure how well someone's lungs are functioning.

Spirometry
A lung function test that measures how much air someone can breathe out and how quickly. This test can be available through primary care.

Biomarker
A characteristic or biological factor that can identify a specific process such as a disease.

Value proposition
An evidence based statement on the additional benefit something could bring, in this case a diagnostic. Value propositions would need to be demonstrated by clinical trials.

Minimal characteristic
A feature that a test must have in order to deliver to the intended use in the target setting.

Optimal characteristic
A feature that a test should ideally have in order to deliver to the intended use in the target setting.

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