



Home Is Where the Health Is: Future-Proofing Healthcare Through Home Testing

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At the onset of the COVID-19 pandemic, the global healthcare landscape had to undergo a swift transformation. Traditional face-to-face healthcare delivery was significantly disrupted, and accommodations had to be made to ensure that patients could be triaged and monitored in ways that protected public health and also enabled timely and accurate diagnosis or treatment of disease without the need for repeated clinic or hospital visits.

The increased use of telephone or video appointments allowed patients to maintain continued contact with their healthcare providers. However, even after the worst of the crisis had passed, budgets, staffing, and resources within the healthcare landscape still required alleviation from the immense pressures of the pandemic, and answers were still needed on how biological samples could be obtained in a safe, quick, and accurate way. Enter: **at-home patient testing**.

In 2017, Scotland became the first country within the UK to overhaul its bowel screening programme and introduce a new quantitative Faecal Immunochemical Test (FIT) in place of the guaiac-based cards. With this came the implementation of new patient packs which provided all of the instructions and tools necessary for patients to collect their faecal samples quickly and hygienically, and return them to the laboratory for automated processing. It was off the back of this initiative that

home testing started to become a viable option on a wider scale, and through the pandemic, new bespoke kits were created in the same way to ensure that symptomatic patients could also be supplied.

Today, the bowel screening programmes across the UK are some of the most successful examples of at-home sample collection, with the combined programmes sending out approximately nine million screening invitations per year. The average return rates across all programmes range between 60-70%,^{1, 2, 3, 4} so although there are still opportunities for improvement, the overall uptake can still be considered successful for triaging the wider population and sending referrals for appropriate further investigation.

Key Challenges for Home Testing

Luckily, healthcare in the UK has continually evolving guidelines, which means that as new problems arise, so do answers and new opportunities. Innovative end-to-end kitting and logistics can now help improve compliance by empowering patients to take their health into their own hands. Alpha Solutions® patient home testing kits are now available with tailored messaging, bespoke instructions and sampling methodologies, thus providing users with the knowledge needed to accurately collect and handle their samples, whilst also reducing the burden on resources within the laboratories and clinics.

Public perception and subsequent compliance for the sample collection process can alter massively depending on the sample type (e.g. faeces, blood, urine, saliva, etc.) collection methodology, frequency of collection, and even just speed of results feedback from their healthcare provider. This means that any messaging about the testing process must be clear, direct, and simple to prevent misconceptions. Equity and accessibility also need to factor into any considerations when

building a home-testing initiative; from average reading-age of the local population to language requirements, as well as physiological issues such as visual impairment or dexterity.

Case Study

Confirmed IBD patients are a particular cohort who need to regularly collect samples for disease monitoring via their faecal calprotectin levels. This cohort may understand more than most the importance of disease monitoring due to the often-lengthy process to confirm a diagnosis, so are typically accustomed to faecal collection via a poo pot, however, even so, timely compliance and general quality of sample has historically been inconsistent – from tiny samples that cannot be extracted to samples which have degraded by the time they've reached the lab.

A poster by Edwards et al., shown at ECCO 2021, illustrates that in a study of 50 IBD patients there was a compliance rate of 70% in home-based testing using the BÜHLMANN IBDoc® versus 52% compliance with hospital-based sampling with a poo pot.⁵ Through the empowerment and ease of at-home testing, with the addition of an easy-to-use bespoke sample collection device, IBD patients routinely using the IBDoc have consistently responded positively. General feedback has shown that they are impressed with both the ease of test and speed of result, as these are available on the dedicated app on the day of testing as opposed to having to call or email clinics to receive results up to two weeks later.

Beside the issue of compliance, home testing has common operational challenges which may affect efficacy and outputs. These can include:

Kit generation and distribution

- ▶ Initial identification of what is needed to ensure kits are fit-for-purpose and appropriate for their intended user. This scoping process may also require consideration of potential risks and benefits, as well as timescales for kit builds and distribution. Additionally, small-scale clinical trials may benefit tremendously from scalable solutions to improve compliance and cost-effectiveness.
- ▶ Regulatory and Quality Control considerations including:
 - ✓ UKCA marking (MHRA registered)
 - ✓ ISO 13485 certified (kit registration and assembly)
 - ✓ UN3373, Category B compliant (where applicable, for biological or infectious substances)
 - ✓ CE/CE IVD marking (where applicable, for kits being utilised outside of the UK)
- ▶ Initialising and maintaining a new distribution network. This task can quickly become an administrative burden – are any specific programme coordinators required? Can an established logistics service be utilised to remove pressures on internal resources?

Patient Sampling

- ▶ There may be significant variations in the way each user collects and returns their sample for processing, particularly for faecal samples which can present in many different consistencies. Interpretation of instructions and sample handling during the collection process is the primary issue as patients may mishandle samples resulting in too much or too little sample being collected. Instructions must be clear and concise to remove ambiguity and achieve the desired outcomes.
- ▶ Multi-step processes that require additional data to be recorded, or labels added may be missed, so should be minimised wherever possible.
- ▶ In addition to the regulatory requirement for transport of biological samples, if returning to a laboratory or clinic, there may be specific packaging requirements to protect sample integrity and reduce the risk of degradation.

Brought to you by Alpha Laboratories, Alpha Solutions is here to support the evolving needs of healthcare in the UK with tailored kitting solutions and comprehensive streamlined fulfilment and distribution services.



The Building Blocks for a Robust Solution

The true promise of at-home sampling lies in its ability to shift care from reactive, crisis-driven responses to a more proactive and integrated part of routine healthcare. By facilitating early triage and monitoring in the community, it can significantly reduce the burden on both primary and secondary care, preventing unnecessary GP appointments and specialist referrals. Moreover, at-home testing empowers patients to take an active role in managing their health and get them onto appropriate treatment pathways as quickly as possible, which is especially critical for those with chronic conditions. To fully realise this potential, however, the implementation of flexible, end-to-end solutions is essential.

As healthcare systems strive to become more resilient and adaptable, home testing with customisable, compliant kits stands out as a viable option for clinically effective, scalable, and patient-centric innovation, which could be a crucial component of future diagnostic toolkits.

The Alpha Solutions at-home portfolio consists of kits for Faecal Immunochemical Testing, Faecal Calprotectin (CALEX® Patient Packs and IBDoc Direct Delivery), and Capillary Blood Collection.

For more information on home testing or to enquire about Alpha Solutions® bespoke kitting and logistics from Alpha Laboratories, visit: alphalabs.co.uk/kits

References:
 1. Bowel cancer screening standards data report 2023-24 - GOV.UK. 2. Scottish Bowel Screening Programme Statistics. 3. Bowel Screening Wales Annual Statistical Report 2022-23 - Public Health Wales. 4. Programme Performance and Standards | Cancer Screening Northern Ireland. 5. BÜHLMANN IBDoc® Publications - Calprotectin Home Testing. 6. Leading Edge 2025 Issue 1.