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WHITEPAPER

Opportunities for sustainable innovation in diagnostics

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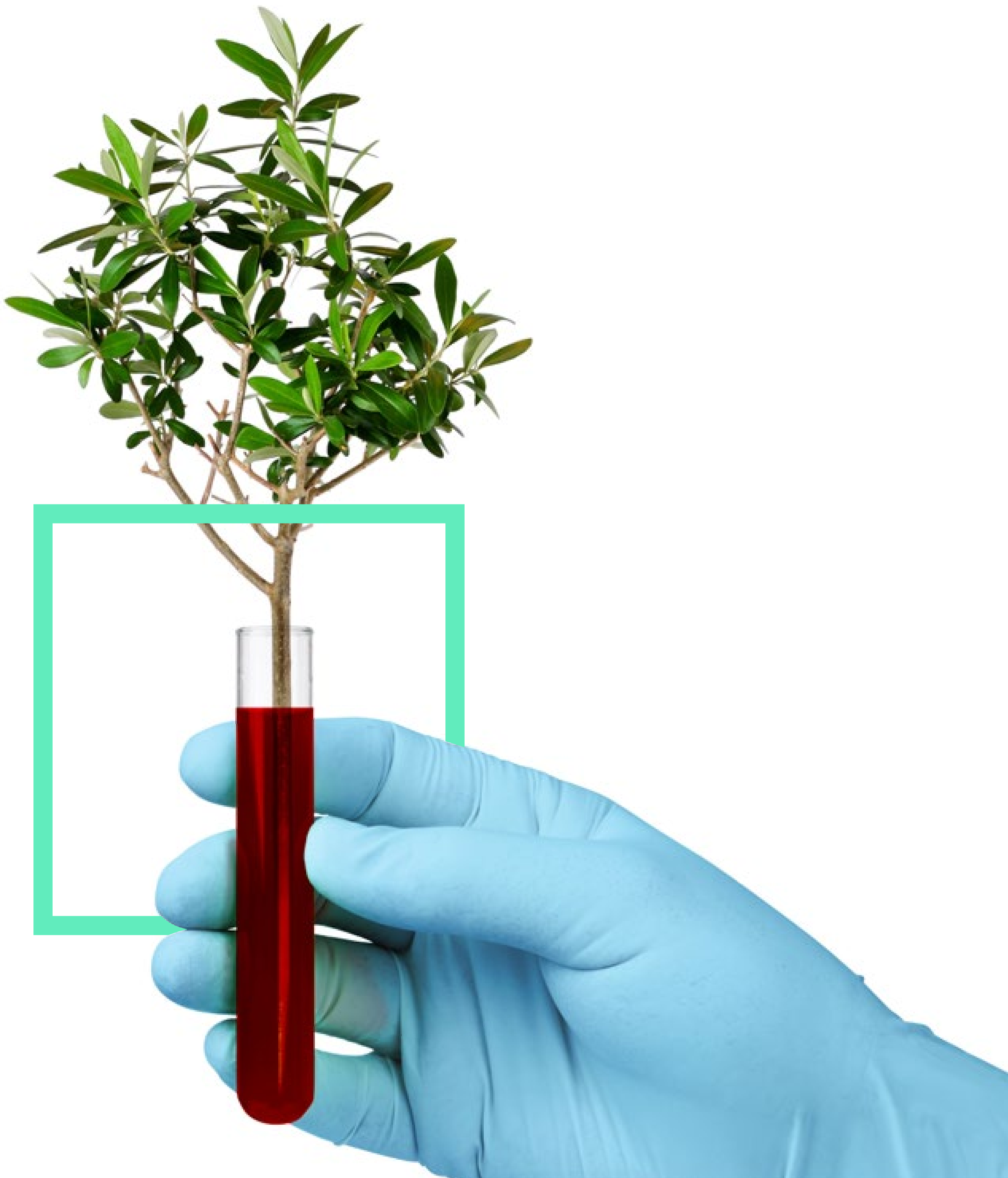

The environmental sustainability of healthcare systems is under scrutiny, and medtech products developed with this in mind will likely be viewed favourably by healthcare buyers. There is also much to be gained from joined-up environmental sustainability efforts between companies in healthcare supply chains. We believe diagnostic testing is ripe for innovation in this vein. Here, we consider how companies can get a head start, evolving existing R&D processes to deliver commercially viable outcomes.

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> When it comes to new product development processes, environmental sustainability is still less prominent than factors surrounding healthcare governance or accessibility.

As concerns surrounding environmental sustainability intensify, the accountability of healthcare systems is moving up the agenda. Many large corporates have made strong Environmental, Social, and Governance (ESG) statements or company pledges that refer to sustainability. Yet when it comes to new product development processes, environmental sustainability is still less prominent than factors surrounding healthcare governance or accessibility. Arguably, it is currently a 'nice to have' rather than a core feature of diagnostics design and development. But change is coming.

While clinical efficacy, patient safety and cost remain paramount, they increasingly need to be balanced with longer-term issues which threaten the planet and wider public health. This brings many implications, both strategic and practical. Sources vary, but it's generally acknowledged that healthcare accounts for more than 4% of global CO_2 emissions. The sector is also associated with high levels of water use and single-use plastics, as well as infectious and hazardous waste. Tackling these issues will require concerted effort and collaboration between companies and stakeholders throughout healthcare supply chains.

In this whitepaper, we focus on the diagnostic tests which inform 70-80% of healthcare decisions and account for a significant portion of the sector's waste and carbon footprint. We show how integrating sustainability considerations with existing R&D approaches can have a positive impact on environmental and commercial performance. Companies which work proactively to establish sustainable products and partnerships could enjoy early mover advantages and competitive differentiation.

Strategies for sustainability

Some industries have already made headway in sustainability, whereas the healthcare industry is currently lagging. This is understandable given the additional constraints necessary for medical products. However, the relatively late arrival to sustainability does have some advantages, such as the opportunity to leverage learnings from other sectors.

For instance, disparities between grandiose public statements on sustainability and the reality of practical implementation have tended to attract criticism in other industries. Companies have learnt that it's critical to align strategic intent with operational and R&D practice to avoid this disconnect. Meaningful gains can only be made when business leaders are invested in sustainability and R&D leaders are empowered to deliver it. Other learnings include the need to think about environmental sustainability holistically. A single-minded focus on one area – such as eradicating single-use plastic – can inadvertently create different or bigger problems elsewhere. Sustainability impact across multiple areas needs to be evaluated and appropriate trade-offs considered.

Improving environmental sustainability demands thorough interrogation of entire products and their supply chains. We need to normalise the inclusion of sustainable goals throughout the product lifecycle, making environmental sustainability as core to the commercial viability as the cost.

A Net Zero Playbook for R&D Leaders

Seven Chief Technology Officers from Fortune 500 companies collaborated with our parent company Science Group to produce a Net Zero Playbook. It outlines shared learnings from their sustainability-focused R&D efforts, such as the need to apply foresight, form tangible objectives, and normalise discussions about net zero alongside other technical and commercial considerations. The principles outlined in the playbook can be applied to environmental sustainability in the broadest sense as well as carbon reduction. Download a copy sustainability.sciencegroup.com/net-zero-playbook.

Stringent medical regulations governing patient safety have traditionally meant that sustainability is a secondary consideration, if considered at all. But voices like those of Jodi Sherman, MD, the associate professor of anaesthesiology at the Yale School of Medicine, are beginning to be heard. In 2019, she co-authored a 'green print' plan to improve healthcare sustainability, saying "We must act to reduce waste and prevent pollution — work that is crucial to protecting public health and improving patient safety, which is at the heart of everything we do." [1] She asserted that the narrow view where patient safety regulations are made in isolation without considering how they impact health systems and public health must change. As the medical sector starts to consider sustainability alongside patient safety, there are new commercial opportunities for companies that can strike an effective balance.

Foresight exercises, like those detailed in Figure 1, are a useful mechanism to identify priorities and categories for sustainable development. Considering wider business threats and opportunities related to environmental sustainability also brings a sense of urgency and relevance that might otherwise be lacking. Together, the four steps outlined in Figure 1 facilitate a pragmatic, systematic approach rooted in commercial need. They underpin a solid business case for investing in the creation of products which may require new ways of thinking. This is critical to win the hearts and minds of decision makers, investors, and business leaders.

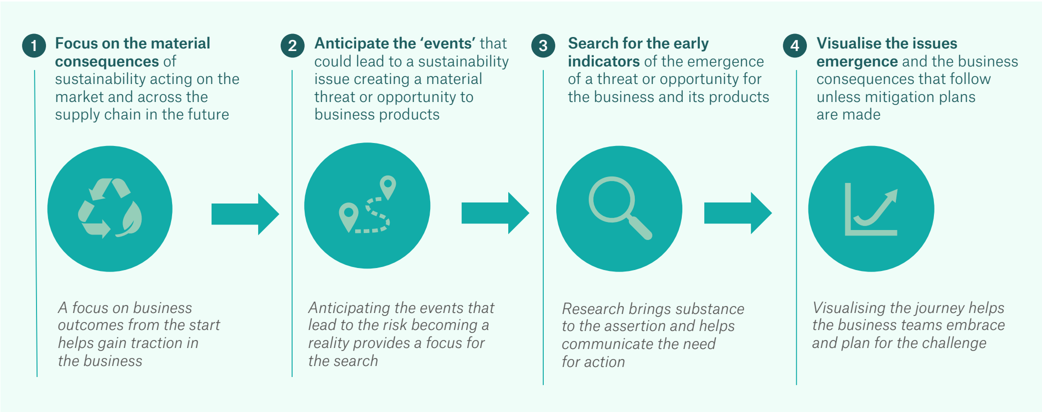
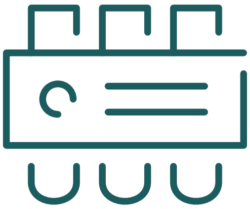


Figure 1: It's useful to anticipate the impact of sustainability concerns before developing solutions.

While sustainable innovation might require a different mindset, we don't believe it's necessary to re-invent the product development process to achieve environmental sustainability goals in parallel with clinical and commercial goals. Sustainability criteria can be incorporated into the requirements of existing systems engineering protocols, as a core aspect of viability.

Sustainable design and development raises complex issues and considerations which need to be acknowledged and addressed from the outset. Normalising the inclusion of sustainable goals throughout the product lifecycle is a critical step. We look at this from the perspective of laboratory diagnostic tests in the next section.

Sustainability in the diagnostic process



Demand for diagnostics is growing, with 14 billion tests currently performed in the US[2] and 630 million in England every year[3]. Diagnostic waste accounts for a tenth of all medical waste, and since much of it is infectious or hazardous, reuse and recycling are challenging. At present, cost and performance are the main considerations shaping the development of diagnostic devices. How can we make sustainability integral to the process without undue compromise of these factors?

The first step is to consider the full lifecycle of a laboratory diagnostic test, identifying environmental impacts at each stage. As Figure 2 indicates, the lifecycle is similar to that of many consumer products, although the hazardous and/or infectious nature of waste brings end of life complications. Disposal of sharps, patient specimens, contaminated equipment, and harmful chemicals needs to be handled with great care. Consequently, most diagnostic waste is incinerated, with 1g of waste generating up to 3g of CO_2. In fact, greenhouse gases are emitted at every stage of the diagnostic test lifecycle, so exploring ways to reduce these emissions is a good place to start.

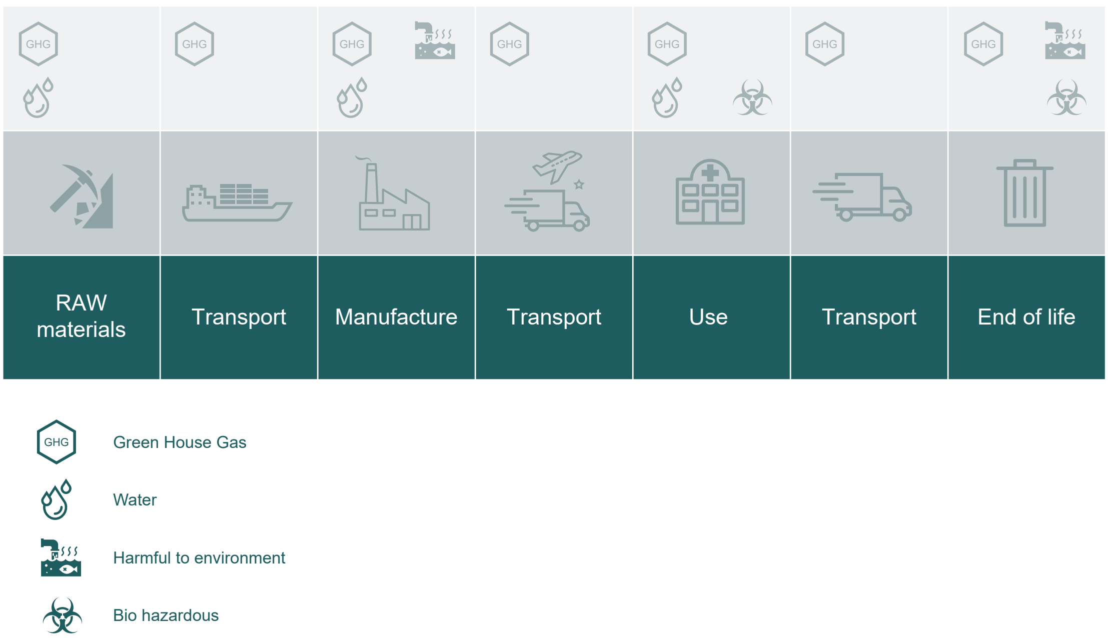


Figure 2: Lifecycle of a laboratory diagnostic test, and environmental impacts.

Innovating around blood testing

An Australian study published in 2020 set out to determine the carbon footprint of five common hospital pathology tests[4]. It determined that sample collection and phlebotomy dominated the overall carbon footprint, and although the CO_2 emissions per test were small, the volume performed meant the cumulative carbon footprint was significant. We've used the findings from this study as a platform to demonstrate how R&D efforts can be directed towards the reduction of CO_2 emissions.

Figure 3 shows the carbon dioxide equivalent (CO_2e) of key lifecycle elements of blood tests for a whole blood count and clinical chemistry. The figures from the original study have been adapted to include the incineration of hazardous waste, which is standard practice in the UK and many other markets.

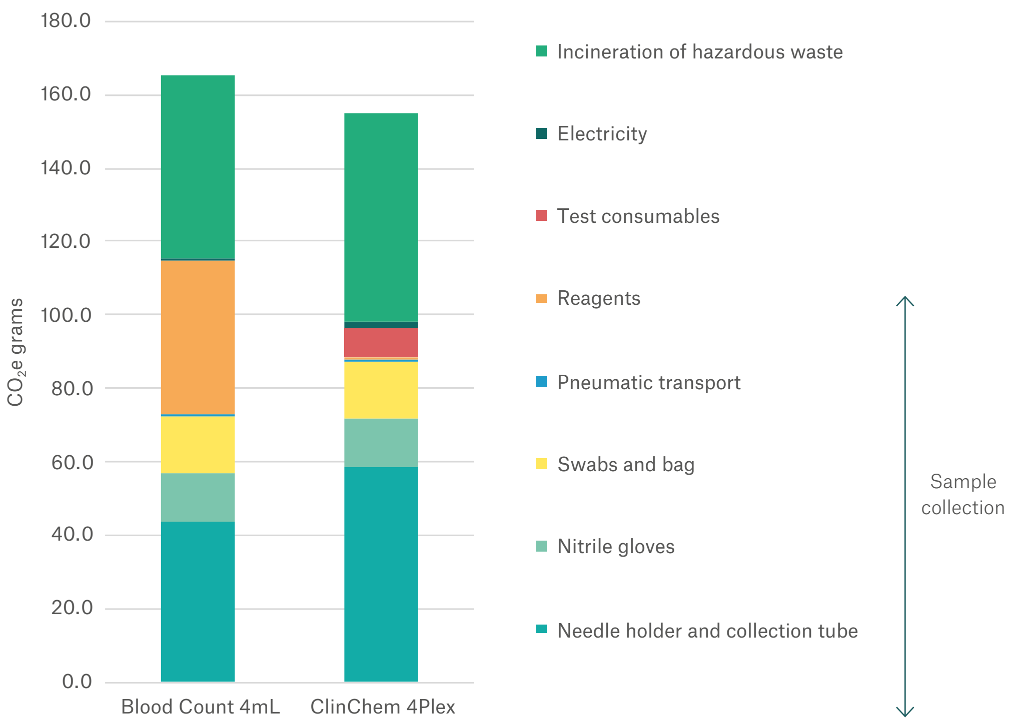


Figure 3: CO_2e breakdown of a whole blood count and a clinical chemistry blood test.[5]

An initial observation is that equipment used for sample collection accounts for around half of the overall CO_2e. Waste incineration represents a significant portion too. The CO_2e of the diagnostic process itself varies according to the test and the amount or type of reagent required. Based on these insights, we've identified four strategies to improve the sustainability posture of blood testing.

1. Collect less blood

In the main, blood tests involve a venous blood draw into vacutainer tubes. The volume collected is typically 4mL, yet many diagnostic tests only require a small portion of this – a complete blood count can be performed using 100μL. If the volume of blood collected was reduced to 500μL it would still be possible to perform multiple tests, but a smaller vacutainer could be used. As Figure 4 indicates, this would immediately reduce carbon emissions linked to 'needle holder and collection tube' and 'incineration of hazardous waste', effecting a 27% reduction in CO_2e for a whole blood count, and a 38% reduction for clinical chemistry. These wins could be taken further if the overall number of blood draws per patient was reduced, for instance by conducting multiplex testing on samples.

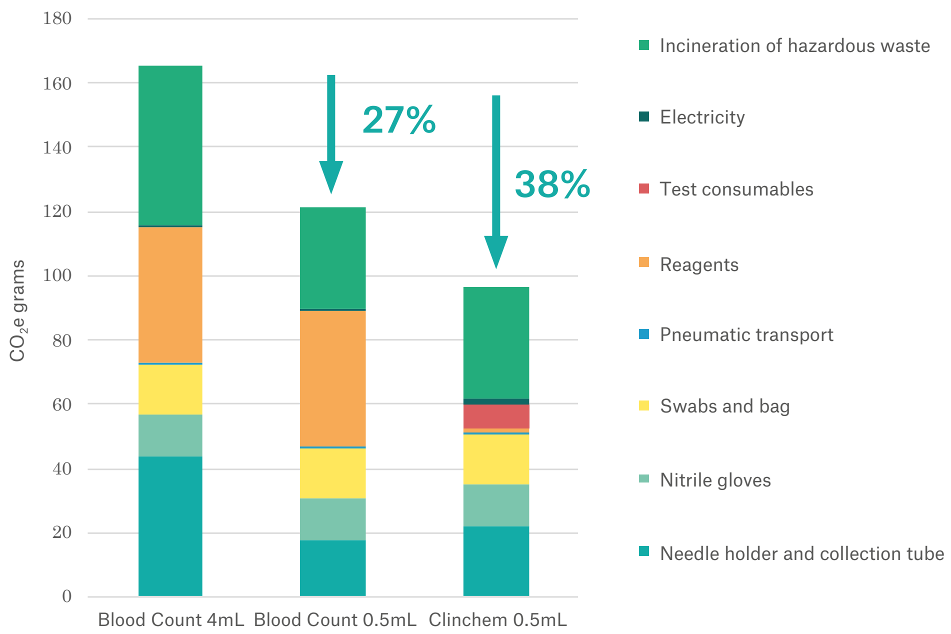
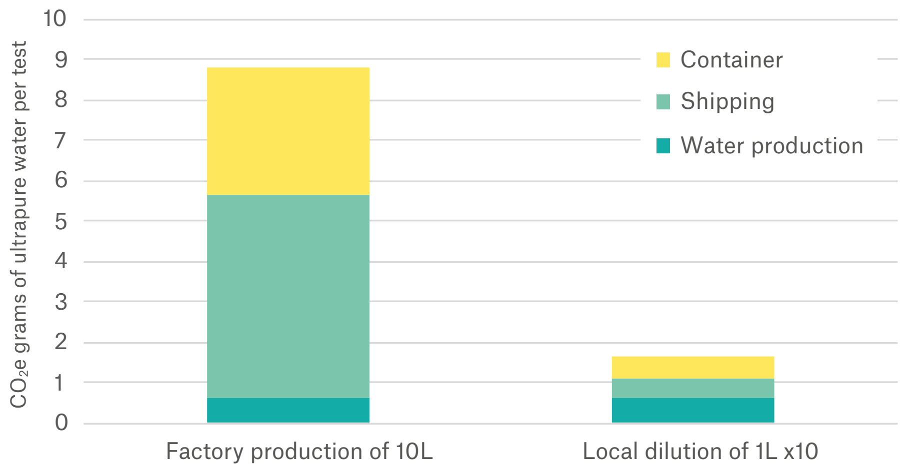


Figure 4: CO_2e reduction when blood collection volume is reduced from 4mL to 500μL. [5]

2. Focus on reagents

Manufacturing the reagents that play a critical role in many blood tests is expensive, and production must be closely monitored for quality control and consistency. Vendors tend to produce reagents centrally and distribute them globally, which makes a notable contribution to the CO_2e of diagnostic tests which require them. According to the Australian study, reagents used in a whole blood count test account for around a third of the total CO_2e.

A large portion of reagents is ultrapure water, so the use of concentrated formulations for reconstitution in the laboratory could cut the carbon emissions linked to transportation. As Figure 5 shows, a x10 concentrate shipped via sea from Singapore to Australia would deliver a 4.5x CO_2e reduction. It's true that dilution at point of use would add a new burden of responsibility to pathologists and introduce a potential failure point. However, this could be addressed via the introduction of an automated process.



Sea shipping from Singapore to Australia in 10L & 1L containers
Ireland to Maine USA is similar.

Figure 5: CO_2e profile for factory production of reagent vs local dilution of an equivalent factory-produced concentrate. [5]

Another avenue worth exploring is reducing the amount of reagent used. If lab instruments were adapted or redesigned to operate with smaller volumes of blood, it would result in a corresponding reduction in the amount of reagent required. At present, lab instruments typically require 100μL of blood per test while point of care technologies only need 5-30μL. On this basis, if we assume that 25μL of reagent diluent is used for 100μL of blood, the amount currently used to perform one test could be used for eight tests (see Figure 6).

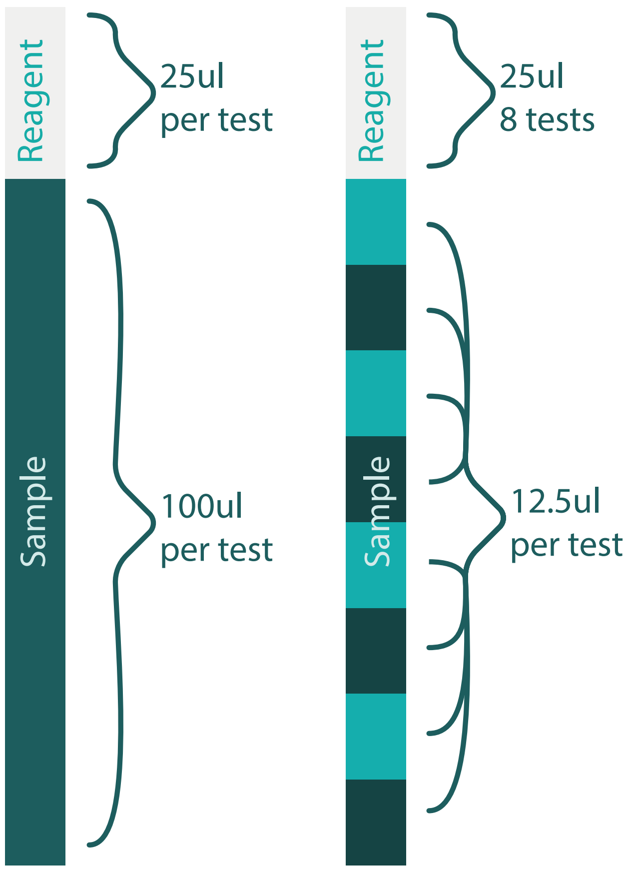


Figure 6: Performing tests on smaller volumes of blood means reagents go further.

3. Consider self-collection

Swapping the venous blood collected by a phlebotomist for patients' self-collected capillary blood could also offer carbon reduction benefits. Self-collection would negate the need for PPE which is identified as a significant CO_2e element in Figure 3 (nitrile gloves). This approach may also reduce the need for patient/phlebotomist journeys, bringing further carbon savings.

Devices for the self-collection of blood on market at present haven't been designed with sustainability in mind. However, there is scope for innovation focused on optimising the materials used, reducing the portion wetted by blood, and making devices safer to dismantle.

4. Improve recovery of device components

Reducing the volume of blood collected has the potential to reduce CO_2e quite significantly, but further improvements could be made if more components used in sample collection devices could be reused or recycled. At present, all components enter a single waste stream destined for incineration. However, an automated system for the separation and disinfection of waste could allow some of the plastics to be recovered. As Figure 7 illustrates, use of well-characterised plastics could allow non-biological waste from laboratories to be disinfected, separated, and channelled into commercial recycling streams. As with the dilution of reagents, this could be facilitated with automation and high throughput analysers.

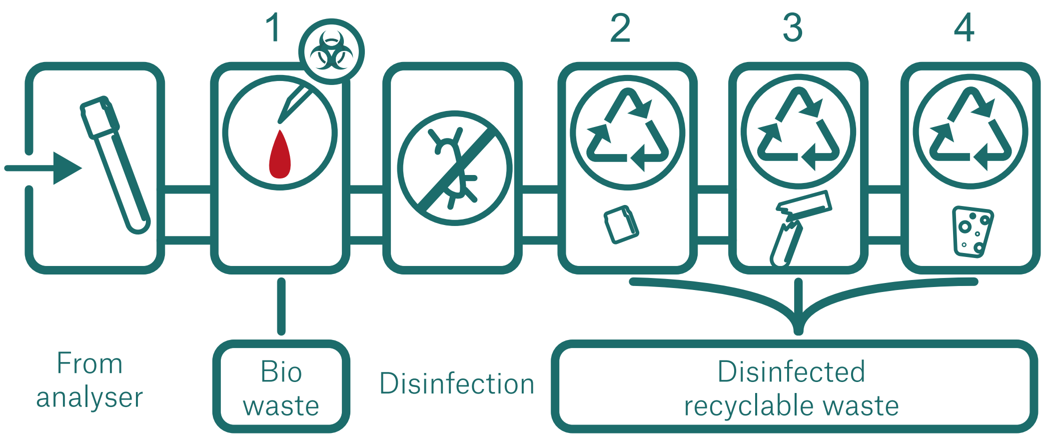


Figure 7: Designing self-collection devices with sustainability in mind could enable the recycling of plastic components.

Beyond carbon reduction

Together, the four approaches outlined above could reduce the CO_2e of blood tests by around 50%. It's not going to solve the climate crisis, especially given the fact that more diagnostic tests are being performed every year. Nevertheless, this example shows how applying a sustainable mindset to the lifecycle of a key medical process can yield fertile ground for innovation. It focuses R&D team efforts as they apply a new lens to existing processes. This can stimulate the development of approaches that create a positive ripple effect extending far beyond sustainability. For instance, collecting a smaller volume of blood is beneficial for very ill or infant patients, and self-collection can be less painful as well as resulting in lower staff burden. Smaller volumes also enable more tests to be performed per square foot of lab space and reduce the cost per test. Finally, cutting down on the amount of reagent used results in lower levels of hazardous chemicals entering waste streams.

Sustainable design makes business sense

Sustainability is no longer a 'nice to have'. Making it a core design feature is a prudent and commercially-sound decision that aligns with the likely evolution of market and regulatory trends. The approaches outlined here are technically feasible. Given the complexity of healthcare systems, bringing approaches like this to life will require industry partnerships or vertical integration strategies. Likeminded companies that understand and align with the need for environmental sustainability have opportunities to collaborate to win market share, derive cost savings, and deliver benefits for individual patients and wider public health.

Foresight-driven R&D combined with lifecycle analysis could reveal opportunities for commercially viable sustainable development in other areas of diagnostics and indeed other aspects of healthcare. Integrating sustainability with existing R&D processes can make a material and cost-effective difference. The potential outcomes are appealing to patients, healthcare leaders, and investors alike. Early movers have much to gain.

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