



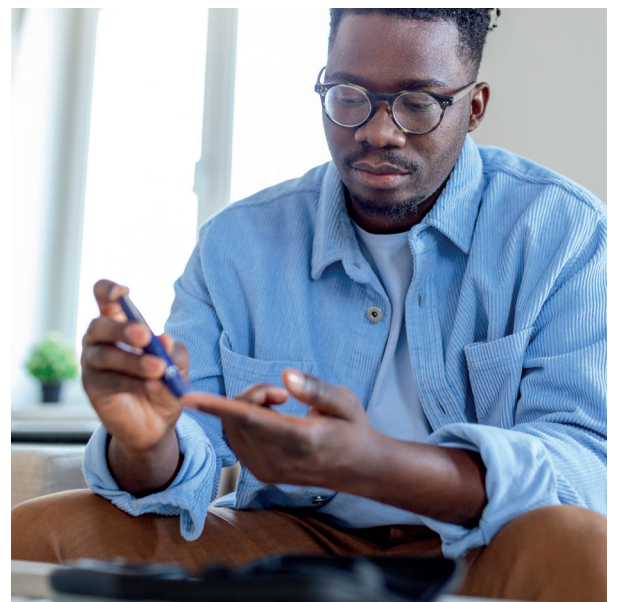
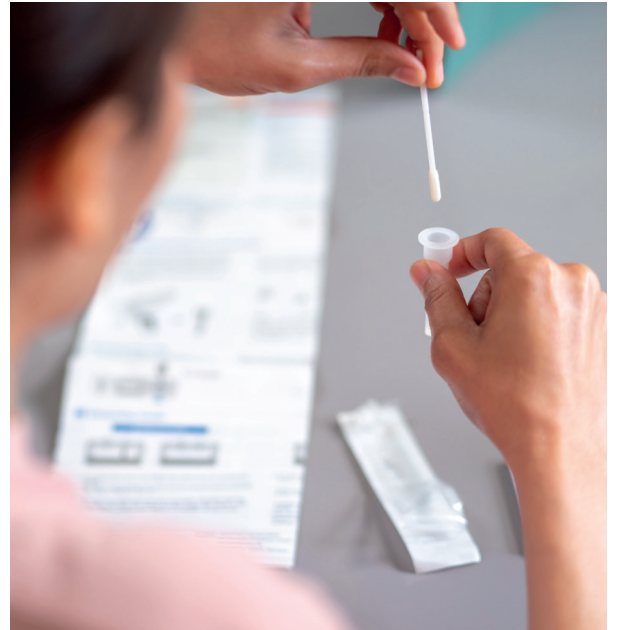
The Technology Partnership
The space to invent.

September 2022

A new era in point-of-care diagnostic testing:

possibilities and practicalities

A TTP report based on a survey of
emergency healthcare professionals



Healthcare systems are under pressure from a multiplicity of sometimes confounding factors, such as increasing backlogs created by the COVID-19 pandemic, staff shortages, changing population demographics, rising prevalence of chronic diseases and spread of infectious diseases.¹⁻⁷

This pressure is further exacerbated by challenges in triaging patients with acute presentations in a timely manner, whether in an emergency department (ED), en route to the ED or in a primary care doctor's clinic, due to a lack of certainty regarding diagnosis or assessment of severity. For the situation to improve, there needs to be a rethinking of the approach to healthcare management and practices, including how broader use of *in vitro* diagnostic point-of-care (IVD POC) testing could help to better inform treatment decision making in the acute setting.

POC assays, such as blood glucose monitoring and urine leucocyte tests, have seen increased use in the healthcare and community settings in recent decades. With their ease of use and quick turnaround time, POC diagnostic tests offer some notable benefits for use in the acute setting compared with central laboratory tests.⁹ The COVID-19 pandemic, leading to the use of lateral flow assays on a mass scale, has also notably underscored the utility and value of POC tests in speeding up the triaging of patients presenting at hospitals, as well as helping to limit the spread of the disease in the community.⁹

To better understand the potential benefits to healthcare systems of the increased adoption of POC testing, TTP commissioned a survey of UK and US ED-based healthcare professionals (HCPs), specifically doctors, nurses and paramedics. This report presents the survey's key findings and examines the opportunities and important considerations for IVD POC testing in the United Kingdom and the United States – within the ED as well as the wider community setting.

Key findings from the survey of emergency department HCPs

- The high level of acceptance of POC testing by HCPs and the general population during the COVID-19 pandemic has paved the way for increased use of these tests in the emergency care setting, with approximately half of the surveyed HCPs agreeing that COVID-19 POC testing greatly alleviated pressure on the healthcare system
- A large majority of the respondents (90%) believed that POC testing was particularly well suited to EDs due to its ability to provide rapid diagnostic results and expedite triage
- There was a strong consensus in wanting more POC testing to be performed in settings other than secondary care, such as primary care (98%), long-term care homes (90%) and ambulances (93%), with 86% in favour of patients receiving POC testing prior to ED admission as a means of alleviating the strain on hospitals
- Septicaemia, infectious diseases and respiratory infections were identified as the leading conditions that would benefit the most from more advanced or greater use of POC testing; however, testing to evaluate acute presentations of more chronic conditions, such as heart disease (43%) and diabetes (35%), was also considered to be vital
- The speed in obtaining results was widely viewed as the leading advantage of POC testing; however, HCPs were concerned about the accuracy of results from such tests and the diversion of ED staff time from patient care as a result of administering them. They also saw the inability of POC assays to test for more than one marker or condition at a time as a disadvantage
- The survey underscored widespread desire for more education and training in POC tests, including for a wider variety of HCPs in line with their increased use to address the lack of experience with these assays among practitioners in some disciplines
- POC test devices have historically been hand-held, providing results rapidly. There is a growing need for them to offer increased functionality, form part of a distributed network and be more available across a wider range of healthcare settings, including ED, primary care clinics, care homes, pharmacies and homes

Abbreviations

COVID-19	coronavirus disease 2019
ED	emergency department
HCP	healthcare professional
HIV	human immunodeficiency virus
IVD	<i>in vitro</i> diagnostic
POC	point-of-care

Increasing use and patient acceptance of IVD testing in healthcare

IVD testing is increasingly playing a key role in guiding healthcare decision making, and COVID-19 has accelerated its adoption into routine practice

IVDs, encompassing a vast range of tools and procedures, play a crucial role in guiding healthcare treatment decisions to prevent or change the course of disease in a patient.¹⁰ IVD tests inform up to 66% of clinical decisions, yet these diverse technologies together account for only about 2% of total healthcare expenditures in Europe and the United States.¹¹ The relatively low cost burden of IVD testing compared with other segments of the health value chain, such as pharmaceutical interventions and medical aids,¹¹ shows there is scope for IVDs to play an expanded role as a cost-effective tool in enhancing medical decision making and treatment outcomes.

The adoption of IVD POC tests by healthcare systems and consumers has been steadily increasing in recent decades. The growing number of POC tests spans a wide array of markers and conditions, from blood glucose, haemoglobin and urine leucocytes to complete blood counts, influenza and HIV.¹²

COVID-19 has increased awareness and acceptance of the potential of IVD POC testing

The COVID-19 pandemic has brought to the fore the power of near-patient or POC testing to slow the spread of infectious diseases and improve overall population health outcomes.^{9,13} Throughout the pandemic, rapid-detection POC tests have been ubiquitous within both hospital and community settings. Such testing has been vital in reducing viral transmission and critical for identifying pre-/asymptomatic cases, otherwise considered to be the “Achilles’ heel” of pandemic control.^{14,15} This experience suggests POC testing has the potential to have a vital and expanded role in the current healthcare environment, where reimbursement and regulatory requirements have driven the shift from reactive, episodic and volume-based care to preventive, coordinated and value-based care.^{13,16}



IVD POC testing offers notable practical advantages over central laboratory analysis

POC assays offer practical advantages compared with IVD laboratory testing, which requires biological samples to be collected and shipped to central laboratories and, combined with the time needed to perform the analysis, results in a delay in obtaining results. In contrast, POC tests require small biological samples, analysis is performed on smaller instruments near the patient, results are returned faster and interpretation is simpler.¹⁷ These practical benefits of POC tests have led to their routine use in hospitals and increased adoption in a variety of healthcare settings across the United Kingdom and the United States.^{13,18} The widespread use and acceptance of POC testing during the COVID-19 pandemic adds further weight to its potential for improving health outcomes and healthcare efficiency on a mass scale.

Significant pressures facing EDs are impacting patient care

Overcrowding in EDs is one of the leading problems facing physicians, nurses and patients that undermines the timely delivery of care.¹⁹ Besides contributing to the strains faced by time-constrained staff who are under pressure to conduct rapid triage, high patient volumes can also impair patient dignity and privacy, and completeness of care. Overcrowding can create additional problems upstream and downstream from the ED itself, from ambulance crews being unable to unload patients to inpatient hospital services being overwhelmed.¹⁹

In addition to overcrowding, an array of pressures are placing healthcare systems, especially secondary care, under increasing strain. These include backlogs of cases caused by the COVID-19 pandemic, staff shortages, changing population demographics, the growing prevalence of chronic conditions and the spread of infectious diseases.¹⁻⁷ As a result, there is now growing impetus to re-examine healthcare management and practices.



Survey findings revealed significant opportunities for IVD POC testing, and highlighted key lessons for manufacturers

Our interest in examining the connection between POC testing and improved patient triaging led us to commission a survey of ED HCPs (doctors, nurses and paramedics) in the United Kingdom and United States. The aim of the survey, conducted in the first quarter of 2022, was to better understand the use of POC testing in the emergency care setting, the impact of COVID-19 on the value of IVD testing, the current behaviour

and views of HCPs regarding the use of such tests for patient triage, and the potential for wider adoption outside of the hospital.

ED-based HCPs were selected for the survey because the emergency care setting represents a key area in which rapid diagnosis and treatment decision making is critical for optimal patient outcomes.

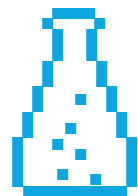
The high level of acceptance of POC testing by HCPs as well as the general population during the COVID-19 pandemic has forged the path for increased use of these tests in the emergency care setting

Half of the surveyed HCPs (51%) agreed that COVID-19 POC testing greatly alleviated pressure on the healthcare system, with 49% agreeing that testing prevented hospitals from becoming even more overwhelmed during the pandemic. Nearly 80% viewed COVID-19 POC tests as reliable and agreed that IVDs had the potential to alleviate the pressures on hospitals by easing the strain on EDs.

Survey respondents



207 HCPs (doctors, nurses and paramedics) across the UK [n=100] and the US [n=107].



All 207 HCPs had been involved with POC and/or lab-centred IVD testing at some level in their roles.

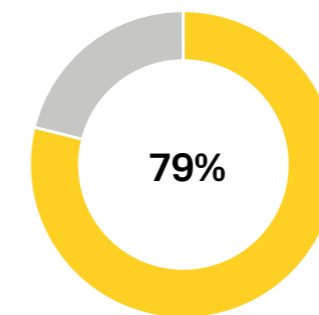


Most respondents had been practicing in emergency medicine for at least 6 years with a third with 20+ years' experience.

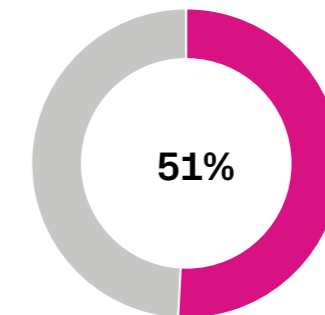


% of HCPs agreeing with statement

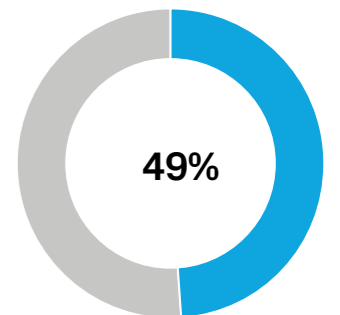
IVDs have the potential to alleviate pressures on the healthcare system



COVID-19 POC testing greatly alleviated pressure on the healthcare system



COVID-19 POC testing prevented the healthcare system from becoming even more overwhelmed during the pandemic



Greater use of POC testing before patients arrive at the hospital could expedite patient triaging and potentially alleviate the growing pressures on healthcare systems

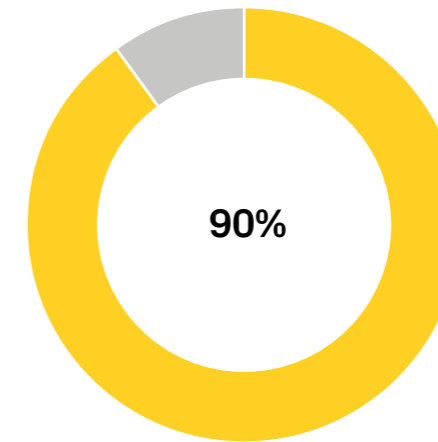
A large majority of the surveyed HCPs (90%) agreed that POC testing was particularly well suited to the ED due to its ability to provide rapid confirmation of diagnoses, thus allowing for faster triage and treatment initiation and reduced patient wait times. Up to 86% favoured POC testing being administered before patients arrived at the ED, with 71% believing that such testing should be performed at home before patients go to the hospital.

“POC tests are always useful – even if not as reliable as lab tests, in an ED setting they can give an important indication.”

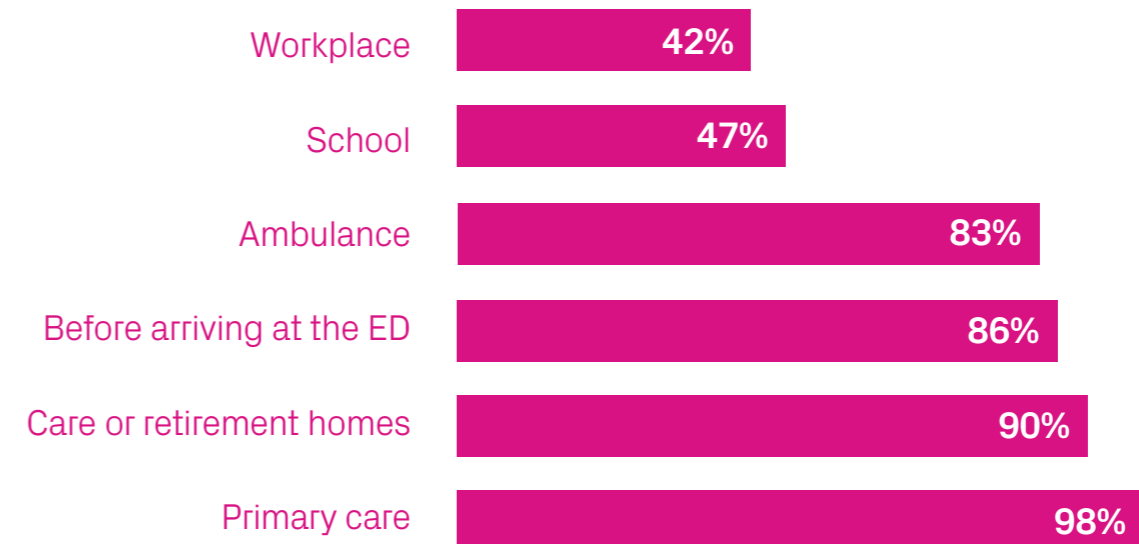
- UK nurse

Moreover, a large majority supported more POC testing being performed in settings outside of secondary care, such as primary care, long-term care homes and ambulances – and to a lesser extent in other settings such as schools (47%) and the workplace (42%). The widened scope of POC testing outside secondary care was viewed as having the potential to reduce the pressure on EDs as well as improve the way in which emergency medicine is administered.

% of HCPs agreeing that POC testing is particularly well suited to the ED



Settings other than the ED in which POC testing should be performed (% of HCPs)



These findings support published evidence showing reduced diagnostic testing turnaround times leading to quicker triaging and enhanced ED throughput.²⁰ In addition, greater availability of user-friendly and clinically valid POC testing in community settings would be in line with recent trends in healthcare consumerism, with patients increasingly wanting to play an active role in their health management.¹³

“As long as they are accurate and reliable, POC testing is very beneficial, especially in the emergency setting.”

- US doctor

Use of POC testing for a broader range of markers and conditions may enable earlier detection of more diseases

As many as 85% of the surveyed HCPs favoured greater use of POC testing for a wider range of illnesses. Septicaemia (49%), infectious diseases (45%) and respiratory infections (43%) were identified as the leading conditions for which POC testing would improve diagnostic and treatment decisions. POC testing to assess acute

presentations of chronic conditions such as heart disease (43%) and diabetes (35%) was also regarded as vital. The early diagnosis of viral and bacterial infections offered by POC testing is also critical for mitigating the spread of nosocomial infections in wards and communities.^{21,22}

Conditions with the greatest perceived need for more advanced or wider use of POC testing (% of HCPs)



Expanded use of POC testing by a wider range of HCPs across more conditions requires the development and delivery of high-quality training

Approximately two thirds of the respondents (65%) agreed they would benefit from more training on the interpretation of results, innovation in the IVD testing field (64%) and awareness of different IVD tests available for use (60%). A large majority of them (83%) believed that a wider variety of HCPs should be trained to deliver POC tests in order to alleviate pressure on individual team members and challenges with them being rate limiters for decision making.

“Sepsis markers – for the emergency department it would be nice to rapidly get these markers, such as lactic acid, as we see so many septic patients.”

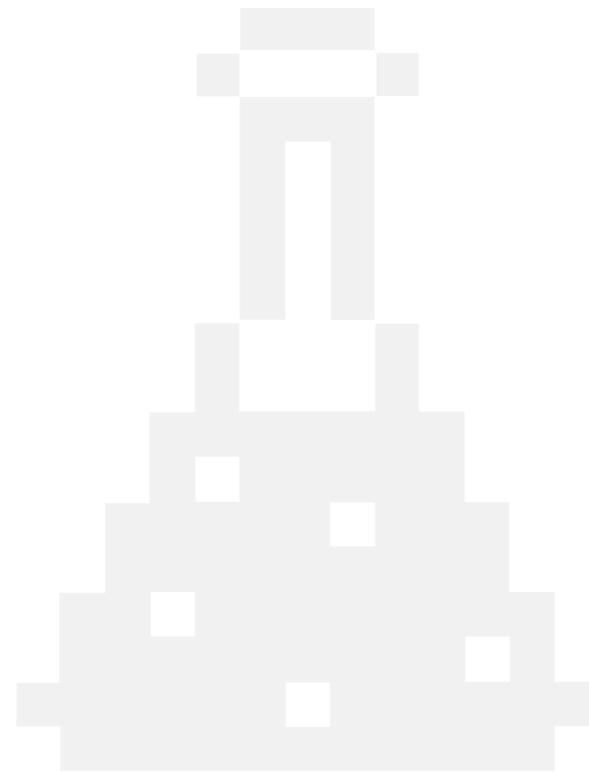
- US nurse

These findings underscore the need for comprehensive training, education and guidelines to accompany any expansion of POC test use – whether in the secondary care or community setting. A robust clinical governance framework would be of paramount importance to ensure systems and processes are in place to monitor and improve testing services, and that testing conforms to acceptable analytical and clinical standards.^{23,24}

While greater use of POC testing has the potential to improve outcomes, the accuracy of results and demands on ED staff time are key concerns

The survey highlighted that, although the speed of obtaining the results was seen as a clear benefit of POC testing, there needs to be a high degree of confidence in the findings to overcome the potentially increased burden on ED staff.

While 87% of the surveyed HCPs thought the delay in receiving results was the main disadvantage of central laboratory testing, 93% of them had a high degree of confidence in those results once they were obtained. By contrast, 59% of them pointed to the limited accuracy of results as a disadvantage of POC testing, with just over half (53%) citing human error during the administration of POC tests as the main accuracy-limiting factor.





“If any test can be both accurate and reproducible, I see no reason it cannot be performed POC. The main issue would be operational – an increased data entry role for bedside nurses/techs.”

- US doctor



According to the survey respondents, another notable limitation of POC assays was their ability to test for only one marker or condition at a time, with 78% of respondents considering central laboratory testing’s multi-analyte capability as a major advantage. A further concern was around the impact of POC testing on ED staff time (37% agreeing that these tests

were potentially time- and/or labour-intensive), which might be diverted from patient care. The final challenge raised was associated with the perceived difficulty around the administration of tests, with more than half of the surveyed HCPs (54%) believing they would be more encouraged to use POC assays if the testing procedure was less complex.



Perceived advantages of POC testing

-  Speed of obtaining test results **(90%)**
-  Wide variety of medical professionals can conduct testing **(83%)**

Perceived disadvantages of POC testing

-  Potentially reduced accuracy of test results **(59%)**
-  Only able to test for one marker or analyte at a time; reduced time for patient care **(30%)**

Perceived advantages of central laboratory testing

-  Confidence in the test results **(80%)**
-  Multiple tests simultaneously **(78%)**

Perceived disadvantages of central laboratory testing

-  Time lags before results are obtained **(87%)**
-  Does not help mitigate spread of certain diseases in the hospitals **(80%)**

Opportunities and important considerations for manufacturers: what can be done to reduce the barriers to increased uptake of POC tests?

The survey brought into sharper focus several key learnings relating to POC testing. It underscored the need for wider adoption of POC testing in community settings to alleviate the strain on hospitals, enabling triaging to be expedited – effectively initiated before a patient arrives in the ED.

There is also a high level of support for POC tests to be performed by a wider range of HCPs outside of the ED, and for those colleagues to receive training on the use of these tests, and education on test benefits. Furthermore, the survey revealed a strong demand for POC tests to cover a wider range of illnesses, with multi-analyte capability, allowing a single device to test for multiple conditions simultaneously, seen as an advantage.

Specific recommendations for POC device manufacturers

Many of the challenges identified by the survey respondents are already being actively addressed by POC instrument manufacturers and are worth repeating here:

- Develop tests for a wider range of targets and conditions
- Improve simplicity of use and address concerns regarding the accuracy and reliability of tests, including reducing subjectivity in analysis and the potential for human error
 - It should be noted that POC assays already have a high degree of accuracy and reliability. Users' perceptions around the accuracy and reliability of these tests represent an important area that needs to be addressed through better education
 - We also note that POC instruments are already in development that improve human factors, thereby decreasing the potential for human error and increasing test reliability, as well as provide laboratory-quality results

- Develop multi-analyte assays so that a single device can test for more than one condition simultaneously
 - The limited availability of space to house multiple devices, and increased efficiency of testing for multiple conditions at a time, make multi-analyte capability a major benefit
 - That said, this issue is already being addressed by POC device manufacturers with the current development of multi-panel POC assays
- Provide better training and guidance for device users and more education about these tests; increased proficiency in their use and understanding of their benefits is crucial to driving IVD POC adoption by HCPs
- Develop POC instruments that can seamlessly integrate with current patient management systems, thereby reducing the need for manual data entry
 - For example, the direct interfacing of POC devices with patients' electronic medical records allows test results to be compiled quickly into one record
- Collaborate with HCPs and policy makers to identify which test features are of the greatest value and align on ways to integrate POC technologies efficiently into current systems
- Generate robust evidence of the clinical utility and value of new POC technologies to healthcare systems in order to ensure favourable coverage and reimbursement decisions



TTP: Accelerating innovation to bring ideas to life

Healthcare systems are rapidly moving towards preventive, coordinated and value-based care. Healthcare is also moving from hospital to clinic to home, with treatment, diagnosis and monitoring becoming decentralised and playing equally important roles in healthcare delivery.

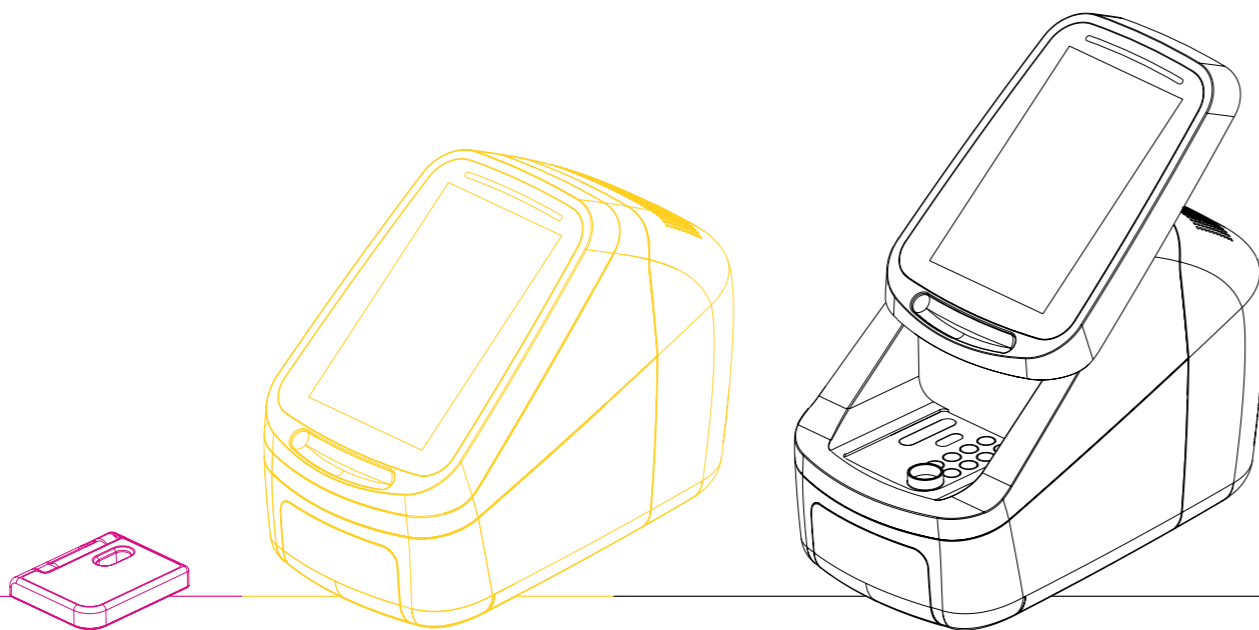
In this changing paradigm, rapid high-quality diagnostic tools are as essential as high-quality treatment.

Over the last few years at TTP, our focus has been on helping our clients develop the very type of systems identified as key for future POC testing device success. These are devices that integrate laboratory-quality processes – such as sample preparation and assay read-out – with software that can seamlessly connect with healthcare information systems, all contained within a small footprint and offering simplicity of use, whilst providing central laboratory-quality results.

Time to market is a key success driver in diagnostics. Along with expertise in diagnostics, TTP has pioneered approaches and platforms that accelerate the development of new products and technologies. At TTP, we partner with our clients and harness our strongest asset – our talented teams of scientists, engineers and designers – to bring ideas to life and deliver solutions. The opportunities and rewards are tremendous.

To get in touch

We would love to hear from you. You can get in contact by calling **+44 1763 262626** or by emailing us at **diagnostics@ttp.com**



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