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British In Vitro Diagnostics Association

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UK Medical Devices Landscape; Opportunities and Challenges.

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Joined BIVDA in June 2020, the national industry association for manufacturers and distributors of IVDs, representing over 230 companies.

Previously at Abbott Diagnostics for 11 years leading the Managed Service Contracting in the UK & Contracts and Pricing in Region North & Russia.

Senior procurement roles at NHS Blood & Transplant, NHS PASA and NHS Surrey & Sussex.

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WHO WE ARE

BIVDA (The IVD technologies industry body) is the go-to organisation supporting members and key stakeholders to provide cost-effective patient outcomes using IVD technologies and innovation to transform patient pathways.

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THE VOICE

Our members come from a highly active and competitive UK IVD Sector with products, equipment, tests, and quality pre-analytical consumables available within robust, highly regulated supply chains.

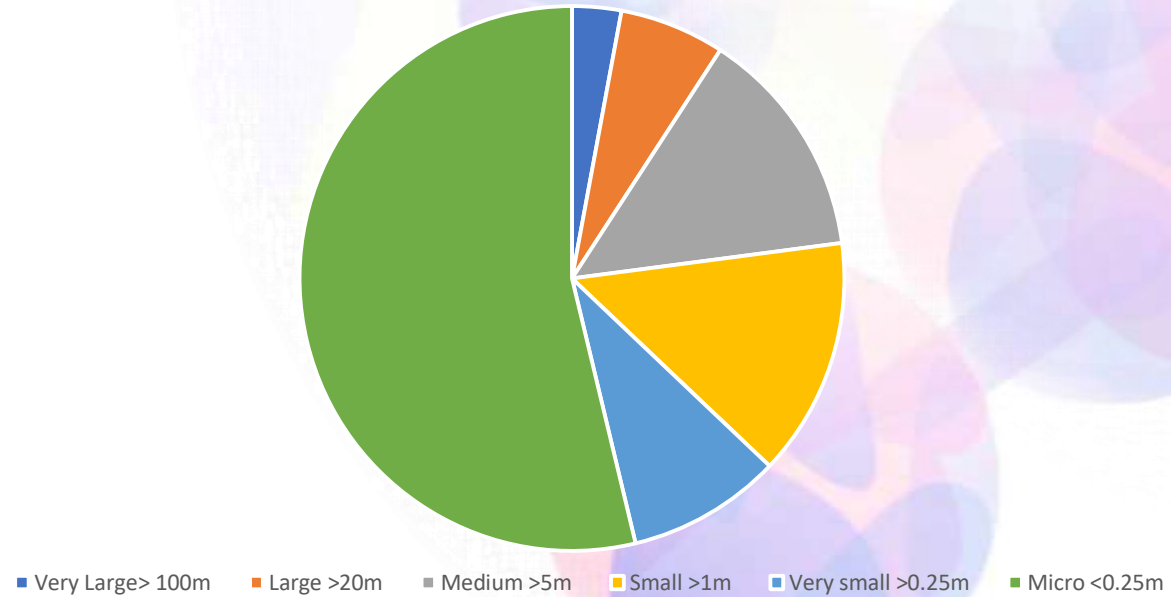
>97% of UK IVD Suppliers are members.

>9,600 people employed across the industry.

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THE VOICE OF THE INDUSTRY

Membership Segmentation





UK IVD MARKET VALUE UK 2023

- According to the recent market audit conducted by BIVDA¹, the U.K. IVD market is approximately £1.2 billion.
- When considering the market on a global scale, the in vitro diagnostics (IVD) market has been estimated to be worth approximately \$91.2 billion U.S. dollars²

1. www.BIVDA.org.uk

2. Next Move Strategy Consulting – Market Research report. <https://www.nextmsc.com/report/in-vitro-diagnostics-ivd-market> Accessed August 2023

POC TESTING MARKET VALUE UK 2023

Global **POC** market, c. \$38.5bn.
50% USA & 50% Rest of World.
Europe c.\$9bn.
UK 1/5 of that = \$1.6bn, or £1bn.*

European stats are very approximate making the UK about £500m.*

The BIVDA market audit gives a figure around £300m, but certainly with a significant amount missing due to non-participants, which will be particularly high in POC testing*

The UK market value for POC testing in 2022 is estimated to be £500m p.a. including glucose self-testing. Substantial growth occurred during the pandemic, including major bulk purchases directly by government, but this level has now returned to 'normal'. *



UK IVD 2020

The UK diagnostics industry had to move quickly to respond to the testing strategies proposed by the UK government, to meet the COVID-19 needs, whilst also maintaining the provision of tests for wider services - this was an extremely challenging time for the industry.

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UK IVD 2023

The pandemic brought point of care testing (POCT) into the spotlight and increased the public awareness that diagnostic tests could be available to be able to test, diagnose and potentially guide treatment for a disease or condition.

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UK LANDSCAPE 2023

The pandemic has provided a chance to consider more closely the potential applications across a wider range of health conditions from acute care conditions like respiratory health (e.g., Flu, RSV), urinary tract infections to longer term monitoring in conditions like diabetes monitoring, and heart failure.

EXAMPLES

Case study 1. Community pathway to rapidly test and treat flu

In the U.K, Roche performed a case study as part of a pathway evaluation project between Innovation Agency, the Academic Health Science Network (AHSN) for the North-West Coast. The case study looked at the use of point of care testing in a community pathway to rapidly test and treat flu.

The purpose of the project was pathway service evaluation aiming to demonstrate whether using rapid diagnostics to diagnose Flu A/B and SARS-CoV-2 alongside digital reporting in the community could improve patient outcomes, reduce the need for hospitalisations and therefore reduce the burden on secondary care, whilst identifying any further system benefits. The project demonstrated that a community flu test and treat pathway, including rapid diagnostics, digital development and connectivity, can be successfully established, implemented and replicated across multiple locations, with the critical factors being cooperation and collaboration from all partners involved. www.roche.co.uk

Case study 2. Group A Streptococcal Infections in the U.K

In late 2022, General Practitioners in the U.K were put on alert when the UK Health and Security Agency confirmed cases of invasive group A Streptococcal infection causing deaths in children. The outbreak highlighted the need for accurate and prompt diagnosis of throat infections, to allow patients to be correctly managed. A positive diagnosis would mean an isolation period away from school or work to prevent further spread, and antibiotics for those that required them. The shortage of antibiotics during this time in 2022, led to further problems and panic. The use of an accurate point of care test to detect Strep A in those patients displaying symptoms had the potential to significantly improve clinical diagnosis and reduce unnecessary antibiotic prescriptions.

More info can be found here: [British Journal of General Practice 2023](#) ¹³

Case study 3. COVID Neutralising Antibodies in a care home setting

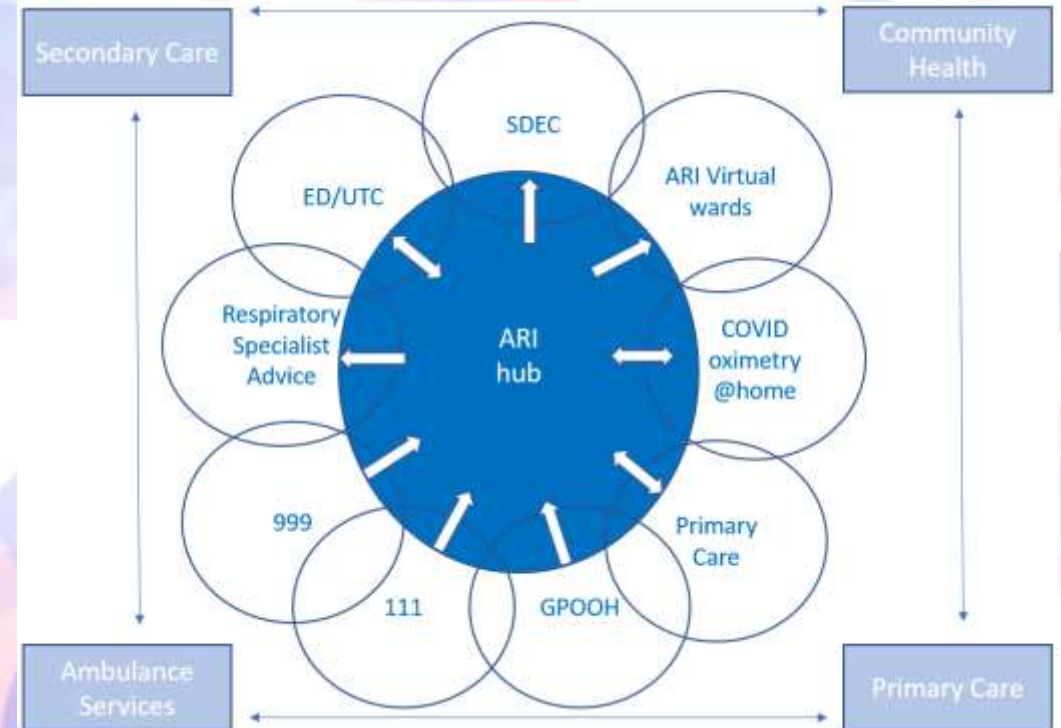
The Covid-19 pandemic placed a huge amount of pressure on frontline staff looking after vulnerable patients and care homes were at the forefront of this due to SARS-CoV-2 infection and Covid disease being particularly severe for individuals >65 years old. Ensuring that staff who work in these homes remain protected and supported against COVID is of paramount importance. This case study looked to learn more about the COVID immunity of staff in care homes, by using a point of care COVID antibody test. Data from this study has provided a better understanding of immunity to SARS-CoV-2 and is a way to help both staff, residents and their families feel supported in a care home setting by using point of care testing.

More info can be found here: [PremaLabs](#)

[Diagnostics website.](#) ¹⁶

- Support local systems to manage ARI demand over winter by providing additional capacity, timely access to same day urgent assessment and preventing hospital attendance and ambulance conveyance.
- Build on existing infrastructure and models, such as 'hot hubs' established during Covid-19.
- Aim to provide same day, face-to-face access to appointments for adults and children.
- Delivered through flexible staffing, hours and appointments and offered in line with local demand / population.
- Integrated across primary, secondary and community care, emergency care and acute trusts. Link with existing services such as virtual wards.
- Patients identified through an initial remote/triage consultation as requiring face-to-face assessment but not requiring hospitalisation.

ARI HUBS





UK LANDSCAPE 2023

There has been a significant increase in POCT options with good performance data that can match lab-based tests.

However, uptake of these tests in community settings is low and clinical utilisation has not improved across the system.



2009 – POCT Industry (BIVDA) Viewpoint - 27th May 2009

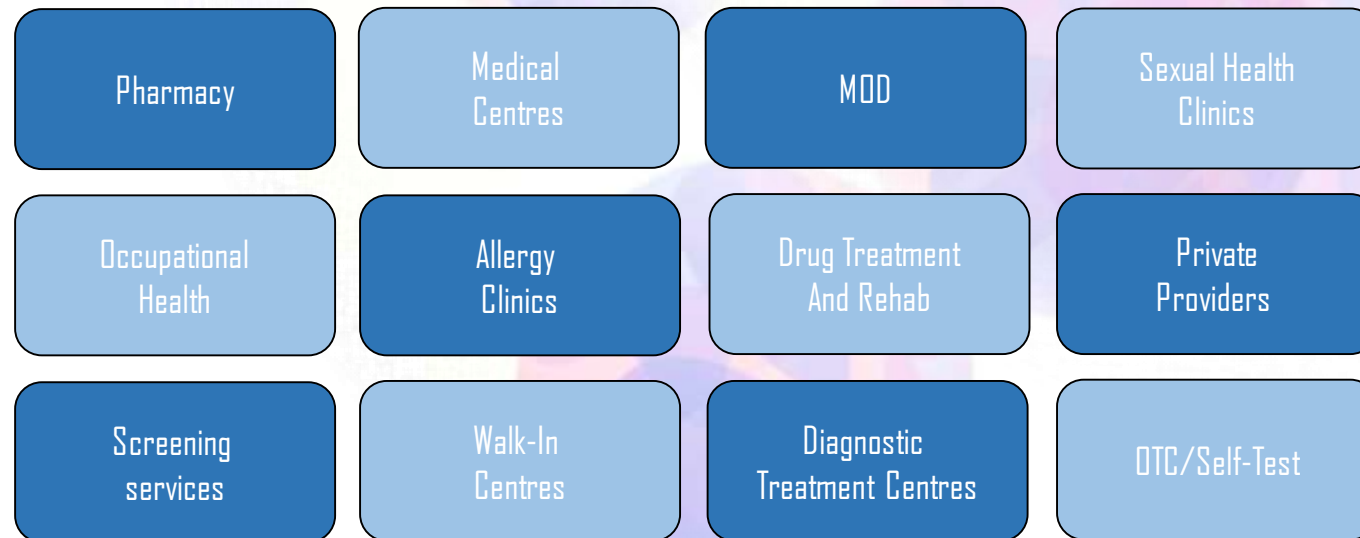
Industry view of adoption by NHS –

- Slow to adopt in community – funding.
- Issues with non-laboratory staff doing POCT.
- May be possible but needs to have real utility.

2009 – POCT Industry Viewpoint

27th May 2009

POCT (Service Delivery Settings) –





2009 – POCT Industry Viewpoint

27th May 2009

Opportunities–

- Faster result.
- Faster treatment and greater choice for the patient.
- Emphasis on prediction and prevention.
- Wider cost benefits to the system.



2009 – POCT Industry Viewpoint

27th May 2009

Barriers and Challenges–

- Costs of POC higher than laboratory.
- Governance and interpretation of results.
- Laboratory back-up.
- Comparability of results/ abnormal results.
- Training and monitoring of staff.
- QC.
- Customer support/ competency.
- Referral mechanisms/treatment.
- Recording of results in the patient record.



2009 – POCT Industry Viewpoint

27th May 2009 - Conclusion

- POC is here to stay.
- Amount of testing will increase.
- Management of change is required – funding, staffing.
- Co-ordination is required – result needs to be connected to patient record and acted upon.



2009 – 2023

14 Years!

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Why?

NHS England* believe that this is due to there being gaps in the evidence.

- How these work in a community setting.
- How these tests integrate into the patient pathway.
- How this maximises clinical impact for patients.
- What the tangible cost/benefits are.

These gaps leave a lack of information on the most appropriate way to improve patient outcomes using POCT outside the acute setting.

Until this is resolved, there will be poor uptake of POCT and patients will not have access to new and improved technology in this area.

*Diagnostics Advisory Group 27th July 2023



OPPORTUNITIES

Fast Time to Result	Short turnaround allows patient result to be delivered while the patient is still present
Faster Diagnosis	With rapid results, comes faster diagnosis, treatment and patient management decisions
Convenience	Test where the patient is at point of need. From a patient access healthcare perspective, can help drive equality.
Improved Patient Experience	Patient/HCP relationship can be improved by building trust and confidence. Patient has less time to wait for information, helps understanding.

OPPORTUNITIES

AMR and
antibiotic
stewardship

Reduced ED
attendance

Increased number
community
appointments

ID of infection type
and CRP allows
Triage of patients

More patients
treated at home

Better patient
experience

High impact on
particular
populations

Better management
of chronic disease

Digital Apps

Economies of
Scale

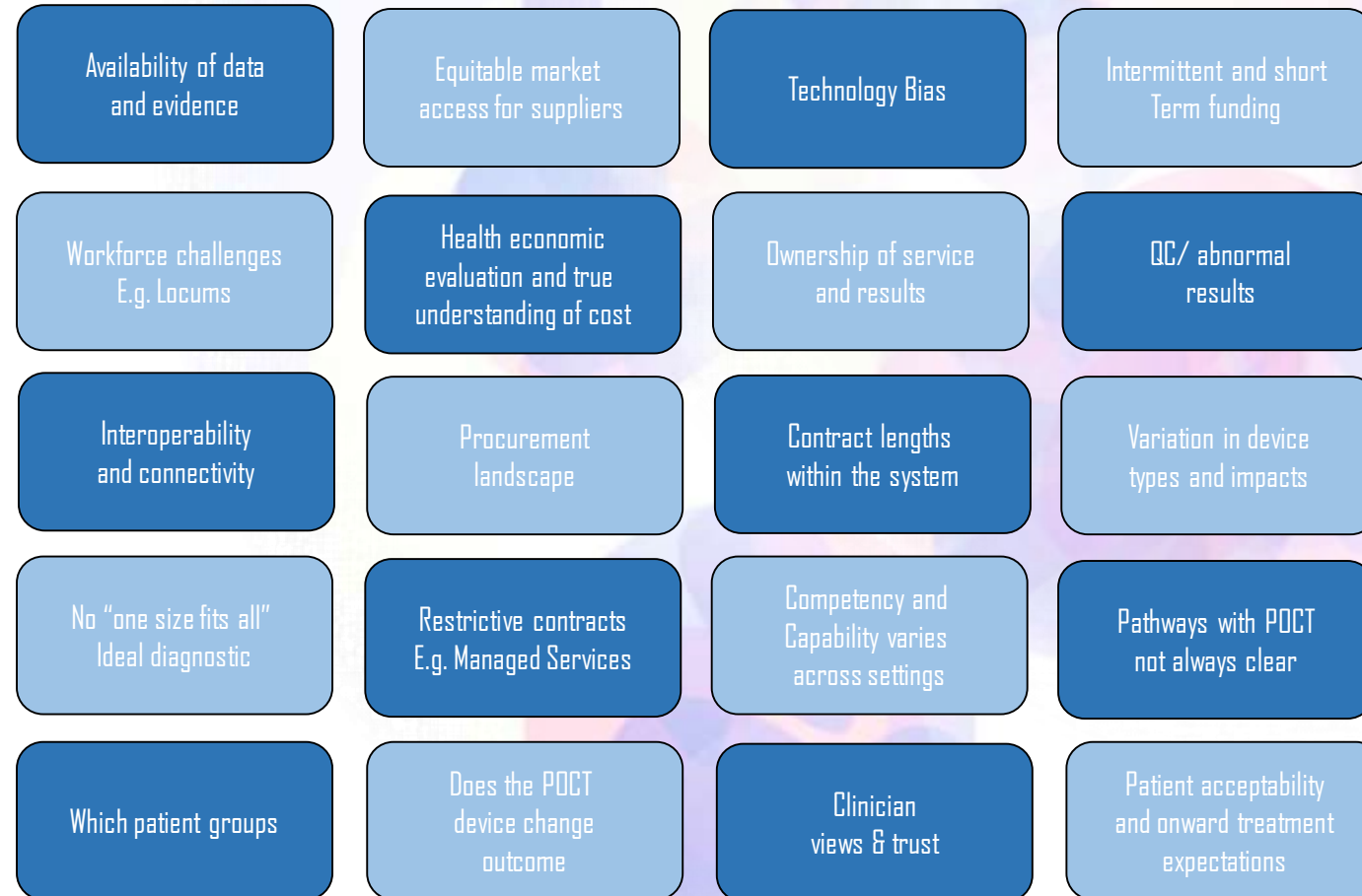
Better Technology

Pharmacy/
OTC/Self-Test

CHALLENGES

Cost and Budgets	Cost per test for POC when comparing against lab-based test – can be higher due to volume. Where the budget and investment sits, is often not where the cost savings are immediately seen.
Perceived lack of supporting Evidence	Possible concerns over lack of diagnostic accuracy compared to lab results. Need independent studies and real world data showing impact on outcomes.
Quality Assurance	Need training (passwords/login) QC, QA, Proficiency schemes. Potential “hidden costs”
Data Connectivity and Management	Compatibility with hospital systems, across sites with considerations for security and access to data.

CHALLENGES



SOLUTIONS

Defined Pathways

Champions of POCT
in Trusts

Champions in POCT
in community

Dedicated budgets

Training

Pooled Real-World
data

Integration of
patient records

Cost effectiveness
studies

Guidance from
the centre

Awareness in
Community settings

Demand signaling

Policy through
Competitive tenders



Next Steps

Recently NICE and IBMS, and the Royal College of Pathologists have issued POCT guidance which examines how POCT can reach into the community and what needs to be in place for success.

BIVDA are preparing a White Paper (Working Title – Point of Care Testing: What next?) Which will cover the content of this presentation.



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