



# Rapid national delivery of UKHSA's clinical evaluation programme for Covid-19 in vitro diagnostic (IVD) devices

MAC's unique ability to deliver innovative and agile solutions has been a key requirement when responding to the rapidly evolving landscape of the pandemic. As part of this effort, MAC has been supporting the UKHSA in evaluating their in-vitro diagnostic devices since 2021.

## Working in partnership with UKHSA

**Objective: to generate real-time evidence underpinning the safe national deployment of new antigen testing technologies.**

The challenges presented by the pandemic, and the absence of existing approved testing devices, required novel approaches to inform rapidly changing testing policies to respond to new variants of the virus. MAC was able to rapidly adapt its methodological approaches and flex the scale and design of the operational delivery models to meet these needs, while ensuring scientific quality and regulatory compliance.

This programme has generated the real-time clinical evidence needed to ensure that novel COVID-19 lateral flow devices (LFDs) could be safely deployed across the UK during the pandemic. It also delivered the post-market follow-up evidence of their continued performance against new disease variants.

## What were the core challenges?



Deployment of evaluation programmes at pace to address real-time public health threats.



Rapid scale-up of staff resources at testing sites.



High volume testing kit preparation, distribution and logistics.



Management of large datasets derived from complex digital channels.

# Clinical Operations and Rapid Study Initiation

With our flexible and partnering approach, MAC clinical operations worked with the UKHSA to quickly plan and implement novel LFD clinical evaluations at high volume.



Agile and consultative approach to client requirements, pivoting to changes as and when required



High volume and resource intensive LFD testing required significant upscaling and coordination in novel settings



The nature of the work required rapid changes of direction and real-time study design to address evolving needs



We adapted to all challenges, offering solutions and strategies for success

## Utilising data-driven insights to provide bespoke solutions

- Developed clear, informative study protocols and testing manuals. This included a patient instruction leaflet, test centre operative scripts and SOPs.
- Worked with multiple large, anonymised and complex testing datasets to develop an adaptive process of reconciliation and cleaning.
- Created robust and detailed statistical analysis plans, thus avoiding bias from data-led analysis.
- Clear communication between biometrics departments to ensure high quality data, analysis and reporting.
- Led manuscript development, supporting the drive to publish the results in peer-reviewed journals.

**MAC led, managed and operationalised eight nationwide LFD trials, culminating in the recruitment of 27,494 participants**



In one six-month period this figure was over 15,000.



Eight core remote sites were set-up at NHS Test and Trace Sites including Heathrow Airport and Etihad Stadium.