

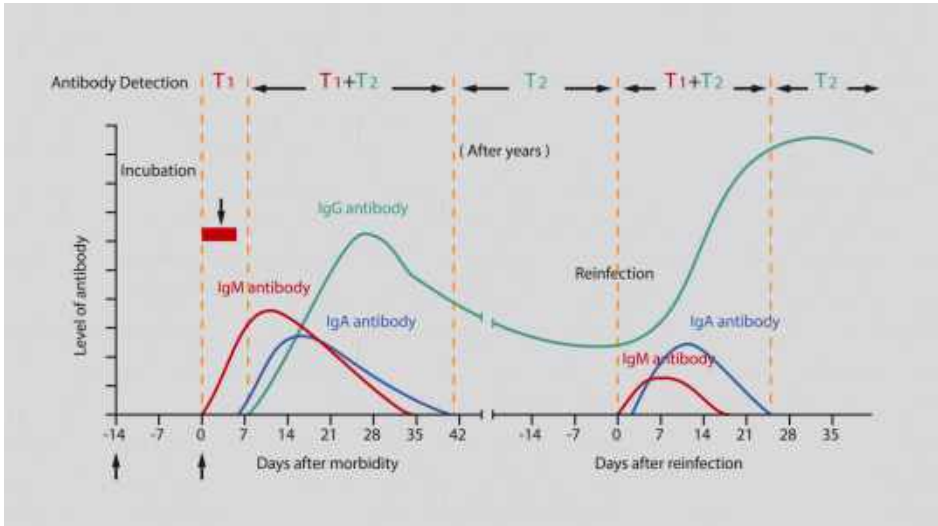
BHA COVID TRIPLE ANTIBODY TESTING OVERVIEW

Executive Summary

- COVID-19 remains the most significant, current global health threat.
- The ability to test for COVID-19 and confirm both current and past cases is vital to any Public Health strategy to identify cases, isolate them early, track disease progression, facilitate contact tracing and reassure the public.
- PCR swab testing for COVID-19 RNA of the oro- and nasopharynx is the preferred option for detecting acute COVID cases but has limitations including:
 - Expense
 - Need for sophisticated laboratory facilities
 - 1-3 day turnaround time to process samples and report back
 - In the UK, over 30% false negatives reported due to variability in swab technique
 - Self-administered tests though to be up to 50% false negative
 - No control element of a test
 - Regular, mass testing presents logistical and financial challenges
- Near patient testing has the potential to provide rapid results and allow time timely clinical decision-making.
- Antibody testing for acute (IgA / IgM) and chronic (IgG) antibodies allow detection of both current and historic infection.

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- The immunological response to COVID infection is shown below:



- A limitation of antibody testing is the time taken for detection. However, experience from the UK has shown the combined detection of IgA/IgM can be detected as early as 4 days after initial COVID infection.
- The triple antibody (IgA, IgM, IgG) test supplied by BHA was developed by Antai Technologies in China, with input from the Chinese Centre for Disease Control, and extensively tested.
- Some key features of the BHA Anti triple antibody test include:
 - Standard lateral flow, immunoassay
 - Test is delivered on site, simple finger prick capillary blood test. Results in 20 minutes.
 - CE marked
 - Multiple, independent validation studies have overall shown:
 - Sensitivity 97%
 - Specificity 100%
 - False positive rate 3%
 - False negative rate 9%

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- Control line as standard
- A huge volume of tests can be processed very rapidly by individuals with minimal training.
- The use of triple antibody testing has been shown to be superior to double antibody (IgG/IgM only).
- Asymptomatic cases of COVID infection are now thought to represent ~50% cases, with some UK studies suggesting even higher. The ability to screen for asymptomatic infection, even with acute antibodies and the associated time delay, is still more effective than no testing at all and present an opportunity for isolation.
- With the COVID infectious period known to be ~2 weeks or even longer, testing for asymptomatic cases and isolating them will be beneficial.
- The Antai triple antibody test has been extensively used in the UK, Germany, China, Turkey, Korea, Dubai, Iraq, Africa.
- Large corporations (in the UK including Rolls Royce, Ocado, Jaguar Landrover, Virgin Group) are using the triple antibody test, in combination with the PCR test, to effectively:
 - Reassure the workforce
 - Improve compliance with isolation and social distancing
 - Detect asymptomatic carriers
 - Prioritise those in need of PCR testing
 - Confirm current or previous COVID cases
- This strategy has been shown to be highly effective, will minimal transmission in these key corporations and communities.
- Near patient antibody testing is a highly cost-effective means of supporting COVID screening.
- Near patient antibody testing can be supported by senior medical input, with clear protocols and can provide a safer, more informed work place than having no testing.
- Confirming if a previous case was indeed COVID is proving to be hugely reassuring and likely to indicate a period (exact length of time not yet clear) of possible immunity.