

## Review

# COVID-19 point-of-Care diagnostics that satisfy global Target Product Profiles

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**Abstract:** COVID-19 pandemic will continue to pose a major public health threat until vaccination-mediated herd immunity is achieved. Most projections predict vaccine will reach a large subset of the population late in 2021 or early 2022. In the meantime, countries are exploring options to remove strict lockdown measures and allow for society and the economy to return to normal function. One possibility is to expand on existing COVID-19 testing strategies by including large-scale rapid point of care diagnostic tests (POCTs). Currently, there is significant variability in performance and features of available POCTs, making selection and procurement of appropriate test for specific use case difficult. In this review, we have used the World Health Organization's (WHO) recently published Target Product Profiles (TPPs) for specific use cases of COVID-19 diagnostic tests to screen for top-performing POCTs on the market. Several top-performing POCTs, based on clinical sensitivity/specificity, the limit of detection, and time to results, that meet WHO TPP criteria for direct detection of SARS-CoV-2 (acute infection), or indirect diagnosis of past infection (host antibodies) are highlighted here.

**Keywords:** COVID-19; point-of-care diagnostic test; target product profile; clinical performance

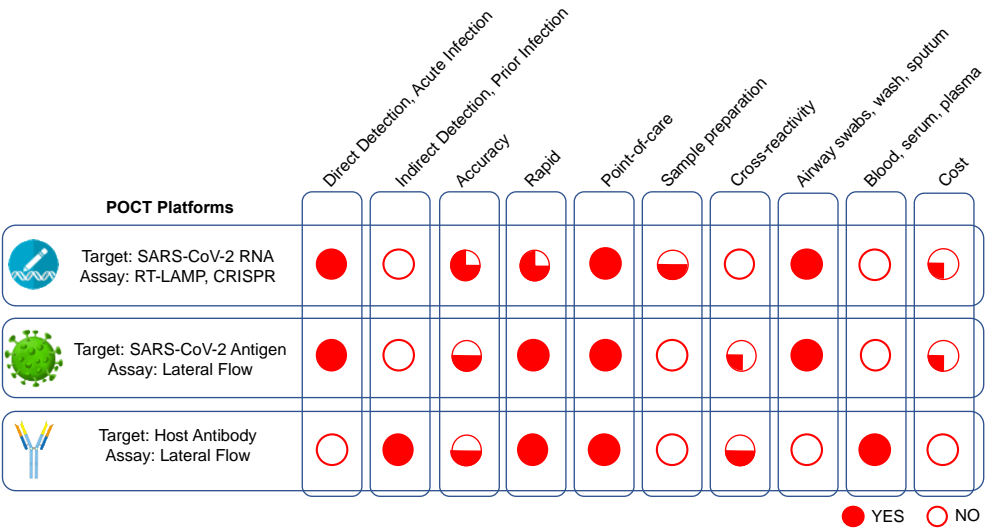
## 1. Introduction

Despite recent successes in vaccine development, the COVID-19 pandemic will continue to pose a major public health threat until a significant number of the global population is vaccinated and herd immunity is achieved. In the meantime, countries are exploring options to balance between preventing the further spread of SARS-CoV-2 and softening the societal lockdown that has caused major political and financial crisis. Most projections predict reaching herd immunity to SARS-CoV-2, primarily by mass vaccination[3], in the third or fourth quarter of 2021[4]. A proposed solution is the large-scale utilization of rapid point-of-care tests (POCTs) into the current COVID-19 testing, tracking, and tracing strategy. Such strategies can help mitigate the impact of pandemic on vulnerable populations while allowing for society and economy to continue to function[1, 6].

The current gold standard for the diagnosis of acute SARS-CoV-2 infection is the reverse transcription polymerase chain reaction (RT-PCR) test that can detect small amounts of viral nucleic acid (e.g., RNA in SARS-CoV-2) in clinical specimens (e.g., nasopharyngeal swabs) with high accuracy[8, 9]. However, RT-PCR usually requires expensive equipment and reagents that have limited its application to centralized laboratories with highly trained laboratory personnel, and typically a turnaround time of 24 hours to several days from specimen collection to the issuance of a result. The management of COVID-19 infection can be severely hindered by such long turnaround times[6]. Furthermore, expanding laboratory-based PCR testing capacity is beyond the financial means of many low- and middle-income countries and its logistics make it less agile to use as a near-patient or community-based test.

POCTs or near-patient tests are rapid de-centralized (outside centralized laboratories) tests that can diagnose acute or prior SARS-CoV-2 infection within minutes of specimen receipt, allowing for rapid decisions concerning patient care and management to prevent further spread (see Box 1). POCTs can be divided into tests that directly detect SARS-CoV-2 (RNA or antigen) for acute diagnosis of COVID-19, or indirectly, by detecting host anti-SARS-CoV-2 antibodies for diagnosis of prior infection[1] (Fig. 1). POCTs that detect viral RNA or antigen(s) are available in several formats which are suitable for decentralized testing. Other than RT-PCR, these include lateral flow tests for antigen detection, RT-LAMP (reverse transcription loop-mediated isothermal amplification), and CRISPR (clustered regularly interspaced short palindromic repeats) for RNA detection. POCTs that detect antibodies have primarily relied on a lateral flow assay format to detect host antibodies (IgG, IgM, IgA) from a small volume of blood, serum, or plasma[10]. In comparison to RT-PCR based technologies, antigen- or RNA-based POCTs generally have lower sensitivity, but all are ideal for the diagnosis of COVID-19 during the first week after the onset of symptoms while the SARS-CoV-2 viral load is typically higher than the test’s limit of detection. Beyond 10 to 14 days after the onset of symptoms, when the viral load is low or undetectable, the performance of these tests diminishes significantly[1, 7]. Although of limited use in diagnosing recent infection, COVID-19 antibody-based POCT can be used to identify prior infection or effective vaccination by detecting host antibodies produced against SARS-CoV-2, which normally peak after 10 days post onset of symptoms [1, 10].

There are more than 300 COVID-19 diagnostic tests that have obtained U.S. Food and Drug Administration (FDA) Emergency Use Authorization (EUA) [11]. The Swiss-based Foundation for Innovative New Diagnostics (FIND) has monitored 850 COVID-19 diagnostic tests to date, with more than 250 which fall under the point-of-care (POCT) or rapid diagnostic test category [12]. As the large-scale testing strategy is a central pillar in response to a pandemic, databases by both the FDA and FIND provide instrumental publicly available information about the developmental status, regulatory approval, and the performance status of COVID-19 diagnostic tests. However, navigating hundreds of diagnostic tests to select reliable and accurate POCTs for procurement decisions can be extremely challenging. In this review, we have screened the FDA EUA and FIND databases to select top-performing POCTs that meet World Health Organization criteria for COVID-19 diagnostic tests [13].



**Figure 1. Features of various COVID-19 POCT technology platforms.** RT-PCR: reverse transcription polymerase chain reaction; CRISPR: cluster regularly interspaced short palindromic repeats; RT-LAMP: reverse transcription loop-mediated isothermal amplification. Adapted and modified from Ghaffari et al., BioProcess International, 2020[2].

**BOX 1 | Benefits and Challenges of POCTs***Definitions:*

- *Rapid Test*: a qualitative or semi-quantitative in vitro diagnostic medical device, intended to be used singly or in a small series, which involves non-automated procedures and has been designed to give a fast result.
- *Point of Care Testing*: testing that is performed near or at the site of the patient, outside a general laboratory environment, with the result leading to possible change in the care of the patient.

*Potential advantages:*

- Improved turnaround time
- Improved monitoring during pandemics where frequent testing is desirable
- Smaller sample (may be less invasive) and reagent volumes
- Advantages in remote regions where access to laboratory is limited
- Economic – POCTs may offer wider economic benefit with a reduced number of clinical visit and fewer hospital admissions
- Greater patient involvement in their own care, improved patient experience
- Availability outside core laboratory normal hours

*Potential disadvantages:*

- Reduced quality of analysis (e.g., sensitivity/specificity)
- Poor record keeping
- Lack of result interpretation
- Unnecessary duplication of equipment
- Data recording may be complex and less robust
- Incompatibility with laboratory results
- POCT can be expensive in absence of economies of scale that come from centralized laboratory testing

**BOX 2 | Performance Parameters and Variability of POCT [1]**

**Analytical Sensitivity:** or limit of detection (LOD) is frequently defined as the lowest amount of analyte (e.g., SARS-CoV-2) that can be accurately measured by the assay. The LOD of a COVID-19 POCTs is typically determined as the lowest SARS-CoV-2 concentration (titrated at increasing concentration into a background) that was detected  $\geq 95\%$  of the time (at least 19 out of 20 replicates tested positive).

**Analytical Specificity:** or cross reactivity is the ability to unequivocally detect a specific analyte (e.g., SARS-CoV-2) and differentiate it from other interfering substances (e.g., other pathogens). The cross-reactivity and potential microbial interference of a COVID-19 test is typically evaluated by testing a panel of commensal and respiratory pathogenic microorganisms (bacteria, viruses, yeast) in the absence or presence of heat inactivated SARS-CoV-2 virus.

**Clinical Sensitivity and Specificity:** clinical or diagnostic sensitivity is the ability of a test to return a positive result when the patient has the disease. Clinical specificity is the ability of the test to produce a negative result when the patient sample does not have the disease. The clinical performance of a COVID-19 POCT is evaluated by using confirmed positive and negative SARS-CoV-2 clinical specimen. Positive SARS-CoV-2 specimen are typically from patients who presented within 7 days of COVID-19 symptom onset.

**Clinical specimen:** for antigen tests, the quality and relevant abundance of SARS-CoV-2 in collected clinical specimens, heavily dependent on the collection site and disease timeline, are critical for the performance evaluation of the assays. For example, the sensitivity of RT-PCR in detection of SARS-CoV-2-infected patients is ~93% in bronchoalveolar lavage fluid, 63% in nasopharyngeal swabs, 72% in sputum, 32% in pharyngeal swabs, and 29% in stool [5]. Furthermore, at ~14 days after the onset of COVID-19 symptoms the viral load becomes low or undetectable and should not be used in diagnostic test clinical performance evaluation [7].

**POCT performance variability:** the significant variability observed in performance between COVID-19 tests can be explained by:

- Differences in test population
- Time of testing; proportion of early versus late COVID-19 disease stage
- Specimen type (nasal swab, saliva, sputum, whole blood, serum/plasma, etc)
- Differences in RT-PCR protocols used as reference assay

**Target Product Profiles Of COVID-19 Rapid Diagnostic Tests**

In addition to key parameters that measure the analytical and clinical performance of a diagnostic test (see Box 2), other practical and strategic criteria play a significant role in the selection of a POCT for a specific use case. The World Health Organization (WHO) has recently called for research and development of simple, rapid, and more affordable

COVID-19 POCT and also encouraged the use of serological or antibody surveys to better understand the extent of and risk factors of this pandemic. To guide these efforts, the WHO and other jurisdictions such as the UK Medicine and Healthcare products Regulatory Agency (MHRA) have published four priority target products profiles (TPPs) for the following use cases [13-15]:

1. Point of care test for suspected COVID-19 cases and their close contacts to diagnose acute SARS-CoV-2 infection,
2. Test for diagnosis or confirmation of acute or subacute SARS-CoV-2 infection, suitable for high-volume needs,
3. Point of care test for prior infection with SARS-CoV-2,
4. Test for prior infection with SARS-CoV-2 for high volume needs.

The emerging POCTs will not necessarily meet all the criteria outlined in the WHO TPP, but the TPP will provide a framework to assist in the manufacturing of products that will meet a use case. In addition, the TPPs can be utilized to compare key features of COVID-19 POCTs and select products that best respond to the public health needs of each region. In this review, we will focus on features of non-PCR COVID-19 POCTs intended for the diagnosis of acute SARS-CoV-2 infection (WHO TPP #1) and detection of prior SARS-CoV-2 infection (WHO TPP #3). Tables 1 and 2 summarize key features of WHO and UK MHRA TPPs for antigen-/RNA- and antibody-based POCTs, respectively. We have used the WHO TPP criteria to screen and identify top-performing COVID-19 POCTs listed on the U.S. Food and Drug Administration (FDA) Emergency Use Authorization (EUA) [11] and the Foundation for Innovative New Diagnostics (FIND) SARS-CoV-2 Diagnostics Performance [12] databases (see Table S1 and S2 in the supplementary file for the full list and detailed features). We chose four critical POCT characteristics to compare performance including clinical sensitivity, clinical specificity, limit of detection, and turn-around time. There are several PCR-based integrated systems that qualify as POC COVID-19 tests. These tests have been previously discussed [2] and are not the focus of this review. We primarily focused on rapid COVID-19 POCTs that can deliver results in under 30 minutes. Next, we used the WHO TPP 'desirable' clinical sensitivity ( $\geq 90\%$  for antigen/RNA and  $\geq 95\%$  for antibody POCTs) as a cut-off for the initial selection of top-performing rapid POCTs.

**Table 1.** TPP Summary: Point of Care Rapid Tests to Detect SARS-CoV-2 infection.

Features	WHO		UK MHRA	
	Acceptable	Desirable	Acceptable	Desirable
Intended Use	Regions with confirmed cases, confirmed outbreaks, and in high-risk groups: early detection of SARS-CoV-2 cases where reference assays are not available or overloaded		Aid in triage of current SARS-CoV-2 infection during the acute phase of infection	Aid in triage of current SARS-CoV-2 infection at any point during active infection
Target Population	Patients with respiratory symptoms; contact with confirmed/probable COVID-19 cases; living in area of cluster		People with COVID-19 clinical signs and symptoms	People with or without COVID-19 clinical signs and symptoms
Target User/Setting	Outside laboratory in screening point of healthcare facilities by trained healthcare workers	Same but can be performed by trained lay workers	Trained healthcare worker at the point of care healthcare and non-healthcare (school, airport, prison) settings	
Target Analyte	SARS-CoV biomarker (assuming SARS-CoV-1 is not circulating)	SARS-CoV-2 only biomarker	Single SARS-CoV-2 RNA or antigen	Dual (or more) SARS-CoV-2 RNA or antigen
Sample Type	NP, OP, Nasal swab, nasal wash, sputum	Anterior nares, saliva/oral fluid, sputum	NP, OP swabs, BAL, NP, nasal wash	Sputum, saliva (not using invasive swab)
Clinical Sensitivity	$\geq 80\%$	$\geq 90\%$	$\geq 80\%$ [70-100%]	$\geq 97\%$ [93-100%]
Clinical Specificity	$\geq 97\%$	$\geq 99\%$	$\geq 95\%$	$\geq 99\%$
Analytical Sensitivity (LOD)	$1 \times 10^6$ copies/ml Ct-25-30	$1 \times 10^4$ copies/ml Ct->30	$< 1 \times 10^4$ copies/ml	$< 1 \times 10^2$ copies/ml
Time to Results	$\leq 40$ min	$\leq 20$ min	$\leq 2$ hr	$\leq 30$ min

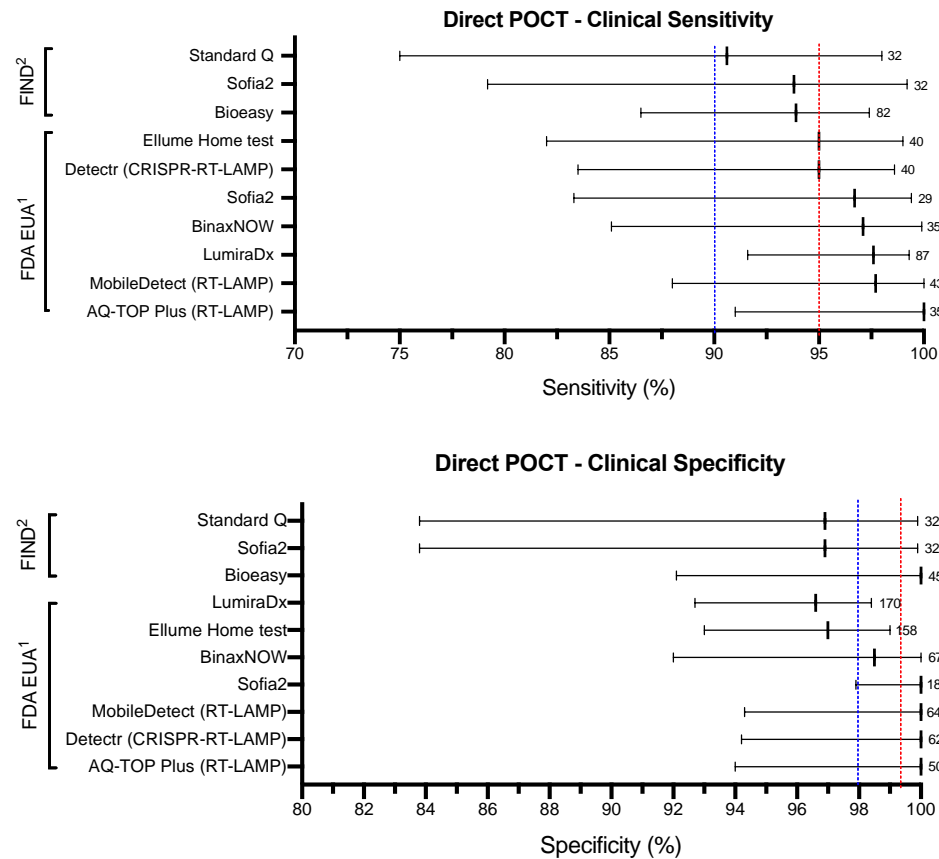
Result Stability	Fixed reading time	Stored image or 6 wks	< 30min	< 1hr
Storage	12mo at 4-30°C	18-24mo at 4-40°C	12mo at 2-8°C	12mo at 4-30°C

Table 2. TPP: Point of Care Rapid Tests for Prior SARS-CoV-2 Infection (Antibody POCT)				
	WHO		UK MHRA	
Features	Acceptable	Desirable	Acceptable	Desirable
Intended Use	Easy to use test to detect prior SARS-CoV-2 infection		Detect prior exposure to SARS-CoV-2	Detect immunity to SARS-CoV-2
Target Population	General population in survey/surveillance studies; group at high-risk of exposure to SARS-CoV-2		Recovered from suspected or confirmed SARS-CoV-2 infection	Group that need to know immunity to SARS-CoV-2
Target User/Setting	Outside laboratory in screening point of healthcare facilities by trained healthcare workers	Same but can be performed by trained lay workers	Health care professionals (clinics, pharmacies, workplace, non-lab settings)	Person trained in operating the test kit (clinics, pharmacies, workplace, non-lab settings)
Target Analyte	At least one isotype or other biomarker specific to prior SARS-CoV-2 infection		Total antibodies to SARS-CoV-2	IgG antibodies to SARS-CoV-2
Sample Type	Plasma/serum, fingerstick, saliva/oral fluids		Fingerstick blood	Fingerstick blood, venous blood, serum/plasma
Clinical Sensitivity	≥90%	≥95%	≥98% [96-100%] (test min 200 positive samples)	
Clinical Specificity	≥97%	≥99%	≥98% [96-100%] (test min 200 negative samples)	
Time to Results	≤ 40min	≤ 20min	≤ 20min	≤ 15min
Result Stability	Fixed reading time	Stored image or 6 wks	< 30min	< 1hr
Storage	12mo at 2-30°C; 70% RH	18-24mo at 2-40°C; 90% RH	12mo at 5-30°C; 80% RH	

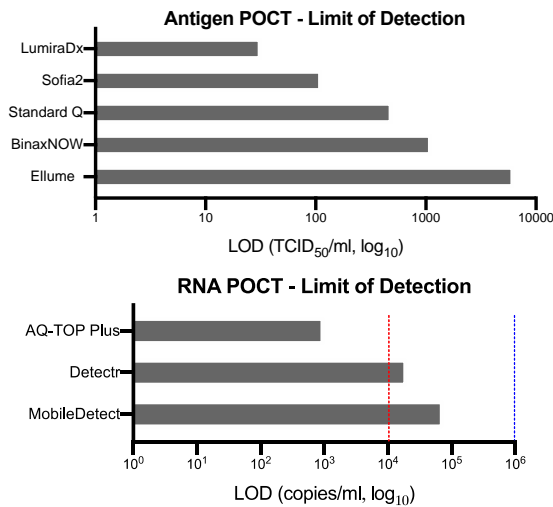
### Direct POCT to Detect Acute SARS-CoV-2 Infection

Rapid, easy-to-use, low-cost, and relatively accurate COVID-19 POCTs can complement RT-PCR testing in timely identification of the majority of patients with early acute SARS-CoV-2 infection and avoiding delays in the isolation of infected individuals. Antigen-based (e.g., lateral flow assay) and RNA-based (e.g., RT-LAMP) POCTs have the potential to detect patients with high viral loads, often during the first week of COVID-19 infection, which are most likely to transmit the virus to others [16, 17]. Here, we review the clinical performance and features of several antigen/RNA POCTs that meet the clinical sensitivity criteria of WHO TPP (≥90%) as shown in Table S1. We identified 8 POCTs with FDA EUA and an additional 3 POCTs from FIND independent performance validation database that met the clinical sensitivity criteria of WHO TPP. The mean clinical sensitivity between all selected antigen/RNA POCTs was 93.7±7.1% with reported confidence intervals ranging from 43.7% to 100%. The mean clinical specificity between all tests was 98.8±1.5% with reported confidence intervals ranging from 81.6% to 100% (Fig 2). In addition to clinical sensitivity and specificity, which can be affected by variability in specimen viral load, it is critical to assess the limit of detection (LOD) for any COVID-19 diagnostic test (see Box 2). The WHO TPP for direct POCTs sets the 'acceptable' and 'desirable' thresholds for LOD at 10<sup>6</sup> and 10<sup>4</sup> genomic copies/ml, respectively. However, due to a lack of consensus on the LOD unit, most direct antigen-based POCTs reviewed here use the TCID<sub>50</sub>/ml unit (viral titer concentration at which 50% of infected cells display cytopathic effect) to define LOD (see Table S1). Therefore, the direct POCTs' LOD are reported as TCID<sub>50</sub>/ml for antigen-based tests (overall mean±SD of 1614.9±2660 TCID<sub>50</sub>/ml) and genomic copies/ml for RNA-based tests (overall mean±SD 3.2×10<sup>4</sup>±3.8×10<sup>4</sup> copies/ml) of (Fig 3). Finally, the average time to results between all tests was 23±11.5 minutes (Fig 4).

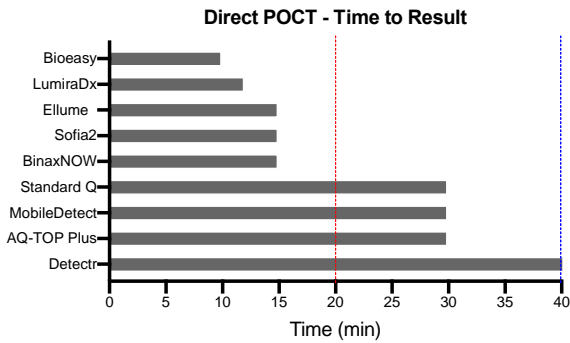




**Figure 2. Clinical sensitivity and specificity of direct POCTs.** Selected POCTs that met WHO TPP (direct detection of SARS-CoV-2) ‘desirable’ clinical sensitivity cut-off. Short vertical lines represent the calculated clinical sensitivity (top panel) and clinical specificity (bottom panel) values. Horizontal bars represent lower and upper 95% confidence intervals. Blue and red lines represent WHO TPP ‘acceptable’ and ‘desirable’ thresholds, respectively. Numbers represent total positive (sensitivity) and negative (specificity) clinical samples tested. All reported values were obtained from FDA, FIND, or manufacturer’s product information sheets and have not been validated by our group. <sup>1</sup> Performance data based on manufacturer’s claims reported in FDA EUA database. <sup>2</sup> Performance data based on independent evaluation tests reported in FIND database.



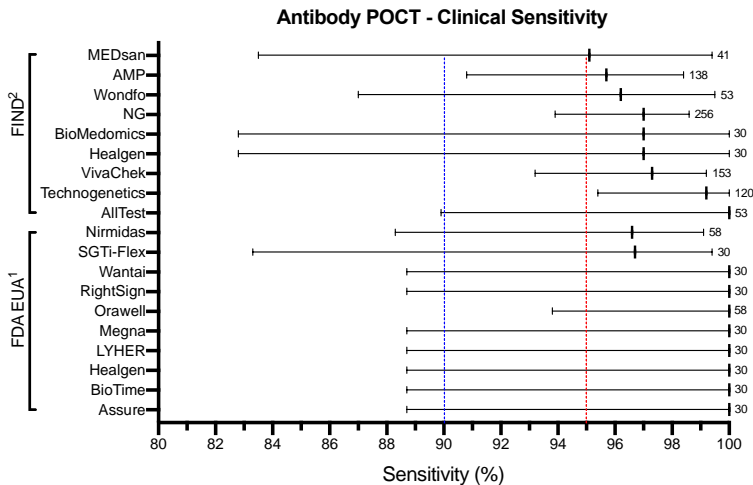
**Figure 3. Analytical Sensitivity (limit of detection) of selected POCTs.** Limit of detection (LOD) of SARS-CoV-2 antigen (left panel: Antigen POCTs) and RNA (right panel: RT-LAMP POCTs) as reporter in manufacturer’s instruction for use (IFU). Blue and red lines represent WHO TPP ‘acceptable’ and ‘desirable’ LOD thresholds, respectively. The LOD thresholds are not available for TCID<sub>50</sub>/ml unit.

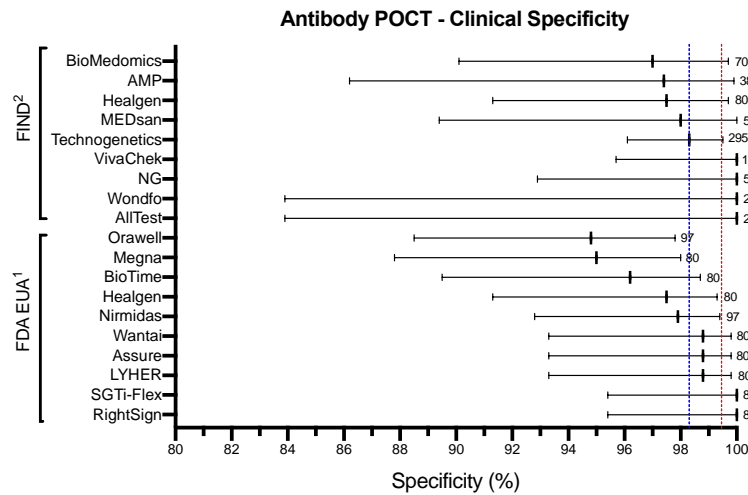


**Figure 4. Time to result of selected direct POCTs.** The time to result of direct (antigen/RNA) POCTs that met the WHO ‘desirable’ clinical sensitivity criteria (see Fig 2) based on manufacturer’s claims. Blue and red lines represent WHO TPP ‘acceptable’ and ‘desirable’ thresholds, respectively.

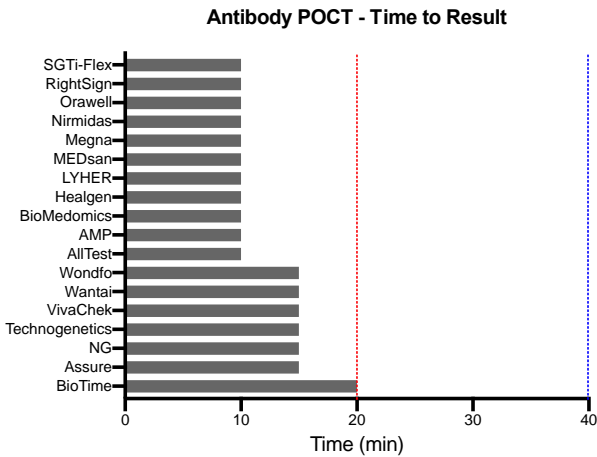
**POCTs to Detect Prior SARS-CoV-2 Infection**

SARS-CoV-2 viral load in airways becomes low or undetectable beyond two weeks post-infection, leading to diminished sensitivity of molecular tests. COVID-19 serological or antibody tests are immune-based assays (e.g., lateral flow assays) that detect immunoglobulins produced by the host in response to SARS-CoV-2 specific antigens. Studies suggest that human immunoglobulins including IgA, IgM, and/or IgG become detectable beyond 10 days after the onset of COVID-19 symptoms [10, 16, 18]. Therefore, antibody POCTs play a complementary role to molecular tests in assessing past infections, characterizing the dynamics of humoral response, and determining the epidemiological features of the viral outbreak including COVID-19 case fatality rates. Antibody POCTs do not play a role in clinical case management since the recency of infection cannot be determined by a single test due to temporal overall and substantial variability of IgA/IgM/IgG responses. We have recently published a detailed review of the performance of hundreds of antibody tests developed in response to the pandemic [10]. Here, we highlight the clinical performance and features of top-performing COVID-19 antibody POCTs that meet the WHO TPP ‘desired’ sensitivity cut-off (Table S2). We identified 10 antibody POCTs with FDA EUA and an additional 9 from the FIND independent performance validation database that met the clinical sensitivity criteria of WHO TPP ( $\geq 95\%$ ). The mean clinical sensitivity between all selected antibody POCTs was  $98.3\pm 1.8\%$  with reported confidence intervals ranging from 83.3% to 100%. The mean clinical specificity between all tests was  $98.2\pm 1.7\%$  with reported confidence intervals ranging from 87.0% to 100% (Fig 4). The criteria for LOD were not defined in WHO TPP for indirect POCTs as currently there is no international standard to express LOD for antibody tests. The average time to results between all tests was  $11.8\pm 3.0$  minutes (Fig 5).





**Figure 5. Clinical sensitivity and specificity of indirect POCTs.** Selected antibody POCTs that met WHO TPP (detection of prior SARS-CoV-2 infection) ‘desirable’ clinical sensitivity cut-off. Short vertical lines represent the calculated clinical sensitivity (top panel) and clinical specificity (bottom panel) values. Horizontal bars represent lower and upper 95% confidence intervals. Blue and red lines represent WHO TPP ‘acceptable’ and ‘desirable’ thresholds, respectively. Numbers represent total positive (sensitivity) and negative (specificity) clinical samples tested. All reported values were obtained from FDA, FIND, or manufacturer’s product information sheet and have not been validated by our group. <sup>1</sup> Performance data based on manufacturer’s claims reported in FDA EUA database. <sup>2</sup> Performance data based on independent evaluation tests reported in FIND database.



**Fig 6. Time to result of selected indirect POCTs.** The time to result of antibody POCTs that met the WHO ‘desirable’ clinical sensitivity criteria (see Fig 2) based on manufacturer’s claims. Blue and red lines represent WHO TPP ‘acceptable’ and ‘desirable’ thresholds, respectively.



**BOX 3 | List of Top-Performing COVID-19 POCTs**

The following COVID-19 POCTs have met the WHO TPP 'desirable' criteria for clinical sensitivity/specificity, LOD, and Time to Results (alphabetical order):

*Direct (antigen/RNA) POCTs:*

- DetectaChem MobileDetect Bio BCC19 Test (RT-LAMP)
- Mammoth Biosciences SARS-CoV-2 Detectr Test (RT-LAMP/CRISPR)
- Quidel Sofia-2 Flu+SARS Antigen Test
- Season Biomaterials AQ-TOP Plus COVID-19 Rapid Test (RT-LAMP)
- Shenzhen Bioeasy Biotechnology Bioeasy Diagnostic Kit COVID-19 Antigen Test

*Indirect (antibody) POCTs:*

- Guangzhou Wondfo Biotech Wondfo SARS-CoV-2 Ab Test <sup>1</sup>
- Hangzhou Biotest Biotech RightSign COVID-19 IgG/IgM Rapid Test
- Hangzhou Alltest Biotech AllTest COVID-19 IgG/IgM Rapid Test <sup>1</sup>
- NG Biotech NG IgG/IgM Rapid Test
- Sugentech SGTi-flex COVID-19 IgG
- VivaCheck Biotech COVID-19 IgM/IgG Rapid Test

<sup>1</sup> These POCTs show relatively low 95% confidence intervals in sensitivity/specificity assessment.

**Concluding Remarks**

The information provided by the FDA and FIND databases can be useful starting points in choosing the most appropriate COVID-19 diagnostic test to use when implementing a testing strategy. By relating critical performance characteristics to how well a product meets the relevant TPP will ensure that suboptimal tests are not used. The limitations of the use of these databases must be acknowledged, however, before finally selecting the appropriate test(s) for a specific diagnostic use case. The FDA database contains details of the data submitted by the manufacturer and reviewed for suitability by the FDA. It is therefore not independently confirmed data. Although the data presented from the FIND database has been generated independent of the manufacturer, it too has its limitations. There is no consensus on a standard protocol for independent validation of COVID-19 diagnostic tests. But as noted, this information does provide an excellent starting point for considering what test to choose. Once a selection is made of potential candidates based on performance data, further considerations will be necessary before choosing the best option(s). These may include further verification of critical performance characteristics, pricing, resourcing (human and material) of the testing, quality control, as well as connectivity issues, where results can inform further public health measures, to name a few.

To date, testing for SARS-CoV-2 infection has mostly relied on RT-PCR assay. However, diagnostic technology for COVID-19 POCTs has improved at a tremendous rate in recent months. As highlighted in this review, there are several POCTs on the market that meet critical performance criteria defined by WHO TPPs. Top-performing direct (antigen/RNA) and indirect (antibody) POCTs cited here (see Box 3) can potentially be used immediately as part of large-scale testing strategies for rapid detection of newly infected individuals or prior infections and the implementation of isolation measures. As we are months away from wide availability of vaccines, direct POCTs can play a critical role in preventing the further spread of SARS-CoV-2. Additionally, antibody POCTs can be utilized to confirm and characterize vaccine-mediated immunity in a large subset of the population to ensure the efficacy and lasting effect of vaccination. Lastly, the true potential of POCTs is only realized with appropriate educational programs to encourage people to take advantage of available and suitable diagnostic tools and to actively participate in isolation measures designed to control the SARS-CoV-2 pandemic.

**Supplementary Materials:** The following are available online at [www.mdpi.com/xxx/s1](http://www.mdpi.com/xxx/s1), Table S1: Direct (antigen/RNA) POCTs WHO TPP Criteria, Table S2: Indirect (antibody) POCTs WHO TPP Criteria,

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writing—review and editing, A.G., R.M. and A.A.; project administration, A.A.; funding acquisition, A.A. All authors have read and agreed to the published version of the manuscript.

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**Conflicts of Interest:** The authors declare no conflict of interest.

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