

Scaling up Laboratory Testing Capacity in the Context of Managing Emerging Pandemic: Lessons Learned from Scaling Up SARS-COV-2 Testing in Rwanda

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Abstract: The coronavirus disease 2019 (COVID-19) has challenged health systems globally. In low and middle-income countries, a unique challenge ensuring the widespread testing that is critical to the response toward the pandemic has persisted. The pandemic has accentuated the need for rapid scale-up of real-time polymerase chain reaction (RT-PCR), a molecular testing technique that was often used for research purposes only, especially in limited-resource settings. Rwanda is a low-income country that has managed to scale up RT-PCR laboratory testing capacity by 15-fold within the first four-month of the COVID-19 pandemic.

Rwanda has been in line with the measures to contain COVID-19 even before 14th March 2020, when the first case of COVID-19 was detected. Due to the transmission of the infection, the scale-up was immediately in place, relying on public, private, non-governmental, and voluntary students from universities to boost the surveillance of the pandemic in the population. In COVID-19 testing, this scale-up relied on

population and government goodwill; research-based actions that included adopting a pooling strategy; optimized use of available human resources; and the use of limited resource funding models to support the established health system governance structure. Initially, the national reference laboratory was the only testing site for COVID-19; however, later, the country implemented decentralized testing, setting up COVID-19 testing centers countrywide. In this article, we highlight the lessons learned from the Rwandan COVID-19 laboratory testing response to guide effective laboratory response in limited-resource settings.

We recommend an appropriate epidemic response algorithm to be developed to classify cases based on epidemiological, clinical, and laboratory information in line with diagnosis methods and sustain quality.

Keywords: COVID-19, LABORATORY, DIAGNOSTICS, SCALING UP, RT-PCR, RWANDA

I. INTRODUCTION

The novel Coronavirus (nCOVID-19), also commonly known as SARSCOV-2, was first reported in the city of Wuhan in China by the end of December 2019(1), but it has now spread throughout the world with varying impact. Scientists are still learning about the disease which was first linked with animals and its substantial impact on one health(2). The disease spreads from person to person through infected air droplets that are projected during sneezing and coughing. It can also be transmitted when humans contact hands or surfaces containing the virus and touch their eyes, nose, or mouth with the contaminated hands(3).

The World health organization (WHO) Director-General has consistently advised governments and all ministries of health to fight the COVID-19 pandemic through widespread testing, contact tracing, and real-time response tactic model(4). Despite the novel vaccines being acknowledged by Stringent Regulatory Authorities and efforts of COVAX to distribute the vaccine evenly across the world, there remain operational and global rational distribution challenges, especially in Low and Middle-Income Countries (LMICs)(5). This implies that testing laboratories remain the cornerstone of managing the pandemic through early detection to identify new cases and their contacts through active surveillance to minimize the transmission of the virus in LMICs.

In the surge to fight the novel coronavirus outbreak, LMICs are characterized by inadequate laboratory capacity for diagnosing the disease (6, 7). Nasopharyngeal and oropharyngeal specimens have been used to detect SARS-CoV-2 RNA (the causal agent of COVID-19) using real-time reverse transcription-polymerase chain reaction (RT-PCR)(8). Other approaches that include serological testing (9) and sophisticated approaches such as scent dog identification of samples to detect COVID-19 have also been employed as of December 2020(10).

Medical laboratories in LMICs face different challenges to satisfy infrastructure, equipment, human resources, and stockpiles of required reagents and supplies despite the introduced Africa Medical Supplies Platform(6). Rwanda has been well-reputed over handling the COVID-19 pandemic so far(11). Considering the overall data from April to November 2020 samples tested, thus this review will highlight the key lessons learned from testing COVID-19 in Rwanda while setting up and decentralizing the RT-PCR testing capacity in Rwanda to increase the testing capacity and the accessibility to laboratory results. The Figure-1 describes the tests conducted by the site in September 2020 and comparable extract for all samples from April- November, and a regional testing capacity analysis.

➤ *The Overview of clinical laboratories and setting up national COVID-19 testing in Rwanda*

The Rwandan clinical laboratory and quality network follows a top-down supervision framework providing services adjusted to the decentralized health system. The Rwanda National Reference (NRL) entered in World health organization's quality improvement steps, also called Stepwise Laboratory Improvement Process Towards Accreditation in the Africa Region (SLIPTA), in July 2009 and benefited from the Strengthening Laboratory Management Toward Accreditation (SLMTA) program(12). The country laboratory was also focusing on quality improvement through the strategic health plan of July 2009, which aimed to strengthen quality starting with four referral hospitals and the National Referral Laboratory(13). The NRL is an ISO 15189 accredited facility(14).

Pre-COVID-19 molecular testing in Rwanda was mainly in monitoring people living with HIV/AIDS (PLWH), patients with Chronic Hepatitis B Virus, and Chronic Hepatitis C Virus. Due to the HIV monitoring program implementation and treatment for all, different laboratories were equipped with semi-automated molecular instruments (COBAS CAPs™ and Abbott m2000 platforms) and trained staff. When COVID-19 broke out in Rwanda, the Rwanda Forensic Laboratory provided technical expertise and provided support to the NRL to set up a national COVID-19 testing site.

As the COVID-19 response in Rwanda evolved, the NRL built capacity through staff training, procurement, and availing testing infrastructure. In this respect, a forecast of reagents and consumables was done. Worldwide, a growing SARS-CoV-2 Diagnostic Technology Landscape explored molecular and serology assays(15). However, despite the ever-increasing market, some of these platforms were still under validation and may not have allowed countries to urgently respond appropriately for a stable and reliable national testing strategy.

Presently, NRL uses Real-Time Polymerase Chain Reaction for SARS-CoV-2 testing. It uses both semi-automated platforms, the ABI 7500 (fast and standard), Bio-Rad CFX96, Rotor-Gene, ABI Quant studio 5 and a fully automated platform, Cobas 6800 (Roche). Also, SARSCOV-2 Gene Xpert from Cepheid is used for emergency cases. The satellite laboratories use Abbott m2000 and Bio-Rad CFX96. The equipment facilitated widespread testing of individuals at risk of the COVID-19 infection and contact tracing of index cases. Further, Rwanda utilized the existing equipment to support COVID-19 testing for other countries like the Central African Republic(16).

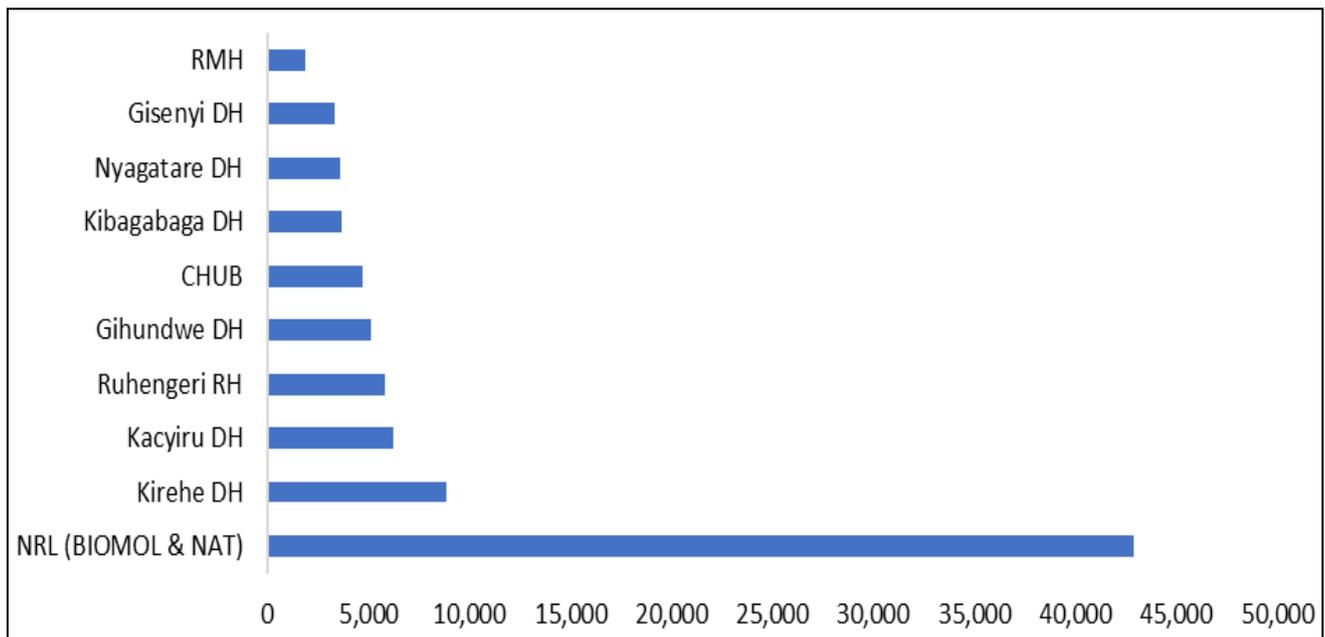


Fig 1: Shows list of testing sites by volume for September 2020

The NRL uses a Detection kit for 2019 Novel Coronavirus kits (2019-nCoV) RNA (PCR Fluorescence Probing) from DaAn® Gene Co Ltd based on detection of N-gene and ORF1ab. Besides, for quality control of results purposes, the Rwanda reference laboratory uses Germany-made technology (TIB-MOLBIOL® GmbH Berlin) as detection and confirmation kits with high sensitivity and specificity to detect COVID-19 for E-gene and RNA dependent RNA polymerase (RdRP) on the 7500 ABI® FAST Machine. The machine has a test capacity of producing 768 COVID-19 test results within 24 hours.

➤ *Setting up the RT-PCT Laboratories and results reporting mechanisms*

Rwanda's national COVID-19 testing algorithm recommends using RT-PCR to detect and confirm COVID-19. This increases confidence between tested positive and negative from suspected samples critical for contact tracing. Under the national reference laboratory's coordination and stewardship, ten new testing laboratories were established and accredited to test for SARS-CoV-2 countrywide as illustrated in figure-1. The result reporting was in one reporting system unilaterally validated through the health management information system (HMIS-DHS2®) and was used for data management of COVID-19 patients on a daily basis.

➤ *Diagnostic testing capacity for SARS-CoV-2*

As demonstrated (Figure 2), shows the increasing testing capacity and scaling up more testing sites increased the national testing capacity and access to PCR testing

services for the community thus supporting the surveillance and quick management of SARS-CoV-2 patients. By September 2020, the national reference laboratory was able to gain the average test capacity of 1500 samples of RT-PCR per day, and together all the ten satellite laboratories were testing 2500 samples per day at minimum. The testing

workflow was established, giving results at an average turnaround time of 24 hours. Negative results were submitted to individuals, and the surveillance team informed them how to take appropriate protective measures. Positive SARS-CoV-2 was submitted to the surveillance team every evening to immediately evacuate the patients to the selected treatment centers and trace the contact to reduce transmission risk.

➤ *Training activities*

Training activities involved a developed module by senior lab scientists to junior scientists and involved sample collection, sample transport, sample registration, sample reception, processing, RNA extraction procedures, amplification, and reporting standard operating procedures to return laboratory results on time. We trained 35 individuals per week to master these procedures and generated a team of trainers, and in total, 350 volunteered technicians were trained to be involved in the testing and reporting of SARS-CoV-2 methods in two months, and the capacity was adequate to have a pool of skilled individuals for all sites. We want to point out key lessons learned by implementing the pandemic scale-up and SARS-CoV-2 laboratories in Rwanda (January –September 2020).

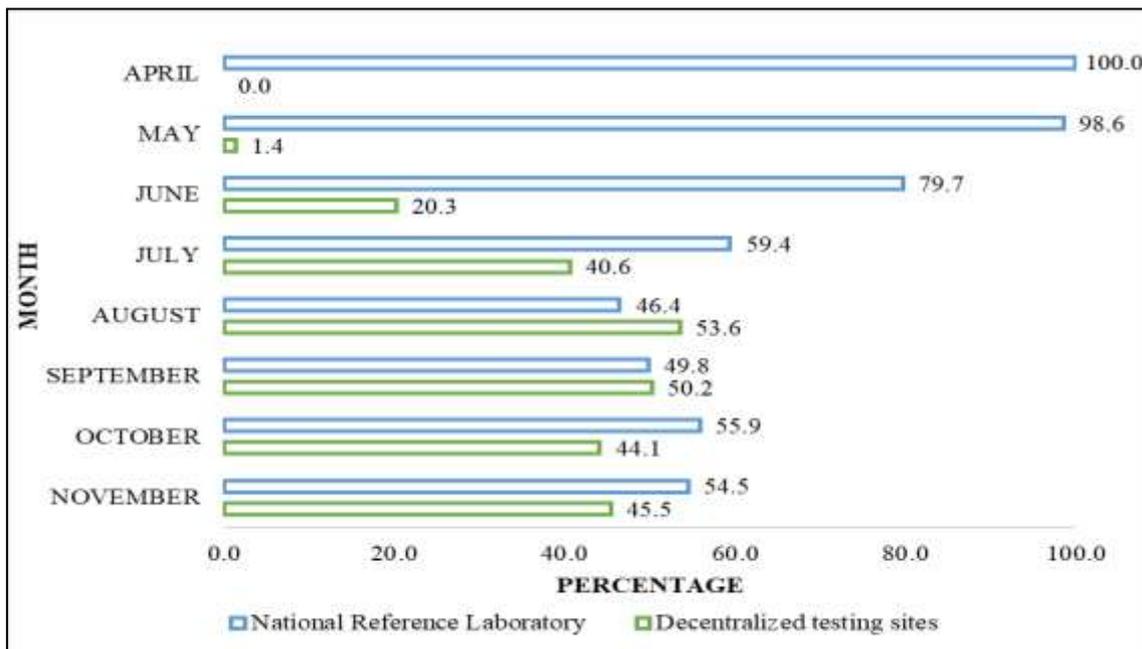


Fig 2: Scaling up the COVID-19 testing capacity for decentralized testing sites

II. LESSON LEARNED FROM COVID-19 TESTING IN RWANDA.

➤ Lesson 1: Promotion of research/evidence-based actions to inform implementation

Rwanda's testing capacity for COVID-19 increased from 200 samples per day to more than 1500 samples per day (Fig 1). Due to the tracing and surveillance system, the number depended on the surge in cases and the clusters of hot spot areas of COVID-19. This ensured smooth and productive surveillance of the virus and building on already existing laboratory, sentinel, and disease surveillance systems. The backbone of the surveillance has been acknowledged for handling outbreak(17). Moreover, strengthening the health research system (HRS) and implementing the research outcome provides efficient management of outbreak (18).

Through research, Rwanda adopted the pooling strategy to scale up testing capacity increasing 15 folds from mid-March to mid-July with a daily capacity of more than 7,000 tests per day when the hot spot clusters increased(19). On 4th September 2020, Rwanda tested 0.43 per 1,000 population, making it the fourth country with the highest testing coverage in Africa after Morocco (0.60 per 1,000), Namibia (0.57 per 1,000), and Lybia (0.46 per 1,000)(20). More importantly, from 15th April to 30th June 2020, Rwanda was among the leading three low-income countries (LICs) with high daily COVID-19 testing per 1000 population, from the 1st July until 16th August 2020. Rwanda becomes the first LIC with the highest daily testing capacity and later until 10th September 2020 when there was a significant reduction in tested cases due to a low positivity rate (from 230 daily cases as of 20th September 2020 to less than 20 cases as of 10th September 2020), Rwanda continued to be among the leading three LICs with high testing capacity and a reputable COVID-19 testing profile in LMICs(21, 22).

Although several researchers and institutions have acknowledged pooling, there is evidence that some limited resource countries have not yet adopted the method, and uncertainty remains high due to the result reliance gap estimated by CDC with $\geq 85\%$ percent positive agreement (PPA) and limited researches(23, 24). However, the method had a limitation of being useful in a low prevalence setting. Therefore, setting-up new testing sites and decentralizing testing to the hot spot areas closed the gap, making the pooling strategy more effective by site consideration.

In spite of the limited resources, Rwanda has contributed to the SARS-CoV-2 genomes by uploading nine sequenced copies(25). However, as other LMICs, Rwanda has been left behind to track the new COVID-19 variants that originated from United Kingdom (UK), Brazil, and South Africa(26). Since 3rd December 2021, COVID-19 cases have consistently risen from 17 new cases to 336 new cases as of 26th January 2021, and the mortality rate increased dramatically, with Rwanda reporting up to nine COVID-19 related death in a single day(27, 28). Thus, this strongly demonstrates the need for surveillance and investigating the new COVID-19 variants to guide policy.

➤ Lesson 2: Optimizing Staff productivity

Apart from being the cornerstone of quality health care, the medical laboratory is a complex, rapidly evolving sector requiring a wide range of skilled workforce competent to use the novel technology on the market in consideration to stock and resource availability(29). In the context of SARS_COV2 diagnosis at NRL, on average, in a two-hour-long manual extraction environment, 45 well-trained laboratory staff directly involved in extraction and amplification were able to run the laboratory for twenty-four hours to amplify 3000 samples with a fluent and quality turnaround time. This implies a staff workload ratio of 15 for 1000 samples to run a

RT PCR SARS-COV2 test for efficiency purposes. By adopting pooling in a low prevalence period, the productivity could even be doubled(19). Countrywide, considering the staffs directly involved in extraction and amplification, in September 2020, 73 staffs tested 86,086 samples with an average of 2870 tests daily.

Rwanda Biomedical Center, in collaboration with Rwanda Joint Task Force for COVID-19, which was initiated in the early pandemic period leads response, boosted staff output. Testing centers got an opportunity of welcoming skilled and well-trained personnel for technical assistance in Covid-19 testing. The staff from public institutions (University of Rwanda, public institutions, and public hospitals) and private sectors (World Health Organization, Local and international Non-governmental Organization, Project San Francisco) come together through public and private institutions partnerships to enforce the response during the pandemic. Professional associations' role was also noticed whereby; the association of biomedical technologists in Rwanda (ATEBIR) nominated supporting staff among their members. This existing partnership helped NRL and other testing sites continue delivering other laboratory services amid staff capacity requirements.

➤ *Lesson 3: Laboratory resources optimization*

Rwandan COVID-19 laboratory response was characterized by the utilization of testing platform resources and was leveraged to increase COVID-19 testing capacity. Assuring the continuous availability of COVID-19 reagents and other suppliers was a major consideration. Due to the pooling influence, 86,086 tests that were tested countrywide required 605 extraction kits, 208 DaAn Gene Co Ltd amplification kits for screening and 70 BGI amplification kits for confirmation. The pooling approach to scale up testing in asymptomatic patients has been acknowledged by U.S Food and Drugs Authority (FDA) with $\geq 85\%$ positive agreement(23). More importantly, given the mode transmission of COVID-19, safety conditions required enforcement despite the existing global shortage of PPEs. Tables 1 and 2 summarize the list of needed reagents, PPE consumables, and equipment for tested 86,086 samples in September 2020.

Rwanda benefited from Abbott m-2000 testing platform in different laboratories across the country to decentralize testing based on the surge in cases and the specific need of testing in an identified area. Based on the financial requirement of PCR-testing, the approach to COVID-19 testing in each part of the country may change due to many factors; however, it's crucial to expand the capacity to test individuals to maximize public effort health measures. Furthermore, when countries are in the process of lift measures to contain the virus, the disease's incidence rate will likely increase. Countries with limited physical resources and human capacity are specifically requested to prioritize testing to understand the disease burden. Thus pooling strategy and

optimizing the utilization existence platforms can contribute significantly.

Table 1: Required supplies for setting up testing in September,2020

N	Item	Item/pack or box	Qty/ month	pack/box/ items
1	Extraction Kit	1	605	605
2	Amplification Kits DaN	1	280	280
3	Amplification Kits BGI	1	70	70
4	Cryovials 1,5ml	100	60000	600
5	Tips 1000µl	100	86400	864
6	Tips 20µl	100	33600	336
7	Tips 10µl	100	13440	134
8	Tips 100µl	100	7680	77
9	Tips 200µl	100	27840	278
10	Ethanol	5	60	12
11	PCR Tubes	100	4000	40
12	Plates sealer	1	4	4
13	Plate standard	1	2	2
14	Covid-19 Ag for validation	50	7531	151

➤ *Lesson 4: Training and decentralization of molecular testing*

Pre-COVID-19, Rwanda Biomedical Centre (RBC) collaborated with the WHO to provide training for the staff in the sample collection of a highly contagious outbreak such as Ebola, and as a result, many health staff was trained across the country for sample collection, packaging, transportation and analysis(30). These trainings were enforced by rigid preparedness on COVID-19 simulation conducted countrywide in different health settings to boost the staff's knowledge towards COVID-19 testing and preparedness.

Two weeks after COVID-19 emerged in Rwanda, the need for staffing was highly acknowledged, and the National reference Laboratory Division had volunteers who were trained during preparedness and were ready to get involved. Also, civil servants with relevant experience and a background in molecular and laboratory testing were placed on secondment to facilitate the testing and sampling of COVID-19. Due to the sporadic cases of COVID-19 in other regions other than Kigali, there was a need to enforce the molecular testing laboratories used to test HIV viral load, Hepatitis B Virus (HBV), and Hepatitis C Virus (HCV) Viral Load for supporting COVID-19 testing.

Table 2: Staff Personal Protective equipment needs for setting up testing

N	Item	Item/pack or box	Qty	pack/box/items
1	Masks N95	20	2778	139
2	Mask KF94	5	275	55
3	Surgical Masks	50	8488	170
4	Face Shield	10	482	48
5	Clean all	6	317	53
6	Lab Coats	100	3704	37
7	Gloves	100	32416	324
8	Autoclave waste big	50	447	9
9	Autoclave waste small	50	343	7
10	Hand Sanitizer	0.5	100.5	201
11	Bleach	0.5	49.5	99
12	Permanent marker	12	110	9
13	Pens	50	600	12
14	Soap	1	4	4

However, in some settings, such as Kirehe District Hospital, where the setting site for COVID-19 for the South-East was settled, there was no existing molecular-based testing and using the East African Community (EAC) Mobile Laboratory Network to intervene in epidemic outbreak response like Dengue, Ebola, COVID-19 testing site was initiated in Kirehe. The employees benefited from onsite training and mentorship during the process. Using BIO-RAD CFX96 Cycler, Kirehe became a testing site running up to 500 tests daily, facilitating monitoring the cross-border truck drivers surveillance of COVID-19 in the Southeast region. Figure 2 and 3 show the scaling up of decentralized testing sites and a trend of COVID-19 testing by decentralized testing sites.

➤ *Lesson 5: The role of laboratory continuous quality improvement, accreditation, and laboratory information system standardization*

National reference laboratory had been already enrolled in the accreditation system and at the time the first case of COVID-19 was detected in Rwanda(31). The laboratory has been Sassed and waiting for an accreditation certificate from the accrediting body. This was another side of quality encouragement and laboratory staff were motivated to work hard while adhering to the quality standards. The PPE were adequately availed to allow the staff to work with safety standards (table1). In addition to the lessons, the laboratory information system (LIS) was functional and operational so it was adopted for capturing COVID-19 data. It was later changed and adopted to the health management information system (HMIS) that is part of the District Health Information Software 2 (DHS2) web-based and fully tangled to the surveillance investigation form of the COVID-19 case and contact information. This responded to the call for health informatics response required (32). This is another lesson that COVID-19 activated in our laboratory information system that strengthened our operations and improved the testing and reporting procedures in Rwanda.

➤ *Lesson 6: Efficient use of funds and donation*

As a LMIC, Rwanda used government funds and gained support from partners to scale up COVID-19 testing to increase the detection rate and monitor activities. In particular, Rwanda had also received other donations, including SARS-COV-2 RT-PCR testing kits from Jack ma and Alibaba foundation for testing COVID-19 and Rapid diagnostic tests, including personal protective equipment and hand sanitizers of all types. All together was necessary at the initial stages of the pandemic when the purchase of kits was complicated at the time of global lockdown. Through were structured systems that monitor government funds, the country has managed to handle the corruption in the COVID-

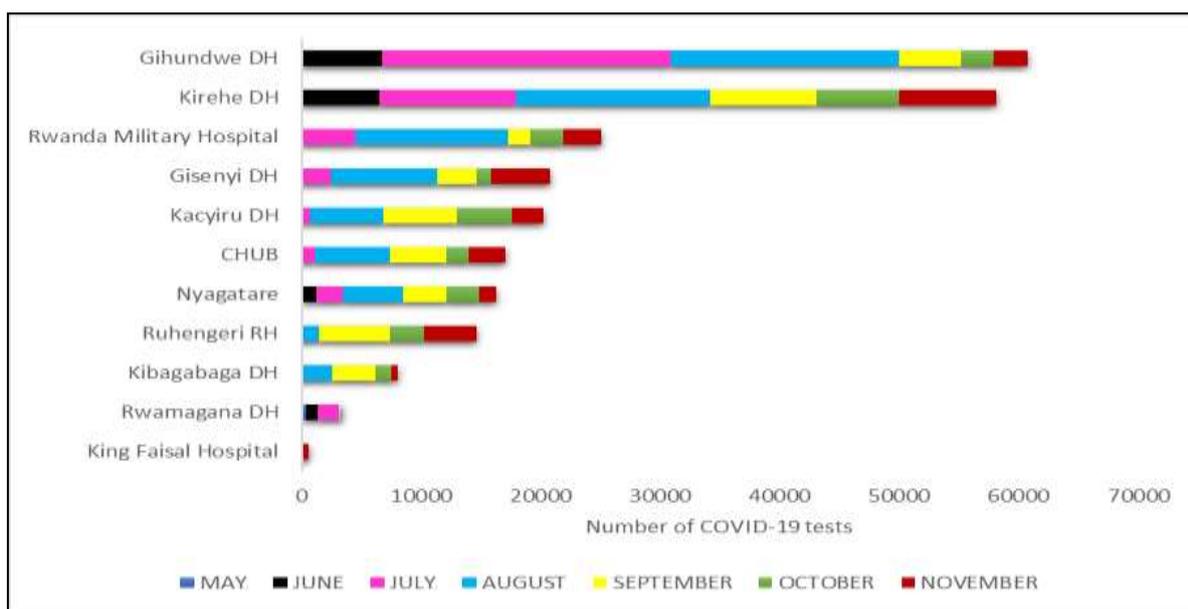


Fig 3: The Trends in COVID-19 testing for decentralized testing sites

19 era, which has been a challenge in developing countries, resulting in miss use (24).

❖ *Limitations/Challenges and bottlenecks during the scale-up process:*

- Insufficient physical and human resources in the laboratory to support new high demand of work: despite the additional work and increased demand, the human resources were not proportionally increased to stand the testing demand in all facilities and testing needed in the community.
- Low engagement of private sector to support the testing needs of several entertainment groups need of testing before gathering such as football and school opening and conferences and meetings, these required access to private testing facilities to meet demand and exiting guidelines were not yet in place for proper coordination to control transmission of the virus to control community transmission.
- Insufficient laboratory and clinical research funding to sustain the health infrastructure for motivating researchers and local scientists to generate new knowledge for SARSCOV-2 from a multidisciplinary team.
- Inadequate sequencing capacity for new strains of SARSCOV-2 emerging/ reported in UK, USA, South Africa, and Nigeria, and other countries. Capacity to monitor new variants/strains is still lacking resources.
- Supply and consumables usually a challenge to get on time, and a variety of supplies are needed for RT-PCR, and delivery lead time is critical while dealing with emergencies and pandemic; there is a challenge of procurement and funds alignment with existing procurement regulations for competitive tendering.

III. CONCLUSION

The need for rapid response to contain the propagation of a pandemic is not questionable. Laboratory testing has played a role in identifying pandemic cases in the community and continuing to be the reliable approach to guide surveillance. Given the limited physical and human resources in developing countries, early research-based actions to drive the effective utilization of resources and funds might be prioritized to boost the laboratory response during SARSCOV-2 outbreak and might be extrapolated to other SARS-like respiratory disease outbreak management in the future. Constant Continuous training of the scientific workforce is essential to ensure that staff is not overwhelmed by new pandemic workload. The information system technology is critical to digitalize all the laboratory reporting information, provide timely feedback, and feed data science for policy action. A constant and continuous research approach in the pandemic period is vital to elucidate new testing methods that give results in short time and decentralization of test at point of care is important to test and control the pandemic before vaccine is introduced and availed

to everyone in need. Future work should utilize scaling up testing capacity to prepare ground for vaccine efficacy studies before and after its roll out to monitor progress in limited resource setting.

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