



## OPEN LETTER

# Maintaining laboratory quality assurance and safety in a pandemic: Experiences from the KEMRI-Wellcome Trust Research Programme laboratory's COVID-19 response [version 1; peer review: 1 approved, 1 approved with reservations]

Horace Gumba <sup>1</sup>, Michael Opiyo <sup>1</sup>, Jennifer Musyoki<sup>1</sup>, Martin Mutunga<sup>1</sup>, Caroline Ngetsa <sup>1</sup>, Salim Mwarumba<sup>1</sup>, Moses Mosobo<sup>1</sup>, Susan Njuguna<sup>1</sup>, Oscar Kai<sup>1</sup>, Arnold W. Lambisia <sup>1</sup>, Domtila Kimani<sup>1</sup>, Robinson Cheruiyot<sup>1</sup>, Patience Kiyuka<sup>1</sup>, Clement Lewa<sup>1</sup>, Elijah Gicheru<sup>1</sup>, Metrine Tendwa<sup>1</sup>, Khadija Said Mohammed <sup>1</sup>, Victor Osoti<sup>1</sup>, Johnstone Makale <sup>1</sup>, Brian Tawa<sup>1</sup>, Calleb Odundo<sup>1</sup>, Wesley Cheruiyot<sup>1</sup>, Wilfred Nyamu<sup>1</sup>, Wilson Gumbi<sup>1</sup>, Jedidah Mwacharo<sup>1</sup>, Lydia Nyamako<sup>1</sup>, Edward Otieno <sup>1</sup>, David Amadi <sup>1</sup>, Nelson Ouma <sup>1</sup>, Boniface Karia<sup>1</sup>, Janet Thoya<sup>1</sup>, Angela Karani<sup>1</sup>, Daisy Mugo<sup>1</sup>, Bonface M. Gichuki <sup>1</sup>, Debra Riako<sup>1</sup>, Shadrack Mutua<sup>1</sup>, John N. Gitonga <sup>1</sup>, Kelly Ominde <sup>1</sup>, Perpetual Wanjiku<sup>1</sup>, Agnes Mutiso<sup>1</sup>, Alfred Mwanzu <sup>1</sup>, Yiakon Sein<sup>1</sup>, Brian Bartilol<sup>1</sup>, Shaban Mwangi <sup>1</sup>, Donwilliams O. Omuoyo <sup>1</sup>, John M. Morobe <sup>1</sup>, Zaydah R. de Laurent <sup>1</sup>, Fredrick Mitsanze<sup>1</sup>, Alfred Mwakubia<sup>1</sup>, Martin Rono <sup>1</sup>, Amek Nyaguara <sup>1</sup>, Benjamin Tsofa<sup>1</sup>, Philip Bejon <sup>1,2</sup>, Charles N. Agoti <sup>1</sup>, Lynette Isabella Ochola-Oyier<sup>1</sup>

<sup>1</sup>KEMRI-Wellcome Trust Research Programme, 230 Hospital Road, Kilifi, 80108, Kenya

<sup>2</sup>Nuffield Department of Medicine, Centre for Clinical Vaccinology and Tropical Medicine, University of Oxford, Churchill Hospital, Old Road, Headington, Oxford, OX3 7LE, UK



**V1** First published: 09 Aug 2021, 6:205  
<https://doi.org/10.12688/wellcomeopenres.16704.1>  
 Latest published: 09 Aug 2021, 6:205  
<https://doi.org/10.12688/wellcomeopenres.16704.1>

## Abstract

Laboratory diagnosis plays a critical role in the containment of a pandemic. Strong laboratory quality management systems (QMS) are essential for laboratory diagnostic services. However, low laboratory capacities in resource-limited countries has made the maintenance of laboratory quality assurance, especially during a pandemic, a daunting task. In this paper, we describe our experience of how we went about providing diagnostic testing services for SARS-CoV-2

## Open Peer Review

Reviewer Status  

	Invited Reviewers	
	1	2
version 1 09 Aug 2021	 report	 report

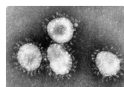
through laboratory reorganization, redefining of the laboratory workflow, and training and development of COVID-19 documented procedures, all while maintaining the quality assurance processes during the COVID-19 pandemic at the Kenya Medical Research Institute (KEMRI) Wellcome Trust Research Programme (KWTRP) laboratory. The KWTRP laboratory managed to respond to the COVID-19 outbreak in Kenya by providing diagnostic testing for the coastal region of the country, while maintaining its research standard quality assurance processes. A COVID-19 team comprising of seven sub-teams with assigned specific responsibilities and an organizational chart with established reporting lines were developed. Additionally, a total of four training sessions were conducted for county Rapid Response Teams (RRTs) and laboratory personnel. A total of 11 documented procedures were developed to support the COVID-19 testing processes, with three for the pre-analytical phases, seven for the analytical phase, and one for the post-analytical phase. With the workflow re-organization, the development of appropriate standard operating procedures, and training, research laboratories can effectively respond to pandemic outbreaks while maintaining research standard QMS procedures.

### Keywords



Quality management system, laboratory pandemic response, quality assurance, coronavirus disease, COVID-19 testing, COVID-19 pandemic



This article is included in the [KEMRI | Wellcome Trust](#) gateway.



This article is included in the [Coronavirus \(COVID-19\)](#) collection.

1. **Talkmore Maruta** , Africa Centers for Disease Control, Addis Ababa, Ethiopia
2. **Angela Amayo** , University of Nairobi, Nairobi, Kenya

Any reports and responses or comments on the article can be found at the end of the article.

**Corresponding authors:** Horace Gumba ([hgumba@kemri-wellcome.org](mailto:hgumba@kemri-wellcome.org)), Lynette Isabella Ochola-Oyier ([LiOchola@kemri-wellcome.org](mailto:LiOchola@kemri-wellcome.org))

**Author roles:** **Gumba H:** Conceptualization, Formal Analysis, Investigation, Methodology, Project Administration, Supervision, Validation, Writing – Original Draft Preparation, Writing – Review & Editing; **Opiyo M:** Conceptualization, Investigation, Methodology, Writing – Original Draft Preparation, Writing – Review & Editing; **Musyoki J:** Methodology, Project Administration, Supervision, Writing – Review & Editing; **Mutunga M:** Formal Analysis, Methodology, Writing – Review & Editing; **Ngetsa C:** Methodology, Supervision, Writing – Review & Editing; **Mwarumba S:** Methodology, Supervision; **Mosobo M:** Methodology, Writing – Review & Editing; **Njuguna S:** Methodology; **Kai O:** Resources, Writing – Review & Editing; **Lambisia AW:** Methodology, Writing – Review & Editing; **Kimani D:** Investigation, Methodology; **Cheruiyot R:** Investigation, Methodology; **Kiyuka P:** Investigation, Methodology; **Lewa C:** Investigation, Methodology; **Gicheru E:** Investigation, Methodology; **Tendwa M:** Investigation, Methodology; **Said Mohammed K:** Investigation, Methodology, Validation; **Osoti V:** Investigation, Methodology; **Makale J:** Investigation, Methodology; **Tawa B:** Investigation, Methodology; **Odundo C:** Investigation, Methodology; **Cheruiyot W:** Investigation, Methodology; **Nyamu W:** Investigation, Methodology; **Gumbi W:** Investigation, Methodology; **Mwacharo J:** Investigation, Methodology; **Nyamako L:** Investigation, Methodology; **Otieno E:** Formal Analysis, Investigation, Methodology, Writing – Review & Editing; **Amadi D:** Formal Analysis, Investigation, Methodology; **Ouma N:** Investigation, Methodology; **Karia B:** Investigation, Methodology; **Thoya J:** Investigation, Methodology; **Karani A:** Investigation, Methodology; **Mugo D:** Investigation, Methodology; **Gichuki BM:** Investigation, Methodology; **Riako D:** Investigation, Methodology; **Mutua S:** Investigation, Methodology; **Gitonga JN:** Investigation, Methodology; **Ominde K:** Data Curation, Investigation, Methodology; **Wanjiku P:** Data Curation, Investigation, Methodology; **Mutiso A:** Data Curation, Investigation, Methodology; **Mwanzu A:** Data Curation, Investigation, Methodology; **Sein Y:** Investigation, Methodology; **Bartilol B:** Investigation, Methodology; **Mwangi S:** Investigation, Methodology, Writing – Review & Editing; **Omuoyo DO:** Investigation, Methodology, Validation; **Morobe JM:** Investigation, Methodology; **de Laurent ZR:** Investigation, Methodology, Validation; **Mitsanze F:** Investigation, Methodology; **Mwakubia A:** Investigation, Methodology; **Rono M:** Investigation, Methodology, Writing – Review & Editing; **Nyaguara A:** Investigation, Methodology, Project Administration, Supervision; **Tsofa B:** Funding Acquisition, Investigation, Methodology, Project Administration, Resources, Visualization, Writing – Review & Editing; **Bejon P:** Funding Acquisition, Investigation, Project Administration, Resources, Writing – Review & Editing; **Agoti CN:** Conceptualization, Investigation, Methodology, Resources, Supervision, Writing – Review & Editing; **Ochola-Oyier LI:** Conceptualization, Formal Analysis, Funding Acquisition, Investigation, Methodology, Project Administration, Resources, Supervision, Validation, Visualization, Writing – Review & Editing

**Competing interests:** No competing interests were disclosed.

**Grant information:** This work was supported by the Wellcome Trust [203077, ]. We are grateful to the KEMRI-Wellcome Core award [203077] funding through Dr Philip Bejon to support the ongoing COVID-19 testing. Lynette Isabella Oyier and Victor Osoti are supported by a Wellcome Trust Intermediate Fellowship awarded to Lynette Isabella Oyier [07568]. This work was supported by the African Academy of Sciences (AAS) through a DELTAS Africa Initiative grant awarded to [DEL-15-003] (awarded to Charles Agoti Nyaigoti). The DELTAS Africa Initiative is an independent funding scheme of the African Academy of Sciences (AAS) Alliance for Accelerating Excellence in Science in Africa (AESA) and supported by the New Partnership for Africa's Development Planning and Coordinating Agency (NEPAD Agency) with funding from the Wellcome Trust [107769] and the UK government. The views expressed in this publication are those of the authors and not necessarily those of AAS, NEPAD Agency, Wellcome Trust or the UK government. Joyce Uchi Nyiro is supported by a Program for Appropriate Technology in Health (PATH) grant (grant # GAT.1890-01665713-SUB). Kelly Ominde was supported by a Broad One Health Endectocide-based Malaria Intervention in Africa (BOHEMIA) grant which is funded by International Drug Purchasing Facility (UNITAID). Jedidah Mwacharo and Perpetual Wanjiku were supported by a European and Developing Countries Clinical Trials Partnership (EDCTP) grant. We are also grateful for Dr Anthony Scott whose Pneumococcal Conjugate Vaccine Impact Study (PCVIS) grant supported Agnes Mutiso, Alfred Mwanzu, Angela Karani and Shadrack Mutua. *The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.*

**Copyright:** © 2021 Gumba H *et al.* This is an open access article distributed under the terms of the [Creative Commons Attribution License](#), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.

**How to cite this article:** Gumba H, Opiyo M, Musyoki J *et al.* **Maintaining laboratory quality assurance and safety in a pandemic: Experiences from the KEMRI-Wellcome Trust Research Programme laboratory's COVID-19 response [version 1; peer review: 1 approved, 1 approved with reservations]** Wellcome Open Research 2021, 6:205 <https://doi.org/10.12688/wellcomeopenres.16704.1>

**First published:** 09 Aug 2021, 6:205 <https://doi.org/10.12688/wellcomeopenres.16704.1>

## Disclaimer

The views expressed in this article are those of the author(s). Publication in Wellcome Open Research does not imply endorsement by Wellcome.

## Introduction

Laboratory diagnosis forms an essential component of any disease outbreak (Nkengasong *et al.*, 2018; Perkins *et al.*, 2017; Wilson *et al.*, 2018). The importance of well-equipped and prepared laboratories in a pandemic response cannot be understated (Kelly-Cirino *et al.*, 2019). Studies have shown that weak laboratory diagnostic capacity has contributed to significant delays in the identification of the recent outbreaks of Ebola (Perkins *et al.*, 2017), Yellow Fever (Berkley, 2018), and Zika (Lowe *et al.*, 2018). This, therefore, emphasizes the importance of investing in stronger laboratory capacity that can respond to disease outbreaks. This should include elaborate and strong quality management systems (QMS). Weak laboratory quality systems in low- and middle-income countries (LMICs) coupled with the low laboratory capacity, and the technical challenges of developing suitable diagnostic tests for pandemic prevention and containment, has made the implementation of laboratory quality assurance (QA) processes during a pandemic a daunting task (Nkengasong *et al.*, 2018; Olmsted *et al.*, 2010).

Coronavirus disease 2019 (COVID-19), was declared a pandemic by the World Health Organization (WHO) (Cucinotta & Vanelli, 2020) on 11<sup>th</sup> March 2020 following its insidious global threat. It was first reported in Wuhan, China in late December 2019 and later spread to more than 200 countries and territories by December 2020. The disease is caused by a virus from the *Coronaviridae* family, defined as ‘severe acute respiratory syndrome coronavirus 2’ (SARS-CoV-2) (Ceraolo & Giorgi, 2020). By the time of writing this paper (6th December 2020), COVID-19 had infected over 67.4 million people and caused over one million deaths worldwide (Dennison Himmelfarb & Baptiste, 2020). When the director-general of WHO advised various stakeholders to ‘test, test and test’ (Adhanom, 2020), it was a clear indication that laboratory involvement in testing would play a vital role in containing the COVID-19 pandemic. Laboratory testing for SARS-CoV-2, the viral agent causing COVID-19, demands that the laboratory produces accurate, reliable, and timely results. In addition, well-trained personnel and a well-established QMS are required to ensure streamlined processes during testing.

Most of the clinical and diagnostic laboratories in LMICs are underfunded and are often overwhelmed during a pandemic (Nkengasong *et al.*, 2018). These laboratories also have feeble and weak quality management systems which if not strengthened makes laboratory diagnosis during a pandemic a daunting task. Thus, redesigning of the research laboratory’s workflow and reorganization to increase testing capacity can help provide a better platform in a pandemic response.

The KEMRI-Wellcome Trust Research Programme (KWTRP) conducts integrated clinical, laboratory, epidemiological, and

health systems research. Research at the KWTRP is constantly conducted within the local health system; often with health managers and policy makers. This has led to research findings from the programme constantly feeding into local and international health policies (The RESYST/DIAHLS learning site team, 2020). The programme is organized into four scientific departments, namely biosciences, clinical, epidemiology, and health systems and research ethics departments. These are supported by the laboratories, demographic surveillance, clinical services, and stakeholder engagement platforms. The laboratory platform of the programme consists of four main state-of-the-art laboratories. These are the clinical trials laboratory (CTL), Short-Turn-around-Time laboratory (STAT), microbiology laboratory and immunology basic science research laboratory. The laboratory has full accreditation to Good Clinical Laboratory Practice (GCLP) standards, through an accreditation scheme operated by Qualogy (UK) Ltd since 2007, (Gumba *et al.*, 2019) and it has been maintaining compliance to GCLP quality standards to date.

Since the confirmation of the first COVID-19 case in Kenya on 13<sup>th</sup> March, 2020 (MoH-Kenya, 2020) KWTRP was mandated by the Kenya government to support the COVID-19 testing for six coastal counties, namely Kilifi, Kwale, Mombasa, Taita Taveta, Tana River and Lamu. To achieve this critical government mandate, we reorganized our laboratory organization, redesigned the laboratory workflow, developed documented procedures, and conducted training for county Rapid Response Teams (RRTs) and laboratory personnel. Since the KWTRP laboratory is primarily a research laboratory in its design, and the laboratory processes and procedures are organized to facilitate research activities, the laboratory was appropriately reorganized to provide COVID-19 diagnostic testing as requested by the government. We leveraged and utilized the existing quality management systems (QMS) in order to maintain the laboratory quality assurance (QA) during the COVID-19 diagnostic testing to provide reliable, valid, accurate and timely results.

In this paper, we provide a detailed description of our experience in reorganizing a research laboratory to provide diagnostic testing, and highlight the lessons learned. The main objective of this paper is to document how to reorganize a laboratory primarily used for research, in order to provide large scale diagnostic testing during a pandemic outbreak, while also maintaining research standard quality management systems in order to provide reliable, valid, accurate and timely results.

## Documenting the process

We employed a laboratory management implementation model consisting of four approaches, namely: laboratory reorganization, redesigning of laboratory workflows to accommodate diagnostic testing, training, and development of documents related to COVID-19 diagnostic testing.

Throughout these processes, detailed notes of planning meetings and implementation processes were maintained so as to facilitate both the implementation and monitoring of the processes. The meeting notes included the number of staff working

in each area, documentation of testing processes and the testing activities were reviewed during planning meetings. In addition, all the implementation outputs (testing organizational structures, workflow charts, and Standard Operating Procedures (SOPs) were produced in hard copies. These were then used in subsequent review meetings and in monitoring the implementation progress. Moreover, regular review and reflection meetings were also held to discuss the testing process implementation challenges, and, where necessary, adjustments were made to the team composition and/or roles, the laboratory workflows, and the documented procedures. Finally, a review of all the meeting notes and implementation outputs was conducted, and our findings were grouped around common themes for easy presentation. In the section below, we outline in detail each of the four management approaches undertaken; and provide detailed account of the outcomes, and lessons learned.

### Ethics statement

This work was conducted as part of the implementation project to document experiences and lessons learned, so as to continuously enhance quality improvements. Formal ethical approval

was thus not needed. Institutional authorization and permission to share this experience was however sought and provided by the director-general, KEMRI.

### Approach taken

In this section, we outline in detail each of the four management approaches undertaken, and provide a detailed account of the outcomes, and lessons learned. We conclude the section by highlighting some of the challenges encountered during the process.

### Laboratory reorganization

Laboratories require a well-coordinated and organized structure. This helps in constant communication and facilitate clear and sometimes rapid decision-making processes during a pandemic. To achieve this, and to streamline the testing process, we established COVID-19 diagnostic testing teams with assigned clear roles and responsibilities to each (Table 1). We formed these teams by reviewing our laboratory human resource capacity, and by assessing the projected testing demands from the counties we had been assigned. Through this, we developed

**Table 1. COVID-19 teams and their responsibilities.** CIFs- Case Investigation Forms, COVID-19- Coronavirus disease 2019, EQA- External Quality Assurance, GCLP- Good Clinical and Laboratory Practice, PT- Proficiency Testing, QA- Quality Assurance, QC-Quality Control, REDCap - Research Electronic Data Capture system, RNA - Ribonucleic acid.

COVID-19 team	Responsibilities
Sample Management team	<ul style="list-style-type: none"> <li>- Sample reception</li> <li>- Performing sample rejection and notifying the head of department for onward communication to counties</li> <li>- Scanning of CIFs to send to the data team</li> <li>- Registering samples in the laboratory information management system and printing sample labels to assist in storage of samples at -80°C</li> </ul>
Specimen Testing (Polymerase Chain Reaction) team	<ul style="list-style-type: none"> <li>- Performing RNA extraction, sample processing and analysis</li> <li>- Performing QC on test runs, weekly QC and PT/EQA</li> <li>- Equipment maintenance and calibration procedures</li> <li>- Preparing sample aliquots and storing</li> </ul>
Data Management team	<ul style="list-style-type: none"> <li>- Data entry to the laboratory database</li> <li>- Performing QC on data entered in REDCap system.</li> <li>- Performing periodic data cleaning and communicating to the laboratory on missed samples</li> </ul>
Health and Safety team	<ul style="list-style-type: none"> <li>- Induction and orientation of laboratory personnel as a first interaction before involvement in COVID-19 work</li> <li>- Training of laboratory staff on the new safety precautions and procedures relating to the pandemic</li> <li>- Performing risk assessments and subsequent training on COVID-19 work</li> <li>- Coordinating infection control measures and waste management from the pandemic work</li> <li>- Carrying out regular day-to-day inspections to ensure the laboratory personnel adhere to laboratory health and safety guidelines</li> </ul>
Laboratory Supplies team	<ul style="list-style-type: none"> <li>- Maintaining and organizing logistical issues of supplies and maintaining stocks</li> <li>- Distributing supplies from the national government to the county RRTs.</li> </ul>
Quality Assurance team	<ul style="list-style-type: none"> <li>- Setting up QA process within the testing process</li> <li>- Ensuring all documented procedures and validation records are approved and determining compliance to GCLP standards through audits and assessments</li> <li>- Coordination of training on testing documented procedures.</li> </ul>
Results Management team	<ul style="list-style-type: none"> <li>- Compilation, review and relaying of the results</li> <li>- Coordinating repeat testing of samples where necessary</li> </ul>



and produced a COVID-19 diagnostic testing organizational structure for the laboratory ([Figure 1](#)), so as to facilitate effective communication and coordination among the teams.

As shown in [Figure 1](#), each of the seven teams had a team lead who acted as a coordinator and focal person for that particular laboratory function/section and reported to the COVID-19 diagnostic testing project manager. The reorganization of the laboratory to form a COVID-19 testing team comprising seven sub-teams also enhanced communication and the coordination of COVID-19 testing activities, which if not clearly addressed could have been a major detractor to the quality assurance system. The reorganization made it possible for us to support testing from six Kenyan coastal counties.

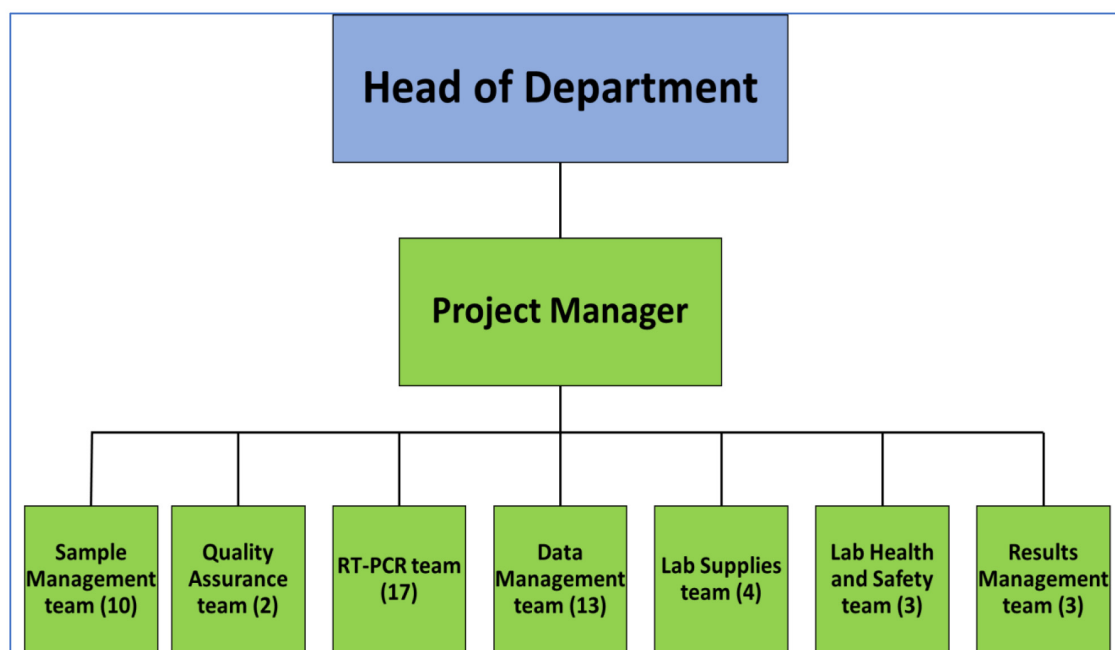
From our experience, the development and implementation of this organizational structure for COVID-19 diagnostic testing significantly enhanced communication and coordination among different teams and greatly facilitated clear and sometimes rapid decision-making processes. This served to promote efficiency and minimize conflict within the laboratory organization and when liaising with the various county RRTs. The day-to-day running of the COVID-19 testing and related work was coordinated by the KWTRP Biosciences Head of Department (HoD). As the work volume increased and with a strong foundation in place, daily activities were managed by the laboratory project manager with oversight from the HoD. Each team was tasked with developing documentation for their COVID-19 testing process. Furthermore, the strong laboratory QMS and dedicated QA team, who were well versed in quality assurance activities, allowed for the easy transfer of QMS into the testing

process, ensuring that accurate and reliable results could be generated during the pandemic. The QA team ensured that SOPs and documentation of the testing process were performed correctly, and that the laboratory complied to the established documented procedures as well as ascribed standards.

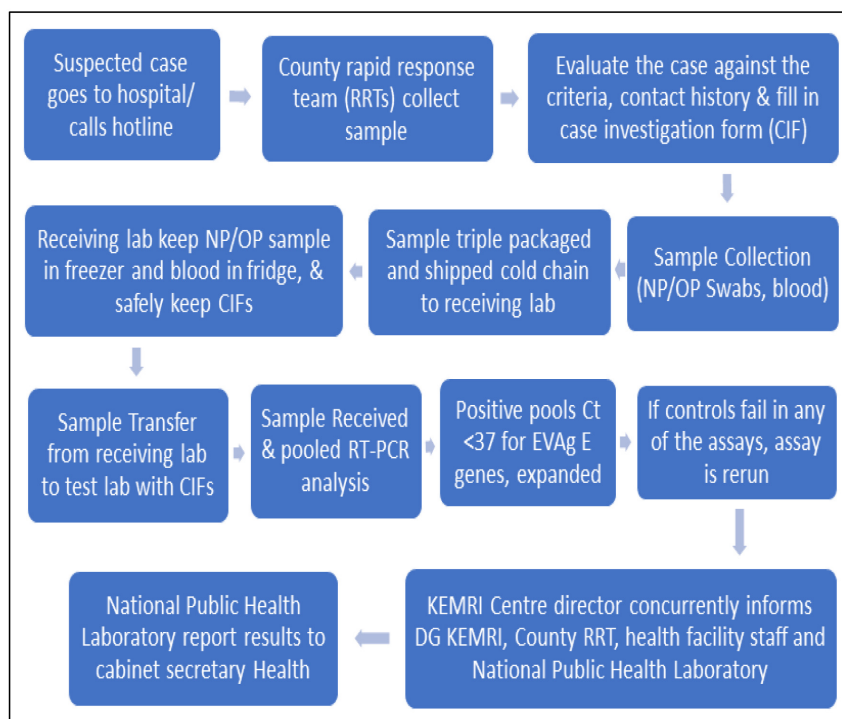
### Redesigning of the laboratory workflow

We undertook process mapping ([Figure 2](#) and [Figure 3](#)) to outline how the COVID-19 testing workflow would happen, i.e., from specimen reception to the release of results. This involved redesigning the already established research systems of SOPs, flow of samples, waste management and training to create a diagnostic environment to support the COVID-19 testing. [Figure 2](#) and [Figure 3](#) outline the workflows that were eventually developed following various team meetings attended by the COVID-19 steering committee.

From our experience in implementing these workflows, we found that once they were fully implemented, we had better coordination of the testing processes and better turnaround time for producing and communicating lab results to all relevant authorities. Process mapping helped to determine the available laboratory infrastructure, facilities, and personnel needed to support COVID-19 testing, while ensuring all the quality assurance activities within the testing process were not compromised. The laboratory workflow was redesigned using the [Sianipar \(2019\)](#) model. This involved dividing the pre-analytical phase into two categories namely: the 'conventional' category and the 'pre-pre-analytical phase'. Using this model helped in identifying error prone areas within the pre-analytical phase and putting measures to minimize them. The 'pre-pre-analytical phase' was



**Figure 1. The organizational structure of the COVID-19 testing teams.** The chart shows the teams that were established to support each other to cover all aspects of the testing process. The numbers in brackets indicate the number of personnel per team.



**Figure 2. The map of the COVID-19 testing process connecting sample collection conducted by the county Rapid Response Teams (RRTs) to the results released to the ministry of health.** CIFs-Case Investigation Forms, DG- Director General, RRT- Rapid Response Teams, NP/OP- nasopharyngeal/oropharyngeal, RT-PCR- real time-Polymerase Chain Reaction.

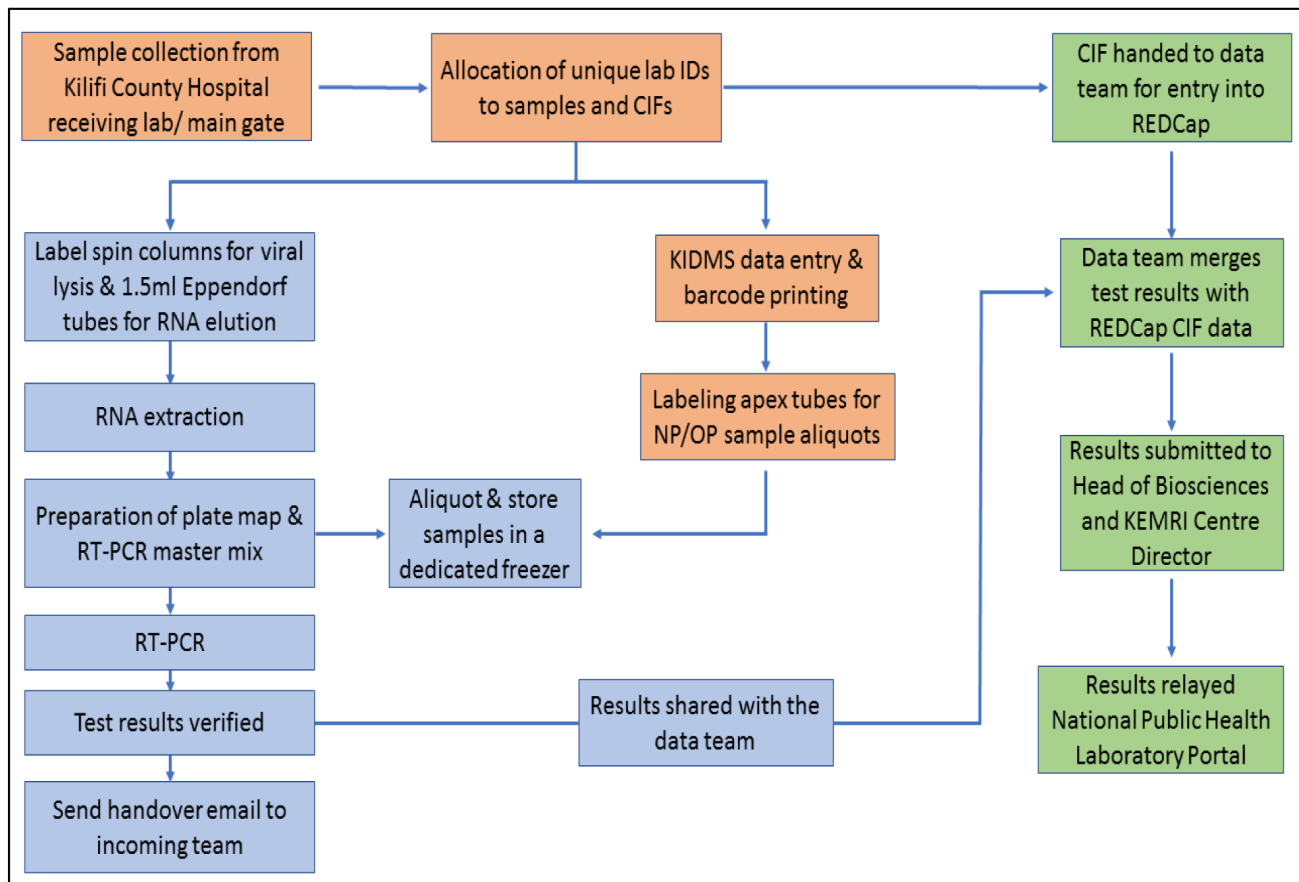
primarily the responsibility of the COVID-19 county RRTs sample collection centers, while the ‘conventional’ category involved the process of centrifuging and aliquoting the samples (Figure 2) which was primarily the role of our laboratory (KWTRP). This was done to minimize the pre-analytical phase errors during the COVID-19 pandemic. In addition, an inventory assessment was made of the adequacy of all available equipment that would be required for SARS-CoV-2 testing, this included safety equipment (biological safety cabinets), sample processing equipment (centrifuges), molecular biology analyzers (real time-polymerase chain reaction (RT-PCR), QIAcube HT, and QIAAsymphony) and other auxiliary equipment such as pipettes and vortex.

Through mapping of the laboratory workflow, the existing systems in place for non-stock items were adapted by the laboratory and supplies team to support the SARS-CoV-2 testing process. Sample collection reagents such as viral transport media (VTM), and RT-PCR testing kits supplied by the government were managed and made available to the COVID-19 RRTs, and documentation of issue and receipt of these items was well recorded. On receipt of supplies, an inventory was taken, and a report was sent back to the supplier outlining the quantities received. Additionally, new reagent consignments were requested in advance to minimize reagent stockouts in the laboratory. The laboratory supplies team performed inventories to ensure there was no understocking or stockouts and that available supplies were distributed to all RRTs. This was an integral part of maintaining quality assurance during SARS-CoV-2 testing.

During the redesigning of the laboratory workflow, the already established Laboratory Information Management System (LIMS) was used to create a database for COVID-19 testing that linked a unique laboratory identifier number of a specimen to its storage in the laboratory’s biobank system (Figure 3). The system that was developed allowed for batch loading of samples to aid in sample reception and printing of barcode labels. Access to LIMS was password restricted. To promote a smooth laboratory and data interface, the existing systems for data entry which REDCap (Version 10.5.1) were modified and customized to support SARS-CoV-2 testing and ensure only reviewed results are authorized and released to the relevant authorities. The data team entered the information from the CIFs into the database and reviewed them to check for any errors in data entries. This was then merged with the final PCR results using the LIMS unique lab identifier to generate individual patient results reports that were shared with the county RRT.

### Training

A total of four different types of training were conducted for two different staff categories (Table 2). All the four types of training were entirely focused on the personnel safety and laboratory preparedness during COVID-19 testing throughout the pandemic. The first training was conducted for county RRTs to equip them with knowledge on proper sample collection and triple packaging to safely transport samples to the laboratory. The rest of the training was performed for laboratory personnel and included risk assessments, infection control procedures, and COVID-19 testing SOPs. These training was designed to



**Figure 3.** Kenya Medical Research Institute (KEMRI) COVID-19 testing flowchart showing how the laboratory teams connected to form a seamless process of testing, from the arrival of samples at the organization's gates, to the release of the results: orange boxes, sample management team processes; blue boxes, real time-polymerase chain reaction (RT-PCR) team processes; green boxes, data management team processes. CIF- Case Investigation Form, NP/OP- nasopharyngeal/oropharyngeal.

**Table 2.** The list of trainings performed, the category of staff trained, and the training purpose.

Training	Category of staff trained	Training purpose
Sample collection and transport	County Rapid Response Teams (RRTs)	<ul style="list-style-type: none"> <li>- To equip the RRTs with methods of collecting the right sample.</li> <li>- Develop policies and procedures to guide sample collection and transport.</li> </ul>
Risk assessment	Laboratory personnel, RRTs	<ul style="list-style-type: none"> <li>- To identify risks and develop mitigation measures</li> <li>- Risk communication protocol</li> <li>- Incident reporting</li> </ul>
Infection control procedures	Laboratory personnel	<ul style="list-style-type: none"> <li>- Waste management</li> <li>- Donning and doffing of Personal Protection Equipment (PPEs)</li> <li>- Disinfection control procedures e.g. washing hands</li> </ul>
SOP training	Laboratory personnel	<ul style="list-style-type: none"> <li>- To equip the laboratory staff with knowledge regarding equipment used and COVID-19 testing procedures</li> </ul>

equip both the RRTs and the laboratory personnel with knowledge of procedures and laboratory safety, including competency testing.

Conducting training that covered the COVID-19 testing process was critical to the successful maintenance of laboratory quality assurance during the COVID-19 testing. Using the existing



laboratory system for training and competency assessment, the COVID-19 testing team and the RRTs were trained on sample collection and transport, risk assessment, infection control procedures, and developed COVID-19 testing SOPs. A risk assessment was carried out for both the county RRTs and the laboratory personnel; and involved identifying laboratory equipment to be used and a possible sample path flow to minimize the risk of infections in the laboratory. Four class 2 biological safety cabinets and a fridge were used only for COVID-19 sample processing and temporary specimen storage, respectively, and for the flow of samples as they came from the field/gates into the laboratory was determined. Provision of 70% (v/v) ethanol for hand-sanitization at the main entry doors, cooler boxes from the field, and laboratory surfaces were provided. In addition, 10% (v/v) bleach was provided in areas where COVID-19 samples were processed. Furthermore, staff were encouraged to maintain social distancing and to use personal protective equipment (PPE), which included N-95 masks, disposable laboratory coats, and goggles. Laboratory personnel were briefed on the existing structure for reporting accidents and incidents using the established procedure within the QMS. A risk communication protocol was also developed to ensure that information is modulated and checked for consistency before relaying it, to avoid the creation of panic during a pandemic. The COVID-19 teams were also trained on infection control procedures. This involved refresher training on use of PPEs, waste management, and triple packaging of COVID-19 samples. Due to the close proximity and close working relationship of the Kilifi County Hospital (KCH), several documents such as tracking logs and SOPs were shared between the institutions to support the Kilifi RRTs. The goal of the infection control procedure training was to ensure safety of the healthcare worker, the laboratory personnel, and the environment to help prevent infections.

#### Development of COVID-19 testing standard operating procedures

To ensure the laboratory maintains the quality assurance within the COVID-19 testing process, we developed and documented

various new SOPs; and reviewed the existing ones to support the COVID-19 diagnostic testing. The SOPs were categorized according to the three phases of the COVID-19 testing process (Table 3).

Procedure for specimen reception and rejection was developed to ensure samples of high integrity were received. The specimen rejection criteria involved checking and excluding leaking samples, duplicate samples, samples collected using the wrong swabs or swabs with no Viral Transport Media (VTM), samples without case investigation forms (CIFs) or specimen tubes with illegible labels (Figure 3). The county RRTs were informed by the project manager of samples with missing CIFs and allowed 48 hours for communication to be received on the missing CIFs. Due to the limitations in sample collection kits and the need for rapid contact tracing from the positive cases, the rejection criteria were leniently revised to accept samples with legible labels but with no CIFs, hence the 48-hour window for communication. Consequently, the existing health and safety documented procedures for specimen transport, processing, and waste management were reviewed with reference to the United States Centers for Disease Control and Prevention (CDC) and the WHO COVID-19 laboratory safety guidelines (Centers for Disease Control and Prevention, 2020; WHO, 2020a; WHO, 2020b; WHO Laboratory Biosafety Manual, 2020).

Development of the SOPs for the COVID-19 testing activities enhanced training and promoted consistency in performing the COVID-19 testing procedures. Since this is a novel virus and the SOPs (Table 3) had to be developed from scratch, there was need to develop validation protocols and have them approved to avoid the risk of generating RT-PCR false-negative or positive results that would undermine the reliability of test results. The validation protocols were developed, and assay performance was optimized to ensure valid and reliable results were generated (Said *et al.*, 2020). Lot numbers of the testing kits and the enzymes were verified, and parallel testing was performed to ensure the kits and the reagents were in good working

**Table 3. The standard operating procedures (SOPs) developed to support COVID-19 testing.**

Testing phase	Standard Operating Procedures (SOPs) developed	SOP number
<b>Pre-analytical phase</b>	Collection of nasopharyngeal and oropharyngeal samples for COVID-19 diagnosis	LVEC-053
	Packaging and transportation of suspected COVID-19 biological specimens	LVEC-052
	COVID-19 sample reception and acceptance procedure	LIMM-SSP-078
<b>Analytical phase</b>	Safe handling and processing of COVID-19 suspected samples in the laboratory	LVEC-054
	RNA extraction from COVID-19 samples using Qiacube HT analyzer	LVEC-055
	Manual RNA extraction from COVID-19 samples using QIAamp viral Mini Kit	LVEC-056
	RNA extraction from COVID-19 samples using Da An gene extraction Kit	LVEC-058
	RNA extraction from COVID-19 samples using Qiamsymphony analyzer	LIMM-SSP-082
	COVID-19 Real Time PCR detection procedure	LVEC-057
	Sample processing and archiving	LIMM-SSP-079
<b>Post-analytical phase</b>	Reporting and release of COVID-19 results	LIMM-SSP-080

condition and consistent in producing reliable results. Procedure- for pooled testing was also developed to enable the laboratory perform testing of approximately 554 samples daily with limited resources (Agoti *et al.*, 2021). The identified positive pools were, on the same day, expanded and ran as singlets to identify the positive samples within the pools. To manage and streamline the pooling of samples during sample preparation, a working tool (Excel spreadsheet) was developed to assist in the pooled testing. This is available in *Extended data*, (Gumba, 2021). Sample IDs were entered into a specimen list worksheet that automatically generated several worksheets with the same specimen unique identifier. The worksheets included a PCR plate map, a worksheet that uploads the specimen list to the RT-PCR analyzer, and a worksheet for the acquisition of raw results from the analyzer to generate an interpreted output (Figure 3). The interpreted results worksheet contained formulas that incorporated the validity criteria (cycle threshold cut-off values) of all negative and positive controls, yielding 'VALID' in green or 'INVALID' in red. The results were reviewed by highly trained and competent personnel who continually monitored results against all controls and carefully defined thresholds for defining a positive or negative test result. This automated approach minimized errors and was an efficient way of handing the results over to the data team, and for handing notes to testing team the next day. Moreover, it provided a standardized tool for the pooling system and results interpretation, and at the same time it took care of the full documentation of all the specimens tested that day. The system also recorded the performance of the QCs, as is required for compliance with GCLP.

## Challenges

We experienced a major challenge of long lead times between ordering and receiving of the RNA extraction kits. The unavailability of qPCR testing kits was another challenge which was due to the high demand of these kits during the pandemic. Moreover, there was limited information on validation and verification studies since most methods were still under development. Additionally, long lead times of global laboratory supplies were experienced, thus we also obtained resources independently and maximized on the available resources (Agoti *et al.*, 2021; Said *et al.*, 2020). Similarly, it was a big challenge of ensuring that individuals were confident in the health and safety measures that were put in place to minimize the risk of infection in the workplace.

## Discussion

The reorganization of the laboratory to form the COVID-19 team with seven sub-teams was our proactive role to meet and sustain the overwhelming and urgent need for testing during the pandemic (Lippi & Mattiuzzi, 2019; Lippi *et al.*, 2020). This allowed us to cope with the intense pressure brought about by testing hundreds of specimens a day, coupled with the large amounts of paperwork and documentation. The formation of the COVID-19 team with assigned responsibilities and the redistribution of the workload across the SARS-CoV-2 testing process enhanced the maintenance of quality assurance and enabled a high standard of testing. Through this process, personnel were empowered to confidently perform their tasks within the

established COVID-19 organizational and management structure. More importantly, involvement of laboratory personnel in all aspects of the SARS-CoV-2 testing process from the onset promoted responsibility, accountability and ownership of processes and decisions made within each team.

Redesigning the laboratory workflow was a critical factor that enhanced maintenance of our laboratory QA processes during the pandemic. This was done by employing the 'warm base' concept which is a concept derived from the manufacturing industry and means being ready for production when a service or a product is needed (Association Public Health Laboratories, 2011). Translated to the laboratory context, it means using the already existing systems to support an outbreak. We did not set up systems from scratch for the novel SARS-CoV-2 pandemic, but we used the already established systems employed in our research and clinical trials laboratory in the laboratory where COVID-19 testing was being performed. The successful maintenance of QA and safety process during the COVID-19 testing was due to mapping of the COVID-19 testing process, conducting training, performing competency and risk assessments. Additionally, the laboratory strengths in health and safety, laboratory supplies and equipment management equally made this possible. Moreover, using the already established equipment management system, the documentation (validation records, installation records, service records and preventive maintenance records) for the identified equipment were rechecked to ensure the equipment were in good working conditions and maintenance activities were performed routinely during the SARS-CoV-2 testing process.

The laboratory also performed interlaboratory comparison for other testing laboratories within the coastal region. In this process, the testing laboratories were sending five already analyzed samples to our laboratory so that we could test and check if the results were comparable. We also enrolled in the molecular SARS-COV-2 external quality assurance (EQA) scheme provided by the Royal College of Pathology Australia (RCPA) and also participated in the proficiency testing organized by the World Health Organization and provided by the National Influenza Laboratory. All these were to ensure that the results being generated by the laboratory are valid, accurate and reliable.

## Conclusions

Ensuring quality assurance in the laboratory during a pandemic and ensuring staff work safely is not a trivial process. However, capitalizing on the existing laboratory systems greatly supported the rapid set up of the COVID-19 testing, yielding reliable, accurate and timely results in a safe work environment. The involvement of key laboratory personnel, the development of documented standard operating procedures and the formation of a COVID-19 team that is organized and properly coordinated, led to the successful maintenance of laboratory quality assurance during these challenging times. The implemented steps, discussions and suggestions highlighted in this paper can be transferable to any laboratory planning to take up testing during a pandemic.

## Data availability

### Underlying data

No underlying data are associated with this article.

### Extended data

Figshare: COVID-19 testing and reporting template. <https://doi.org/10.6084/m9.figshare.14554341.v1> (Gumba, 2021).

This project contains the following extended data:

- QMS-F228 COVID-19 Blank Template (pools & singlets).xlsx (template used to key in sample IDs, generate plate maps and automatically populate results for pools and singlets).

-QMS-F228 COVID-19\_SINGLETs\_Blank Template.xlsx (template used to key in sample IDs, generate plate maps and automatically populate results for singlets only).

Data are available under the terms of the [Creative Commons Attribution 4.0 International license](#) (CC-BY 4.0).

## Acknowledgements

We are thankful for the Ministry of Health Rapid Response Teams for collecting and bringing samples to our laboratory. We are also grateful for the data clerks: Patience Rehema, Frida Lewa, Nancy Kililo, Shadrack Mramba, Khamisi Katana, Sarah Baya, Claris Mapenzi, Mishi Omar, Saida Garama, Samuel Mwasambu, Noel Lughanje, Javan Nyale, Patrick Mwaro and Rommy Ndaa team for their support in data entry and excellent data management, and in reporting to the national government. We are immensely grateful to the entire laboratory team for their concerted efforts in performing SARS-CoV-2 testing while maintaining the quality assurance processes. This manuscript was submitted for publication with the permission of the Director KEMRI.

## References

- Adhanom T: **Opening remarks at the media briefing on COVID-19.** World Health Organization, 2020; 26–28.  
[Reference Source](#)
- Agoti CN, Mutunga M, Lambisia AW, *et al.*: **Pooled testing conserves SARS-CoV-2 laboratory resources and improves test turn-around time: experience on the Kenyan Coast [version 2; peer review: 3 approved].** *Wellcome Open Res.* 2021; 5: 186.  
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
- Association of Public Health Laboratories: **Lessons from a Virus Public Health Laboratories Respond to the H1N1 Pandemic.** 2011.  
[Reference Source](#)
- Berkley S: **Health security's blind spot.** *Science.* 2018; 359(6380): 1075.  
[PubMed Abstract](#) | [Publisher Full Text](#)
- Centers for Disease Control and Prevention: **Coronavirus Disease 2019 Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19).** Decentralized and Point of Care Testing Procedures with a High Likelihood to Generate Droplets or, 2019, 2020; 2–4.  
[Reference Source](#)
- Ceraolo C, Giorgi FM: **Genomic variance of the 2019-nCoV coronavirus.** *J Med Virol.* 2020; 92(5): 522–528.  
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
- Cucinotta D, Vanelli M: **WHO declares COVID-19 a pandemic.** *Acta Biomed.* 2020; 91(1): 157–160.  
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
- Dennison Himmelfarb CR, Baptiste D: **Coronavirus Disease (COVID-19) Implications for Cardiovascular and Socially At-risk Populations.** *J Cardiovasc Nurs.* 2020; 35(4): 318–321.  
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
- Gumba H: **COVID-19 testing and reporting template.** *figshare.* Dataset. 2021. <http://www.doi.org/10.6084/m9.figshare.14554341.v1>
- Gumba H, Musyoki J, Mosobo M, *et al.*: **Implementation of Good Clinical Laboratory Practice in an Immunology Basic Research Laboratory: The KEMRI-Wellcome Trust Research Laboratories Experience.** *Am J Clin Pathol.* 2019; 151(3): 270–274.  
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
- Kelly-Cirino CD, Nkengasong J, Kettler H, *et al.*: **Importance of diagnostics in epidemic and pandemic preparedness.** *BMJ Glob Health.* 2019; 4(Suppl 2): e001179.  
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
- Lippi G, Mattiuzzi C: **Project management in laboratory medicine.** *J Med Biochem.* 2019; 38(4): 401–406.  
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
- Lippi G, Mattiuzzi C, Bovo C, *et al.*: **Current laboratory diagnostics of coronavirus disease 2019 (COVID-19).** *Acta Biomed.* 2020; 91(2): 137–145.  
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
- Lowe R, Barcellos C, Brasil P, *et al.*: **The zika virus epidemic in brazil: From discovery to future implications.** *Int J Environ Res Public Health.* 2018; 15(1): 96.  
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
- Moh-Kenya: **First Case of Coronavirus Disease Confirmed in Kenya.** Ministry of Health, 2020.  
[Reference Source](#)
- Nkengasong JN, Yao K, Onyebujoh P: **Laboratory medicine in low-income and middle-income countries: progress and challenges.** 2018; 391(10133): 1873–1875.  
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
- Olmsted SS, Moore M, Meili RC, *et al.*: **Strengthening laboratory systems in resource-limited settings.** *Am J Clin Pathol.* 2010; 134(3): 374–380.  
[PubMed Abstract](#) | [Publisher Full Text](#)
- Perkins MD, Dye C, Balasegaram M, *et al.*: **Diagnostic preparedness for infectious disease outbreaks.** *Lancet.* 2017; 390(10108): 2211–2214.  
[PubMed Abstract](#) | [Publisher Full Text](#)
- Said K, de Laurent ZR, Omuoyo DO, *et al.*: **An optimisation of four SARS-CoV-2 qRT-PCR assays in a Kenyan laboratory to support the national COVID-19 rapid response teams [version 1; peer review: 1 approved, 1 approved with reservations].** *Wellcome Open Res.* 2020; 5: 162.  
[Publisher Full Text](#)
- Sianipar O: **Quality Improvement Efforts in Pre-Analytical Phase.** 2019; 26(1): 7–9.  
[Publisher Full Text](#)
- The RESYST/DIAHLS learning site team: **Learning sites for health system governance in Kenya and South Africa: reflecting on our experience.** *Health Res Policy Sys.* 2020; 18(1): 44.  
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
- WHO: **Getting your workplace ready for COVID-19.** 2020a; 1–8.  
[Reference Source](#)
- WHO: **The COVID-19 Risk Communication Package For Healthcare Facilities.** Who, 2020b; 1–11.  
[Reference Source](#)
- WHO Laboratory Biosafety Manual: **Laboratory biosafety guidance related to the novel coronavirus (2019-nCoV).** Who, 2020; 1–12.  
[Reference Source](#)
- Wilson ML, Fleming KA, Kuti MA, *et al.*: **Access to pathology and laboratory medicine services: a crucial gap.** *Lancet.* 2018; 391(10133): 1927–1938.  
[PubMed Abstract](#) | [Publisher Full Text](#)

# Open Peer Review

Current Peer Review Status:  

---

## Version 1

Reviewer Report 06 September 2021

<https://doi.org/10.21956/wellcomeopenres.18419.r45504>

© 2021 Amayo A. This is an open access peer review report distributed under the terms of the [Creative Commons Attribution License](#), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.



**Angela Amayo** 

Department of Human Pathology, University of Nairobi, Nairobi, Kenya

The rationale for this report on how the research laboratory established Covid-19 testing is not explicitly described. The authors should be clear on what the reader should take home. Is there an outstanding feature about the approach they used? Is it the only one that could guarantee success in analytical quality and safety in Covid testing or was it the most efficient? The rationale can be improved if the authors mentioned the approaches that were available for them to explore, and gave reasons why they used this model. They could also mention whether the fact that this is a well-equipped research laboratory made it more adaptable to quickly respond to the testing needs to support public health control of the pandemic, which would support advocacy for more investments in laboratories in developing countries.

The authors have not mentioned differing views because this letter just described the activities they implemented. This area can be improved if the researchers adopted an implementation science approach providing data before and after implementation of these activities. Such an audit approach would allow the readers to interrogate the extent to which the goals of the project were realised, and determine the effectiveness of the approach used. For example, the researchers indicate that there was redesigning of the laboratory workflow and the new design is provided (Fig 2 and 3) but the old design is not shown so one cannot assess how much re-designing was actually undertaken. The outcomes of these process changes could have been discussed.

The paper can serve to guide on what are the minimum laboratory capabilities to ensure analytical quality and safety in a pandemic, and what is needed for a research laboratory to change its processes to meet the needs of a clinical service laboratory.

**Is the rationale for the Open Letter provided in sufficient detail?**

Partly

**Does the article adequately reference differing views and opinions?**

No

**Are all factual statements correct, and are statements and arguments made adequately**

**supported by citations?**

Yes

**Is the Open Letter written in accessible language?**

Yes

**Where applicable, are recommendations and next steps explained clearly for others to follow?**

Yes

**Competing Interests:** No competing interests were disclosed.

**Reviewer Expertise:** Clinical Chemistry and Laboratory Management, including quality assurance.

**I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.**

Reviewer Report 19 August 2021

<https://doi.org/10.21956/wellcomeopenres.18419.r45502>

© 2021 Maruta T. This is an open access peer review report distributed under the terms of the [Creative Commons Attribution License](#), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.



**Talkmore Maruta** 

Africa Centers for Disease Control, Addis Ababa, Ethiopia

1. The manuscript is well articulated.
2. The concept of "warm design" referenced in the discussion, should be introduced and described in the "Approach Taken" section.
3. Under 'Approach taken', authors can consider including the time frame needed to implement these changes and observe the reported outcomes.
4. The other major intervention was training, but this is not discussed in the "Discussion section"

**Is the rationale for the Open Letter provided in sufficient detail?**

Yes

**Does the article adequately reference differing views and opinions?**



Yes

**Are all factual statements correct, and are statements and arguments made adequately supported by citations?**

Yes

**Is the Open Letter written in accessible language?**

Yes

**Where applicable, are recommendations and next steps explained clearly for others to follow?**

Yes

***Competing Interests:*** No competing interests were disclosed.

***Reviewer Expertise:*** Laboratory systems strengthening, public health, surveillance, emergency response

**I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.**

---