INSTRUCTIONS FOR COMPLETING THE LAP TEMPLATE

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Instructional Text Sections:
Add appropriate information to fields in **Red Text**
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Informational or follow up fields are in **Green Text**

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Table of Contents Section:
The Table of Contents has been formatted to automatically generate page numbers as you complete the template.

- **In the body of your Analytical Plan**, you can change or delete any of the headings listed.
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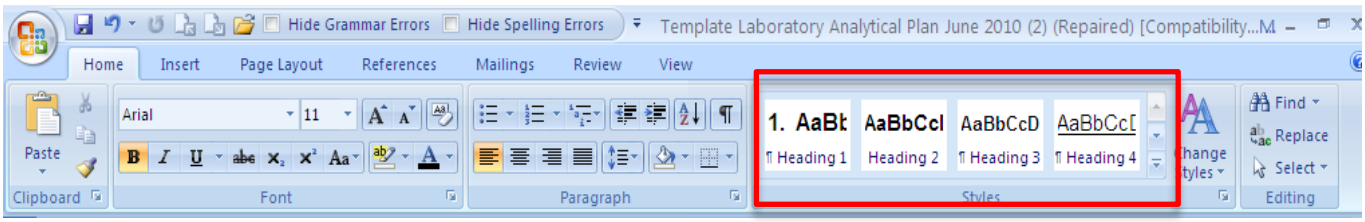
  For first level topics. Enter heading in the text → select text → click on heading 1 (see picture red box below)
  Numbering is done automatically.

  For second level topics numbering is not done automatically. This should be done manually: for example: type 2.1 → tab → write heading text → select <2.1 + heading text> → click on heading 2 (see picture red box below)

  For third level topics numbering is also not done automatically. This should be done manually: for example: type 2.1.1 → tab → write heading text → select <2.1.1 + text> → click on Heading 3 (see picture red box below)

  For the appendices and other fist level headings without automatic numbering (e.g. abbreviation section) select text →click on Heading 4 (see picture red box below)



- To update the Table of Contents to reflect any changes you made, right-click on the Table of Contents (not on the numbers), select update field
- Select Update Page Numbers Only if you did not make any changes to the Headings.
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Laboratory Analytical Plan Template	Version: 1 Supersedes: none Effective Date:

Protocol Title: **Surveillance and epidemiologic evaluation of COVID-19 in Kenya (SEECK) – Virological and Serological surveillance studies.**

	NAME	SIGNATURE	DATE
AUTHOR	Angela Karani		
REVIEWING AUTHORITY	Katherine Gallanger (for SEECK team)		
QA UNIT AUTHORITY	Horace Gumba		
APPROVAL AUTHORITY (Sponsor/Principal Investigator)	Dr. Ambrose Agweyu		

Study/Protocol Details

Protocol Number / Protocol Title	KEMRI/SERU/CGMR-C/203/4085	
Protocol Version	1.0	
Sponsor details and contact		**Tel:**

Abbreviations

Abbreviation	Term
COVID-19	Coronavirus disease 2019
SARS-CoV-2	Severe acute respiratory syndrome coronavirus 2
MOH	Ministry of Health
EOC	Emergency Operation Centre
ELISA	Enzyme Linked immunoabsorbent assay
Rt-PCR	Real-time Polymerase Chain Reaction
ANC	Antenatal Care
KNH	Kenyatta National Hospital
HCW	Health Care Workers
NHCFW	Non-Health Care Frontline Workers
RNA	Ribonucleic Acid
CGTRH	Coast General Training and Referral Hospital
MBH	Mbagathi Hospital
JOOTRH	Jaramogi Odinga Oginga Traching and Referral Hospital
NP/OP	Nasopharyngeal/Oropharyngeal
KCH	Kilifi County Hospital
VTM	Viral Transport Medium
AKUH	Aga Khan University Hospital
HDSS	Health Demographic Surveillance System

Table of Contents

<Update after finalizing LAP, see instructions on first page >

1. Introduction

The facilities of **KEMRI-Wellcome Trust Research Laboratories** are accredited under Good Clinical Laboratory Practice by Qualogy Ltd an independent accreditation service (Accreditation number 01407).

The current documented and approved SOPs of **KEMRI-Wellcome Trust Research Laboratories**, will be used during the conduct of the work defined within this analytical plan. Historical information of all SOPs is retained in the Q-Pulse system.

The Laboratory will adhere to standards of GCLP, the Analytical Plan and applicable SOPs to ensure proper conduct of this study.

2. Study Introduction/background

COVID-19 is an infectious disease caused by a recently identified virus - Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The disease was first identified in late 2019 in China, and has since spread globally, resulting in more than 3 million infections and more than 200,000 deaths as of April 2020. In Kenya, the first case of SARS-CoV-2 infection was reported on 13th March. Since then, the number of confirmed cases has steadily risen to more than 300 over a period of six weeks. The Ministry of Health has established an Emergency Operation Centre (EOC) to coordinate the technical national response to the epidemic. At county level, Rapid Response Teams implement case identification, contact tracing and isolation. KEMRI-Centre for Geographic Medicine, Coast (CGMRC) has a longstanding partnership with the Ministry of Health, providing technical support for research and capacity building through four scientific departments: Epidemiology and Demography, Biosciences, Clinical Research, and Health System and Research Ethics. KEMRI CGMRC has been mandated by the Ministry of Health to perform a series of activities aimed at improving the understanding of the COVID-19 pandemic and supporting the national and county emergency response to the COVID-19 pandemic.

3. Purpose of the study

Our aim is to collect and analyse data to help understand various aspects of COVID-19 and to apply this knowledge to guide national planning to limit the negative effects of the pandemic in Kenya. For example, it would be of considerable benefit to the Ministry if they knew the groups of individuals who are more likely

have poor outcomes and then use this information to plan for control measures to protect these groups. We will investigate questions such as:

- How common is COVID-19 infection in children and adults admitted to hospital and healthy adults such as healthcare workers?
- What proportion of the population has been exposed to SARS-CoV-2?
- How does COVID-19 affect patients that are undernourished or that are infected with HIV?

4. Study/Project Tasks Organization

Site/Laboratory	Name	Project Title/Responsibility	Contact
KEMRI-wellcome Trust Kilifi	Horace Gumba	QA	HGumba@kemri-wellcome.org
	Ambrose Agweyu	Principal Investigator	AAgweyu@kemri-wellcome.org
	Anthony Scott	Head of IBD Thematic Group and Co-PI COVID-19 serosurveillance	Ascott@kemri-wellcome.org
	Katherine Gallagher	Workstream lead: Antenatal Care	KGallagher@kermi-wellcome.org
	Anthony Etyang	Workstream lead: Healthcare worker testing	AEtyang@kemri-wellcome.org
	Eunice Kagucia	Workstream lead: other frontline worker testing	EKagucia@kemri-wellcome.org
	Ifedayo Adetifa	Workstream lead: HDSS residents	IAdetifa@kemri-wellcome.org
	George Warimwe	Workstream lead: Antibodies testing assay.	GWarimwe@kemri-wellcome.org
	Amek Nyaguara	Head of Surveillance	ANyaguara@kemri-wellcome.org
	Shirine Voller	Project manager COVID-19 serosurveillance	SVoller@kemri-wellcome.org

	Geoffrey Omuse	Workstream co-lead symptomatic PCR-positive individuals	Geoffrey.omuse@aku.edu
	Eric Ochomo	Head of Entomology: Oversee sample processing, storage and shipment to KWTRP	eochomo@kemricdc.org
	Angela Karani	Laboratory section Head-IBD: Sample coordination and processing	AKarani@kemri-wellcome.org
	Isabella Oyier	Head of Bioscience: In charge of the labs processing the samples	LIOchola@kemri-wellcome.org
	Jennifer Musyoki	Immunology project manager: Lab workflow coordination	JMusyoki@kemri-wellcome.org
	Henry Karanja	Research Officer: ELISA work	HKaranja@kemri-wellcome.org
	Caroline Ngetsa	Lab Manager -CTL: Lab data coordination	CNgetsa@kemri-wellcome.org
	Martin Mutunga	Laboratory Section Head-VEC group: PCR work	MMutunga@kemri-wellcome.org

5. Laboratory study roles and tasks

Laboratory Section	Roles and Tasks	Responsibility
KEMRI-CGMRC, Immunology & Microbiology Lab, Kilifi	• Sample reception and storage. • Processing of NP/OP & Blood samples.	Jennifer Musyoki Angela Karani
IPR-Nairobi	• Blood Sample processing & Shipment	
KEMRI-CGHR	• Sample processing and Shipment	Eric Ochomo

6. Laboratory Assays and their associated procedures

The assays noted in the table below will be used for performing the study specific laboratory tests:

Test/Assay	Assay Kit	Type of Sample Tested	Clinic/Laboratory Location	SOP (Indicate SOP No)
Serological assays for IgG/IgM to SARS-CoV-2	Mt. Sinai Laboratory COVID-19 ELISA Antibody Test (2-step ELISA)[1]	Plasma from an EDTA/ heparinised tube	KEMRI-CGMRC	LVEC-SSP-029
Real-Time RT- PCR	RNeasy 96 RNA QIAcube HT Kit	NP/OP SWAB	KEMRI-CGMRC	LVEC-055
	QIAamp Viral RNA Extraction Mini Kit	NP/OP SWAB	KEMRI-CGMRC	LVEC-056
	Quantifast Multiplex RT-PCR Kit	NP/OP SWAB	KEMRI-CGMRC	LVEC-057

[1] Amanat F, Stadlbauer D, Strohmeier S, et al. A serological assay to detect SARS-CoV-2 seroconversion in humans. *Nature Medicine* 2020.

7. Sampling Strategy/Planning

7.1 Sample collection

The study samples will be collected using site specific SOPs for Nasopharyngeal and oropharyngeal swabs and bloods. This is a multi-site study and samples will be collected as summarized in the table attached in Appendix B.

7.2 Laboratory Requisition Form

Each study will have its own sample collection forms and database. The requisition forms are appended to this document or are in draft and will be appended in an amendment as specified below:

1. ANC serosurveillance: Samples from KNH will be accompanied by individual lab requisition forms QMS-F230), samples from KCH will be accompanied by a sample transit log QMS-F229
2. Lab requisition form for HCW:
    a. Samples from KNH will be accompanied by a study specific data collection form QMS-F231.
    b. Samples from the other study sites (Kilifi, Mombasa) will be accompanied by the MoH COVID-19 Case Investigation Form QMS/Doc/Ex/04 and transport manifest/ summary sheet completed by the sub-county Rapid Response Team.
3. Non-healthcare frontline workers: Samples will be accompanied by the MoH COVID-19 Case Investigation Form QMS/Doc/Ex/04 and transport manifest/ summary sheet completed by the sub-county Rapid Response Team.
4. Samples from Nairobi and Kisumu HDSS will be accompanied by individual lab requisition forms (XXX-XXX) and those from the KHDSS residents will be accompanied by a sample transit log (XXX-XXX).
5. Lab requisition form confirmed asymptomatic cases:
   Samples will be accompanied by a study specific data collection form adapted from the MoH COVID-19 Case Investigation Form QMS/Doc/Ex/04 and sample transit log xxxxx
6. Lab requisition form confirmed symptomatic cases
   Samples will be accompanied by a study specific data collection form adapted from the MoH COVID-19 Case Investigation Form QMS/Doc/Ex/04 and sample transit log xxxxxx

7.3 Sample Labelling

Every sample will be labelled with a unique ID number, specimen type and the date of sample collection. Sample IDs will differ in format. The labelling is summarised in the table below:

Table: Summary of Sample Labelling in the lab.

Substudy	Study No.	Site	Label	Key
ANC		KNH	**KNHANC(0001-**	**KNH-Hospital ANC-workstream 0001-generated serial number**
		KCH	**National ID (up to 10 numerical digits)**	
HCW	**254**	KNH KCH, CGTRH MBH JOOTRH	**National ID (up to 10 numerical digits)**	
N-HCFW	**251**	Kilifi (KLF) Mombasa (MSA) Taita Taveta (TT)	**KWT-P**	
		Nairobi (NRB) Busia (BSM)	**FWTN (00001-99999)** **FWTB (00001-99999)**	**FW-Frontline worker** **Sector id-Trucker(T), Food service(F), KPA (K).** **County ID-Nairobi(N), Busia(B) etc.** **Sample ID-00001-99999**
HDSS		KLF (Kilifi) NRB (Nairobi) KSM(Kisumu) MSA (Mombasa)	**SS-KLF- (0001-0999)** **SS-NRB- (0001-0999)** **SS-KSM- (0001-0999)**	**SS- Serosurvey** **Location- KLF, NRB, KSM** **Sample ID-0001-0999)**
Asymptomatic RT-PCR-confirmed SARS-CoV-2 infected individuals		MOHEOC	**KNHASY (0001-**	**KNH-Hospital ASY-workstream 0001-generated serial number**
Asymptomatic RT-PCR-confirmed SARS-CoV-2 infected individuals		KNH AKUH KCH CGTRH	**KNHSYM (0001-**	**KNH-Hospital SYM-workstream 0001-generated serial number**

7.4 Sample Reception

Samples from all the study sites will be received according to SOP LIMM-SSP-078. Any samples that do not meet the acceptance criteria will be rejected as per the SOP LQSP-014 and notification done to the sample source.

7.5 Sample Processing

The sample processing and storage for the various samples is summarized in the table below:

Table Summary of Sample processing, storage and testing.

Sample Processing & storage								Sample Testing		
Sample Type	**Collection tube**	**Description of sample processing**	**Responsible lab**	**Processed sample type**	**Processed sample storage**	**Storage condition**	**Processing procedure**	**Test description**	**Responsible person**	**Test procedure**
Venous blood	**Green top (Heparin)**	**Plasma separation for antibody testing**	**Immunology lab-KWTRP**	**Plasma**	**yes**	**-80°C**	**LIMM-SSP-079**	**2-step ELISA**	**Microbiology Lab**	**LVEC-SSP-029**
			IPR-Nairobi				**As per the institution's procedure**			
			CGHR-Alupe				**As per the Institution's procedure**			
	EDTA	**Plasma separation for antibody testing**	**Immunology lab-KWTRP**	**Plasma**	**yes**	**-80°C**	**LIMM-SSP-079**	**2-step ELISA**	**Microbiology Lab**	**LVEC-SSP-029**
NP/OP swab	**VTM**	**Real-Time rt-PCR for detection of SARS-CoV-2**	**Microbiology lab-KWTRP**	**NP/OP**	**yes**	**-80°C**		**Real-Time rt-PCR**	**Microbiology lab**	**LVEC-055 LVEC-056 LVEC-057**

7.6 Sample Chain of custody

The following process will be followed for the sample chain of custody at each site:

Off-site Labs

- Sample collection will be done at the various designated study site as highlighted in the table xx for sample collection.
- Labelling of the primary samples will be as per the defined nomenclature summarised in table on sample labelling section 7.3 or the MOH COVID case investigation form unique identifier.
- The staff in the collection site will fill in the study specific request forms to document sample collection.
- A transport transit form will be filled into document specimen collection and transfer to the laboratory.
- The processing lab will receive the samples and check the requisition form and transit log against the delivered samples.
- The receiving lab will document the received samples into their sample reception databases.
- The receiving labs will process the samples according to their corresponding site-specific SOPs or SSPs.

- The processed samples from off-site labs will be stored for onwards shipment to KWTRP Kilifi labs whereas those received in Kilifi from the coastal study sites will be processed and stored for further test assays.

KWTRP Lab
Plasma aliquots generated at the collaborating labs in Nairobi, Kisumu and Busia will be shipped to the KWTRP labs in Kilifi for testing and long-term storage.

The following will be done:

- Offsite labs will ship the samples under cold chain (dry ice) as per the IATA guidelines or their specific shipment SOPs if available.

- On receipt, the samples will be counterchecked against the specimen transit logs and as highlighted in LIMM-SSP-078.
- Processing and storage of the samples will as be highlighted in the sample processing table under section 7.5.

8. Sample Storage and Shipment

Blood samples from Kilifi County will be processed the same day of collection. Serum or plasma will be separated in the KWTRP Laboratories and the samples will be stored for testing.
Serum or plasma samples from distal sites will be packaged and received in shippers with dry ice as per IATA guidelines and will be stored at -80ºC for testing with either virological or serological assays. SOP no. LIMM-SSP-079 will be our source of reference.

9. Equipment/Materials and Reagents

Equipment/Analysers	Lab Reagents, Materials & Kits
Adjustable pipettes (10µl,100µl,1000µl)	Plastic racks
Vortex	Sterile, RNase-free barrier pipette tips (10µL, 100µL, 1000µL)
Microcentrifuge (adjustable, up to 13000 rpm)	Microcentrifuge tubes (1.5ml Eppendorf)
QIAcube High-throughput (HT) Instrument (Qiagen)	QIAamp Viral RNA Extraction Mini Kit with all components
Biohazard cabinet	Ethanol
ABI 7500 Real time PCR Machine	Sterile falcon tubes
Scanner	Paper towel
Computer	Red waste bag
Freezer (-80°C)	Marker pen
Centrifuge	QIAcube HT tip disposal box
	QIAcube HT plasticware (Qiagen, 950067)
	RNeasy 96 RNA QIAcube HT Kit (Qiagen Cat No 74171)
	DNA off
	Microamp Optical 96-Well Reaction Plate
	Microamp Optical Adhesive Film
	Quantifast Multiplex RT-PCR kit (Cat no. 204954)
	Nuclease free or Molecular Biology grade water

	Primers and probes
	Positive control material
	Personal protective wear (gloves, Lab coat)
	Barcode labels
	Marker pens and pens
	Case investigation forms
	Stapler
	Staples
	Paper punch
	Staple remover
	Sterile applicator sticks
	Wide mouth Pasteur pipette

9.1 Equipment Calibration and Maintenance

Maintenance/calibration of equipment will be done daily/weekly and monthly as per specific equipment SOPs. All equipment for the study have valid service contracts and service records are available and maintained.

9.2 Reagent validation/Parallel testing

The study will use the already established procedures currently being used for performing the study specific assays. Validation plan SOP (LQSP-026) will be used to validate any new reagents or equipment that will be brought for the study

10. Reporting of Test Results

10.1 Result reporting, Release and Approval of Reports

Once studies begin, receipt of samples and storage will be reported weekly.
Serological assay results will be reported 2-weekly.

Study	Task	Duration
ANC	Receipt and storage of samples	Weekly
	Serological assays	2-weekly
HCW	??	
NHCFW	Serological Assays	weekly
	RT-PCR	As generated.
ASY	??	
SYM	??	
HDSS	Receipt and storage of samples	2-weekly
	Serological Assays	As generated

10.2 Results from External Laboratories

N/A

11. External Quality Assurance

11.1 Proficiency Testing

Proficiency testing <update table with the study assays/tests and their associated EQA where necessary>

Test	EQA Program/Provider	Frequency (cycles per year)
SARS-CoV- testing	RCPA	2 x annually
SARS-CoV- testing	MOH	X4 annually
SARS-CoV- testing	KEMRI	
Serological assays for IgG/IgM to SARS-CoV-2	WHO	To be discussed with the service provider

11.2 Audit/Monitoring Program

Audit/monitoring Program

Laboratory Name	Auditors/Monitors	Frequency
Microbiology and Immunology Laboratory	Qualogy;	2 x annually
Laboratory QA unit	QA auditors	X3 annually

12. Appendices (Provide all the tables and list of information relevant to the project)

Appendix A: Laboratory Accreditation certificates

CERTIFICATE OF ACCREDITATION

Good Clinical Laboratory Practice

Name and address of Company Accredited

KEMRI Laboratories
Kilifi and Mtwapa
Kenya

Date of Accreditation
22nd November 2019

Category of Accreditation
Full Accreditation

Accreditation is continuous from the date of the previous accreditation on 3rd May 2018

The above laboratory has satisfactorily implemented the requirements set out in the Good Clinical Laboratory Practice (GCLP) standard, 2011, ISBN 978-1-904610-00-7

Date of Assessment: 21st and 22nd November 2019

Re-assessment due date: Quarter 1/2 2021

Type of work accredited: Immunology, STAT laboratory, CTL, Microbiology, Serology, Virology, TB, BioBank, Molecular, Insectary and Safety Laboratories

Accreditation number: 01407

Laboratory first Accredited: December 2007

T R Stiles, Director
GCLP Accreditation Scheme

GCLP Accreditation Scheme operated by Qualogy 2002 Ltd www.qualogy.co.uk

Appendix B: Table: Summary of expected samples per study.

STUDY	Time point/visit	Sample Tube	Site	Volume(mls)	Sample type	Approximate no. of samples
ANC sero-surveillance	Once (residual blood from samples collected at ANC appointments)	Green Top (heparin)	KNH	5	Blood	2160
		EDTA	KCH	4		
HCW sero-surveillance	Baseline	Green Top (Heparin) NP/OP in VTM	KNH, KCH, CGTRH, MBH, JOOTRH	5	Blood and NP/OP swab	1000
	4 months	Green Top (Heparin) NP/OP in VTM	KNH, KCH, CGTRH, MBH, JOOTRH	5	Blood and /NP/OP swab	1000
	8 months	Green Top (Heparin) NP/OP in VTM	KNH, KCH, CGTRH, MBH, JOOTRH	5	Blood and /NP/OP swab	1000
	12 months	Green Top (Heparin) NP/OP in VTM	KNH, KCH, CGTRH, MBH, JOOTRH	5	Blood and /NP/OP swab	1000

Non-healthcare frontline worker sero-surveillance (Truckers, KPA, KAA, KA, Restaurants)	Baseline	Green Top (Heparin) NP/OP in VTM	KLF, MSA, TT, BSA, NRB	5	Blood and /NP/OP swab	2100
	3 months	Green Top (Heparin) NP/OP in VTM	KLF, MSA, TT, BSA, NRB	5	Blood and NP/OP swab	2100
	6 months	Green Top (Heparin) NP/OP in VTM	KLF, MSA, TT, BSA, NRB	5	Blood and /NP/OP swab	2100
HDSS residents	Once	Green Top (Heparin)	KLF, NRB, KSM	5	Blood	2400
Asymptomatic RT-PCR-confirmed SARS-CoV-2 infected individuals	Baseline	Green Top (Heparin)	MOHEOC	5	Blood	200
	2 weeks	Green Top (Heparin)	MOHEOC	5	Blood	100
	4 weeks	Green Top (Heparin)	MOHEOC	5	Blood	100
	8 weeks	Green Top (Heparin)	MOHEOC	5	Blood	100

	3 months	Green Top (Heparin)	MOHEOC	5	Blood	100
	6 months	Green Top (Heparin)	MOHEOC	5	Blood	100
Asymptomatic RT-PCR-confirmed SARS-CoV-2 infected individuals	Baseline	Green Top (Heparin)	KNH, AKUH, KCH, Coast General TRH	5	Blood	200
	2 weeks	Green Top (Heparin)	KNH, AKUH, KCH, Coast General TRH	5	Blood	100
	4 weeks	Green Top (Heparin)	KNH, AKUH, KCH, Coast General TRH	5	Blood	100
	8 weeks	Green Top (Heparin)	KNH, AKUH, KCH, Coast General TRH	5	Blood	100
	3 months	Green Top (Heparin)	KNH, AKUH, KCH, Coast General TRH	5	Blood	100
	6 months	Green Top (Heparin)	KNH, AKUH, KCH, Coast General TRH	5	Blood	100