SA COVID-19 POC STUDY - INFORMATION SHEET AND CONSENT FORMS

FOR SYMPTOMATIC PERSONS UNDER INVESTIGATION PRESENTING TO HEALTH FACILITIES

One copy will stay with the study team for filing. A second copy will be given to the participant.

TITLE: Investigating Point of Care Diagnostic Strategies to Optimise the Rapid Diagnosis of COVID-19 in routine public and private health care settings in South Africa

(SA COVID-19 POC STUDY)

Principal Investigators:

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INTRODUCTION

You are invited to take part in a COVID-19 study called the South African COVID-19 point of care study or the SA COVID-19 POC study. This information leaflet gives you more information about this research study. Before you agree to take part in this study you should fully understand the study and what is required. If you have any questions - do not hesitate to ask us. You should not agree to take part unless you fully understand and are happy with all the procedures involved. You may choose not to take part in this study or leave this study at any time.

WHY ARE WE DOING THIS STUDY?

Like many countries in the world, South Africa is experiencing a COVID-19 pandemic, caused by the SARS-CoV-2 virus. This virus comes from a family of viruses called coronaviruses.

At the moment, the best way to detect SARS-CoV-2 is to conduct a test called real-time Reverse transcription polymerase chain reaction (RT-PCR). Whilst this test is accurate, the test can only be done in a laboratory by highly skilled laboratory staff, and the results take a long time to reach the person who wants to know if they are infected, or not. This test is also expensive.

This study focuses on investigating new rapid tests to detect infection with SARS-CoV-2. These new tests can be conducted in the community/clinics/hospitals by other health workers, besides laboratory staff. These new tests are quick and cheap, and results are available after approximately 5-30 minutes depending on the type of test used. We are doing this study to check whether these results are accurate. If we find that these rapid tests are accurate then we may be able to use these rapid tests in the community to do mass COVID-19 testing. Mass testing is important to help us quickly identify who is infected, so they may be cared for, and isolated to prevent the spread of the virus to others. We are planning to test approximately 5000 people for this study from at least three health facilities.

EXPLANATION OF PROCEDURES TO BE FOLLOWED

We will collect information from you, such as your age and whether you are a male or female. We will also ask you how you are feeling today, any other illnesses you have and what treatment you are on. Some questions may be sensitive e.g. questions about whether you have HIV, TB, diabetes (sugar) and hypertension so that we can understand the relationship

between these diseases and COVID-19. You may choose not to answer these questions.

As part of the study we will be doing the following tests:

1. **Finger prick COVID-19 rapid test**: We will **prick you** and **do a rapid test(s) using one or more kits for COVID-19**. The rapid test result(s) can be given to you, but it will not be your final confirmed COVID-19 result because the result(s) may be wrong. Your true COVID-19 test result will come from RT-PCR testing in the laboratory. If you test RT-PCR or rapid test COVID-19 positive, we will follow you up in 5 to less than 14 days and possibly at 25-30 days, 3, 6, 9 and 12 months.
2. **Blood tests**: We will collect approximately **six teaspoons of blood at the first visit** and **up to six teaspoons of blood at each follow-up visit**, in special tubes.
    - At follow-up, in the **Western Cape site**, we will take **four more teaspoons of blood** to do additional tests on immune function on 100 people because the laboratory that specializes in these tests is located in the Western Cape.
    - We will also take **4 more teaspoons of blood from a group of participants (or from all participants if budget allows),** for more detailed tests to understand how the body responds to COVID-19. These additional 4 teaspoons will be used for more detailed tests to understand how the body responds to COVID-19.
    - In **summary**, we could take between **six and fourteen teaspoons of blood** from you at each visit if you are in the **Western Cape**, and **between six and ten teaspoons of blood** from you at each visit,if you are in **Limpopo and Gauteng province**.
    - It is safe to take this amount of blood. We will send specimens to the laboratory for COVID-19 testing including how the soldiers of the body (the immune system) respond to COVID-19 infection. We will collect swabs for COVID-19 RT-PCR testing in the laboratory.
3. **Naso or naso-pharyngeal swab:** We may also collect **one additional naso- or nasopharyngeal swab for genome analysis – this means to see what genes the virus has.**
4. **Saliva sample:** We will take a saliva sample to test whether COVID-19 can be diagnosed using saliva.
5. **Nasal swab**: If your site is testing rapid tests that detect the SARS-CoV-2 virus then we will ask for a nasal swab to see if we can find virus particles in your nasal swab.

Any residual samples will be stored in a biorepository, so that we can do additional diagnostic testing as new tests become available, or so that we can test for antibodies and study other immune factors such as cytokines and white blood cells which assist in fighting the infection. Your samples will be stored under strictly controlled conditions and all of the data linking the data with your identity will be protected. It may become necessary to transfer some of the material to laboratories around the country but this will be under strict control. You will be able to withdraw your material from storage if you are concerned about this aspect.

We will also ask to interview and take blood from people in your house who are well. Only 500 people who test COVID-19 RT-PCR and rapid test negative will be followed up. This follow-up visit will involve repeating the swabs. We will also repeat the rapid test(s) and will take more blood, as explained above. The blood will be used to find antibodies to COVID-19 disease. They may tell us whether you have no COVID-19 infection, recent infection or past infection. We will time key activities related to this study (i.e. sample collection and result

notification).

RISK AND DISCOMFORT INVOLVED.

You might feel discomfort when the swab is taken and some pain when blood is taken. Taking blood rarely causes infection. The specimens will be taken by trained staff who will wear appropriate protective equipment.

POSSIBLE BENEFITS OF THIS STUDY.

You will learn if you are infected with COVID-19 or not. You will contribute to our knowledge about better testing methods for COVID-19.

REIMBURSEMENT

We will provide a reimbursement to the value of R150 for today's visit and every follow-up visit if you are being followed up. This is for your time and any inconvenience.

HAS THE STUDY RECEIVED ETHICAL APPROVAL?

Yes, the study was approved by the SAMRC Ethics Committee and abides by the Declaration of Helsinki (updated Oct 2008), which deals with the recommendations guiding doctors in biomedical research involving human/subjects.

CONFIDENTIALITY

Although we will use your name, ID number or hospital numbers to identify your samples and results, we will not use any information that can identify you, when the findings of the study are published.

Your personal information may however be disclosed if required by law or by the Department of Health.

STUDY WITHDRAWAL

This study is voluntary, and you can withdraw at any round of testing. If you shows signs of distress at the time of taking blood, then you will be offered the option of withdrawing from the test at that time. If some tests have already been done when you change your mind, we will still use the data from them unless you tell us not to.

CONSENT FOR SAMPLE STORAGE

Once testing for this study has been completed, there might be blood left over. We would like to store the remaining blood for future testing. Any future testing that will be done, will also be approved by the Ethics Committee. If you choose not to give consent for the remaining blood to be stored for future studies, you may still continue with this study participation, and your blood will be discarded after testing for this study.

For more information you may contact: Prof Ameena Goga: +27 12 339 8524 or Ameena.Goga@mrc.ac.za If you have any additional queries, please contact the SAMRC Ethics committee: Adri Labuschagne, tel. (021) 938 0687; adri.labuschagne@mrc.ac.za

CONSENT TO PARTICIPATE IN A STUDY: FOR SYMPTOMATIC PERSONS UNDER INVESTIGATION: TITLE: TITLE: Investigating Point of Care Diagnostic Strategies to Optimise the Rapid Diagnosis of COVID-19 in routine public and private health care settings in South Africa: (SA COVID-19 POC STUDY)

The content of this document and the study has been explained to me, before signing. I have been given the opportunity to ask questions and am satisfied that they have been answered satisfactorily. I understand that if I do not participate, I can still access testing, treatment and care at the local clinic or hospital. I hereby volunteer to take part in this study.

Consent	Yes	No
I have been informed that this study is about developing better ways to diagnose COVID-19		
I consent to participate in this study		
I agree to answer questions to understand more about the COVID-19 disease		
I agree for my naso-pharyngeal specimens to be used for this study		
I agree to my blood being used for rapid tests for COVID-19 diagnosis		
I agree to giving blood to check for immune responses to COVID-19		
I agree to my blood specimens being used for formal antibody/ neutralizing antibody assay testing in the laboratory, and to understand how SARS-CoV2 affects my blood		
I agree to be contacted for further follow up		
I agree to follow-up visits for an interview and to take more blood, if this is needed, to understand the disease. This may be at my home, in hospital or in an isolation facility		
I agree to a follow-up visit to screen my contacts who are not sick if I test COVID-19 positive		
I agree to giving a saliva specimen		
I agree to my specimens being stored for additional testing such as advanced immune system responses to COVID-19 and structure/genetics of the virus causing COVID-19. I understand that any additional testing will be approved by an ethics committee		
I agree to giving nasal swabs for SARS-CoV2 antigen testing		
I agree to being timed during study procedures (enrolment, sample collection, result notification)		
I agree that the study team can access my results from the NHLS including my routine SARS-CoV-2 result and any other relevant blood results		

_____ _____ _____

Participant Name Participant Signature Date

_____ _____ _____

Staff Conducting IC Staff Signature Date

_____ _____ _____

*Witness Name *Witness Signature Date

* Witness name, signature and date are required on this consent form only when the consenting participant is not able to read (illiterate)

*It has been explained in full to me why my right to confidentiality and to privacy may be limited in respect to the Department of Health. Signed*_____