# IN THE HIGH COURT OF SOUTH AFRICA (WESTERN CAPE DIVISION, CAPE TOWN)

Case NO: 5852/2021

In the matter between:

**RICARDO MAARMAN** 

**Applicant** 

And

THE PRESIDENT OF THE REPUBLIC OF SOUTH AFRICA

First Respondent

THE MINISTER OF CO-OPERATIVE GOVERNANCE AND TRADITIONAL AFFAIRS

Second Respondent

PROFESSOR SALIM ABDUL KARRIEM obo THE GOVERNMENTAL COVID-19 ADVISORY COMMITTEE

Third Respondent

THE NATIONAL DEPARTMENT OF HEALTH

Fourth Respondent

#### **FILING NOTICE**

**KINDLY TAKE NOTICE THAT** the Respondents herein file their Answering, Confirmatory ant Explanatory Affidavits evenly herewith.

SIGNED AT CAPE TOWN ON THIS

**DAY OF MAY 2021** 

THE STATE ATTORNEY

Per: M Nkabini

First to Fourth Respondents' Attorneys

4th Floor

THE STATE ATTORNEY Per: Mr M Nkabini Tel: 021-441-9200

22 Long Street CAPE TOWN

Ref No: 891/21/P6

TO: THE REGISTRAR

Western Cape High Court

CAPE TOWN

AND TO: T VICTOR & ASSOCIATES

24 Viola Road

**BLOUBERGSTRAND** 

CAPE TOWN Tel: 077078168

C/o ROB GREEN ATTORNEYS

Room 305 Benzal House 3 Barrack Street CAPE TOWN

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#### RESPONDENTS' ANSWERING AFFIDAVIT

I, the undersigned,

#### **PROFESSOR ADRIAN J PUREN**

do hereby make oath and say:

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#### INTRODUCTION

- I am an adult male and employed as the Acting Executive Director: of the National Institute for Communicable Diseases ("NICD"). I am carrying out my principal duties at 1 Modderfontein Road, Sandringham, Johannesburg, Gauteng Province.
- 2. The NICD is a national public health institute of the South Africa, providing reference to microbiology, virology, epidemiology, surveillance, and public health research to support the South African Government's response to communicable disease threats. The NICD thus serves as a resource of knowledge and expertise of communicable diseases to the South African Government, Southern African Development Community countries and the African continent. The main goal of the NICD is to be the national organ for South Africa for public health surveillance of communicable disease.
- 3. Before commenced my employment with the NICD: I graduated as a medical doctor from the University of the Witwatersrand and obtained a Medical degree (1986) and a Ph (1993). I received further training at the University of Oxford and University of Colorado Health Sciences Center in the fields of immunology and Cytokines.
- 4. I was appointed at the NICD to implement a HIV diagnostic and vaccine laboratory in July 1999. Subsequently, I was appointed as a Deputy Director for Virology Division that included several sections including Centres for Respiratory Diseases



and Meningitis, Centre for Vaccines and Immunology and Centre for HIV and STIs,

I have thus gained extensive experience and practical knowledge in virology,
virology diagnostics and surveillance.

- I serve as the technical manager for quality assurance at the NICD and have a knowledge and understanding of the matters relating to requirements for providing accurate and key results in line with the ISO standards.
- 6. I am accordingly duly authorised to depose to this affidavit on behalf of the Fourth Respondent. In the interest of simplicity, the first, second and fourth Respondents will be referred to, herein, by their abbreviated title (the first Respondent as "the President", the second Respondent as "CoGTA" and the fourth Respondent as "the NDOH" or the Respondents.)
- 7. The facts set out in this affidavit are within my personal knowledge or are derived from documents and information under my control, unless the context indicates otherwise, and are true.
- 8. As will appear from the allegations (including the annexures thereto) in the founding affidavit, the Applicant's application turns, to a large extent, if not exclusively, on the documents he attached to his founding affidavit, the authenticity and contents whereof are disputed and which I have perused.
- Where required, the facts set out in this affidavit are supported and confirmed by affidavits depose to by the appropriate persons in CoGTA or NDOH or both, with



personal knowledge of the relevant facts and will be filed together with this affidavit.

Where legal submissions are made during this affidavit, they are based upon the advice of my legal representatives. I believe such advice to be correct.

10. I have read the founding affidavit of the Applicant and respond thereto as follows:

#### POINTS IN LIMINE

- 11. At the outset I point out that there are several legal issues which arise from the averments set out in the Applicant's founding affidavit, which requires comment before I deal with the balance of the averments, therein.
- 12. The comments below will be raised by way of legal objections/points in limine in relation to three issues, viz: non-compliance with the regulations, self-created urgency and no prima facie or strong case for the relief sought.

### THE FIRST POINT IN LIMINE:

Non-compliance with the National Health Act, 2003

13. In terms of paragraph 2 of the Notice of Motion the Applicant seeks an order that the Respondents "produce the isolated and purified physical SARS-COV-2 virus, not a culture isolate or any mixture within which the supposed virus is, nor a



photograph or the RNA sequence only, to the Applicant at the place in terms of their safety measures of choice, within 7 days".

- 14. NDOH contends that on the face of the relief in paragraph 2, *supra*, the Applicant's request amounts to, *inter alia*, an acquisition or importation or handling of human pathogens. Because the Applicant requested the Court to order that the Respondents "produce" the isolated and purified physical SARS-CoV2 to him within 7 days.
- 15. The NDOH contends that any, one (or more) of the processes, contemplated in paragraph 2, above, seem to fall within the scope of the National Health Act, 2003, Regulations relating to the registration of microbiological laboratories and the acquisition, importation, handling, maintenance, and supply of the human pathogens ("the NHA Regulations"). Put differently, to give effect to his relief, he would, amongst others, be required to "acquire" "receive" or "handle" human pathogens, as contemplated in the NHA Regulations.
- 16. Accordingly, the NDOH contends that the Applicant, <u>before</u>, he can claim that he has a right to the relief under paragraph 2, <u>supra</u>, he <u>must</u> comply with the express requirements of the NHA Regulations.
- 17. Section 1(a) of the NHA Regulations defines "human pathogen" means-

"an infectious substance (b) the toxin of an infectious substance, or (c) any diagnostic specimen, vector or other material that contains, or that is



reasonably suspected to contain an infectious substance or a toxin of an infectious substance".

"infectious substance" means- (a) a micro-organism, virus or parasite that is capable of causing human disease, or (b) an artificial produced hybrid or mutant micro-organism that contains genetic components of any micro-organism capable of causing human disease."

"microbiological laboratory" means a laboratory which handles human pathogens capable of colonising in humans, irrespective of whether or not the laboratory undertakes specific culture of such human pathogens or merely receives and handles tissue and other specimens potentially infected or infested which such human pathogens, and including laboratories which handle infected or infested, or potentially infected or infested, indigenous vectors of human pathogens, or exotic vector species irrespective of whether they are infected or infested."

18. Section 3 of the NHA Regulations 2003 provides that-

No person shall:

"(a) acquire, receive or import human pathogens; or

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- (b) handle, manipulate, maintain, store, culture or in any way process, issue or in any way dispose of human pathogens so acquired, received, or imported, unless the person -
  - (i) is registered with the department as a microbiological laboratory in terms of regulation 6(1)(a)(ii);
  - (ii) is assigned a BSL code in terms of regulation 6(1)(a)(iii)
  - (iii) Is in possession of permit issued in terms of regulation 6(1)(b) to conduct the activities referred to in paragraph (a) or (b) in respect of human pathogens in accordance with the BSL code of the laboratory indicated in the permit; and
  - (iv) conduct an activity referred to in (a) or (b) as the case may be, in accordance with the provisions of these regulations and the standards."
- 19. The NDOH contends that the Applicant, on his own case, he is not competent nor permitted to request the relief sought referred to in paragraph 2 above. Accordingly, the NDOH contends that the Applicant on, at least, two grounds would be disqualified to request the relief in his Notice of Motion.
  - 19.1. Firstly, in paragraph 2 of the founding affidavit the Applicant merely describes himself as "an adult male, Ricardo Maarman who holds an MA International Politics obtained at the University of Leicester in the UK. He specialises in post-cold World Order, International Security Intelligence and



Security & US Foreign Policy". Thus, on his own description he would not qualify.

- 19.2. Secondly, his founding affidavit contains no positive or other averments which indicates or show that he, was registered as a microbiological laboratory with the Department, as contemplated in section 3(a) of the NHA Regulations. In addition, it not suggested by the Applicant that he is in the process or doing so. In any event, even if he was (which is denied) his expertise or lack thereof would still preclude him from requesting the relief sought.
- 20. In all the circumstances, the NDOH the contends that the Applicant's relief sought in paragraph 2 of his Notice of Motion appears to be unlawful, in that, it is contrary to the requirements of the NHA Regulations.
- 21. In the premises his application fell to be dismissed with costs. Should the Court nevertheless consider his application, then the NDOH contends that his applications must be dismissed on the grounds set out, below.

#### THE SECOND POINT IN LIMINE

Whether the Applicant has made out a case for urgency in his affidavit

ky You 22. In paragraph 1 of the Notice of Motion (read with paragraphs 10 to 24 of the founding affidavit) the Applicant prays for an order along the following lines:

"That this application is heard as a matter of urgency and that the Applicant's failure to comply with the time limits imposed by the Rules of this Honourable Court be condoned in terms of Rule 6(12)."

23. In support of his urgent application the Applicant in paragraphs 10 to 21 of the founding affidavit set out the purported grounds which he asserted renders this matter urgent. To avoid unnecessary repetition, herein, I will only refer some of the Applicant's averments set out in his founding affidavit, below. In doing so, I do not thereby concede and/or acknowledge the correctness or otherwise of his averments set out below (or those expressly excluded, herein). I turn to the Applicant's averments, below:

"I respectfully submit that this matter cannot wait to be dealt with in the ordinary course, as such, I ask the Court to dispense with the forms and service provided for in the Rules and in my non-adherence with the normal rules procedure as set out in Rule 6.

This matter is of such urgency that it simply cannot wait for the normal procedure to be complied with. I respectfully submit that this application should be heard other than in the normal course, otherwise the relief which we seek will be rendered ineffective.

Currently the entire state is under lockdown level 1, which is a serious violation of the citizens' fundamental rights. To date, the Minister of Health has uttered and there are circulating discussions that the lockdown



measures will be tightened which begs for those measures to be scrutinised.

There is a massive nationwide rollout of a vaccine claimed by the Respondent that must be used in the prevention of being infected by the alleged virus.

This vaccine rollout has begun in other countries and it has resulted in deaths and vaccine injuries.

The National disaster has been declared and is ongoing for almost a year affecting the entire nation with dire consequences.

The outcome of the order could very well mean a quick recovery to normal circumstances for the entire nation.

In South Africa, there is vast unemployment and poverty. As such, the question of the very cause threatens to drastically increase the already desperate circumstances must at least be thoroughly investigated and with utmost haste.

...And each week of continual lockdown will, in the long run, cause more loss of lives than the virus itself."

24. The Respondents (CoGTA and NDOH) contend that the Applicant's application fell to be dismissed, in that, he failed to, amongst other factors, show that he will not otherwise be afforded substantial redress at a hearing in due course. The Respondents (CoGTA and NDOH) contend that the Applicant faintly asserted in paragraph 11, without more, that "this matter is of such urgency that it simply cannot wait for the normal procedures to be complied with". Apart from the latter statement, no material facts or circumstances are advanced in his founding



affidavit wherein he claims that he will not be afforded substantial redress at a hearing in due course.

- 25. The Respondents contend that the <u>only</u> reasonable inference which could be drawn from the lack of any particularity or facts, in the founding affidavit, about the substantial redress, stems from the fact that the Applicant, in essence, is seeking *final* relief in this matter. In other words, the granting of an interdict, in the manner framed by the Applicant, would be dispositive of any matter between the parties. This is so because the Applicant is not seeking the relief in paragraph 2 of the Notice of Motion *pending* the resolution of the main (or other) proceedings.
- 26. Thus, the Applicant in paragraph 2, *supra*, is seeking final relief or relief with final effect. In any event, the Applicant is not suggesting that he is seeking (through the interdict) any "freezing" of existing rights which are threatened by irreparable harm.
- 27. The above, notwithstanding, the Respondents contend that the urgency in this matter appears to be self-created. Although it lacks the requisite factors to show urgency, the only allegation in the founding affidavit which contains some 'elements' of alleged urgency appears in paragraph 20, where he alleged that:

"In South Africa, there is vast unemployment and poverty as such, the question of the very cause threatens to drastically increase the already desperate circumstances must at least be thoroughly investigated and with utmost haste".



- 28. The Respondents contend that the above allegation should be read against, amongst others, the allegations contained in paragraph 62 where the Applicant asserted that he has a reasonable suspicion about the existence of SARS-CoV-2 virus". On the Applicant's version, if the SARS COV 2-virus does not exist then, amongst other restrictions, the lockdown restrictions are unlawful or irregular and as such violates his fundamental rights.
- 29. The Respondents contend that the Applicant commits an elementary error, in that, no right is absolute and may in appropriate circumstances be limited in terms of section 36 of the Constitution.
- 30. In any event, the Respondents contend that there appears to be a disconnect, on the one hand between the claim for urgency and on the other, the allegations in paragraph 10 to 21 of the founding affidavit, in support thereof. Put differently, the allegations in the founding affidavit do not support the Applicant's cause of action.
- 31. Nevertheless, the Respondents contend that if the Applicant failed to comply with the requirements of section 3 of the NHA Regulations then this Court may, in any event, not exercise its discretion in favour of the Applicant. In addition, the relief sought contains the risk that the Court, in granting the relief sought, might thereby enters, into the exclusive domain of the Executive or organs of state (in circumstances where no case is made out that the Executive or the organ of state commit an irregularity or violate the Constitution.)

- 32. I turn to the self-created urgency which emerge from the allegations in paragraphs
  51 to 57 of the founding affidavit. Due to the repetition of the latter allegations, I
  only restate the gist of the allegations set out in the founding affidavit, below:
  - 32.1. The Applicant knew about the National Lockdown restrictions, at least since 15 March 2020.
  - 32.2. On the Applicant's own version, he knew or reasonable should have known that in or during January 2020 the world became aware of the so-called Coronavirus.
  - 32.3. He knew or reasonably should have learnt about the vaccination rollout programs in this country, since March 2021 or earlier.
  - 32.4. In addition, the reported case of infected persons in the country are in the public domain, on a daily or weekly basis.
  - 32.5. The instances when the President address the citizens of the country about restrictions is, similarly, in the public domain. The President mostly recently in or during the beginning of April 2021 address the citizens of the country.



- 33. Despite all the above information at his disposal, at the time, the Applicant now wishes to leapfrog the court procedures and insist that he must be heard on an urgent basis, whilst no discernable case is made out in his founding affidavit.
- 34. More importantly, the Applicant rushes to Court, despite, the fact that he on his own case has an alternative remedy. This is evident from paragraph 132 of his affidavit that "the applicant has a right to access to information in terms of section 32 of our Constitution, and that is what he is essentially requesting here."
- 35. The Applicant put up no grounds or facts why he omitted to invoke his right to access to information. The Respondents contend that it is, in any event, not suggested by the Applicant in his affidavit that he in or during March or April 2021 submitted a request for information and his request was declined by the Respondents.
- 36. Accordingly, the Respondents contend that it is plain, that on his own version, the Applicant has an alternative remedy which he should have invoked <u>before</u> launching this urgent application.
- 37. In the circumstances, the Respondents contend that the Applicant's failure to do so, should be regarded as an abuse of the Court process. This is so because, not only is he requesting relief with far reaching consequences for how the Executive and organs of state should positively comply with their constitutional obligations



(by protecting the population and the health resources) but the net effect of his relief might very well place the lives of millions at risk. Because the Applicant establishes no factual basis how he will come with the provisions of the NHA Regulations. Accordingly, the handover the physical virus to him, as requested, poses serious dangers for the effective protections of the population.

38. In the premises the Respondents contend that this Applicant's application fell to be dismissed on this ground also. Should the Court, nevertheless, be amenable to consider his application (which ought to be rejected) then the Respondents contend his application should be dismiss on the ground set out below.

#### THE THIRD POINT IN LIMINE

- 39. The Respondent contends that the Applicant's application for a mandatory interdict is not an *ordinary interdict*. The Respondents contend that it is common cause that the Applicant is seeking a mandatory interdict against the Executive and organs of state (first, second and fourth Respondents).
- 40. The Respondents contend that in the absence of *mala fides* on the part of the Respondents, the Court does not readily grant such an interdict. Moreover, the Respondents contend that the Court only grants an interdict, such as that sought by the Applicant in the present instance upon a strong case being made out for

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that relief. The Applicant failed to make out such a string case and for the reason(s) referred to above and hereunder.

41. In terms of the Notice of Motion (read with paragraphs 129 to 141) of the founding affidavit the Applicant seeks the following relief:

"That the Respondents "produce" the isolated and purified physical SARS-COV-2 virus (not a culture isolate of any mixture within which the supposed virus is, nor a photograph or the RNA- sequence only) to the Applicant at a place in terms of their security measures of choice, within 7 days."

42. The Respondents contend that in terms of paragraph 2 of his Notice of Motion, if the relief is granted, they would be obliged to perform a positive act, *viz.*: to "produce" the isolated and purified SARS-COV-2 virus to the Applicant" even if the Applicant failed to comply with the provisions of section 3 of the NHA Regulations. The Respondent contend that since the Applicant has no legal basis to request the relief, this should be end of the matter. However, for consistency I, nevertheless, deal with the grounds advance in the founding affidavit, below.

Whether the Applicant has made out a prima facie case in the founding affidavit

Ad paragraphs 129 to 141 of the founding affidavit



43. The Applicant in his founding affidavit sets out the alleged basis for the relief sought in the Notice of Motion. The Applicant in paragraph 129(a) to (i) to thereof, alleged that he (and the public have the following undisputed *prima facie* rights, viz.:

#### Prima facie right

#### 43.1. Ad paragraph 129

"The Applicant and the public have the following undisputable prima facie right to (a) to human dignity; (b) life; (c) bodily and psychological integrity; (d) to make decisions concerning the security and control over their body; (e) freedom to practice their trade, occupation and professional; (f) not to be treated in a cruel, inhumane and degrading way; (g) the right to have access to health care services; (h) freedom to movement; and (i) just administration."

#### 43.2. Ad paragraph 130

"Not to have limitations imposed on their rights entrenching the Bill of Rights and if so, that it must be restrictively interpreted, so as to impose minimum limitation on those rights, in accordance with section 36 of the Constitution."

#### 43.3. Ad paragraph 131

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"That the Bill of Rights be applied to all law, including the DMA."

#### 43.4. Ad paragraph 132

"The Applicant has a right to access to information in terms of section 32 of our Constitution, and that is what he is essentially requesting here."

#### 43.5. Ad paragraph 133

"From the above it is clear that a strong case has been made out by the Applicant and those it is acting on behalf of, have at least prima facie right."

- 44. The Respondents contend that there appears to be a disconnect between the relief sought in paragraph 2 of the Notice of Motion and the fundamental rights claimed in the paragraphs set out, in paragraphs 129 to 133, *supra*. Because the Applicant failed to show which, if any of the rights referred to above, is/are threatened by an impending or imminent irreparable harm. In addition, the Applicant failed whether any member of the public (which he claims to represent) right(s) was/were threatened by an impending or imminent irreparable.
- 45. The Respondent contend that on the Applicant's case the prima facie right which he must establish is not merely a catalogue of rights, as envisage in paragraph 129 (a) to (i), *supra*, in order, for the Court to grant an order in terms whereof the Respondents would be compelled "to produce of the isolated and purified physical".



SARS-COV-2 virus." The Respondents contend that the prima face right must be a right to which, if not protected by an interdict, irreparable harm would ensue. I have already pointed out in paragraph 44, *supra*, no such case is made out on the papers by the Applicant.

- 46. In any event, the Respondents contend that the allegations contained, inter alia, in paragraphs 129 (read with 134 to 138) of the founding affidavit failed to demonstrate a prima facie right that is threatened by an impending or imminent irreparable harm. Alternatively, the above facts in the founding affidavit failed to demonstrate a prima facie case for the relief sought in the Notice of Motion.
- 47. Similarly, the facts set out in, *inter alia*, paragraphs 129 (read with paragraph 134 to 138) of the founding affidavit failed to demonstrate a clear right that is threatened by an impending or imminent irreparable harm.

#### Reasonable apprehension of irreparable and imminent harm

48. In paragraph 134 the Applicant in support of the assertion of reasonable apprehension of irreparable and imminent harm alleged that:

#### 48.1. At paragraph 134

"I submit that harm is apparent in this instance, as set out throughout this founding affidavit."



#### 48.2. Ad paragraph 135

"Without the relief sought to prevent further harm the Applicant and the rest of South Africa will continue to suffer irreparable financial, material, physical and psychological harm."

#### 48.3. Ad paragraph 138

"From the above it is clear that a strong case has been made out by the Applicant and those it is acting on behalf of the existence of the reasonable apprehension of irreparable and imminent harm."

49. The Respondents contend that there is another difficulty with the Applicant's assertion that he has prima facie right to an interim urgent interdict against the Respondents, is this: He is seeking the interim interdict ostensibly to protect the catalogue of rights set out in paragraph 129(a) to (i) of the founding affidavit. However, the difficulty with the Applicant's case is that he established no facts or circumstances how the "production" of the isolated and purified physical SARS-COV-2 virus would protect those fundamental rights. To this end he commits an elementary error by not establishing facts or circumstances to support his cause of action.



- 50. What is, however, plain from paragraph 136 to 137 of the founding affidavit is that he is, essentially, complaining about the lockdown restrictions. If this is the case, then, the Respondents contend no case is made out for an attack on those restrictions. Put more accurately, no case is made out to show the declaration of a national state of disaster (RM7) and the subsequent regulations ad directive were/are unconstitutional. Because it is not suggested in his founding affidavit (in addition to the interdict) that he complains that the lockdown restrictions are unlawful or otherwise offend the provisions of the Constitution.
- 51. The allegations on paragraphs 136 to 137 reads:

#### 52. Ad paragraph 136

"The public further stands severely prejudiced with the arbitrary infringements of their fundamental rights should the Respondents continue to ignore their rights."

#### 53. Ad paragraph 137

"At the current rate, the South African Government will run out of money to pay the salaries of state employees, it is submitted that if South Africa's present economically restricted lockdown measures are not discontinued immediately, the Respondents may cause 29 times more deaths with the measures aimed to prevent the spread than the virus itself."



- 54. In all the circumstances, the Respondents contend that there is misalignment between the relief sought for an interdict and *source* of the harm.
- The Respondents further contend that it is plain from the structure of the Notice of Motion, the Applicant seems to pray for final relief or a mandatory interdict with final effect. This is evident from prayers 1 and 2 of the Notice of Motion. It is also evidence from allegations in paragraphs 129 to 141 of the founding affidavit. Put differently, the Applicant is not seeking a provisional order which is designed to protect his rights pending an (the main) application to be brought to establish his rights. That is the purpose of the interim interdict is to freeze the position until the Courts decides where his rights lie.
- 56. In the premises, the Respondents contend that the Applicant's application fell to be dismissed with costs.

#### Hearsay evidence

57. The Respondents contend that the Applicant's application is largely, if not, exclusively founded on statements and documents, the authenticity of which are disputed. Notwithstanding the dispute about the authenticity of those documents, the Respondents contend that a large, if not, the entire case in support of the relief sought under paragraph 2 of the Notice of Motion, appears to consist of hearsay evidence.



- 58. I will, accordingly, not deal with those individual paragraphs and documents which offend the rules of evidence and the Uniform Rules of Court in this affidavit. The Respondents intend to launch an interlocutory application in this regard. Accordingly, my responses below will be confined to those allegations which invite a scientific response.
- 59. I will, similarly, not expressly deal with those averments which relates to CoGTA.
  In this regard, a supporting affidavit, explanatory and confirmatory affidavits will be deposed to by the relevant employees.

#### THE AVERMENTS CONTAINED IN THE FOUNDING AFFIDAVIT

#### 60. Ad paragraphs 1 to 2 thereof:

- 61. Denied.
  - 61.1. As is evident from paragraph 2 of the founding affidavit, the Applicant's expertise falls within the domain of 'social science'. In particular, he appears to specialise in, amongst others, Post-cold war world order, international security, intelligence, and US foreign policy.
  - 61.2. Whereas the subject matter of SARS-COV2 seems to fall within the broader branches of microbiology, virology, and epidemiology. There is no evidence that the Applicant is a specialist or had otherwise gain expert knowledge in

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any of the branches of science. To this end, the NDOH dispute the Applicant's claim about his personal knowledge and his expertise in the relevant branch of science.

- 61.3. I am advised that the documentary material attached to his founding affidavit constitutes hearsay evidence. The NDOH denies that it consented to the submission or use of those documents.
- 61.4. Save as aforesaid, the balance of the allegations contained in this paragraph are denied.

#### 62. Ad paragraphs 3 to 5 thereof:

The allegations contained in these paragraphs are noted but not disputed.

#### 63. Ad paragraphs 6 to 9 thereof:

- 64. Denied.
  - 64.1. The NDOH denies that this matter is urgent. The NDOH repeats the submissions set out in paragraphs 22 to 38, supra.
  - 64.2. The NDOH denies that the Applicant is entitled to the relief sought in paragraph 7 (read with paragraph 2 of his Notice of Motion). The grounds



upon which the NDOH claims that the Applicant is not entitled to the relief sought are more fully traverse in paragraphs 13 to 21 and 39 to 56, supra.

- 64.3. In particular, the NDOH denies that the Applicant is registered as a microbiological laboratory. The NDOH avers that there are minimum requirements which must be met before a person or laboratory can be registered. For ease of reference, I attached hereto a copy of the minimum requirements for laboratories, marked ("AP1").
- 64.4. When a person/laboratory is so registered the NDOH issued a permit to the laboratory. I also attached hereto, a flow chart of how a permit is obtained, marked ("AP2").
- 64.5. Save as aforesaid the balance of the averments is denied.

#### 65. Ad paragraphs 10 to 24 thereof:

- 66. Denied.
  - 66.1. The NDOH repeat the submissions in paragraphs 23 to 23, supra.

### 67. Ad paragraphs 25 to 31 thereof:

The allegations herein are noted, but not admitted.



### 68. Ad paragraph 32 thereof:

The allegations herein are noted.

#### 69. Ad paragraph 33 thereof:

- 70. Denied.
- 71. The NDOH avers that the allegations in this paragraph amounts to a statement which are not supported by any material facts or circumstances.
- 72. In any event, there are no corroborating evidence in support of the Applicant's claim that he acts for or in the interests of the public.

### 73. Ad paragraphs 34 to 39 thereof:

The allegations contained herein are noted, but not admitted.

- 74. Ad paragraphs 40 to 44 (read with paragraphs 46, 47, 48 and 49) thereof:
- 75. Denied.
- 76. The NDOH avers that the allegations contained in the above paragraphs are argumentative and fell to be struck from the affidavit.



77. In any event, the NDOH denies that the Applicant could have any personal knowledge in respect of the matters set out in paragraphs 40 to 42, above.

### 78. Ad paragraphs 45 thereof:

#### 79. Denied.

- 79.1. The NDOH dispute the basis upon which the Applicant advance the submission in this paragraph.
- 79.2. It is common cause that he is not qualified as an expert or otherwise expertise in the fields of microbiology or epidemiology.
- 79.3. Despite the patent lack of the requisite expertise the Applicant seeks to venture deep into branches of science, without the benefit of a qualified expert.
- 79.4. More importantly, despite the grave knowledge deficits, the Applicant persist with this application on an urgent basis.
- 79.5. The NDOH avers that the Applicant does not only (through this application) place the Court a great disadvantage, in that, the Court is not qualified nor possess the requisite scientific knowledge. But, in doing so, I am advised, he also contravene the Rules of this Court, in particular Rule 36(9).

## 80. Ad paragraph 50 thereof:

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The allegations contained herein are noted but not admitted.

## 81. Ad paragraphs 51 to 60 thereof:

The NDOH avers that these averments are dealt with in the supporting affidavit deposed to by Deputy-Director General from CoGTA.

# 82. Ad paragraphs 61 to 63 thereof:

- 83. The NDOH avers that in lockdown restrictions were lawfully impose in the context of the prevailing COVID 19 pandemic to, amongst others, to save lives and control the rapid spread of infections in the country.
  - 83.1. The NDOH avers that assertions by the Applicant that "some disruption is lives may only be necessary if we are assured beyond doubt of the existence of the SARS-COV2, appears to be baseless.
  - 83.2. It is not plain what is the source of the opinion advanced in paragraph 61 of the founding affidavit, in particular, his claim that such disruptions depend on an assurance beyond doubt. In addition, the Applicant failed to provide any qualified expert opinion or any peer review which supports his claim.



- 83.3. In any event, he is not qualified as an expert in the relevant field, it is accordingly unclear on what basis, if any, he advanced his findings.
- 83.4. Save as aforesaid the balance of the allegations is denied.

## 84. Ad paragraphs 64 to 71 thereof:

- 85. Denied.
- 86. In amplification of the aforesaid denial the NDOH avers as follows:
  - 86.1. Protocols for isolation and culturing of "physical virus" are now well established. There are many clear review manuscripts to support this statement. It is not done routinely for diagnosis, as it will be impractical and will not be conducive to patient management.
  - 86.2. The nature of the SARS COV-2 has been established not only through RT-PCR in sequencing but also in electron microscopy.
  - 86.3. I confirm that this has been achieved by the NICD where I carry out my principal duties. I refer below to certain criteria/methodologies use, viz. Koch and the Bradford-Hill criteria/methodologies.

### The Koch criteria

III.

- 86.4. Koch postulates that the following needs to be satisfied to determine causation of a disease:
  - (a) the organisms must be regularly associated with the disease and its characteristic lesions.
  - (b) the organisms must be regularly associated with the disease host and grown in culture.
  - (c) the disease must be reproduced when a pure culture of the organism is introduced into a healthy susceptible host.
  - (d) the same organisms must be re-isolated from the experimentally infected host.
- 86.5. There have been significant advances with new diagnostic methodologies and sequencing, and further associations are made:
  - 86.5.1. A nucleic acid sequencing belonging to a putative pathogen should be present in most cases of an infectious disease. Microbial nucleic acids should be found preferentially in those organs or gross anatomic sites known to be diseased and not in those organs that lack pathology. Fewer, or no, copy numbers of



pathogens-associated nucleic acid sequences should occur in hosts or tissues without disease. With resolution of disease, the copy number of pathogen-associated nucleic acid sequence should decrease or become undetectable. With clinical relapse, the opposite should occur.

- 86.5.2. When sequence detection predates disease, or sequence copy number correlates with severity of disease or pathology, the sequence-disease association is more likely to be a causal relationship.
- 86.6. The nature of the micro-organism inferred from the available sequence should be consistent with the known biological characteristic of that group or organisms.
- 86.7. Tissue-sequence correlates should be sought at the cellular level: efforts should be made to demonstrate specific in situ hybridization of microbial sequence to areas of tissue pathology and to visible micro-organisms or to areas where micro-organisms are presumed to be located. These sequence base forms with evidence for microbial causation should be reproducible.

# The Bradford-Hill criteria

- 86.8. Causation may also be determined by the Bradford-Hill criteria (Koch postulates are not possible for all pathogens):
- 86.9. Strength (effect size): the association between SARS COV-2 infections and COVID-19 presentation is strong.
- 86.10. Consistency (reproducibility): consistent findings observed by persons in different places with different samples strengthens the likelihood of an effect. This has been done for SARS-COV-2 and COVID-19 in many ways by many different groups around the world.
- 86.11. Specificity: causation is likely if there is a very specific population at a specific site and disease with no other likely explanation. The more specific an association between a factor and an effect is, the bigger the probability of a causal relationship. These criteria may be a bit problematic for COVID-19.
- 86.12. I think one supporting evidence here is that one Island that is free from COVID-19 and no SARS COV-2 detected.
- 86.13. Temporality: the effect is to occur after the cause (and if there is an expected delay between the cause and the expected effect, then the effect must occur after the delay. COVID-19 was not reported before the emergence of SARS COV-2.



- 86.14. Biological gradient (dose-response relationship): greater exposure should generally lead to greater incidents of the effect.
- 86.15. I think the effect of lockdown measures etc. can be named here, i.e., reduced risk, reduced cases, this is but one example there are many other examples which could be identified.
- 86.16. Plausibility: a plausible mechanism between cause and effect is helpful (but Bradford-Hill noted that knowledge of the mechanisms is limited by current knowledge).
- 86.17. We know from SARS and MERS that zoonotic coronavirus is involved in respiratory illness.
- 86.18. Coherence: coherence between epidemiological and laboratory findings increased the likelihood of an effect. This has also been found now many times.
- 86.19. Experiment: occasionally it is possible to appeal to experimental evidence. This is where the animal models can come in. For ease of reference, I attached a recent article which comments on: Animal models for SARS-Cov2/COVID 19 research- A commentary, marked ("NM3")



86.20. Analogy: the use of analogies or similarities between the observed association and any other associations. SARS and MERS sets' the precedent for zoonotic coronaviruses emerging to cause respiratory diseases in humans, although no difference in epidemiology/clinical spectrum.

# 87. Ad paragraphs 72 to 128 thereof:

- 88. The NDOH avers that the allegations (including the annexures thereto) constitute hearsay evidence and as such fell to be strike out from this affidavit.
- 89. The NDOH further avers that the complaint about the hearsay evidence forms part of an interlocutory application (which will be heard with this application).
- 90. Save as aforesaid the allegations contained in paragraphs 72 to 79 are denied, as if specifically, traverse, herein.

# 91. Ad paragraphs 129 to 141 thereof:

- 92. Denied.
- 93. The NDOH repeats the submission set out in paragraphs 42 to 56.
- 94. Save as aforesaid the balance of the averments contained in paragraphs 129 to 141 are denies, as if, specifically, traverse, herein.

### 95. Ad paragraphs 134 to 138:

The allegations contained herein are denied.

### 96. Ad paragraph 142 thereof:

- 97. Denied.
  - 97.1. The NDOH avers that the Applicant is not permitted and/or competent to received, and/or handle and/or otherwise deal with this or any other infectious virus.
  - 97.2. The NDOH repeats the grounds set out in paragraphs 13 to 21, supra, in support of the aforesaid averments.
  - 97.3. Save as aforesaid the balance of the averments is denied.

### 98. Ad paragraph 143 thereof:

- 99. Denied.
- The NDOH avers that on the Applicant's own case, he established in paragraph 132 that he does have an alternative remedy.



- 101. In any event, the NDOH avers that the must first overcome the hurdles referred to in paragraphs 13 to 21, supra, before he could possibly assert any claim to the existence of a right.
- 102. Save as aforesaid the balance of the averments is denied.

Professor Adrian J Puren

certify that:-

The deponent signed this affidavit and swore, and acknowledged that he/she: -

- a) knew and understood the contents thereof;
- b) had no objection to taking the oath; and,
- c) considered the oath to be binding on his/her conscience.

The deponent then uttered the words, "I swear that the contents of this declaration are true, so help me God".

Full names: 1 lockers AM

Designation and area: COASTABLE

Street address: NO OI MODDERCHICIA RD

SANDRINGHAM) OIL TIG 4800 COMMISSIONER OF OATHS

SOUTH AFRICANDOLICE SERVICE

Annexure A





Private Bag X828, PRETORIA, 0001 Civitas Building, c/o Struben and Thabo Sehume Streets Enquiries: send to emails: registrationlaboratories@health.gov.za & DOH.COVID19@nhls.ac.za

## CONDUCTING SARS CoV-2 DIAGNOSTIC TESTING MINIMUM REQUIREMENTS FOR LABORATORIES

**AUGUST 2020** 

### introduction

and the Health Professionals Council of South Africa (HPCSA). Department of Health (DOH), the Department of Employment and Labour (DEL), the Council for the Non-Proliferation of Weapons of Mass Destruction (NPC) for the National Department of Health (NDoH). The minimum requirements checklist takes into consideration the legislative requirements as set out by the Health Laboratory Service (NHLS), including the National Institute for Communicable Diseases (NICD) and National Institute for Occupational Health (NIOH) subjects. A set of minimum requirements were drafted for laboratories who wish to conduct SARS-CoV-2 diagnostic testing in consultation with the National Diagnostic Laboratories in South Africa are required to comply with a number of legislative requirements in order to perform diagnostic testing for human

human pathogens, must be in possession of a permit issued by the Department of Health (DoH), authorizing the laboratory to conduct the work as described laboratories that acquire, receive or import human pathogens; or handle, manipulate, maintain, store, culture or in any way process, issue and/or dispose of One of the major regulations relevant to laboratories that wish to embark on clinical diagnostic testing, is Regulation 178. This Regulation stipulates that all

### Scope

SARS-CoV-2 pandemic This checklist is relevant to all South African laboratories, in both the public and in the private sector, that perform diagnostic testing in response to the current

### Instructions to Laboratories

- All laboratories intending to do diagnostic SARS COV-2 testing should complete the checklist; this checklist represents the minimum requirements to be met by laboratories, that will be allowed to conduct diagnostic testing for SARS COV-2;
- N First step is to ensure the laboratories are compliant with the requirements described in the checklist (Annexure A);
- ţų Complete registrationlaboratories@health.gov.za and copy the DOH.COVID19@nhls.ac.za within seven (7) working days of receiving the checklist the checklist providing descriptions of compliance in the "comments" section, and return the completed checklist to
- Should you fail to return the minimum checklist within the allotted time, your laboratory will be removed from the testing & reporting register,

- Ų Regardless of the information presented in the initial checklist, the laboratory will be afforded a period of one (1) calendar month to achieve compliance with the minimum requirements listed
- Ġ If compliant, an application form for authorisation to handle the SARS CoV-2 will be sent to the laboratory/facility. If non-compliant after this one month Laboratories that still fail to show compliance will be required to cease with their SARS-CoV-2 testing. period, the laboratory may request an extension of an additional 1 month, but may not provide SARS-CoV-2 testing until compliance is achieved.
- The laboratory/facility will be allowed to report results and will be issued with a permit (valid for one year), to conduct SARS-CoV-2 diagnostic testing.

### Conclusion

legally compliant medical laboratory sector and greater government oversight regarding patient testing and pathogen security enhancement and strengthening of biosafety and biosecurity regulations to better serve the country and its people. This ultimately brings us closer to 2021 International Health Regulations (IHR) requirements and will ultimately ensure that the diagnostic results are of the highest standard. It also paves a way to a hindering on the country's response efforts to this global pandemic. This unique and previously uncharted territory has highlighted opportunities for the Patient specimen testing is a highly valued capacity for South Africa during this pandemic and these minimum requirements are not intended to be restrictive or

# Annexure A: Minimum requirements to be met by laboratories conducting SARS-CoV-2 testing

	Personnel	Requirement	Yes/No	Comments
	<ul> <li>A minimum of one Health Professions Council of South Africa (HPCSA) registered person working in the lab</li> <li>Registration with the HPCSA in any medical laboratory discipline e.g. Microbiology, Virology, Chemical Pathology, Haematology, Cytology etc.</li> <li>Provide registration numbers for people working in the laboratory/facility.</li> </ul>	Person must have physical presence in the lab -; There has to be a physical presence of an HPCSA registered person in the testing laboratory;		
N	Quality requirements			
27	Participate in External Quality Assessment/ Proficiency Testing (PT) program/s for existing test(s), if laboratory is already participating in PT for SARS-CoV-2, please provide proof)	Once approved – register for SARS-CoV-2 testing in first month		
2,2	Must undergo a quality assurance audit	Applicants will be required to provide evidence of a quality management system in effect at the laboratory.		
N N	Proof of accreditation If laboratory is accredited.	NOTE: Even though accreditation is not a requirement it will guide the audit process mentioned above		
2,2.2	Provide proof that the laboratory was testing for other coronaviruses before March 2020.	Example of a test results showing method excluding personal patient identifiers and information		
က	Occupational Health and Safety requirements			

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The vehicle on registration should be registered as a transporter of "Dangerous Goods". Vehicles should be appropriately marked and monitored by tracking devices.	Provide details of the manager appointed as the COVID-19 Compliance Officer	Access control to facility	Emergency procedures in place	Provide proof of a process for the appointment of health and safety representative(s) HSR and the appointment thereof. Provide evidence that health and safety committees have been established and meetings are held, where applicable (number of HSRs dependent on the number of employees i.e. 1 HSR per < 50 laboratory employees)	If the employer has assigned any duties in terms of the Occupation Health & Safety (OHS) Act, a copy of the assignment in terms of Section 16.2 of the OHS Act to be provided.	A record of control measures implemented and where relevant including any maintenance validation records to be provided	The risk assessment must include control measures to be implemented to minimise the risks identified.	Must have a valid documented risk assessment that includes but is not limited to biological, chemical, physical and ergonomic risks.
Registration - license disc	Appointment letter	Photograph of the facility main lab access signage	Documented procedures	Establish a Committee if more than one HSR	E.g. Assignment letter describing the delegation of responsibilities for occupational health and employee safety.	Risk assessment control measure e.g. Equipment service vertification/validation	All control measures to be considered, engineering, administrative and PPE	Include emergency procedures, training decontamination, Personal Protective Equipment (PPE), Occupational Health and Safety Policies

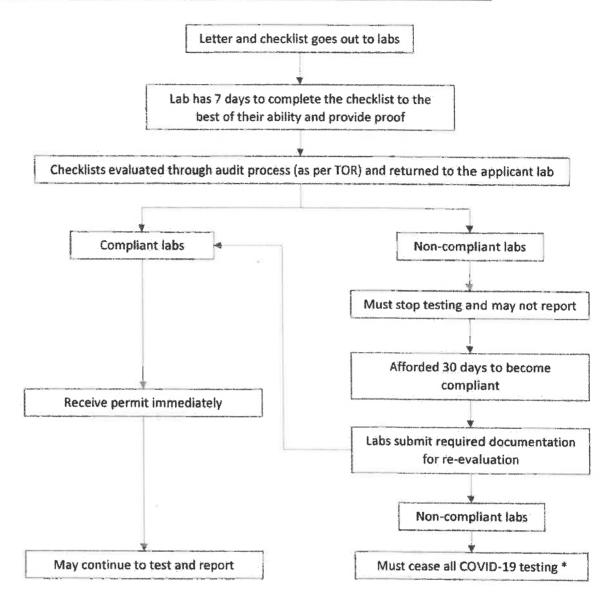


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Able to submit result data (negative and positive) to SOAP web. service		Information Technology for Reporting Data to NICD	Laboratory issued with a permit from the National Department of Health as a Microbiological Laboratory that handles SARS-CoV-2 (excluding normal labs that test for other coronaviruses) – relevant for all labs that do not regularly test for coronaviruses)	Laboratory is in possession of a permit issued in terms of Regulation 178 to conduct the activities as described in Regulation 178 in respect of human pathogens in accordance with the Biosafety Level (BSL) code of the laboratory indicated on the permit; (i.e. BSL2)	Laboratory registrations and permits	Provide proof of an agreement between the facility and a registered health care risk waste management service provider for the removal, treatment and/ or disposal of chemical waste.	Provide details of registration of either the Provincial or National Waste Information System in terms of the National Waste Information Regulations as a generator of waste	Waste Management	Licensed driver trained to transport UN3373 Category B biological substances by training organisation that is registered with the Transport & Education Training Authority (TETA)
All results must ultimately be reported to the NICD as SARS-CoV-2 is a notifiable medical condition. For more information on the process please see:	Access to a LIS system to submit date		Expiry date of permit – valid for one year from date of issue of permit and will then be reviewed	Regulation 178 Permit or temporary approval		PO for company to safely remove waste.	Copy of registration Online process put link		Public Drivers Permit Certificate with TETA full registration number

		https://www.nicd.ac.za/nmc-	
		overview/	
7.3	Data submitted per XML specification		
7.4	Quality data in line with requirements as stipulated in NMC regulations	Must have quality checks in place	

CAP2

Annex B - Process flow for obtaining a Permit to conduct SARS-CoV-2 diagnostic testing



<sup>\*</sup> extra month extension may be granted at the discretion of the evaluator—i.e. if there is a legitimate reason that criteria cannot be met in the allotted first month, possibly outside the control of the lab e.g. advertising and recruitment of an HPCSA registered person

This would only be based on exceptional circumstances if there is a legitimate reason for the extra time, AND on condition that the lab does not conduct testing until the permit is in hand

### IN THE HIGH COURT OF SOUTH AFRICA (WESTERN CAPE DIVISION, CAPE TOWN)

Case No: 5852/2021

in the matter between:

**RICARDO MAARMAN** 

**Applicant** 

and

THE PRESIDENT OF THE REPUBLIC OF SOUTH AFRICA

First Respondent

THE MINISTER OF CO-OPERATIVE GOVERNANCE AND TRADITIONAL AFFAIRS

Second Respondent

PROFESSOR SALIM ABDUL KARRIEM obo THE GOVERNMENTAL COVID-19 ADVISORY COMMITTEE

Third Respondent

THE NATIONAL DEPARTMENT OF HEALTH

Fourth Respondent

### **CONFIRMATORY AFFIDAVIT**

I, the undersigned,

### SABELO SIYABONGA SANDILE BUTHELEZI

do hereby make oath and say:

- 1. I am an adult male and employed as the Director-General in the office of the Fourth Respondent.
- 2. I am duly authorised to depose to this affidavit on behalf of the Fourth Respondent.
- 3. The facts contained herein are within my personal knowledge, and are both true and correct, unless the context indicates otherwise.
- 4. I have read the main answering affidavit deposed to by Professor Adrian J Puren on behalf of the Fourth Respondent, the supporting affidavit on behalf of CoGTA and/or the National Disaster Management Centre and I confirm that the facts set out therein, insofar as they pertain to the Fourth Respondent and such facts fall within my knowledge or are based on institutional knowledge of the Fourth Respondent gained in the course of my work as the Director-General and from documents now under my control, unless the context indicates otherwise, and are true and correct.

Sabelo Siyabonga Sandile Buthelezi

I certify that the deponent has acknowledged that he knows and understand the contents of this affidavit, which was signed and deposed to before me at Preson's on this the 35 day of MAY 2021 and the provisions of the regulations contained in the Government Gazette Notice R1258 of 21 July 1972, as amended, and the government Gazette Notice R1648 of 19 August 1977, as amended, have been complied with

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2021 -05- 25

DIVISION: VISIBLE POLICING SOUTH AFRICAN POLICE SERVICE

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COMMISSIONER OF OATHS
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### IN THE HIGH COURT OF SOUTH AFRICA (WESTERN CAPE DIVISION, CAPE TOWN)

In the matter between:

RICARDO MAARMAN

Applicant

and

THE PRESIDENT OF THE REPUBLIC OF SOUTH
AFRICA

First Respondent

THE MINISTER OF CO-OPERATIVE GOVERNANCE
AND TRADITIONAL AFFAIRS

Second Respondent

PROFESSOR SALIM ABDUL KARRIEM obo THE
GOVERNMENTAL COVID-19 ADVISORY COMMITTEE

Third Respondent

THE NATIONAL DEPARTMENT OF HEALTH

Fourth Respondent

I, the undersigned,

**PROFESSOR KOLEKA MLISANA** 

**EXPLANATORY AFFIDAVIT** 

do hereby make oath and say:

No. c

Case No: 5852/2021

- I am an adult female. The principal place where I carry out my duties is at 1
   Modderfontein Road, Sandringham, Johannesburg.
- I am duly authorised to depose to this affidavit on behalf of the Government Covid
   Advisory Committee.
- 3. The facts set out in this affidavit are within my personal knowledge and are derived from documents and information under my control, unless the context indicates otherwise and are true.
- 4. I have read the affidavits of the Applicant, including the answering affidavit of Professor Adrian J Puren and the supporting affidavits thereto and I confirm the correctness of the contents thereof insofar as it relates to the recommendations of the Ministerial Advisory Committee on COVID-19.
- The purpose of this affidavit is to explain the position of Professor Salim Abdool
  Karim, the Third Respondent, who is cited in his official capacity as the head of the
  Ministerial Advisory Committee on COVID-19 (the Committee). I confirm that
  Professor Karim resigned as chairperson of the Committee on 26 March 2021.
- 6. I confirm that I am the chairperson of the committee and that I am duly authorised to deal with all matters pertaining to the Committee.

PROFESSOR KOLEKA MLISANA

I certify that the deponent has acknowledged that she knows and understand the contents of this affidavit, which was signed and deposed to before me at Preson's on this the 25 day of MAY 2021 and the provisions of the regulations contained in the Government Gazette Notice R1258 of 21 July 1972, as amended, and the government Gazette Notice R1648 of 19 August 1977, as amended, have been complied with

WARCEMENG MAKEWATE CHURLY

COMMISSIONER OF OATHS WARRANT OATICEL MURLUPH NUTCH BUILDING