



15 December 2023

Submission: Commonwealth Government COVID-19 Response Inquiry terms of reference

- ***Governance including the role of the Commonwealth Government, responsibilities of state and territory governments, national governance mechanisms (such as National Cabinet, the National Coordination Mechanism and the Australian Health Protection Principal Committee) and advisory bodies supporting responses to COVID-19.***

Dear Panel Members,

1. We welcome the opportunity to provide input into the *Commonwealth Government COVID-19 Response Inquiry*. We believe the terms of reference are severely restrictive and will not achieve the aims of a true inquiry where the panel (however constituted) are to establish positives and negatives relating to Covid response. Whilst we appreciate the need to constrain submissions, the present restriction does not afford the community with procedural fairness or natural justice. Nevertheless, for the purposes of adhering to the terms of reference, our submission relates to the above referred term.
2. The limit of 3 pages and 5 annexures per submission compounds the issue of transparency as it restricts a comprehensive analysis. The restrictive nature of this inquiry clearly runs contrary to the aims and objectives of Australia's, national, State and local government response during the centralised national push for vaccine uptake as articulated in "*Op COVID SHEILD – National COVID Vaccine Campaign Plan – 3 August 2021*". It is clear that the Commonwealth Government together with the States and Territories, coordinated, funded, promoted and planned a national vaccination campaign involving the Australian population. Thus, restricting this inquiry is not satisfactory as it limits the identification of damages and adverse consequences that may bring Commonwealth, State and Territory Governments and representatives into disrepute.
3. This inquiry must extend to examining the potential breach of Australian Constitution, particularly s51(23A) – Civil Conscription in the wake of the Nuremberg hearings post World War II where human experimentation and clinical trials were imposed upon certain groups without consent. History reminds us of the Nuremberg trials and consequences on those that took unilateral actions to the detriment of humanity.
4. To be clear, this submission does not suggest the COVID-19 claims are a hoax, rather it attempts to bring some proportionality and balance to the decision-making process in a manner that is consistent with the practices of participatory democratic governance and **real science (that is open for consultation and transparent)**.¹ The lack of public consultation and concealment of contracts is a concern.

Independence of Panel

5. We certainly respect the panel of independent experts, however, I personally discussed and communicated with [REDACTED] on 14 September 2021 where I clarified that the global experts were not antivaxxers. In no way are we suggesting that the [REDACTED] lacks integrity, rather, the independence of the panel must be impartial.

Dismissing International Experts who did not agree with the Government Narrative

6. Experts and physicians with experience successfully treating covid patients were labelled antivaxxers or lacking an explanation, whilst those with no experience treating covid patients with an emphasis on academic writings were classified as impressive. From the outset, Australian Experts had the advantage of learning from international peers, but the expertise of the international experts and advice relating to non-vaccine approaches were dismissed and rejected.

¹ Letter to Parliamentarians (Brad Hazard et al), (7 July 2021) available at: <https://www.aflsolicitors.com.au/information/blog-post-title-one-5gt2>. This should be seen as Notice to public officials and institutions.

Associates

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Banning Medications demonstrating therapeutic efficacy denied to the Australian Population

7. The declaration known as the *Biosecurity (Human Biosecurity Emergency) (Human Coronavirus with Pandemic Potential) Declaration 2020* was made under section 475 of the Act. According to the Commonwealth The declaration at clause 6 states that:
 - a. *The Human coronavirus with pandemic potential is an infectious disease;*
 - b. *that has entered Australian territory; and*
 - c. *that is fatal in some cases; and*
 - d. *that there was no vaccine against, or antiviral treatment for, immediately before the commencement of this instrument; and*
 - e. *that is posing a severe and immediate threat to human health on a nationally significant scale.*
8. The thrust of this summary relates to subsection (d) (above) indicates that there were medications available, but they were banned. Future investigations must get access to the advice given to Ministers including the reasons for banning ivermectin and hydroxychloroquine.
9. Australian institutions and experts were placed on notice early in the Covid flu period as to the efficacy of alternative therapeutics. Instead of targeting Doctors providing therapeutic alternatives, it appeared as though experts, Government and media were all focussed on one manner of treatment (vaccines). As a consequence, Australians were denied access to potentially life saving medications. Conduct of this nature should attract civil and potentially criminal penalties.
10. The safety of the community is paramount consideration, but it is important that public consultation is encouraged and that includes reporting deaths from vaccines too. Daily reports of people with a sniffle, but no mention of deaths. See **Annexure A – Autopsy Report (NSW Health).**

11. In one case, [REDACTED]

[REDACTED] In other words, medications such as ivermectin in combination with other medications provided insight to potentially greater therapeutic benefit to both the vaccinated and vaccinated using alternative treatments. This aspect is very concerning as it demonstrates that experts, regulators, and Government took a unilateral step to impose a selective class of treatments whilst denying other treatments. (*I have provided this de identified data set and treatment protocol that was known to have efficacy early in the outbreak in this submission – See Annexure B – Statement of [REDACTED] together with primary patient data.*)

Foundations of the Challenge and Movement towards protecting Human Rights in Australia

12. AFL Solicitors is in a unique position to provide commentary on the proposed submission being the first law firm to advocate on behalf of the community and we continue to do so to the present in industrial relations, mandates, fines, mask fines, heavy handed policing such as pepper spraying minors for no mask and incarcerating people attending protests against the lockdowns in breach of the Nelson Mandella rules: protecting the Rights of Persons Deprived of Liberty.² Many were conducted on a pro bono basis to support the community due to the ostracization by key Australian institutions who would previously have acted impartially.
13. The harsh, disproportionate, immoral, unethical, legally unreasonable, and sometimes unlawful behaviours militated against Australia's obligations to the Siracusa Principles and *International Covenant on Civil and Political Rights* (ICCPR). It is submitted that any curtailment of human rights should be the least restrictive measures. The persistent use of terms such "antivaxxer" and "selfish" ('to name a few) amounted to a social platform of divisive community messaging. In some cases, people experiencing (reported) side effects were gaslighted by Media and called antivaxxers.³ Mainstream media encouraging families to disown and kick out their family members if they were not vaccinated. It may be claimed that these were unilateral actions, but all matters must be taken in their totality. We say the messaging from Government and experts facilitated in the whole of government approach to subject citizens who declined the vaccine to ridicule, gaslighting and abuse.

Testing and Closures

² Nelson Mandella rules: protecting the Rights of Persons Deprived of Liberty <https://www.un.org/en/un-chronicle/nelson-mandela-rules-protecting-rights-persons-deprived-liberty>

³ <https://caldronpool.com/medical-doctor-responds-to-health-minister-calling-the-unvaccinated-extremely-selfish/>.



14. Lining up daily to get tested with a PCR test that appears to be not fit for purpose and being potentially misleading and deceptive as was raised early in the Covid event. See **Annexure C – Expert Opinion**
15. The prolonged and disproportionate measures advocated by Ministers together with Health Experts and promulgated by the media led to closures to places of worship (religious instructions)⁴, community support groups (indigenous and non-indigenous). By way of example, people could not attend their place of religion or receive assistance from their pastors or community groups but could attend a brothel, purchase alcohol and attend large stores (but not small business even if they followed the same protocols). It is difficult to comprehend how this logical inversion became national policy purportedly to address a contagion with an estimated 99.5% survivability rate (*for most of the community with children being almost nil risk of severe disease unless immune compromised*). Please refer to **Annexure D – Statement of [REDACTED]**. The logical inversion occurred where the supposed deadly level of transmissibility had imaginary limits. For example, you couldn't sing and stand but you could walk and talk, could not attend dying family members in hospital, mother losing a twin child due to Queensland and NSW border closure. Schools were closed causing many Australian children to lose vital education, something Australia will pay for in the future.

Governments Employers - Mandated Clinical Trial

16. From the outset it should be noted that Greg Hunt (*former Federal Health Minister as he was then*) stated this was the world's largest clinical trial. This statement on its own demonstrates that there was no reasonable way any Minister, expert, media representative or community celebrities could have possibly stated the Covid Vaccines were safe and effective. Yet the public record is littered with such statements and a complete investigation needs to be undertaken without limitation. Unverified statements had the effect of curtailing fundamental rights, freedoms and provided Government and employers with a self-professed power to molest and inject the public on mass by breaching the fundamental right to bodily integrity. Any notion that people had a choice is misleading, fanciful, and offensive to those who did nothing more than exercise their fundamental rights. The amount of Australian citizens that lost their jobs during this time can only be described as industrial relations pogrom. We continue to advocate for emergency service personnel and the community in Courts.

Is bodily integrity a fundamental right?

17. Bodily integrity is a fundamental right under the common law. It has a long history in our legal system and forms the foundation of the law of tort. In *Collins v Wilcock* [1984] 1 WLR 1172, Robert Goff LJ made its centrality very clear: '*The fundamental principle, plain and incontestable, is that every person's body is inviolate. It has long been established that any touching of another person, however slight, may amount to a battery. ...The breadth of the principle reflects the fundamental nature of the interest so protected.* (emphasis added)'. In his discussion of the principle, Robert Goff LJ went on to quote Blackstone's 'Commentaries, 17th ed. (1830), vol. 3, p. 120' and, in doing so, highlights the longevity and durability of the principle as a fundamental common law right:
- [REDACTED]

18. Well before anyone else in Australia, the efficacy safety of the vaccines (especially as a standalone) was questioned with evidence provided. Issues relating to mRNA and genotoxicity, including gene therapy was being pushed. Please refer to **Annexure E – [REDACTED]**. This supports our contention that vaccinations were not required as the only mechanism, as outlined **Annexure B**. During COVID, these principles were violated by implementing lockdowns, excluding people from Churches, but at same time allowing them attend brothels, buying alcohol, and attending large stores. The same rules and laws were rarely available for small family businesses.⁵

Employment Consequences – the illogical inversion of Law

19. As a consequence, many employers relied on the State Government pressure and so-called epidemiological experts to justify how a vaccine that did not prevent (*nor tested to stop or reduce transmission*) was efficacious. Either case suggests there was a disproportionate response towards employees who were now being subjected to further shots in order to maintain employment.

⁴ *Athavle v State of New South Wales & Ors* [2021] FCA 1075 (Freedom of Religion case).

⁵ *Athavle v State of New South Wales* [2021] FCA 1075



Annexure "A"



Health
Pathology

Forensic & Analytical
Science Service



AUTOPSY REPORT FOR THE CORONER

Name: [REDACTED]

Forensic Medicine Case No.: [REDACTED]

COPS Event No.: [REDACTED]

Coroner's Case No.: [REDACTED]

Coroner:

Deputy State Coroner [REDACTED]

Age: [REDACTED]

Sex: Male

Pathologist: [REDACTED]

Pathologist's qualifications:

MRAS (hon); RCV FRCPA (Anatomical Pathologist)
Post Fellowship Diploma in Forensic Pathology
(Forensic Pathologist)

Time & date of autopsy:

09:00 hours on [REDACTED] August 2021

Place of autopsy:

Forensic Medicine Wollongong
Forensic & Analytical Science Service

Autopsy Assistant: [REDACTED]

Also present at autopsy:

[REDACTED] Resident Medical Officer

Nature of examination performed
as per Coronial Direction:

Coronial Autopsy Examination

OPINION

I acknowledge that I have read the Expert Witness Code of Conduct in Schedule 7 of the NSW Uniform Civil Procedure Rules 2005, and agree to be bound by the Code.

Based on what I have observed, my experience and training, and the information supplied to me:

[REDACTED] died on 26 July 2021 at [REDACTED]
and that the cause of death is as follows:

1. DIRECT CAUSE:

Disease or condition directly leading to death:

(a) RAPIDLY PROGRESSING GRANULOMATOUS MYOCARDITIS
FOLLOWING PFIZER CONFIRMATY COVID-19 VACCINATION

ANTECEDENT CAUSES:

Morbid conditions, if any, giving rise to the above cause, stating the underlying condition last:

(b)

(c)

2. Other significant conditions contributing to the death but not relating to the disease or condition causing it:

CARDIAC SARCOIDOSIS
HYPERTENSION

REPORT SUMMARY

History:

The following information was provided from a variety of sources, which may include police and medical records. It is acknowledged that some personal or other details provided may be inaccurate.

The deceased is [REDACTED]. According to the PTA and medical records received from the General Practitioner, the following events took place.

15 June 2021	Recommenced on Ramipril 2.5 mg for hypertension
20 July 2021:	Pfizer Comirnaty vaccination for COVID-19
22 July 2021:	Unwell with posterior chest pain and a cough
23 July 2021:	Continued to be unwell
24 July 2021:	COVID-19 swab performed
25 July 2021:	Continued to be unwell
26 July 2021:	Negative COVID-19 swab result
28 July 2021:	Unwell with worsening chest pain followed by collapse Resuscitation was unsuccessful

The deceased has a past history of hypertension and a work place accident in 2019, with fracture of the ankle.

Post Mortem Findings:

At autopsy, the body was that of an adult male with evidence of a recent medical intervention. There were no external injuries.

Internal examination revealed a large heart with severe right and chronic grade 3 mitral regurgitation involving the 1/3 - 2/3 areas of both the left and right ventricles of the heart. There were 10-12 mm of circumferential giant cells and dense, pale, fibrofatty cells within the subacute myocarditis muscle. There was inflammatory infiltrate including extensive infiltration of lymphocytes, plasma cells and lymphocytes. A small area of necrosis comprising three-quarters was evident. There were foci of the per myocardial area of the myocardium separating fat & connective tissue along the central myocardial edge consisting of granular thin walled blood vessels and no other myocardial area consisting of "very thick cellular" fat infiltrate. No T lymphocyte increases and associated multinucleated giant cells (see comments below).

Blanks sent to receive for organisms and molecular testing of the myocardium for COVID-19 were negative.

The lungs were heavily oedematous and contained a small amount of white mucus (~ 2 mm in diameter) which were also present in the trachea and oesophagus. These corresponded to grossly edematous lungs with no associated evidence of inflammatory infiltrates as seen in the heart. There were no thrombi present.

The remaining organs were unremarkable apart from a moderately fatty liver (estimated 40%) - there were no thrombi present in the vascular distribution to any other organ.

The serum myelase level was below limits seen in sarcoidosis.

Toxicology demonstrated raised levels of paracetamol.

The post mortem CT scan demonstrated perihilar lymphadenopathy and enlarged lymph nodes.

Comments:

1. The deceased had previously been registered as being in cardiac failure (heart/lung transplant).
Comment:
Cardiac sarcoidosis is a category of disease that includes epithelioid sarcoidosis, giant cell myocarditis and fibrotic cardiomyopathy. The latter was excluded by specific stains.
2. Granulomas were seen in the deceased's heart, liver and spleen or are more typical of granulomatous than cardiac sarcoidosis. Traditionally these have been described as two diseases with quite different morphology and outcome. Recent articles suggests that sarcoid and giant cell myocarditis may represent the extreme ends of the spectrum of a single disease.¹ And this is supported in this case, as the deceased's myocardium showed a clear focus free from cardiac sarcoidosis, indicating giant cell myocarditis. It appears unlikely that these represent two separate disease processes or rather a transmogrification of form of the disease to a severe form of the same condition.
Comment:
The heart shows a clear histological demarcation between established forming sarcoidosis and acute fulminating granulomatous myocarditis with a giant cell myocarditis morphology. Furthermore the transition from the chronic sarcoidosis to the fulminating myocarditis can be histologically dated to the time period of the COVID-19 mRNA vaccination. Thus it appears reasonable to state that the deceased's previously undiagnosed cardiac sarcoidosis may have transmogrified to a fulminating myocarditis as a result of the Pfizer (Comirnaty) COVID-19 vaccination. It is noted that myocarditis has been reported in association to the Pfizer COVID-19 vaccination.²
3. A pathophysiological interplay between sarcoid sarcoidosis and COVID-19 or Pfizer COVID-19 vaccination is possible. A proposed mechanism is that the SARS-CoV-2 protein which is responsible for COVID-19 has a high affinity for Angiotensin Converting Enzyme 2 (ACE2), a membrane bound enzyme determinant for the conversion of angiotensin II to angiotensin III. ACE2 is largely expressed in the tissues of the lungs, heart, digestive tract and renal tubuli. COVID-19 downregulates the expression of ACE2 as the receptor is carried into the cell with the virus. This leads to a blunting of angiotensin II when it operates upstream in COVID-19 infection. There is an
Comment:
There is no evidence of COVID-19 infection in this case.

¹ Myocarditis and Outcome of Cardiac Sarcoidosis in Children and Adults. Nishimura Y, Sano H, et al. *Circulation*. 2018;138:e103-e111.

² COVID-19 cardiomyopathy in patients with COVID-19: a report of the European Society of Cardiology. *Eur Heart J*. 2020; 41:139-141.

³ Worldwide COVID-19 Case Fatality Rate as of July 2021.

association with ACE2 polymorphism and progression of pulmonary sarcoidosis by stimulating an inflammatory state mediated by the presence of angiotensin 2.⁴

- 6 A possible therapeutic implication of this case might be that sarcoid patients receive an echocardiogram prior to Pfizer mRNA COVID-19 vaccination to detect cardiac involvement or that alternative vaccination types are considered. Review of these complex areas by a specialist in Immunology (I suggest Professor Dwyer at Prince of Wales Hospital) is recommended.

Conclusion:

Based on the history and autopsy findings, including evaluation of the histopathology report, the cause of death is due to COVID-19 disease. Ocular CT changes reported following Pfizer COVID-19 mRNA vaccination.

¹ Vaidya R, Chaturvedi S, et al. COVID-19 and sarcoidosis: a case report and review of literature. *Int J Clin Exp Pathol*. 2020;13(12):1020-1026. doi:10.15557/IJCEP-2020-0371

SUMMARY OF SIGNIFICANT PATHOLOGICAL FINDINGS:

1. **CHOLESTERIC MACROPHAGE CYCLES.**
2. **ACUTE Lymphocytic Leukemia.**
3. **CHRONIC LYMPHOCYTIC LEUKEMIA, TRANSFORMED TO ACUTE Lymphocytic Leukemia.**
 - a. **CHRONIC PHASE.**
 - b. **CHRONIC LYMPHOCYTIC LEUKEMIA, TRANSFORMED TO ACUTE Lymphocytic Leukemia.** This was a case of chronic lymphocytic leukemia which had been present for approximately 10 years. There was a progressive increase in the number of white blood cells and a decrease in the number of red blood cells. The spleen was enlarged and there was some infiltration of the skin. The bone marrow was hypercellular and contained a large number of lymphocytes. The lymphocytes were atypical and showed evidence of transformation to acute lymphocytic leukemia.
4. **CHRONIC LYMPHOCYTIC LEUKEMIA AND MELANOMA.**
5. **CHRONIC LYMPHOCYTIC LEUKEMIA.**
6. **CHRONIC LYMPHOCYTIC LEUKEMIA, TRANSFORMED TO ACUTE Lymphocytic Leukemia.**
7. **CHRONIC PHASE.**
8. **CHRONIC PHASE.**

DOCUMENTATION AND OTHER MATERIAL AVAILABLE:

ALL REQUESTED MATERIALS ARE BEING MAILED TO YOU. ADDITIONAL MATERIALS ARE BEING MAILED TO THE HOSPITALS LISTED ON THE ATTACHED SHEET.

ADDITIONAL MATERIALS ARE BEING MAILED TO THE ATTACHED HOSPITALS.

1. **CHRONIC LYMPHOCYTIC LEUKEMIA, TRANSFORMED TO ACUTE Lymphocytic Leukemia.**
2. **CHRONIC LYMPHOCYTIC LEUKEMIA, TRANSFORMED TO ACUTE Lymphocytic Leukemia.**
3. **CHRONIC LYMPHOCYTIC LEUKEMIA, TRANSFORMED TO ACUTE Lymphocytic Leukemia.**
4. **CHRONIC LYMPHOCYTIC LEUKEMIA, TRANSFORMED TO ACUTE Lymphocytic Leukemia.**

ADDITIONAL MATERIALS ARE BEING MAILED TO THE ATTACHED HOSPITALS.

SPECIMENS RETAINED FOR FURTHER EXAMINATION:

Specimens were collected for toxicology
Two cranium areas retained for further examination
Two bones were retained for histology
Femoral bone and clavicle were retained for histology
Cervical rib was taken for histology
ECTA test, gelatin substrate, and controls
Sputum for PPA & T
Sputum for Cryptosporidium
A 1 cm fixed lung tissue sent to COVILAB Plus
Photographs were taken by 40 mm 70 scope

AUTOPSY FINDINGS

EXTERNAL EXAMINATION OF THE BODY:

Body height: [REDACTED] m Body weight: [REDACTED] kg Body mass index: 27.9 kg/m²

The body was that of an adult male, whose appearances were consistent with the stated age of 51 years.

A red identification name tag was attached to both wrists, stating the identity of the deceased as [REDACTED] autopsy number [REDACTED]. A yellow police identification name tag was attached to the right ankle, confirming the identity of the deceased as previously stated.

The deceased was clothed in white socks, black tracksuit pants and olive coloured underpants.

Scars:

- On the medial aspect of the right and left malleoli there were longitudinal scars measuring 30 mm and 40 mm

[REDACTED]
The body had been refrigerated.

Hypostasis was present and distributed posteriorly except in areas exposed to pressure.

Rigor mortis was present.

Decomposition changes were not present.

The head hair was medium in length and black in colour.

The eyelids were normal with no petechiae.

The eyes were normal with no haemorrhages.

The ears were normal with no blood in the ear canals.

The nose was normal with no blood in the nostrils.

The lips, gums and frenula were normal.

The teeth were natural.

The external genitalia were unremarkable.

The hands and feet were unremarkable.

Evidence of Medical Intervention:

- Defibrillation pads
- Intravenous cannula in the right and left cubital fossa - both capped

Evidence of Injury:

Nil.

INTERNAL EXAMINATION OF THE BODY:

Head and Central Nervous System:

The brain weighed 1302 g

The scalp showed no evidence of injury or other abnormality

The skull was of normal thickness with no fractures

The dura was intact and the venous sinuses were patent and normal. There was no extradural or subdural haemorrhage.

The meninges were thin and translucent. There was no subarachnoid haemorrhage.

The right vertebral artery showed congenital narrowing. The remaining cerebral arteries showed normal architecture, were free of atheroma, and no aneurysms or thrombi were identified.

The cranial nerves were normal

The cerebra' hemispheres showed a normal sulcal-gyral pattern. There was no uncal / subfalcine herniation. The cerebral hemispheres were sectioned in the coronal plane from the frontal region to the occipital region. There were no abnormalities on cut sections of the cortical grey ribbon, white matter, deep grey nuclei, or ventricular system.

The brainstem showed no external abnormalities. There was no cerebellar herniation.

The midbrain, brainstem, upper cervical cord and cerebellum were sectioned and there were no abnormalities.

The spinal cord was not examined but the cut end appeared unremarkable.

Neck:

The mouth, tongue and oropharynx were normal

The strap muscles of the neck were unremarkable

The thyroid gland was unremarkable.

The thyroid and hyoid cartilage were unremarkable

The common carotid arteries were unremarkable

Cardiovascular System:

The heart weighed 565 g

(Above normal predicted heart weight as a function of the body height and weight)¹

The pericardial sac contained serous fluid.

The left anterior descending, left circumflex and right coronary arteries were unremarkable

The endocardium was pale

The foramen ovale was closed.

The left ventricular thickness was 13 mm, the right ventricular thickness was 1 - 4 mm and the interventricular septum measured 12 - 13 mm.

The left and right ventricular myocardium showed widespread areas of softening with petechial discoloration and areas of haemorrhage. The endocardium in particular was extensively pale and soft with involvement of the papillary muscles.

The heart valves were unremarkable.

The thoracic and abdominal aorta was unremarkable.

The superior vena cava, inferior vena cava and portal venous system were unremarkable.

¹ Silberman, AS & Gruenwald, E. In: Pathology of Drug Abuse, 1st Edn, 1991, CRC Press, 640-643

Post Mortem Findings (continued) - cont.

Respiratory System:

The right lung weighed 1032 g. The left lung weighed 976 g. The sternum, ribs and thoracic spinal column were unremarkable. The pleural cavities showed no adhesions or fluid. The trachea and major bronchi were unremarkable. The mucosa was unremarkable. The lungs were heavily congested. There were no focal lesions. There were a number of small white nodules measuring 1 - 2 mm in diameter present. The diaphragm was unremarkable.

Gastrointestinal System:

The abdomen was unremarkable. There was no fluid or blood in the peritoneal cavity. No free abdominal subserous fluid was present. The omentum was unremarkable. The stomach was empty. The mucosa of the stomach had an unobtrusive appearance. The fundic and large bowel were unremarkable. The appendix was normal. The liver weighed 1176 g and was heavily congested. Small white nodules measuring 1 cm in diameter were present. The superficial and deep surfaces of the liver were unremarkable. The gallbladder was unremarkable. The colon and rectum was patent. The pancreas was unremarkable.

Urinary System:

The right kidney weighed 143 g. The left kidney weighed 157 g. There was no significant cortical calcification. The kidneys had a smooth surface. The capsule was "slightly edematous" with a few fine stippled areas. The superficial and deep surfaces were unremarkable. There were small white nodules as present in the intestine. The collecting systems were unremarkable. There was urine in the bladder. The bladder mucosa was unremarkable. The prostate was unremarkable. The testes were not visualized.

Endocrine System:

The thyroid gland was unremarkable. The pituitary gland was unremarkable.

Hematopoietic System:

No vertebral marrow was recovered from the vertebral column. The spleen weighed 149 g. The superficial and cut surfaces of the spleen had a uniform mottled appearance. There were small white nodules measuring 1 - 2 mm were present. The thymus gland was not identified.

MICROSCOPIC EXAMINATION OF TISSUES:

- Brain:** Sections of the cortex, brainstem, cerebellum, deep nuclei and meningeal pia mater have been examined. There is no evidence of infection, infestation, trauma, tumor or degenerative disease.
- Heart:** Serial sections of the myocardium show bland fibrosis in addition to inflammation. However, in the which are large numbers of multinucleated giant cells. Other sections of the left and right ventricle show acute necrosis of the myocardium with large numbers of inflammatory cells including lymphocytic monocytes and plasma cells associated with multinucleated giant cells.
- A zonal appearance comprising three zones, is evident in some sections. There is a "core" of the pericardial zone of the myocardium, reparative tissue containing fibroblasts, myocytes and macrophages some of which contain hemosiderin and an inner endocardial zone constituting a heavy mixed inflammatory infiltrate with associated multinucleated giant cells. Myocarditis requires a component.
- PAK and silver stains were negative for organisms. Ziehl-Neelsen was negative for mycobacteria. Masson's Trichrome demonstrated the costal fibrosis.
- Lungs:** Sections of lungs show a normal alveolar architecture with occasional alveolar macrophages present. The bronchi show a normal architecture with post mortem autolysis of the living epithelium. The bronchial gland vessels are present and unremarkable. Small well-formed granulomas with multinucleated giant cells are present.
- Liver:** The liver showed a normal architecture with preservation of the two plates. There are no periparticle chronic tubular lesions. The portal tracts and central veins are present and unremarkable. Small well formed granulomas with multinucleated giant cells are present.
- Kidneys:** The kidney shows a normal glomerular and tubular architecture with moderate subendothelial thickening of the tubules. The Bowman spaces and the interstitial spaces are unremarkable. There is a small benign non-mucinous fibrotic adhesions. There are no granulomas.
- Spleen:** The spleen is enlarged, showing morphology difficult to interpret. No abscesses are seen. Some well formed granulomas with multinucleated giant cells are present.
- Thyroid:** The section shows moderate autolysis and is otherwise unremarkable.

IMMUNOLOGY:

Please see form - FHM FTL-32 for an indication of drugs and poisons in blood detected by LC QTOF MS and Immunoassay screening tests.

Blood Preserved	Amphetamine	Barbiturates	Blood Preserved	LC QTOF MS SCREEN
ND	ND	ND	ND	Detected
ND	ND	ND	ND	Detected
ND	ND	ND	ND	Detected
ND	ND	ND	ND	Detected

Results of quantitative tests:

(ND = Not detected)

Results of screening tests:

See report (T2021 00 1996).

ANALYTICAL TOXICOLOGY REPORT:

Pancreas: The Pancreas is a solid organ making morphology difficult to interpret. No abnormalities are seen.

Adrenal glands: Normal.

[REDACTED]
[REDACTED]
[REDACTED]

MSI DOCUMENT RE-POSI.

100-0420

PC

12 SEP 2021

APPENDIX
A

[REDACTED]

MFPS (Hons) BDiv FRCPA Dp Forensic Path
Staff Specialist Forensic and Anatomical Pathologist
Forensic Medicine [REDACTED]

■ September 2021

Annexure "B"

2

(on separate page)

Name [REDACTED]
Address [REDACTED]
Occupation Board Certified Physician, MD
Date 15 September 2021

I say on oath:

- 1 My name is [REDACTED], and my address is [REDACTED]
[REDACTED], and I say on oath:
- 2 I am a Board-Certified physician in the United States of America. I own three Urgent Care Centers in [REDACTED]. My work with COVID-19 patients has made me an expert in this field. I have treated almost 6000 patients, and my family and I have also had COVID-19 in October 2020.
- 3 Although I am in the United States of America, my opinion covers both global and Australian conditions.
- 4 I present extensive clinical Data in early treatment of Covid19 that demonstrates that when managed and treated early Covid19 is NOT a disease that would merit states of emergency to be declared
- 5 In my extensive clinical data, I show the records of over 5700 Covid19 positive patients. From that group of over 5700 patients, I lost zero patients where treatment was started before day 7 and lost 4 patients after day 7 (with 2 of those 4 dying on the same day, we sent them to hospital). From my set of 5700+ patients only 7 needed to go to Hospital. See my patient data excel file.
- 6 I have treated face to face almost 6000 positive patients in my practice with approximately 64% of them having one or more symptoms. We started evaluating patient in person from March 2020 and continue to do so today. I have a successful treatment record with under 4 deaths from 6000 patients treated.
- 7 I have been actively researching the COVID-19 epidemic using my expertise.
- 8 I annex my curriculum vitae and mark that as "JB1".
- 9 I annex my expert report hereto and mark that as "Ex-JB2".
- 10 I annex my COVID patient data excel file and mark that as "JB3".
- 11 I am aware of the Expert Code of Conduct (Code) as stipulated in the Rules of the Court, I have read a copy of the Code, and the documents regarding the emergency

declaration imposing lockdown. I agree to comply with the provisions of the Code
and the intent of these provisions.

12 I am available to give evidence via audio visual means as and when the Court sees fit.

SWORN at Sydney

Signature of deponent _____

Name of witness _____

Address of witness _____ Sydney NSW 2000

Capacity of witness Solicitor

And as a witness, I certify the following matters concerning the person who made this affidavit (the deponent)

- 1 I saw the face of the deponent [REDACTED] on [REDACTED] (date) and he/she was not wearing a face covering. At [REDACTED] (date) the deponent handed the deponent with covering, a face covering, but I am satisfied that the deponent had a special justification for not removing the covering.
- 2 I have known the deponent for at least 12 months.

I have confirmed the deponent's identity using the following identification document

Identification document relied on (may be original or certified copy)*

Signature of witness _____

Note: The deponent and witness must sign each page of the affidavit. See UCPR 35.7B.

[The only "special justification" for not removing a face covering is a legitimate medical reason (at April 2021).
[1 "Identification documents" include current driver licence, proof of age card, Medicare card, credit card, Centrelink pension card, Veterans Affairs card, student card, student identity card, citizenship certificate, birth certificate, passport or see [Qantas Recognition 2021](#) or refer to the guidelines in the NSW Department of Attorney General and Justice's "[Judges of the Peace Handbook](#)" section 2.3 "Witnessing an affidavit" at the following address: <http://www.p.nsw.gov.au/Documents/jp%20handbook%202014.pdf>]

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Curriculum Vitae

EDUCATIONAL BACKGROUND

American University of the Caribbean St Martin, NA

Doctor of Medicine

Masters of Health Science

Graduated with Full Honors

Vice President of Student Body

Alpha Omega Phi Honor Society Member

Wrote and Implemented Honor Code

Loma Linda University Loma Linda, CA

Bachelors of Science in Emergency Medical Care

Graduated Cum Laude

Vice President of Student Body

National Dean's List '97 and '98

PROFESSIONAL TRAINING EXPERIENCE

Arrowhead Regional Medical Center Internship

Family Practice Residency at ARMC (2 yrs)

Fellowship in Hospital Medicine through SHM

Board recertified in Family Medicine

EXPERIENCE

CEP

- o ER physician

- o Arrowhead Regional Medical Center

Primary Critical Care Medical Group

- o Desert Regional Medical Center

- o Hospitalist

Beaver Medical Group

- o Inpatient Program Director over Redlands Community and San Gorgonio Memorial Hospitals

Cogent Healthcare, Nashville Tennessee

- o Program Medical Director at St. Bernardines in San Bernardino, CA.

Graybill Medical Group, Fallbrook, CA

- o Family Physician

- o Medical Director of Skilled Nursing Facility

Owner of Tyson Medical Inc

- Independent contractor and owner All Valley Urgent care

ORGANIZATIONAL EXPERIENCES

Clinical Integration Project at St. Bernardines

Transformational Care projects (ER throughput,

Observation status, discharge by noon projects.

Society of Hospital Medicine – Fellowship Status

Leadership I, II, III completion

ADDITIONAL INFORMATION

- Computer Skill Microsoft office(Word, Excel, Power Point) and internet
- Interest Kids, music, golf, softball coach, travelling
- Abilities and attitude Team player, work hard and play hard, Lead by example not by force. Do what you love and money will follow.

The undersigned hereby certifies that all information given in this document is true, complete, and correct.



Part 1 - Instructions

This report was prepared on the instructions of AFL Solicitors contained in a letter dated 12 September 2021.

The 'Terms of Reference' were summarized in the letter of instruction as:

1. Assess the seriousness of the risk to the health of the general population presented by the disease COVID-19.
2. Assess the likely impact of the NSW Government's COVID-19 responses on the public health generally of the people of NSW.
3. In your opinion, what are the proportionate and reasonable public health responses to the COVID-19?
4. What is the 'Delta' strain of the SARS-CoV-2 virus and does the 'Delta' strain have universal properties or does 'Delta' vary across bio-geographical areas.
5. How many COVID-19 patients have you treated?
6. How many people have you treated for Covid-19 vaccine injury?
7. In your clinical experience, what are the safest and most effective treatments available for COVID-19?
8. What safe and effective treatments for COVID-19 were available in March 2020?

As per letter of instruction, enclosed in this report:

1. Curriculum Vitae - My CV is annexed to this Report at B'.
2. Code of Conduct Statement.
3. COVID Report – 'The Clinical results of early outpatient treatment of Covid-19 is at Annexure A'.

Introduction

1. My name is [REDACTED]. I am a Board-Certified physician in the United States of America. I own three Urgent Care Centers in [REDACTED]. My work with COVID-19 patients has made me an expert in this field. I have treated more than 5700 patients, and my family and I have also had COVID-19 in October 2020.
2. The following report is based upon my own clinical experience. [REDACTED]

3. I confirm that no deaths related to COVID-19 were recorded for any patients treated using the following treatment protocols before day seven.

Part 2 – Expert Evidence

1. **Assess the seriousness of the risk to the health of the general population presented by the disease Covid-19.**

The current risk of health to the general population from COVID-19 should be looked at from age groups and risk factors. It is well known by the Centers for Disease Control and Prevention (CDC) data kept here in the US¹ that those over 80 have the highest mortality rate at 14.8%, 70-79yrs at 8.0%, 60-69yrs at 3.6%, 50-59 at 1.3%, 40-49 at 0.4% and under 40 at 0.2%, finally 0-9 virtually 0%.

This data is essentially based on cases where Early Treatment was not adopted. While the Delta Variant is causing more cases and certainly more issues in the younger population with increased hospitalizations, the mortality rate has not gone up as of yet; this confirms the seriousness of this virus, however. Indications from UK Data Technical Briefings indicate the case fatality rate (CFR) of the Delta Variant is close to 3 times lower than the Alpha Variant.²



¹ CDC Daily Report (https://www.cdc.gov/coronavirus/2021-04-09-data-and-treatment-COVID-19-deaths-by-age-risk-factor.html) and the document "CDC COVID-19 Risk Factors for Death and Case Fatality Rates by Age Group - United States, January 2020-June 2020" (https://www.cdc.gov/coronavirus/2021-04-09-data-and-treatment-COVID-19-deaths-by-age-risk-factor.html#CaseFatalityRate) which of concern and variants under investigation in England Technical Briefing 22 see Table 4

2. Assess the likely impact of the NSW Government's Covid-19 responses on the public health generally of the people of NSW.

There are four major pillars to infectious disease pandemic response:

- 1) Contagion control (stop the spread of the virus)
- 2) Early ambulatory, home-based treatment
- 3) Late-stage treatment in hospital
- 4) Vaccination

In my opinion of the current Public Health practices of NSW as well as the USA, the focus has been only on 2 of 4 pillars to infectious disease response being:

- 1) Contagion control (stop the spread of the virus)
- 4) Vaccination

This narrow focus has likely led to a Hospitalization and Death outcomes that could have and should have been reduced by at least 80%.

Contagion Control Pillar 1) Understanding what is possible

While the initial spread of the virus during a pandemic should always be the initial focus, that window is now closed as this virus has spread worldwide and cannot be controlled as you can clearly see from places around the world that have tried so desperate to do just that. We now have current co-spread to zoonotic origins of gorillas (Zoo Atlanta), dogs and Cats (University of East Anglia, Norwich-based research facility the Earlham Institute and University of Minnesota) have said.³

This means COVID is here to stay, and no amount of sequestration is going to make the virus disappear. We must learn to live with this virus just like influenza that we deal with every year. Therefore, I feel it is a disproportionate measure of the NSW Government's Covid-19 response to implement lockdowns beyond making sure sick people isolate.

³ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8060003/>

Impacts of Disproportional Pillar 1) Response

We know that low Vitamin D⁴ levels are a poor prognostic factor, therefore not allowing people outside during the day actually increases mortality. We also know that UV light kills the virus suggesting being outside during the day would be better than being indoors. From what we know of disproportionate lock downs for this Pillar, the NSW Government's disproportionate responses for children and adults is likely resulting in significant mental health issues.

Missing Pillar 2) Early ambulatory, home-based treatment

This has been a critical mistake in the Management of Covid19 and has elevated the impact of COVID-19 to a level that has led to declared states of emergency.

I present in my submission extensive the clinical Data of my practice covering the early treatment of Covid19. This data demonstrates that, when managed and treated early, Covid19 is NOT a disease that would merit states of emergency to be declared.

In my extensive clinical data, I show the records of over 5700 Covid19 positive patients. From that group of over 5700 patients, I lost zero patients where treatment was started before day 7 and I lost 4 patients after day 7 (with 2 of those 4 patients dying on the same day, we sent them to hospital). From my set of 5700+ patients only 7 needed to go to Hospital. See my patient data excel file ([see Annexure A](#)).

In my opinion, banning or obstructing medications used in well-known protocols that include FDA/TGA approved medications such as Hydroxychloroquine and Ivermectin in the outpatient setting has led to unnecessary morbidity and mortality from a virus that is easily treatable early in the disease process.

To illustrate this critical point I compare the rate of Deaths and Hospitalization in my group of patients with those managed by NSW Health and other state Health Authorities.

⁴ COVID-19 treatment success for vitamin D
SCOTT et al (2020)

In my Group of Covid 19 patients Health Outcomes:

4 deaths of 5700+ patients (reminder those four patients were not treated before day 7)

If we multiply my data by 20 it would extrapolate to

80 deaths of 114,000 + patients

1440 Hospitalizations

I refer you to the Australian Government Covid 19 Health outcome statistics.¹

On 14 September 2021:

1098 deaths in under 80,000 cases

1374 Hospitalizations

in the

Pillar 3) Late-stage treatment in hospital

This is when patients have been left at home without treatment for so long and their immune system cannot fend off the inflammatory response.

This is where Oxygen, low pressure ventilation strategies have been the most effective, and this is where Zithromax, Hydroxychloroquine and Zinc together showed a 50% reduction in Mortality (Henry Ford Institute).⁴

[REDACTED] and his critical care group also showed that using Ivermectin⁵ in this group lowered Mortality by 76%.⁶

The use of IV vitamin D3 has also shown to be beneficial in clinical settings.⁷

Use of Steroids especially Dexamethasone has lowered Mortality rates and provided a safe and effective response for patients both pre and post infection.^{8,9} Full dose Lovenox in these patients has improved mortality as well, by preventing DVT's and Pulmonary emboli.¹⁰

¹ www.health.gov.au/sites/default/files/documents/2021-09/COVID-19-health-outcomes-report-14-september-2021.pdf (14 SEPTEMBER 2021)

⁴ Treatment with hydroxychloroquine, azithromycin, and combination in patients hospitalised with COVID-19. <https://doi.org/10.1186/s13071-020-03727-0>

⁵ COVID-19 treatment studies for Ivermectin <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8330003/>

⁶ Safety of the ivermectine treatment in COVID-19. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8330003/>

⁷ Ivermectin study for COVID-19. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8330003/>

⁸ Dexamethasone in the treatment of COVID-19. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8330003/>

⁹ Steroids and their specific benefits for treating the disease: Benefits in COVID-19 Assessments by Steroidated Patients <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8330003/>

If NSW Government Health Policy fails to implement the early treatments of pillar 2 there is an expected resultant surge in hospital admissions.

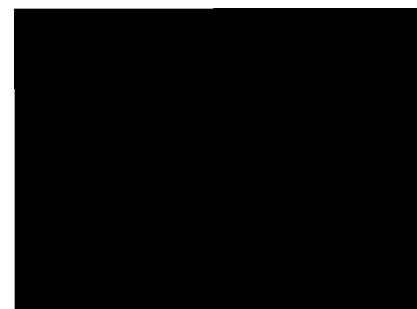
If NSW Government Health policy also fails to implement the above measures for pillar 3) Hospital treatments, this will further contribute to the resultant deaths from Covid19 Government health policy.

4) Vaccination Policy

While this would be the most beneficial prior to pandemic levels, this does not appear to be working as such, when you look at the new technology Vaccines' inability to prevent the spread of Covid; including infections with COVID, hospitalizations from COVID and even death from COVID.

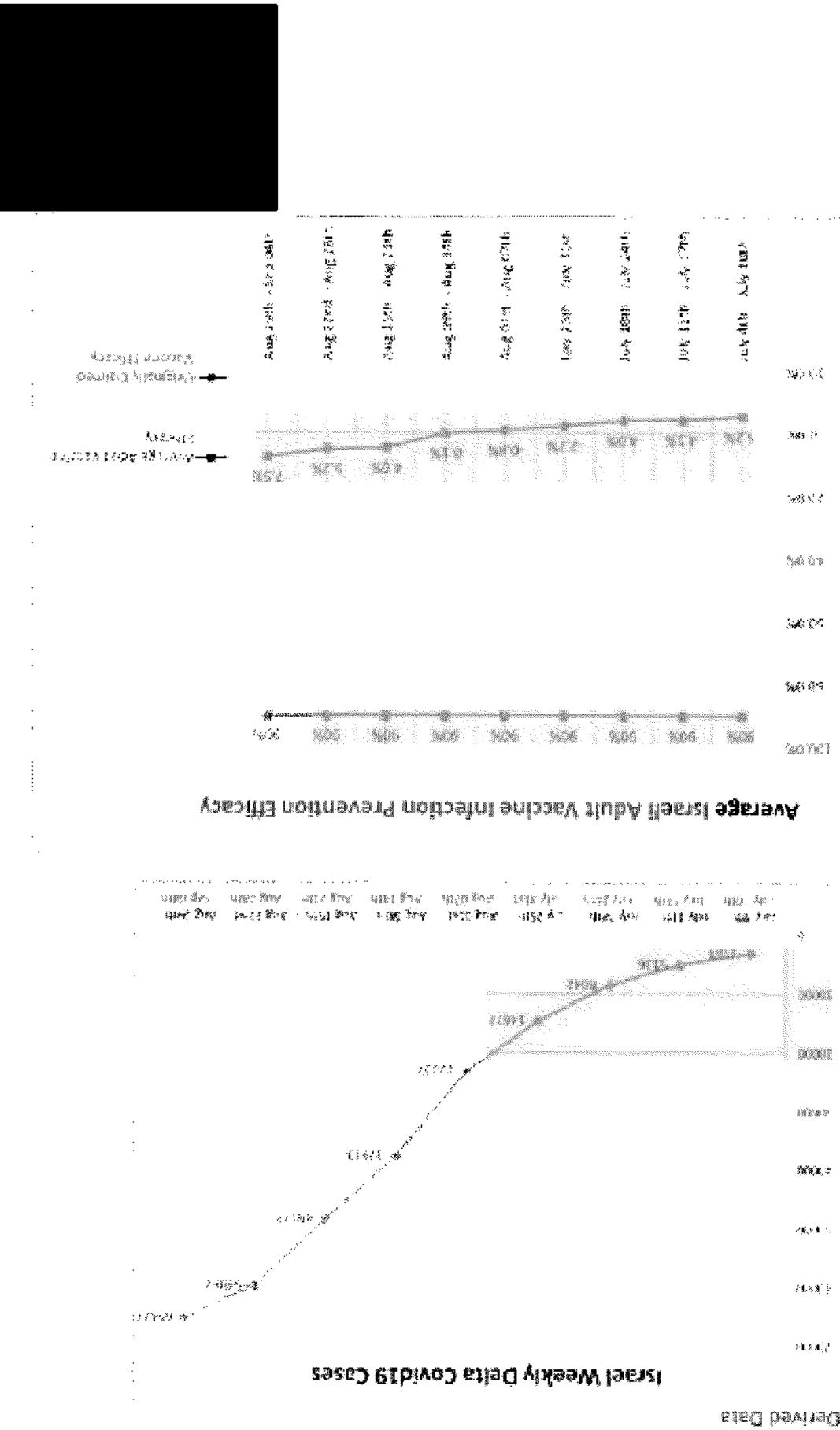
The simple science behind the failure in a pandemic situation is the concept of Sterile vs non-sterile (doesn't prevent infection) vaccines. The current Vaccines are non-sterile vaccines.

Also, the current vaccines create or utilize a very specific protein (S-protein or Spike protein) which has been evaded by the Delta variant. We are already hearing about other variants that are also evading vaccines, variant Mu by as much as 40% in Colombia and Variant Beta in Africa. The more pressure we put on the virus the more likely it is to mutate. We are seeing approximately 35% breakthrough cases in our population, which is about 60% vaccinated, in our Urgent care currently. When you look at the breakthrough case of both Israel¹⁷ and UK¹⁸ the efficacy is less than 20% at this time, which is consistent with what we are seeing here in our clinic.



¹⁷ Israel Vaccination Rates by Age: https://covid19.cdc.atspace.com/covid19_vaccination_by_age_group.html

¹⁸ SARS-CoV-2 variants of concern and variants under investigation in the United Kingdom: <https://www.gov.uk/government/statistics/sars-cov-2-variants-of-concern-and-variants-under-investigation-in-the-united-kingdom>



The impact of NSW Government Policy relying so heavily on Vaccination is a policy that cannot work and is wasting a lot of resources that should be diverted toward the pillars of Early Treatments.

Early treatment has been ignored by almost every nation on the planet. This makes absolutely no sense at all in the real world of medicine and is likely placing the lives of Australians at greater risk of contracting Covid19, being injured by Covid19 and dying of Covid19. It is common knowledge that the sooner you treat any illness the better the outcomes. At this stage there does not appear to be a sound scientific argument that can rationalize why Governments and Regulators are choosing to do nothing, rather than implement early intervention strategies that have demonstrated to be safe and efficacious in clinical settings. We know this is an RNA virus that uses RNA polymerase to replicate. We should be using drugs that prevent viral replication and that needs to be done early to be most effective. Examples of drugs that can reduce the replication process include Zinc and Remdesivir.

3. In your opinion, what are the proportionate and reasonable public health responses to the COVID-19?

A very good article¹⁴ with references to current Australian Covid19 Statistics and the impact of Covid19 in Australia gives an excellent reference to the proportional and reasonable responses to Covid 19

I provide the link to the article and the article, which backs up all the relevant statistics with hyperlinks to Australian Government and Health Authority sources for the Data.

In my opinion the proportional and reasonable responses to Covid19 should focus on:

No1: Early Treatment as this minimizes morbidity and mortality as I have been able to show with my clinical practice and the clinical outcomes I present. We found that with Covid19 our clinical mortalities were lower than seasonal influenza.

I would immediately make available to GPs the option to prescribe any and all approved FDA[TGA] medications in an unrestricted off label use to treat covid19.

No2: Healthy People should be allowed to function in their day to day as normal participants

¹⁴ See the facts Covid19 in Australia by the numbers <http://www.covid19australia.com/covid19australia.html>

in their society. Expanding on this there is no reason for children to be locked out of school and I would emphasize that such measures are completely disproportionate responses. In the US we are seeing significant mental health issues with children and reductions in IQ as a result of School closures.

No3: Mass vaccination during a pandemic should exclude those with natural immunity, should exclude those under the age of 20 due to the very low risk profile of Covid19 and the high adverse event profile and due to the unknown long term adverse effects which could include fertility issues, cognitive issues, autoimmune disorders, cancers and prion type diseases including Alzheimer's, Parkinson's and dementia. Vaccination should be offered to the elderly and those with significant co-morbidities on an informed consent basis where the safety data is made available as part of the informed consent process.

For the healthcare sector in Australia where prior exposure or natural immunity has not taken place there is an argument for vaccinating that group to reduce the spread of Covid19. However the vaccine that is currently in use still does not prevent the spread of Covid19 ; therefore these particular non-sterile vaccines would only be useful for the health care providers if their efficacy was above 50% ; the data from places like Israel and the UK suggest that it is far lower and again it should be mentioned these vaccine are missing significant portions of safety data which could severely impact the health care sector if mandated).

No4: Hospitalization should be focused on the ability to use any and all drugs that have been shown to be efficacious ; I would immediately make available to Doctors the option to prescribe any and all approved FDA(TGA) medications in an unrestricted off label use to treat covid19. I would make reference to the FLCCC Math plus protocol.¹²

¹² <https://www.flccc.org/hospital-treatment-protocol-for-covid-19/>

What drugs help zinc as an ionophore?

Hydroxychloroquine (HCQ) and Ivermectin are powerful ionophores and both have anti-viral properties. We know those drugs have FDA approval with well-known safety profiles, however, appears to be ignoring the safety and efficacy profiles and relying solely on the vaccines.

We also know that a balanced immune system is also helpful. By adding Vitamin C and N-acetyl-cystine (NAC) we can improve immune health. We saw from early deaths that blood clotting was an issue, so the addition of Aspirin lowered mortality by 20% alone. We also saw that those who did poorly were low on Vitamin D3, therefore all patients should be allowed to go outside as much as possible and take vitamin D3. We saw that the respiratory symptoms were being caused by a cytokine storm (inflammatory response) this was countered using Steroids Budesonide, Dexamethasone, and Solumedrol. We also use HCQ for its anti-inflammatory properties here and have added Colchicine and Fenofibrate to this response. We learned later that another asthma drug was also underutilized for its Leukotriene inhibition in the lungs, that was Montelukast or Singulair. Now perhaps, the most underutilized drug early on when it was its most effective was Monoclonal antibody treatment (Regeneron). This was highly effective and still seems to be, but effects are being lost due to variants. All of these are outpatient treatments. All have been ignored.

4. What is the 'Delta' strain of the SARS-CoV-2 virus and does the 'Delta' strain have universal properties or does 'Delta' vary across bio-geographical areas?

The Delta strain is a variation in the Spike Protein of SARS-CoV-2 and appears to have come from India. The variation has been seen all over the world at this time, including at my Clinic and in Australia.

5. How many COVID-19 patients have you treated?

I have treated face to face almost 6000 positive patients in my practice with approximately 64% of them having one or more symptoms. We started evaluating patient in person from March 2020 and continue to do so today. I have a successful treatment record with under 4 deaths from 6000 patients treated.

I am aware that the Therapeutic Goods Administration of Australia "Database of Adverse Event Notifications – medicines – medicine summary – 01/01/2021 – 14/08/2021"¹⁶ has provided information about deaths and injuries attributed to vaccines. This report states:

1. "number of reports 48,459";
2. "reported cases with a single suspected medicine 47,764" and
3. "number of cases where death was reported outcome – 459"

It is clear from the Australian Therapeutic Administrations own information that the vaccines are causing more harm to the Australian population than other treatments that were readily available. It is my opinion that treatment protocols in Australia should include a number of options with an emphasis on saving lives and protecting those who are most vulnerable. Presently, the risks to Australians associated to vaccines is greater than that of other available medications such as triple therapy ivermectin.

6. How many people have you treated for Covid-19 vaccine injury?

I have treated around 100 patients with vaccine injuries in my practice from peri-carditis in adolescents to neurologic disorders, shingles, myalgias, arthralgias and "brain fog" as my patient call it.

¹⁶ Sotrovabaty COVID-19 vaccine (BNT162b2 mRNA) - COVID-19 vaccine (176) | COVID-19 Vaccine (Type not specified) | COVID-19 vaccine AstraZeneca (ChAdOx1 nCoV-19 (viral vector)) - Spikevax COVID-19 vaccine (Fluadimix) (mRNA)

7. In your clinical experience, what are the safest and most effective treatments available for COVID-19?

Early treatment is the safest and most effective. That includes:

- A) Zithromax 500mg on day 1, then 250 daily for 4 days
- B) Zinc 25mg twice a day
- C) Hydroxychloroquine 400mg twice a day on day 1, then 200mg three times a day for the next 4 days.
- D) Ivermectin 12mg on Day 1 and 3
- E) NAC 600mg daily
- F) Vitamin C 500mg daily
- G) D3 5000 IU daily
- H) Monoclonal antibody infusion on all patients with comorbidities or over 50yrs old.
- I) If pulmonary symptoms present: Singulair 10mg at night
- J) Nebulized Budesonide 0.5mg/2ml every 6hrs with nebulizer
- K) Dexamethasone 6mg IM every 3 days until improved
- L) If positive CXR add Colchicine 0.6mg daily and Fenofibrate 140mg daily
- M) Aspirin 325mg for all patients over 16yrs, 81mg for under 16yrs

8. What safe and effective treatments for COVID-19 were available in March 2020?

All the treatments listed above except Monoclonal Antibody were available in March 2020.

The safety profile on all the drugs listed above are well known and all are FDA approved except Monoclonal treatment which is EUA. Once step further, Hydroxychloroquine has no black box warning and has been around for over 50 years.

Ivermectin has no black box warning and has also been around for 50 years.

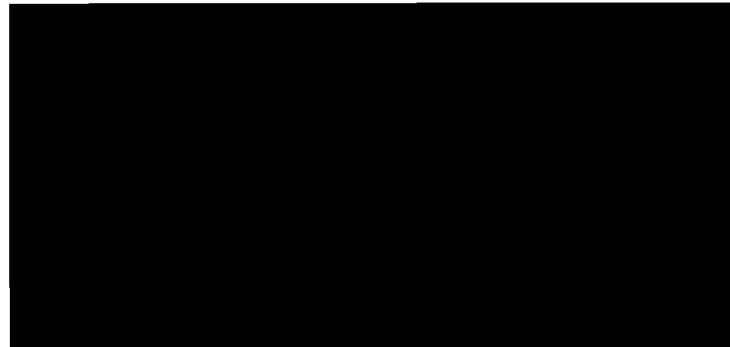
Both drugs have been shown to have multiple uses as antiviral drugs, anti-inflammatory and anti-parasitic or malarial properties. Both those drugs have been given over a billion times and have both been listed on the WHO lists of Essential Medicines of the World.

Ivermectin even won the Nobel prize for curing River Blindness. The CDC recommends Ivermectin for all immigrants for Middle Eastern Asia and Africa. Therefore, it is inappropriate to disallow the use of these medications based on the bias of "They don't work".



If I am wrong, people will still die. If I am right, thousands will live. The medications are not the cause of death. The withholding of early treatment is responsible for mass hospitalizations and unnecessary deaths.

Dated: 14 September 2021



Code of Conduct

I am aware of the Expert Code of Conduct (Code) as stipulated in the Rules of the Court, I have sighted a copy of the Code, and I agree to comply with the provisions of the Code and the intent of these provisions.

Expert opinion by [REDACTED]

14 September 2021

Molecular biologist, RT-PCR specialist and Cell biologist, trained Virologist (Diploma, PhD-thesis) and Immunologist (Habilitation).

I have read the documents you forwarded to me including the Expert Code of Conduct as stipulated in the Supreme Court of NSW Rules of Court, and I agree to comply with the provisions and the intents of those provisions.

According to the NSW Pathology website, RT-qPCR testing for SARS-CoV-2 in NSW is conducted at 40-45 cycle threshold. As set out in the following report, results produced at this level of cycle threshold are meaningless and are of no diagnostic value

Regarding the evidentiary question, "What is the power of the RT-qPCR assay and currently used rapid tests to detect SARS-CoV-2 coronavirus infection?"

1. Nucleic acid detection by RT-qPCR test

Prefix: Reverse transcriptase-quantitative polymerase chain reaction (RT-qPCR) assays are unsuitable as a diagnostic tool for the detection of an active infection with SARS-CoV-2 for numerous reasons.

1.1 Explanation of terms/basics

In a polymerase chain reaction (PCR), a defined short piece of deoxyribonucleic acid (DNA) (usually 100-1000 bases) is amplified using the enzyme polymerase. The piece of DNA to be amplified is flanked with the help of two very short single-stranded DNA segments, the "primers".

These primers usually consist of a defined sequence of 18-25 nucleic acid bases (the primer sequence) that specifically match the regions on the DNA that flank the section to be amplified. To ensure PCR specificity, these primers must explicitly match only this flanking region and no other region of a DNA, neither in the target organism nor in another DNA. With

the help of large gene databases and corresponding software programs (e.g. primer blast <https://www.ncbi.nlm.nih.gov/tools/primer-blast/>), these primers can be selected highly specifically in the PCR design. Specialized companies then synthesize the molecular chains from the submitted primer sequences and deliver them to the PCR laboratory or the manufacturer of PCR kits. Here, these primers must then be tested with valid positive and negative controls under a wide variety of experimental conditions and optimized in use. This ensures that only the DNA searched for is detected and amplified with the primer pair used, and that no other similar DNA segments are detected, a mandatory prerequisite for specificity.

Once the primers have been found and are specific, the DNA to be amplified can be mixed with the primer pair, various auxiliary chemicals and the polymerase enzyme in a reaction batch and the chain reaction started.

PCR procedure: The following steps are repeated in cycles.

1. the mixture is boiled at over 90°C (denatured). This separates the DNA strands, which are usually present as a double strand, into single strands to enable the subsequent attachment of the primers.
2. During the subsequent cooling down to the so-called "annealing temperature", the primers can attach to their matching regions on the separated DNA strands. The binding of the primers, the annealing, only occurs in a narrowly limited temperature range, the so-called melting temperature. This depends mainly on the base composition of the primers and therefore their sequence will ideally always be chosen so that both primers have the same melting temperature of about 60°C. The annealed primers form the DNA strands. The attached primers form the starting point for the polymerase.
3. starting from the primers, this polymerase completes the single-stranded DNA, which is present due to the heating, into a matching double strand (elongation), usually at approx. 72°C.

Due to the position of the two primers on the flanking sides of the sought DNA section, the elongation reactions on the single strands are in opposite directions, since the polymerase always works in one direction only. At the end of this step, two identical new double-stranded DNA molecules have now been created from an original double-stranded DNA, which are separated again by boiling, then amplified into 4 identical DNA molecules with the aid of primer addition and the polymerase, and so on.

Each PCR cycle consisting of boiling-annealing-elongation causes a doubling of the DNA section sought, so that the amplification takes place in the logarithm of 2 and thus an extremely high number of copies of the original starting material is available very quickly. Thus, after 10 PCR cycles, $2^{10} = 1,024$ DNA copies are obtained from one DNA strand, after 20 cycles already more than 1 million (1,048,576) and after 30 cycles more than 1 billion (1,073,741,824) copies.

In the quantitative PCR (qPCR) technique, as currently used worldwide mainly for the detection of genomic RNA from SARS-CoV-2, a third short piece of DNA, similar to the two primers, is used which can bind appropriately in the middle of the DNA section sought, the "probe". Unlike the two primers (which are nucleic acids only), this probe is additionally bound to two molecules, a fluorescent dye at one end and another molecule (quencher), which can prevent the emission of fluorescence as long as both are simultaneously (i.e., in close proximity to each other) on the sample. During the elongation step, the polymerase now degrades this probe. This separates the quencher from the fluorescence molecule and the latter can now emit its color signal. This color signal is detected and measured in the device performing the PCR (thermocycler). Thus, with each PCR cycle, more and more fluorescence signals are released according to the increasing number of copies, the probe "glows" more and more. And the curve of color signal intensity increases with each cycle. At a certain value, the curve then exceeds the background noise (threshold) and is considered positive. The number of cycles at which this threshold is exceeded is referred to as the CT value (CT stands for "cycle threshold").

The faster the fluorescence rises (lower CT), the more initial copies of the DNA sought were present in the PCR approach. Since neither the primers nor the enzyme polymerase always work 100% specifically, a fraction of non-specific DNA is also copied in each PCR run. And the more cycles the PCR runs, the greater the risk that even these few non-specific reactions will exceed the threshold value. Therefore, from a CT value of 40, a false positive signal due to non-specific starting materials must be assumed with the greatest probability. A reliable PCR should therefore require no more than 30-35 cycles to generate a clear "positive" signal; in the case of active infections with sought-after viruses, a sufficient number of cycles of 25-30 can be assumed (see also point 3.2).

The reverse transcriptase reaction (RT) is required if the starting nucleic acid to be amplified is not present as DNA but as ribonucleic acid (RNA), as is the case with SARS-CoV-2 as an RNA virus. Since only DNA can be amplified in PCR, an RNA must first be converted into DNA. This is performed with the help of the enzyme "reverse transcriptase", which creates a complementary copying strand of DNA from RNA, which then serves as the starting material for the PCR.

In order to evaluate the reliability of a result obtained by RT-qPCR or even PCR, the sensitivity and specificity of the test system used are evaluated using defined samples of diluted correct target genes (e.g. RNA of the sought virus, the positive control) and very similar, but not sought target genes (e.g. closely related viruses, negative control to exclude cross-reaction). Further, due to very high amplification cycles, false positives can result from amplification of nonsense signals as well.

The sensitivity indicates how sensitively the test can detect even the smallest amounts of the target gene sought, while the specificity describes how reliably the test excludes the possibility that other, closely related genes can also lead to a positive result (false positive).

The higher the specificity, the more certain it is that the PCR system itself will not produce false positive results.

However, this does not exclude false positive events, which can be caused by laboratory contamination with target genes, contamination of test chemicals and contamination directly during sample collection. These contamination-related false positive results can be excluded by rigorous quality assurance and standard operating procedures (SOPs), the use of specially trained personnel and permanent external control in the form of interlaboratory comparisons.

1.2 Basic information on diagnostic significance

The inventor of the PCR test, Nobel Prize winner Kary Mullis, who died in August 2019, repeatedly pointed out that his test is solely suitable for making a molecule (deoxyribonucleic acid, DNA) or fragment of DNA, which is otherwise invisible to the human eye, visible by amplification. But not to allow a statement on whether what has been made visible is dangerous or causes illness.

In particular, a PCR test - even if performed correctly - cannot provide any information on whether a person is infected with an active pathogen or not. This is technically impossible, because the test procedure includes a complete destruction of the biological material and separation of nucleic acids from all other material, such destroying any structure necessary for biological function like replication and infection. Further the test cannot distinguish between "dead" matter, such as a completely harmless genome fragment as a remnant of the body's own immune system's fight against a cold or flu (such genome fragments can still be found many months after the immune system has "taken care" of the problem), and "living" matter, i.e. a "fresh" virus capable of reproducing.

Explicitly, this is listed as a disadvantage of PCR on the information sheet of the Swiss Federal Office for Civil Protection FOCP Spiez Laboratory as follows:

"Whether a pathogen is infectious (virulent, "alive") or not remains unknown" (https://www.labor-spiez.ch/ndfl/de/dok/pqs/B3_021_Pakete_PCR_d.pdf). Also [REDACTED]

[REDACTED] the director of the Department of Viral Sciences at Erasmus University and expert advisor to WHO, thus one of the central virologists of the Corona question and at the same time co-author on the RT-qPCR publication of Corman/Drosten in Eurosurveillance confirms in an interview with NPO Radio 1 (26.11. 2020 as part of her podcast "Virusfeiten" <https://www.nporadio1.nl/odcasts/virusfeiten/46542/4-blijvend-moe-na-corona-misschien-helpt-een-aspirientje/>) in response to the presenter's statement that the PCR test does not necessarily show that one is contagious, that this is correct, because the PCR shows whether one has viral RNA on one's person (minute 0:09 in <https://www.youtube.com/watch?v=etlsF7Invq2c>)

Explicitly the decisive passage of the interview with [REDACTED]:

[REDACTED] ...there are some stories circulating that say, well, the PCR test is not good.

Interviewer: At least it doesn't necessarily show that you're contagious.

[REDACTED] Yeah, exactly. And that's also true. Because the PCR shows that you have the viral RNA with you. That's literally what PCR does. And whether that RNA is in a virus particle that is still intact and also infectious. Or whether it's just residual RNA that can be detected long after infection. There is no way to distinguish between the two. You can get a feel for it by looking up "How much is there?". But you can't tell that difference very well. That is: this test is great for saying "you've had it", but this test is less good for saying "at this point you're still infectious".

Interviewer: you're talking about the PCR test right now, aren't you?

[REDACTED] Yes."

In original: (Dutch)

[REDACTED] ...er circuleren wat verhalen waarin gezegd wordt, nou ja, de PCR test ist niet goed.
Interviewer: Althans die toont niet perse aan dat je besmettelijk bent.

[REDACTED] Ja precies. En dat klopt ook. Want de PCR toont aan dat jij het virus RNA bij je hebt. Dat is letterlijk wat de PCR doet. En of dat RNA in een virus deeltje zit dat nog intact is en ook besmettelijk is. Of dat het gewoon restjes RNA zijn, die je nog een tijd lang nadat iemand geïnfecteerd is geweest, kunt ontdekken, dat onderscheid zie je niet. Je kunt een beetje een gevoel krijgen door te kijken "hoeveel is het?". Maar dat verschil is niet goed te maken. Dat betekent, die test is prima om te zeggen "je hebt het gehad", maar die test is minder geschikt om te zeggen "op dit moment ben je nog besmettelijk".

Interviewer: Over de PCR test heb je het nu, huh?

[REDACTED] ja"

* For example, PCR is also used in forensics to amplify residual DNA present from hair remains or other trace materials by means of PCR in such a way that the genetic origin of the perpetrator(s) can be identified ("genetic fingerprint").

The Swedish Ministry of Health states on its official website (<https://www.folkhelsemyndigheten.se/publicerat-material/publikationsarkiv/v/vegledning-gm-kriterier-for-bedømning-av-smittsikhet-vid-covid-19/>): "The PCR technology used in tests to detect viruses cannot distinguish between viruses capable of infecting cells and viruses that have been rendered harmless by the immune system, and therefore these tests cannot be used to determine whether someone is infectious or not. RNA from viruses can often be detected for weeks (sometimes months) after infection but does not mean that a person is still

infectious.” In the original note: “PCR-tekniken som används i test för att påvisa virus kan inte skilja på virus med förmåga att infektera celler och virus som askadliggjorts av immunförsvaret och därför kan man inte använda dessa test för att avgöra om någon är smittsam eller inte. RNA från virus kan ofta påvisas i veckor (ibland månader) efter insjuknandet men innebär inte att man fortfarande är smittsam.” This assessment was confirmed on 19.04.2021.

So, even if everything is done “correctly” when performing the PCR including all preparatory steps (PCR design and establishment, sample collection, preparation and PCR performance) and the test is positive, i.e.: detects a genome sequence, which may also exist in one or even the specific “Corona” virus (SARS-CoV-2), this does not mean under any circumstances that the person, who was tested positive, must be infected with a replicating SARS-CoV-2 and thus infectious = dangerous for other persons.

Rather, for the detection of an active infection with SARS-CoV-2, further, and specifically diagnostic methods such as the isolation of reproducible viruses must be used (gold standard).

1.3 Factors influencing the reliability of the PCR test

In fact, however, the results of a PCR test depend on a number of parameters which, on the one hand, cause considerable uncertainties and, on the other hand, can be specifically manipulated in such a way that many or few (apparently) positive results are obtained.

1.3.1 Number of independent target genes (“targets”)

The protocol “Diagnostic detection of Wuhan coronavirus 2019 by real-time PCR” (<https://www.who.int/docs/default-source/coronavirus/wuhan-virus-assay-v1991527e5122341d9928/a1b17c11f902.pdf>), originally published by WHO on 13/01/2020, described the sequence of PCR detections of three independent partial genes of the virus later renamed SARS-CoV-2. The sequence referred to the E gene, the RdRp gene, and then the N gene. Already on 17.01.2020 a change followed by the WHO with the protocol “Diagnostic detection of 2019-nCoV by real time PCR” (https://www.who.int/docs/default-source/coronavirus/protocol-v2-1.pdf?sfvrsn=a9ef618c_2) in which the N gene was removed as detection and thus instead of the original three targets only two targets were recommended. On March 02, 2020, a WHO test protocol “Laboratory testing for coronavirus disease 2019 (COVID-19) in suspected human cases” (<https://apps.who.int/iris/bitstream/handle/10665/331329/WHO-COVID-19-laboratory-2020-4-eng.pdf?sequence=1&isAllowed=y>), which was updated again, pointed out that „.... In areas where COVID-19 virus is widely spread a simpler algorithm might be adopted in which for example screening by RT-PCR of a single discriminatory target is considered sufficient....“

(page 3 below), whereupon the laboratories widely switched to analyzing only one target. As a result, many laboratories specialized only in the E gene detection as the sole target as a valid PCR, as e.g. explicitly described by the Augsburg laboratory on 03.04. (only still available in the Internet cache: https://www.oder-spree-piraten.de/wp-content/uploads/2020/05/GesamtA4ndertes_Dekundlayout-der-SARS-CoV2-PCR-Ergebnisse-Labor-Augsburg-MVZ-GmbH.pdf

However, the outstanding importance of the number of independent target genes analyzed by PCR results from the following calculation:

The three targets E, RdRp and N gene originally specified in the WHO protocol for the detection of SARS-CoV-2 were rapidly used in many laboratory and commercial test systems. An interlaboratory comparison by Institut Instant e.V. (https://corona-ausschuss.de/wp-content/uploads/2020/07/Instant-Ringversuch_Virusgenom-Nachweis-SARS-CoV-2.pdf) showed a mean specificity for these genes of:

Target of the SARS-CoV-2 genome	Number of test analyzed	Specificity A (test sample cell culture without virus)	Specificity B Test Sample contains related Coronavirus (HCoV 229E)	Mean % detected correct	Mean specificity absolute	Mean error rate (1-abs. Spec.)
E-gen	24	99,46%	95,17%	97,31	0,9731	0,0269
RdRp-gen	13	97,80%	90,66 %	94,23	0,9423	0,0577
N-gen	21	98,20%	87,95 %	93,08	0,9308	0,0692

In a mixed population of 100,000 tests, even no true infected person would result due to the mean error rate:

For E-only genetic test: $100,000 \times 0.0269 = 2690$ false positives.

For E and RdRp test in sequence: $100,000 \times (0.0269 \times 0.0577) = 155$ false positive

For all three genes [E, RdRp, N]: $100,000 \times (0.0269 \times 0.0577 \times 0.0692) = 10$ false positives

This means that the specification of the WHO to successively reduce the number of target genes of SARS-CoV-2 to be tested from three to one resulted in an increase in the number of persons tested falsely positive in the above calculation example from 10 with three genes to almost 3000 with only the E gene per 100,000 tests performed. If the 100,000 tests carried out were representative of 100,000 citizens of a city/county within 7 days, this question of the

target genes used alone would result in a difference of 10 compared to 155 compared to 2690 with regard to the "7-day incidence" and, depending on this, the severity of the restrictions on the freedom of the citizens taken.

Evaluation: The calculation example also shows how daily case numbers can be manipulated by "playing to the specifications" regarding the targets to be detected for the laboratories. In view of the immense impact on political decisions, which are determined by the absolute numbers of positive tests and the "7-day incidence" derived from them, the specification of the WHO (and also of the RKI) to reduce the target genes has clearly been suitable to artificially inflate the "pandemic" by a factor of 300 by wrong test specifications.

This is an evidence-free procedure, which on the one hand entails enormous personal restrictions of quarantine/isolation, which the falsely "positively tested" persons have to suffer, and on the other hand willingly accepts the enormous social and economic restrictions and damages via the "7-day incidence number".

If the correct target number of three or even better (as e.g. in Thailand) up to six genes had been consistently used for PCR analysis, the rate of positive tests and thus the "7-day incidence" would have been reduced almost completely to zero.

1.3.2 Number of cycles performed (CT value)

In addition to the number of target genes detected, especially in the case of only one or a maximum of two genes, the number of cycles of amplification in the qPCR up to the "positive" result and the resulting CT value are decisive factors. The smaller the CT value of a sample in a qPCR, the higher the initial amount of DNA in the sample. Under standardized conditions, this correlates with (in the case of viruses) the initial amount of viruses, the so-called viral load, which should ideally be expressed as "number of viral copies" per ml of sample. This viral load also correlates in the case of SARS-CoV-2 with the cultivability of infectious viruses in cell culture as published with the participation of C. Drosten already in March 2020. (Figure 1e in Wolfel et al., <https://doi.org/10.1101/641586>)

Here, a minimum quantity of 10^6 RNA copies/ml was necessary in order to be able to grow viruses from the sample, in another work from the group of C. Drosten (from May 2021) even an average of 10^5 viruses in the sample was necessary for a positive cell culture (supplemental Figure S4 from <https://pubmed.ncbi.nlm.nih.gov/34035154/>). In the latter work, it was also found that none of the 25,381 individuals tested had viral genomes per ml in the sample in the case of a determined viral load below 10^5 (Table S1), whereas RT-qPCR from the original protocol (Corman V et al., [10.2807/1560-7917.ES.2020.25.3.2000045](https://doi.org/10.2807/1560-7917.ES.2020.25.3.2000045)) can already deliver a positive result at approx. 4 copies per sample preparation (5µl corresponding to approx. 10^3

copies/ml), i.e. already by a factor of 1000-10000 earlier than in a sample with an actual infectious virus load.

Even commercial PCR test systems, so-called "kits", sometimes show detection limits of less than 10 copies/reaction, such as kits from the company TIB-Molbiol (https://www.roche.com/assets/lm_pdf/MDx_53-Q/77_96_Wuhan-R-gene_V20D204_09155376001%20%28%29.pdf).

In technical terms, a distinction must be made here between "colonization" of the throat with a few individual viruses that do not cause infection and a genuine "infection". The latter is accompanied by viruses capable of multiplying, which then leads to a) a symptomatic illness and b) infectivity, i.e. the ability to infect other persons.

Christian Drosten already described this aspect in 2014 in an interview in the "Wirtschaftswoche" (<https://www.wifo.de/tecnologia/forschung/virologe-drosten-im-gespraech-2014-die-who-kann-nur-empfehlungen-aussprechen/9903228-2.html>) in connection with MERS: "Yes, but the method (note: PCR is meant) is so sensitive that it can detect a single hereditary molecule of this virus. If such a pathogen, for example, sits across a nurse's nasal mucosa for just one day (note: this would be the above-mentioned "colonization") without her becoming ill or otherwise noticing anything about it, then suddenly she is a Mers case. Where previously deathly ill people were reported, now suddenly mild cases and people who are actually perfectly healthy are included in the reporting statistics." [...] "Because what is initially of interest are the real cases (Note: These are the "infected") Whether asymptomatic or mildly infected hospital workers are really virus carriers, I think, is questionable. Even more questionable is whether they can pass the virus on to others." The latter is a crucial statement also with respect to the SARS-CoV-2 viruses, which are very closely related to MERS. But it is precisely this point about virus transmission (and thus driving the pandemic) that is the rationale for the intervening measures such as quarantine/isolation orders, the "lockdowns," and the so-called AHA rules.

Further evidence for the relevance of the CT value

A Canadian study by Jared Bultard/Guillaume Poliquin in Clinical Infectious Diseases 2020, which can be read at the link (<https://doi.org/10.1093/cid/ciaa638>), came to the conclusion as early as May 2020, that no reproducible virus was found above a CT value of 24. This means that the attempt to subsequently cultivate reproducible viruses from smear samples that only resulted in a positive test at a higher CT value failed. According to this study, above a CT value of 24, the amount of detectable viral genetic material is so low that the positive test could no longer be interpreted in terms of an active infection. A large study by Jaffar et al. ([10.1093/cid/ciaa1491](https://doi.org/10.1093/cid/ciaa1491)) set the limit for the cultivability of SARS-CoV-2 from patient sample material at a CT value of 30.

In a study comparing antigen testing/RT-qPCR and virus cultivation from the CDC (<https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciac303/6224406>), successful virus cultivation was described for a CT range of 17.4-28.8, where only at a CT of <25 all specimens were from symptomatic individuals and were associated with successful virus cultivation. When the CT was between 25 and 29, in 18.2% Virus isolation was positive. In the original: "Virus was isolated from specimens with Ct values ranging from 17.4-29.8; virus was isolated from all specimens with a Ct value <25 and from 18.5% (5/27) of specimens with a Ct value ≥25." (center of page 9). Irrespective of this check using virus cultivation, however, all samples that were positive in two target sequences from the "N gene" with a CT up to 40 were considered "true positive".

In his NDR podcast of Feb. 16, 2021, C. Drosten explicitly named that an increase in CT from 25-27 across the border of 28 means that individuals from whom these smears were obtained with the higher CT are no longer infectious. "And again, you see a Ct shift from 25 to 27 approximately, 27, 28. And that's a range where, in our estimation, that's really where infectivity ends. If you see such a patient sample and you would ask, is the patient still infectious, I would say: No, this is now slowly no longer an infectious area. You can correlate that." (page 4 (top right column in <https://www.ndr.de/nachrichten/info/coronaskript270.pdf>)

With these CT data, C. Drosten presumably refers mainly to a study on vaccine efficacy in Israel, which was verified by RT-qPCR. This study, which was available in a preprint publication ("Decreased SARS-CoV-2 viral load following vaccination" (<https://www.medrxiv.org/content/10.1101/2021.02.21.251283v1>)) and in the meantime is available regularly under the title "Initial report of decreased SARS-CoV-2 viral load after inoculation with the BNT162b2 vaccine" (<https://www.nature.com/articles/s41591-021-01316-7>), is also referred to in a letter from the German Robert Koch Institute (RKI; AZ: ID3176 of 31.03.2021) to the German Federal Ministry of Health. In this study, PCR tests after vaccination (with BNT162b2) show that in vaccinated subjects who became positive for SARS-CoV-2 in the PCR from day 12 after the first vaccination, the CT for the three tested genes (E, N, RdRp using the Seegene Allplex test kit, which has a specificity of 96-98.4 according to the instant EQA scheme 340) increases from a mean CT of 25 to a mean CT of 27.

Compared with a similarly SARS-CoV-2 PCR positive unvaccinated cohort, this study establishes vaccination success based on a CT decrease of 1.64-2.33. „Finally, applied on all infections (post-vaccination and unvaccinated, n=5,794), a multivariate linear regression model accounting for age, sex and vaccination quantify Ct regression coefficients ranging from 1.64 (N gene) to 2.33 (RdRp) for vaccination after 12 days or longer prior to infection sampling“, which is arithmetically equivalent to a 4-fold reduction in viral load in vaccinated versus unvaccinated. In the original: „As a difference of 1 Ct unit is equivalent to a factor of about 1.94 in viral particles per sample, these Ct differences represent a viral load ratio ranging from 2.96 to 4.58.“

It is also noteworthy in the PCR analyses description, that the CT values up to 40 were analyzed and evaluated in this work (Extended Data Figure 4).

Accordingly, in a new recommendation dated April 16, 2021, the CDC also addresses the CT in SARS-CoV-2 PCR to the effect that it should have a value of no more than 28 in order to send PCR products from "vaccine breakthroughs" (i.e., RT-qPCR positive individuals after complete vaccination) to the laboratory for sequencing (<https://www.cdc.gov/vaccines/covid-19/downloads/information-for-laboratories-COVID-vaccine-breakthrough-case-investigation.pdf>).

Also, a study from South Korea mentions a CT of ≤ 25 as the upper limit of clinically relevant "positives" and uses this value for comparison with the goodness of antigen tests. Original quote: "... based on a clinically significant Ct value of ≤ 25 [...] (p. 3 in <https://ikms.org/DOIx.php?id=10.3346/ikms.2021.36.e101>).

Unanimous scientific opinion (including Dr. Fauci of the US CDC, but also a number of scientists quoted in the New York Times in August 2020, <https://www.nytimes.com/2020/08/29/health/coronavirus-testing.html>) is that all "positive" results detected only after a cycle of 35 have no scientific (i.e.: no evidence-based) basis. In contrast, the RT-qPCR test for the detection of SARS-CoV-2, propagated worldwide with the help of the WHO, was (and following it all other tests based on it as a blueprint) set to 45 cycles without defining a CT value for "positive".

Also as early as May 2020, a position paper was issued by the National Centre for Infectious Disease in Singapore (<https://www.ncid.sg/Documents/Period%20of%20Infectivity%20Position%20Statementv2.pdf>), which points out that:

1. it is important to note that viral RNA detection by PCR does not equate to infectiousness or viable virus
2. the cycle threshold value (CT) of the PCR, as a surrogate marker for the viral RNA content, already detects viral RNA from a CT of 30, but no longer the presence of replicable viruses and the persons concerned are not infectious.

Original text extract "6. A surrogate marker of 'viral load' with PCR is the cycle threshold value (Ct). A low Ct value indicates a high viral RNA amount, and vice versa. As noted above, detection of viral RNA does not necessarily mean the presence of infectious or viable virus. In a local study from a multicenter cohort of 73 COVID-19 patients, when the Ct value was 30 or higher (i.e., when viral load is low), no viable virus (based on being able to culture the virus) has been found."

The RKI also states on its homepage as of 11.08.2020, (https://www.rki.de/DE/Content/InfAZ/N/Neuartiges_Coronavirus/Vorl_Testung_nCoV.html

#doc13490982bodyText4) "First results from diagnostics at RKI show that loss of cultivability in cell culture was associated with an RNA amount of <250 copies/5 µL RNA determined by real-time PCR (note: is RT-qPCR). This RNA level corresponded to a Ct value >30 in the test system used."

A recent study from South Korea (<https://www.ncbi.nlm.nih.gov/doi/full/10.1056/NEJMCo2027040>) sets the limit for virus cultivability at a CT value of **28.4**.

In another recent study from Frankfurt (<https://www.ncbi.nlm.nih.gov/doi/10.1101/2077-0383/10/2/328>), it was shown that of 64 RT-qPCR positive patient samples (one gene tested), virus cultivation in cell culture was only possible from 33 (=52%). These infectious samples were already positive up to a mean CT value of 26 (Supplementary Figure 1), whereas virus cultivation was no longer possible from the samples with a higher CT.

In the round robin Instant e.V. (http://www.finddx.org/covid-19/pipeline/?section=molecular-assays#diag_tab) see also next point, the enormous range of CT values even for highly standardized samples between the different laboratories and also with regard to the different target genes becomes apparent. For example, here the CT for the same defined diluted sample of SARS-CoV-2 (sample number 340061) for the WHO-recommended genes varies between 15.40 (E gene), 20.40.7 (N gene) and 19.5-42.8 (RdRp gene). This impressively demonstrates an extreme lack of test standardization within the participating (and certified) laboratories.

Against this background, it is disconcerting when RT-qPCR is still considered the "gold standard" by the RKI (and WHO) without defining the exact validations and external certification conditions (and without these apparently being fully monitored by the authorities).

Assessment:

In general, RT-qPCR cannot detect intact, propagable (infectious) viruses, not even the complete intact viral genome, but only one bit and of the sought section. In principle, it is possible to define a threshold (CT_{th}) above which a positive PCR signal no longer correlates with replication viruses, by validation w/ a parallel virus cultivation in cell culture for well-adjusted and correctly performed PCR tests. This has been a well-practiced routine in blood product monitoring (for HIV and Hepatitis viruses) for years.

This stringent validation then allows - as long as the test system's NDT unchanged - as a surrogate marker an estimation of the viral load and thus the possible infectivity of the tested sample, but never definitive detection. As soon as a component of the PCR test system (or its chemicals, plants, goods, enzymes, protocol procedures or mechanics) is changed in one of the application steps, it is mandatory to revalidate the system.

From all the information published so far (see above), it can be assumed that any CT value above 35 is no longer associated with the culturability of infectious viruses and is therefore the absolute threshold for the decision "positive", also irrespective of the test system used. The CT range 25-35 may still be validly assessed as "positive in the sense of infectivity" in a test-dependent manner if, as described, it has been compared with a virus cultivation by adequate validation in the performing laboratory.

CT ≤ 25 : positive

CT 26-35 : positive only if matched with viral culture

CT > 35 : negative

The strict evaluation of the CT value mainly matters when the target number is one, but generally applies to each individual target.

The threshold CT 25 was already introduced in December 2020 by the English "Office of national statistics (ONS), here with CT above 25 as negative. Table sheet 2 (Data) in the linked Excel data sheet (link below). Results: "...The analysis shows: - People with a higher concentration of viral genetic material (positive cases with low Ct values; below 25) are more likely to be infectious in a household than those with lower concentrations (positive cases with high Ct values; above 25)." (<https://www.ons.gov.uk/peoplepopulationandcommunity/healthandsocialcare/conditionsanddiseases/adhocs/12683coronaviruscovid19infectionssurveycycletresholdandhouseholdtransmissionanalysis>).

With reference to this ONS threshold, the authors of a large cohort study from Münster, Germany (<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8166461/>), using RT-qPCR of the ORF-1ab and E genes in smear samples from 162457 individuals, concluded that: „RT-PCR test positivity should not be taken as an accurate measure of infectious SARS-CoV-2 incidence“.

This study showed that a total of 2.6% of the samples had a positive RT-qPCR result. The CT threshold above which the samples were considered definitely negative was set at 40. The samples were also analyzed according to the number of samples that became positive up to a cutoff value of 25 (always both genes, personal information on request to A. Speisberg).

The results showed that in asymptomatic individuals only 0.4% (68 of 16,874 individuals) had a positive RT-qPCR test with a mean CT of almost 29. Of these, only 2.7% (= 18 individuals) had a CT of up to 25, which was considered by the authors "indicating a likelihood of the person being infectious". Converted, this means that in only 18 of 16874 (=0.1%) asymptomatic (healthy) individuals did PCR indicate possible infectivity with respect to SARS-CoV-2.

Also, of 6212 symptomatic individuals from the peak periods of the first two "Corona waves," only 403 individuals (=6.5%) had a positive RT-qPCR for SARS-CoV-2 with a mean CT of 27.8 (1st wave) and 26.6 (2nd wave). Of these positives, a maximum (in the 2nd wave) of 40% (= 145/367) and in the first wave even only 26.5% (=10/36) individuals had a CT of up to 25 and could thus be classified as probably infectious. Consequently, only 155 of 6212 symptomatic (ill) persons (=2.5%) could be assumed to be possibly infectious with SARS-CoV-2.

Values from Table 1 of: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8166461/>

In this respect, it can be assumed that all CT values higher than 30 may no longer be used to assess whether the person from whom the sample was obtained "is infectious", but rather the UK ONS CT of 25 must be used.

Accordingly, the information of the NSW government on SARS-CoV2 NAT declaring: "**Generally the cut-off or threshold is set at a Ct of 40**" (<https://www.pathology.health.nsw.gov.au/covid-19-info/sars-cov2-nat>) is beyond all acceptable thresholds for the valuable decision about an real infection with the SARS-CoV-2 virus, even if it is used as the "**diagnostic test of choice for acute symptomatic COVID-19 disease**"

However, taken on its own, without information about the matching with the specific number of viral genomes (viral load) and the correlation with a cultivability of corresponding virus quantities, the CT value even at low numbers is worthless as an evaluation criterion of a positive PCR detection.

1.3.3 Adequate controls

In order to correctly assess sensitivity and specificity of an RT-qPCR, adequate samples must be included in each reaction run. This begins at the test site with "blank swabs" to reliably exclude contamination at the sample collection site, continues with extraction controls to ensure the correct isolation of reproducible RNA with all subsequent processing steps, i.e. an artificially produced defined RNA which is carried and processed in all steps of sample preparation up to PCR and for which PCR is then also carried out with the aid of suitable primers. This excludes the possibility of inhibitory substances or errors preventing the amplification of RNA during sample processing.

Such defined controls have been available through instant e.V. since November 2020. From the booklet accompanying the shipment of the defined (https://www.instant-ev.de/fileadmin/uploads/user_upload/Dokumente/Virologie/20210118_E_Begleithett_quantitative_Betuzsproben_1_und_2_SARS-CoV-2.pdf), the following aspects can generally be identified:

public institutions such as the German Red Cross Institute or the Fraunhofer Institute inactivated SARS-CoV-2 virus strain. This would be an additional task of the RKL and other carried in parallel as patient samples) and a positive control, ideally consisting of an Furthermore, each control test series must include a series of external negative controls (i.e.,

but it's again the implementation and the regulation).
 already solved. Mind you, in the jail, the technique and the lab testing is not the correct here, can even do it in such a way that this inherent problem of non-comparability of Ct values is validate the test results, but this is obviously not happening (according to C. Drossten), "We would be available and would have to be requested by the authorities or the laboratories to between created," means; since autumn 2020, suitable controls for virus load determination Koch Institute agree of application on this technical laboratory basis that this now recommendations are also made and applied by the state health offices or also by the Robert (pg.18); "What does not happen at the moment, however, is that additional complaints (that this standardization does not take place with calibrations produced by him) simply because these test manufacturers don't standardize on the Ct value." [pg. 17] He further manufacturer's test shows that this is already a seriously infectious concentration. That's for whom a value of, say, 25 is nothing at all worrying, while the same value of 25 in another test system, the differences there are sometimes considerable. There are test manufacturers who are not good company compare them numerically as long as we are in the same analytical context; ... But we can hardly compare them numerically as long as we are in the same values that we have here, they are not easily comparable between the individual test (https://www.mdr.de/nachrichten/medizin/1306.pdf) as follows; "And normally the Ct The extreme variation of Ct values in the different test systems is addressed by C. Drossten in this

should be the actual reference sample for assessing the tested patient sample.
 series in order to be able to cover the laboratory must always carry the defined samples in each test example shows that each laboratory must always carry the higher concentration samples. This sample (figure 2) and a spread of Ct values of 10-16 for the higher concentration sample. This across all tests from reporting laboratories, there was a spread of Ct values of 12-38 for this the RQF Bene between 24.8 (lab 4) and 33.0 (lab 1) with the N gene already at a Ct of 22.1. for the E gene for the sample with 106 copies/ml between 21.9 (lab 4) and 28.7 (lab 1) and was shown despite defined sample in reference laboratories. For example, this Ct value varied depending on the tested genes and the performing laboratory, a wide range of Ct values

- The strain BetaCoV/Luun-Ch/Chviroba/2020 was used as a control as a heat-inactivated sample with controlled viral counts corresponding to 10^6 and 10^7 RNA copies/ml, since this according to the database (<https://www.europe-an-virus-archive.co/m/virjs/human-2019-ncoy-isolate>), this strain was obtained in Munich on 28.01.2020 and is sold via Charité.

Germany) to isolate a sufficient number of SARS-CoV-2 viruses from patient samples in the laboratory facilities available there (safety level 4). Those institutions then could cultivate defined strains from these as controls, to inactivate these and to deliver them in defined virus numbers as controls to the testing laboratories via the local supervisory authorities. However, since this important service is still not offered even after more than a year of the "pandemic", the positive control usually consists of a synthetic RNA that only encodes the target genes of the test system. This positive control can also be used to determine the lower detection limit of the PCR. This is specified by some commercial kits as 20 or fewer viral genomes per sample and thus (see point 1.3.2.) already detects a virus quantity in the smear that is below the infectious dose by a factor of 10^3 , i.e. has no diagnostic/prognostic value whatsoever. An overview of the currently used commercial kits with their line data can be found at http://www.finddx.org/cov-0-19/pipeline/?section=molecular-assays#diag_tab.

Interlaboratory tests:

Correctly performed controls also include the participation of the laboratories performing the tests in so-called "interlaboratory comparisons" (see also 1.3.1.). In these, an anonymized panel of test samples is made available by an external provider. In the case of virus detection, these contain negative samples and samples with closely related viruses (inactivated) to check the specificity (these samples must not give a positive signal) and positive samples with different dilutions of the virus sought (inactivated) to determine the sensitivity (from which number of viruses does the PCR become positive, with which CT value).

In the case of SARS-CoV-2, the first EQA scheme "Virus Genome Detection - SARS-CoV-2 (340)" by the association "INSTANT e.V." was ready in April 2020. According to the report, 488 laboratories participated in this EQA scheme, of which 463 reported results. The results can be read in the published commentary (Zeichhardt M: "Kommentar zum Extra Ringversuch Gruppe 340 - Virusgenom-Nachweis SARS-CoV-2", available at: <https://corona-ausschuss.de/wp-content/uploads/2020/07/Instand-Ringversuch-Virusgenom-Nachweis-SARS-CoV-2.pdf>) and show two deviations from the usual EQA procedure, which already here pointed to laboratory problems with RT-qPCR for the detection of SARS-CoV-2:

For example, page four of the publication states, "*Important evaluation notice: only 4 of the 7 samples tested in this Extra EQAS will be considered for obtaining a certificate of successful participation.*" The footnote on page 10 of the commentary states, "*In the April 17, 2020 interim evaluation, all participants in the Extra INSTANT EQA trial (340) Virus Genome Detection of SARS-CoV-2 April 2020 were notified ahead of time of the sample characteristics of samples 340059, 340060, and 340064. The results of these 3 samples will not be considered for the granting of a certificate [...]*" The reason for this exclusion of certain samples is explained on page 4 of the commentary: "*While the extra ring trial was still running, INSTANT e.V. received urgent requests from Germany and abroad to reveal the properties of the*

samples to be tested before the end of the extended submission period, i.e., before April 28, 2020, so that laboratories can improve their test method in the short term in case of possible incorrect measurements." (page 4 above in INSTANT e.V. report)

This procedure is very unusual for a real round robin test and thus no longer represents an independent external verification procedure of the participating laboratories.

Despite the samples already detected and the reduced test scope, sample mix-ups occurred in a large number of laboratories - as stated on page 18 of the commentary: "For sample 340064 (SARS-CoV-2 positive diluted 1 : 100 000), the reduced success rate of only 93.7 % is essentially based on incorrect result assignments (mix-ups) for sample 340064 and sample 340065 (negative for SARS-CoV-2 and positive for HCoV 229E). The mix-ups for samples 340064 and 340065 involved 24 laboratories with a total of 59 results per sample. See also section 2.4.2.1 [...]." Thus, a large number of laboratories mistakenly confused sample 340064 (slightly diluted SARS-CoV-2) with sample 340065 (negative for SARS-CoV-2 and positive for the closely related virus HCoV 229E).

Apart from the startling fact that a considerable number of samples were obviously mixed up even under highly standardized procedures in an interlaboratory comparison (which raises the question of the corresponding rate of sample mix-ups and thus wrongly assigned swab samples under mass testing conditions), it is striking that all reported mix-ups concerned only these two samples, but not the samples with the final numbers 61 (very highly diluted SARS-CoV-2) and 62 (negative), which were also evaluated. The detailed results of a second round robin test from June/July 2020 (https://www.instand-ev.de/System/rv_files/Zusammenfassung%20der%20Probeneigenschaften%20und%20Qualitaet%20Virologie%20340%20Juni%202020%2020200911a.pdf) are still not publicly available.

1.3.4 Exclusion of contaminations of reagents and "problems in the course of action".

The best PCR design can still lead to false positive results if either the underlying reagents / kits are contaminated with positive samples or, much more likely, contamination occurs in the laboratory workflow. Since PCR is an extremely sensitive method (exponential reaction course) that can detect few molecules of a DNA, laboratory contamination by PCR end products is a major problem in clinical diagnostics (described e.g. already in 2004 in Aslanuadeh J et al., <http://www.ncbi.nlm.nih.gov/content/34/4/389.full.pdf+html>: „A typical PCR generates as many as 10^9 copies of target sequence and if aerosolized, even the smallest aerosol will contain as many as 10^6 amplification products [6]. If uncontrolled, within a relatively short time the buildup of aerosolized amplification products will contaminate laboratory reagents, equipment, and ventilation systems [6].“)

This extreme risk of contamination requires that the diagnostic laboratories working with PCR take the utmost care in testing - very competent staff, contamination-proof environment, permanent independent control.

Already in the above mentioned round robin 340 in April a problem with "false positive" results appeared, which was commented as follows (page 20 de owl): "In addition, in some cases the tests with the SARS-CoV-2 negative control samples 340060, 340062 and 340065 indicate specificity problems, which are independent of mix-ups of the samples 340064 and 340065. Classification is needed as to whether these false positives are due to a specificity problem with the tests used or to carriage of SARS-CoV-2 during test performance by the operators with other samples in this EQA or the laboratories in question." (page 21 bottom in https://www.fz-juelich.de/strukturphysik/standards/ewd/Systenreferenzen/340/2020/2020_3400502.pdf). For only up to this EQA scheme, see details point 3.3, end of paragraph.

H. against this background one further sees how, for example, according to a BGC report, work is carried out openly and extremely contamination-prone with untrained personnel in large test laboratories in Fog (and <https://www.radiologie.com/search?text=UKM&ItemID=1>, it is not surprising if even in Germany and other countries (where such reports have not yet been filmed) occasional reports of "false positive cases" due to laboratory contamination are found in the media (e.g. <https://www.aufspur.de/2020/05/25/aufspur-berichtet-von-falsch-positiven-pcr-testen-in-sachsen-anhalt/> - link at the end of the section). Even under controlled laboratory conditions, contamination due to PCR steps cannot be safely excluded in such a highly sensitive method. Thus, the problem of false positive PCR results in SARS-CoV-2 diagnostics due to laboratory procedures has already pointed out in the first publication of RT-qPCR (Corman et al., <https://doi.org/10.1101/291715>). In four individual test reactions, weak initial reactivity was seen but they were negative upon retesting with the same assay" (....) most probably to handling issues..."

Even if the course of action in the laboratory functions optimally and is extremely monitored in order to greatly minimize laboratory-related contamination, an unexpected source of false positive results can arise here in the contamination of the materials/chemicals used ex-manufacturer. For example, the swab materials used to take samples may already be contaminated as works - as in the case of the "phantom of Heilbronn", in which the cotton swabs used to take DNA traces at the crime scenes were contaminated with the DNA of a packaging worker from the manufacturer's plant, thus hampering forensics with false traces for years (<https://www.farben.dkfz.de/Heilbronn/Kriminallab/gr-a-emittiert/Seite-02-Abberaten/02-09/heilbronner-kriminallab-192541.htm>).

In the case of SARS-CoV-2 diagnostics, a contamination problem due to PCR primers containing positive controls ex works was also published in June 2020 (Wernike et al., DOI: <https://doi.org/10.1101/113684>). Here, it had been noticed that over pure water samples with several independent primer batches give unambiguous positive SARS-CoV-2 detection in RT-qPCR

"However, there were also printers/sample sets that displayed very low-level contaminations, which were detected only during thorough internal validation."

Also, some false-positive results of SARS-CoV-2 RT-qPCR testing reported in the daily press in summer 2020 were attributed to material issues (e.g., https://www.br.de/nachrichten/bayern/probleme-in-augsburger-labor-bringen-falsche-testergebnisse_SEh5Dq4) and e.g. in the United States where 77 football players were tested positive for SARS-CoV-2 and then a second confirming test revealed that the results of the first tests were all false positive (<https://www.nfl.com/news/all-77-false-positive-covid-19-tests-come-back-negative-upon-retests>)

Evaluation:

Even with ideal RT-qPCR design and good laboratory practice with adequate validation, problems in daily handling procedures as well as externally via samples already contaminated ex-factory can significantly influence the quality of results of RT-qPCR and lead to false positive results.

1.3.5 Commercial PCR test kits: Approval for diagnostics?

Very early on, commercial PCR test systems, the "PCR kits", were used in routine laboratories for diagnostics, although the majority of them were declared for "RUO" ("research use only").

The first, and therefore most concise test manufacturer, the Berlin (Germany) company TIB Molbiol, whose company owner [REDACTED] was already listed as author on the WHO protocol recommendations alongside Christian Drosten, deserves special mention. The kits, which are accordingly based on the WHO recommendations, are used via the company Roche on their large-scale automatic machines "Cobas" and should therefore make up a large percentage of the kits used for routine diagnostics of SARS-CoV-2 in Germany and around the world.

Exact figures cannot be determined, however, TIB Molbiol has already delivered more than 60 million of these tests worldwide in 2020 according to its own information (<https://www.tib-molbiol.de/ds/covid-19>), although these are still declared as "Not tested for use in diagnostic procedures" (e.g. header in https://www.roche-as.es/lm.pdf/MDx_53-0777_96_Wuhan-R-gene_V200204_09155376001%20%282%29.pdf). The corresponding package inserts with the protocol information and kit descriptions of the company TIB Molbiol were astonishingly according to metadata of the originally available PDFs (can be provided electronically) already on 15.01.2020 (!!!) completely with ROCHE SAP number are still available unchanged (albeit with metadata analysis 06.02.2020) parallel to other test kits, which now have an approval for in vitro diagnostics.

In the meantime (as of July 2021), there is a wide range of PCR detection systems (https://www.theglobalfund.org/media/9629/cov-c19_diagnosticproducts_list_en.pdf), many of which are also approved for in vitro diagnostics (IVD) of SARS-CoV-2. (e.g. here: https://www.gerusig.com/assets/files/Path_COVID_19_CE_STED_IFU_Issue_500.pdf). In the description of these kits it reads under 1. „Intended use: “Positive results are indicative of the presence of SARS-CoV-2 RNA. Positive results do not rule out co-infection with other bacteria or other viruses. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Positive and Negative results must be combined with clinical observations, patient history, and epidemiological information”

1.4 Relationship between positive nucleic acid detection in RT-qPCR, disease and infectivity.

Only those actually infected with replicating viruses and also viruses released from the cells to the outside in sufficient "infectious" quantity can pass on the virus and carry the risk of disease, and thus should be used to determine the progression of an infection rate and wave of disease

"PCR detection is the standard test for diagnosing viral infections such as SARS-CoV-2. The test detects individual pathogen genes but not intact pathogens." And, "There is a possibility that the test will be positive beyond the duration of infection because "viral debris" is still present in the nose or throat. Reliable proof of infectivity is only possible with elaborate tests that involve laboratory testing to determine whether the material from the swabs can kill living cells." This was written by the German medical journal "Dt. Ärzteblatt" on 02/01/2021 (<https://www.aerzteblatt.de/nachrichten/1207451>). Also, the CDC points out under "Disadvantages" of NAATs (nucleic acid amplification tests = PCR) "A positive NAAT diagnostic test should not be repeated within 90 days, because people may continue to have detectable RNA after risk of transmission has passed" (below in summary table at: <https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html#previous>)

"The PCR assay detects gene segments of SARS-CoV-2; it does not tell us whether they are infectious viruses or viral remnants after passed through infection. This would require pathogen culturing." Was stated in an August 2020 publication by the head of Frankfurt's public health department (https://www.laekh.de/fileadmin/user_upload/leitarchiv/Coronartikel/2020/10_2020/Die_Covid-19-Pandemie_in_Frankfurt_am_Main.pdf). And in his expert opinion of April 21 for a court in Heidelberg (to be viewed anonymously here: https://www.corodok.de/wp-content/uploads/2021/05/Gutachten-Prof.-Drosten.v. 31.3.2021_anonymisiert.pdf), the expert C. Drosten confirms that an RT-PCR test can also be positive if "at least the section to be detected from the genome of the virus is present in the tested sample". This means that genetic material fragments can also yield positive results in the PCR without originating from

an intact, replication competent virus, thus also providing an alleged virus detection in non-infectious samples.

In a CDC publication dated 7/13/20 titled "CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel For Emergency Use Only Instructions for Use", (<https://www.fda.gov/media/134922/download>), on p. 38 under the heading "Limitations" (still found on p. 37): "*Detection of viral RNA may not indicate the presence of infectious virus or that 2019-nCoV is the causative agent for clinical symptoms.*"

That a mRNA detection of SARS-CoV-2 does not necessarily correlate with disease and should not be used as the sole criterion for disease assessment, but is only an aid to confirm a clinical diagnosis, is also clearly described in WHO Information "Notice for IVD Users 2020/05, Nucleic acid testing (NAT) technologies that use polymerase chain reaction (PCR) for detection of SARS-CoV-2" dated Jan. 13, 2021 (published Jan. 20, 2021 at <https://www.who.int/news-room/item/20-01-2021-who-information-notice-for-ivd-users-2020-05>): : „*Where test results do not correspond with the clinical presentation, a new specimen should be taken and retested using the same or different NAT technology.*“

Further: : "Most PCR assays are indicated as an aid for diagnosis, therefore, health care providers must consider any result in combination with timing of sampling, specimen type, assay specifics, clinical observations, patient history, confirmed status of any contacts, and epidemiological information"

Also in a publication in Lancet [[https://www.thelancet.com/journals/lancet/article/PHI50140-6736\(21\)00425-6/fulltext#%20](https://www.thelancet.com/journals/lancet/article/PHI50140-6736(21)00425-6/fulltext#%20)], the authors refer to the RT-qPCR assay as follows: : „*In our view, current PCR testing is therefore not the appropriate gold standard for evaluating a SARS-CoV-2 public health test*“, because, in their opinion, the PCR still comes up positive even when those tested are no longer positive, since the RNA can persist in the body for weeks and months even after the immune system has successfully combated it, without the person still being infectious. „*Once SARS-CoV-2 replication has been controlled by the immune system, RNA levels detectable by PCR on respiratory secretions fall to very low levels when individuals are much less likely to infect others. The remaining RNA copies can take weeks, or occasionally months, to clear, during which time PCR remains positive*“

In a May 2021 publication in Science led by C. Drosten (DOI: 10.1126/science.abb5273) examining the infectivity of SARS-CoV-2, the authors define in the very first sentence of the abstract the parameters for quantifying and potentially passing on the virus as „... viral load and whether samples yield a replicating virus isolate in cell culture.“ They further state in the introduction that viral load is determined by viral RNA concentration and successful virus isolation in cell culture assays. Furthermore, they point out that even "... viral load and cell culture infectivity cannot be translated directly to *in vivo* infectiousness, and the impact of social context and behavior on transmission is very high, these quantifiable parameters can generally be expected to be those most closely associated with transmission likelihood".

In his NDR Podcast 94 of June 22, 2021

(<https://www.ndr.de/nachrichten/info/coronaskript30b.pdf> | page 16, C. Drosten addresses the relationship between CT value and infectivity as follows: "...that a case just because the patient has a high CT value at this moment, that is, because he may not be infectious right now, so he has little virus, he has virus, but he has little virus,..."

1.4.1 Sample preparation excludes the detection of replication-capable viruses.

Another important aspect in assessing whether an RT-qPCR test relates to a statement about the infectivity of a person who has tested positive, i.e. the extent to which the positive RT-qPCR result indicates the presence of replication-capable viruses, is the preparation of the sample for RT-qPCR.

The RNA of the gene sought (here: SARS-CoV-2 virus genome) must be isolated from the swab material in order to be usable for gene detection in RT-qPCR. A crucial step in this process is the complete denaturation of all biological material and separation of the main components protein, lipids and nucleic acids in order to finally have the RNA available as a starting base for RT-qPCR. The original protocol of Chomczynski and Sacchi from 1987 (<https://pubmed.ncbi.nlm.nih.gov/2440339/>, <https://pubmed.ncbi.nlm.nih.gov/17406285/>) is still part of almost all protocols for purification of biological material for RNA isolation, whether prepared in the laboratory or in purchased "extraction kits". Components of the original extraction solution are phenol/chloroform and isoamyl alcohol, and various modified commercial solutions contain similar acting but less toxic substances. All of them have in common that they completely destroy any living or reproducible biological structure.

This means that in the laboratory process of preparing a smear sample, which is mandatory prior to RT-qPCR, any biological material, be it a vital cell, a virus capable of reproducing, or even just cell debris and gene residues, is denatured in such a way that it is no longer possible to determine whether the material originates from an intact or even reproducible organism or from samples that have already been damaged or destroyed. Due to this extraction and preparation process, it is not possible to conclude from a positive RT-qPCR that replication-capable viruses are present in the smear sample; only the isolated RNA can be detected, regardless of the source.

1.5 Conclusion: Significance of RT-qPCR Tests for the Detection of SARS-CoV-2 Coronavirus Infection

1) In view of the problems outlined in section 1.3, RT-qPCR is not a suitable and reliable (and approved) diagnostic tool for the detection of infectious (replication capable) SARS-CoV-2 viruses.

Furthermore, the sole RT-qPCR test result is only a laboratory value, which, in view of the aspect outlined in point 1.4, does not permit any statement about the presence of infectious viruses and may only be used at all in conjunction with a clinical symptom diagnosis (ascertained by healthcare providers, in Germany medical doctors).

Summary: RT-qPCR is not suitable for the detection of SARS-CoV-2 infection in **asymptomatic individuals** by means of a nasopharyngeal swab, as is done uncritically in large numbers and predominantly by non-medical personnel **WITHOUT** (crucially here: contrary to the WHO requirement!) taking a medical history and ascertaining the symptoms of those tested.

2. Antigen detection by means of a rapid test

2.1 Explanation of terms/basics of the rapid test

The "rapid tests" currently used for the diagnosis of SARS-CoV-2 are based on the principle of an antigen test according to the "lateral flow" test procedure. This detects a protein component (protein) of the virus.

An antigen is a three-dimensional structure of proteins and other organic materials that can be recognized and bound by antibodies (immunoglobulins).

In the case of viral antigens, these are usually individual protein components (proteins) from the viral structure. These can be either complete structural proteins such as the "spike" protein located on the surface (S protein, these are the "stalked buttons" in the virus drawings) or the envelope protein ("envelope" - E protein) or that protein from which the nuclear envelope is built (nucleocapsid – N protein). Fragments of these complete structural proteins are also often sufficient to be bound by antibodies. These are the so-called epitopes, which also represent the actual antibody binding site on the intact structural protein. Each structural protein usually has a large number of epitopes, so that different antibodies can bind simultaneously to different epitopes of the same protein.

In case of SARS-CoV-2, the major antigens (the above-mentioned, S, E, and N proteins) are those that trigger an immune response in the body when infected with the virus. As a result, the body forms antibodies that specifically recognize these antigens, then bind to them (antigen-antibody reaction) to neutralize the viruses and render them destructible to immune cells.

This antigen-antibody reaction can be used in the laboratory to search for the antigens in any sample with synthetically produced antibodies.

The basic principle of the so-called antigen tests in the laboratory (these aim at the detection of antigens by antibodies, unlike RT-PCR, which detects nucleic acids) is that two matching

antibodies are produced *in vitro*, which recognize two different epitopes of the antigen being searched for, a so-called "antibody pair". Both antibodies must be selected in such a way that they can only recognize and bind the desired epitope on the antigen sought, but not other structures or similar antigens. They must therefore be highly specific in order to be used in diagnostics. This high specificity of diagnostic antibodies is ensured in test development by matching them with many very similar epitopes. All antibodies that bind **undesired epitopes** are discarded until only one ideal antibody pair remains that meets the requirements of very high specificity, high binding property (sensitivity) and no mutual interference.

The antigen test is then built on this antibody pair, in which the antigen sought is bound by both antibodies simultaneously and is sandwiched between them like the fry inside the sandwich bun (hence "sandwich test").

For the lateral flow rapid antigen tests, which are currently used in broad-spectrum population testing for the detection of SARS-CoV-2 antigens, this sandwich test system is now used.

Here, the first of the two specific antibodies is bound to a carrier material in such a way that its antigen binding site points freely upwards. This is the **test region** in the rapid test where a color change gives the signal "positive". The second antibody is coupled with a detection system that is later responsible for the color reaction and is located as a depot directly next to the site in the rapid test at which the sample is dripped on.

Test procedure: If the antigen, in this case the protein of SARS-CoV-2, is present in the swab sample, it binds with the first specific antibody from the depot after dropping into the test field of the detection cassette. Capillary forces cause the mixture of antigen with bound first antibody and excess unbound antibody to migrate from the depot towards the test field. Here, the second specific antibody fixed there then binds the antigen with the first antibody already bound to it. The solution migrates beyond the test field over another field where the excess antibodies are captured (control field). The detection system of the test begins to show a chemical color reaction wherever the first antibodies are bound. In the control field, this is caused by the surplus first antibodies that are now bound here and have "brought along" the detection system, thus indicating that the test has in principle functioned without interference.

In the test field, there is only a color change if an antigen was actually in the sample and was bound via the second antibody fixed there. Since the antigen has already arrived at the test field with the first antibody and the detection system, the chemical color reaction also begins here, which leads to the color change (usually a violet stripe) at the test region.

Whenever the antigen sought is present in the swab sample, it can bind the first antibody and transport it together with the detection system to the fixed second antibody, which then intercepts this antigen-antibody-detection system complex and thus causes the positive signal at this point.

The color change at the test site (signal "positive"), which causes the visible stripes in the rapid test, is a chemical reaction and therefore can be influenced by reaction conditions such as pH or chemicals that come with the sample and is a clear weakness in the reliability of the test.

This explains the many videos circulating on the internet that detect SARS-CoV-2 using the rapid antigen tests in apple juice, red wine, beer, etc.

2.2 Basic information on the diagnostic significance of the rapid antigen test

Like RT-PCR, **rapid antigen tests** cannot in principle determine whether the viral antigen found belongs to an intact, infectious virus or is a remnant (fragment) of viruses that have been killed by the immune system.

Irrespective of this general limitation of the significance with regard to infectivity, rapid tests only have an indicative character, not a reliable diagnostic significance.

The most well-known rapid test before Corona times was the rapid pregnancy test, which works according to the same principle of the antibody-antigen test. However, here the pregnancy hormone (HCG) acts as an antigen. If this is present in sufficient quantity in the tested urine, the test indicates "positive" - in this case, presumably pregnant. However, the rapid test alone will never be sufficient as a well-founded proof of pregnancy; in this case, the doctor will use HCG detection in the blood as well as an ultrasound to make the diagnosis.

The rapid antigen tests for the detection of SARS-CoV-2 components can also only give an indication of possible colonization or infectivity and are subject to similar limitations as RT-qPCR.

2.3 Factors influencing the reliability of rapid antigen tests

2.3.1 Pre-test probability

In an infographic entitled "Understanding Corona rapid test results" (https://www.rki.de/DE/Content/InfAZ/N/Neuartiges_Coronavirus/Infografik_Antigentest_PDF.pdf?__blob=publicationFile), the RKI clearly explains how the probability that a test result is correct depends on the so-called pre-test probability, i.e., on the actual number of genuinely infected persons in the tested population. This aspect of pre-test probability applies to both the rapid antigen tests and equally to the RT-qPCR tests.

The calculation example presented by the RKI for the interpretation of the rapid antigen tests assumes a realistic scenario starting from a sensitivity (susceptibility) of the antigen tests of 80% and a specificity (reliability) of 98%, whereby it is also explicitly mentioned here

(https://www.rki.de/DE/Content/InfAZ/N/Neuartiges_Coronavirus/Vorl_Testung_nCoV.html): "The considerable differences in performance of the various commercially available tests must be taken into account here (reference to: <https://www.medrxiv.org/content/10.1101/2020.10.01.20203836v1>)."

Assuming five persons out of 10,000 tested are truly infected with SARS-CoV-2, 200 false positive tests and four true positive tests will still show up. This means that one truly infected person per 10,000 would be missed, but 200 would get a false positive result and therefore have to be quarantined/isolated until RT-qPCR testing then gives the "all clear". This would mean in the case of a school test with e.g. 1000 students, that 20 would get a false "You are Corona positive" and the school would first be closed as an "outbreak site" until the retesting by RT-qPCR gives the all-clear. Such cases have already been reported in the press.

- For example, in Altdorf near Nuremberg (Germany), 29 of 180 high school students tested positive in a rapid antigen test; upon examination, 28 of them turned out to be negative (https://www.merkur.de/bayern/nuernberg/nuernberg-corona-bayern-test-flasko-schnelltests-fehlerhaft-positiv-schule-altdorf-gymnasium_xr_90253265.html).

- In Potsdam (Germany), 12 of 36 teachers tested positive with a rapid antigen test and were sent into quarantine. After review, all test results turned out to be false positives (<https://www.news4teachers.de/2021/03/sorgen-schnelltests-fuer-chaos-an-schulen-falscher-alarm-liegt-grundschule-lahm/>).

- Medscape even headlined, "200 false positives, 8 detected, 2 missed - why pediatric and adolescent physicians are skeptical of mass rapid testing" (<https://deutsch.medscape.com/artikelansicht/4909842>)

And even if the rate of genuinely infected persons in the tested group were very high, as in the second calculation example from the RKI (with 1000 out of 10,000 tested persons), the hit rate of the rapid tests would be poor and 180 persons would receive a false positive result and 200 a false negative test. This is where the poor sensitivity of the test comes into play.

In the "Hinweisen zur Bewertung der Ergebnisse aus AG-Testen" (Note: Antigen rapid tests, Notes on the evaluation of results from AG tests) on the webpage of the RKI, the problem of false positive antigen tests is addressed: "A positive test result by means of AG test triggers the suspicion of a transmission-relevant infection with the SARS-CoV-2 and requires a follow-up test by means of PCR to avoid false positive results. In view of the potentially significant consequences of incorrect results, there are high requirements not only for the sensitivity of antigen tests, but also for their specificity. Thus, with low prevalence/pretest probability and low test specificity, a high number of false-positive results and a corresponding additional burden on the OGD due to imposition and, if necessary, withdrawal of measures would have to be expected."

https://www.rki.de/DE/Content/InfAZ/N/Neuartiges_Coronavirus/Vorl_Testung_nCoV.html

2.3.2 Sensitivity

Due to the fact that in the antigen test there is no such strong [exponential] amplification of the output signal as in RT-qPCR, but only a limited signal amplification due to the chemical color reaction, this type of test is significantly less sensitive than the RNA detection by RT-qPCR used for comparison.

This "underperformance" of rapid antigen tests is the subject of a Lancet article ([https://www.thelancet.com/journals/lancet/article/PUS0140-6736\(21\)00425-6/fulltext%20](https://www.thelancet.com/journals/lancet/article/PUS0140-6736(21)00425-6/fulltext%20)), but here the negative test result in the rapid antigen test (here called LFT, lateral flow test) is relativized to: "[...] in all six observed cases, viral loads were very low (CT ≥29 reflecting around <1000 RNA copies per ml in the laboratory used)—when LFT should be negative."

A study from Norway (<https://pubmed.ncbi.nlm.nih.gov/33736946/>) confirms this finding that in asymptomatic individuals, rapid tests have an unsatisfactorily high inaccuracy, and that only in symptomatic individuals are reasonably accurate detections made of those who are actually infected. The authors conclude: "Our results indicate that the test correctly identified most infectious individuals. Nevertheless, the sensitivity is considerably lower than for PCR."

In a comparison of rapid antigen tests (3 different manufacturers) with unspecified RT-qPCR results ("different RT-qPCR methods" in the original): "using different RT-qPCR methods" in 5066 cases, of which 101 (=2%) had a positive RT-qPCR result, the parallel antigen test had a sensitivity of only 42.6%, with 16 false positive results (0.32%) and 58 false negative (1.15%) results, compared to RT-qPCR, in which CT values up to 35 were considered positive (corresponding to a converted viral load of 31 RNA copies/ml).

Here, positive antigen tests correlated very well with a high viral load (mean 2.7×10^6 copies/ml) and low CT (up to 22, Figure 4) and typical disease symptoms, with low viral load (with less than 10^6 RNA copies/ml) considered to be the limit of infectivity, i.e. by the RKI) and especially asymptomatic individuals, the rapid tests were often negative, which is considered a deficiency. In this publication (<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8234263/pdf/main.pdf>), but against the background of the identification of infectious individuals should be more reliable than RT-qPCR when evaluated with too high CT values.

Also C. Drostén explains in his podcast (No. 94 page 15) of 22.06.2021 to the self-test (antigen test): "There must be already proper virus to get the test positive. But there also has to be a good amount of virus to infect someone. This is a good match. This is a good threshold. Even in the thresholds, it's a good match. So we actually estimate that the infectivity threshold is about where the detection threshold is." These antigen tests are 15.*

(<https://www.ndr.de/nachrichten/info/coronaskript306.pdf>)

This alleged lack of sensitivity is the most common criticism when the unreliability of rapid antigen tests is reported. For example, the Pharmaceutical Newspaper (<https://www.pharmazeutische-zeitung.de/in-der-praxis-deutschland-anzuverlaessiger-als-auf-dem-papier-123017/>) writes: "Rapid antigen tests could detect mostly "highly infectious people with high viral loads," Keppler explains. "However, it is not the case that an infection could be reliably excluded by the negative result of a rapid test." Here, however, the basis is comparing the rapid antigen test with RT-qPCR and criticizing the fact that only some of the RT-qPCR positive swab samples also became positive in the rapid antigen test.

For example, in Epidemiological Bulletin 3/2021, the RKI reports on a study using rapid tests in a Stuttgart clinic (from page 11 in: https://www.rki.de/DE/Content/Infekt/EpidBull/Archiv/2021/Ausgaben/03_21.pdf;jsessionid=d15F8B09E615AFCED77C344398B8052AF.internet051?blob=publicationfile). Here, Table 1 shows that of 18 RT-qPCR positive for SARS-CoV-2 RNA asymptomatic individuals, only 7 also had a positive signal in the rapid antigen test, and of symptomatic individuals, 36 of 42. Accordingly, the discussion states, "Because of the very limited sensitivity of the antigen test in asymptomatic individuals, single testing in this population cannot adequately exclude SARS-CoV-2 infection. Highly contagious individuals with low Ct values (i.e., high viral load) are detected with adequate confidence." Here, the data show, "At a Ct value of 22 or less, the detection rate of the antigen test was 100%."

This example shows very clearly that a reliable antigen test, when performed correctly, correlates very well for symptomatic individuals with rapid response in RT-qPCR (low CT value), but not for asymptomatic, and only high CT value RT-qPCR positive, individuals. This speaks to the real-world significance of rapid antigen testing in terms of detecting a high viral load in symptomatic individuals. However, according to these data, the test is unsuitable for testing asymptomatic persons, both to reliably identify possibly infected persons and to reliably identify healthy persons as negative.

Such a finding was also obtained in the current Frankfurt study (<https://www.mdpi.com/2077-0383/10/2/328>), where three rapid antigen tests (here AG-RDT, antigen rapid diagnostic test) were matched with a viral culture from the same samples in cell culture and correlated to RT-qPCR. The authors write about this in the abstract: „In contrast, three Ag-RDTs demonstrated a more significant correlation with cell culture infectivity (61.8–82.4%).“ This means that from those samples that were positive in the antigen test, a positive result was also seen in the virus culture with a significantly higher hit rate than with the significantly more sensitive RT-qPCR "positives".

A recently published study by the CDC also points to the high concordance of the antigen test with actual interrogatable virus in a sample from symptomatic patients (<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7821766/>). Here, a commercial rapid antigen test was matched with a virus cultured in cell culture and RT-qPCR. It showed a high hit rate (positive result) of the antigen test only when the samples also contained replicating

Many of the rapid antigen tests have so far only been granted special approval by the BfArM in procedure for CE marking and have not yet undergone a regular conformity assessment.

2.3.3 Reliability (specificity) - exclusion of false positive results

- Samples from which no viruses can be grown in cell culture are mostly negative in evaluated CT values (mostly above 33) in RT-qPCR. These samples are predominantly from asymptomatic tested individuals and prove that these random "positives", without clinical symptoms do not have an infectious viral load.
- Samples from which no viruses can be grown in cell culture are mostly negative in evaluated CT values (mostly above 33) in RT-qPCR. These samples are predominantly from asymptomatic tested individuals and prove that these random "positives", without clinical symptoms do not have an infectious viral load.
- Samples from which no viruses can be grown in cell culture are mostly negative in evaluated CT values (mostly above 33) in RT-qPCR. These samples are predominantly from asymptomatic tested individuals and prove that these random "positives", without clinical symptoms do not have an infectious viral load.

- Samples from which viruses can be grown in cell culture, i.e., which have a high (infectious) viral load, are identified with good accuracy by the rapid antigen tests and by RT-PCR with low viral load.
- Samples from which viruses can be grown in cell culture, i.e., which have a high (infectious)

In general, it can be stated from these published data:

"AgPCRs were found to range between around 2 million and 9 million copies per swab with virus cultivation in cell culture. In terms of analytical sensitivity, the detection range of AgPCRs only lead to success (= sufficiently high viral load) in 1/5 of cases when compared with viruses cultivated in cell culture. A viral load of 2.9x10⁴ copies per smear is specified as the detection limit, which would nevertheless only lead to success (= sufficiently high viral load) in 1/5 of cases when compared with viruses cultivated in cell culture, i.e., in terms of analytical sensitivity, the detection range of AgPCRs only lead to success (= sufficiently high viral load) in 1/5 of cases when compared with viruses cultivated in cell culture." might enable short cuts in detection making in various areas of health care and public health." A limit of detections that approximately correlate viruses concentrations at which patients are infected weak of symptoms, which marks the infectious period in most patients. The AgPCRs with range of most AgPCRs work with SARS-CoV-2 viral loads typically observed in the first week of infection making in various areas of health care and public health."

In a recent publication of the working group of Christian Drosten (<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8026170/> he is the last author), in which a difference antigen tests are tested for reliability, the correlation "positive antigen test" and viral load as well as infectivity is explicitly described. Already in the abstract it says: "The sensitivity

of the 124 samples (= 9%) which were RT-qPCR positive (here with a CT of 33-34) but antigen positive in the rapid antigen test and RT-qPCR (here with a CT of approx. 27), but only from 11 viruses. Here, viruses could be grown from 85 of the total 147 samples (= 58%) which were rapid test negative.

Another study from the CGC (<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8026170/>) correlated a positive antigen test with a CT of less than 29, and the culturability of virus in cell culture (also to CT29). All subject samples positive in RT-qPCR with a CT 33 were negative in antigen detection.

accordance with §11 of the Medical Devices Act (https://www.bfarm.de/DE/Medizinprodukte/Antigentests/_node.html). In addition, these tests are widely performed by untrained, non-medical personnel or even as "self-tests"

Regarding this problem of performing rapid antigen tests, Professor Oliver Keppler, M.D., chief of virology at the Max Pettenkofer Institute at Munich's Ludwig Maximilian University, calls for the following in an article in the Jan. 13, 2021, issue of *Pharmazeutische Zeitung* (DOI: 10.1007/s00430-020-00698-8): "[...] these tests would also absolutely have to be performed correctly. "This should be in the hands of trained professionals," he says. "Now there is the idea of recruiting large numbers of job seekers to perform such tests in nursing homes. If untrained personnel are used, I'm concerned that the reliability of the test results will suffer even further"

In a recent interview [<https://www.br.de/nachrichten/wissen/virologe-keppler-kritisiert-corona-schnelltests-falsche-sicherheit,91900d/2>], O. Keppler comments on the question "How reliable is a positive test result?" as follows: "Unfortunately, there are also problems with the specificity of the rapid antigen tests: Depending on the incidence and the test used, according to RKI data, there are about ten "false" positives for every "true" positive. This also has serious consequences for the person affected: Immediate report to the health department and quarantine until a negative PCR is obtained, compile contact lists. This causes a great deal of expense, loss of work and school for several days, and last but not least, unwarranted anxiety. It also further undermines confidence in the national testing strategy."

A recent Cochrane review article (<https://www.cochrane.de/de/news/aktualisierter-cochrane-review-bewertet-zuverlaessigkeit-von-schnelltests-zum-nachweis-von-covid-19>) also concludes that rapid antigen tests are significantly more reliable in symptomatic individuals than in asymptomatic tested individuals. However, even in symptomatic individuals, the reliability of the best of the rapid tests evaluated in this study is significantly limited, leading the authors to describe the following scenarios:

1. "In a population of 1000 symptomatic individuals, 50 of whom actually have COVID-19, these rapid tests can be expected to correctly identify approximately 40 individuals as COVID-19 infected and miss between 6 and 12 cases of COVID-19. Between 5 and 9 of the positive test results would turn out to be false positives upon review."
2. "In a group of 10,000 persons without symptoms, in which 50 persons are truly infected with SARS-CoV 2, between 24 and 35 persons would be correctly identified as virus carriers, and between 15 and 26 cases would be missed. One would have to expect that the tests would yield between 125 and 213 positive results and that between 90 and 189 of these positive results would actually be false positives."

Also in the current publication of the working group of C. Drosten at the Charité the problem of "false positives" - here however under controlled laboratory conditions - is pointed out and discussed. The tests reviewed reacted falsely positive with various common respiratory viruses - which was confirmed by negative RT-qPCR using E-gene detection. "All negative samples that showed a SARS-CoV-2 false-positive result in AgPOCTs were retested and confirmed as false-positive with SARS-CoV-2 RT-rtPCR." (page 5 in <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8026170/> top.) The authors around C. Drosten consider a false positive rate of up to 3% as acceptable and in two tests even found exceptions of 5% false positives. „We observed acceptable rates of false-positive results (<3%) with most AgPOCTs, but rates greater than 5% with two assays in particular“

Thus, even under controlled laboratory conditions with skilled personnel, an average of 30 false positive results would be obtained with commercial rapid tests out of 1000 rapid tests due to cross-reactivity with other respiratory viruses or "unknown factors", according to the publication by C. Drosten. („thus, a specific factor other than the tested pathogens was likely to have caused positive signals“)

The fact that the high rate of false positive tests in large-scale testing in the population occurs at a time of low viral incidence is shown by an article in the German Ärztezeitung of 04.07.2021 (<https://www.aerztezeitung.de/Wirtschaft/80-Prozent-der-positiven-Corona-Schnelltests-falsch-positiv-421053.html>). At the end of the regular cold season (May), about 50% of rapid tests were already reported as false positive, and this rate increased until it reached 80% false positive tests in June. The data of the article are based on the information of the Hamburg senate on a small inquiry of the CSU parliamentary group. The evaluation was based on a total of 308,000 reported antigen rapid tests in Hamburg of which 218 tests were positive (= 0.07% of those tested) and after PCR confirmation then only 44 (=0.014% of all those tested) remain.

For the consequences of false positive results due to lack of test specificity, see under 2.3.1. "Pre-test probability"

2.5 Conclusion:

The rapid antigen tests used for mass testing cannot provide any information about infectivity, since they can only detect protein components without any connection to an intact, replicable virus. 1.

- 1) In order to allow an estimation of the infectivity of the tested persons, the respective positive test (similar to RT-qPCR) would have to be individually compared with a cultivability of viruses from the test sample, which is impossible under the extremely variable and unverifiable test conditions.

2. The low specificity of the tests causes a high rate of false positives, which result in unnecessary personnel (quarantine) and societal (e.g. schools closed, "outbreak notifications") efforts until they turn out to be false alarms.

Statement

I assure that I have prepared the expert opinion impartially and to the best of my knowledge and belief and based on valuable and official scientific and public sources.

Signature:

14 September 2021

Address:

Dpt. OB/Gyn, Research Lab, University Hospital of Würzburg
Würzburg, Germany.

e-mail:

7

sworn testimony pro bono. I multiple court challenges to various lockdown policies testimony on school mask mandates, I have also provided expert affidavits and policy regarding COVID-19, including two such occasions when I provided legislatures, and Florida Governor regarding various aspects of the science and I have been invited to testify several times to the U.S. Congress, U.S. state

6

in addition to my published work on COVID-19, I have been invited to serve as a peer reviewer for many scientific journals to review COVID-19 related submissions by other scientists. These journals include the British Medical Journal, Health Affairs, the Journal of Infectious Disease, the Annals of Internal Medicine, and several other journals. I have also submitted to the New England Journal of Medicine, and by editor scientists. In addition to my scientific publications, I have published a book reviewing the efficacy of lockdown policies in slowing disease spread, including the first published population seroprevalence study, and an empirical analysis of the epidemic. Among these papers include two highly cited papers.

5

I have actively researched the COVID-19 epidemic using my expertise in infectious disease epidemiology and health economics. To date, I have published

4

multiple editorials, including on economic, epidemiological, public health issues six papers in peer-reviewed journals related to the epidemic, and I have published six papers in peer-reviewed journals related to the epidemic, and I have published

3

I have worked at Stanford as a Professor of Medicine continuously since 2001 and I have spent most of my career in the United States of America, my opinion covers both global and Australian conditions.

2

Although I am in the United States of America, my opinion covers both global and economics, with a focus on infectious disease epidemiology.

1

I am [REDACTED] years of age, and I am employed as a tenured Professor of Medicine at Stanford University in California in the United States of America.

I say on oath:

Date 15 September 2021

Occupation Professor of Epidemiology

Name [REDACTED]

Address [REDACTED]

(On separate page)

In Florida, California, Maryland, and Michigan, as well as in Quebec, Alberta, and Nunavut, Canada. Among the cases I have advised include three religious liberty cases that have reached the U.S. Supreme Court and two cases involving the provision of in-person schooling (one in Florida and one in California).

- 8 I annex my curriculum vitae and mark that as "JB1".
- 9 I annex my expert report hereeto and mark that as "JB2".
- 10 I am aware of the Expert Code of Conduct (Code) as stipulated in the Rules of the Court; I have read a copy of the Code, and the documents regarding the emergency declaration imposing lockdown. I agree to comply with the provisions of the Code and the intent of these provisions.
- 11 I am available to give evidence via audio visual means as and when the Court sees fit.

SWORN at

Sydney

Signature of deponent

Sydney NSW 2000

Name of witness

Address of witness

Capacity of witness

Solicitor

Act as a witness, I certify the following matter concerning the person who made the affidavit that the person:

- 1 saw the face of the deponent. [REDACTED] (I have seen the face of the deponent on [REDACTED])
- 2 did not see the face of the deponent because the deponent was wearing a face covering or had an unaffected face. (I have seen the deponent had a significant problem breathing when wearing a face covering.)
- 3 have informed the deponent to at least 12 months.

Signature of witness

[REDACTED]

Note: The deponent and witness must sign and affix their name to this document. See page 1 for details.

¹ "Properly signed" affidavit for NSW referring to facts concerning a single grade nuclear reactor (at April 2012).

² "Identifiable documents" include current driver licence, credit card, Medicare card, credit card, California permanent voter's Affairs identification card, student identity card, library card, telephone bill, etc. (See, e.g., section 2(1) of the Privacy Handbook, section 2(3) "Identifying an individual in personal information from other personal information held by the body".)

[REDACTED] September 2021

Address
[REDACTED]

Phone
[REDACTED]

Email
[http://\[REDACTED\]](http://[REDACTED])

RESEARCH INTERESTS:
[REDACTED]

A. ACADEMIC HISTORY:

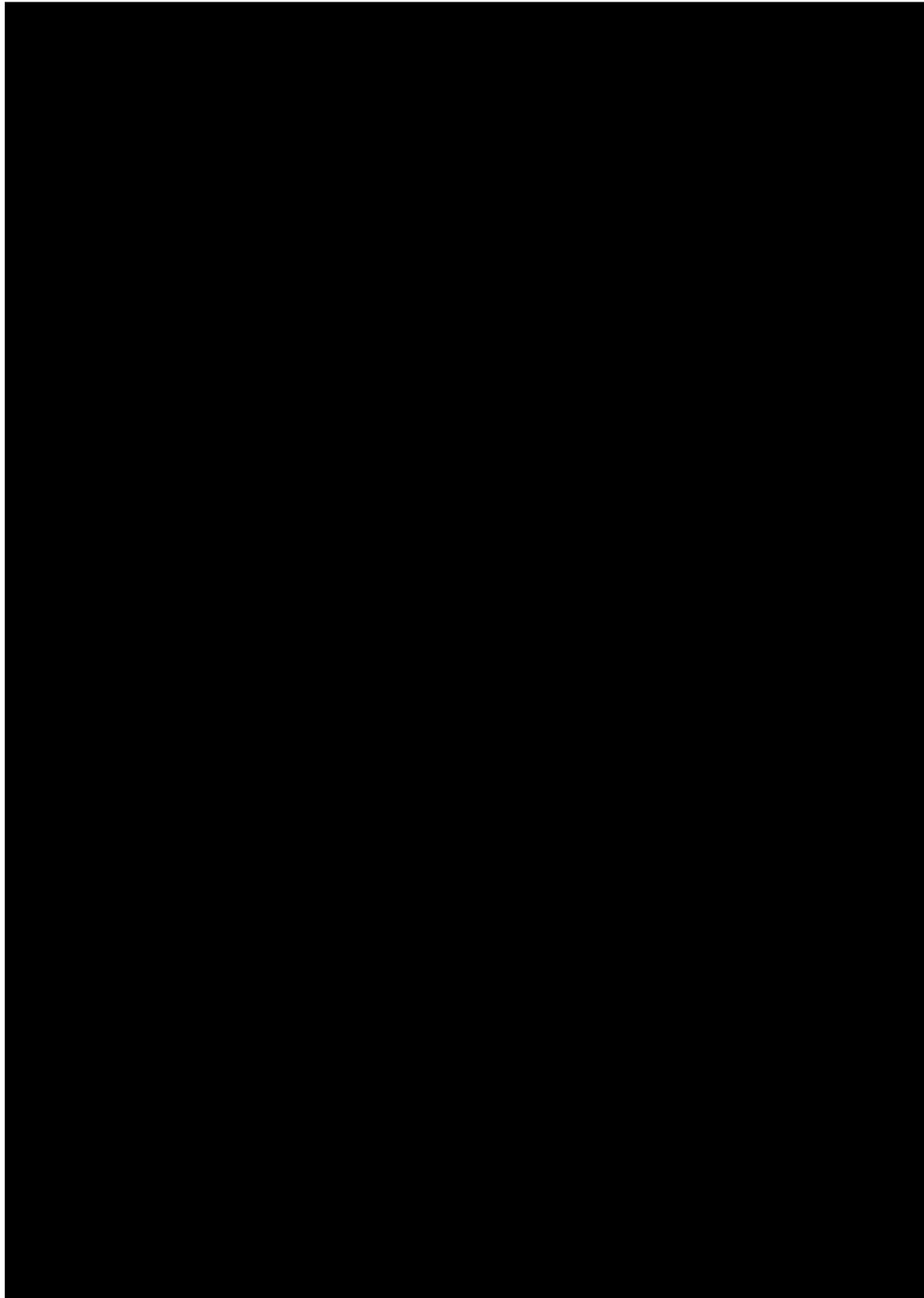
Stanford University
Stanford University School of Medicine
Stanford University Department of Economics

B. EMPLOYMENT HISTORY:
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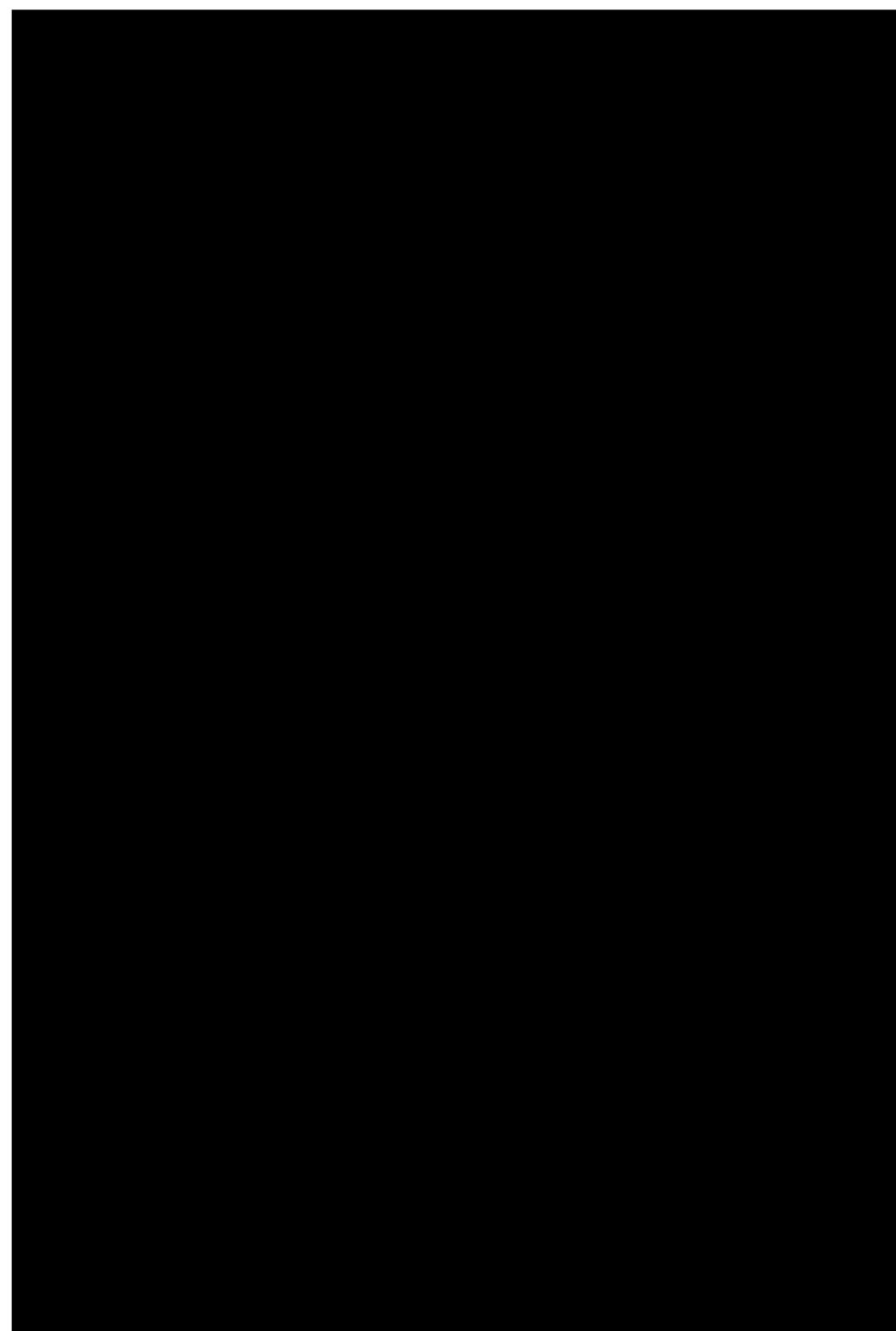
C. SCHOLARLY PUBLICATIONS:

PEER-REVIEWED ARTICLES (154 total)
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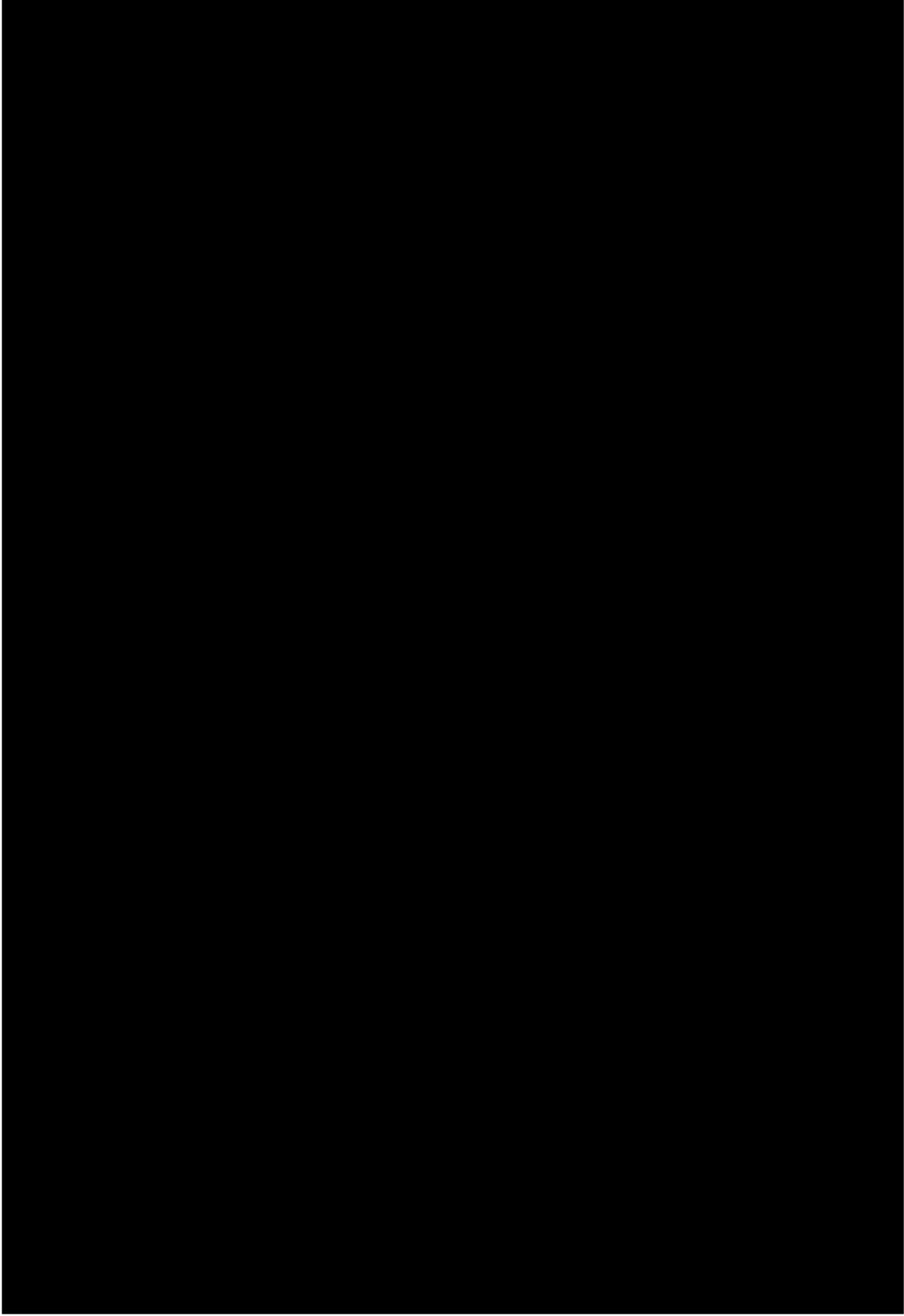
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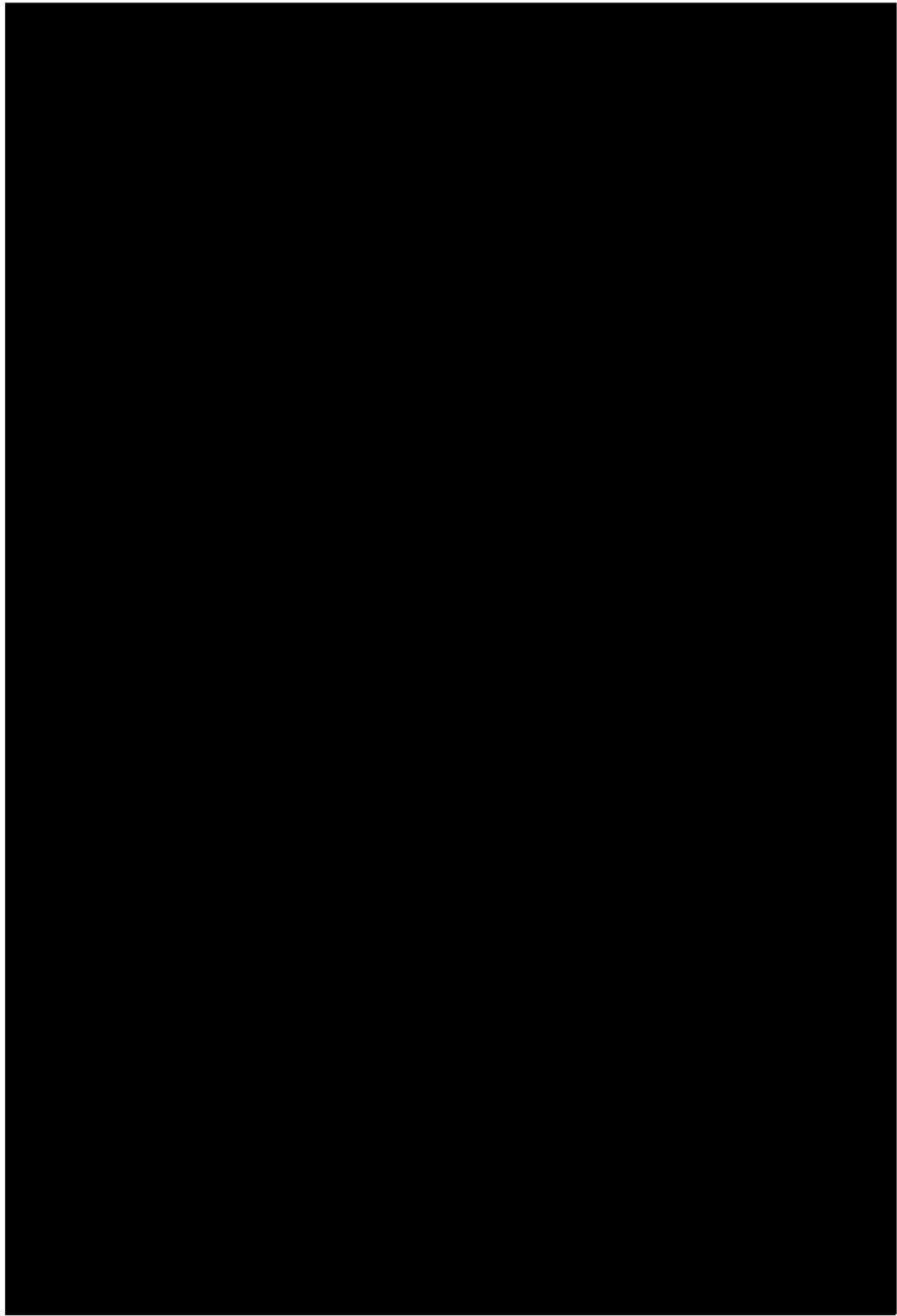
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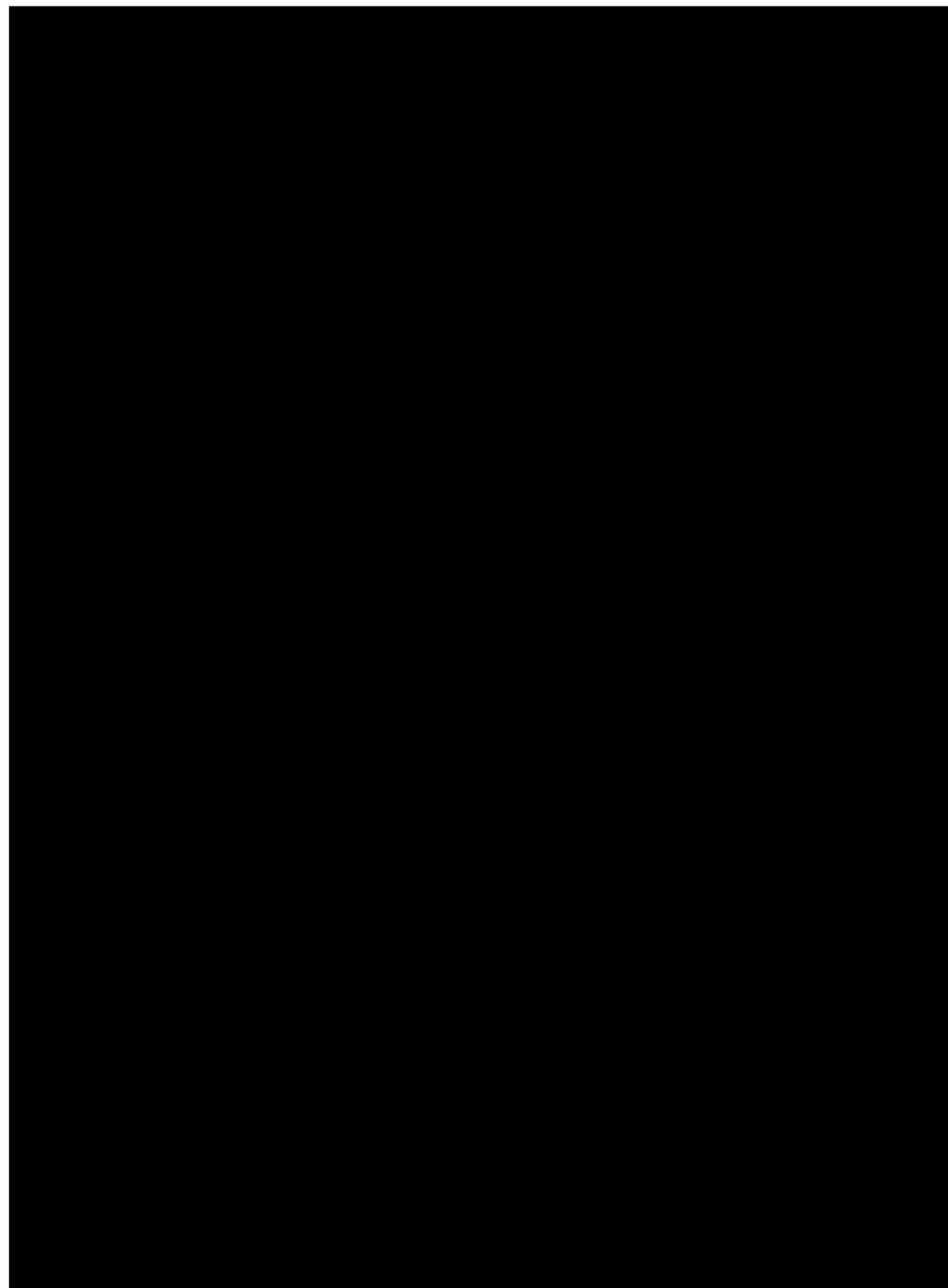
September 2021



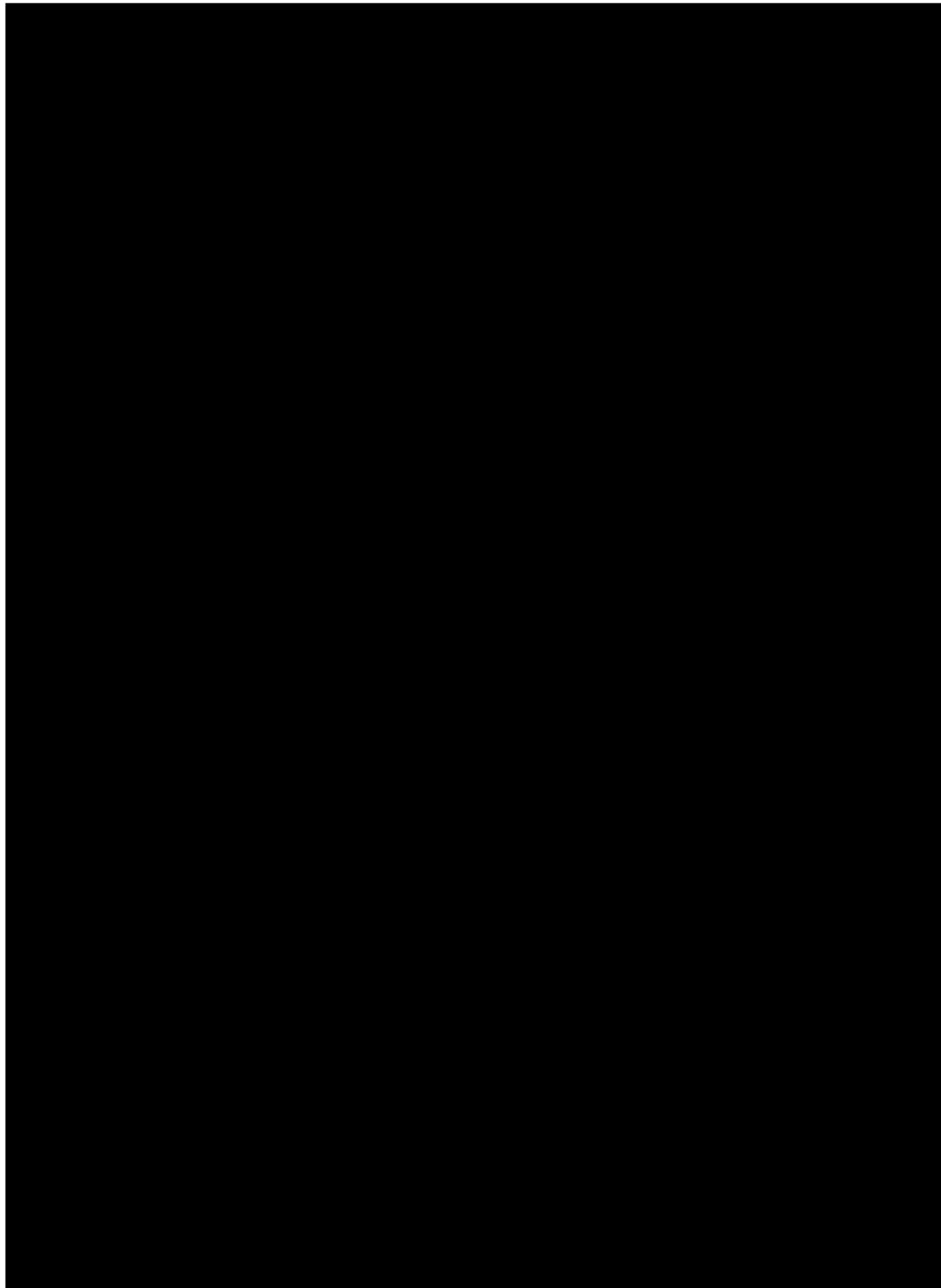
September 2021



September 2021



September 2021



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September 2021

