CLIENT AND HEALTH CARE WORKER COVID 19 ANTIBODY TEST INFORMATION SHEET:

INTRODUCTION:

Covid-19 virus is rapidly evolving and the full characteristics of the SARS-CoV-2 are still being revealed. Zens Medical Laboratory Guideline will continue to be updated as information comes through. Therefore, it is essential that healthcare workers seeking assistance via Zens Medical Guideline need to follow the most upto date guideline in regards to the infection.

Coronaviruses (CoV) are a large family of respiratory viruses that can cause diseases ranging from the common cold to the Middle-East Respiratory Syndrome (MERS) and the Severe Acute Respiratory Syndrome (SARS). SARS-CoV and MERS-CoV initially emerged from zoonotic (animal) sources; similarly initial infections with the Wuhan associated SARS-CoV-2 have been associated with a seafood / animal market. Subsequently, human-to-human transmission of SARS-CoV-2 has now been confirmed, including cases acquired by healthcare workers.

Common signs and symptoms of SARS-CoV-2 infection include fever, cough, and Dyspnoea of varying severity. Chest imaging may show bilateral infiltrates. In more severe cases, infection can cause pneumonia, severe acute respiratory syndrome, kidney failure and even death. Some patients become infected but don't develop any symptoms or feel unwell.

Furthermore, about 80% of patients recover from the disease without needing special treatment. About 1 in 6 people infected become seriously ill and fatality rate is variable where the average ranges from 2-4%

PRE-TEST AND POST- TEST PATIENT COUNSELING AND CONSENT IS MANDATORY

ZENS MEDICAL CENTRE CONSENT FORM FOR THE CORONAVIRUS ANTIBODY TEST and MOHMS TREATMENT

I have been informed that my blood obtained from a finger stick or vein, a urine sample, or an oral sample from my mouth, will be tested for antibodies to the Corona- Virus, the virus that causes COVID 19.

I acknowledge that I have been given an explanation of the test, including its uses, benefits, limitations and the meaning of test results. I have been informed that the Serological test results are confidential and shall not be released without my written permission, except to: Ministry of Health and Medical Services of Fiji and as permitted under state law.

I understand that I have the right to withdraw my consent for the test at any time before the test is complete. I have been given the opportunity to ask questions concerning the test for COVID 19 antibodies, and I acknowledge that my questions have been answered to my satisfaction. By my signature below, I consent to be tested for COVID 19 rapid test.

_____ _____

Patient/Parent/Guardian Signature Date

_____ _____

Witness _____ Date _____

AT THIS TIME, I DO NOT WANT TO BE TESTED FOR THE CORONAVIRUS

_____ _____

Patient/Parent/Guardian Signature Date

_____ _____

Witness _____ Date _____

The above is to ensure that patients understand that this test is solely for the purpose of surveillance and not acute diagnosis of the disease.

RECOMMENDED INDICATIONS FOR ANTIBODY TESTING

Zens Medical Centre recommends that antibody testing is to be used ONLY for surveillance and epidemiological studies of COVID 19 and SHOULD NOT BE USED FOR ACUTE DIAGNOSIS OF THE DISEASE.

If patient is symptomatic, we recommend using PCR, which is the gold standard for acute diagnosis of COVID 19.

SPECIMEN COLLECTION AND PREPARATION

SPECIMEN REQUIRED IS SERUM SAMPLE FREE OF HAEMOLYSIS. SPECIMEN NEEDS TO BE COLLECTED IN STERILE TUBE AND KEPT AT 2-8^{o}C AND KEPT UPRIGHT.

Collection is done at a dedicated collection room which has been isolated from other General Out-Patient Department (GOPD). This collection centre is based at our Nadi Centre:

Standard Operational Procedure are being strictly adhered to during the collection process, to ensure the safety of patient and the health care worker alike. Below is the process that is being followed during blood collection:

A. Complete washing hand and arm 1 palm above elbow
B. Dry Hand and arm using paper towel
C. Discard paper towel in the yellow bin provided
D. Put on Mask provided
E. Take a seat and place your arm on the table through the plastic wall
F. After bleeding, chairs, table and the sink is wiped out.

ERFORMANCE CHARACTERISTICS:

Sensitivity- Clinical sensitivity for IgM and IgG was determined in China and was found to be 78.65% and 91.21% respectively and when used in conjunction with each other, clinically sensitivity was significantly higher at 89.9% and 95.60% respectively

Specificity-The clinical specificity for IgM and IgG was found to be 96.50% and 96.0% respectively

RESULT INTERPRETATION AND TEST GUIDELINES:

- Non-reactive: A result less than 0.900 AU/mL (<0.900AU/mL) is considered to be non-reactive
- Equivocal: A result in the interval between 0.900 and 1.100 ($0.900 \leq x < 1.10$ is considered to be equivocal
- Reactive: A result greater than or equal to 1.10 AU/mL ($\geq$1.10AU/mL) is considered to be reactive.

IGM

Positive IgM result indicates patient highly likely has a current COVID-19 infection, since the, specificity of the test reagent is high. All positive results are to be correlated clinically, and a Polymerase Chain Reaction (PCR) test is recommended.

Negative result may suggest either the client does not have a current infection or it is to early in the disease phase to be detected, therefore we suggest a PCR or a repeat IgM and IgG

IGG

Positive result is highly likely indicative of a COVID-19 virus infection as the specificity is 100%.

Negative result suggest highly likely that the patient either has not been previously infected with COVID 19 at all or has not acquired immunity to the virus as it may be too early in the phase of the disease or because of Acquired Immune Deficiency.

Therefore, clinical correlated is strongly suggested.

EQUIVOCAL RESULTS FOR IGG AND IGM

Equivocal results are suggestive of the antibodies not being either sufficient or insufficient to conclude an infection or non-infection respectively.

Equivocal results solicits a repeat of both the test in few days and/or a PCR test for confirmation.

Clinical correlation is strongly advised.

Please refer to the figure below (Fig 1):

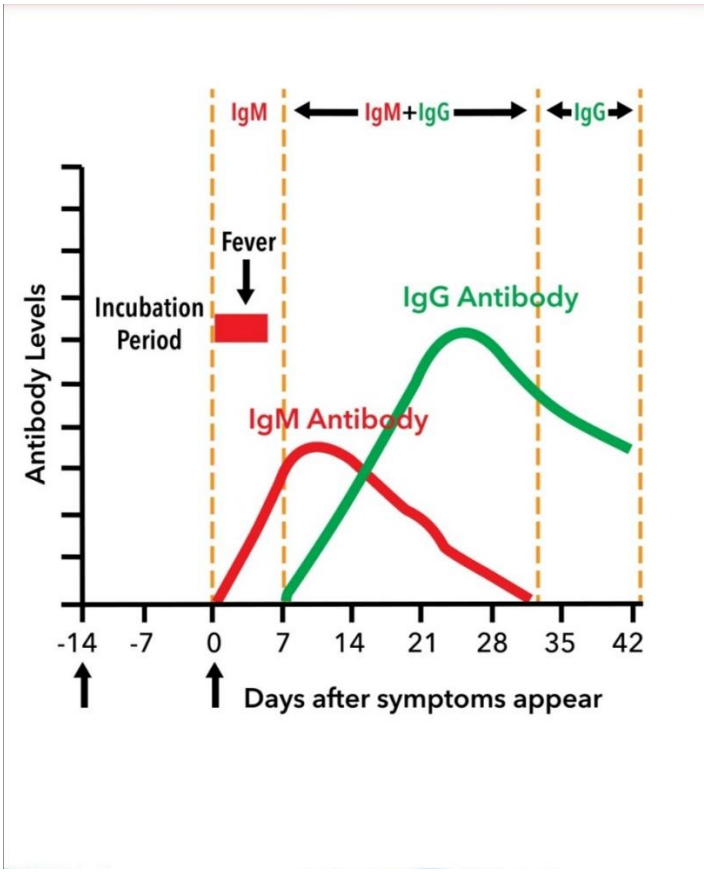

Figure 1: the graph above summarizes how both the antibodies rise and fall during the period of infection…

TECHNICAL INFORMATION ON LABORATORY TESTING FOR COVID 19 TEST:

PRINCIPLE OF TESTS:

IGM:

The MAGLUMI 2019-nCov IgM (CLIA) assay is an indirect chemiluminescence immunoassay.

The prediluted sample (or calibrator/control, if applicable), buffer, magnetic microbeads coated with anti-human IgM monoclonal antibody are mixed thoroughly and incubated, forming immune-complexes. After precipitation in a magnetic field, decant the supernatant, and perform a wash cycle. Then add 2019-nCoV recombinant antigen labelled with ABEI and incubate to form complexes. After precipitation in a magnetic field, decant the supernatant, and then perform another wash cycle. Subsequently, the starter 1+2 are added to initiate a chemiluminescent reaction. The light signal is measured by photomultiplier as relative light units (RLUs), which is proportional to the concentration of 2019-nCoV IgM present in the sample (or calibrator/control if applicable).

IGG:

The MAGLUMI 2019-nCov IgG (CLIA) assay is a capture chemiluminescence immunoassay.

The prediluted sample (or calibrator/control, if applicable), buffer, magnetic microbeads coated with 2019-nCov recombinant antigen are mixed thoroughly and incubated, forming immune-complexes. After precipitation in a magnetic field, decant the supernatant, and perform a wash cycle. Then add ABEI labelled with anti-human IgG antibody and incubate to form complexes. After precipitation in a magnetic field, decant the supernatant, and then perform another wash cycle. Subsequently, the starter 1+2 are added to initiate a chemiluminescent reaction. The light signal is measured by photomultiplier as relative light units (RLUs), which is proportional to the concentration of 2019-nCoV IgG present in the sample (or calibrator/control if applicable).

KIT COMPONENTS

Materials provided: IGM

COMONENTS	CONTENTS	100 tests (REF:1302190 16M
Magnetic Microbeads	Magnetic micobeads coated with anti-human IgM monoclonal antibody, PBS buffer and BSA, NaN_3 (<0.1%).	2.5mL
Calibrator Low	2019-nCoV IgM, PBS Buffer and BSA, NaN_3 (<0.1%).	1.0mL
Calibrator high	2019-nCoV IgM, PBS buffer, and BSA, NaN_3 (<0.1%).	1.0mL
Buffer	PBS buffer, Goat anti-Human IgG, Goat anti-Human IgA Mouse IgG, Goat IgG and BSA, NaN_3 (<0.1%).	23.5mL
ABEI Label	2019-nCov recombinant antigen labeled with ABEI, Tris-HCL buffer, Mouse IgG, Goat IgG and BSA, NaN_3 (<0.1%).	23.5Ml
Diluent	PBS buffer, Goat anti-Human IgG, Goat anti-Human IgA	23.5mL

	Mouse IgG, Goat IgG and BSA, NaN_3 (<0.1%).	
Negative Control	PBS buffer contatining BSA, NaN_3 (<0.1%).	1.0Ml
Positive Control	2019-nCoV IgM, PBS buffer, containing BSA and NaN_3 (<0.1%).	

All reagants are provided ready-to-use

Materials provided: IGG

COMONENTS	CONTENTS	100 tests (REF:1302190 16M
Magnetic Microbeads	Magnetic micobeads coated with 2019 n-CoV recombinant antigen, PBS buffer and BSA, NaN_3 (<0.1%).	2.5mL
Calibrator Low	2019-nCoV IgG, PBS Buffer and BSA, NaN_3 (<0.1%).	1.0mL
Calibrator high	2019-nCoV IgG, PBS buffer, and BSA, NaN_3 (<0.1%).	1.0mL
Buffer	Nacl and BSA, NaN_3 (<0.1%).	23.5mL
ABEI Label	Anti- Human IgG antibody labeled with ABEI, Tris-HCL buffer, Mouse IgG, Goat IgG and BSA, NaN_3 (<0.1%).	23.5Ml
Diluent	PBS buffer,and BSA, NaN_3 (<0.1%).	23.5mL
Negative Control	PBS buffer contatining BSA, NaN_3 (<0.1%).	1.0Ml
Positive Control	2019-nCoV IgG, PBS buffer, containing BSA and NaN_3 (<0.1%).	

All reagents are provided ready-to-use

CALIBRATION:

IGM & IGG

Traceability: this method has been standardized against the SNIBE internal reference substance.

Test of assay specific calibrators allows the RLU values to adjust the assigned master curve to adjust to assigned master curve. Results are determined via a calibration curve which is instrument-specifically generated by 2-point calibration and a master curve (10 calibrators) provided via the reagent Radio Frequency Identification (RFID) CHIP.

Recalibration is recommended if any of the following condition occurs:

. After each exchange of lots (reagent of starter 1+2)

. Every week and/or each time a new reagent kit is used.

. After instrument service is required

. If controls lie outside the expected range

QUALITY CONTROL

IGM & IGG

It is recommended that government regulations need to be followed for quality control frequency.

Internal quality control is only applicable with MAGLUMI system. For instructions for use and target value refer to **2019-nCoV IgM Quality control and 2019-nCoV IgG Quality control information** respectively. User needs to judge results with their own standards and knowledge.

For details about entering quality control values, refer to the operating instructions of MAGLUMI series Fully-atuo chemiluminescence immunoassay analyzer.

To monitor system performance, quality control materials (negative control and positive control) are required. Test all quality control samples with the same level of care as patient samples. A satisfactory level of performance is achieved when analyte values obtained are within the acceptable Control Range for the system or within your range as determined by an internal laboratory quality control scheme. If the quality control results do not fall within the Expected values or within the laboratory's established values, measurement of the quality control should be repeated. If the quality control results do not fall within the range, do not report results and take the following actions:

. Verify that the materials are not expired

. Verify that required maintenance was performed

. Verify that the assay was performed according to the instruction for use

. Rerun the assay with fresh quality control samples

. If necessary, contact your local technical support provider or distributor for assistance

DENATURING OF SAMPLE PRIOR TO TESTING:

BEFORE CENTRIFUGING OR OPENING SPECIMEN, INCUBATE SPECIMEN IN THE INCUBATOR AT 56 DEGREES CELCIUS FOR 30 MINUTES. THIS DENATURES THE VIRUS PROTEIN, AFTER WHICH, SPECIMEN CAN BE PROCESSED.

PROCEDURE OF TEST:

IIGM

- Take the reagent kit out of the box and observe the sealing film and other parts of the reagent kit to see if there is any leakage. In case of leakage please contact your local distributor immediately, and then tear off the kit sealing film carefully.
- Open the reagent area door; hold the reagent handle to get the RFID label close to the RFID reader (for about 2s); the buzzer will beep; one beep sound indicates successful sensing.
- Keeping the reagent straight, insert to the bottom along the blank reagent track.
- Observe whether the reagent information is displayed successfully in the software interface, otherwise repeat the above steps.
- Re-suspension of the magnetic micro beads takes place automatically when the kit is loaded successfully, ensuring the magnetic micro beads are totally re-suspended homogenous prior to use.

Assay Calibration:

Click <calibration> or <Batch Calibration> button tp execute calibration operation; for specific information on ordering calibrations, refer to the Calibration Section of the Operating instructions.

Execute recalibration according to the calibration interval required in this packet insert.

Quality Control:

In order to avoid manual error in the entry of QC information, the provided barcode labels of quality control in the kit can be used attached on the tests tubes.

If users do not use the provided barcode labels for positive and negative controls contained within the packaging, then quality controls should be ordered manually.

For specific information on ordering quality controls, refer Quality Control Section of the Operating Instructions.

Sample Testing:

Order the samples in the Sample Area of the software and click <start> button to execute testing. For specific information on ordering patient specimens, refer to the Sample Ordering Section of the operating instructions.

To ensure proper test performance, strictly adhere to the operating instructions of MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer.

DILUTIONS: The high concentration samples can be diluted automatically by analyzers or manually. The recommended dilution is 1:19 with diluent 2019-nCoV IgM negative human samples.

After manual dilution, multiply the result by the dilution factor. After dilution by the analyzer, the analyzer software automatically takes the dilution into account when calculating the sample concentration.

The automatic sample dilution is available after the dilution settings are done in the MAGLUMI series Fully-automated chemiluminescence immunoassay analyzer.

LIMITATIONS:

. This test is suitable only for investigating single samples, not for pooled samples.
. Bacterial contamination or repeated freeze-thaw cycles may affect the test results.
. Assay results should be utilized in conjunction with other clinical and laboratory methods to assist the clinician in making individual patient diagnostic decisions.
. Assay results should not be used as a sole basis for the diagnosis and execution of novel coronavirus pneumonia, but only as a supplement to existing viral nucleic acid detection reagents and imaging features.
. It is recommended to be used in conjunction with 2019-nCoV IgG testing to improve clinical sensitivity.
.If the 2019-nCoV IgM results are inconsistent with clinical evidence, additional testing is suggested to confirm the result.
. HAMA antibodies in the test samples may cause interference in immunoassays.

CAUTION: this product requires the handling of human specimens. it is recommended that all human sourced materials be considered potentially infectious and handled in accordance with the 29 CFR 1910.1030 Occupational exposure to bloodborne pathogens. Biosafety Level 2 or other appropriate biosafety practices should be used for materials that contain or are suspected of containing infectious agents.

All samples, biological reagents and materials used in the assay should be considered potentially able to transmit infectious agents. They should therefore be disposed in accordance with the national guidelines for such waste disposal.

This product contains Sodium Azide. Dispose of contents and container must be in accordance with local, regional and national regulations.