Snibe Diagnostic

CE 130219018M

MAGLUMI 2019-nCoV IgM/IgG

Cat. # 130219018M

℞ *For U.S.A. only, Federal law restricts this device to sale and distribution by or on the order of a physician, or to a clinical laboratory; and use is restricted to by or on the order of a physician.*

For in vitro diagnostic use

For Emergency Use Authorization Only

For Prescription Use only

INTENDED USE

The MAGLUMI 2019-nCoV IgM/IgG is an *in vitro* chemiluminescence immunoassay intended for the qualitative detection and differentiation of immunoglobulin M (IgM) and immunoglobulin G (IgG) antibodies to SARS-CoV-2 in human serum and serum in separating gel tubes (SST) using the MAGLUMI 2000 series fully-automated chemiluminescence immunoassay analyzer. The MAGLUMI 2019-nCoV IgM/IgG is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. At this time, it is unknown for how long antibodies persist following infection and if the presence of antibodies confers protective immunity. The MAGLUMI 2019-nCoV IgM/IgG should not be used to diagnose acute SARS-CoV-2 infection. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C 263a, that meet requirements to perform moderate or high complexity testing.

Results are for the detection and differentiation of SARS CoV-2 antibodies. IgM and IgG antibodies to SARS-CoV-2 are generally detectable in blood several days after initial infection, although the duration of time antibodies are present post-infection is not well characterized. Individuals may have detectable virus present for several weeks following seroconversion.

Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.

The sensitivity of the MAGLUMI 2019-nCoV IgM/IgG early after infection is unknown. Negative results do not preclude acute SARS-CoV-2 infection. If acute infection is suspected, direct testing for SARS-CoV-2 is necessary.

False positive results for the MAGLUMI 2019-nCoV IgM/IgG may occur due to cross-reactivity from pre-existing antibodies or other possible causes.

The MAGLUMI 2019-nCoV IgM/IgG is only for use under the Food and Drug Administration's Emergency Use Authorization.

SUMMARY AND EXPLANATION OF THE TEST

The novel coronavirus (2019-nCoV) causes an epidemic of acute respiratory syndrome in humans[1] and belongs to the genus *Betacoronavirus*. The virus has an envelope; viral particles are round or oval, often polymorphic, and the diameter is 60 - 140nm. Its genetic characteristics are significantly different from SARS-CoV and MERS-CoV. Current research shows that it has more than 85% homology with bat SARS-like coronavirus (bat-SL-CoVZC45)[2].

2019-nCoV is mainly transmitted through respiratory droplets and can also be transmitted through direct contact. The symptoms of infection seen so far are mainly patients with pneumonia infected by the novel coronavirus[2].

Research has shown that IgM and IgG antiviral antibodies can be detected in serum samples from a patient[3]. After human infection with 2019-nCoV, its antigen stimulates the immune system to produce an immune response, and corresponding antibodies appear in the blood after several days.

The kit should not be used to diagnose or exclude acute SARS-CoV-2 infection or to inform infection status. The test is used as an aid to identify patients with antibodies to SARS-CoV-2 indicating recent or past infection.

The World Health Organization announced the interim name of the novel coronavirus as 2019-nCoV on January 7, 2020: The International Committee on Taxonomy of Viruses (ICTV) announced Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) as the official name of the virus on February 11, 2020. On the same day, the Director General of the World Health Organization (WHO) Tedros Adhanom Ghebreyesus announced that the name for the disease associated with infected with SARS-CoV-2 would be officially named "COVID-19," short for coronavirus disease 2019.

PRINCIPLE OF THE TEST

The MAGLUMI 2019-nCoV IgM/IgG is a capture chemiluminescence immunoassay for IgM and an indirect chemiluminescence immunoassay for IgG. There are two cassettes that are run separately one for the detection of IgG antibodies to SARS-CoV-2 and another for the detection of IgM antibodies to SARS-CoV-2 from barcoded patient samples. After both cassettes have been run individually, one report with results for both IgM and IgG detection is generated by the system.

MAGLUMI 2019-nCoV IgM/IgG – Cassette for IgM Detection

The sample (serum in standard sampling tubes or tubes containing separating gel (SST)), buffer, and magnetic microbeads coated with anti-human IgM monoclonal antibody are mixed thoroughly and incubated, forming immune-complexes. After precipitation in a magnetic field, the supernatant is decanted, and a wash cycle is performed. Then, the 2019-nCoV recombinant antigen, expressing the full-length spike and nucleocapsid proteins, labeled with ABEI is added and incubated to form complexes. After precipitation in a magnetic field, the supernatant is decanted and another wash cycle is performed. Subsequently, the Starter Buffer is added to initiate a chemiluminescent reaction. The light signal is measured by a photomultiplier as relative light units (RLUs), which is proportional to the concentration of IgM present in the sample. The test is performed with the MAGLUMI 2000 series fully automated chemiluminescence immunoassay analyzer.

MAGLUMI 2019-nCoV IgM/IgG – Cassette for IgG Detection

The sample (serum in standard sampling tubes or tubes containing separating gel (SST)), buffer and magnetic microbeads coated with 2019-nCoV recombinant antigen, expressing the full-length spike and nucleocapsid proteins, are mixed thoroughly and incubated, forming immune-complexes. After precipitation in a magnetic field, the supernatant is decanted, and a wash cycle is performed. Then, the anti-human IgG antibody labeled with ABEI is added and incubated to form complexes. After precipitation in a magnetic field, the supernatant is decanted and another wash cycle is performed. Subsequently, the Starter Buffer is added to initiate a chemiluminescent reaction. The light signal is measured by a photomultiplier as relative light units (RLUs), which is proportional to the concentration of IgG presented in the sample. The test is performed with the MAGLUMI 2000 series fully automated chemiluminescence immunoassay analyzer.

KIT COMPONENTS – One kit contains two cassettes, one for SARS-CoV-2 IgG detection and another for SARS-CoV-2 IgM detection. The components for IgG and IgM detection with the MAGLUMI 2019-nCoV IgM/IgG are provided below and can be ordered under Catalog # 130219018M.

Cassette	Components	Contents	100 tests
For SARS CoV-2 IgG antibodies	**Magnetic Microbeads**	Magnetic microbeads coated with 2019-nCoV recombinant antigen, PBS buffer and BSA, NaN_3 (<0.1%)	2.5 mL
	Calibrator Low	2019-nCoV IgG, PBS buffer and BSA, NaN_3 (<0.1%)	1.0 mL
	Calibrator High	2019-nCoV IgG, PBS buffer and BSA, NaN_3 (<0.1%)	1.0 mL
	Buffer	NaCl and BSA, NaN_3 (<0.1%).	23.5 mL
	ABEI Label	Anti-human IgG antibody labeled with ABEI, Tris-HCl buffer, Mouse IgG, Goat IgG, and BSA, NaN_3 (<0.1%)	23.5 mL
	Diluent	PBS buffer and BSA, NaN_3 (<0.1%)	23.5 mL
	Negative Control	PBS buffer, containing BSA, NaN_3 (<0.1%)	1.0 mL
	Positive Control	2019-nCoV IgG, PBS buffer, containing BSA and NaN_3 (<0.1%).	1.0 mL
For SARS-CoV-2 IgM antibodies	**Magnetic Microbeads**	Magnetic microbeads coated with anti-human IgM monoclonal antibody, PBS buffer and BSA, NaN_3 (<0.1%).	2.5 mL
	Calibrator Low	2019-nCoV IgM, PBS buffer and BSA, NaN_3 (<0.1%).	1.0 mL
	Calibrator High	2019-nCoV IgM, PBS buffer, and BSA, NaN_3 (<0.1%).	1.0 mL
	Buffer	PBS buffer, Goat anti-Human IgG, Goat anti-Human IgA Mouse IgG, Goat IgG and BSA, NaN_3 (<0.1%).	23.5 mL
	ABEI Label	2019-nCoV recombinant antigen labeled with ABEI, Tris-HCl buffer, Mouse IgG, Goat IgG, and BSA, NaN_3 (<0.1%).	23.5 mL
	Diluent	PBS buffer, Goat anti-Human IgG, Goat anti-Human IgA Mouse IgG, Goat IgG and BSA, NaN_3 (<0.1%).	23.5 mL
	Negative Control	PBS buffer, containing BSA, NaN_3 (<0.1%).	1.0 mL
	Positive Control	2019-nCoV IgM, PBS buffer, containing BSA and NaN_3 (<0.1%).	1.0 mL
All reagents are provided ready-to-use.			

Components Required but Not Included in the MAGLUMI 2019-nCoV IgM/IgG Test Kit :

Component	Catalog number	Contents	Quantity/Volume
Reaction Module	630003	polypropylene	64/box

Starter Buffer	130299004M	Catalyst in 1.5% NaOH, 0.18% H2O2	230 mL×1
Wash Concentrate	130299005M	Tris-HCl buffer solution	714 mL×1
Light Check	130299006M	ABEI (N-(4-Aminobutyl)-N-ethylisoluminol), BSA	2mL×5

Instrument
MAGLUMI 2000 series fully-automated chemiluminescence immunoassay analyzer

Please order all above from Shenzhen New Industries Biomedical Engineering Co., Ltd. (SNIBE) or our authorized representative.

CALIBRATION

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

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

Recalibration is recommended if any of the following conditions occurs:

- After each exchange of lots (Reagent or Starter Buffer).
- 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

Follow government regulations or accreditation requirements for quality control frequency.

Quality controls (positive and negative controls) are only applicable with MAGLUMI system.

For details about entering quality control values, refer to the operating instructions of MAGLUMII 2000 series fully-auto chemiluminescence immunoassay analyzer.

To monitor system performance, quality control materials (positive and negative) are required. Treat all quality control with the same level of care as patient samples. A satisfactory level of performance is achieved when analyte values obtained are within the acceptable pre-established ranges. If the quality control results fall outside the pre-established ranges of less than 0.7 AU/mL for negative controls and 2.8-5.2 AU/mL for positive controls, measurement of the quality control should be repeated. If the quality control results still falls outside the pre-established range, do not report results and take the following actions:

- Verify that the quality control materials (positive and negative) are not expired.
- Verify that the analyzer required maintenance was performed.
- Verify that the assay was performed according to the instruction for use.
- Rerun the assay with new quality control samples (positive and negative).
- If necessary, contact your local technical support provider or distributor for assistance.

SPECIMEN COLLECTION AND PREPARATION- WARNINGS AND PRECAUTIONS

- Serum in standard sampling tubes or tubes containing separating gel is the recommended sample matrix. The sample volume required for a single determination is 10 µL.
- Samples may be infectious so heat inactivated of the samples at 56°C for 30 minutes should be performed before testing, or according to the requirements of state and local governments[2].
- Ensure that complete clot formation in specimens has taken place prior to centrifugation. Some specimens, especially those from patients receiving anticoagulant or thrombolytic therapy, may exhibit increased clotting time.
- If the specimen is centrifuged before complete clotting, the presence of fibrin may cause erroneous results. Samples must be free of fibrin and other particulate substances.
- Grossly hemolyzed specimens or specimens containing particulate matter or exhibiting obvious microbial contamination should not be used. All specimens should be inspected for bubbles and bubbles removed before analysis for optimal results.
- All samples (patient specimens and controls) should be tested within 3 hours of placing them on board the MAGLUMI System. Refer to the SNIBE service for more detailed discussion of onboard sample storage constraints. (website : https://www.snibe.com/zh_en/en_index.aspx)

- Specimens removed from the separator gel, cells, or clot may be stored for 3 days at 2-8°C. If longer storage is required, the specimens should be kept at -20°C or colder[4].
- Avoid more than three freeze and thaw cycles. Frozen specimens must be mixed thoroughly after thawing by low speed vortex or by gently inverting.
- For optimal results, specimens should be free of fibrin, red blood cells, or other particulate matter. Such specimens may give inconsistent results and must be transferred to a centrifuge tube and centrifuged at ≥ 10,000RCF (Relative Centrifugal Force) for 10 minutes. Transfer clarified specimens to a sample cup or secondary tube for testing. For centrifuged specimens with a lipid layer, transfer only the clarified specimen and not the lipemic material.
- Before shipping specimens, it is recommended that specimens be removed from the separator, red blood cells, or clot. When shipped, specimens should be packaged and labeled in compliance with applicable state, federal and international regulations covering the transport of clinical specimens and infectious substances. Specimens should be shipped frozen.

WARNING AND PRECAUTIONS FOR USERS

- IVD For *In Vitro* Diagnostic Use.
- For Emergency Use Authorization Only
- For Prescription Use only
- This test has not been FDA cleared or approved; this test has been authorized by FDA under an EUA for use by laboratories certified under CLIA and meet requirements to perform moderate or high complexity tests.
- This test has been authorized only for the presence of IgG or IgM antibodies against SARS-CoV-2, not for any other viruses or pathogens.
- This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.
- Follow the package insert carefully. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.

Safety Precautions

- **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 of in accordance with the practices of your institution. Discard all materials in a safe and acceptable manner and in compliance with prevailing regulatory requirements.
- This product contains Sodium azide. Dispose of contents and container must be in accordance with all local, regional and national regulations.
- Refer to safety data sheets, which are available on request.

Handling Precautions

- Do not use reagent kits beyond the expiration date.
- Do not interchange reagent components from different reagents or lots.
- Prior to loading the Reagent Kit on the system for the first time, the Reagent Kit requires mixing to re-suspend magnetic microbeads that have settled during shipment. For magnetic microbeads mixing instructions, refer to the Preparation of the Reagent section of this package insert.
- To avoid contamination, wear clean gloves when operating with a reagent kit and sample.
- Over time, residual liquids may dry on the septum surface. These are typically dried salts which have no effect on assay efficacy.
- To avoid evaporation of the liquid in the opened reagent kits in a refrigerator, it is recommended that the opened reagent kits be sealed with reagent seals contained within the packaging. The reagent seals are "single use," and if more seals are needed, please contact Shenzhen New Industries Biomedical Engineering Co., Ltd. (SNIBE) or our authorized representative. .For detailed discussion of handling precautions during system operation, refer to the SNIBE service information (website : https://www.snibe.com/zh_en/en_index.aspx)

STORAGE AND STABILITY

- Store at 2-8°C. Do not freeze.
- Keep upright for storage to facilitate later proper resuspension of magnetic microbeads.
- Keep away from sunlight.

Stability of the reagent	
unopened at 2-8°C	until the stated expiration date
opened at 2-8°C	6 weeks
onboard	4 weeks

- To ensure the best kit performance, it is recommended to place opened kits in the refrigerator after the end of the intraday test work.

TEST PROCEDURE

Preparation of the Reagent

- Take the reagent kit out of the box and inspect 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. 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 2 seconds); 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.
- Resuspension of the magnetic microbeads takes place automatically when the kit is loaded successfully, ensuring the magnetic microbeads are totally resuspended and homogenous prior to use.

Assay Calibration

- Click **<Calibration>** or **<Batch Calibration>** button to execute the 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 package insert.

Quality Control

- In order to avoid manually error in entry of QC information, the provided barcode labels of quality control (positive and negative)) in the kit should be attached to the test tubes.
- If users do not use the provided barcode labels for positive and negative controls contained within the packaging, then quality controls (positive and negative) should be ordered manually.
- For specific information on ordering quality controls (positive and negative), refer to the Quality Control Section of the Operating Instructions.

Sample Testing

- Carefully transfer serum samples with each minimum volume of 160μL into sample tubes.
- Load sample tubes to sample racks and start testing.
- Order the samples in the Sample Area of the software and click the **<Start>** button to execute testing. For specific information on ordering patient specimens, refer to the Sample Ordering Section of the Operating Instructions.
- Samples from the same patient must be loaded in separate cassettes due to the design of the cleared instrument, MAGLUMII™ series fully-automated chemiluminescence immunoassay analyzer and a single report results for both IgM and IgG SARS-CoV-2 antibodies will be generated per patient.

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

LIMITATIONS

- This test is suitable only for investigating single samples, not for pooled samples.
- The product can only be used with MAGLUMII™ series fully-auto chemiluminescence immunoassay analyzer.
- The MAGLUMI 2019-nCoV IgM/IgG has not been evaluated for specimens other than human serum.
- 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 decisions.
- Assay results should not be used to diagnose or exclude acute COVID-19. Direct viral nucleic acid detection or antigen detection methods should be performed if acute infection is suspected.
- Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions.
- A negative or non-reactive result can occur if the quantity of antibodies for the SARS-CoV-2 virus present in the specimen is below the detection limit of the assay, or the virus has undergone minor amino acid mutation(s) in the epitope recognized by the antibody detected by the test.
- Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.
- SARS-CoV-2 IgM and IgG antibodies may be below detectable levels in patients who have been exhibiting symptoms for less than 8 days.
- If the results are inconsistent with clinical evidence, additional testing is suggested to confirm the result.
- HAMA antibodies in test samples may cause interference in immunoassays at concentrations greater than 30ng/mL.
- It is not known at this time if the presence of antibodies to SARS-CoV-2 confers immunity to re-infection.
- A positive result may not indicate previous SARS-CoV-2 infection. Consider other information including clinical history and local disease prevalence, in assessing the need for a second but different serology test to confirm an immune response.

- Not for the screening of donated blood.
- The performance of this test was established based on the evaluation of a limited number of clinical specimens. Clinical performance has not been established with all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time

Conditions of Authorization for the Laboratory

The MAGLUMI 2019-nCoV IgM/IgG Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Patients, and authorized labeling are available on the FDA website:

https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas

Authorized laboratories using the MAGLUMI 2019-nCoV IgM/IgG must adhere to the Conditions of Authorization indicated in the Letter of Authorization as listed below:

- Authorized laboratories[a] using the MAGLUMI 2019-nCoV IgM/IgG will include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.
- Authorized laboratories will use the MAGLUMI 2019-nCoV IgM/IgG as outlined in the authorized labeling. Deviations from the authorized procedures, including the authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use the product are not permitted.
- Authorized laboratories that receive the MAGLUMI 2019-nCoV IgM/IgG will notify the relevant public health authorities of their intent to run the assay prior to initiating testing.
- Authorized laboratories using the MAGLUMI 2019-nCoV IgM/IgG will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
- Authorized laboratories will collect information on the performance of the MAGLUMI 2019-nCoV IgM/IgG and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH EUA Reporting@fda.hhs.gov) and to Snibe Co. Ltd (pgshugart@carolinachemistries.com and MAGLUMI Technical Support (http://www.snibe.com/zh_en/en_services.aspx?id=66)) any suspected occurrence of false reactive or false non-reactive results and significant deviations from the established performance characteristics of the assay of which they become aware.
- All laboratory personnel using the MAGLUMI 2019-nCoV IgM/IgG must be appropriately trained in immunoassay techniques and use appropriate laboratory and personal protective equipment when handling this kit, and use the MAGLUMI 2019-nCoV IgM/IgG Combo Test Kit in accordance with the authorized labeling. All laboratory personnel using the assay must also be trained in and be familiar with the interpretation of results of the the MAGLUMI 2019-nCoV IgM/IgG.
- Snibe Co. Ltd., authorized distributors, and authorized laboratories using the MAGLUMI 2019-nCoV IgM/IgG will ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

[a] The letter of authorization refers to, “Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform moderate and high complexity tests” as “authorized laboratories".

RESULTS

Calculation of Results

The analyzer automatically calculates the numerical output in each sample by means of a calibration curve which is generated by a two-point calibration master curve procedure. The results are expressed in absorbance unit AU/mL. The results are reported to the end user as “Reactive” and “Non-Reactive”. No AU/mL numerical values are reported to the end user. For further information please refer to the operating instructions of MAGLUMI series fully-automated chemiluminescence immunoassay analyzer.

Interpretation of Results

- Non-reactive: A result less than 1.00 AU/mL (<1.00 AU/mL) is considered to be non-reactive.
- Reactive: A result greater than or equal to 1.00 AU/mL (≥1.00 AU/mL) is considered to be reactive.

Analyte	Results	Interpretation	Description*
SARS-CoV-2 IgG	<1.00 AU/mL	SARS-CoV-2 IgG Non-Reactive	IgG antibodies against SARS-CoV-2 are not detected
	≥1.00 AU/mL	SARS-CoV-2 IgG Reactive	IgG antibodies against SARS-CoV-2 are detected
SARS-CoV-2 IgM	<1.00 AU/mL	SARS-CoV-2 IgM Non-Reactive	IgM antibodies against SARS-CoV-2 are not detected
	≥1.00 AU/mL	SARS-CoV-2 IgM Reactive	IgM antibodies against SARS-CoV-2 are detected

*If external controls are outside the pre-established ranges do not report results and test the sample again.

PERFORMANCE CHARACTERISTICS

Precision

Precision of the MAGLUMI 2019-nCoV IgM/IgG assay was determined as described in the CLSI EP5-A3.2. Controls and three human serum pools containing different levels of analyte were assayed in duplicate at three sites over 5 days, with three runs per day, and one lot of reagent for each run. The results are summarized in the following table:

Analyte	Sample	Mean Value (AU/mL)	N	Repeatability		Between-Lot		Between-Day		Between-Site		Reproducibility	
				SD (AU/mL)	%CV	SD (AU/mL)	%CV	SD (AU/mL)	%CV	SD (AU/mL)	%CV	SD (AU/mL)	%CV
IgG	NQC	0.293	90	0.024	NA	0.005	NA	0.008	NA	0.023	NA	0.035	NA
	PQC	3.915	90	0.199	5.08	0.069	1.76	0.032	0.82	0.265	6.77	0.340	8.68
	S1	0.491	90	0.043	NA	0.015	NA	0.004	NA	0.013	NA	0.047	NA
	S2	3.486	90	0.212	6.08	0.060	1.72	0.050	1.43	0.071	2.04	0.237	6.80
	S3	9.807	90	0.159	1.62	0.122	1.24	0.082	0.84	0.639	6.52	0.675	6.88
IgM	NQC	0.293	90	0.020	NA	0.006	NA	0.007	NA	0.007	NA	0.023	NA
	PQC	3.920	90	0.167	4.26	0.046	1.17	0.062	1.58	0.284	7.24	0.339	8.65
	S1	0.492	90	0.033	NA	0.016	NA	0.009	NA	0.012	NA	0.040	NA
	S2	1.797	90	0.037	2.06	0.018	1.00	0.053	2.95	0.088	4.90	0.111	6.18
	S3	3.411	90	0.076	2.23	0.000	0.00	0.049	1.44	0.226	6.63	0.244	7.15

Potentially Interfering Substances The effect of potential interference substances of the performance of the MAGLUMI 2019-nCoV IgM/IgG assay was evaluated using one negative serum sample and one positive serum sample spiked with whether SARS-CoV-2 IgG or SARS-CoV-2 IgM antibodies. Both cassettes (for IgM and IgG) were tested separately according to the instructions for use. No interference was observed up to the concentrations included in the table below:

Potential Interferent		Highest Concentration of Potential Interferent tested with no Interferent Effect
Endogenous	Bilirubin	40 mg/dL
	Triglycerides	1000 mg/dL
	Hemoglobin	2000 mg/dL
	Rheumatoid Factor	1500 IU/mL
	Anti-Mitochondrial	1:64(titer)
	HAMA	30 ng/mL
Exogenous	Total IgG	1600 mg/dL
	Total IgM	280 mg/dL
	Interferon α	1500 U/mL
	Ribavirin	90 mg/dL
	Oseltamivir	1.0 mg/dL
	Levofloxacin	1.776 mg/dL
	Azithromycin	1.201 mg/dL
	Ceftriaxone sodium	81.03 mg/dL
	Meropenem	80.15 mg/dL
	Tobramycin	2.4 mg/dL
	Diphenhydramine	4.5 mg/dL
	Oxymetazoline	2.5 mg/dL
	Sodium chloride	45 mg/dL
	Beclomethasone	2.5 mg/dL
	Dexamethasone	18 mg/dL
	Triamcinolone acetonide	5.5 mg/dL
	Budesonide	3.2 mg/dL
	Mometasone	2.5 mg/dL
	Fluticasone propionate	2.5 mg/dL

Cross-Reactivity

The cross-reactivity of the MAGLUMI 2019-nCoV IgM/IgG was evaluated by testing SARS-CoV-2 seronegative serum samples from patients with antibodies to various viruses and other possible cross- reactants. The cassette used for IgM detection was tested with the potential cross-reactants separately from the cassette for IgG detection following the instructions for use. No false positive results were observed. The results of the potential interference study are listed in the following table:

Condition	Number of Samples Containing Potential Cross-Reactants	Number of False Positive Results	
		SARS-CoV-2 IgM	SARS-CoV-2 IgG
Influenza A virus antibodies	17	0	0
Influenza B virus antibodies	19	0	0
Parainfluenza virus antibodies	23	0	0
Respiratory syncytial virus antibodies	7	0	0
Adenovirus antibodies	9	0	0
EBV NA IgG	10	0	0
EBV VCA IgG	4	0	0
EBV VCA IgM	6	0	0
Measles virus	2	0	0
CMV IgG	6	0	0
CMV IgM	2	0	0
Varicella zoster virus antibodies	2	0	0
M. pneumonia IgG	3	0	0
M. pneumonia IgM	4	0	0
Chlamydia pneumoniae IgG	3	0	0
Chlamydia pneumoniae IgM	3	0	0
Monilia albicans	1	0	0
Antinuclear Antibodies (ANA)	6	0	0
anti-HCV (IgG and IgM)	5	0	0
anti-HBV (IgG and IgM)	5	0	0
anti-HIV (IgG and IgM)	16	0	0
Total	159	0	0

CLINCAL PERFORMANCE

A total of 490 subjects were enrolled to evaluate the MAGLUMI 2019-nCoV IgM/IgG test clinical performance. Among the 490 serum samples collected, 264 were from SARS-CoV-2 PCR-confirmed positive subjects while 226 were from SARS-CoV-2 PCR-confirmed negative subjects. All samples collected were tested using the MAGLUMI 2019-nCoV IgM/IgG test. The negative percent agreement (NPA) and the positive percent agreement (PPA) were calculated. Out of the 226 PCR negative subjects 3 tested positive with the MAGLUMI 2019-nCoV IgM/IgG (2 false positive for IgG and 1 for IgM), so the NPA is 98.67% (95% CI: 96.17% - 99.55%

The following tables describe the PPA calculations, by time of sampling days post symptom onset, for IgG and IgM separately as well as combined.

MAGLUMI 2019-nCoV IgM/IgG – SARS-CoV-2 IgG PPA (Stratified by Days Post-Symptom Onset)

Days Post Symptom Onset	PCR Total Positive	PCR Comparator		
		IgG Positive Results	IgG PPA	95% Confidence Interval (CI)
≤7	16	5	31.25%	14.16% - 55.60%
8-14	106	96	90.57%	83.50% - 94.80%
≥15	142	142	100.00%	97.37% - 100.00%
Total	264	243	92.05%	88.15% - 94.74%

MAGLUMI 2019-nCoV IgM/IgG - SARS-CoV-2 IgM PPA (Stratified by Days Post-Symptom Onset)

Days Post Symptom Onset	PCR Total Positive	PCR Comparator		
		IgM Positive Results	IgM PPA	95% CI
≤7	16	7	43.75%	23.10% - 66.82%
8-14	106	83	78.30%	69.54% - 85.08%
≥15	142	110	77.46%	69.92% - 83.56%
Total	264	200	75.76%	70.24% - 80.53%

MAGLUMI 2019-nCoV IgM/IgG – SARS-CoV-2 IgM and IgG Combined PPA (Stratified by Days Post-Symptom Onset)

Days Post Symptom Onset	PCR Total Positive	PCR Comparator		
		IgG/IgM combined Positive Results	IgG/IgM Combined PPA	95% CI
≤7	16	7	43.75%	23.10% - 66.82%
8-14	106	99	93.40%	86.99% - 96.76%
≥15	142	142	100%	97.37% - 100.00%
Total	264	248	93.94%	90.38% - 96.24%

SYMBOLS EXPLANATIONS

	Consult instructions for use		Manufacturer
	Temperature limit (Store at 2-8°C)		Use-by date
	Contains sufficient for <n> tests		Keep away from sunlight
	This way up	CONTENTS	Kit components
IVD	*In vitro* diagnostic medical device	LOT	Batch code

REF	Catalogue number

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