REGIONE CAMPANIA
AZIENDA OSPEDALIERA DI CASERTA
SANT'ANNA E SAN SEBASTIANO
DI RILIEVO NAZIONALE E DI ALTA SPECIALIZZAZIONE

Determina Dirigenziale N. 105 del 11/03/2020

PROPONENTE: **UOC PROVVEDITORATO ED ECONOMATO**

OGGETTO: **Fornitura di n.200 test 2019 nCoVC IgM e IgG per la diagnosi di screening rapida di infezioni da Coronavirus 2019, da destinare alla UOC Patologia Clinica - Acquisto ex art. 63, comma 2, lett c del D.Lgs. n.50/2016 e smi.**

Oggetto: Fornitura di n.200 test 2019 nCoVC IgM e IgG per la diagnosi di screening rapida di infezioni da Coronavirus 2019, da destinare alla UOC Patologia Clinica - Acquisto ex art. 63, comma 2, lett c del D.Lgs. n.50/2016 e smi.

Direttore UOC PROVVEDITORATO ED ECONOMATO

PREMESSO CHE

-il Direttore della UOC Patologia Clinica, Dott. Arnolfo Petruzziello, con l'allegata nota (Prot. n.7141 del 27/02/2020 – allegato n.1), facendo seguito alle *"…recenti note diramate a livello ministeriale…"* , ha richiesto alla scrivente Direzione l'acquisizione *"…con urgenza…."* dei Kit sottoindicati per la diagnosi di screening rapida di infezioni da Coronavirus 2019:

a) MAGLUMI 2019 nCoV IgM (CLIA) - n.100 test;

b) MAGLUMI 2019 nCoV IgG (CLIA) - n.100 test;

- con la suindicata nota, il precitato Direttore ha anche precisato che:

a) il test in questione è disponibile su piattaforma MAGLUMI, *"….sistema diagnostico già in possesso …"* della UOC Patologia Clinica;

b) la Ditta presso la quale approvvigionarsi è la MEDICAL SYSTEM Spa.;

CONSIDERATO CHE

- i prodotti in questione sono correlati alla diagnosi dei casi sospetti di Coronavirus;
- nel caso di specie, ricorre l'esigenza urgenza indifferibile di approvvigionarsi a tutela della salute pubblica;

DATO ATTO che quest'Azienda con delibera dell'allora D.G. n.185/2019 (agli atti), nell'aggiudicare la fornitura triennale di Sistemi Diagnostici per la UOC Patologia Clinica, ha disposto, tra l'altro, l'affidamento del lotto n.32 (Immunometria speciale a completamento di profili clinici – CIG. n. 74986891EC) in favore della Ditta MEDICAL SYSTEM Spa. (Stralcio del prospetto di aggiudicazione – allegato n.2) ;

RILEVATO CHE

- in data 02/03/2020, la scrivente (Prot. n.7318) ha richiesto alle Ditte Medical System Spa. (allegati n.3) di produrre con la massima urgenza offerta per l'affidamento della fornitura di cui trattasi;

- la suddetta Ditta ha prodotto offerta (allegato n.4) , secondo la configurazione ivi riportata, qui richiamata e trascritta e per l'importo complessivo di ciascuna tipologia di test pari ad € 1.440,00 oltre Iva al 22%;

- in data 05/03/2020 la scrivente, al fine di assicurare il regolare prosieguo dell'istruttoria, ha rimesso la suindicata offerta (allegato n. 5) al precitato Direttore

CONSIDERATO CHE detto Direttore ha dichiarato che *" …il prodotto è conforme…"*, come da specifica apposta sulla offerta rimessagli in copia(allegato n.6)*;*

VISTO l'art. 63, comma 2, lett. c del D.Lgs. n.50/2016 e smi;

ESAMINATI tutti gli atti innanzi richiamati ed allegati alla presente

ATTESTATO che la presente proposta di determinazione è formulata previa istruttoria ed estensione conformi alla normativa legislativa vigente in materia e può essere pubblicata integralmente;

DETERMINA

per i motivi espressi in narrativa di:

I - DI AFFIDARE alla Ditta Medical System Spa. la fornitura sottoindicata, da destinare alla UOC Patologia Clinica per la diagnosi di screening rapida di infezioni da Coronavirus 2019 e per l'importo complessivo di € 2.880,00 oltre Iva al 22%:

Descrizione prodotto	Codice prodotto	TEST/CONF	Prezzo LISTINO	Sconto	Prezzo conf.	Prezzo a test
MAGLUMI 2019 nCoV IgG (CLIA) -	130219015 M	100 CE	€ 1.600,00	10%	€ 1.440,00	€ 14,40
MAGLUMI 2019 nCoV IgM (CLIA) -	130219016 M	100 CE	€ 1.600,00	10%	€ 1.440,00	€ 14,40

II - DI DARE ATTO che il costo derivante dal presente provvedimento è pari ad € 3.516,60 Iva inclusa al 22% ed è da imputarsi sul conto economico 5010105010 "Dispositivi medico-diagnostici in vitro" bilancio 2020;

III - DI NOTIFICARE copia di detto provvedimento alla Ditta MEDICAL SYSTEM Spa.;

IV - DI TRASMETTERE copia del medesimo, ai sensi di legge, al Collegio Sindacale, alla UOC proponente, ai Direttori delle UU.OO.CC. Gestione Economico - Finanziaria, Patologia Clinica e Farmacia Ospedaliera per gli adempimenti di rispettiva competenza;

V - DI PUBBLICARE integralmente la presente determinazione.

UOC PROVVEDITORATO ED ECONOMATO
IL DIRETTORE
Dott.ssa Antonietta Costantini

ATTESTAZIONE DI VERIFICA E REGISTRAZIONE CONTABILE
(per le proposte che determinano un costo per l'AORN – VEDI ALLEGATO)

All 1

AORN CASERTA

REGIONE CAMPANIA
AZIENDA OSPEDALIERA DI RILIEVO NAZIONALE
E DI ALTA SPECIALIZZAZIONE
"SANT'ANNA E SAN SEBASTIANO" DI CASERTA

Alla c.a. del Direttore UOC Provveditorato
UOC Farmacia
E p.c. Subcommissario Sanitario
SEDE

Oggetto: acquisto urgente test rapido anti Covid 2019

In relazione alle recenti note diramate a livello ministeriale si richiede con **urgenza** l'acquisizione del test 2019 nCoV IgM e IgG per la diagnosi di screening rapida di infezione da Coronavirus 2019. Essendo il test disponibile su piattaforma Maglumi, sistema diagnostico già in possesso di questa UOC, si richiede l'acquisizione in trattativa diretta dalla Ditta Medical System (vedi allegato)

Maglumi 2019 nCoV IgM (CLIA) 100 test
Maglumi 2019 nCoV IgG (CLIA) 100 test

Caserta li, 27/02/2020

Il Direttore UOC Patologia Clinica
Dott. Arnolfo Petruzziello

A.O.R.N. SANT'ANNA E SAN SEBASTIANO - CASERTA - DIPARTIMENTO DEI SERVIZI SANITARI - DIRETTORE DOTT. Arnolfo Petruzziello

A.O.R.N. Sant'Anna e San Sebastiano
CASERTA
U.O.C. Patologia Clinica
Direttore: *Dott. Arnolfo Petruzziello*

È urgente, si ma procedere
su le richieste 28/02/2020
Dott.ssa Tantillo

U.O.C. PATOLOGIA CLINICA
Dipartimento dei Servizi Sanitari
Via F. Palasciano – 81100 Caserta
Tel. Direzione: 0823 232764; Segreteria: 0823 232144/2150; Ambulatorio 0823 232132
e.mail: patologiaclinica@ospedale.caserta.it; patologiaclinica.dir@ospedale.caserta.it
Direttore Dott. Arnolfo Petruzziello

Snibe Diagnostic

CE REF 130219016M: 100 tests

MAGLUMI™ 2019-nCoV IgM (CLIA)

INTENDED USE

The kit is an *In Vitro* chemiluminescence immunoassay for the qualitative determination of IgM antibodies to novel coronavirus (2019-nCoV IgM) in human serum or plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer.

SUMMARY AND EXPLANATION OF THE TEST

The novel coronavirus (2019-nCoV) causes an epidemic of acute respiratory syndrome in humans in Wuhan[1], belonging to the genus Betacoronavirus. It has an envelope, particles are round or oval, often polymorphic, and the diameter is 60 ~ 140nm. Its genetic characteristics are significantly different from SARSr-CoV and MERSr-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 contact. The sources of infection seen so far are mainly patients with pneumonia infected by the novel coronavirus[2].

Research has shown that detection of IgM and IgG antiviral antibodies in the serum samples from a patient[3]. After human infection in 2019-nCoV, its antigen stimulates the immune system to produce an immune response, and corresponding antibodies appear in the blood. Among them, 2019-nCoV IgM appears earlier, and then 2019-nCoV IgM titers decrease, the 2019-nCoV IgG potency rose rapidly.

This kit is mainly used for the assisted diagnosis of the novel coronavirus (2019-nCoV) infection.

2019-nCoV, named by the World Health Organization on January 7, 2020, is announced the official name: Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) by the International Committee on Taxonomy of Viruses (ICTV) on February 11, 2020. On the same day, the Director-General of the World Health Organization (WHO) Tan Desai announced that pneumonia infected with SARS-CoV-2 will be officially named "COVID-19".

PRINCIPLE OF THE TEST

The MAGLUMI 2019-nCoV IgM (CLIA) assay is a capture 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 labeled 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 a 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).

KIT COMPONENTS

Material Provided

Component	Contents	100 tests (REF: 130219016M)
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.

Accessories Required But Not Provided

MAGLUMI Series:

Reaction Module	REF: 630003
Starter 1+2	REF: 130299004M;130299012M; 130299027M
Wash Concentrate	REF: 130299005M
Light Check	REF: 130299006M
Reaction Cup	REF: 130105000101
Maglumi 600	REF: 23020018
Maglumi 800	REF: 23020003
Maglumi 1000	REF: 23020009
Maglumi 2000	REF: 23020006
Maglumi 2000 Plus	REF: 23020007
Maglumi 4000	REF: 23020014
Maglumi 4000 Plus	REF: 23020037
MAGLUMI X8	REF: 010101008801
Biolumi 8000	REF: 23010001

Please order accessories 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.

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

Follow government regulations or accreditation requirements 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 Information***. 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-auto chemiluminescence immunoassay analyzer.
To monitor system performance, quality control materials (negative control and positive control) are required. Treat 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 appropriate 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 still 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.

SPECIMEN COLLECTION AND PREPARATION

- Human serum or plasma may be used with the 2019-nCoV IgM (CLIA) assay. Serum including samples collected using standard sampling tubes, tubes containing separating gel or procoagulant inert separation tubes. For plasma samples, the anticoagulants including K_2-EDTA, K_3-EDTA, Na_2 -EDTA, have been tested and may be used with this assay.
- Do not use grossly hemolyzed specimens.
- Inspect all specimens for bubbles. Remove bubbles with an applicator stick before analysis. Use a new applicator stick for each specimen to prevent cross contamination.
- Specimens removed from the separator gel, cells or clot may be stored 5 days at 2-8°C.
- Specimens can be stored more than 5 days frozen at -70°C or colder. Avoid repeated freezing and thawing. Frozen specimens must be mixed thoroughly after thawing by low speed vortexing 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 specimen 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..
- The sample volume required for a single determination is 10 µL.

WARNING AND PRECAUTIONS FOR USERS

- IVD For *In Vitro* Diagnostic Use.
- 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 refrigerator, it is recommended that the opened reagent kits to 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.

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

TEST PROCEDURE

Preparation of the Reagent

- 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 agent 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.
- Resuspension of the magnetic microbeads takes place automatically when the kit is loaded successfully, ensuring the magnetic microbeads are totally resuspended homogenous prior to use.

Assay Calibration

- Click **<Calibration>** or **<Batch Calibration>** button to 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 manual.

Quality Control

- In order to avoid manually error in entry of QC information, the provided barcode labels of quality control in the kit can be used attached on the test tubes.
- Strictly follow the quality control procedures when using the quality controls..
- 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 to the Quality Control Section of the Operating Instructions.

Sample 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.

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

DILUTION

Samples with concentrations above 30.0 AU/mL can be diluted automatically by analyzers or manually. 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 dilution settings are done in the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer user software. Please refer to the operating instructions of MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer.

LIMITATIONS

- This test is suitable only for investigating single samples, not for pooled samples or heat-inactivated specimens.
- Bacterial contamination or repeated freeze-thaw cycles may affect the test results.
- Fresh sample is recommended. If a low positive result was get, repeated test should be conducted after centrifuged especial severely or using additional test to confirm the result.
- Assay results should be utilized in conjunction with other clinical and laboratory methods to assist the clinician in making individual patient diagnostic decisions.
- If the 2019-nCoV IgM results are inconsistent with clinical evidence, additional testing is suggested to confirm the result.
- HAMA antibodies in test samples may cause interference in immunoassays.

RESULTS

Calculation of Results
The analyzer automatically calculates the concentration in each sample by means of a calibration curve which is generated by a 2-point calibration master curve procedure. The results are expressed in AU/mL. For further information please refer to the operating instructions of MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer.

Interpretation of Results
Results obtained with the 2019-nCoV IgM assay can be interpreted as follows:

- Non-reactive: A result less than 0.900 AU/mL (<0.900 AU/mL) is considered to be non-reactive.
- Gray zone: A result in the interval between 0.900 and 1.10 (0.900≤ x<1.10 AU/mL) is considered to be equivocal.
- Reactive: A result greater than or equal to 1.10 AU/mL (≥1.10 AU/mL) is considered to be reactive.

PERFORMANCE CHARACTERISTICS

Precision
Precision for 2019-nCoV IgM assay was determined as described in the CLSI EP5-A3. 2 controls and 3 samples containing different concentration of analyte were assayed in duplicate at three sites on five days, with 3 runs per day, one lot of reagent for each run and 2 replicates per run. The result is summarized in the following table:

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
NQC	0.296	90	0.025	NA	0.011	NA	0.003	NA	0.019	NA	0.034	NA
PQC	3.911	90	0.164	4.19	0.062	1.59	0.062	1.59	0.293	7.49	0.347	8.87
S1	0.501	90	0.048	NA	0.009	NA	0.007	NA	0.023	NA	0.055	NA
S2	3.517	90	0.162	4.61	0.053	1.51	0.041	1.17	0.054	1.54	0.183	5.20
S3	14.710	90	0.269	1.83	0.072	0.49	0.127	0.86	0.589	4.00	0.664	4.51

Endogenous interference
Two serum samples (one negative sample, one positive sample) were spiked with potential endogenous interference. The results of the interferences are listed in the following table:

Interference	No interference up to
Hemoglobin	2000 mg/dL
Bilirubin	40 mg/dL
Triglycerides	1000 mg/dL
Rheumatoid Factor	1500 IU/mL
HAMA	30 ng/mL

Drug interference
Two serum samples (one negative sample, one positive sample) were spiked with potential endogenous interference. The results of the interferences are listed in the following table:

Interference	No interference up to
Acetylcysteine	15 mg/dL
Ampicillin sodium	100 mg/dL
Cefoxitin	250 mg/dL
Metronidazole	20 mg/dL
Tetracycline	5 mg/dL
Aspirin	100 mg/dL
Rifampin	6 mg/dL
Acetaminopthen	20 mg/dL
Ibuprofen	50 mg/dL
Theophylline	10 mg/dL
Lamivudine	30 mg/dL
Entecavir	0.5 mg/L
Telbivudine	60 mg/dL
Adefovir	1 mg/dL

Analytical specificity
Clinical 2019-nCoV IgM negative samples, which contain potential cross-reactants including influenza virus type A antibody, influenza virus type B antibody, parainluenza virus antibody, respiratory syncytial virus antibody, adenovirus antibody, EBV NA IgG, EBV VCA IgM/IgG, CMV IgM/IgG, M.Pneumonia IgM/IgG, chlamydia pneumoniae IgM/IgG, Candida albicans, ANA were used to evaluate the cross-reactivity of 2019-nCoV IgM assay. Of all the potential cross-reactants, none were found to cause false positive in the 2019-nCoV IgM assay.

Clinical Sensitivity
The clinical sensitivity was determined for 87 confirmed novel coronavirus infected specimens. The clinical sensitivity was calculated to be 48.28%.

Specimen Category	2019-nCoV IgM (CLIA)		
	N	Positive	%Sensitivity
Clinical confirmed positive samples	87	42	48.28%

Clinical specificity

The clinical specificity was determined for 370 non- novel coronavirus infected specimens, normal samples and interference samples. The clinical specificity was calculated to be 100%.

Specimen Category	2019-nCoV IgM (CLIA)		
	N	Negative	%Specificity
negative specimens	370	370	100%

REFERENCES

1. Zhou, P., Yang, X., Wang, X. et al. A pneumonia outbreak associated with a new coronavirus of probable bat origin. Nature (2020). https://doi.org/10.1038/s41586-020-2012-7.
2. Diagnosis and treatment of pneumonitis caused by novel coronavirus (version 4).
3. Na Zhu, Ph.D., Dingyu Zhang, et al.A Novel Coronavirus from Patients with Pneumonia in China, 2019[J].New England Journal of Medicine, 2020.

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Eiffestrasse 80, 20537 Hamburg, Germany
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SYMBOLS EXPLANATIONS

	Consult instructions for use		Manufacturer
2-8°C	Temperature limit (Store at 2-8°C)		Use-by date
Σ	Contains sufficient for <n> tests		Keep away from sunlight
	This way up	EC REP	Authorized representative in the European Community
IVD	*In vitro* diagnostic medical device	CONTENTS	Kit components
REF	Catalogue number	LOT	Batch code

Snibe Diagnostic

CE REF 130219015M: 100 tests

MAGLUMI™ 2019-nCoV IgG (CLIA)

INTENDED USE

The kit is an *In Vitro* chemiluminescence immunoassay for the qualitative determination of IgG antibodies to novel coronavirus (2019-nCov IgG) in human serum or plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer.

SUMMARY AND EXPLANATION OF THE TEST

The novel coronavirus (2019-nCoV) causes an epidemic of acute respiratory syndrome in humans in Wuhan[1], belonging to the genus Betacoronavirus. It has an envelope, particles are round or oval, often polymorphic, and the diameter is 60 ~ 140nm. Its genetic characteristics are significantly different from SARSr-CoV and MERSr-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 contact. The sources of infection seen so far are mainly patients with pneumonia infected by the novel coronavirus.[3]

Research has shown that detection of IgM and IgG antiviral antibodies in the serum samples from a patient[3]. After human infection in 2019-nCoV, its antigen stimulates the immune system to produce an immune response, and corresponding antibodies appear in the blood. Among them, 2019-nCoV IgM appears earlier, and then 2019-nCoV IgM titers decrease, the 2019-nCoV IgG potency rose rapidly.

This kit is mainly used for the assisted diagnosis of the novel coronavirus (2019-nCoV) infection.

2019-nCoV, named by the World Health Organization on January 7, 2020, is announced the official name: Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) by the International Committee on Taxonomy of Viruses (ICTV) on February 11, 2020. On the same day, the Director-General of the World Health Organization (WHO) Tan Desai announced that pneumonia infected with SARS-CoV-2 will be officially named "COVID-19".

PRINCIPLE OF THE TEST

The MAGLUMI 2019-nCoV IgG (CLIA) assay is an indirect chemiluminescence immunoassay.

The prediluted sample (or calibrator/control, if applicable), buffer and 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 labeled with anti-human IgG antibody, and incubate to form complexes. After precipitation in a magnetic field, decant the supernatant, and perform another wash cycle. Subsequently, the Starter 1+2 are 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 2019-nCoV IgG presented in the sample (or calibrator/control, if applicable).

KIT COMPONENTS

Material Provided

Component	Contents	100 tests (REF: 130219015M)
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%).	1.0 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%).	

All reagents are provided ready-to-use.

Accessories Required But Not Provided

MAGLUMI Series:	
Reaction Module	REF: 630003
Starter 1+2	REF: 130299004M;130299012M; 130299027M
Wash Concentrate	REF: 130299005M
Light Check	REF: 130299006M
Reaction Cup	REF: 130105000101
Maglumi 600	REF: 23020018
Maglumi 800	REF: 23020003
Maglumi 1000	REF: 23020009
Maglumi 2000	REF: 23020006
Maglumi 2000 Plus	REF: 23020007
Maglumi 4000	REF: 23020014
Maglumi 4000 Plus	REF: 23020037
MAGLUMI X8	REF: 010101008801
Biolumi 8000	REF: 23010001

Please order accessories 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.

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

Follow government regulations or accreditation requirements for quality control frequency.

Internal quality control is only applicable with MAGLUMI system. For instructions for use and target value refer to ***2019-nCoV IgG Quality Control Information***. 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-auto chemiluminescence

immunoassay analyzer.
To monitor system performance, quality control materials (negative control and positive control) are required. Treat 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 appropriate 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 still 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.

SPECIMEN COLLECTION AND PREPARATION

- Human serum or plasma may be used with the 2019-nCoV IgG (CLIA) assay. Serum including samples collected using standard sampling tubes, tubes containing separating gel or procoagulant inert separation tubes. For plasma samples, the anticoagulants including K_2-EDTA, K_3-EDTA, Na_2 -EDTA, have been tested and may be used with this assay.
- Do not use grossly hemolyzed specimens.
- Inspect all specimens for bubbles. Remove bubbles with an applicator stick before analysis. Use a new applicator stick for each specimen to prevent cross contamination.
- Specimens removed from the separator gel, cells or clot may be stored 5 days at 2-8°C.
- Specimens can be stored more than 5 days frozen at -70°C or colder. Avoid repeated freezing and thawing. Frozen specimens must be mixed thoroughly after thawing by low speed vortexing 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 specimen 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.
- The sample volume required for a single determination is 10 µL.

WARNING AND PRECAUTIONS FOR USERS

- IVD For *In Vitro* Diagnostic Use.
- 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 refrigerator, it is recommended that the opened reagent kits to 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.

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

TEST PROCEDURE

Preparation of the Reagent

- 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 agent 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.
- Resuspension of the magnetic microbeads takes place automatically when the kit is loaded successfully, ensuring the magnetic microbeads are totally resuspended homogenous prior to use.

Assay Calibration

- Click **<Calibration>** or **<Batch Calibration>** button to 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 manual.

Quality Control

- In order to avoid manually error in entry of QC information, the provided barcode labels of quality control in the kit can be used attached on the test tubes.
- Strictly follow the quality control procedures when using the quality controls.
- 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 to the Quality Control Section of the Operating Instructions.

Sample 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.

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

analyzer.

DILUTION

The automatic sample dilution is available after dilution settings are done in the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer user software. Please refer to the operating instructions of MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer. The recommended dilution factor is 20 times (1:19, 1part sample with19 parts diluent).After automatic dilution, multiply the result by the dilution factor.

LIMITATIONS

- This test is suitable only for investigating single samples, not for pooled samples or heat-inactivated specimens.
- Bacterial contamination or repeated freeze-thaw cycles may affect the test results.
- Fresh sample is recommended. If a low positive result was get, repeated test should be conducted after centrifuged especial severely or using additional test to confirm the result.
- Assay results should be utilized in conjunction with other clinical and laboratory methods to assist the clinician in making individual patient diagnostic decisions.
- If the 2019-nCoV IgG results are inconsistent with clinical evidence, additional testing is suggested to confirm the result.
- HAMA antibodies in test samples may cause interference in immunoassays.

RESULTS

Calculation of Results

The analyzer automatically calculates the concentration in each sample by means of a calibration curve which is generated by a 2-point calibration master curve procedure. The results are expressed in AU/mL. For further information please refer to the operating instructions of MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer.

Interpretation of Results

Results obtained with the 2019-nCoV IgG assay can be interpreted as follows:

- Non-reactive: A result less than 0.900 AU/mL (<0.900 AU/mL) is considered to be non-reactive.
- Gray zone: A result in the interval between 0.900 and 1.100(0.900≤ x<1.10 AU/mL) is considered to be equivocal.
- Reactive: A result greater than or equal to 1.10 AU/mL (≥1.10 AU/mL) is considered to be reactive.

PERFORMANCE CHARACTERISTICS

Precision

Precision for 2019-nCoV IgG assay was determined as described in the CLSI EP5-A3.2 controls and 3 human serum pools containing different concentration of analyte were assayed in duplicate at three sites on five days, with 3 runs per day, one lot of reagent for each run and 2 replicates per run. The result is summarized in the following table:

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
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

Endogenous interference

Two serum samples (one negative sample, one positive) were spiked with potential endogenous interference. The results of the interferences are listed in the following table:

Interference	No interference up to
Hemoglobin	2000 mg/dL
Bilirubin	40 mg/dL
Triglycerides	1000 mg/dL
Rheumatoid Factor	1500 IU/mL
HAMA	30 ng/mL

Drug interference

Two serum samples (one negative sample, one positive) were spiked with potential endogenous interference. The results of the interferences are listed in the following table:

Interference	No interference up to
Acetylcysteine	15 mg/dL
Ampicillin sodium	100 mg/dL
Cefoxitin	250 mg/dL
Metronidazole	20 mg/dL
Tetracycline	5 mg/dL
Aspirin	100 mg/dL
Rifampin	6 mg/dL
Acetaminopthen	20 mg/dL
Ibuprofen	50 mg/dL
Theophylline	10 mg/dL
Lamivudine	30 mg/dL
Entecavir	0.5 mg/L
Telbivudine	60 mg/dL
Adefovir	1 mg/dL

Analytical specificity

Clinical 2019-nCoV IgG negative samples, which contain potential cross-reactants including Influenza virus type A antibody, Influenza virus type B antibody, parainluenza virus antibody, respiratory syncytial virus antibody, adenovirus antibody, EBV NA IgG, EBV VCA IgM/IgG, CMV IgM/IgG, M.Pneumonia IgM/IgG, chlamydia pneumoniae IgM/IgG, Candida albicans, ANA were used to evaluate the cross-reactivity of 2019-nCoV IgG assay. Of all the potential cross-reactants, none were found to cause false positive in the 2019-nCoV IgG assay.

Clinical Sensitivity

The clinical sensitivity was determined for 91 confirmed novel coronavirus infected specimens. The clinical sensitivity was calculated to be 91.21%.

Specimen Category	2019-nCoV IgG (CLIA)		
	N	Positive	%Sensitivity
Clinical confirmed positive samples	91	83	91.21%

Clinical specificity

The clinical specificity was determined for 370 non- novel coronavirus infected specimens, normal samples and interference samples. The clinical specificity was calculated to be 100%.

Specimen Category	2019-nCoV IgG (CLIA)		
	N	Negative	%Specificity
negative specimens	370	370	100%

REFERENCES

1.Zhou, P., Yang, X., Wang, X. et al. A pneumonia outbreak associated with a new coronavirus of probable bat origin. Nature (2020). https://doi.org/10.1038/s41586-020-2012-7.

2. Diagnosis and treatment of pneumonitis caused by novel coronavirus (version 4).

3. Na Zhu, Ph.D., Dingyu Zhang, et al. A Novel Coronavirus from Patients with Pneumonia in China, 2019[J]. New England Journal of Medicine, 2020.

Shenzhen New Industries Biomedical Engineering Co., Ltd.
No.23, Jinxiu East Road, Pingshan District, 518122 Shenzhen, P.R. China
Tel: +86-755-21536601 Fax: +86-755-28292740

EC REP **Shanghai International Holding Corp. GmbH (Europe)**
Eiffestrasse 80, 20537 Hamburg, Germany
Tel: +49-40-2513175 Fax: +49-40-255726

SYMBOLS EXPLANATIONS

	Consult instructions for use		Manufacturer
2°C 8°C	Temperature limit (Store at 2-8°C)		Use-by date
Σ	Contains sufficient for <n> tests		Keep away from sunlight
	This way up	EC REP	Authorized representative in the European Community
IVD	*In vitro* diagnostic medical device	CONTENTS	Kit components
REF	Catalogue number	LOT	Batch code

All. 2

DITTA	PRODOTTO	PUNTEGGIO TECNICO RIPARAMETRATO	OFFERTA ECONOMICA: ALL. 5 PREZZO TOTALE TRIENNALE OFFERTO	PUNTEGGIO ECONOMICO	TOTALE PUNTEGGIO
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
IMMUNOMETRIA SPECIALE A COMPLETAMENTO DI PROFILI CLINICI				7498889[illegible]	
DITTA	PRODOTTO	PUNTEGGIO TECNICO RIPARAMETRATO	OFFERTA ECONOMICA: ALL. 5 PREZZO TOTALE TRIENNALE OFFERTO	PUNTEGGIO ECONOMICO	TOTALE PUNTEGGIO
MEDICAL SYSTEM	[illegible]	[illegible]	[illegible]	[illegible]	100

All 3

Unità Operativa Complessa Provveditorato ed Economato
Direttore: Dott.ssa Antonietta Costantini
Telefono:0823-232462
e-mail-: provveditorato@ospedale.caserta.it
pec: provveditorato@ospedalecasertapec.it

A.O.O. UOC Affari Generali - Ufficio Protocollo Generale
Protocollo: 0007318/U Data: 02/03/2020 09:49
Ufficio: UOC AFFARI GENERALI
Classifica:

Anticipata a mezzo posta elettronica

Spett.le Ditta MEDICAL SYSTEM

Oggetto: Fornitura di test rapido anti Covid 2019 – Richiesta urgente di offerta

Si invita codesta Spett.le Ditta a voler formulare e far pervenire, con la massima urgenza, all'indirizzo di posta certificata "provveditorato@ospedalecasertapec.it" migliore offerta per la seguente fornitura, destinata alla UOC Pataologia Clinica

- n.100 test Maglumi 2019 nCo V Igm (CLIA);
- n.100 test Maglumi 2019 nCo V IgG (CLIA).

I test richiesti saranno effettuati su piattaforma Maglumi, sistema diagnostico in possesso della suindicata UOC. In allegato, si rimette la documentazione di interesse, acquisita dal Reparto richiedente.
Si chiede di indicare percentuale di sconto di listino della Ditta produttrice.

Luogo di consegna:
U.O.C. Farmacia AORN "S. ANNA E S. SEBASTIANO" via G. La Pira, Caserta.
Nella bolla di consegna, debitamente datata e numerata, secondo le vigenti disposizioni di legge in materia, dovrà essere indicato il numero del buono d'ordine, oltre alla descrizione del prodotto, la quantità, ecc. La Ditta effettuerà le consegne a proprio rischio e con carico delle spese di qualsiasi natura.

Cessione dei crediti, cessione del contratto e subappalto
La cessione dei crediti derivanti dal presente contratto è soggetta alle disposizioni di cui all'art.106 del D.lgs. n.50/2016. In particolare, le cessioni dei crediti devono essere stipulate con atto pubblico o scrittura privata autenticata ed essere notificate alla stazione appaltante. Le stesse diventano efficaci ed opponibili alla stazione appaltante decorsi 45 giorni dalla notifica qualora non vengano rifiutate con apposita comunicazione.
È fatto divieto alla Ditta aggiudicataria di cedere a terzi, in tutto o in parte, l'oggetto del contratto, pena l'immediata risoluzione dello stesso nonché il risarcimento di ogni conseguente danno. Non è ammesso il subappalto.

Fatturazione:
Si comunica che a far data dal 31 Marzo 2015 quest'Amministrazione accetterà le fatture solo nel formato elettronico secondo l'allegato A del DM n.55/2013 e s.m.e.i. Le fatture elettroniche indirizzate alla presente Azienda Ospedaliera devono contenere i seguenti elementi specifici (come riportato sul sito: www.indicepa.gov.it):

Denominazione Ente:	Azienda Ospedaliera Sant'Anna e San Sebastiano di Caserta
Codice IPA:	aosa_061
Codice Univoco Ufficio:	551B2G
Nome dell'Ufficio:	FATTURAZIONE
Cod. fisc. del Servizio di F.E.:	02201130610
Partita Iva :	02201130610

Pagamento:
il pagamento avverrà nei 60 (sessanta) giorni dalla data di ricezione delle fatture da parte del Servizio Economico-Finanziario dell'AORN, dopo l'acquisizione del visto di regolare esecuzione del Responsabile della UO di destinazione.
Ai sensi e per gli effetti dell'art. 3) della legge 136 del 2010 e s.m.i. il fornitore deve assumere gli obblighi di tracciabilità dei flussi finanziari; pertanto, per non incorrere nella risoluzione del contratto, ai sensi dell'art. 3) comma 9 bis della suddetta legge, deve comunicare mediante dichiarazione sostitutiva dell'atto di notorietà - art. 47 DPR 445/2000 - gli estremi del c/c postale o bancario dedicato su cui effettuare i pagamenti, unitamente alle generalità ed al codice fiscale dei soggetti delegati ad operare sul conto, allegando fotocopia dei documenti di riconoscimento.
Il fornitore prende atto che il mancato utilizzo del conto corrente postale o bancario, ovvero degli altri strumenti che assicurino la tracciabilità dei movimenti finanziari, costituisce causa di risoluzione del contratto ai sensi dell'art. 3), comma 9 bis della legge 136/2010 e s.m.i.
L'impresa affidataria accetta, inoltre, tutte le clausole di cui al "Protocollo di Legalità" di cui la medesima società ha preso visione ed ha scaricato sul sito www.ospedale.caserta.it ad eccezione delle previsioni di cui all'art.2 co.2 punti h) e i) e di quelle di cui all'art.7 co.1 e all'art.8 co.1 clausola 7) e 8). (vedi delibere AORN n.6 del 31.01.14 e n.357 del 21.11.14)

Controversie
Per la soluzione di controversie eventualmente insorte nel corso dell'esecuzione della fornitura, sarà inizialmente tentata la composizione in via amministrativa. In caso di perdurante disaccordo la risoluzione del contenzioso sarà affidata al competente Tribunale di Santa Maria Capua Vetere.

Norme comuni

Per quanto non previsto espressamente dalla presente, si rinvia alla disciplina comunitaria e nazionale vigente in materia di contratti pubblici.

Si precisa che con la presente lettera questa Azienda non assume alcun impegno contrattuale e, di conseguenza, può procedere alla revoca della medesima in qualsiasi momento senza ulteriore comunicazione.

Il Direttore U.O.C. Provveditorato - Economato
Dott.ssa Antonietta Costantini

Commissario Straordinario Azienda Ospedaliera di Rilievo Nazionale Sant'Anna e San Sebastiano – Caserta
Via Palasciano 81100 – Caserta
Tel. 0823/232456-2468-2473-2665
e-mail: carmine.mariano@aorncaserta.it - direzionegenerale@ospedale.caserta.it
direzionegenerale@ospedalecasertapec.it

Snibe Diagnostic

CE REF 130219016M: 100 tests

MAGLUMI™ 2019-nCoV IgM (CLIA)

INTENDED USE

The kit is an *In Vitro* chemiluminescence immunoassay for the qualitative determination of IgM antibodies to novel coronavirus (2019-nCoV IgM) in human serum or plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer.

SUMMARY AND EXPLANATION OF THE TEST

The novel coronavirus (2019-nCoV) causes an epidemic of acute respiratory syndrome in humans in Wuhan[1], belonging to the genus Betacoronavirus. It has an envelope, particles are round or oval, often polymorphic, and the diameter is 60 ~ 140nm. Its genetic characteristics are significantly different from SARSr-CoV and MERSr-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 contact. The sources of infection seen so far are mainly patients with pneumonia infected by the novel coronavirus[2].

Research has shown that detection of IgM and IgG antiviral antibodies in the serum samples from a patient[3]. After human infection in 2019-nCoV, its antigen stimulates the immune system to produce an immune response, and corresponding antibodies appear in the blood. Among them, 2019-nCoV IgM appears earlier, and then 2019-nCoV IgM titers decrease, the 2019-nCoV IgG potency rose rapidly.

This kit is mainly used for the assisted diagnosis of the novel coronavirus (2019-nCoV) infection.

2019-nCoV, named by the World Health Organization on January 7, 2020, is announced the official name: Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) by the International Committee on Taxonomy of Viruses (ICTV) on February 11, 2020. On the same day, the Director-General of the World Health Organization (WHO) Tan Desai announced that pneumonia infected with SARS-CoV-2 will be officially named "COVID-19".

PRINCIPLE OF THE TEST

The MAGLUMI 2019-nCoV IgM (CLIA) assay is a capture 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 labeled 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 a 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).

KIT COMPONENTS

Material Provided

Component	Contents	100 tests (REF: 130219016M)
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.

Accessories Required But Not Provided

MAGLUMI Series:

Reaction Module	REF: 630003
Starter 1+2	REF: 130299004M;130299012M; 130299027M
Wash Concentrate	REF: 130299005M
Light Check	REF: 130299006M
Reaction Cup	REF: 130105000101
Maglumi 600	REF: 23020018
Maglumi 800	REF: 23020003
Maglumi 1000	REF: 23020009
Maglumi 2000	REF: 23020006
Maglumi 2000 Plus	REF: 23020007
Maglumi 4000	REF: 23020014
Maglumi 4000 Plus	REF: 23020037
MAGLUMI X8	REF: 010101008801
Biolumi 8000	REF: 23010001

Please order accessories 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.

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

Follow government regulations or accreditation requirements 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 Information***. User needs to judge results with their own standards and knowledge.

AORN CASERTA

REGIONE CAMPANIA
AZIENDA OSPEDALIERA DI RILIEVO NAZIONALE
E DI ALTA SPECIALIZZAZIONE
"SANT'ANNA E SAN SEBASTIANO" DI CASERTA

Alla c.a. del Direttore UOC Provveditorato
UOC Farmacia
E p.c. Subcommissario Sanitario
SEDE

Oggetto: acquisto urgente test rapido anti Covid 2019

In relazione alle recenti note diramate a livello ministeriale si richiede con **urgenza** l'acquisizione del test 2019 nCoV IgM e IgG per la diagnosi di screening rapida di infezione da Coronavirus 2019. Essendo il test disponibile su piattaforma Maglumi, sistema diagnostico già in possesso di questa UOC, si richiede l'acquisizione in trattativa diretta dalla Ditta Medical System (vedi allegato)

Maglumi 2019 nCoV IgM (CLIA) 100 test
Maglumi 2019 nCoV IgG (CLIA) 100 test

Caserta lì, 27/02/2020

Il Direttore UOC Patologia Clinica
Dott. Arnolfo Petruzziello

A.O.R.N. SANT'ANNA E SAN SEBASTIANO DIPARTIMENTO DEI SERVIZI SANITARI DIRETTORE DOTT. Arnolfo Petruzziello CASERTA

A.O.R.N. Sant'Anna e San Sebastiano
CASERTA
U.O.C. Patologia Clinica
Direttore: Dott. *Arnolfo Petruzziello*

È urgente, di mia procedere
in tal senso 28/02/2020
Dott.ssa Costantini

U.O.C. PATOLOGIA CLINICA
Dipartimento dei Servizi Sanitari
Via F. Palasciano – 81100 Caserta
Tel. Direzione: 0823 232764; Segreteria: 0823 232144/2150; Ambulatorio 0823 232132
e.mail: patologiaclinica@ospedale.caserta.it; patologiaclinica.dir@ospedale.caserta.it
Direttore Dott. Arnolfo Petruzziello

For details about entering quality control values, refer to the operating instructions of MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer.
To monitor system performance, quality control materials (negative control and positive control) are required. Treat 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 appropriate 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 still 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.

SPECIMEN COLLECTION AND PREPARATION

- Human serum or plasma may be used with the 2019-nCoV IgM (CLIA) assay. Serum including samples collected using standard sampling tubes, tubes containing separating gel or procoagulant inert separation tubes. For plasma samples, the anticoagulants including K_2-EDTA, K_3-EDTA, Na_2 -EDTA, have been tested and may be used with this assay.
- Do not use grossly hemolyzed specimens.
- Inspect all specimens for bubbles. Remove bubbles with an applicator stick before analysis. Use a new applicator stick for each specimen to prevent cross contamination.
- Specimens removed from the separator gel, cells or clot may be stored 5 days at 2-8°C.
- Specimens can be stored more than 5 days frozen at -70°C or colder. Avoid repeated freezing and thawing. Frozen specimens must be mixed thoroughly after thawing by low speed vortexing 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 specimen 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..
- The sample volume required for a single determination is 10 µL.

WARNING AND PRECAUTIONS FOR USERS

- IVD For *In Vitro* Diagnostic Use.
- 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 refrigerator, it is recommended that the opened reagent kits to 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.

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

TEST PROCEDURE

Preparation of the Reagent

- 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 agent 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.
- Resuspension of the magnetic microbeads takes place automatically when the kit is loaded successfully, ensuring the magnetic microbeads are totally resuspended homogenous prior to use.

Assay Calibration

- Click **<Calibration>** or **<Batch Calibration>** button to 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 manual.

Quality Control

- In order to avoid manually error in entry of QC information, the provided barcode labels of quality control in the kit can be used attached on the test tubes.
- Strictly follow the quality control procedures when using the quality controls..
- 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 to the Quality Control Section of the Operating Instructions.

Sample 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.

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

DILUTION

Samples with concentrations above 30.0 AU/mL can be diluted automatically by analyzers or manually. 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 dilution settings are done in the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer user software. Please refer to the operating instructions of MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer.

LIMITATIONS

- This test is suitable only for investigating single samples, not for pooled samples or heat-inactivated specimens.
- Bacterial contamination or repeated freeze-thaw cycles may affect the test results.
- Fresh sample is recommended. If a low positive result was get, repeated test should be conducted after centrifuged especial severely or using additional test to confirm the result.
- Assay results should be utilized in conjunction with other clinical and laboratory methods to assist the clinician in making individual patient diagnostic decisions.
- If the 2019-nCoV IgM results are inconsistent with clinical evidence, additional testing is suggested to confirm the result.
- HAMA antibodies in test samples may cause interference in immunoassays.

RESULTS

Calculation of Results
The analyzer automatically calculates the concentration in each sample by means of a calibration curve which is generated by a 2-point calibration master curve procedure. The results are expressed in AU/mL. For further information please refer to the operating instructions of MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer.
Interpretation of Results
Results obtained with the 2019-nCoV IgM assay can be interpreted as follows:

- Non-reactive: A result less than 0.900 AU/mL (<0.900 AU/mL) is considered to be non-reactive.
- Gray zone: A result in the interval between 0.900 and 1.10 (0.900≤ x<1.10 AU/mL) is considered to be equivocal.
- Reactive: A result greater than or equal to 1.10 AU/mL (≥1.10 AU/mL) is considered to be reactive.

PERFORMANCE CHARACTERISTICS

Precision
Precision for 2019-nCoV IgM assay was determined as described in the CLSI EP5-A3. 2 controls and 3 samples containing different concentration of analyte were assayed in duplicate at three sites on five days, with 3 runs per day, one lot of reagent for each run and 2 replicates per run. The result is summarized in the following table:

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
NQC	0.296	90	0.025	NA	0.011	NA	0.003	NA	0.019	NA	0.034	NA
PQC	3.911	90	0.164	4.19	0.062	1.59	0.062	1.59	0.293	7.49	0.347	8.87
S1	0.501	90	0.048	NA	0.009	NA	0.007	NA	0.023	NA	0.055	NA
S2	3.517	90	0.162	4.61	0.053	1.51	0.041	1.17	0.054	1.54	0.183	5.20
S3	14.710	90	0.269	1.83	0.072	0.49	0.127	0.86	0.589	4.00	0.664	4.51

Endogenous interference
Two serum samples (one negative sample, one positive sample) were spiked with potential endogenous interference. The results of the interferences are listed in the following table:

Interference	No interference up to
Hemoglobin	2000 mg/dL
Bilirubin	40 mg/dL
Triglycerides	1000 mg/dL
Rheumatoid Factor	1500 IU/mL
HAMA	30 ng/mL

Drug interference
Two serum samples (one negative sample, one positive sample) were spiked with potential endogenous interference. The results of the interferences are listed in the following table:

Interference	No interference up to
Acetylcysteine	15 mg/dL
Ampicillin sodium	100 mg/dL
Cefoxitin	250 mg/dL
Metronidazole	20 mg/dL
Tetracycline	5 mg/dL
Aspirin	100 mg/dL
Rifampin	6 mg/dL
Acetaminopthen	20 mg/dL
Ibuprofen	50 mg/dL
Theophylline	10 mg/dL
Lamivudine	30 mg/dL
Entecavir	0.5 mg/L
Telbivudine	60 mg/dL
Adefovir	1 mg/dL

Analytical specificity
Clinical 2019-nCoV IgM negative samples, which contain potential cross-reactants including influenza virus type A antibody, influenza virus type B antibody, parainfluenza virus antibody, respiratory syncytial virus antibody, adenovirus antibody, EBV NA IgG, EBV VCA IgM/IgG, CMV IgM/IgG, M.Pneumonia IgM/IgG, chlamydia pneumoniae IgM/IgG, Candida albicans, ANA were used to evaluate the cross-reactivity of 2019-nCoV IgM assay. Of all the potential cross-reactants, none were found to cause false positive in the 2019-nCoV IgM assay.

Clinical Sensitivity
The clinical sensitivity was determined for 87 confirmed novel coronavirus infected specimens. The clinical sensitivity was calculated to be 48.28%.

Specimen Category	2019-nCoV IgM (CLIA)		
	N	Positive	%Sensitivity
Clinical confirmed positive samples	87	42	48.28%

Clinical specificity
The clinical specificity was determined for 370 non- novel coronavirus infected specimens, normal samples and interference samples. The clinical specificity was calculated to be 100%.

Specimen Category	2019-nCoV IgM (CLIA)		
	N	Negative	%Specificity
negative specimens	370	370	100%

REFERENCES

1. Zhou, P., Yang, X., Wang, X. et al. A pneumonia outbreak associated with a new coronavirus of probable bat origin. Nature (2020). https://doi.org/10.1038/s41586-020-2012-7.
2. Diagnosis and treatment of pneumonitis caused by novel coronavirus (version 4).
3. Na Zhu, Ph.D., Dingyu Zhang, et al.A Novel Coronavirus from Patients with Pneumonia in China, 2019[J].New England Journal of Medicine, 2020.

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SYMBOLS EXPLANATIONS

	Consult instructions for use		Manufacturer
2°C 8°C	Temperature limit (Store at 2-8°C)		Use-by date
Σ	Contains sufficient for <n> tests		Keep away from sunlight
	This way up	EC REP	Authorized representative in the European Community
IVD	*In vitro* diagnostic medical device	CONTENTS	Kit components
REF	Catalogue number	LOT	Batch code

Snibe Diagnostic

CE REF 130219015M: 100 tests

MAGLUMI™ 2019-nCoV IgG (CLIA)

INTENDED USE

The kit is an *In Vitro* chemiluminescence immunoassay for the qualitative determination of IgG antibodies to novel coronavirus (2019-nCov IgG) in human serum or plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer.

SUMMARY AND EXPLANATION OF THE TEST

The novel coronavirus (2019-nCoV) causes an epidemic of acute respiratory syndrome in humans in Wuhan[1], belonging to the genus Betacoronavirus. It has an envelope, particles are round or oval, often polymorphic, and the diameter is 60 ~ 140nm. Its genetic characteristics are significantly different from SARSr-CoV and MERSr-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 contact. The sources of infection seen so far are mainly patients with pneumonia infected by the novel coronavirus.[2]

Research has shown that detection of IgM and IgG antiviral antibodies in the serum samples from a patient[3]. After human infection in 2019-nCoV, its antigen stimulates the immune system to produce an immune response, and corresponding antibodies appear in the blood. Among them, 2019-nCoV IgM appears earlier, and then 2019-nCoV IgM titers decrease, the 2019-nCoV IgG potency rose rapidly.

This kit is mainly used for the assisted diagnosis of the novel coronavirus (2019-nCoV) infection.

2019-nCoV, named by the World Health Organization on January 7, 2020, is announced the official name: Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) by the International Committee on Taxonomy of Viruses (ICTV) on February 11, 2020. On the same day, the Director-General of the World Health Organization (WHO) Tan Desai announced that pneumonia infected with SARS-CoV-2 will be officially named "COVID-19".

PRINCIPLE OF THE TEST

The MAGLUMI 2019-nCoV IgG (CLIA) assay is an indirect chemiluminescence immunoassay.

The prediluted sample (or calibrator/control, if applicable), buffer and 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 labeled with anti-human IgG antibody, and incubate to form complexes. After precipitation in a magnetic field, decant the supernatant, and perform another wash cycle. Subsequently, the Starter 1+2 are 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 2019-nCoV IgG presented in the sample (or calibrator/control, if applicable).

KIT COMPONENTS

Material Provided

Component	Contents	100 tests (REF: 130219015M)
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%).	1.0 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

All reagents are provided ready-to-use.

Accessories Required But Not Provided

MAGLUMI Series:	
Reaction Module	REF: 630003
Starter 1+2	REF: 130299004M;130299012M; 130299027M
Wash Concentrate	REF: 130299005M
Light Check	REF: 130299006M
Reaction Cup	REF: 130105000101
Maglumi 600	REF: 23020018
Maglumi 800	REF: 23020003
Maglumi 1000	REF: 23020009
Maglumi 2000	REF: 23020006
Maglumi 2000 Plus	REF: 23020007
Maglumi 4000	REF: 23020014
Maglumi 4000 Plus	REF: 23020037
MAGLUMI X8	REF: 010101008801
Biolumi 8000	REF: 23010001

Please order accessories 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.

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

Follow government regulations or accreditation requirements for quality control frequency.

Internal quality control is only applicable with MAGLUMI system. For instructions for use and target value refer to ***2019-nCoV IgG Quality Control Information***. 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-auto chemiluminescence

immunoassay analyzer.
To monitor system performance, quality control materials (negative control and positive control) are required. Treat 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 appropriate 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 still 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.

SPECIMEN COLLECTION AND PREPARATION

- Human serum or plasma may be used with the 2019-nCoV IgG (CLIA) assay. Serum including samples collected using standard sampling tubes, tubes containing separating gel or procoagulant inert separation tubes. For plasma samples, the anticoagulants including K_2-EDTA, K_3-EDTA, Na_2 -EDTA, have been tested and may be used with this assay.
- Do not use grossly hemolyzed specimens.
- Inspect all specimens for bubbles. Remove bubbles with an applicator stick before analysis. Use a new applicator stick for each specimen to prevent cross contamination.
- Specimens removed from the separator gel, cells or clot may be stored 5 days at 2-8°C.
- Specimens can be stored more than 5 days frozen at -70°C or colder. Avoid repeated freezing and thawing. Frozen specimens must be mixed thoroughly after thawing by low speed vortexing 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 specimen 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.
- The sample volume required for a single determination is 10 µL.

WARNING AND PRECAUTIONS FOR USERS

- IVD For *In Vitro* Diagnostic Use.
- 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 refrigerator, it is recommended that the opened reagent kits to 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.

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

TEST PROCEDURE

Preparation of the Reagent

- 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 agent 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.
- Resuspension of the magnetic microbeads takes place automatically when the kit is loaded successfully, ensuring the magnetic microbeads are totally resuspended homogenous prior to use.

Assay Calibration

- Click **<Calibration>** or **<Batch Calibration>** button to 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 manual.

Quality Control

- In order to avoid manually error in entry of QC information, the provided barcode labels of quality control in the kit can be used attached on the test tubes.
- Strictly follow the quality control procedures when using the quality controls.
- 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 to the Quality Control Section of the Operating Instructions.

Sample 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.

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

analyzer.

DILUTION

The automatic sample dilution is available after dilution settings are done in the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer user software. Please refer to the operating instructions of MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer. The recommended dilution factor is 20 times (1:19, 1part sample with19 parts diluent).After automatic dilution, multiply the result by the dilution factor.

LIMITATIONS

- This test is suitable only for investigating single samples, not for pooled samples or heat-inactivated specimens.
- Bacterial contamination or repeated freeze-thaw cycles may affect the test results.
- Fresh sample is recommended. If a low positive result was get, repeated test should be conducted after centrifuged especial severely or using additional test to confirm the result.
- Assay results should be utilized in conjunction with other clinical and laboratory methods to assist the clinician in making individual patient diagnostic decisions.
- If the 2019-nCoV IgG results are inconsistent with clinical evidence, additional testing is suggested to confirm the result.
- HAMA antibodies in test samples may cause interference in immunoassays.

RESULTS

Calculation of Results

The analyzer automatically calculates the concentration in each sample by means of a calibration curve which is generated by a 2-point calibration master curve procedure. The results are expressed in AU/mL. For further information please refer to the operating instructions of MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer.

Interpretation of Results

Results obtained with the 2019-nCoV IgG assay can be interpreted as follows:

- Non-reactive: A result less than 0.900 AU/mL (<0.900 AU/mL) is considered to be non-reactive.
- Gray zone: A result in the interval between 0.900 and 1.100(0.900≤ x<1.10 AU/mL) is considered to be equivocal.
- Reactive: A result greater than or equal to 1.10 AU/mL (≥1.10 AU/mL) is considered to be reactive.

PERFORMANCE CHARACTERISTICS

Precision

Precision for 2019-nCoV IgG assay was determined as described in the CLSI EP5-A3.2 controls and 3 human serum pools containing different concentration of analyte were assayed in duplicate at three sites on five days, with 3 runs per day, one lot of reagent for each run and 2 replicates per run. The result is summarized in the following table:

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
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

Endogenous interference

Two serum samples (one negative sample, one positive) were spiked with potential endogenous interference. The results of the interferences are listed in the following table:

Interference	No interference up to
Hemoglobin	2000 mg/dL
Bilirubin	40 mg/dL
Triglycerides	1000 mg/dL
Rheumatoid Factor	1500 IU/mL
HAMA	30 ng/mL

Drug interference

Two serum samples (one negative sample, one positive) were spiked with potential endogenous interference. The results of the interferences are listed in the following table:

Interference	No interference up to
Acetylcysteine	15 mg/dL
Ampicillin sodium	100 mg/dL
Cefoxitin	250 mg/dL
Metronidazole	20 mg/dL
Tetracycline	5 mg/dL
Aspirin	100 mg/dL
Rifampin	6 mg/dL
Acetaminopthen	20 mg/dL
Ibuprofen	50 mg/dL
Theophylline	10 mg/dL
Lamivudine	30 mg/dL
Entecavir	0.5 mg/L
Telbivudine	60 mg/dL
Adefovir	1 mg/dL

Analytical specificity

Clinical 2019-nCoV IgG negative samples, which contain potential cross-reactants including Influenza virus type A antibody, Influenza virus type B antibody, parainluenza virus antibody, respiratory syncytial virus antibody, adenovirus antibody, EBV NA IgG, EBV VCA IgM/IgG, CMV IgM/IgG, M.Pneumonia IgM/IgG, chlamydia pneumoniae IgM/IgG, Candida albicans, ANA were used to evaluate the cross-reactivity of 2019-nCoV IgG assay. Of all the potential cross-reactants, none were found to cause false positive in the 2019-nCoV IgG assay.

Clinical Sensitivity

The clinical sensitivity was determined for 91 confirmed novel coronavirus infected specimens. The clinical sensitivity was calculated to be 91.21%.

Specimen Category	2019-nCoV IgG (CLIA)		
	N	Positive	%Sensitivity
Clinical confirmed positive samples	91	83	91.21%

Clinical specificity

The clinical specificity was determined for 370 non- novel coronavirus infected specimens, normal samples and interference samples. The clinical specificity was calculated to be 100%.

Specimen Category	2019-nCoV IgG (CLIA)		
	N	Negative	%Specificity
negative specimens	370	370	100%

REFERENCES

1.Zhou, P., Yang, X., Wang, X. et al. A pneumonia outbreak associated with a new coronavirus of probable bat origin. Nature (2020). https://doi.org/10.1038/s41586-020-2012-7.

2. Diagnosis and treatment of pneumonitis caused by novel coronavirus (version 4).

3. Na Zhu, Ph.D., Dingyu Zhang, et al. A Novel Coronavirus from Patients with Pneumonia in China, 2019[J]. New England Journal of Medicine, 2020.

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Tel: +86-755-21536601 Fax: +86-755-28292740

EC REP **Shanghai International Holding Corp. GmbH (Europe)**
Eiffestrasse 80, 20537 Hamburg, Germany
Tel: +49-40-2513175 Fax: +49-40-255726

SYMBOLS EXPLANATIONS

	Consult instructions for use		Manufacturer
2°C 8°C	Temperature limit (Store at 2-8°C)		Use-by date
Σ	Contains sufficient for <n> tests		Keep away from sunlight
	This way up	EC REP	Authorized representative in the European Community
IVD	*In vitro* diagnostic medical device	CONTENTS	Kit components
REF	Catalogue number	LOT	Batch code

provveditorato@ospedalecasertapec.it

Da:	posta-certificata@pec.aruba.it
Inviato:	lunedì 2 marzo 2020 10:17
A:	provveditorato@ospedalecasertapec.it
Oggetto:	ACCETTAZIONE: fornitura test rapido anti COVID 2019_RICHIESTA URGENTE DI OFFERTA
Allegati:	daticert.xml
Firmato da:	posta-certificata@pec.aruba.it

Ricevuta di accettazione

Il giorno 02/03/2020 alle ore 10:17:26 (+0100) il messaggio
"fornitura test rapido anti COVID 2019_RICHIESTA URGENTE DI OFFERTA" proveniente da
"provveditorato@ospedalecasertapec.it"
ed indirizzato a:
gare.medicalsystems@legalmail.it ("posta certificata")

Il messaggio è stato accettato dal sistema ed inoltrato.
Identificativo messaggio: opec292.20200302101726.30523.599.2.65@pec.aruba.it

provveditorato@ospedalecasertapec.it

Da:	Posta Certificata Legalmail <posta-certificata@legalmail.it>
Inviato:	lunedì 2 marzo 2020 10:18
A:	provveditorato@ospedalecasertapec.it
Oggetto:	CONSEGNA: fornitura test rapido anti COVID 2019_RICHIESTA URGENTE DI OFFERTA
Allegati:	postacert.eml (6,35 MB); daticert.xml
Firmato da:	posta-certificata@legalmail.it

Ricevuta di avvenuta consegna

Il giorno 02/03/2020 alle ore 10:18:05 (+0100) il messaggio "fornitura test rapido anti COVID 2019_RICHIESTA URGENTE DI OFFERTA" proveniente da "provveditorato@ospedalecasertapec.it" ed indirizzato a "gare.medicalsystems@legalmail.it" è stato consegnato nella casella di destinazione.

Questa ricevuta, per Sua garanzia, è firmata digitalmente e la preghiamo di conservarla come attestato della consegna del messaggio alla casella destinataria.

Identificativo messaggio: opec292.20200302101726.30523.599.2.65@pec.aruba.it

Delivery receipt

The message "fornitura test rapido anti COVID 2019_RICHIESTA URGENTE DI OFFERTA" sent by "provveditorato@ospedalecasertapec.it", on 02/03/2020 at 10:18:05 (+0100) and addressed to "gare.medicalsystems@legalmail.it", was delivered by the certified email system.

As a guarantee to you, this receipt is digitally signed. Please keep it as certificate of delivery to the specified mailbox.

Message ID: opec292.20200302101726.30523.599.2.65@pec.aruba.it

MEDICAL SYSTEMS S.p.A.
16165 GENOVA STRUPPA (ITALY)
Via Rio Torbido, 40
Tel. 010.83401
Fax 010.808362
www.medicalsystems.it
info@medicalsystems.it
Numero Verde 800-801005 UFFICIO ORDINI
Numero Verde 800-804016 CUSTOMER SERVICE

DG/UG/kb
Prot. n. 172

Spettabile
AORN "S. ANNA E S. SEBASTIANO"
UOC Provveditorato ed economato
Via Palasciano – Piano Terra Palazzina A
81100 CASERTA – CE

Genova, 02 marzo 2020

Oggetto: Fornitura di test anti Covid-2019 – integrazione Offerta per la Fornitura triennale di prodotti per la U.O.C. di Patologia Clinica. Integrazione ex delibera del D.G. n. 186/2019 del Lotto 32 "Immunometria Speciale a completamento di profili clinici
Rif.to : Vs. richiesta Prot. 0007318/u del 02/03/2020

Il sottoscritto Alessandro Pater, nato a Sanremo (IM) il 09.09.1970 e residente a Genova in C.so A. Saffi n. 29/9, in qualità di Amministratore Unico di Medical Systems S.p.A. con sede legale e amministrativa a Genova – Via Rio Torbido n. 40, con codice fiscale n. 0024866059, partita IVA n. 02405380101, iscritta alla CCIAA di Genova al n. REA n. 250502 e al Registro delle Imprese al n. 00248660599 dal 19.02.1996, codice attività 46463, con capitale sociale interamente versato di € 7.280.000,00=, si pregia di sottoporVi la propria migliore offerta come indicato nello schema di offerta allegato alla presente (ALL 1), che costituisce parte integrante della presente.

MODALITA' DI FORNITURA

DURATA FORNITURA : la fornitura avrà durata triennale dalla data della Vs. conferma di acquisto con possibilità di proroga, previa Vs. richiesta;

VALIDITA' OFFERTA : 90 gg. data di scadenza della presentazione dell'offerta;

IVA 22% : a Vs. carico ed esclusa dal prezzo indicato;

IMBALLO E TRASPORTO : a ns. carico;

TERMINI DI CONSEGNA : immediata, fatta salva la disponibilità di magazzino e comunque entro 5 gg. dal Vs. gradito ordine per i reagenti;

Documento firmato digitalmente da Alessandro Pater – Amministratore Unico Medical Systems Spa (D.L.g.s n.82/2005 e succ.mod.)

MEDICAL SYSTEMS S.p.A.
16165 GENOVA STRUPPA (ITALY)
Via Rio Torbido, 40
Tel. 010.83401
Fax 010.808362
www.medicalsystems.it
info@medicalsystems.it
800-801005
800-804016

MODALITA' DI FATTURAZIONE: per reagenti e consumabili (il cui costo include l'utilizzo della strumentazione e assistenza tecnica) : per ogni confezione di prodotto ordinato e consegnato, così come risulta dalla bolla di consegna;

PAGAMENTO : Nei termini di legge.

Grati dell'attenzione ed in attesa di un Vs. cortese cenno di riscontro in merito, porgiamo cordiali saluti.

L'Amministratore Unico
Alessandro Pater

Documento firmato digitalmente da Alessandro Pater – Amministratore Unico Medical Systems Spa (D.L.g.s n.82/2005 e succ.mod.)

MEDICAL SYSTEMS S.p.A.
16165 GENOVA STRUPPA (ITALY)
Via Rio Torbido, 40
Tel. 010.83401
Fax 010.808362
www.medicalsystems.it
info@medicalsystems.it
800-801005 OFFICIO ORDINI
800-804016 CUSTOMER SERVICE

MODALITA' DI FATTURAZIONE: per reagenti e consumabili (il cui costo include l'utilizzo della strumentazione e assistenza tecnica) : per ogni confezione di prodotto ordinato e consegnato, così come risulta dalla bolla di consegna;

PAGAMENTO : Nei termini di legge.

Grati dell'attenzione ed in attesa di un Vs. cortese cenno di riscontro in merito, porgiamo cordiali saluti.

L'Amministratore Unico
Alessandro Pater

dd 5

Da "provveditorato@ospedalecasertapec.it" <provveditorato@ospedalecasertapec.it>
A "Patologia Clinica" <patologiaclinica@ospedalecasertapec.it>
Data giovedì 5 marzo 2020 - 10:51

test rapido anti COVID 2019 - invio preventivo ditta Medical system

Si rimette in allegato l'offerta prot. n. 172 della ditta Medical System per la fornitura di test anti covid 2019, da voi richiesti il 27 u.s. (prot. 7141/i).
UOC Provveditorato Ed Economato

Allegato(i)

fornitura covid 2019.PDF (508 Kb)

Da "posta-certificata@pec.aruba.it" <posta-certificata@pec.aruba.it>
A "provveditorato@ospedalecasertapec.it" <provveditorato@ospedalecasertapec.it>
Data giovedì 5 marzo 2020 - 10:51

CONSEGNA: test rapido anti COVID 2019 - invio preventivo ditta Medical system

Ricevuta di avvenuta consegna

Il giorno 05/03/2020 alle ore 10:51:44 (+0100) il messaggio
"test rapido anti COVID 2019 - invio preventivo ditta Medical system" proveniente da
"provveditorato@ospedalecasertapec.it"
ed indirizzato a "patologiaclinica@ospedalecasertapec.it"
è stato consegnato nella casella di destinazione.
Identificativo messaggio: opec292.20200305105142.22556.23.2.69@pec.aruba.it

Allegato(i)

daticert.xml (964 bytes)
postacert.eml (699 Kb)
smime.p7s (7 Kb)

MEDICAL SYSTEMS S.p.A.
16165 GENOVA STRUPPA (ITALY)
Via Rio Torbido, 40
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info@medicalsystems.it
800-801005
800-804018

DG/UG/kb
Prot. n. 172

Spettabile
AORN "S. ANNA E S. SEBASTIANO"
UOC Provveditorato ed economato
Via Palasciano – Piano Terra Palazzina A
81100 CASERTA – CE

Genova, 02 marzo 2020

Oggetto: Fornitura di test anti Covid-2019 – integrazione Offerta per la Fornitura triennale di prodotti per la U.O.C. di Patologia Clinica. Integrazione ex delibera del D.G. n. 186/2019 del Lotto 32 "Immunometria Speciale a completamento di profili clinici

Rif.to : Vs. richiesta Prot. 0007318/u del 02/03/2020

Il sottoscritto Alessandro Pater, nato a Sanremo (IM) il 09.09.1970 e residente a Genova in C.so A. Saffi n. 29/9, in qualità di Amministratore Unico di Medical Systems S.p.A. con sede legale e amministrativa a Genova – Via Rio Torbido n. 40, con codice fiscale n. 00248660599, partita IVA n. 02405380101, iscritta alla CCIAA di Genova al n. REA n. 250502 e al Registro delle Imprese al n. 00248660599 dal 19.02.1996, codice attività 46463, con capitale sociale interamente versato di € 7.280.000,00=, si pregia di sottoporVi la propria migliore offerta come indicato nello schema di offerta allegato alla presente (ALL 1), che costituisce parte integrante della presente.

MODALITA' DI FORNITURA

DURATA FORNITURA	:	la fornitura avrà durata triennale dalla data della Vs. conferma di acquisto con possibilità di proroga, previa Vs. richiesta;
VALIDITA' OFFERTA	:	90 gg. data di scadenza della presentazione dell'offerta;
IVA 22%	:	a Vs. carico ed esclusa dal prezzo indicato;
IMBALLO E TRASPORTO	:	a ns. carico;
TERMINI DI CONSEGNA	:	immediata, fatta salva la disponibilità di magazzino e comunque entro 5 gg. dal Vs. gradito ordine per i reagenti;

Documento firmato digitalmente da Alessandro Pater – Amministratore Unico Medical Systems Spa (D.L.g.s n.82/2005 e succ.mod.)

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800-801005
800-804016

MODALITA' DI FATTURAZIONE: per reagenti e consumabili (il cui costo include l'utilizzo della strumentazione e assistenza tecnica) : per ogni confezione di prodotto ordinato e consegnato, così come risulta dalla bolla di consegna;

PAGAMENTO : Nei termini di legge.

Grati dell'attenzione ed in attesa di un Vs. cortese cenno di riscontro in merito, porgiamo cordiali saluti.

L'Amministratore Unico
Alessandro Pater

All 6

9/3/2020 il prodotto è conforme e si effettuano le VITA[?] ... [illegible]

Adottare provvedimento

A.O.R.N. SANT'ANNA E SAN SEBASTIANO - CASERTA - DIPARTIMENTO DEI SERVIZI SANITARI - DIRETTORE Dott. Arnolfo Petruzziello

Documento firmato digitalmente da Alessandro Pater – Amministratore Unico Medical Systems Spa (D.L.g.s n.82/2005 e succ.mod.)

NOME	CODICE	TEST/CONF.		PREZZO DI LISTINO	SCONTO	PREZZO CONFEZIONE	PREZZO A TEST
MAGLUMI 2019-nCoV IgG	130219015M	100	CE	€ 1.600,00	10%	€ 1.440,00	€ 14,40
MAGLUMI 2019-nCoV IgM	130219016M	100	CE	€ 1.600,00	10%	€ 1.440,00	€ 14,40

REGIONE CAMPANIA
AZIENDA OSPEDALIERA DI CASERTA
SANT'ANNA E SAN SEBASTIANO
DI RILIEVO NAZIONALE E DI ALTA SPECIALIZZAZIONE

ATTESTAZIONE DI VERIFICA E REGISTRAZIONE CONTABILE
relativa alla DETERMINA DIRIGENZIALE con oggetto:

Fornitura di n.200 test 2019 nCoVC IgM e IgG per la diagnosi di screening rapida di infezioni da Coronavirus 2019, da destinare alla UOC Patologia Clinica - Acquisto ex art. 63, comma 2, lett c del D.Lgs. n.50/2016 e smi.

ATTESTAZIONE DI VERIFICA E REGISTRAZIONE CONTABILE 1 (per le proposte che determinano un costo per l'AORN)

Il costo derivante dal presente atto : €3.516,60

- è di competenza dell'esercizio 2020 , imputabile al conto economico 5010105010 - Dispositivi medico-diagnostici in vitro (IVD)
  da scomputare dal preventivo di spesa da inserire su apposito centro di costo Corona Virus che presenta la necessaria disponibilità
- è relativo ad acquisizione cespiti di cui alla Fonte di Finanziamento

---

Caserta li, 11/03/2020

il Dirigente GEF incaricato
UOC GESTIONE ECONOMICO FINANZIARIA
Eduardo Scarfiglieri

REGIONE CAMPANIA
AZIENDA OSPEDALIERA DI CASERTA
SANT'ANNA E SAN SEBASTIANO
DI RILIEVO NAZIONALE E DI ALTA SPECIALIZZAZIONE

Determina Dirigenziale N. 105 del 11/03/2020

PROPONENTE: **UOC PROVVEDITORATO ED ECONOMATO**

OGGETTO: **Fornitura di n.200 test 2019 nCoVC IgM e IgG per la diagnosi di screening rapida di infezioni da Coronavirus 2019, da destinare alla UOC Patologia Clinica - Acquisto ex art. 63, comma 2, lett c del D.Lgs. n.50/2016 e smi.**

In pubblicazione dal 11/03/2020 e per il periodo prescritto dalla vigente normativa in materia (art.8 D.Lgs 14/2013, n.33 e smi)

Atto immediatamente esecutivo

UOC AFFARI GENERALI

Direttore Eduardo Chianese

Elenco firmatari

Antonietta Costantini - UOC PROVVEDITORATO ED ECONOMATO

Eduardo Scarfiglieri - UOC GESTIONE ECONOMICO FINANZIARIA

Eduardo Chianese - UOC AFFARI GENERALI