FORMULARUL OFERTEI (F3.1)

Data: **21 ian 2021, 15:35 - 25 ian 2021, 12:55**
Procedura de achiziție **ocds-b3wdp1-MD-1611047043861**
Anunț de participare Nr.:
Către: ***IMSP Institutul de Cardiologie***

Biosistem-mld SRL declară că:

a) Au fost examinate şi nu există rezervări faţă de documentele de licitaţie, inclusiv modificările nr.

b) Biosistem-mld SRL se angajează să furnizeze, în conformitate cu documentele de licitaţie şi condiţiile stipulate în specificaţiile tehnice şi de formare a preţurilor, următoarele bunuri şi/sau servicii

Test Rapid Antigen Covid-19

c) Suma totală a ofertei fără TVA constituie: 28,083.00 lei
douăzeci şi opt mii optzeci şi trei lei

d) Suma totală a ofertei cu TVA constituie: 30,330.00 lei
treizeci mii trei sute treizeci lei

e) Prezenta ofertă va rămîne valabilă pentru perioada de timp specificată în FDA3.8., începînd cu data-limită pentru depunerea ofertei, în conformitate cu FDA4.2., va rămîne obligatorie şi va putea fi acceptată în orice moment pînă la expirarea acestei perioade

f) În cazul acceptării prezentei oferte, Biosistem-mld SRL se angajează să obţină o Garanţie de bună execuţie în conformitate cu FDA6, pentru executarea corespunzătoare a contractului de achiziţie publică.

g) Nu sîntem în nici un conflict de interese, în conformitate cu art. 74 din Legea nr. 131 din 03.07.2015 privind achiziţiile publice

h) Compania semnatară, afiliaţii sau sucursalele sale, inclusiv fiecare partener sau subcontractor ce fac parte din contract, nu au fost declarate neeligibile în baza prevederilor legislaţiei în vigoare sau a regulamentelor cu incidenţă în domeniul achiziţiilor publice

Semnat: _____ Digitally signed by Poiata Vitalie
Date: 2021.01.22 14:27:17 EET
Reason: MoldSign Signature
Location: Moldova

Nume: Poiata Vitalie

În calitate de: Director

Ofertantul: Biosistem-mld SRL

Adresa: mun.Chisinau, Albisoara 16/1 of.7

Data: 21 ian 2021, 15:35 - 25 ian 2021, 12:55

BIOSISTEM-MLD S.R.L.

FORMULAR INFORMATIV DESPRE OFERTANT

Data: 21 ian 2021, 15:35 - 25 ian 2021, 12:55

Licitaţia nr.: ocds-b3wdp1-MD-1611047043861

A. Ofertanţi individuali

1. Informaţii generale		
1.1.	Numele juridic al ofertantului	Biosistem-mld SRL
1.2.	Adresa juridică a ofertantului în ţara înregistrării	mun.Chisinau, Albisoara 16/1 of.7
1.3.	Statutul juridic al ofertantului	
	Proprietate	Privata
	Formă de organizare juridică	SRL
	Altele	
1.4.	Anul înregistrării ofertantului	2010
1.5.	Statutul de afaceri al ofertantului	Antreprenor
	Producător	
	Agent local/Distribuitor al producătorului străin	Da
	Intermediar	
	Companie de antrepozit	
	Altele	
1.6.	Informaţia despre reprezentantul autorizat al ofertantului	
	Numele	Poiata Vitalie
	Locul de muncă şi funcţia	Director
	Adresa	mun.Chisinau, Albisoara 16/1 of.7
	Telefon / Fax	+ 37322 808517/ 808719
	E-mail	info@biosistem-mld.com; biosistem.mld@gmail.com
1.7.	Numărul de înregistrare pentru TVA	0607490
1.8.	Numărul de identitate al ofertantului pentru impozitul pe venit (pentru ofertanţii străini)	
1.9.	Ofertantul va anexa copiile/originalele	**Documente obligatorii:**
2. Informaţii de calificare		
2.1.	Numărul de ani de experienţă generală a ofertantului în livrări de bunuri şi servicii	11
2.2.	Numărul de ani de experienţă specifică a ofertantului în livrarea bunurilor similare	11
2.3.	Valoarea monetară anuală a livrărilor de bunuri similare în fiecare din ultimii 5 ani	*“Nu se aplică”*
2.4.	Disponibilitate de resurse financiare (bani lichizi sau capital circulant, sau de resurse creditare, extras din cont bancar etc.). Enumeraţi şi anexaţi copiile documentelor justificative	*“Nu se aplică”,*

2.5.	Detalii privind capacitatea de producere / echipamente disponibile	*"Nu se aplică",*
2.6.	Livrări majore de bunuri similare pe parcursul ultimilor 5 ani de activitate. Indicaţi detaliile livrărilor respective, inclusiv cele în proces de efectuare sau abia angajate, sau aşteptate, cu datele preconizate de livrare	Nu se aplică
3. Informaţii financiare		
3.1.	Rapoarte financiare sau extrase din bilanţul financiar, sau declaraţii de profit / pierderi, sau rapoartele auditorilor pentru ultimul an de activitate. Enumeraţi mai jos şi anexaţi copii: Raportul financiar 2017	
3.2.	Denumirea, adresa, numerele de telefon, telex şi fax ale băncilor care pot oferi caracteristici despre ofertant în cazul contactării de către autoritatea contractantă	
	2038, mun. Chişinău, bd. Moscovei, 14/1 Banca: BC Moldinconbank SA fil. Invest	
3.3.	Informaţie privind litigiile în care ofertantul este sau a fost implicat:	
	a) Orice proces pe parcursul ultimilor 5 ani: nu sunt	
	Cauza litigiului	Rezultatul sau sentinţa şi suma implicată
	nu-s	
	b) Procese curente, pe parcursul anului fiscal curent: nu sunt	
	Cauza litigiului	Situaţia curentă a procesului

Semnat: _____

Nume: Poiata Vitalie

Funcţia în cadrul firmei: Director

Denumirea firmei şi sigiliu: Biosistem-mld SRL

Specificaţii tehnice (F4.1)

Numărul procedurii de achiziţie:	ocds-b3wdp1-MD-1611047043861 din 21 ian 2021, 15:35 - 25 ian 2021, 12:55
Denumirea procedurii de achiziţie:	Test Rapid Antigen Covid-19

Nr. Lot	Denumire Lot	Cod CPV	Denumirea bunurilor şi/sau a serviciilor	Modelul articolului	Ţara de origine	Producătorul	Specificarea tehnică deplină solicitată de către autoritatea contractantă	Specificarea tehnică deplină propusă de către ofertant	Standarde de referinţă
1	*2*	*3*	*4*	*5*	*6*	*7*	*8*	*9*	*10*
1	Test Rapid Antigen Covid-19	33100000-1	Test Rapid Antigen Covid-19	SARS-CoV-2 Antigen Detection Kit (Colloidal Gold-Based)	China	Dirui Industrial Co., Ltd. / Nanjing Vazyme Medical Technology Co., Ltd	- Uşor de folosit - Foarte sensibil cu încărcături virale ridicate: 97,56% - Rezultate rapide şi fiabile ale testelor în doar 15 minute. - Testarea poate fi efectuată folosind probe nazo şi orofaringiene. -Poate fi depozitat la temperatura camerei -Toate componentele testului - inclusiv tampoane sterile - sunt incluse. -Să nu există reactivitate încrucişată cu coronavirusuri patogene umane (cum ar fi hCoV-229E, -HKU1, -NL63 şi -OC43) şi nici virusuri gripale (cum ar fi gripa A / B) - Specificitatea diagnosticului (97 – 100%). - Echivalent NADAL COVID-19 Ag Test	- Uşor de folosit - Foarte sensibil cu încărcături virale ridicate: 97,56% - Rezultate rapide şi fiabile ale testelor în doar 15 minute. - Testarea poate fi efectuată folosind probe nazo şi orofaringiene. -Poate fi depozitat la temperatura camerei -Toate componentele testului - inclusiv tampoane sterile - sunt incluse. -Să nu există reactivitate încrucişată cu coronavirusuri patogene umane (cum ar fi hCoV-229E, -HKU1, -NL63 şi -OC43) şi nici virusuri gripale (cum ar fi gripa A / B) - Specificitatea diagnosticului (97 – 100%). - Echivalent NADAL COVID-19 Ag Test	ISO, CE

Semnat: _____ Numele, prenumele: Poiata Vitalie

În calitate de: Director

Ofertantul: Biosistem-mld SRL

Adresa: mun.Chisinau, Albisoara 16/1 of.7

BIOSISTEM-MLD S.R.L.

Specificații de preț (F4.2)

Numărul procedurii de achiziție	ocds-b3wdp1-MD-1611047043861 din 21 ian 2021, 15:35 - 25 ian 2021, 12:55
Denumirea procedurii de achiziție:	Test Rapid Antigen Covid-19

Nr. Lot	Denumire Lot	Denumirea bunurilor şi/sau a serviciilor	Cod CPV	Cantitatea	Unitatea de măsură	Preț unitar (fără TVA)	Preț unitar (cu TVA)	Suma fără TVA	Suma cu TVA	Termenul de livrare/ prestare
1	*2*	*3*	*4*	*5*	*6*	*7*	*8*	*9*	*10*	*11*
1	Test Rapid Antigen Covid-19	Test Rapid Antigen Covid-19	33100000-1	300	buc	93.61	101.10	28,083.00	30,330.00	la comanda
							TOTAL Oferta	**28,083.00**	**30,330.00**	

Semnat: _____ Numele, prenumele: Poiata Vitalie

În calitate de: Director

Ofertantul: Biosistem-mld SRL

Adresa: mun.Chisinau, Albisoara 16/1 of.7

[Address] Floor 1-3, Building C2, Red Maple Park of Technological Industry, Kechuang Road, Economy & Technology Development Zone, Nanjing, China
[Tel] +86 25 8436 5701 [Website] www.vazymemedical.com

[BASIC INFORMATION]

Manufacturer: Nanjing Vazyme Medical Technology Co., Ltd.
Address: Floor 1-3, Building C2, Red Maple Park of Technological Industry, Kechuang Road, Economy & Technology Development Zone, Nanjing, China.
Tel: +86 25 8436 5701
E-mail: support@vazyme.com
Website: www.vazymemedical.com

EC REP
Obelis s.a.
Bd Général Wahis 53 1030 Brussels, Belgium
Tel:+(32)2732-59-54
Fax:+(32)2732-60-03
E-mail: mail@obelis.net

* Disposable swabs included in this kit have been individually CE marked by a third manufacturer. Please see below details and CE mark applied by said third manufacturer.
Name and Registered address of third manufacturer:
Jiangsu Changfeng Medical Industry Co., Ltd.
Touqiao Town, Guangling District, Yangzhou, Jiangsu 225109 China
European Authorized representative of the third manufacturer:
Landlink Gmbh Dorfstrasse 2/4, Emmendingen
CE mark applied on Disposable swabs by third manufacturer:
CE 0197

[APPROVAL DATE& MODIFICATION DATE OF INSTRUCTION FOR USE]

October 22, 2020

[Symbols]

EC REP	Authorized Representative In the European Community
IVD	For in vitro diagnostic use only
4°C ~ 30°C	Stored at 4 ~ 30°C
	Production Date
Σ	Tests per kit

REF	Catalog #
LOT	Batch Code
	Do not reuse
	Do not use if package damaged

	Manufacturer
	Expire Date
	Consult instructions for use
CE	CE Mark

Nanjing Vazyme Medical Technology Co., LTD.
Floor 1-3, Building C2, Red Maple Park of Technological Industry, Kechuang Road, Economy & Technology Development Zone, Nanjing, China
www.vazymemedical.com

IVD CE

EC REP
Obelis s.a.
Bd Général Wahis 53 1030 Brussels, Belgium

Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Antigen Detection Kit (Colloidal Gold-Based)

[PRODUCT NAME]

Generic Name: Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Antigen Detection Kit (Colloidal Gold-Based)

[SPECIFICATION]

20 tests/kit

[INTENDED USE]

The test kit is applicable to detect the antigen of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Antigen in human throat swab, Nasal swab samples.

[PRINCIPLE OF DETECTION]

The double antibody sandwich method is adopted in the product, and measurement is conducted in the form of solid-phase immune chromatography. The sample to be tested will diffuse upwards at the charging end under capillary action, and then SARS-CoV-2 antigen in the sample will combine with the antibody in the marker pad and form colloidal gold antibody-antigen complex; The complex continues to diffuse to the nitrocellulose membrane with the sample, and then blocked by T-line (test line) packed with antibody, and form colloidal gold labeled antibody-antigen-immune complex packed with antibody. The rest unblocked colloidal gold complex continues to move upwards, and combine with C-line (quality control line), indicating that the reaction is completed.

[COMPONENTS PROVIDED IN THIS KIT]

Components	Description
Test Cassette-20	Aluminum foil bag, desiccant, test strip, and plastic card. The test strip consists of absorbent paper, nitrocellulose membrane, sample pad, colloidal gold marker pad, and polyvinyl chloride pane. Nitrocellulose membrane T-line (test line) is packed with about 1.0mg/mL SARS-CoV-2 monoclonal antibody, while C-line (quality control line) is packed with about 1.0 mg/mL internal reference protein C, and the marker pad contains about 40 OD anti-mouse SARS-CoV-2 antibody colloidal gold complex.
Sample Eluent-20	phosphate buffer with surfactant 0.5 mL/piece (0.01M, pH7.4±0.2).
Disposable swabs*-20	For sample collection and transfer.

Note: DO NOT interchange the components from different batches.
Materials Required but not provided:
• timer
• tube rack for specimens
• any necessary personal protective equipment

[STORAGE CONDITIONS & SHELF LIFE]

The shelf life of this kit is18 months at 4°C~30°C.
Once the package of the Test Cassette is opened (4°C~30°C, humidity <65%), it must be used within 1 hour.

[Address] Floor 1-3, Building C2, Red Maple Park of Technological Industry, Kechuang Road, Economy & Technology Development Zone, Nanjing, China
[Tel] +86 25 8436 5701 [Website] www.vazymemedical.com

[SPECIMEU REQUIREMENTS]

1. Applicable sample types of the test card include throat swab, Nasal swab.
2. Sampling:

1) Nasal Swab: The sampling personnel shall hold the head of the sampled personnel gently with one hand, and the swab with the other hand, put it inside the nostril, and go deep along nose bottom. Given the arced nasal passage, be cautious to act gently, and avoid traumatic bleeding. As the swab top reaches to the rear wall of the pharyngonasal cavity, rotate for a cycle gently (in case of reflective cough, stay for a minute), and then take it out slowly, and put it inside the elution tube.

2) Throat Swab: The sampled personnel shall rinse the mouth with saline solution at first, and then the sampling personnel shall put the swab into sterile saline solution (prevent from putting the swab into the virus preserving fluid, and avoid antibiotics from causing allergies), hold the sampled personnel's head up slightly, with their mouth open wide, and give out the sound of "Ah", expose the pharyngeal tonsils at two sides, and then use the swab to pass the root of tongue, and swipe the pharyngeal tonsils at the two sides of the sampled personnel for at least 3 times, and then swipe the rear wall of the throat upwards and downwards for at least 3 times, and then put the swab into the elution tube.

3. Samples shall be eluted in 1h, and tested as soon as possible afterwards. In case of failing to process immediately, please store under the following conditions: It can be stored for 1 day under 2°C-8°C, and for a long term under -70°C and below.
4. Samples shall be fully recovered to the room temperature before test. Cryo-preserved samples can only be used after being fully melted, re-warmed and evenly mixed, and prevent from repeated freezing and thawing.

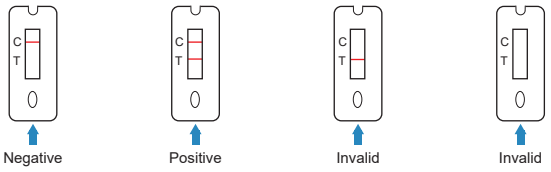
[TEST METHODS]

Read the instructions for use carefully before use.

1. The test cassette must be at room temperature before use, and the test must be operated at room temperature.
2. Remove the test cassette from the foil pouch and place on a flat, dry table.
3. After specimen collection, add the portion of swab where sample was collected to 0.5 mL sample eluent for even elution.
4. Cover the upper cover of the elution tube and place it upside down above the sample hole of the reagent card, gently squeeze the elution tube, add 4 drops (about 80 μL) to the charging hole of the reagent card, and start counting.
5. Read the results after 10 minutes. The result is invalid after 15 minutes.

[INTERPRETING TEST RESULTS]

The test results are analyzed as follows:



1. Negative result: Only one red quality control line (C-line) is visible.
2. Positive result: Two clear red lines are visible, one is the quality control line (C-line), while the other is the T test line.
3. Invalid result: No red lines are visible or only the test line is visible, without the quality control line (C-line), indicating that the test of the item is wrong or the test result is invalid, and retest is required.

[LIMITATIONS OF TEST METHODS]

1. The test result of the product is for clinical reference only, and shall not be used as the only basis for clinical diagnosis. Clinical management of patients shall be combined with the symptoms/physical signs, medical history, other laboratory tests, therapeutic response, epidemiology, etc., and suspicious samples shall be retested after certain periods.
2. Test accuracy can be influenced by the sampling process, and improper sampling and storage will influence the test result. It's requested to avoid high temperature and direct sunlight.
3. The reagent only provides qualitative test of SARS-CoV-2 antigen in the sample, and quantitative test is impossible.
4. Due to restrictions of antigen test reagent methodology, negative result cannot eliminate the possibility of being infected with SARS-CoV-2, for antigen in the sample may be lower than the test limit, and shall be judged in combination with other test results and clinical considerations, to provide accurate diagnosis.
5. The kit is used to test SARS-CoV-2 antigen in the sample, and whether the virus in the sample is invalid, with no relation to the cell cultivation result of the same sample.
6. SARS-CoV-2 positive antigen cannot eliminate other infectious agents.
7. Tiny changes in the amino acid of SARS-CoV-2 within the target area may cause the failure to test monoclonal antibody or decrease the test sensitivity.
8. When collecting a nasal swab sample, use the nasal swab supplied in the kit.
9. Proper specimen collection, storage and transport are critical to the performance of this test.

[PRODUCT PERFORMANCE INDICATORS]

1. Lowest limit of detection (LOD): S1~S4 are positive for SARS-COV-2 , S5-S6 are positive or negative for SARS-CoV-2.
2. Positive coincidence rate: PC1-PC8 are positive for SARS-CoV-2.
3.Negative coincidence rate: NC1-NC20 are negative for SARS-CoV-2.
4. Repeatability: CV1-CV2 are positive for SARS-CoV-2.
5. Precision between batches: 3 batches of kit are used to test the repeatability, and the corresponding results can meet the requirements for repeatability.
6. Cross reaction: The test result is negative for staphylococcus aureus, streptococcus pneumoniae, measles virus, mumps virus, Adenovirus Type III, mycoplasma pneumoniae, Deputy Flu Type II, human metapneumovirus, coronavirus OC43, coronavirus 229E, auxiliary bordetella pertussis, influenza B virus, A-H1N1, A-H3N2, avian influenza virus, EB virus, enterovirus, rhinovirus and other reactions, without cross reactions.

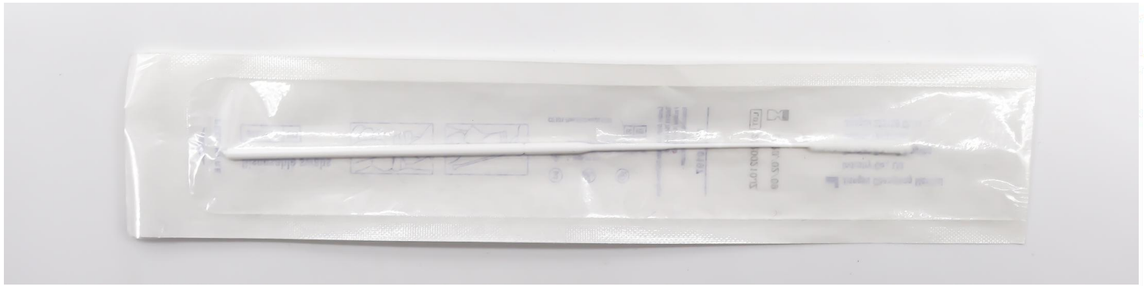
[PRECAUTIONS]

1.Inspectors shall receive professional training and read the specification carefully before operation, and operate the test in strict accordance with the specification of the kit.
2.Leave test Cassette sealed in its foil pouch until just before use. Do not use if pouch is damaged or open.
3.Do not use kit past its expiration date.
4.Do not mix components from different kit lots.
5. Do not reuse the used test card.
6.Wear protective clothing such as laboratory coats, disposable gloves, and eye protection when specimens are collected and evaluated.
7.For each test, please treat all components of this kit as biohazardous waste and dispose of these as per site, local, regional and national regulations and procedures.

SARS-CoV-2 Antigen Detection Kit
(Colloidal Gold-Based)

Product information

Cat. No	Specimen	Packing Size	Shelf Life	Storage	Qualification
C8602C	Nasal swab/Throat swab	20 Tests/Kit	18 Months	4°C- 30°C	CE



Component List：

- ✓ Instruction for Use
- ✓ Nasal swab
- ✓ Elution tubes (with prepacked eluent buffer)
- ✓ Test casstte

Order No.: GR 9973- 2020
Ref No.: AF 0047-2020

Annex A - List of Devices

(Recital 29 of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices)

#	Catalogue reference number	Commercial Name	Generic Device Term	Short description and intended use	GMDN/ EDMS Code	Class
1.	C8602C	Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Antigen Detection Kit (Colloidal Gold-Based)	SARS-CoV-2 antigen IVD, kit, immunochromatographic test (ICT), rapid	The test kit is applicable to detect the antigen of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Antigen in human throat swab, Nasal swab samples.	64787	All others

* Annex A is part of the Agreement.

** The here above product list classification is based on the classification claim of the manufacturer and under its sole responsibility (IVD 98/79/EC).

EUROPEAN AUTHORISED REPRESENTATIVE CENTER
Obelis SA
SINCE 1997

Obelis s.a.

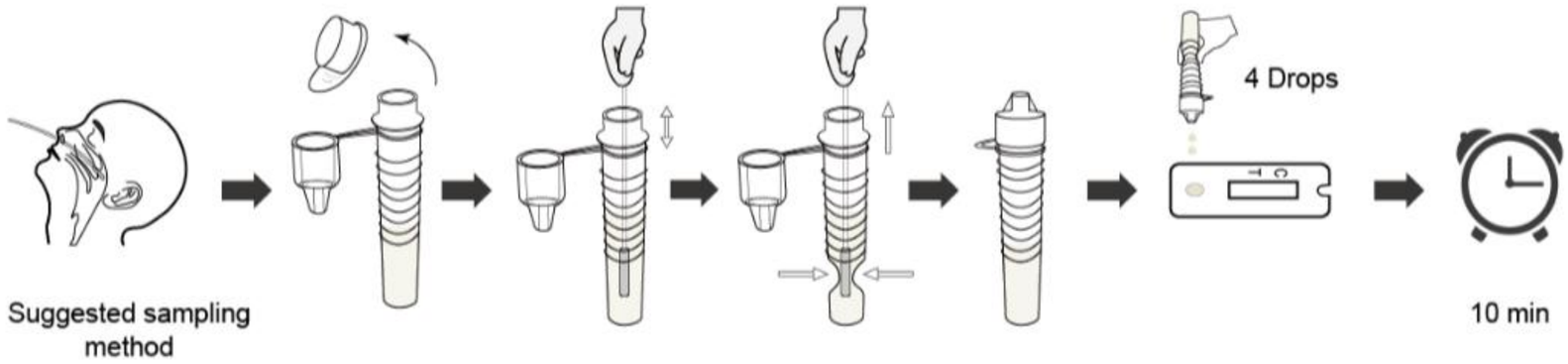
Signature:

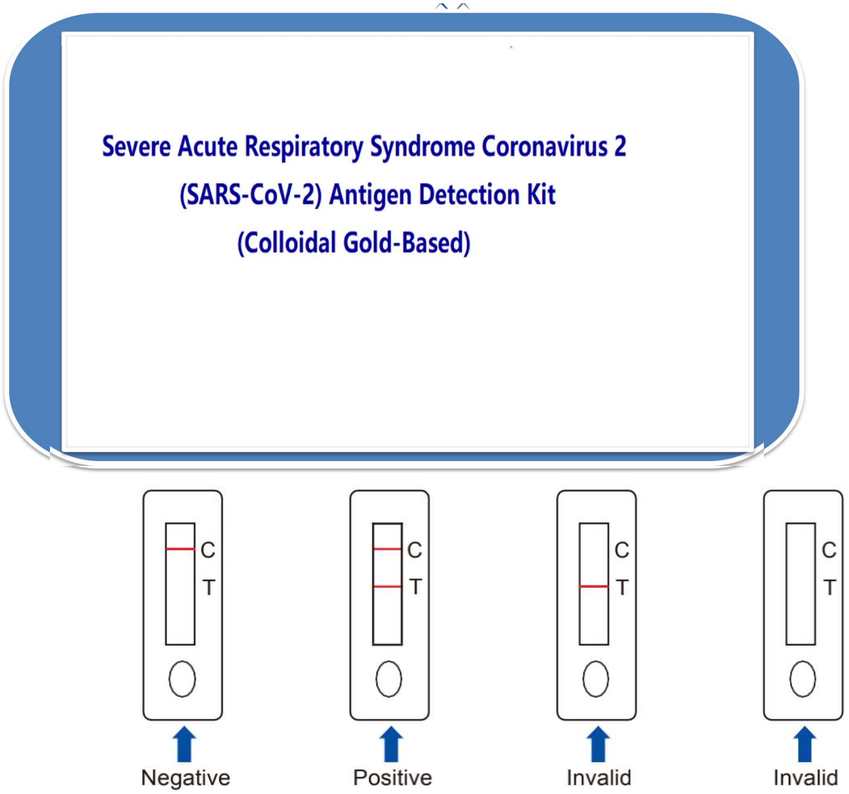
Stamp:

Obelis s.a. - O.E.A.R.C.
Registered Address :
Bld Général Wahis 53
1030 Bruxelles
Tel. +32 2 732 59 54 - Fax +32 2 732 60 03

Test Procedure

- Get result rapidly (10 min), suitable for large-scale screening.
- Easy to operate, no equipment needed.
- Detect virus directly, faster than PCR test
- High accuracy and good consistency with PCR test
- Room-temperature storage

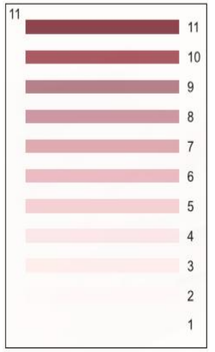




Performance of Antigen Detection kit

I

Concentrationof N Protein	* Color #	Concentration of S Protein	* Color #	Dilution ratio of Vaccine	* Color #
0.1 ug/mL	9	0.1 ug/mL	9	1:50	6
0.01 ug/mL	5	0.01 ug/mL	5	1: 10^2	6
1.0 ng/mL	4	1.0 ng/mL	2	1: 10^3	3
100.0 pg/mL	2	100.0 pg/mL	1	1: 10^4	2
10.0 pg/mL	1	10.0 pg/mL	0	1: 10^5	0
1.0 pg/mL	0	1.0 pg/mL	0	1: 10^6	0
0	0	0	0	N/A	N/A



Standard colorimetric card of Colloidal gold

II

SARS-CoV-2 Antigen Detection kits meet the requirements of National Institutes for Food and Drug Control

1. Lowest limit of detection (LOD): S1~S4 are positive for SARS-COV-2 , S5-S6 are positive or negative for SARS-CoV-2.
2. Positive coincidence rate: PC1-PC8 are positive for SARS-CoV-2.
3. Negative coincidence rate: NC1-NC20 are negative for SARS-CoV-2.
4. Repeatability: CV1-CV2 are positive for SARS-CoV-2.
5. Precision between batches: 3 batches of kit are used to test the repeatability, and the corresponding results can meet the requirements for repeatability.
6. Cross reaction: The test result is negative for staphylococcus aureus, streptococcus pneumoniae, measles virus, mumps virus, Adenovirus Type III, mycoplasma pneumoniae, Deputy Flu Type II, human metapneumovirus, coronavirus OC43, coronavirus 229E, auxiliary bordetella pertussis, influenza B virus, A-H1N1, A-H3N2, avian influenza virus, EB virus, enterovirus, rhinovirus and other reactions, without cross reactions.

Performance of Antigen Detection kit

III

Hospital: Santa Ana hospital, Manila, Philippines

Sample size: 200, including 21 (+) and 179 (-).

The antigen positive samples were collected from clinical confirmed infected patients and the presence of SARS-Cov-2 antigen were confirmed with Sansure Biotech Nucleic Acid Diagnostic Kit and RT- qPCR system.

Sensitivity: 100% [95%CI: 84.54%, 100.00%]
Specificity: 100% [95%CI: 97.90%, 100.00%]

		Result of Clinical Diagnosis		Total
		Confirmed(+)	Negative (-)	
Kit test result	Positive	21	0	21
	Negative	0	179	179
Total		21	179	200

* With more clinical data provided, product performance data will keep updated.

CERTIFICATE OF IVD NOTIFICATION

Ref. No.: AF 0047-2020

Order No.: GR 9973- 2020

BELGIUM

Date: 27/10/2020

THIS IS TO CERTIFY THAT, ACCORDING TO THE COUNCIL DIRECTIVE 98/79/EC, OBELIS S.A. (O.E.A.R.C.) PERFORMED ALL NOTIFICATION DUTIES AND RESPONSIBILITIES AS THE EUROPEAN AUTHORIZED REPRESENTATIVE (EC REP) OF:

NAME: NANJING VAZYME MEDICAL TECHNOLOGY CO., LTD

ADDRESS: FLOOR 1-3, BUILDING C2, RED MAPLE PARK OF TECHNOLOGICAL INDUSTRY, KECHUANG ROAD, ECONOMY & TECHNOLOGY DEVELOPMENT ZONE, NANJING, CHINA

AS STIPULATED AND DEMANDED BY THE AFOREMENTIONED DIRECTIVE.

The Manufacturer declares that the IVD device complIES with the Directive including all essential requirements.

The Manufacturer has provided Obelis s.a. (O.E.A.R.C.) with all the appropriate declarations according to the 98/79/EC Directive – article 10 requirements including the EC Declaration of Conformity confirming that his In-Vitro Diagnostics medical devices, as stipulated here above, are fulfilling the applicable requirements of the European Council Directive 98/79/EC

The notification of the following In-Vitro Diagnostic medical device has been completed by Obelis s.a. (O.E.A.R.C.) on the 26/10/2020 in compliance with the European Council Directive 98/79/EC - article 10 requirements.

IN-VITRO DIAGNOSTIC MEDICAL DEVICES: PLEASE SEE ANNEX A - LIST OF DEVICES (1 PAGE, 1 DEVICE)

As of the 27/10/2020, and as long as the manufacturer will continue complying with the hereabove mentioned requirements* he therefore:

- Is required to affix the CE marking on this device;

- Place this device in the Territory of Belgium and/or the other EEA Member States (excluding territories not in alignment with Decision 2010/227/EU).

G. ELKAYAM C.E.O

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Mr. G. Elkayam CEO
Obelis sa

Obelis European Authorized Representative Center is a member of the European Association of Authorized Representatives (E.A.A.R.), ISO 9001 : 2015 and ISO 13485 : 2016 certified in accordance to the profession of a European Authorized Representative.

* This is not a CE mark and is only provided as a template for informational purposes.

** This Certificate will be automatically void if the notification is rejected by the EU Authorities or upon termination of the EAR agreement.

Order No.: GR 9973- 2020
Ref No.: AF 0047-2020

Annex A - List of Devices

(Recital 29 of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices)

#	Catalogue reference number	Commercial Name	Generic Device Term	Short description and intended use	GMDN/ EDMS Code	Class
1.	C8602C	Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Antigen Detection Kit (Colloidal Gold-Based)	SARS-CoV-2 antigen IVD, kit, immunochromatographic test (ICT), rapid	The test kit is applicable to detect the antigen of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Antigen in human throat swab, Nasal swab samples.	64787	All others

* Annex A is part of the Agreement.

** The here above product list classification is based on the classification claim of the manufacturer and under its sole responsibility (IVD 98/79/EC).

Obelis s.a.

Signature:

Stamp:

G.ELKAYAM C.E.O.

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