# Specificații tehnice (F4.1)

Numărul licitației:		ocds-b3wdp1-MD-1611047043861				Data: "25" ianuarie 2021		Alternativa nr.: nu
Denumirea licitației:		Test Rapid Antigen Covid-19 IMSP Institutul de Cardiologie				Lot: 1		Pagina: _1_din _1_
Cod CPV	CPV N/no Denumirea bunurilor și/sau a serviciilor Modelul articolului Țara de origine Producăto		Producătorul	Specificarea tehnică deplină solicitată de către autoritatea contractantă	Specificarea tehnică propusă de către ofertant	Standarde de referință		
1	2	3	4	5	6	7	8	9
33100000-1	1	Test Rapid Antigen Covid-19	COVID-19 Antigen Rapid Test	China	AllTest	Uşor de folosit -Foarte sensibil cu încărcături virale ridicate: 97,56% -Rezultate rapide și fiabile ale testelor în doar 15 minute. -Testarea poate fi efectuată folosind probe nazo și orofaringiene. -Poate fi depozitat la temperatura camerei -Toate componentele testului - inclusiv tampoane sterile - sunt incluse. -Să nu există reactivitate încrucișată cu coronavirusuri patogene umane (cum ar fi hCoV-229E, -HKU1, - NL63 și -OC43) și 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: 96.4%; -Rezultate rapide și fiabile ale testelor în doar 15 minute. -Testarea poate fi efectuată folosind probe nazo și orofaringiene. -Poate fi depozitat la temperatura camerei sau 24 de ore la o temperatură de 2-8°C -Toate componentele testului - inclusiv tampoane sterile - sunt incluse. -Să nu există reactivitate încrucișată cu coronavirusuri patogene umane (cum ar fi hCoV-229E, -HKU1, - NL63 și -OC43) și nici virusuri gripale (cum ar fi gripa A / B) - Specificitatea diagnosticului (97 – 100%). - Echivalent NADAL COVID-19 Ag Test	CE, ISO

Semnat:\_\_\_

\_\_\_\_ Numele, Prenumele Jighili Tatiana

În calitate de: administrator

Ofertantul: \_\_\_\_\_ SRL Triumf-Motiv \_\_\_\_\_ Adresa: \_\_\_\_\_ str. Grenoble 193 of 1301

# Specificații de preț (F4.2)

Numărul licitației ocds-b3wdp1-MD-1611047043861				Data: "25" ianuarie 2021			Alternativa nr.: nu		
<b>Denumirea licitației:</b> Test Rapid Antigen Covid-19 IMSP Institutul de Cardiologie				Lot: 1				Pagina: _1_din _1_	
Cod CPV	N/no	Denumirea bunurilor și/sau a serviciilor	Unitatea de măsură	Cantitate	Preț unitar (fără TVA) lei	Preț unitar (cu TVA), lei	Suma fără TVA, lei	Suma cu TVA, lei	Termenul de livrare/prestare
1	2	3	4	5	6	7	8	9	10
33100000-1	1	Test Rapid Antigen Covid-19	buc	300	154,66	185,59	46398,00	55677,60	2021 la solicitare timp de 2 zile
			Jighili	Susprunorme Lan	Trum -	Total	46398,00	55677,60	



Semnat:\_\_\_\_\_

Numele,Prenumele

În calitate de: administrator

Ofertantul: \_\_\_\_\_ SRL Triumf-Motiv \_\_\_\_\_ Adresa: \_\_\_\_\_ str. Grenoble 193 of 1301



**COVID-19 Antigen Rapid Test** (Nasopharyngeal Swab)

> Package Insert REF ICOV-502 Enalish

COVID-19 Antigen Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of SARS-CoV-2 antigens present in human nasopharynx. For professional in vitro diagnostic use only.

#### [INTENDED USE]

The COVID-19 Antigen Rapid Test (Nasopharvngeal Swab) is a rapid chromatographic immunoassay for the gualitative detection of SARS-CoV-2 antigens in nasopharyngeal swab specimens from individuals with suspected SARS-CoV-2 infection in conjunction with clinical presentation and the results of other laboratory tests.

Results are for the detection of SARS-CoV-2 Antigens. An antigen is generally detectable in upper respiratory specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.

Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions. Negative results should be treated as presumptive and confirmed with a molecular assay, if necessary for patient management. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19

The COVID-19 Antigen Rapid Test is intended for use by trained clinical laboratory personnel.

#### [SUMMARY]

The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

#### [PRINCIPLE]

The COVID-19 Antigen Rapid Test (Nasopharyngeal Swab) is a gualitative membrane-based immunoassay for the detection of SARS-CoV-2 Antigens in human nasopharyngeal swab specimen, SARS-CoV-2 antibody is coated in the test line region. During testing, the specimen reacts with SARS-CoV-2 antibody-coated particles in the test. The mixture then migrates upward on the membrane by capillary action and reacts with the SARS-CoV-2 antibody in test line region. If the specimen contains SARS-CoV-2 Antigens, a colored line will appear in test line region as a result of this. If the specimen does not contain antigens to SARS-CoV-2, no colored line will appear in the test line region, indicating a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

#### [REAGENTS]

The test contains anti-SARS-CoV-2 antibody as the capture reagent and anti-SARS-CoV-2 antibody as the detection reagent.

#### [PRECAUTIONS]

- 1. This package insert must be read completely before performing the test. Failure to follow directions in package insert may vield inaccurate test results.
- 2. For professional in vitro diagnostic use only. Do not use after expiration date.
- 3. Do not eat, drink or smoke in the area where the specimens or kits are handled.
- 4. Do not use test if pouch is damaged.
- 5. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout in the collection, handling. storage, and disposal of patient samples and used kit contents.
- 6. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- 7. Wash hands thoroughly after handling.
- 8. Please ensure that an appropriate amount of samples are used for testing. Too much or too little sample size may lead to deviation of results.
- 9. Viral Transport Media (VTM) may affect the test result: extracted specimens for PCR tests cannot be used for the test.
- 10. The used test should be discarded according to local regulations.
- 11. Humidity and temperature can adversely affect results.

#### **[STORAGE AND STABILITY]**

Store as packaged in the sealed pouch at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

#### **[SPECIMEN COLLECTION, TRANSPORT AND STORAGE]**

#### Specimen Collection

IVD

1. Insert a sterile swab into the nostril of the patient, reaching the surface of the posterior nasopharynx.

- 2. Swab over the surface of the posterior nasopharynx.
- 3. Withdraw the sterile swab from the nasal cavity.



#### Specimen transport and storage

Specimens should be tested as soon as possible after collection

If swabs are not been processed immediately, it is highly recommended the swab sample is placed into a dry, sterile, and tightly sealed plastic tube for storage. The swab specimen in dry and sterile condition is stable for up to 8 hours at room temperature and 24 hours at 2-8°C.

#### **[SPECIMEN PREPARATION]**

Only the extraction buffer and tubes provided in the kit is to be used for swab specimen preparation.

Please refer to the Procedure card for detailed information of Specimen Extraction.

1. Place the swab specimen in the Extraction tube with Extraction Buffer (Approx. 350ul). Rotate the swab for approximately **10 seconds** while pressing the head against the inside of the tube to release the antigen in the swab.

2. Remove the swab while squeezing the swab head against the inside of the Extraction tube as you remove it to expel as much liquid as possible from the swab. Discard the swab in accordance with your biohazard waste disposal protocol.

\*NOTE: The storage of the specimen after extraction is stable for 2 hours at room temperature or 24 hours at 2-8°C.

#### [MATERIALS]

Material Provided · Test cassettes Sterile swabs · Package insert Extraction Buffer Extraction tubes and tips (Optional) Workstation

Allow the test, extracted specimen and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

- 1. Remove the test cassette from the sealed foil pouch and use it within one hour. Best results will be obtained if the test is performed immediately after opening the foil pouch
- 2. Invert the specimen extraction tube and add 3 drops of extracted specimen (approx.100µl) to the specimen well(S) and then start the timer.
- 3. Wait for the colored line(s) to appear. Read the result at 15 minutes. Do not interpret the result after 20 minutes



#### **[INTERPRETATION OF RESULTS]**

#### (Please refer to the illustration above)

**POSITIVE:**\* Two distinct colored lines appear. One colored line should be in the control region (C) and another colored line should be in the Test region (T). Positive result in the Test region indicates detection of SARS-COV-2 antigens in the sample. \*NOTE: The intensity of the color in the test line region (T) will vary based on the amount of SARS-COV-2 antigen present in the sample. So any shade of color in the test region (T) should be considered positive.

NEGATIVE: One colored line appears in the control region (C). No apparent colored line appears in the test line region (T).

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor. **[QUALITY CONTROL]** 

#### Internal Quality Control

Internal procedural controls are included in the test. A colored line appearing in the control region (C) is an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique. A clear background is an internal negative procedural control. If the test is working properly, the background in the result area should be white to light pink and not interfere with the ability to read the test result.

#### External Quality Control

Positive/negative controls are not included in this kit. However, in compliance with Good Laboratory Practice (GLP), these controls are recommended.<sup>1</sup>

#### [LIMITATIONS]

- 1. The test Procedure and the Interpretation of test Result must be followed closely when testing for the presence of SARS-CoV-2 antigens in the human nasopharyngeal specimens from suspected individuals. For optimal test performance, proper sample collection is critical. Failure to follow the procedure may give inaccurate results.
- 2. The performance of the COVID-19 Antigen Rapid Test (Nasopharyngeal swab) was evaluated using the procedures provided in this product insert only. Modifications to these procedures may alter the performance of the test. Viral Transport Media (VTM) may affect the test result: extracted specimens for PCR tests cannot be used for the tost
- 3. The COVID-19 Antigen Rapid Test (Nasopharyngeal swab) is for in vitro diagnostic use only. This test should be used for detection of SARS-CoV-2 Antigens in human nasopharyngeal specimens as an aid in the diagnosis of patients with suspected SARS-CoV-2 infection in conjunction with clinical presentation and the results of other laboratory tests. Neither the quantitative value nor the rate of increase in the concentration of SARS-CoV-2 antigens can be determined by this qualitative test.
- 4. The COVID-19 Antigen Rapid Test (Nasopharyngeal Swab) will only indicate the presence of SARS-CoV-2 Antigens in the specimen and should not be used as the sole criteria for the diagnosis of SARS-CoV-2 infections.
- 5. The results obtained with the test should be considered with other clinical findings from other laboratory tests and evaluations.
- 6. If the test result is negative or non-reactive and clinical symptoms persist. It is recommended to re-sample the patient a few days later and test again or test with a molecular diagnostic device to rule out infection in these individuals.
- 7. The test will show negative results under the following conditions: The concentration of the novel coronavirus antigens in the sample is lower than the minimum detection limit of the test.
- 8. Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.
- 9. Excess blood or mucin on the swab specimen may interfere with test performance and may yield a false positive result.
- 10. The accuracy of the test depends on the quality of the swab sample. False negatives may result from improper sample collection or storage.
- 11 Positive results of COVID-19 may be due to infection with non-SARS-CoV-2 coronavirus strains or other interference factors.

#### [EXPECTED VALUES]

The COVID-19 Antigen Rapid Test (Nasopharyngeal Swab) has been compared with a leading commercial RT-PCR test. The correlation between these two systems is no less than 98%.

#### **[PERFORMANCE CHARACTERISTICS]**

#### Sensitivity, Specificity and Accuracy

The COVID-19 Antigen Rapid Test (Nasopharyngeal Swab) has been evaluated with

[DIRECTIONS FOR USE]

 Procedure card Materials required but not provided • Timer

specimens obtained from the patients. RT-PCR is used as the reference method for the COVID-19 Antigen Rapid Test (Nasopharyngeal Swab). Specimens were considered positive if RT-PCR indicated a positive result. Specimens were considered negative if RT-PCR indicated a negative result.

#### Nasopharyngeal Swab Specimen

		ntigon Ropid Tost	RT-	Total		
	COVID-19 A	niigen Kapiu Tesi	Positive	Negative	Total	
COVID-19		Positive	80	1	81	
	Antigen	Negative	3	120	123	
	Total		83	121	204	
Relative Sensitivity Relative Specificity Accuracy			96.4% (95%CI*: 89.8%~99.2%)			
			99.2% (95%Cl*: 95.5%~99.9%)			
			98.0% (95%CI*: 95.1%~99.5%)			

\*Confidence Intervals

#### Specificity Testing with Various Viral Strains

The COVID-19 Antigen Rapid Test was tested with the following viral strains. No discernible line at either of the test-line regions was observed at these concentrations:

Description	Test Level
Adenovirus type 3	3.16 x 10 <sup>4</sup> TCID50/ml
Adenovirus type 7	1.58 x 10 <sup>5</sup> TCID50/ml
Human coronavirus OC43	2.45 x 10 <sup>6</sup> LD50/ml
Influenza A H1N1	3.16 x 10 <sup>5</sup> TCID50/ml
Influenza A H3N2	1 x 10 <sup>5</sup> TCID50/ml
Influenza B	3.16 x 10 <sup>6</sup> TCID50/ml
Human Rhinovirus 2	2.81 x 10 <sup>4</sup> TCID50/ml
Human Rhinovirus 14	1.58 x 10 <sup>6</sup> TCID50/ml
Human Rhinovirus 16	8.89 x 10 <sup>6</sup> TCID50/ml
Measles	1.58 x 10 <sup>4</sup> TCID50/ml
Mumps	1.58 x 10 <sup>4</sup> TCID50/ml
Parainfluenza virus 2	1.58 x 10 <sup>7</sup> TCID50/ml
Parainfluenza virus 3	1.58 x 10 <sup>8</sup> TCID50/ml
Respiratory syncytial virus	8.89 x 10 <sup>4</sup> TCID50/ml

**TCID50** = Tissue Culture Infectious Dose is the dilution of virus that under the conditions of the assay can be expected to infect 50% of the culture vessels inoculated. **LD50** = Lethal Dose is the dilution of virus that under the conditions of the assay can be expected to kill 50% of the suckling mice inoculated.

#### Precision

#### Intra-Assay&Inter-Assay

Within-run and Between-run precision has been determined by using three specimens of COVID-19 standard control. Three different lots of COVID-19 Antigen Rapid Test (Nasopharyngeal Swab) have been tested using negative SARS-COV-2 Antigen weak and SARS-COV-2 Antigen Strong. Ten replicates of each level were tested each day for 3 consecutive days. The specimens were correctly identified>99% of the time.

#### Cross-reactivity

The following organisms were tested at 1.0x10<sup>8</sup> org/ml and all found to be negative when tested with the COVID-19 Antigen Rapid Test (Nasopharyngeal Swab):

0 1	( , , , , , , , , , , , , , , , , , , ,
Arcanobacterium	Pseudomonas aeruginosa
Candida albicans	Staphylococcus aureus subspaureus
Corynebacterium	Staphylococcus epidermidis
Escherichia coli	Streptococcus pneumoniae
Moraxella catarrhalis	Streptococcus pygenes
Neisseria lactamica	Streptococcus salivarius
Nesseria subllava	Streptococcus sp group F

#### **BIBLIOGRAPHY**

1. Westgard JO, Barry PL, Hunt MR, Groth T. A multi-rule Shewhart for quality control in clinical chemistry, Clinical Chemistry 1981;27:493-501

#### Index of Symbols

IVD	For in vitro diagnostic use only	$\sum_{i=1}^{n}$	Tests per kit	EC REP	Authorized Representative
2°C - 30°C	Store between 2-30°C	$\square$	Use by	2	Do not reuse
$\odot$	Do not use if package is damaged	LOT	Lot Number	REF	Catalog #
	Manufacturer	Ĩ	Consult Instructions For Use		





Number: 146288105 Effective Date: 2020-11-16







# Certificate

No. Q5 095123 0007 Rev. 03

### Holder of Certificate:

### Hangzhou AllTest Biotech Co., Ltd.

550#, Yinhai Street Hangzhou Economic and Technological Development Area 310018 Hangzhou PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

Hangzhou AllTest Biotech Co., Ltd. 550#, Yinhai Street, Hangzhou Economic and Technological Development Area, 310018 Hangzhou, PEOPLE'S REPUBLIC OF CHINA

**Certification Mark:** 



**Design and Development, Production and Distribution of In** Scope of Certificate: Vitro Diagnostic Kit for Obstetrics and Gynecology, Infectious Disease, Drug of Abuse, Vitamin, Special Protein, Oncology, Cardiology and Biochemistry, and Digital test for pregnancy and ovulation. Home use, Clinical Laboratory use

**POCT** analyzer.

**Applied Standard(s):** 

2020-08-05

EN ISO 13485:2016 Medical devices - Quality management systems -Requirements for regulatory purposes (ISO 13485:2016) DIN EN ISO 13485:2016

and Near Patient In-vitro Diagnostic Devices and the related

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

**Report No.:** 

SH20106401

Valid from: Valid until:

Date,

2020-09-25 2023-09-24

**Christoph Dicks** Head of Certification/Notified Body



# EC Declaration of Conformity

Manufacturer: Name: HANGZHOU ALLTEST BIOTECH CO.,LTD. Address: #550, Yinhai Street, Hangzhou Economic & Technological Development Area, Hangzhou -310018, P.R. China

European Representative: Name: Lotus NL B.V. Address: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

Product Name: COVID-19 Antigen Rapid Test Model: Cassette Classification: Other Device of IVDD 98/79/EC Conformity Assessment Route: IVDD 98/79/EC Annex III EDMA Code: 15 70 90 08 00

We, HANGZHOU ALLTEST BIOTECH CO., LTD., herewith declare that we are exclusively responsible for this declaration of conformity. We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

### DIRECTIVES

General applicable directives:

DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27October 1998 on in vitro diagnostic medical devices

Standard Applied: EN ISO 13485:2016, EN ISO 14971:2012, EN 13975:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN 13612:2002/AC:2002, EN ISO 17511:2003, EN ISO 23640:2015, EN 13641:2002, EN ISO 15223-1:2016

Place, Date of Issue: in Hangzhou on 18/11/2020

Signature: on Ora

Name: Soar Gao (Position: General Manager)

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«TRIUMF-MOTIV» SRL C/F 1012600021180, TVA - 0308703 IBAN: MD90EN000000222446621858 Energbank filiala Botanica, ENEGMD22858 or. Chisinau, str. Grenoble 193 of. 1301, tel.: 022-76-88-41, 022-76-84-62

# DECLARAȚIA

# Obligația de a oferi mostre de produse la solicitarea

În termen de 3 zile la solicitare autorității contractante se vor prezenta mostre pentru evaluare, testare si confirmarea specificațiilor tehnice propuse de la operatorul economic desemnat cîstigator.

Administrator Jighili Tatiana

