

SARS-CoV-2

Antigen Rapid Test Kit

(Colloidal gold Immunoassay)

This product is used for in vitro qualitative detection of novel coronavirus (SARS-CoV-2) antigen in human oropharyngeal swabs, nasal swabs and nasopharyngeal swabs.

Characters:

- ✓ Non-invasive
- ✓ No device needed
- ✓ Get result in 15 mins
- ✓ Specificity: 100%
- ✓ Sensitivity: over 92%
- ✓ Easy to use
- ✓ Cost-effective

Specification and Photo

Catalogue No: CoV2Ag-25

Packing specification: 25T/kit

MAIN COMPONENTS:

1. Test Card: 1 test/pouch
2. Desiccant: 1 piece/pouch, silica gel
3. Swab: 25 pieces/pack
4. Sample treatment solution: 25 vials/pack
5. Tube cap: 25 pieces/pack

Product Photo:

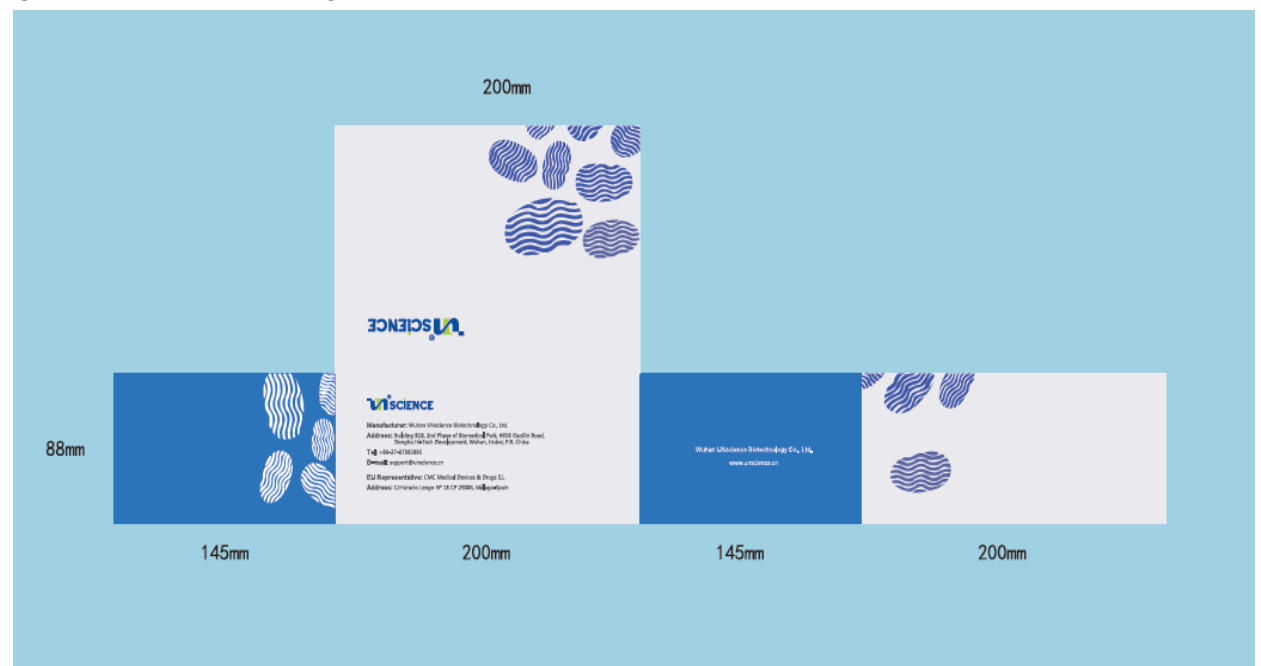




Color Box and Package

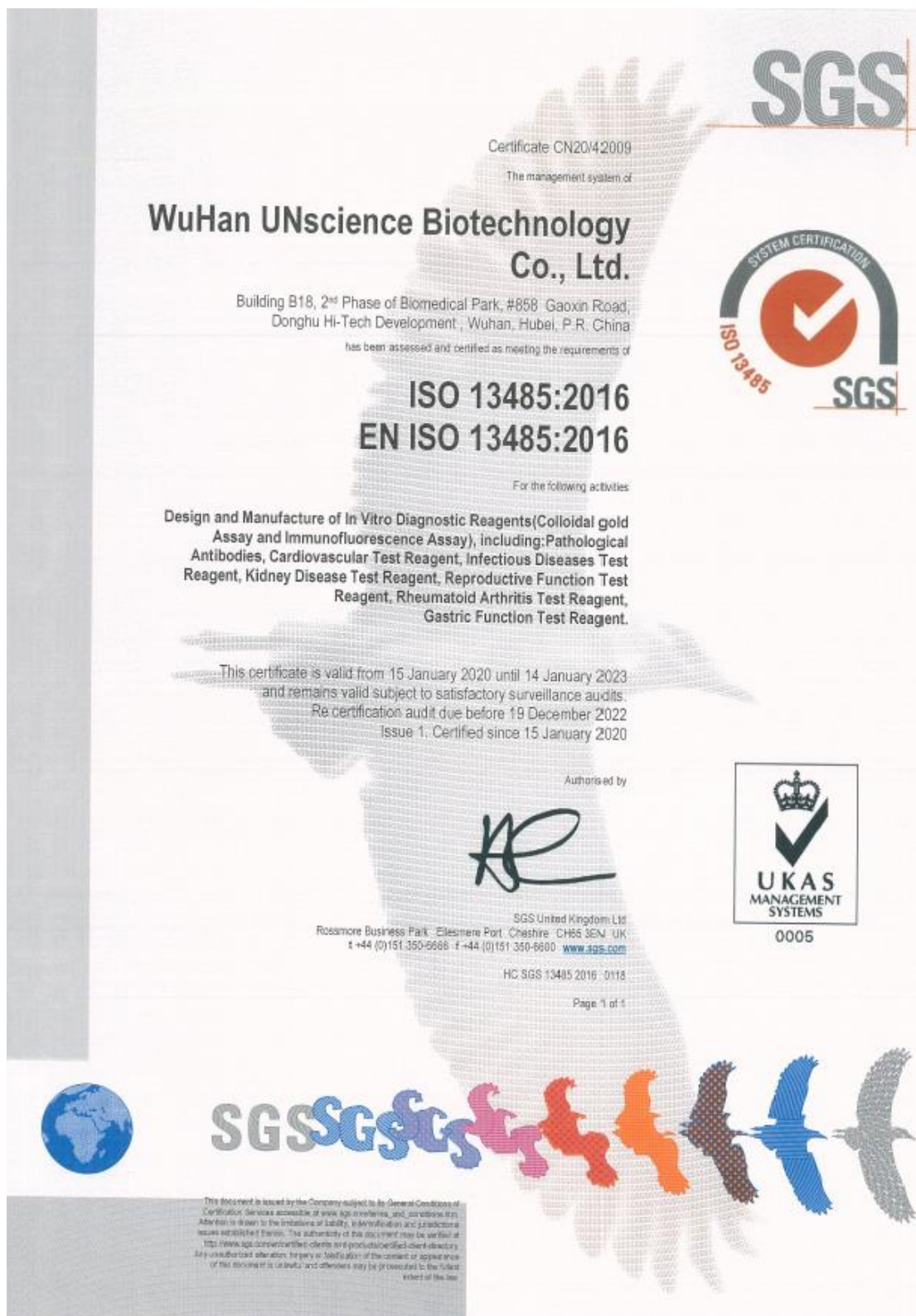
Color Box Size:

One color box contain 25Tests




Copy of Certification

- ISO 13485:2016



- Declaration of Conformity



EC Declaration of Conformity

according to the Directive 98/79/EC

Manufacturer	WuHan UNscience Biotechnology Co., Ltd.
Address	Building B18, 2nd Phase of Biomedical Park, #858 GaoXin Road, Donghu Hi-Tech Development, Wuhan, Hubei, P.R. China
EC Representative Address	CMC Medical Devices & Drugs S.L C/Horacio Lengo N 18 CP 29006, Málaga-Spain

We, the manufacturer, declare under our sole responsibility that

the medical device(s)	SARS-CoV-2 Antigen Rapid Test Kit
Type/model	20T/25T/40T/100T
Classification	Others in vitro diagnostic device (IVD)



is/are in conformity with the relevant provisions and requirements of Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

Applied harmonised standards, national standards or other normative documents	EN ISO 13485:2016	EN ISO 23640:2015
	EN ISO 15223-1:2016	EN 1041:2008
	EN ISO 14971:2012	

Conformity assessment procedure	Module A (EC Declaration of Conformity) (Annex III, except point 6)
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Signed on: 10 October, 2020
Signature of General Manager

Place: Wuhan, Hubei, China



- CE Certification

EC REP CERTIFICATE



CMC MEDICAL DEVICES & DRUGS SL NO. CMC/CE/2020/02122020.13

CONFIRMED THAT CMC MEDICAL DEVICES & DRUGS S.L. Is the European Authorized Representative of

WuHan UNscience Biotechnology Co., Ltd.

Building B18, 2nd Phase of Biomedical Park, #858 GaoXin Road, Donghu Hi-Tech Development, Wuhan, Hubei, P.R. China

The certificate remains valid until the expiration agreement of EC REP, manufacturing conditions, the quality system or relevant legislation are changed. The validity is conditioned by positive results of periodic surveillance audits.

The product liability rests with the manufacturer in accordance with applicable directive and standard, after fulfilling of the relevant EU legislation requirements, the manufacturer shall affix relevant CE marking to all above mentioned models of the medical device.

Complies with the applicable essential requirements of the council directive 98/79/EEC in vitro diagnostics as amended.

The products in Annex I was registered in Spanish MOH with number **RPS/2780/2020**



Issued on: 02/12/2020



Valid until: 01/12/2021

Authorized Signatory
CMC Medical Devices & Drugs SL

- CE Certification

EC REP CERTIFICATE



ANNEX I Medical Device Products

SARS-CoV-2 & Influenza Antigen Combo Rapid Test Kit

Influenza Virus A&B Antigen Rapid Test Kit

D-Dimer(D-D) Test Kit

COVID-19 IgG/IgM Rapid Test Kit

CE

- CE Registration

La notificación se ha realizado correctamente.

Datos de registro	
Código de Expediente:	RPS/2780/2020
Fecha Registro:	02/12/2020 17:27:51
Nº registro General:	RPS/2780/2020
Oficina:	ETEL
Nº registro Oficina:	RPS/2780/2020

Registro de Responsables de Productos Sanitarios - RPS/2780/2020

Datos de la notificación

Datos de registro

Nº Registro: RPS/2780/2020 Fecha Registro: 02/12/2020

Datos del Responsable

Tipo de Responsable (*): Tipo de entidad:

CIF (*): 892218149 Nombre (*): CHIC MEDICAL DEVICES & DRUGS S.L.

Dirección (*): C/ MORACIO LENGU Nº 18

Localidad (*): MELILLA

Provincia (*):

Teléfono (*): 992214994 Fax:

e-mail (*): info@chicmedicaldevices.es Web:

Datos del Fabricante

Nombre o Razón Social (*): Wuhan Ufficiency Biotechnology Co., Ltd.

Dirección (*): Building 818, 2nd Phase of Biomedical Park, 4555 Gaoxin Road,

Localidad (*): Dongchu Hi-Tech Development, Wuhan, Hubei, P.R. China

País (*): CP:

Teléfono (*): 861061740112 Fax:

e-mail (*): support@ufficiency.com Web:

Relación de Productos

Listado de Productos Sanitarios

1 Fila, mostrando todas las filas.

Nombre Comercial	Tipo de Producto	Estado del producto	Acción
2019-COVID-19 INFLUENZA ANTIGEN COMBO RAPID TEST KIT	Diagnostics In Vitro	Primeros Comunicados	
INFLUENZA VIRUS A/B4 ANTIGEN RAPID TEST KIT	Diagnostics In Vitro	Primeros Comunicados	
D-DIMER(D-D) TEST KIT	Diagnostics In Vitro	Primeros Comunicados	
COVID-19 IgG/IgM RAPID TEST KIT	Diagnostics In Vitro	Primeros Comunicados	

International Registration

- German bfarm registration
 - Peru registration
 - Ukraine registration
 - Greece registration
 - Italian registration
-
- German bfarm registration

Liste der Antigen-Tests zum direkten Erregernachweis des Coronavirus SARS-CoV-2,

die Gegenstand des Anspruchs nach § 1 Satz 1 gemäß "Dritte Verordnung zur Änderung der Verordnung zum Anspruch auf bestimmte Testungen für den Nachweis des Vorliegens einer Infektion mit dem Coronavirus SARS-CoV-2 (Coronavirus-Testverordnung – TestV)" sind.

Alle Daten gemäß Übermittlung des Herstellers, verbindlich sind ausschließlich die Angaben in den jeweiligen Gebrauchsinformationen.

Weitere Hinweise zur vom BfArM bereitgestellten Liste sowie zu den der Listung und ggfs. auch Streichung von der Liste zugrundeliegenden Kriterien finden Sie auf unserer [Webseite zu Antigentests auf SARS-CoV-2](#).

unsience

Los

Aktionen

Nach 'unsience' suchen

Zurücksetzen

	Hersteller			Deutscher Vertreter	Europäischer Bevollmächtigter				Sensitivität		Spezifität				
Test-ID	Name	Stadt	Land	Name	Name	Stadt	Land	Handelsname des Tests	Testort *	Artikelnum...	%	95%iges Vertrau...intervall	%	95%iges Vertrau...intervall	Gebrauch...anweisung
AT429...	Wuhan Unsience Biotechnology Co. Ltd.	Wuhan	CN	Biozol Diagnostica Vertrieb GmbH	CMC Medical Devices & Drugs SL	Málaga	ES	SARS-CoV-2 Antigen Rapid Test Kit	POC (ohne Gerät)	CoV2Ag-25	96,33	90,9 - 98,9	99,57	97,6 - 99,9	Link öffn...
Gesamt 1															

Greece registration

Κοινοποίηση In Vitro (Διαγνωστικής) - Προϊόντα

Προϊόντα αίτησης

Μπορείτε να επεξεργαστείτε άμεσα το όνομα, την περιγραφή και τον κωδικό κατασκευαστή κίνησης 'κλικ' στο αντίστοιχο κελί.

Προβολή 1 έως 1 από 1.

α.α.	Όνομα (EL/EN)	Περιγραφή (EL/EN)	Κωδ. κατασκ.	Κατηγορία	Κωδικός προϊόντος	
1 >	SARS-CoV-2 Antigen Rapid Test Kit		CoV2Ag-25	Άλλο προϊόν	2830000644533	
	SARS-CoV-2 Antigen Rapid Test Kit					

Italian registration

Search by Medical Device / Assembled

Device Type:

Registration ID assigned by the BD / RDM System:

Code assigned by the manufacturer:


Trade name and model:

CND classification (valid only for class medical devices, active implantable and IVD):

CND description (valid only for class medical devices, active implantable and IVD):


CE class (valid only for medical class, active implantable and IVD devices):

Ukraine Independent Validation

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“BCM “UKRAINE.” LLC

Immunoblot method
Method using PCR 
(confirmatory method)

ELISA _____
Immunochromatographic Analysis 
(method to be verified)

CONFIRMATORY METHOD

Name of the Method: one-step PCR with reverse transcription using test-kit «LiliF™ COVID-19 Multi Real-time RT-PCR Kit», Korea

Executors of Verification Method:

Name	Position
Demchyshyna Iryna Victorivna	Head of the Laboratory
Hluzd Oleksandra Anatoliivna	Virologist
Korshak Iryna Mychaliivna	Virologist
Dovchenko Liubov Vasylivna	Laboratory Assistant

Environmental Conditions during the Testing:

Date	Environment Temperature, °C	Relative Humidity, %	Other Influential Conditions
11.01.2021	22°C (extrac.) 22°C (amplif.)	56% (extrac.) 56% (amplif.)	
12.01.2021	22°C (extrac.) 22°C (amplif.)	56% (extrac.) 56% (amplif.)	
13.01.2021	22°C (extrac.) 22°C (amplif.)	56% (extrac.) 56% (amplif.)	
14.01.2021	22°C (extrac.) 22°C (amplif.)	56% (extrac.) 56% (amplif.)	
15.01.2021	22°C (extrac.) 22°C (amplif.)	56% (extrac.) 56% (amplif.)	


Equipment:

Name, Type, Manufacturer	Serial No.	Verification	Calibration
CFX96 Real-Time System, Bio-Rad	785BR21721	Not subject	Not subject

Used Test-Kits:

Name	Manufacturer	Lot	Exp. dates
DNA/RNA Extraction Kit	Patho Gene-Spin	101653053	2022-09
COVID-19 Multi Real-Time RT-PCR Kit	LiliF™, Korea	H215060553	2021-07-20




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The Results of the Testing of Samples using Confirmatory Method


Samples for Verification of Sensitivity				Samples for Verification of Specificity			
No.	Information about Samples			No.	Information about Samples		
	ID sample	Date	Interpretation		ID sample	Date	Interpretation
1.	54879	12.01.2021	Positive (Ct-34/35/34)	1.	54899	12.01.2021	Negative
2.	54885	12.01.2021	Positive (Ct-28/29/28)	2.	54901	12.01.2021	Negative
3.	54886	12.01.2021	Positive (Ct-30/30/31)	3.	54902	12.01.2021	Negative
4.	54887	12.01.2021	Positive (Ct-34/35/34)	4.	54903	12.01.2021	Negative
5.	54888	12.01.2021	Positive (Ct-27/28/27)	5.	54904	12.01.2021	Negative
6.	54889	12.01.2021	Positive (Ct-25/26/26)	6.	54905	12.01.2021	Negative
7.	54892	12.01.2021	Positive (Ct-33/34/33)	7.	54906	12.01.2021	Negative
8.	54895	12.01.2021	Positive (Ct-20/21/20)	8.	54907	12.01.2021	Negative
9.	54900	12.01.2021	Positive (Ct-22/22/22)	9.	54908	12.01.2021	Negative
10.	54921	12.01.2021	Positive (Ct-30/30/29)	10.	54909	12.01.2021	Negative
11.	54928	12.01.2021	Positive (Ct-21/23/21)	11.	54910	12.01.2021	Negative
12.	54929	12.01.2021	Positive (Ct-16/17/15)	12.	54911	12.01.2021	Negative
13.	54934	13.01.2021	Positive (Ct-16/17/15)	13.	54912	12.01.2021	Negative
14.	54946	13.01.2021	Positive (Ct-24/25/25)	14.	54913	12.01.2021	Negative
15.	54948	13.01.2021	Positive (Ct-28/29/28)	15.	54914	12.01.2021	Negative
16.	54963	14.01.2021	Positive (Ct-23/24/22)	16.	54915	12.01.2021	Negative
17.	54964	14.01.2021	Positive (Ct-22/23/22)	17.	54916	12.01.2021	Negative
18.	54965	14.01.2021	Positive (Ct-25/27/25)	18.	54917	12.01.2021	Negative
19.	55085	15.01.2021	Positive (Ct-19/18/19)	19.	54918	12.01.2021	Negative
20.	55086	15.01.2021	Positive (Ct-22/21/21)	20.	54919	12.01.2021	Negative
21.	55107	15.01.2021	Positive (Ct-31/33/0)	21.	54920	12.01.2021	Negative



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22.	55108	15.01.2021	Positive (Ct-27/30/0)	22.	54922	12.01.2021	Negative
23.	55109	15.01.2021	Positive (Ct-28/32/0)	23.	54923	12.01.2021	Negative
24.	55110	15.01.2021	Positive (Ct-25/25/26)	24.	54924	12.01.2021	Negative
25.	55111	15.01.2021	Positive (Ct-31/35/0)	25.	54925	12.01.2021	Negative
26.	55113	15.01.2021	Positive (Ct-31/32/32)	26.	54926	12.01.2021	Negative
27.	55114	15.01.2021	Positive (Ct-21/22/22)	27.	54927	12.01.2021	Negative
28.	55115	15.01.2021	Positive (Ct-29/28/28)	28.	54933	13.01.2021	Negative
29.	55116	15.01.2021	Positive (Ct-29/28/29)	29.	54935	13.01.2021	Negative
30.	55117	15.01.2021	Positive (Ct-26/26/26)	30.	54936	13.01.2021	Negative
31.	55118	15.01.2021	Positive (Ct-23/23/24)	31.	54937	13.01.2021	Negative
32.	55119	15.01.2021	Positive (Ct-30/30/30)	32.	54938	13.01.2021	Negative
33.	55120	15.01.2021	Positive (Ct-24/23/24)	33.	55017	14.01.2021	Negative
34.	55121	15.01.2021	Positive (Ct-29/29/29)	34.	55018	14.01.2021	Negative
35.	55122	15.01.2021	Positive (Ct-19/18/19)	35.	55020	14.01.2021	Negative
36.	55123	15.01.2021	Positive (Ct-22/21/21)	36.	55021	14.01.2021	Negative
37.	55124	15.01.2021	Positive (Ct-18/18/18)	37.	55022	14.01.2021	Negative
38.	55126	15.01.2021	Positive (Ct-21/21/21)	38.	55023	14.01.2021	Negative
39.	55127	15.01.2021	Positive (Ct-31/31/31)	39.	55030	14.01.2021	Negative
40.	55128	15.01.2021	Positive (Ct-33/33/34)	40.	55140	15.01.2021	Negative
41.	55129	15.01.2021	Positive (Ct-35/34/35)	41.	55141	15.01.2021	Negative
42.	55130	15.01.2021	Positive (Ct-28/28/28)	42.	55142	15.01.2021	Negative
43.	55131	15.01.2021	Positive (Ct-28/28/28)	43.	55143	15.01.2021	Negative
44.	55132	15.01.2021	Positive (Ct-26/26/26)	44.	55144	15.01.2021	Negative
45.	55133	15.01.2021	Positive (Ct-25/25/25)	45.	55145	15.01.2021	Negative




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46.	55134	15.01.2021	Positive (Ct-21/21/21)	46.	55147	15.01.2021	Negative
47.	55135	15.01.2021	Positive (Ct-19/18/18)	47.	55148	15.01.2021	Negative
48.	55136	15.01.2021	Positive (Ct-24/23/24)	48.	55149	15.01.2021	Negative
49.	55137	15.01.2021	Positive (Ct-23/23/23)	49.	55125	15.01.2021	Negative
50.	55138	15.01.2021	Positive (Ct-23/24/24)				
51.	55139	15.01.2021	Positive (Ct-22/21/21)				

METHOD TO BE VERIFIED

Name of the Method: Immunochromatographic test using of Rapid tests Kit for the detection of SARS-CoV-2 Antigen (Immunoassay using Colloidal Gold)

Executors of Verification Method:

Name	Position
Demchyshyna Iryna Viktorivna	Head of the Laboratory
Hluzd Oleksandra Anatoliivna	Virologist
Dovchenko Liubov Vasylivna	Laboratory Assistant


Environmental Conditions during the Testing:

Date	Environment Temperature, °C	Relative Humidity, %	Other Influential Conditions
11.01.2021	21°C	60%	
12.01.2021	22°C	56%	
13.01.2021	22°C	56%	
14.01.2021	21°C	60%	
15.01.2021	22°C	56%	

Used Test-Kits:

Name	Manufacturer	Lot	Exp. dates
SARS-CoV-2 Antigen Rapid Test Kit	Wuhan Unscience Biotechnology Co., Ltd	20201030	2022.04.29




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The Results of the Testing of Samples using Method to be verified


Samples for Verification of Sensitivity				Samples for Verification of Specificity			
No.	Information about Samples			No.	Information about Samples		
	ID sample	Date	Interpretation		ID sample	Date	Interpretation
1.	54879	12.01.2021	Negative	1.	54899	12.01.2021	Negative
2.	54885	12.01.2021	Positive	2.	54901	12.01.2021	Negative
3.	54886	12.01.2021	Negative	3.	54902	12.01.2021	Negative
4.	54887	12.01.2021	Negative	4.	54903	12.01.2021	Negative
5.	54888	12.01.2021	Positive	5.	54904	12.01.2021	Negative
6.	54889	12.01.2021	Positive	6.	54905	12.01.2021	Negative
7.	54892	12.01.2021	Negative	7.	54906	12.01.2021	Negative
8.	54895	12.01.2021	Positive	8.	54907	12.01.2021	Negative
9.	54900	12.01.2021	Positive	9.	54908	12.01.2021	Negative
10.	54921	12.01.2021	Negative	10.	54909	12.01.2021	Negative
11.	54928	12.01.2021	Positive	11.	54910	12.01.2021	Negative
12.	54929	12.01.2021	Positive	12.	54911	12.01.2021	Negative
13.	54934	13.01.2021	Positive	13.	54912	12.01.2021	Negative
14.	54946	13.01.2021	Positive	14.	54913	12.01.2021	Negative
15.	54948	13.01.2021	Positive	15.	54914	12.01.2021	Negative
16.	54963	14.01.2021	Positive	16.	54915	12.01.2021	Negative
17.	54964	14.01.2021	Positive	17.	54916	12.01.2021	Negative
18.	54965	14.01.2021	Positive	18.	54917	12.01.2021	Negative
19.	55085	15.01.2021	Positive	19.	54918	12.01.2021	Negative
20.	55086	15.01.2021	Positive	20.	54919	12.01.2021	Negative
21.	55107	15.01.2021	Negative	21.	54920	12.01.2021	Negative
22.	55108	15.01.2021	Negative	22.	54922	12.01.2021	Negative
23.	55109	15.01.2021	Negative	23.	54923	12.01.2021	Negative
24.	55110	15.01.2021	Negative	24.	54924	12.01.2021	Negative
25.	55111	15.01.2021	Negative	25.	54925	12.01.2021	Negative
26.	55113	15.01.2021	Negative	26.	54926	12.01.2021	Negative
27.	55114	15.01.2021	Negative	27.	54927	12.01.2021	Negative
28.	55115	15.01.2021	Positive	28.	54933	13.01.2021	Negative
29.	55116	15.01.2021	Positive	29.	54935	13.01.2021	Negative
30.	55117	15.01.2021	Negative	30.	54936	13.01.2021	Negative
31.	55118	15.01.2021	Positive	31.	54937	13.01.2021	Negative
32.	55119	15.01.2021	Negative	32.	54938	13.01.2021	Negative
33.	55120	15.01.2021	Negative	33.	55017	14.01.2021	Negative
34.	55121	15.01.2021	Negative	34.	55018	14.01.2021	Negative
35.	55122	15.01.2021	Positive	35.	55020	14.01.2021	Negative
36.	55123	15.01.2021	Positive	36.	55021	14.01.2021	Negative
37.	55124	15.01.2021	Positive	37.	55022	14.01.2021	Negative
38.	55126	15.01.2021	Negative	38.	55023	14.01.2021	Negative
39.	55127	15.01.2021	Positive	39.	55030	14.01.2021	Negative
40.	55128	15.01.2021	Negative	40.	55140	15.01.2021	Negative
41.	55129	15.01.2021	Negative	41.	55141	15.01.2021	Negative



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42.	55130	15.01.2021	Negative	42.	55142	15.01.2021	Negative
43.	55131	15.01.2021	Negative	43.	55143	15.01.2021	Negative
44.	55132	15.01.2021	Negative	44.	55144	15.01.2021	Negative
45.	55133	15.01.2021	Negative	45.	55145	15.01.2021	Negative
46.	55134	15.01.2021	Positive	46.	55147	15.01.2021	Negative
47.	55135	15.01.2021	Positive	47.	55148	15.01.2021	Negative
48.	55136	15.01.2021	Positive	48.	55149	15.01.2021	Negative
49.	55137	15.01.2021	Negative	49.	55125	15.01.2021	Negative
50.	55138	15.01.2021	Positive				
51.	55139	15.01.2021	Positive				




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THE RESULTS OF THE VERIFICATION EXPERIMENT

Results of Verification of Sensitivity		Results of Verification of Specificity	
ID sample	Interpretation obtained Results	ID sample	Interpretation obtained Results
54879	False Negative	54899	True Negative
54885	True Positive	54901	True Negative
54886	False Negative	54902	True Negative
54887	False Negative	54903	True Negative
54888	True Positive	54904	True Negative
54889	True Positive	54905	True Negative
54892	False Negative	54906	True Negative
54895	True Positive	54907	True Negative
54900	True Positive	54908	True Negative
54921	False Negative	54909	True Negative
54928	True Positive	54910	True Negative
54929	True Positive	54911	True Negative
54934	True Positive	54912	True Negative
54946	True Positive	54913	True Negative
54948	True Positive	54914	True Negative
54963	True Positive	54915	True Negative
54964	True Positive	54916	True Negative
54965	True Positive	54917	True Negative
55085	True Positive	54918	True Negative
55086	True Positive	54919	True Negative
55107	False Negative	54920	True Negative
55108	False Negative	54922	True Negative
55109	False Negative	54923	True Negative
55110	False Negative	54924	True Negative
55111	False Negative	54925	True Negative
55113	False Negative	54926	True Negative
55114	False Negative	54927	True Negative
55115	True Positive	54933	True Negative
55116	True Positive	54935	True Negative
55117	False Negative	54936	True Negative
55118	True Positive	54937	True Negative
55119	False Negative	54938	True Negative
55120	False Negative	55017	True Negative
55121	False Negative	55018	True Negative
55122	True Positive	55020	True Negative
55123	True Positive	55021	True Negative
55124	True Positive	55022	True Negative
55126	False Negative	55023	True Negative
55127	True Positive	55030	True Negative
55128	False Negative	55140	True Negative
55129	False Negative	55141	True Negative
55130	False Negative	55142	True Negative
55131	False Negative	55143	True Negative



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55132	False Negative	55144	True Negative
55133	False Negative	55145	True Negative
55134	True Positive	55147	True Negative
55135	True Positive	55148	True Negative
55136	True Positive	55149	True Negative
55137	False Negative	55125	True Negative
55138	True Positive		
55139	True Positive		
SENSITIVITY		SPECIFICITY	
Obtained Results	Target Value	Obtained Results	Target Value
92.156 (47/51)	90.323%*	100.0 (49/49)	99.213%
Conclusion: Sensitivity of the Method is verified		Conclusion: Specificity of the Method is verified	

* In calculating the Sensitivity were taken into account the Results of testing nasopharyngeal swabs by PCR. Ct are not greater than or equal to 25.

Person responsible for the Development
and Implementation of the Quality
Management System – Hluzd O.A.

(signature)

15 January 2021

(stamp for documents of Government Agency
«Public Health Center of Ministry of Health of Ukraine»)

Agreed
Head of the Laboratory of virological
Research – Demchyshyna I.V.

(signature)

15 January 2021

