CÔNG TY TNHH 5M HEALTHCARE

Địa chỉ: Tầng 6, tòa nhà 97-99 Láng Hạ, Láng Hạ, Đống Đa, Hà Nội

Hotline: 0941929119

Hà Nội, ngày 19 tháng 05 năm 2024

BÁO GIÁ

Kính gửi: QUÝ BỆNH VIỆN

Công ty TNHH 5M Healthcare xin gửi đến Quý Bệnh viện bảng báo giá như sau:

1. Mặt hàng – Đơn giá:

TT	Tên thiết bị y tế	Chủng loại	Số đăng ký lưu hành – Tiêu chuẩn chất lượng	Hãng sản xuất/ Xuất xứ	Quy cách đóng gói	Đơn vị tính	Số lượng	Đơn giá (VNĐ)
1	**Khay thử xét nghiệm định tính kháng nguyên vi rút Sars-CoV-2, Cúm A/B, Andenovirus (ADV), vi rút hợp bào hô hấp (RSV) và vi rút liên cầu nhóm A(Strep A)**	**SARS-CoV-2/ FluA/ FluB+ADV/ RSV/ S A Antigen Combo Rapid Test Kit (LFIA)**	**- Số đăng ký lưu hành: 2400105ĐKLH/ BYT-HTTB** **- Tiêu chuẩn chất lượng: ISO 13485 CFS**	**Medomics Medical Technology Co.,Ltd. (Trung Quốc)**	**20 khay thử/ hộp**	**Khay thử**	**01**	**85.000**

Giá trên là giá đã gồm thuế VAT và chi phí vận chuyển đến kho của Quý Bệnh viện.

2. Chất lượng:

- Hàng mới 100%.
- Sản xuất năm 2024.

3. Phương thức thanh toán:

- Thanh toán 50% giá trị hợp đồng sau khi ký hợp đồng.
- Thanh toán 50% giá trị hợp đồng còn lại trước khi giao hàng.
- Thanh toán bằng tiền Việt Nam, bằng chuyển khoản hoặc tiền mặt.

4. Giao hàng

- Địa điểm giao hàng: Tại kho của Quý Bệnh viện.

5. Ghi chú:

Báo giá có hiệu lực: 03 tháng kể từ ngày báo giá.

Rất mong nhận được sự hợp tác của Quý Bệnh viện.

Chân thành cảm ơn và trân trọng kính chào

ĐẠI DIỆN CÔNG TY

CÔNG TY TNHH 5M HEALTHCARE

GIÁM ĐỐC

Đỗ Văn Tiến

BỘ Y TẾ	CỘNG HÒA XÃ HỘI CHỦ NGHĨA VIỆT NAM
	Độc lập - Tự do - Hạnh phúc
Số: 2400105ĐKLH/BYT-HTTB	*Hà Nội, ngày 04 tháng 02 năm 2024*

GIẤY CHỨNG NHẬN ĐĂNG KÝ LƯU HÀNH THIẾT BỊ Y TẾ THUỘC LOẠI C, D

Căn cứ Nghị định số 98/2021/NĐ-CP ngày 08 tháng 11 năm 2021 của Chính phủ về quản lý trang thiết bị y tế;

Căn cứ Nghị định số 07/2023/NĐ-CP ngày 03 tháng 3 năm 2023 của Chính phủ sửa đổi, bổ sung một số điều của Nghị định số 98/2021/NĐ-CP ngày 08 tháng 11 năm 2021 của Chính phủ về quản lý trang thiết bị y tế.

Bộ Y tế cấp chứng nhận đăng ký lưu hành cho thiết bị y tế (mới 100%) như sau:

1. Tên thiết bị y tế: Khay thử xét nghiệm định tính kháng nguyên vi rút Sars-CoV-2, Cúm A/B, Andenovirus (ADV), vi rút hợp bào hô hấp (RSV) và vi rút liên cầu nhóm A(Strep A)
2. Tên thương mại *(nếu có)*:
3. Mã Global Medical Device Nomenclature - GMDN *(nếu có)*:
4. Loại thiết bị y tế: TTBYT Loại D
5. Tên, địa chỉ của chủ sở hữu thiết bị y tế: Jiangsu Medomics Medical Technology Co.,Ltd, F3, Building C, No.3-1 Xinjinhu Road, Jiangbei New Area, Nanjing, Jiangsu, 210030, CHINA
6. Tên, địa chỉ của chủ sở hữu số lưu hành: CÔNG TY TNHH 5M HEALTHCARE, Tầng 6, Tòa nhà 97-99 Láng Hạ, Phường Láng Hạ, Quận Đống Đa, Thành phố Hà Nội.
7. Mục đích sử dụng; Tên, địa chỉ cơ sở bảo hành: *Theo phụ lục đính kèm.*
8. Thông tin chi tiết thiết bị y tế (Chủng loại; Mã sản phẩm; Quy cách đóng gói; Tên cơ sở sản xuất; Địa chỉ cơ sở sản xuất và Nước sản xuất): *Theo phụ lục đính kèm.*

Giấy chứng nhận này được cấp theo Quyết định số 259/QĐ-BYT ngày 02 tháng 02 năm 2024./.

Nơi nhận:
- CÔNG TY TNHH 5M HEALTHCARE;
- Bộ trưởng (để b/c);
- TT. Đỗ Xuân Tuyên (để b/c);
- Hải quan cửa khẩu;
- Lưu: VT, HTTB.

TUQ. BỘ TRƯỞNG
CỤC TRƯỞNG
CỤC CƠ SỞ HẠ TẦNG VÀ THIẾT BỊ Y TẾ

Nguyễn Minh Lợi

PHỤ LỤC ĐÍNH KÈM

1. Mục đích sử dụng:

Bộ xét nghiệm nhanh kháng nguyên SARS-CoV-2/FluA/FluB+ADV/RSV/SA (LFIA) là một phương pháp sắc ký miễn dịch dựa trên xét nghiệm in vitro một bước. Nó được thiết kế để xác định định tính nhanh chóng SARS-CoV-2, vi rút Cúm A, vi rút Cúm B, Adenovirus (ADV), vi rút hợp bào hô hấp (RSV) và kháng nguyên liên cầu nhóm A (STREP A) trong các mẫu bệnh phẩm từ những người nghi ngờ nhiễm COVID -19, Cúm A , Cúm B, Adenovirus (ADV), Virus hợp bào hô hấp (RSV) và Streptococci nhóm A (STREP A). Nó có thể được sử dụng để phát hiện SARS-CoV-2, Cúm A , Vi rút cúm B, Adenovirus (ADV), Vi rút hợp bào hô hấp (RSV) và Streptococci nhóm A (STREP A). Phương pháp này thường được sử dụng như một phương pháp phụ trợ trong chẩn đoán lâm sàng, nhưng không phải là cơ sở duy nhất.

2. Tên, địa chỉ cơ sở bảo hành:

3. Thông tin chi tiết thiết bị y tế:

STT	Tên thiết bị y tế	Chủng loại	Mã sản phẩm (Nếu có)	Quy cách đóng gói (Nếu có)	Tên cơ sở sản xuất	Địa chỉ cơ sở sản xuất	Nước sản xuất
1	Khay thử xét nghiệm định tính kháng nguyên vi rút Sars-CoV-2, Cúm A/B, Andenovirus (ADV), vi rút hợp bào hô hấp (RSV) và vi rút liên cầu nhóm A(Strep A)	SARS-CoV-2/FluA/FluB+ADV/RSV/SA Antigen Combo Rapid Test Kit (LFIA)	123015-20-01	20 khay thử/ hộp	Jiangsu Medomics Medical Technology Co.,Ltd	F3, Building C, No.3-1 Xinjinhu Road, Jiangbei New Area, Nanjing, Jiangsu, 210030	CHINA

SARS-CoV-2/FluA/FluB+ADV/RSV/SA Antigen Combo Rapid Test Kit (LFIA)

Test cassette: 1pc/bag

REF	Specification
123015-20-01	20 pcs/Box

FOR *IN VITRO* DIAGNOSTIC USE ONLY.
FOR PROFESSIONAL USE ONLY

Instruction for Use

CÔNG TY TNHH 5M HEALTHCARE

Introduction

Coronavirus (CoV) belongs to the order Nidovirales under the Coronaviridae family with 4 genera: α, β, γ and δ. The α and β genera are only pathogenic to mammals, while γ and δ genera mainly cause bird infections. CoV is mainly transmitted through direct contact with secretions or through aerosols and droplets. There is also evidence supporting fecal-oral transmission.
7 kinds of human coronaviruses (HCoV) that cause human respiratory diseases have been identified so far, including: HCoV-229E, HCoV-NL63, HCoV-OC43, HCoV-HKU1, SARS-CoV, MERS-CoV and SARS-CoV-2. SARS-CoV-2 is one of the most contagious viral pathogens that causes human respiratory tract infections (RTI). Currently, the patients infected by SARS-CoV-2 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 clinical manifestations include fever, fatigue, cough and other symptoms, accompanied by dyspnea, which can rapidly develop into life-threatening severe pneumonia, respiratory failure, acute respiratory vesicle syndrome, septic shock, multiple organ failure, and severe metabolic acid-base imbalance.
Influenza, usually called flu, is an acute respiratory infection caused by Influenza virus. It is highly contagious. It is mainly spread through coughing and sneezing. It usually breaks out in spring and winter. It is mainly divided into Influenza A and B Influenza virus. Influenza A viruses are highly variable, followed by Influenza B viruses. Therefore, Influenza A viruses are more prevalent and severe, followed by Influenza B viruses. Influenza A includes H1N1, H3N2, H5N1, H7N9, and Influenza B includes Influenza B (Victoria) and Influenza B (Yamagata).
Human adenovirus(ADV) belongs to the adenoviridae family, mammalian adenovirus genus, which is a double-stranded DNA virus without an envelope, mainly infects human respiratory tract, digestive tract and urogenital tract. The main ADV related to respiratory diseases is ADV-B Group (ADV-3, 7, 11, 14, 16, 21, 50, 55), ADV-C Group (ADV-1,2,5,6) and ADV-E group (ADV-4). Acute respiratory adenovirus (ADV) infection which is one of the most common acute respiratory infections in infants and young children, it mainly causes fever, cough, dyspnea and other symptoms.
Respiratory syncytial virus (RSV) belongs to Pneumovirus of Paramyxoviridae with only one serotype, which is a single stranded negative-strand RNA virus with an envelope. RSV infection mainly causes bronchiolitis and pneumonia in infants under 6 months of age and upper respiratory tract infections such as rhinitis and colds in older children and adults.
Group A streptococci, STREP A, is called streptococcus pyogenes, which belongs to β hemolytic streptococcus. Common mode of transmission is spread through the respiratory tract. STREP A can invade any part of the human body, but upper respiratory tract infection is the most common, followed by skin and soft tissue infection. STREP A can cause both suppurative diseases and non- suppurative complications. STREP A is also an indirect cause of the allergic diseases rheumatic fever and acute glomerulonephritis.

Intended Use

SARS-CoV-2/FluA/FluB+ADV/RSV/SA Antigen Combo Rapid Test Kit (LFIA) is an immunochromatography based one step in vitro test. It is designed for the rapid qualitative determination of SARS-CoV-2, Influenza A, Influenza B virus, Adenovirus(ADV), Respiratory syncytial virus(RSV) and Group A streptococci (STREP A) antigen in swab samples from individuals suspected of COVID-19, Influenza A, Influenza B, Adenovirus(ADV), Respiratory syncytial virus(RSV) and Group A streptococci (STREP A). It can be used for detecting SARS-CoV-2, Influenza A, Influenza B virus, Adenovirus(ADV), Respiratory syncytial virus(RSV) and Group A streptococci (STREP A). Which is often used as an auxiliary method in the clinical diagnosis, but not as the only basis.

Test Principle

SARS-CoV-2/FluA/FluB+ADV/RSV/SA Antigen Combo Rapid Test Kit (LFIA) uses a double antibody sandwich method to detect SARS-CoV-2, Influenza A,Influenza B, Influenza B virus, Adenovirus (ADV), Respiratory syncytial virus (RSV) and Group A streptococci (STREP A) by colloidal gold immunochromatography. When the appropriate amount of test samples treated with lysis buffer is added to the sample well of the test cassette, the sample will move forward along the test strip by capillary action. If the sample contains SARS-CoV-2, Influenza A/B virus, Adenovirus(ADV), Respiratory syncytial virus (RSV) and Group A streptococci (STREP A) antigen, and the concentration is higher than the limit of detection, the antigen will form immune complexes with corresponding Nucleocapsid Protein antibody labeled with colloidal gold respectively, which are captured by lines nCoV line, Flu A line, Flu B line, ADV line, RSV line and SA line. If test sample contains SARS-CoV-2 virus, forming a red nCoV line, indicating a positive result for SARS-CoV-2. If test sample contains Influenza A virus, forming a red Flu A line, indicating a positive result for Influenza A. If test sample contains Influenza B virus, forming a red FluB line, indicating a positive result for Influenza B. If test sample contains Adenovirus, forming a red ADV line, indicating a positive result for Adenovirus. If test sample contains Respiratory syncytial virus, forming a red RSV line,indicating a positive result for Respiratory syncytial virus. If test sample contains Group A streptococci, forming a red SA line, indicating a positive result for Group A streptococci.
Additionally, the test strip also contains a control line (C line). The C line should be formed to indicate that the sample has been transported properly through the membrane regardless of whether sample contains antigens or not. If the C line does not appear, it indicates that the test result is invalid and the sample need to retest.

Test Kit Contents

Test kit contains test cassettes, sterile swabs, Dilution buffer and dropper,Instructions for use,Test-tube Rack

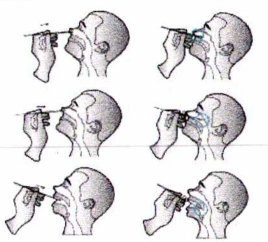
REF	Components / Specification	Test Cassette	Sterile Swab	Dilution buffer and dropper	Instruction for use	Test-tube Rack
123015-20-01	20 pcs/Box	20	20	20	1	1

Storage Instructions

The test kit should be stored away from direct sunlight at 2°C to 30°C with a shelf-life of 24 months. Do not freeze.

Sample Requirements

One test cassette can only be used to test one sample type. Sample types include anterior nasal secretion, nasopharyngeal secretion and throat secretion.
Note: The recommended sample is a throat swab as group A streptococci have been found to be more likely to cause lower respiratory tract infections.



• Anterior Nasal Sampling: Insert the swab into a nostril (2.5 cm). Be sure to collect any nasal drainage that may be present.
Carefully rotate the swab in a circular path against the inside of the nostril at least 5 times. Using the same swab repeat the procedure in the other nostril.

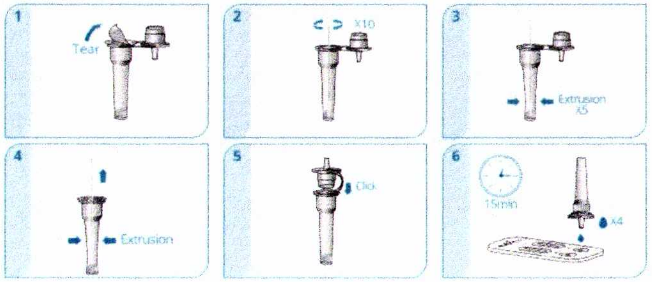
• Nasopharyngeal secretion collection: Take out a swab from the pouch, insert the swab into one of the patient's nostrils until it reaches the posterior nasopharynx where is the most secretion, gently rotate and rub the swab over the surface of the posterior nasopharynx for several times before taking it out.

• Throat secretion collection: Insert the whole swab completely into the throat from the mouth, centering on the throat wall and the reddened area of the palate tonsil, wipe both sides of the pharyngeal tonsil and posterior pharyngeal wall with moderate force. Try to avoid the tongue before taking it out.

Sample should be treated with lysis buffer provided in this kit as soon as possible after collection. If the sample cannot be processed immediately, it should be stored immediately in a dry, sterilized and strictly sealed plastic tube. It can be stored at 2°C-8°C for 8 hours. Could be stored at -70°C for long term storage.

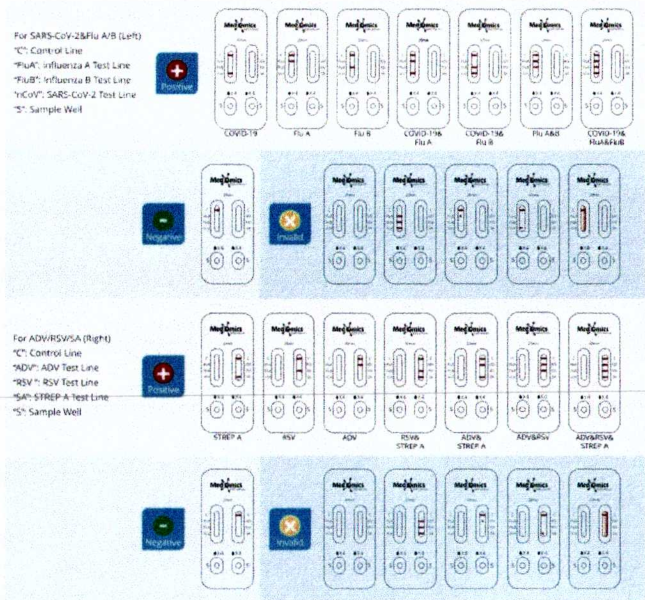
Testing Procedure

Do not open pouch until ready to use. Prep necessary materials: Timer | Tube rack for sampling tubes and specimens | Any necessary personal protective equipment.
1 | Sampling: Open the seal of the sampling tube containing lysis buffer. Insert the swab (after collection) into the buffer. Rotate the swab against the inner tube wall
10 times and squeeze the swab from the outer tube wall 5 times to completely dissolve the sample in the buffer, then move the swab up until it is resting on the sample solution, squeeze the swab from the outer tube wall in order to leave the sample in the tube as much as possible. Remove and discard the swab, cover the tube with the dropper.
2 | Test procedures: Open the aluminum foil pouch, take out the test cassette and lay it on a clean flat surface, then mark the cassette with the patient ID or sample number and add 4 drops (approximately 100 μL) processed sample extract into the sample well.
The result should be observed within 15-25 minutes. Results observed after 30 minutes are invalid.



Display of Results/Expected Values

Negative result: If only the quality control C line appears and the detection line is not visible, the sample contains no SARS-CoV-2, Influenza A, Influenza B, ADV, RSV and STREP A or the concentration is lower than the limit of detection and the result is negative.
Positive result:
• SARS-CoV-2 positive result: If the control line (C line) and the test line (nCoV line) appear at the same time, it means that the SARS-CoV-2 has been detected and the result is positive.
• Influenza A positive result: If both the control line (C line) and the Influenza A test line (Flu A line) appear at the same time, it means that Influenza A antigen has been detected in the sample and the result of Influenza A is positive.
• Influenza B positive result ; If both the control line (C line) and the Influenza B test line (Flu B line) appear at the same time, it means that Influenza B antigen has been detected in the sample and the result of Influenza B is positive.
• ADV positive result: If the control line (C line) and the test line (ADV line) appear at the same time, it means that the ADV has been detected and the result is positive.
• RSV positive result: If both the control line (C line) and the test line (RSV line) appear at the same time, it means that RSV antigen has been detected in the sample and the result of RSV is positive.
• STREP A positive result ; If both the control line (C line) and the test line (SA line) appear at the same time, it means that STREP A antigen has been detected in the sample and the result of STREP A is positive.
If the quality control C line appears, and more red lines appear in the detection line area, indicating that the sample contains one or more pathogenic microorganisms.
Invalid result: If the C line does not appear, the result is invalid and a new test must be performed again.
Note:
The intensity of color that the test line area (nCoV line/Flu A line/Flu B line) shows will vary according to the concentration of SARS-CoV-2 antigen, Influenza A antigen and Influenza B antigen. The result should be determined on whether the nCoV line is formed or not, and is irrelevant to the color intensity. Therefore, any intensity of color in the test area (nCoV line/Flu A line/Flu B line) should be considered positive.
The intensity of color that the test line area (ADV line/RSV line/SA line) shows will vary according to the concentration of ADV antigen, RSV antigen and STREP A antigen. The result should be determined on whether the test line is formed or not, and is irrelevant to the color intensity. Therefore, any intensity of color in the test area (ADV line/RSV line/SA line) should be considered positive.



Test Method Limitations

1.The accuracy of the test is dependent on the quality of the sample. Improper sampling or storage, using expired samples or repeated frozen-thawed samples can affect the test results. Test results can also be affected by temperature and humidity.
2.Negative results may be caused by low concentration of SARS-CoV-2, Influenza A, Influenza B, ADV, RSV, STREP A antigens in the sample and therefore cannot completely rule out the possibility of infection.
3.Some medication (e.g. high concentration of over-the-counter (OTC) or prescription medication such as nasal spray) in the collected samples may interfere with the test result. Please perform the test again if the result is in doubt.
4.This product is only for qualitative testing and the specific concentration of each indicator must be measured using other quantitative methodologies.
5.The test results of this kit are for clinical reference only and are not the sole basis for clinical diagnosis. The clinical diagnosis and treatment of patients should be comprehensively considered in combination with their symptoms/signs, medical history, other laboratory tests and treatment response.

Product Performance

• Limit of Detection-LoD
Limit of Detection (LoD) studies determined the lowest detectable concentration of SARS-CoV-2, Influenza A, Influenza B, ADV, RSV and STREP A at which 100% of all (true positive) replicates test positive.

	Virus Strain	LoD ($TCID_{50}$/mL)
SARS-CoV-2	BetaCoV/JS02/human/2020	10[illegible]
Influenza A	A/Brisbane/02/2018 (H1N1)	10[illegible]
	A/PUERTO/8/1934 (H1N1)	10[illegible]
	A/Kansas/14/2017 (H3N2)	10[illegible]
	A/Aichi/2/1968 (H3N2)	10[illegible]
	A/Anhui/1/2013 (H7N9)	10[illegible]
Influenza B	B/Colorado/06/2017 (Victoria)	10[illegible]
	B/Phuket/3073/2013 (Yamagata)	10[illegible]
	B/Chaoyang Beijing/12977/2017 (Yamagata)	10[illegible]

	Virus Strain	LoD ($TCID_{50}$/mL)
ADV	ADV-1	10[illegible]
	ADV-2	10[illegible]
	ADV-3	10[illegible]
	ADV-4	10[illegible]
	ADV-7	10[illegible]
	ADV-55	10[illegible]
RSV	RSV A	10[illegible]
	RSV B	10[illegible]
	Bacterial strain	**LoD(CFU/mL)**
STREP A	STREP A	10[illegible]

• Cross Reactivity
Cross reactivity of SARS-CoV-2/FluA/FluB+ADV/RSV/SA Antigen Combo Rapid Test Kit (LFIA) was evaluated by testing commensal and pathogenic microorganisms listed in the following table that may be present in the clinical samples. Each of the bacterium, viruses, and yeast were tested in triplicate with no false positive results of SARS-CoV-2 virus, Influenza A, Influenza B, ADV, RSV and STREP A.

Potential Cross-Reactant	Concentration Tested	Cross Reactivity (Yes/No)					
		SARS-CoV-2	Flu A	Flu B	ADV	RSV	STREP A
Human coronavirus OC43	1.0 x 10[illegible] $TCID_{50}$/mL	No	No	No	No	No	No
Human coronavirus NL63	1.0 x 10[illegible] $TCID_{50}$/mL	No	No	No	No	No	No
Human coronavirus HKU1	1.0 x 10[illegible] $TCID_{50}$/mL	No	No	No	No	No	No
MERS-coronavirus	1.0 x 10[illegible] $TCID_{50}$/mL	No	No	No	No	No	No
SARS-coronavirus	1.0 x 10[illegible] $TCID_{50}$/mL	No	No	No	No	No	No
SARS-CoV-2	1.0 x 10[illegible] $TCID_{50}$/mL	/	No	No	No	No	No
H1N1(2009)	1.0 x 10[illegible] $TCID_{50}$/mL	No	/	No	No	No	No
Influenza A H1N1 Seasonal	1.0 x 10[illegible] $TCID_{50}$/mL	No	/	No	No	No	No
Influenza A H3N2	1.0 x 10[illegible] $TCID_{50}$/mL	No	/	No	No	No	No
Influenza A H5N1	1.0 x 10[illegible] $TCID_{50}$/mL	No	/	No	No	No	No
Influenza A H7N9	1.0 x 10[illegible] $TCID_{50}$/mL	No	/	No	No	No	No
Influenza B Victoria	1.0 x 10[illegible] $TCID_{50}$/mL	No	No	/	No	No	No
Influenza B Yamagata	1.0 x 10[illegible] $TCID_{50}$/mL	No	No	/	No	No	No
Parainfluenza virus Type 1	1.0 x 10[illegible] $TCID_{50}$/mL	No	No	No	No	No	No
Enterovirus CA16e	1.0 x 10[illegible] $TCID_{50}$/mL	No	No	No	No	No	No
ADV-1	1.0 x 10[illegible] $TCID_{50}$/mL	No	No	No	/	No	No
ADV-2	1.0 x 10[illegible] $TCID_{50}$/mL	No	No	No	/	No	No
ADV-3	1.0 x 10[illegible] $TCID_{50}$/mL	No	No	No	/	No	No
ADV-4	1.0 x 10[illegible] $TCID_{50}$/mL	No	No	No	/	No	No
ADV-7	1.0 x 10[illegible] $TCID_{50}$/mL	No	No	No	/	No	No
ADV-55	1.0 x 10[illegible] $TCID_{50}$/mL	No	No	No	/	No	No
RSV-A	1.0 x 10[illegible] $TCID_{50}$/mL	No	No	No	No	/	No
RSV-B	1.0 x 10[illegible] $TCID_{50}$/mL	No	No	No	No	/	No
Mycoplasma pneumoniae	1.0 x 10[illegible] CFU/mL	No	No	No	No	No	No
Staphylococcus aureus	1.0 x 10[illegible] CFU/mL	No	No	No	No	No	No
Staphylococcus epidermidis	1.0 x 10[illegible] CFU/mL	No	No	No	No	No	No
Bordetella pertussis	1.0 x 10[illegible] CFU/mL	No	No	No	No	No	No
Legionella pneumophila	1.0 x 10[illegible] CFU/mL	No	No	No	No	No	No
Streptococcus pneumoniae	1.0 x 10[illegible] CFU/mL	No	No	No	No	No	[illegible]
Haemophilus influenzae	1.0 x 10[illegible] CFU/mL	No	No	No	No	No	No
Streptococcus pneumoniae	1.0 x 10[illegible] CFU/mL	No	No	No	No	No	No
Mycobacterium tuberculosis	1.0 x 10[illegible] CFU/mL	No	No	No	No	No	No
Candida albicans	1.0 x 10[illegible] CFU/mL	No	No	No	No	No	No

• Interfering Substances Effect
A study was performed to evaluate and demonstrate that the endogenous substances naturally present or drugs that may be artificially introduced into clinical samples do not inference with the detection of SARS-CoV-2, Influenza A, Influenza B, ADV, RSV and STREP A in the SARS - CoV-2/ Flu A / Flu B+ADV / RSV / SA Antigen Combo Rapid Test Kit (LFIA) at the concentrations listed below. Dilute tested items with Swab as sample matrix in the absence or presence of heat inactivated SARS-CoV-2, Influenza A, Influenza B, ADV, RSV and STREP A.

Type	Potential Interfering Substances	Concentration	Interference(Yes/No)
Endogenous Substance	Mucin	2% w/v	No
	Whole Blood	5% w/v	No
	Icteric (Bilirubin)	40 mg/dL	No
	Rheumatoid factor	200 IU/mL	No
	Triglycerides	15 mg/L	No
	Hemoglobin	100 mg/L	No
	Anti-nuclear antibody	>1:40	No
	Pregnant	10-fold dilution	No
	Total IgG	90 g/L	No
	Total IgM	4 g/L	No
	Total IgA	80 g/L	No

Type	Potential Interfering Substances	Concentration	Interference(Yes/No)
Exogenous Substance	Mupirocin	0.25% w/v	No
	Tamiflu (Oseltamivir Phosphate)	0.5% w/v	No
	Fluticasone Propionate	5% w/v	No
	Fluconazole	5% w/v	No
	Zincum gluconium (i.e., Zicam)	5% w/v	No
	Alkalol	10% w/v	No
	Phenol	15% w/v	No
	Phenylephrine hydrochloride	15% v/v	No
	Oxymetazolin hydrochloride	15% v/v	No
	Cromolyn	15% w/v	No
	Oxymetazoline	15% w/v	No
	Galphimia glauca, Sabadilla	20% w/v	No
	Albuterol	0.005 mg/dL	No
	Acarbose	0.03 mg/dL	No
	Oseltamivir	0.04 mg/dL	No
	Chlorphoniramine	0.08 mg/dL	No
	Diphenhydramine	0.08 mg/dL	No
	Glimepiride (Sulfonylureas)	0.164 mg/dL	No
	Chlorothiazide	2.7 mg/dL	No
	Acetylsalicylic acid	3 mg/dL	No
	Amoxicillin	5.4 mg/dL	No
	Ibuprofen	21.9 mg/dL	No
	Beclomethasone	4.79 ng/mL	No
	Indapamide	140 ng/ml	No
	Flunisolide	0.61 µg/ml	No
	Guaiacol glyceryl ether	1 µg/mL	No
	Biotin	1.2 µg/mL	No
	Zanamivir	17.3 µg/mL	No
	Tobramycin	24.03 µg/mL	No
	Sulfur	9.23 µg/ml	No
	Ribavirin	26.7 µg/mL	No
	Ephedrine	0.1 mg/mL	No
	Benzocaine	0.13 mg/mL	No
	Menthol	0.13 mg/mL	No
	Budesonide	0.5 mg/mL	No
	Triamcinolone	0.8 mg/mL	No
	Dexamethasone	0.8 mg/mL	No
	Sodium chloride with preservatives	4.44 mg/mL	No
	Lopinavir	16.4 µg/L	No
	Ritonavir	16.4 µg/L	No
	Chloroquine phosphate	0.99 mg/L	No
	Ivermectin	4.4 mg/L	No

Clinical performance

• Clinical performance with Throat swabs

1. SARS-CoV-2 Test

The performance of SARS-CoV-2/FluA/FluB+ADV/RSV/SA Antigen Combo Rapid Test Kit (LFIA) was established with 134 throat swabs collected from patients with COVID-19 symptoms within 7 days after onset of symptoms. Two swabs were collected with the same people, an Throat swab tested directly using SARS-CoV-2/FluA/FluB+ADV/RSV/SA Antigen Combo Rapid Test Kit (LFIA) and a Throat swab tested by the RT-PCR Test Kit. Clinical samples were evaluated to be positive or negative using RT-PCR reference method.
Test result of SARS-CoV-2

	RT-PCR		
Medomics Ag test	SARS-CoV-2 Positive	Negative	Total
SARS-CoV-2 Positive	128	0	128
Negative	6	1035	1061
Total	134	1035	1189

Sensitivity: 95.52% (90.51%~98.34%) Specificity: 100.00% (99.64%~100.00%)
PPV: 100.00% (97.16%~100.00%) NPV: 99.42% (98.75% ~ 99.79%)
Accuracy: 99.49%(98.89% ~ 99.81%) Kappa: 0.9742 95%CI: 0.9536 ~ 0.994

2.Influenza A Test

The performance of SARS-CoV-2/FluA/FluB+ADV/RSV/SA Antigen Combo Rapid Test Kit (LFIA) was established with 103 Throat swabs collected from patients with Influenza symptoms within 7 days after onset of symptoms. Two swabs were collected with the same people, an Throat swab tested directly using SARS-CoV-2/FluA/FluB+ADV/RSV/SA Antigen Combo Rapid Test Kit (LFIA) and a throat swab tested by the Comparison Test Kit. Clinical samples were evaluated to be positive or negative using Comparison reference method.

	RT-PCR		
Medomics Ag test	Influenza A Positive	Negative	Total
Influenza A Positive	94	0	94
Negative	9	1066	1075
Total	103	1066	1169

Sensitivity: 91.26% (84.06% ~ 95.93%) Specificity: 100.00% (99.65%~100.00%)
PPV: 100.00% (96.15% ~ 100.00%) NPV: 99.16% (98.42% ~ 99.62%)
Accuracy: 99.23% (98.54%~99.65%) Kappa: 0.9501 95%CI: 0.9177~0.9825

3.Influenza B Test

The performance of SARS-CoV-2/FluA/FluB+ADV/RSV/SA Antigen Combo Rapid Test Kit (LFIA) was established with 106 throat swabs collected from patients with influenza symptoms within 7 days after onset of symptoms. Two swabs were collected with the same people, an throat swab tested directly using SARS-CoV-2/FluA/FluB+ADV/RSV/SA Antigen Combo Rapid Test Kit (LFIA) and a throat swab tested by the Comparison Test Kit. Clinical samples were evaluated to be positive or negative using Comparison reference method.

	RT-PCR		
Medomics Ag test	Influenza B Positive	Negative	Total
Influenza B Positive	98	0	98
Negative	8	1063	1071
Total	106	1063	1169

Sensitivity: 92.45% (85.67%~96.69%) Specificity: 100.00% (99.65%~100.00%)
PPV: 100.00% (96.31%~100.00%) NPV: 99.27% (98.53% ~ 99.68%)
Accuracy: 99.32% (98.66% ~ 99.70%) Kappa: 0.9570 95%CI 0.9274 ~ 0.9867

4.ADV Test

The performance of SARS-CoV-2/FluA/FluB+ADV/RSV/SA Antigen Combo Rapid Test Kit (LFIA) was established with 121 Throat swabs collected from patients with ADV symptoms within 14 days after onset of symptoms. Two swabs were collected with the same people, an Throat swab tested directly using SARS-CoV-2/FluA/FluB+ADV/RSV/SA Antigen Combo Rapid Test Kit (LFIA) and a Throat swab tested by the Comparison Test Kit. Clinical samples were evaluated to be positive or negative using Comparison reference method.

	RT-PCR		
Medomics Ag test	ADV Positive	Negative	Total
ADV Positive	113	1	114
Negative	8	1047	1055
Total	121	1048	1169

Sensitivity: 93.39% (87.39% ~ 97.10%) Specificity: 99.90% (99.47% ~ 100%)
PPV: 99.12% (95.21% ~ 99.98%) NPV: 99.24% (98.51% ~ 99.67%)
Accuracy: 99.23% (98.54% ~ 99.65%) Kappa: 0.9574 95%CI 0.9297 ~ 0.9851

5. RSV Test

The performance of SARS-CoV-2/FluA/FluB+ADV/RSV/SA Antigen Combo Rapid Test Kit (LFIA) was established with 146 Throat swabs collected from patients with ADV symptoms within 14 days after onset of symptoms. Two swabs were collected with the same people, an Throat swab tested directly using SARS-CoV-2/FluA/FluB+ADV/RSV/SA Antigen Combo Rapid Test Kit (LFIA) and a Throat swab tested by the Comparison Test Kit. Clinical samples were evaluated to be positive or negative using Comparison reference method.

	RT-PCR		
Medomics Ag test	Respiratory syncytial virus Positive	Negative	Total
RSV Positive	139	1	140
Negative	7	1022	1029
Total	146	1023	1169

Sensitivity: 95.21% (90.37%~98.05%) Specificity: 99.90% (99.46% ~ 100%)
PPV: 99.29% (96.08% ~ 99.98%) NPV: 99.32% (98.60% ~ 99.73%)
Accuracy: 99.32% (98.66% ~ 99.70%) Kappa: 0.9681 95%CI 0.9461 ~ 0.9901

6. STREP A Test

The performance of SARS-CoV-2/FluA/FluB+ADV/RSV/SA Antigen Combo Rapid Test Kit (LFIA) was established with 118 Throat swabs collected from patients with ADV symptoms within 14 days after onset of symptoms. Two swabs were collected with the same people, an Throat swab tested directly using SARS-CoV-2/FluA/FluB+ADV/RSV/SA Antigen Combo Rapid Test Kit (LFIA) and a Throat swab tested by the Comparison Test Kit. Clinical samples were evaluated to be positive or negative using Comparison reference method.

	RT-PCR		
Medomics Ag test	STREP A Positive	Negative	Total
STREP A Positive	114	2	116
Negative	4	1049	1053
Total	118	1051	1169

Sensitivity: 96.61% (91.55% ~ 99.07%) Specificity: 99.81% (99.31% ~ 99.98%)
PPV: 98.28% (93.91% ~ 99.79%) NPV: 99.62% (99.03% ~ 99.90%)
Accuracy: 99.49% (98.89% ~ 99.81%) Kappa: 0.9715 95%CI: 0.9488~0.9942

• Clinical performance with Nasopharyngeal swabs

1. SARS-CoV-2 Test

The performance of SARS-CoV-2/FluA/FluB+ADV/RSV/SA Antigen Combo Rapid Test Kit (LFIA) was established with 107 swabs collected from patients with COVID-19 symptoms within 7 days after onset of symptoms. Two swabs were collected with the same people, an Nasopharyngeal swab tested directly using SARS-CoV-2/FluA/FluB+ADV/RSV/SA Antigen Combo Rapid Test Kit (LFIA) and a Throat swab tested by the RT-PCR Test Kit. Clinical samples were evaluated to be positive or negative using RT-PCR reference method.

	RT-PCR		
Medomics Ag test	SARS-CoV-2 Positive	Negative	Total
SARS-CoV-2 Positive	103	0	103
Negative	4	1049	1053
Total	107	1049	1156

Sensitivity: 96.26% (90.70%~98.97%) Specificity: 100.00% (99.65%~100.00%)
PPV: 100.00% (96.48%~100.00%) NPV:9 9.03% (99.03% ~ 99.90%)
Accuracy: 99.65%(99.12% ~ 99.91%) Kappa: 0.9791 95%CI 0.9586 ~ 0.9995

2.Influenza A Test

The performance of SARS-CoV-2/FluA/FluB+ADV/RSV/SA Antigen Combo Rapid Test Kit (LFIA) was established with 90 swabs collected from patients with influenza symptoms within 7 days after onset of symptoms. Two swabs were collected with the same people, an Nasopharyngeal swab tested directly using SARS-CoV-2/FluA/FluB+ADV/RSV/SA Antigen Combo Rapid Test Kit (LFIA) and a Throat swab tested by the RT-PCR Test Kit. Clinical samples were evaluated to be positive or negative using RT-PCR reference method.Clinical samples were evaluated to be positive or negative using Comparison reference method.

	RT-PCR		
Medomics Ag test	Influenza A Positive	Negative	Total
Influenza A Positive	87	0	87
Negative	3	1066	1069
Total	90	1066	1156

Sensitivity: 96.67% (90.57% ~ 99.31%) Specificity: 100.00% (99.65%~100.00%)
PPV: 100.00% (95.85% ~ 100.00%) NPV: 99.72% (99.18% ~ 99.94%)
Accuracy: 99.74% (99.24%~99.95%) Kappa: 0.9816 95%CI: 0.9609~1.0024

3.Influenza B Test

The performance of SARS-CoV-2/FluA/FluB+ADV/RSV/SA Antigen Combo Rapid Test Kit (LFIA) was established with 99 swabs collected from patients with influenza symptoms within 7 days after onset of symptoms. Two swabs were collected with the same people, an Nasopharyngeal swab tested directly using SARS-CoV-2/FluA/FluB+ADV/RSV/SA Antigen Combo Rapid Test Kit (LFIA) and a Throat swab tested by the RT-PCR Test Kit. Clinical samples were evaluated to be positive or negative using RT-PCR reference method.

	RT-PCR		
Medomics Ag test	Influenza B Positive	Negative	Total
Influenza B Positive	96	0	96
Negative	3	1057	1060
Total	99	1057	1156

Sensitivity: 96.97% (91.40%~99.37%) Specificity: 100.00% (99.65%~100.00%)
PPV: 100.00% (96.23%~100.00%) NPV: 99.72% (99.17% ~ 99.94%)
Accuracy: 99.74% (99.24% ~ 99.95%) Kappa: 0.9832 95%CI 0.9642 ~ 1.0022

4.ADV Test

The performance of SARS-CoV-2/FluA/FluB+ADV/RSV/SA Antigen Combo Rapid Test Kit (LFIA) was established with 142 swabs collected from patients with ADV symptoms within 7 days after onset of symptoms. Two swabs were collected with the same people, an Nasopharyngeal swab tested directly using SARS-CoV-2/FluA/FluB+ADV/RSV/SA Antigen Combo Rapid Test Kit (LFIA) and a Throat swab tested by the RT-PCR Test Kit. Clinical samples were evaluated to be positive or negative using RT-PCR reference method.

	RT-PCR		
Medomics Ag test	ADV Positive	Negative	Total
ADV Positive	136	0	136
Negative	6	1014	1020
Total	142	1014	1156

Sensitivity: 95.77% (91.03% ~ 98.43%) Specificity: 100% (99.64% ~ 100%)
PPV: 100% (97.32% ~ 100%) NPV: 99.39% (98.73% ~ 99.78%)
Accuracy: 99.48% (98.88% ~ 99.81%) Kappa:0.9755 95%CI 0.9559 ~ 0.9950

5. RSV Test

The performance of SARS-CoV-2/FluA/FluB+ADV/RSV/SA Antigen Combo Rapid Test Kit (LFIA) was established with 218 swabs collected from patients with RSV symptoms within 7 days after onset of symptoms. Two swabs were collected with the same people, an Nasopharyngeal swab tested directly using SARS-CoV-2/FluA/FluB+ADV/RSV/SA Antigen Combo Rapid Test Kit (LFIA) and a Throat swab tested by the RT-PCR Test Kit. Clinical samples were evaluated to be positive or negative using RT-PCR reference method.

	RT-PCR		
Medomics Ag test	Respiratory syncytial virus Positive	Negative	Total
RSV Positive	211	0	211
Negative	7	938	945
Total	218	938	1156

Sensitivity: 96.79% (93.50%~98.70%) Specificity:100% (99.61% ~ 100%)
PPV:100% (98.27% ~ 100%) NPV: 99.26% (98.48% ~ 99.70%)
Accuracy: 99.39% (98.76% ~ 99.76%) Kappa: 0.9800 95%CI 0.9652 ~ 0.9948

• Clinical performance with Nasal swabs

1. SARS-CoV-2 Test

The performance of SARS-CoV-2/FluA/FluB+ADV/RSV/SA Antigen Combo Rapid Test Kit (LFIA) was established with 107 swabs collected from patients with COVID-19 symptoms within 7 days after onset of symptoms. Two swabs were collected with the same people, an Nasal swab tested directly using SARS-CoV-2/FluA/FluB+ADV/RSV/SA Antigen Combo Rapid Test Kit (LFIA) and a Throat swab tested by the RT-PCR Test Kit. Clinical samples were evaluated to be positive or negative using RT-PCR reference method.

	RT-PCR		
Medomics Ag test	SARS-CoV-2 Positive	Negative	Total
SARS-CoV-2 Positive	102	0	102
Negative	5	1049	1054
Total	107	1049	1156

Sensitivity: 95.33% (89.43%~98.47%) Specificity: 100.00% (99.65%~100.00%)
PPV: 100.00% (96.45%~100.00%) NPV: 99.03% (98.90% ~ 99.85%)
Accuracy: 99.57%(98.99% ~ 99.86%) Kappa:0.9737 95%CI: 0.9507 ~ 0.9967

2.Influenza A Test

The performance of SARS-CoV-2/FluA/FluB+ADV/RSV/SA Antigen Combo Rapid Test Kit (LFIA) was established with 90 swabs collected from patients with Influenza symptoms within 7 days after onset of symptoms. Two swabs were collected with the same people, an Nasal swab tested directly using SARS-CoV-2/FluA/FluB+ADV/RSV/SA Antigen Combo Rapid Test Kit (LFIA) and a Throat swab tested by the RT-PCR Test Kit. Clinical samples were evaluated to be positive or negative using RT-PCR reference method. Clinical samples were evaluated to be positive or negative using Comparison reference method.

	RT-PCR		
Medomics Ag test	Influenza A Positive	Negative	Total
Influenza A Positive	86	0	86
Negative	4	1066	1070
Total	90	1066	1156

Sensitivity: 95.56% (89.01% ~ 98.78%) Specificity: 100.00% (99.65%~100.00%)
PPV: 100.00% (95.80% ~ 100.00%) NPV: 99.63% (99.05% ~ 99.90%)
Accuracy: 99.65% (99.12%~99.91%) Kappa: 0.9754 95%CI: 0.9513~0.9995

3.Influenza B Test

The performance of SARS-CoV-2/FluA/FluB+ADV/RSV/SA Antigen Combo Rapid Test Kit (LFIA) was established with 99 swabs collected from patients with influenza symptoms within 7 days after onset of symptoms. Two swabs were collected with the same people, an Nasal swab tested directly using SARS-CoV-2/FluA/FluB+ADV/RSV/SA Antigen Combo Rapid Test Kit (LFIA) and a Throat swab tested by the RT-PCR Test Kit. Clinical samples were evaluated to be positive or negative using RT-PCR reference method.

	RT-PCR		
Medomics Ag test	Influenza B Positive	Negative	Total
Influenza B Positive	94	0	94
Negative	5	1057	1062
Total	99	1057	1156

Sensitivity: 94.95% (88.61%~98.34%) Specificity: 100.00% (99.65%~100.00%)
PPV: 100.00% (96.15%~100.00%) NPV: 99.53% (98.90% ~ 99.85%)
Accuracy: 99.57% (98.99% ~ 99.86%) Kappa: 0.9717 95%CI: 0.9470 ~ 0.9964

4.ADV Test

The performance of SARS-CoV-2/FluA/FluB+ADV/RSV/SA Antigen Combo Rapid Test Kit (LFIA) was established with 142 swabs collected from patients with ADV symptoms within 7 days after onset of symptoms. Two swabs were collected with the same people, an Nasal swab tested directly using SARS-CoV-2/FluA/FluB+ADV/RSV/SA Antigen Combo Rapid Test Kit (LFIA) and a Throat swab tested by the RT-PCR Test Kit. Clinical samples were evaluated to be positive or negative using RT-PCR reference method.

	RT-PCR		
Medomics Ag test	ADV Positive	Negative	Total
ADV Positive	135	0	135
Negative	7	1014	1021
Total	142	1014	1156

Sensitivity: 95.07% (90.11% ~ 98.00%) Specificity: 100% (99.64% ~ 100%)
PPV:100% (97.30% ~ 100%) NPV: 9 9.39% (98.59% ~ 99.72%)
Accuracy: 99.39% (98.76% ~ 99.76%) Kappa: 0.9713 95%CI: 0.9501 ~ 0.9925

5. RSV Test

The performance of SARS-CoV-2/FluA/FluB+ADV/RSV/SA Antigen Combo Rapid Test Kit (LFIA) was established with 218 swabs collected from patients with RSV symptoms within 7 days after onset of symptoms. Two swabs were collected with the same people, an Nasal swab tested directly using SARS-CoV-2/FluA/FluB+ADV/RSW/SA Antigen Combo Rapid Test Kit (LFIA) and a Throat swab tested by the RT-PCR Test Kit. Clinical samples were evaluated to be positive or negative using RT-PCR reference method.

	RT-PCR		
Medomics Ag test	Respiratory syncytial virus Positive	Negative	Total
RSV Positive	210	0	210
Negative	8	938	946
Total	218	938	1156

Sensitivity: 96.33% (92.90%~98.40%) Specificity: 100% (99.61% ~ 100%)
PPV:100% (98.26% ~ 100%) NPV: 99.15% (98.34% ~ 99.63%)
Accuracy: 99.31% (98.64% ~ 99.70%) Kappa: 0.9771 95%CI: 0.9612 ~ 0.9929

Warnings and Precautions

- This test kit is used for in vitro diagnosis only.
- This test kit should be used by qualified person with professional experience or proper training.
- This test kit should be used within 1 hour after opening the package, and samples from transport media will reduce sensitivity. The test cassette should not be used if being wet or polluted.
- Proper protection should be taken during testing to avoid splashing when adding sample.
- Dispose of all used or damaged test cassettes, sampling tubes, droppers, swabs, or other kit components as biohazardous materials.
- Negative results do not rule out SARS-CoV-2, Influenza A, Influenza B, ADV, RSV and STREP A infection, particularly in those who have been in contact with the virus.
- Nasopharyngeal swabs and nasal swabs are not suitable for STREP A antigen testing at this time; Throat swabs are recommended to ensure the accuracy of the test results

References

1. LY Wang, PR Chen, G W Zheng, et al. Research progress on novel coronavirus test methods. Modern Medicine and Clinic, 2020.
2. K Tugba, W Ralph, L Hakho. Molecular and Immunological Diagnostic Tests of COVID-19: Current Status and Challenges. IScience, 2020, 23 (8). Doi: 10.1016/j.isci.2020.101406
3. WHO recommendations on the use of rapid testing for inflfluenza diagnosis. World Health Organisation, July 2005.
4.Tian X , Fan Y , Wang C , et al. Seroprevalence of Neutralizing Antibodies against Six Human Adenovirus Types Indicates the Low Level of Herd Immunity in Young Children from Guangzhou, China[J]. Chinese Journal of Virology: English Edition, 2021, 36(3):9.
5.Jing J , Chen Y , Wang Z . Specific IgG antibodies against F and G glycoproteins of respiratory syncytial virus (RSV) in asthmatic children after infection with the virus[J]. Chinexe Journal of Pediatrics, 1998.
6.Kim S, Lee NY. Asymptomatic infection by streptococcus pyogenes in schoolchildren and diagnostic of antideoxy ribonuclease B. J Korean Med Sci, 2005, 20: 938 - 940.

Jiangsu Medomics Medical Technology Co.,Ltd.

EC REP

CE V1.0.02A

IVD In Vitro Diagnostic Medical Device | LOT Batch code | REF Catalogue Number | STERILE EO Sterilized using ethylene oxide | EC REP Authorized representative in the European Community | Do Not Re-use | Do not use if package is damaged | Caution | Contains sufficient for <n> tests | Consult instructions for use | Use-by date | Date of manufacture | Manufacturer | Temperature limit | This way up | Fragile, handle with care | Stacking Limit By number | Keep away from sunlight | Keep dry