

Shenzhen Emeng Health Technology Co., LTD
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# 8 Minute Results Rapid Antigen Test Kit with CE ISO Certifications ,Strep A Rapid Test Kit

#### **Basic Information**

Place of Origin: chinaBrand Name: DVOTCertification: CE/ISO

Model Number: Strep A Rapid Test Kit

Minimum Order

800test

Quantity:

• Price:

0.9-1 USD

• Packaging Details: 800T/PER CTN Weight :16.6 KGS CTN SIZE

:57\*54\*34CM

• Delivery Time: 15-20 work days

• Payment Terms: D/P, T/T, Western Union, MoneyGram

• Supply Ability: 1000000pcs



#### **Product Specification**

• Type: Rapid Test Kit

• Accuracy: 98%

Keyword: Antigen Rapid TestResult Time: 8 Minutes To Get

Certifications: CE ISOTime Of Use: DisposableTest Time: 8 Minutes

• Highlight: ce strep a rapid test,

ce group a streptococcus rapid test, disposable strep a rapid test



#### More Images







#### **Product Description**

#### 8 Minute Results Rapid Antigen Test Kit with CE ISO Certifications, Strep A Rapid Test Kit

#### **Product Description:**

Antigen Rapid Test Kits are designed to detect specific viral proteins, also known as antigens, in the body. These proteins are typically found on the surface of a virus and can help identify the presence of an infection. The test is performed using a sample from the nose or throat, and the results are displayed on a test strip.

One of the advantages of using Antigen Rapid Test Kits is that they are disposable, which makes them a costeffective option for testing large groups of people. They are also easy to use and do not require any specialized equipment or training to perform. The result time of 8 minutes to get makes them a quick and efficient option for identifying potential cases of the virus.

Certifications are an important consideration when it comes to diagnostic test kits. The Antigen Rapid Test Kit has CE and ISO certifications, ensuring that they meet high standards for quality and safety. These certifications provide peace of mind for both healthcare providers and patients, knowing that the tests are reliable and accurate.

Overall, the Medical Diagnostic Test Kits, specifically the Antigen Rapid Test Kit, play a crucial role in identifying and controlling the spread of infectious diseases. With their disposable, cost-effective, and quick result time attributes, they are an essential tool for healthcare providers and individuals alike.

#### **Technical Parameters:**

Certifications	CE, ISO
Test Time	8 Minutes
Keyword	Antigen Rapid Test
Result Time	8 Minutes To Get
Time Of Use	Disposable
Accuracy	98%
Туре	Rapid Test Kit
Infectious Disease Test Kit	Yes
Home Testing Kits	No
Diagnostic Antigen Test Kit	Yes

#### **Applications:**

The Strep A Rapid Test Kit is a disposable product that can be used at home by individuals who suspect they have a Strep A infection. The kit is easy to use and comes with all the necessary components for a self-test. The test kit can accurately detect the presence of Strep A with an accuracy rate of 98%.

The Strep A Rapid Test Kit is ideal for individuals who are looking for an affordable and convenient way to test for Strep A from the comfort of their own homes. This makes it a popular choice for parents who want to test their children for Strep A without having to take them to a doctor's office. The kit is also suitable for individuals who frequently suffer from Strep A infections and want to monitor their condition at home.

The Strep A Rapid Test Kit is also an excellent choice for healthcare providers who need a reliable and accurate diagnostic tool for their patients. The kit is easy to use and provides results in just a few minutes, making it a time-saving option for busy healthcare professionals.

In conclusion, the Strep A Rapid Test Kit from DOVT is an excellent Antigen Rapid Self Test Kit that is suitable for a wide range of applications. Whether you are a healthcare provider or an individual looking for a convenient way to test for Strep A at home, this kit is an excellent choice. So, get your hands on this Antigen Rapid Test Kits and ensure your health is always under control.

#### **Support and Services:**

Our Medical Diagnostic Test Kits are designed to provide accurate and reliable results for a variety of medical conditions. Our technical support team is available to assist with any questions or issues that may arise during the

testing process.

At our company, we are committed to providing the highest level of support and service to our customers. Contact us today to learn more about our Medical Diagnostic Test Kits and the services we offer.

#### **Advantages:**

Conventional identification procedures for Group A Streptococcus from throat swabs involve the isolation and subsequent identification of viable pathogens by techniques that require 24 to 48 hours or longer. DVOT Strep A detects either viable or nonviable organisms directly from a throat swab, providing results within 8 minutes.

DVOT Strep A Rapid Test Kit offers a simple and highly sensitive screening assay to make a presump- tive diagnosis of Group A Strept coccal respiratory infection.



#### Pathogen and product description

Group A Streptococcal (Strep) infections are caused by Group A Streptococcus, a bacterium responsible for a variety of health problems. These infections can range from mild skin infection or sore throat to severe,life-threatening conditions such as toxic shock syndrome (multi-organ failures) and necrotizing fasciitis (soft tissue disease), commonly known as flesh eating disease. Most people are familiar with strep throat, which along with minor skin infection, is the most common form of the disease. Health experts estimate that more than 10 million mild infections (throat and skin) like these occur every year.

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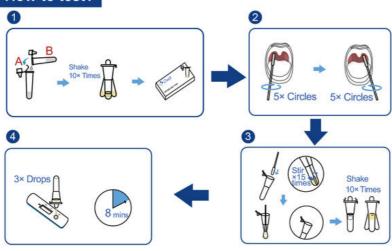
DVOT Strep A Rapid Test Kit offers a simple and highly sensitive screening assay to make a presumptive diagnosis of Group A Strept coccal respiratory infection.



### **EXCELLENT CLINICAL COMPARISON RESULT**

Items	Sensitivity	Specificity
Strep A Rapid Test Kit	92.5%	98.11%

# How to test?



# Result Reading



# The packing details



СВ	
QTY:	800PCS(40Boxs)
G.W:	15.5KGS
MEAS:	57x54x36cm

CERTIFICATE

## NOTIFICATION OF REGISTRATION

Spanish Medicines and Health Products Administration

This is to certify that, according to the European Council Directive 98/79/EC, The manufacturer has completed the registration of the listed products:

MANUFACTURER: Feng Chun Yuan Medical Equipment (Shenzhen) Co., Ltd ADDRESS: Room 1304&1306, No.48, Xinyu Road, Xiangshan Community, Xinqiao Street, Baoan District, Shenzhen, China 518000

SRN#: CN-MF-000002326 Mail: market@fcy-medical.com

The manufacturer has provided EU authorized representative with all the appropriate declaration according to the European Council Directive 98/79/EC including the Declaration of Conformity confirming that its in vitro diagnostic medical device, as stipulated here below, is fulfilling the essential requirements of the European Council Directive 98/79/EC.

IVD Devices: Strep A Rapid Test Kit Classification: Others

Where the manufacturer affix the CE mark to the device listed they must ensure that all the essential requirements of European Council Directive 98/79/EC are met. The notification of abovementioned device has been completed by the European Authorized Representative in Spain. The Spain Competent Authority is notifed of the manufacture's device and has allocated registration. The registration number is RPS/1389/2024.

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Riomavix S.L. (ES-AR-000001202)
Calle de Almansa 55, 1D, Madrid 28039 Spain



DEPARTAMENTO DE

N/REF: PS/RPS/1389/2024

O F I C I O

Comunicación: RPS/1389/2024 Nº AEMPS: 24-02001 23/05/2024 Fecha:

Anotación de la comunicación Asunto:

en el Registro de Responsables de la puesta en el mercado de Productos Sanitarios

RIOMAVIX SL Calle de Almansa 55,1D 28039 - Madrid MADRID

Madrid, Comunidad de

Con fecha 23/05/2024 ha sido registrada en la aplicación de Registro de Responsables de la puesta de mercado de Productos Sanitarios (RPS) de la Agencia Española de Medicamentos y Productos Sanitarios (AEMPS) la comunicación presentada por RIOMAVIX SL, con la siguiente información:

1. Número de identificación asignado en el registro

RPS/1389/2024

2. Responsable de la puesta en el mercado de los productos sanitarios

Empresa RIOMAVIX SL

Calle de Almansa 55,1D 28039 - Madrid (MADRID) Madrid, Comunidad de

En calidad de Representante

3. Legislación que declara cumplir:

DIV - Directiva 98/79/EC.

4. Página(s) adicional(es) de productos sanitarios incluidos en esta comunicación.

REGISTRO DE RESPONSABLES DE LA PUESTA EN EL MERCADO DE PRODUCTOS SANITARIOS DEPARTAMENTO DE PRODUCTOS SANITARIOS

Nota-Esta notificación no tiene el carácter de una autorización sanitaria de comercialización, ni entraña un juicio sobre la conformidad del producto con la legislación vigente Únicamente avala el cumplimiento del Registro de Responsables según el articulo 9 del RD 1662/2000 por el que se regulan los Productos Sanitarios para Diagnóstico in vitro.

Agencia Española de Medicamentos y Productos Sanitarios (AEMPS) Fecha de la firma: 23/05/2024 CSV: Q3WKLE99AD

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