

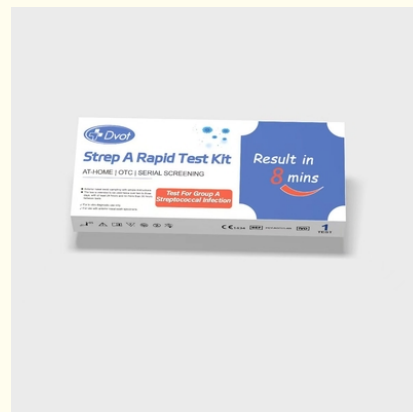
## Strep A Rapid Test Kit 98% Accuracy Disposable Home Antigen Rapid Test Kit - CE\ISO Certified

### Our Product Introduction

For products please visit us on [oxygenconcentratormedical.com](http://oxygenconcentratormedical.com)

#### Basic Information

- Place of Origin: china
- Brand Name: DVOT
- Certification: CE/ISO
- Model Number: Strep A Rapid Test Kit
- Minimum Order Quantity: 800test
- 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

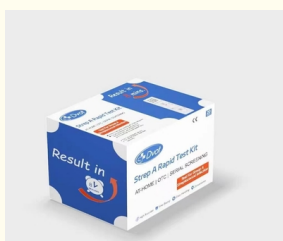


#### Product Specification

- Time Of Use: Disposable
- Certifications: CE ISO
- Keyword: Antigen Rapid Test
- Result Time: 8 Minutes To Get
- Type: Rapid Test Kit
- Test Time: 8 Minutes
- Accuracy: 98%
- Highlight: disposable strep a rapid test, disposable group a streptococcus rapid test, ce strep a rapid test



#### More Images



## Product Description

### Strep A Rapid Test Kit,98% Accuracy Disposable Home Antigen Rapid Test Kit - CEISO Certified

#### Product Description:

Our Antigen Rapid Test Kits are easy to use and require no additional equipment. With a disposable design, these kits are convenient and safe for use in various settings. The test procedure is straightforward and involves collecting a sample from the nose using a swab. The collected sample is then placed into a special buffer solution, and the test kit is used to detect the presence of the virus antigen in the sample. Results are available in just 8 minutes, making it an ideal solution for mass testing and screening in various settings such as schools, workplaces, and healthcare facilities.

In addition to our Antigen Rapid Test Kits, we also offer Antibody Rapid Test Kits. These test kits are designed to detect the presence of antibodies in a person's blood, indicating that they have previously been infected with the virus. Our Antibody Test Kits deliver accurate results in just 8 minutes, making it an excellent solution for individuals who suspect they may have been infected with the virus in the past.

#### Technical Parameters:

| Product Attribute | Value                       |
|-------------------|-----------------------------|
| Product Type      | Infectious Disease Test Kit |
| Keyword           | Antigen Rapid Test          |
| Type              | Rapid Test Kit              |
| Test Time         | 8 Minutes                   |
| Result Time       | 8 Minutes To Get            |
| Accuracy          | 98%                         |
| Certifications    | CE,ISO                      |
| Time Of Use       | Disposable                  |
|                   |                             |

#### Applications:

The Strep A Rapid Test Kit is a type of Antigen Rapid Test Kit, which is designed to detect the presence of Strep A antigens in the patient's saliva sample. This test kit is easy to use and provides results in just 8 minutes, making it a quick and efficient tool for medical professionals.

This Antibody Test Kit is suitable for a wide range of medical applications. It can be used in hospitals, clinics, and other medical facilities to diagnose Strep A infections. This test kit is also suitable for use in schools, workplaces, and other settings where there is a risk of Strep A infection.

It also offers the following 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 presumptive diagnosis of Group A Streptococcal respiratory infection.

#### Support and Services:

Our Medical Diagnostic Test Kits are backed by comprehensive technical support and services to ensure accurate and reliable results. Please contact our if you have some questions about this product!



# Strep A Rapid Test Kit

## 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.

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.

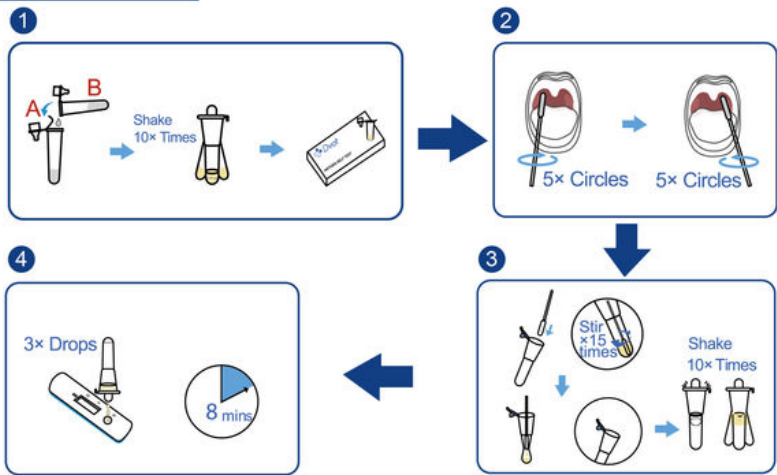
**DVOT Strep A Rapid Test Kit** offers a simple and highly sensitive screening assay to make a presumptive diagnosis of Group A Streptococcal respiratory infection.



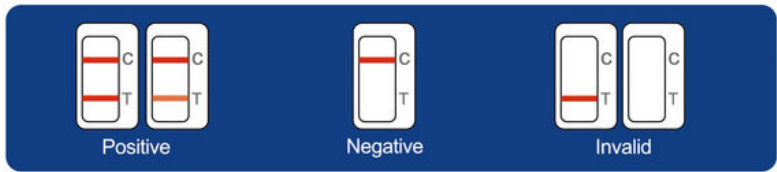
EXCELLENT CLINICAL COMPARISON RESULT

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

How to test?



Result Reading



The packing details

|        |                 |
|--------|-----------------|
| CB     |                 |
| QTY :  | 800PCS(40Boxes) |
| G.W :  | 15.5KGS         |
| MEAS : | 57x54x36cm      |

x20      x40

## NOTIFICATION OF REGISTRATION

Spanish Medicines and Health Products Administration

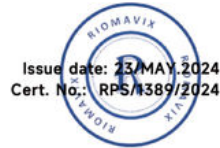
This is to certify that, according to the European Council Directive 98/79/EC,  
The manufacturer has completed the registration of the listed products:

**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 notified of  
the manufacture's device and has allocated registration. The registration number is  
RPS/1389/2024 .



Riomavix S.L. (ES-AR-000001202)  
Calle de Almansa 55, 1D, Madrid 28039 Spain  
Email: info@jiameiconsulting.com

N/REF: PS/RPS/1389/2024

**O F I C I O**

**Comunicación:** RPS/1389/2024  
**Nº AEMPS:** 24-02001  
**Fecha:** 23/05/2024  
**Asunto:** **Anotación de la comunicación 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 artículo 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

Puede comprobar la autenticidad del documento en la sede de la AEMPS: <https://localizador.aemps.es>

CSV: Q3WKLE99AD



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