# DECLARATION OF CONFORMITY

**Manufacturer:** **Zhuhai Lituo Biotechnology Co., Ltd.**

**Address:** No.35, Yongan Three Road, Hongqi Town, Jinwan District, Zhuhai, Guangdong, China.

**European Representative:** CMC Medical Devices & Drugs S.L
C/Horacio Lengo Nº 18, CP 29006, Málaga-Spain

**Product Name:** COVID-19/FluA/FluB Antigen Detection Kit (Colloidal Gold)

**Model/Spec.:** 25 Tests / Kit, 5 Tests/Kit, 1 Test/Kit

**Classification:** (The way of conformity certification is applying for product CE certification in accordance with 98/79/EC Annex I): Other IVD.

**Conformity Assessment Procedures:**

The products are a kind of in vitro diagnostic medical device, according to 98/79/EC Article 9 Conformity assessment procedures for Annexes III. We here with declare that the above mentioned product meet the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer. The products comply with the essential requirements in accordance with Annex I of the In vitro Devices Directive 98/79/EEC.

## DIRECTIVES

**General applicable directives:**

**Medical Device Directive:** COUNCIL DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 1998 on in vitro diagnostic medical devices.

**Standards:** 98/79/EC; EN ISO13485:2016; EN ISO14971:2012; EN13612:2002/AC:2002; EN13641:2002; EN ISO23640:2015; EN ISO17511-2003; EN ISO18113-1:2011; EN ISO18113-3:2011; EN ISO15223-1:2012

All applicable harmonized Standards (published in the official Journal of the European Communities).

**Place/Date CE mark was affixed: Zhuhai Lituo Biotechnology Co., Ltd.**

CE

Signature:

Xuean Yong

General Manager

28 December, 2020

Digitally signed by Moldoveanu Ruxanda
Date: 2021.01.25 09:23:56 EET
Reason: MoldSign Signature
Location: Moldova

REGISTRATION NO. 04718Q10000532

# CERTIFICATE OF QUALITY MANAGEMENT SYSTEM FOR MEDICAL DEVICES

This is to certify that the quality management system of

Zhuhai lituo biotechnology co.,ltd

Registered Address:No.35,Yongan Three Road,Hongqi Town,Jinwan District,Zhuhai,Guangdong,China Postcode: 519090

Manufacturing Address:No.35,Yongan Three Road,Hongqi Town,Jinwan District,Zhuhai,Guangdong,China

Has been assessed and conformed to the following standard(s)

YY/T 0287-2017 idt ISO 13485:2016

The certificate is valid for the following scope:

The design, development, production and service of Vaginitis Detection System, Vaginal Secretion Analyzer, Automated Blood Culture System, Gram Staining Machine and in-vitro diagnostic kit(within the scope of administrative licensing/record).

Date of issue: October 29,2018

Date of expiry: October 28,2021

General Manager:

BEIJING HUA GUANG CERTIFICATION OF MEDICAL DEVICES CO., LTD.

Note: This certificate will not be valid until the organization has been approved in the annual audits. The certificate information are available on the website of the certification and accreditation administration of the People's Republic of China (www.cnca.gov.cn) or the website of CMD (www.cmdc.com.cn). Address: 5th floor of Zhong Lian building, No.jia88, An Ding Men Wai street, Dongcheng district, Beijing 100011, P.R. China Telephone: 010-62351993

LITUO

**Accurate**

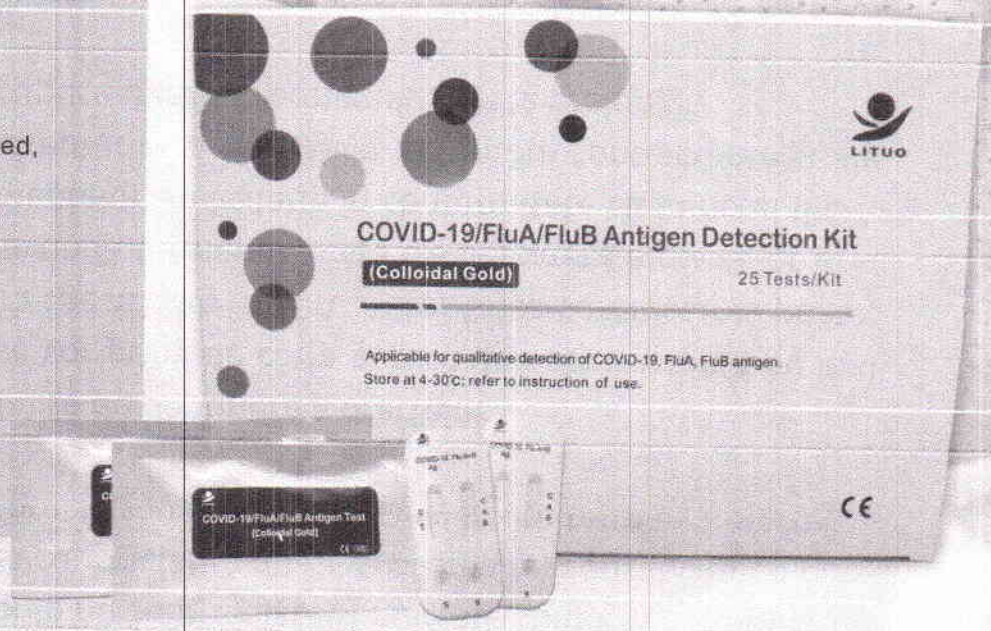
one sample, three results

**Rapid**

On-site inspection,
results in 10-15 minutes

**Easy**

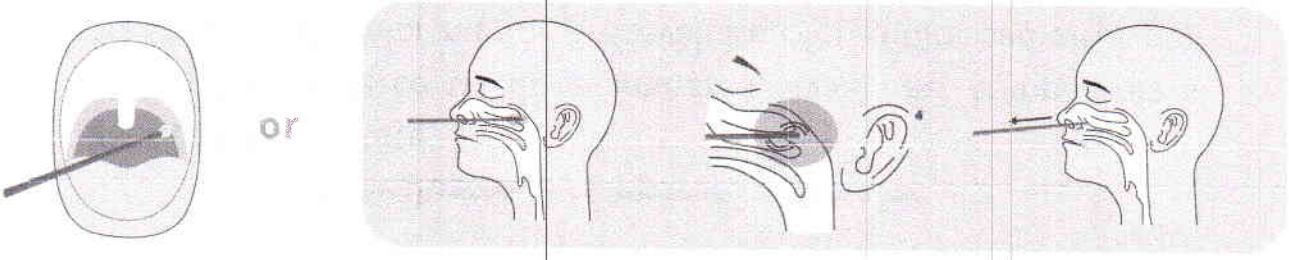
No equipment required,
easy to operate




# COVID-19/FluA/FluB Antigen Detection Kit

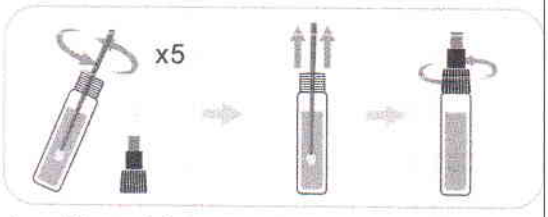
# Operation process & result interpretation

## 1



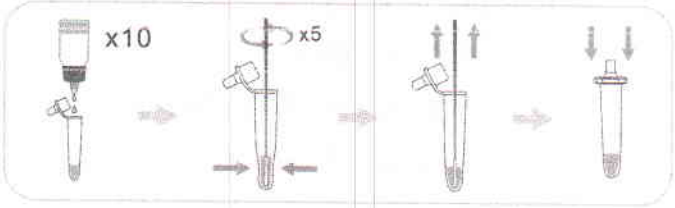

**Nasopharyngeal swab collection:** Insert the sampling swab into the nostril and go deep into the back wall of the nasopharynx through the lower nasal passage. When encountering resistance, gently lift the nasopharyngeal swab until it feels like touching the wall. After the swab reaches the nasal cavity, stay for 15s and then rotate 3 turns. Rotate slowly to take it out.
**Nasal swab collection:** gently rotate and push into the nasal cavity, press the swab on the nasal wall three times, then take it out.
**Oropharynageal swab collection:** collect at the back wall of the pharynx or both sidesof tonsils; avoid touching the tongue.

## 2



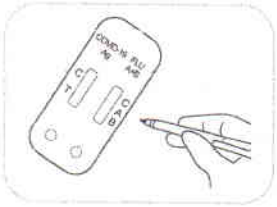

Insert the swab into extraction buffer. Stir the swab more than 5 times and squeeze the swab to overflow the specimen. Take out swab and tighten the cap.

or



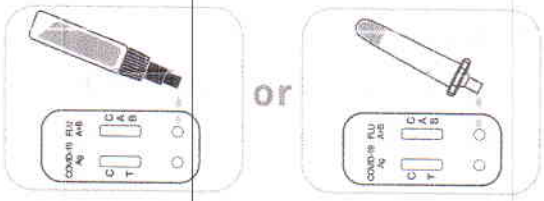

Add10 drops (about 500μl) dropsof buffer into the extraction tube. Stir theswab more than 5 times and squeeze the swab to overflowthe specimen. Take out swab and put the nozzle.

## 3



Open the foil pouch, take out the test card and make a mark.

## 4

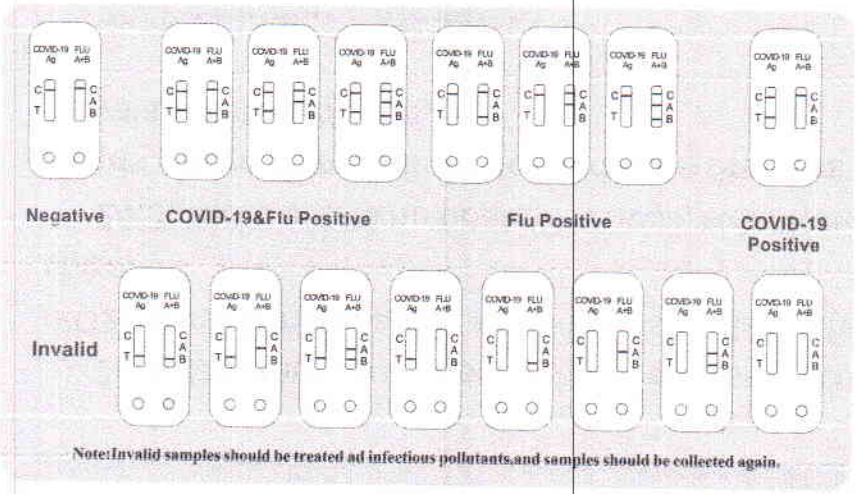



Add 3 drops (about 100μl) of the extracted specimen to the specimen well.

## 5


Read the results between 10 to 15 minutes.

# Result interpretation




## Storage conditions & shelf life

The original package should be stored in a dark and dry place at 4-30°C. Shelf life is 24 months. The test card should be used within 1 hour after opening the aluminum foil pouch.

## Product components& specifications

Test card, extraction bufer, swab, instruction of use,
25 tests/kit , 5 tests/kit ,1test/kit