Monkeypox Virus (MPV) Antigen Rapid Test Kit (Colloidal Gold)

Instruction for Use

IVD

Read this instruction carefully before use

A rapid test for the qualitative detection of Monkeypox Virus antigen in oropharyngeal swab, nasopharyngeal swabs,Anterior nasal swab and Fecal specimens.For professional medical institutions use only,Not for self testing.

PRODUCT NAME

Monkeypox Virus (MPV) Antigen Rapid Test Kit(Colloidal Gold)

SPECIFICATION

25 tests/kit, 5 tests/kit, 1 test/kit

INTENDED USE

This product is suitable for the qualitative detection of Monkeypox virus in nasopharyngeal swab, nasal swab, oropharyngeal swab, sputum or fecal samples. It provides an aid in the diagnosis of infection with Monkeypox virus.

INTRODUCTION

Monkeypox is a rare viral infectious disease similar to human smallpox caused by monkeypox virus, and it is also a zoonotic disease. Mainly found in the tropical rain forests of central and western Africa. The main route of transmission is animal-to-human transmission. People are infected with the disease by being bitten by infected animals or by direct contact with the blood and body fluids of infected animals. The Monkeypox virus is a high fatality rate virus,so the early screening test is very important to control the Monkeypox virus spread.

PRINCIPLE

The Monkeypox virus Antigen Detection Kit is an immunochromatographic membrane assay that uses highly sensitive monoclonal antibodies to detect Monkeypox virus. The test strip is composed of the following parts: namely sample pad, reagent pad, reaction membrane, and absorbing pad. The reagent pad contains the colloidal-gold conjugated with the monoclonal antibody against the Monkeypox virus; the reaction membrane contains the secondary antibodies for Monkeypox virus. The whole strip is fixed inside a plastic device. When the sample is added into the sample well, conjugates absorbed in the reagent pad are dissolved and migrate along with the sample. If Monkeypox virus antigen is present in the sample, the complex of the anti-Monkeypox virus conjugate and the virus will be captured by the specific anti-Monkeypox virus monoclonal antibodies coated on the test line region (T). Absence of the T line suggests a negative result. To serve as a procedural control, a red line will always appear in the control line region (C) indicating that proper volume of sample has been added and membrane wicking effect has occurred.

COMPONENTS

Materials Provided

Components	25 tests/kit	5 tests/kit	1 tests/kit
Cassettes	25 cassettes with dependent sealed foil pouch	5 cassettes with dependent sealed foil pouch	1 cassette with dependent sealed foil pouch
Sample Diluent Solution With Dropper	25tubes (300ul/tube)	5tubes (300ul/tube)	300ul/tube
Cotton Swab	25 pcs	5 pcs	1 pcs
Package insert	1 pcs	1 pcs	1 pcs

Main ingredients of test cassettes:

Mouse anti-MPV antibody, Goat anti-rabbit IgG polyclonal antibody, MPV antibody, rabbit IgG, Colloidal gold conjugate, Other test device support; one desiccant.

Main ingredients of Sample Diluent Solution:

Neutral salt buffer

Reagents of different batch numbers cannot be used interchangeably.

MATERIALS REQUIRED BUT NOT PROVIDED

Timer for timing use

PRECAUTIONS

- Read this IFU carefully before use.
- Do not spill solution into the reaction zone.
- Do not use test if pouch is damaged.
- Do not use test kit after expiration date.
- Do not mix Sample Diluent Solution and Transfer Tubes from different lots.
- Do not open the Test Cassette foil pouch until ready to perform the test.
- Do not spill solution into the reaction zone.
- For professional use only.
- For in-vitro diagnostic use only
- Do not touch the reaction zone of the device to avoid contamination.
- Avoid cross-contamination of samples by using a new specimen collection container and specimen collection tube for each sample.
- All patient samples should be treated as if capable of transmitting disease. Observe established precautions against microbiological hazards throughout testing and follow standard procedures for proper disposal of specimens.
- Do not use more than the required amount of liquid.
- Bring all reagents to room temperature (15~30°C) before use.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when testing.
- Evaluate the test result after 20 minutes and not beyond 30 minutes.
- Store and transport the test device always at 2~30°C.

STORAGE AND STABILITY

- The kit should be stored at 2~30°C, valid for 12months.
- The test must remain in the sealed pouch until use.
- Do not freeze.
- Cares should be taken to protect components in this kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

SPECIMEN COLLECTION AND HANDLING

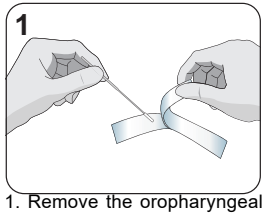
1.Prepare Materials

Open the package,take out the MPV Antigen test card in pouch, the Tube filled with the extraction buffer and the swab. When you are ready to proceed with the test,open the foil pouch of the MPV Antigen test card.

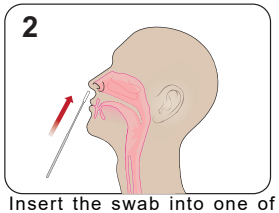
2.Collect Sample

2.1 Anterior Nasal Swab collection:

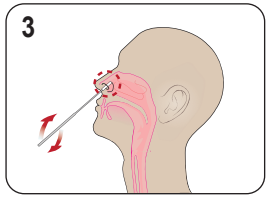
Note: Failure to swab properly may cause false negative results.



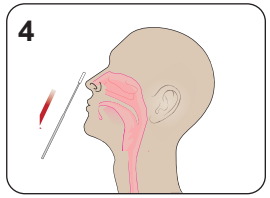
1. Remove the oropharyngeal swab from the pouch.



2. Insert the swab into one of patient's nostrils up to 1 inch from the edge of the nostril.



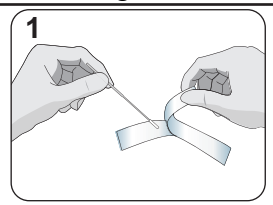
3. Slowly roll the swab 5 times over the surface of the nostril. Using the same swab repeat this collection process in the other nostril. Take approximately 15 seconds to collect the specimen.



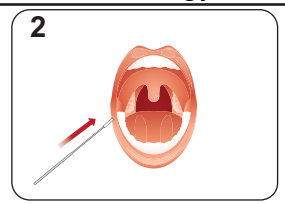
4. Slowly remove the swab from the nostril while rotating it.

2.2 Oropharyngeal Specimen collection:

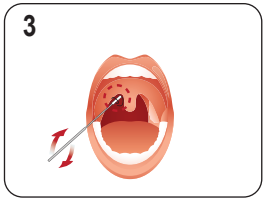
Note: Failure to swab properly may cause false negative results.



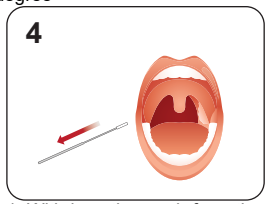
1. Remove the oropharyngeal swab from the pouch.



2. Tilt patient's head back 70 degree



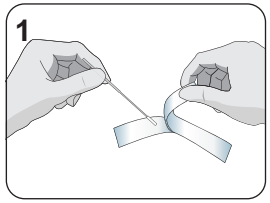
3. Insert swab into the oral cavity without touching the gums, teeth and tongue (A tongue depressor may be used.) Swab the posterior pharyngeal wall using a rotatory motion.



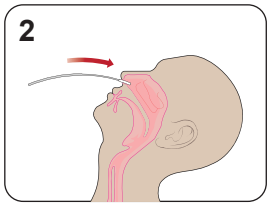
4. Withdraw the swab from the oral cavity.

2.3 Nasopharyngeal Swab collection:

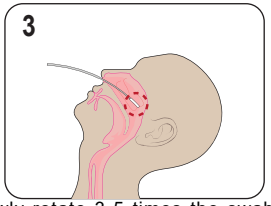
Note: Failure to swab properly may cause false negative results.



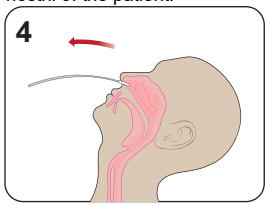
1. Remove the oropharyngeal swab from the pouch.



2. Tilt patient's head back 70 degrees. Gently and slowly insert the swab into one of patient's nostrils until it reaches the posterior nasopharynx; keep insert until resistance is equivalent to that from the ear to the nostril of the patient.



3. Slowly rotate 3-5 times the swab over the surface of the posterior nasopharynx.



4. Leave swab in place for several seconds to absorb secretions. Slowly remove the swab from the nostril while rotating it.

2.4 Fecal Specimen collection:

Consider any materials of human origin as infectious and handle them using standard biosafety procedures.

To prepare specimens using solid stool samples follow Procedure A below. To prepare specimens using watery stool samples follow Procedure B below.

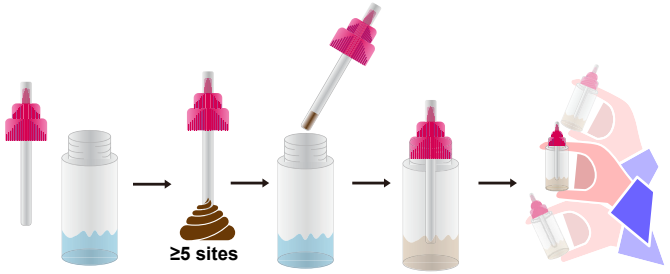
Procedure A: Solid stool samples

Step 1: Collect a random stool sample in a clean, dry receptacle.

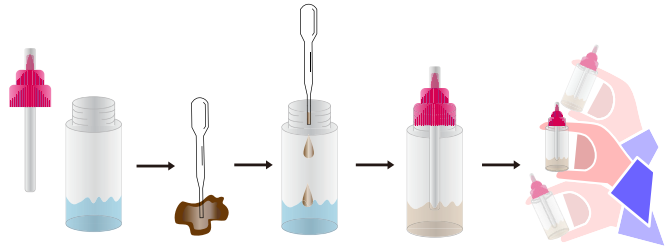
Step 2: Open the stool collection device by unscrewing the top and use the collection stick to randomly pierce the stool sample in at least five different sites. Do not scoop stool sample as this may lead to an invalid test result.

Step 3: Ensure stool sample is only in the grooves of the collection stick. Excess stool sample may lead to an invalid test result.

Step 4: Replace the collection stick and tighten securely to close the stool collection device.
Step 5: Shake the stool collection device vigorously.



Procedure B: Watery stool samples
Step 1: Collect a random stool sample in a clean, dry receptacle.
Step 2: Open the stool collection device by unscrewing the top.
Step 3: Fill the plastic dropper with the sample; dispense 2 drops (70-85uL) into the stool collection device.
Step 4: Replace the collection stick and tighten securely to close the stool collection device.
Step 5: Shake the stool collection device vigorously.

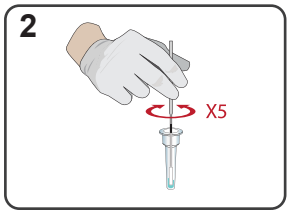


NOTE: Specimens extracted may be stored at 2-8°C for up to 3 days. If longer storage is required, freezing at ≤-20°C is recommended.
NOTE:Failure to swab properly may cause false negative results.

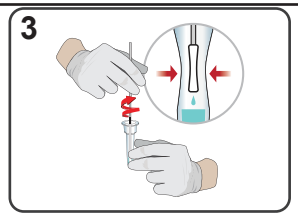
3.Process Sample

3.1Instructions must be read entirely before test, Leave the reagent and sample at room temperature for 30min before use to rewarm to room temperature. 3.2Use the cassette as soon as possible after opening the inner packing.
3.3Open the aluminum foil bag at the tear hole, take out the test card and lay it flat.
3.4 Apply 3 full drops of the sample diluent solution(90-100ul) vertically into the sample well of the test cassette.

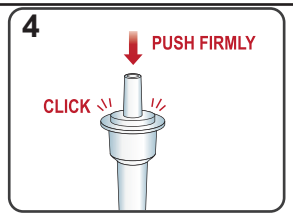
1. Peel off aluminum foil seal from the top of the extraction vial containing the extraction buffer.



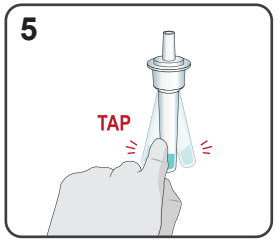
2. Place the swab into the extraction vial. Rotate the swab vigorously at least 5 times.



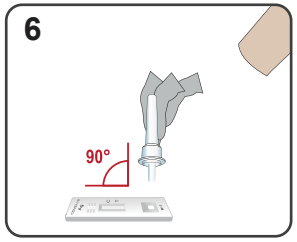
3. Remove the swab by rotating against the extraction vial while squeezing the sides of the vial to release the liquid from the swab. Properly discard the swab.



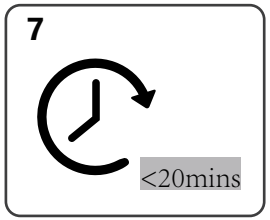
4. Close the vial by pushing the cap firmly onto the vial.



5. Mix thoroughly by flicking the bottom of the tube.



6. Invert the extraction vial and hold the sample vertically above the sample well. Squeeze the vial gently. Allow three (3) drops of sample to fall into the sample well.

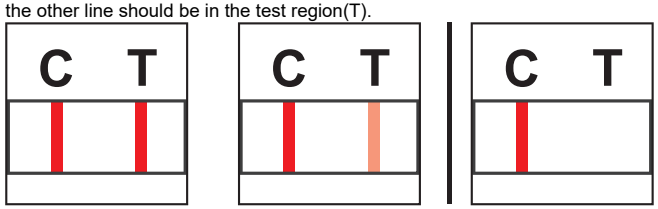


7. Start the timer by clicking the "Start Timer" button, immediately after adding sample to the sample port. The result will be ready in 20 minutes.

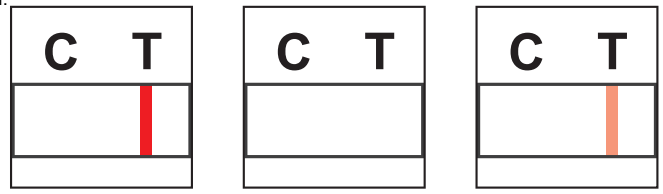
The results are observed after 20minutes and showed on clinical significance after 20 minutes.

RESULT INTERPRETATION

Positive: Two distinct red lines appear. One line should be in the control region(C) and the other line should be in the test region(T).



Negative: One red line appears in the control region(C). No red line appears in the test region(T).The negative result does not indicate the absence of analyses in the sample, it only indicates the level of tested analyses in the sample is less than cut-off level.



NOTE:
The intensity of the color in test region (T) may vary depending on the concentration of aimed substances present in the specimen. Therefore, any shade of color in the test region should be considered positive. Besides, the substances level cannot be determined by this qualitative test.Insufficient specimen volume, incorrect operation procedure, or performing expired tests are the most likely reasons for control band failure.

PERFORMANCE CHARACTERISTICS

1.Sensitivity, Specificity and Accuracy
The product performance was evaluated with clinical specimens, taking commercial RT-PCR kit as the gold standard.

Nasopharyngeal Swab	RT-P		
BESTest	Positive	Negative	Total
Positive	43	1	44
Negative	2	299	301
Total	45	300	345
Relative Sensitivity: 95.55%(95%CI:89.53%-100%); Relative Specificity:99.66%(95%CI:99.01%-100%); Overall agreement: 99.13%%(95%CI:98.52%-99.74%)			

Anterior Nasal Swab	RT-PCR		
BESTest	Positive	Negative	Total
Positive	43	2	45
Negative	2	398	400
Total	45	400	445
Relative Sensitivity: 95.55%(95%CI:89.53%-100%); Relative Specificity:99.5%(95%CI:98.93%-100%); Overall agreement: 99.10%%(95%CI:98.56%-99.64%)			

Oropharyngeal Swab	RT-PCR		
BESTest	Positive	Negative	Total
Positive	43	1	44
Negative	2	269	271
Total	45	270	315
CT value≤35: Relative Sensitivity:95.55% (95%CI:89.53%-100%); Relative Specificity:99.63% (95%CI:98.93%-100%); Overall agreement: 99.05% (95%CI:98.41%-99.69%)			

Fecal	RT-PCR		
BESTest	Positive	Negative	Total
Positive	43	1	44
Negative	2	299	301
Total	45	300	345
CT value≤30:Relative Sensitivity: 95.55%(95%CI:89.53%-100%); Relative Specificity:99.66%(95%CI:99.01%-100.0%); Overall agreement: 99.13%(95%CI:98.52%-99.74%)			

2.Limit of Detection(LOD)
The LoD of this product is about 0.05 ng/mL Monkeypox recombinant protein solution.
3.Cross-reactivity
No cross-reactivity observed with pathogens listed below:

Substance	Concentration	Result
Varicella-zoster virus	1×106 pfu/mL	positive
Rubella virus	1×105 CFU/mL	Negative
Coxsackie virus	1×106 pfu/mL	Negative
Measles	1×106 pfu/mL	Negative
Herpes simplex virus-Type I	1×106 pfu/mL	Negative
Herpes simplex virus-Type II	1×105 CFU/mL	Negative

4.Interfering Substances

This kit has no interference with HAMA, Human serum Albumin, Antinuclear antibody, Antimitochondrial antibody, Cholesterol, Bilirubin conjugated, Lipids, Hemoglobin, Bilirubin unconjugated, Rheumatoid factor, et al.

QUALITY CONTROL

1.Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique.
2.External controls are not supplied with this kit. It is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

TEST LIMITATIONS

1.This product is used for in vitro diagnosis only.
2.Must strictly follow the instructions for operation and interpretation of the results.
3.The product is qualitatively tested, and the result cannot be used as a quantitative basis.should be tested using reagents within the validity period.
3.The cassetes, collectors,droppers,and tubes are for single person one-time use, cannot be reused.
4.Because the sample titer is different, the red lines of the test line will show different shades of color, all of which indicate positive results. The depth of the test line color cannot be used as the basis for determining the antibody titer in the sample.
5.The samples stored at low temperature should be balanced to room temperature and fully mixed before testing.
6.Samples and waste must be treated as a potential source of infection and the desiccant in the foil bag is not edible.

SYMBOLS

Symbol	Used For	Symbol	Used For
	Use-by date		Consult instructions for use
	Batch code		In vitro diagnostic medical device
	Temperature limit		Manufacturer
	Please don't reuse it		Keep away from sunlight
	Don’t use the product when the package is damaged		Keep dry
	Date of manufacture		Tests per kit
	CE Mark		Biological Risks
	Authorized representative in the European Community		

BASIC INFORMATION

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