Monkeypox Virus Detection Kit (RT-PCR)

[PRODUCT NAME]

Monkeypox Virus Detection Kit (RT-PCR)

[PACKAGE SPECIFICATION]

24 Tests/Kit；48 Tests/Kit

[INTENDED USE]

The kit is used for qualitative detection of monkeypox virus nucleic acid in vitro and for clinical auxiliary diagnosis and treatment.

[INSPECTION PRINCIPLE]

The kit can detect monkeypox virus nucleic acid by designing specific primers and TaqMan probes for the conserved sequence of monkeypox virus specific gene. The kit is designed with a two-color fluorescence detection system. FAM fluorescence is used to detect monkeypox virus nucleic acid and Cy5 fluorescence is used to detect internal reference genes.

[MAIN COMPONENTS]

Table 1 Main Components

Number	Composition	Specifications	Composition Description
1	PCR reaction solution	120 μL/vial	Taq DNA polymerase, dNTP, etc
2	Primer probe mixture	240 μL/vial	Primers and probes
6	Positive quality control	50 μL/vial	plasmid DNA
7	Negative quality control	50 μL/vial	Purified water

Note: 1. Within the validity period of each component, the components in different batch number kits cannot be exchanged.

2. The quality control material is plasmid DNA containing target gene sequence, which does not have any biological activity, so it will not cause harm to human. The above ingredients do not include any biological materials such as animals, pathogens, human tissues and body fluids, so the safety of the product to users and the environment during transportation and use can be guaranteed.

Need but Not Provided Material:

Reagent: commercial nucleic acid extraction kit.

Consumables: fluorescent quantitative PCR reaction tube.

[STORAGE CONDITIONS AND VALIDITY PERIOD]

The kit is stored and transported at - 35 ℃ to 0 ℃ (± 5 ℃) and is valid for 12 months.

The kit is valid within 5 times after repeated freeze-thaw verification.

See the product label for the production date and service life.

[APPLICABLE INSTRUMENTS]

ABI 7500 PCR Instrument

[SAMPLE REQUIREMENTS]

1. Test specimen type

(1) Plasma: Collect fresh anticoagulant blood (non-heparin);

(2) Rash Exudate: Wipe the rash exudate with a sterile swab, put it into a sterile test tube (containing 1ml sterile normal saline), plug the test tube tightly with a sterile cotton ball, and send it for sealed examination. The specimen can be immediately used for testing.

2.Extraction of nucleic acid from test specimens

Extract the nucleic acid of the specimen to be tested by using the commercialized nucleic acid extraction kit; The extracted nucleic acid can be stored at 2 ~ 8 ℃ for no more than 2 days and - 20 ± 5 ℃ for no more than 180 days.

[TEST PROCEDURE]

1. Take the nucleic acid of the specimen to be tested and the control substance of Negative and Positive properties, shake and mix well, and centrifuge instantaneously for standby.

2. Thaw the kit at room temperature, shake and mix all components, and centrifuge instantaneously for standby.

3. Calculate the volume of PCR reaction solution and primer probe mixture required according to the number of test specimens n, plus Negative-Positive control (2) and loss (0.5). Take the following table as an example, configure PCR amplification reaction solution in a new EP tube, mix it upside down and centrifuge instantaneously.

Table 2 Preparation of PCR Amplification Reaction Solution

Component	PCR Amplification Reaction Solution
PCR reaction solution	5*（n+2.5）μL
Primer probe mixture	10*（n+2.5）μL
Total volume	15*（n+2.5）μL

4. Pack the PCR amplification reaction solution into the PCR reaction tube according to 15 μL/tube, and add 5 μL the samples prepared in step 1, positive control and negative control respectively. The operation shall be carried out on ice, press the pipe cover, mix upside down, and centrifuge at 2000 rpm for 10 seconds.

5. Carefully place the reaction tube to be detected in the PCR amplification detector, set the PCR amplification parameters according to the requirements of the following table, and set the target gene fluorescent reporter group as FAM fluorescence, the internal reference gene fluorescent reporter group as Cy5 fluorescence, and the quenched fluorescent group as NFQ-MGB.

6. Set the reaction procedure of PCR according to the following steps:

Table 3 PCR amplification cycle parameters

Step gathering	Number of cycles	Temperature	Time	Collect Fluorescence Signal
1	1	95℃	10 min	no
2	45	95℃	15 sec	no
		58℃	60 sec	yes

7. After the sample is put on the machine, save the file and run the program.
8. ABI 7500 software analysis software threshold value setting: the FAM channel threshold value is set to 5000.

[POSITIVE JUDGMENT VALUE AND INTERPRETATION OF TEST RESULTS]

1. The negative quality control FAM/Cy5 channel has no signal, indicating that there is no pollution in the test, and the result analysis can be continued.
2. The Ct value of positive quality control FAM/Cy5 channel ≤ 35 indicates that the experimental system is normal and the result analysis can be continued.
3. All test sample reaction holes shall have Cy5 signal, and the CT value of Cy5 signal shall be ≤ 35. If there is no Cy5 signal or Cy5 Ct> 35, it is necessary to re-extract the sample nucleic acid and repeat the test.
4. Detect the FAM channel of the sample. If there is an S-shaped amplification curve and the Ct value is ≤ 35, the sample is positive for monkeypox virus nucleic acid detection; If there is no amplification curve or Ct value > 35, the sample is negative for monkeypox virus nucleic acid detection.

[LIMITATIONS OF TEST METHODS]

1. The test results of this kit are only for clinical reference and should not be used as the basis for the diagnosis of patients. Clinicians should comprehensively judge the test results in combination with other diagnostic results.
2. Negative results can not completely exclude the existence of Monkeypox Virus nucleic acid. Excessive degradation of nucleic acid or the concentration of target gene in the amplification reaction system is lower than the detection limit can also lead to negative results.
3. Unreasonable specimen collection, transportation and treatment, as well as improper test operation and experimental environment may lead to false negative or false positive results.
4. This kit is limited to the specified sample type and detection system.

[PERFORMANCE CHARACTERISTICS]

1. Positive coincidence rate: three enterprises' positive reference materials P1-P3 were tested, and the test results should be positive, with a positive coincidence rate of 100%.
2. Negative coincidence rate: three negative reference materials N1-N3 of enterprises were tested, and the test results should be negative, with a negative coincidence rate of 100%.
3. Precision: test the precision quality control products J1-J2 of the enterprise, repeat the test for 10 times, and the coefficient of variation (CV%) calculated by Ct value CV ≤ 5.0%.
4. Limit of Detection: when the monkeypox virus content is 1000 copies/ml, the target gene can be accurately detected.

[PRECAUTIONS]

1. This kit is only used for in vitro diagnosis. Please read the instructions carefully before use and operate in strict accordance with the instructions.

2. The operation shall be carried out by personnel with professional experience or qualified training.

3. The laboratory shall be used separately according to reagent preparation area, sample processing area, reaction solution preparation area and amplification detection and analysis area. During operation, work clothes, hats, shoes, gloves, etc. Should be fully worn. Items in each area shall be used exclusively and shall not be cross used to avoid pollution.

4. The test results will be affected by the source of the specimen itself, the collection process, specimen quality, transportation conditions, pretreatment and other factors, as well as the quality of nucleic acid extraction, the model of fluorescent quantitative PCR instrument, the operating environment and the limitations of current molecular biology technology. As a result, very few specimens may get false positive or false negative test results. Users should understand the potential errors that may exist in the detection process and the limitations of accuracy.

5. Before use, the kit shall be fully melted, mixed and centrifuged to make the liquid concentrate at the bottom of the reagent tube.

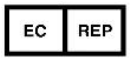
6. All reagents in this kit have been specially prepared for the above tests. Replacing any reagent in the kit at will may affect the use effect. The components of kits of different batch numbers cannot be mixed.

7. Please use this kit within the validity period. Do not use expired kit components.

8. Strictly prevent pollution, and pay attention to prevent leakage when preparing the reaction solution, so as to prevent fluorescent substances from polluting the instrument.

9. The test table shall be wiped with 75% alcohol before and after use, and the workbench and various experimental supplies shall be disinfected regularly.

[INDEX OF SYMBOLS]

	Lot number		For in vitro diagnostic use only
	Temperature Limitation		Consult instruction for use
	Use by		Contains sufficient for <n> tests
	Fragile, Handle With Care		Keep dry
	Manufacturer		This Way Up
	Authorized Representative in the European Community		Catalogue number

	Date of manufacture	CE	CE Marking

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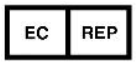

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