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See the following pages for more information!

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siehe unsere Liefer- und Versandbedingungen

Zuschläge

- Mindermengenzuschlag
- Trockeneiszuschlag
- Gefahrgutzuschlag
- Expressversand

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CE IVD

mole Bioscience

Monkeypox Virus Nucleic Acid Detection Kit
Fluorescent Probe-Based Real-Time PCR Assay

INTRODUCTION

Monkeypox virus is an enveloped double-stranded DNA virus that belongs to the Orthopoxvirus genus of the Poxviridae family. It is a viral zoonosis with symptoms similar to those seen in the past in smallpox patients. Cases of monkeypox virus, a rare viral disease typically found in Africa, have been detected in the US, Australia, and a number of European countries in recent days.

TEST PRINCIPLE

This kit uses polymerase chain reaction (PCR) combined with Taqman fluorescent probe technology to identify Monkeypox virus nucleic acid in plasma and rash exudate specimen.

PRODUCT ADVANTAGES

High sensitivity
The limit of detection of the kit is 200 copies/mL.

Reliable Results
Using a quality control system with dUTP enzyme pollution prevention system and internal control supervise system, the results are more reliable

Rapid Diagnosis
Test 94 samples at the same time within 70 mins, helping rapid clinical diagnosis

ORDERING INFORMATION

Cat No.	Product Description	Specification	Certification
R60101T2050	Monkeypox Virus Nucleic Acid Detection Kit	50 Tests/Box	CE

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Monkeypox Virus Nucleic Acid Detection Kit

(Fluorescent Probe-Based Real-Time PCR Assay)

Instructions for Use

English VER 2.0

REF R60101T2050 50 Tests/Box Basic UDI 697089547MPXV003R

PRODUCT NAME

Monkeypox Virus Nucleic Acid Detection Kit (Fluorescent Probe-based Real-time PCR Assay)

INTENDED USE

This kit is used for qualitative detection of Monkeypox Virus（MPXV）DNA in plasma or rash exudate samples. For professional in-vitro diagnostic use.

SUMMARY AND EXPLANATION

Monkeypox Virus (MPXV) belongs to the Poxviridae family, the genus Orthopoxvirus; it is a DNA virus with a relatively complex structure. Monkeypox is a viral disease characterized by skin rash, which is transmitted from animals to humans through close contact, and can be transmitted from human to human. It is mainly distributed in the tropical rainforest regions of Central and West Africa.

TEST PRINCIPLE

This kit uses polymerase chain reaction (PCR) combined with Taqman fluorescent probe technology to identify and detect Monkeypox Virus DNA in plasma and rash exudate samples. FAM fluorescence-labeled TaqMan probe for the conserved sequence of Monkeypox Virus. VIC/HEX fluorescence-labeled TaqMan probe for a human gene as an internal control.

MATERIAL PROVIDED

Seq.	Labels	Main Contents	*No.* (50 tests)
1	Buffer (MPXV)	Containing magnesium ion, deoxynucleotide solution, *etc.*	1 tube (800μL /tube)
2	Enzyme mixture (MPXV)	Containing DNA polymerase and UNG solution	1 tube (30μL/tube)
3	Primers/Probes (MPXV)	Containing specific primers and probes solutions	1 tube (250μL/tube)
4	Positive Control (MPXV)	Containing Monkeypox virus gene and Internal Control gene fragments	1 tube (500μL/tube)
5	Negative Control (MPXV)	Containing Internal Control gene fragments	1 tube (500μL/tube)

OTHER MATERIALS REQUIRED BUT NOT PROVIDED

The following list includes the materials that are required for use but not included in this Kit:

- Nucleic acid extraction kit.
- Nuclease-free consumables: Filter tips, 1.5mL tubes, PCR-well strips or 96-well plate.
- Experimental equipment: Centrifuge for 1.5mL tubes and PCR-well strips or 96-well plate (if available), Vortex. Real-time PCR instrument (thermocycler).
- Others: Micropipettes (0.5-20μL, 10-100μL, 20-200μL,100-1000μL), Powder-free disposable gloves, Microplate sealing film.

STORAGE CONDITIONS AND SHELF LIFE

The shelf life of this kit is 12 months from the manufacturing date when stored at - (20±5) ℃. It is suggested to transport the kits in a sealed foam box with ice packs. Never leave the kit for more than 3 days at 37 ℃; Never repeat freeze-thaw more than 10 times for this kit (The effects of repeated freeze-thaw more than 10 times for this kit haven't been verified).

APPLICABLE EQUIPMENT

Applicable to ABI 7500 Real-Time PCR thermocycles, for other Real-Time PCR thermocyclers, please consult the manufacturer/your distributor before use.

ACCEPTABLE SPECIMENS

The objects of sample collection are patients or suspected patients of the Monkeypox Virus. The specimens to be collected is plasma or rash exudate.

SPECIMENS COLLECTION AND STORAGE

Plasma: Take 1 mL venous blood using a disposable syringe, place the blood in a sterile test tube with anticoagulant (non-heparin), centrifuge it at 1000 g for 15 minutes in half an hour after collection, and take the supernatant, which is the plasma. The plasma should be operated immediately or stored at -(20±5) ℃ or -80℃ for test.

Rash exudate: Wipe the rash exudate with a sterile swab and place it in a sterile test tube with preservation solution. Break the swab at break point and close the tube tightly, the collected specimen should be used for immediate testing.

Please pay attention to the aseptic operation during sample collection. During the transportation and storage of clinical specimen, the repeated freeze-thaw should be avoided. If the transportation cannot be guaranteed at - (20±5) ℃, the samples should be transported at least at 0-8 ℃. The shelf life of the samples at - (20±5) ℃ is 4 months. The accurate clinical information of the samples, such as specimen number, date of onset and date of collection, should be attached during the transport and preservation process.

TEST METHODOLOGY

1. Nucleic Acid Extraction (Pre-PCR)

Extract viral nucleic acid according to the instructions of the nucleic acid extraction kits. The extracted nucleic acid should be tested immediately or stored at -(20±5) ℃. The types of samples that require nucleic acid extraction include:

1.1. Clinical sample: the clinical sample to be tested;

1.2. Positive Control: Take 200μL positive control and process it at same time with the samples.

1.3. Negative Control: Take 200μL negative control and process it at same time with the samples.

* We have validated the following kits for nucleic acid extraction from plasma or rash exudate specimen:

- Nucleic Acid Extraction Kit (Magnetic Bead Method) (Mole Bioscience), using the 32M, 96M or FAST96 instruments (Mole Bioscience). recommended*.
- Viral RNA Extraction Kit (Spin Column) (Mole Bioscience). recommended*.

If you use nucleic acid extraction kits from other suppliers, please verify first.

2. Amplification Processes (PCR)

2.1. Preparation of Amplification Reagent (PCR Room I)

To prepare the PCR reaction mixtures, take primers/probes tube and buffer tube from the kit. Thaw them on ice or at 2-8℃. Take out of enzyme mixture tube. Shake well and centrifuge all reagent tubes at low speed shortly. Prepare the Amplification PCR Mixture according to the following ratios:

Reagent	Buffer (MPXV)	Enzyme mixture (MPXV)	Primers/Probes (MPXV)
Volume (μL)	15.0	0.5	4.5

Calculate the volume of each reagent. Add the reagents into an appropriate volume centrifugal tube, mix well and centrifuge shortly. Total number of PCR mixtures = number of samples + 1 positive control + 1 negative control.

Add 20.0μL of the PCR mixture into each of the PCR well/tube, and then transfer the plates/tubes to the PCR room II.

2.2. Add the Templates (PCR Room II)

Add 10.0 μL of nucleic acid extracted from each sample (prepared in the first step: Pre-PCR) into each PCR well/tube which was added with PCR reaction mixture solution. Vortex the sealed the plate or tubes to mix well and then centrifuge at 2000-3000rpm for 1min.

2.3. Amplification (Detection Area)

Put the reaction tube into the Real-Time PCR thermocycles, and set the cycle parameters as follows:

Steps	Cycles	Temperature (℃)	Time (min: sec)
1	1	50	02:00
2	1	95	02:00
3	45	95	00:05
		60*	00:30

Fluorescence signal collection is set as FAM (MPXV) and VIC/HEX (Internal Control), *The signal data is collected at 60°C. When using the ABI7500, select the 'Quencher' and 'Passive reference' columns as "none". Set the reaction volume per tube/well to 30 μL.

CUT-OFF VALUE

The cut-off value of FAM is 43.00, it is determined by ROC curve. The cut-off value of internal control is determined to be 35.00 by limited dilution.

EXPLANATION OF THE TEST RESULTS

After the reaction is over, the instrument automatically saves the results, and after analyzing the image, adjust the Start value, End value and Threshold value of Baseline (self-adjustable, start value can be between 3 and 15, End value can be between 5 and 20). Adjust the amplification curve of the negative control and make it straight or below the threshold line.

For positive control, the Ct value in FAM channel should be ≤ 30.00, in VIC/HEX channel should be ≤ 35.00. For negative control, the Ct value in FAM channel should be negative, in VIC/HEX channel should be ≤ 35.00. The above conditions must be met at the same time in the same test, otherwise the PCR reaction is considered invalid and the test needs to be reconducted. Details as follows:

1. When the Ct value in HEX/VIC channel (Internal Control) of the sample is ≤ 35.00, the Ct value in FAM channel (MPXV) is > 43.00 or there is no typical S-type amplification curve, the tested sample is determined as a Monkeypox Virus negative sample.
2. When the Ct value in HEX/VIC channel (Internal Control) of the sample is ≤ 35.00, the Ct value in FAM channel is ≤ 43.00 with a typical S-shaped amplification curve, the tested sample is determined as a Monkeypox Virus positive sample.
3. When the concentration of Monkeypox Virus in the sample is too high, the amplification of the internal control might be inhibited, it can be directly reported as a Monkeypox Virus positive sample, or the nucleic acid can be diluted and retested.
4. When the FAM signal and HEX/VIC signal are both negative, please re-sampling or re-extract nucleic acid.

LIMITATIONS OF THE TEST METHOD

The results of this kit are only for aiding to diagnosis and shall not be used as the sole basis for diagnosis or exclusion, and should be analyzed by combination with clinical symptoms. A negative result indicates the viral concentration in the sample is lower than the detection limitation of the kit, in this situation, the infection cannot be excluded.

The optimal sample type and the time to reach maximum titer after infection have not been verified. Therefore, collecting samples in the same patient at different times and multiple locations may help to avoid false-negative results.

The following conditions can also cause a false positive or false negative test result:

1. The results can be affected by collecting, disposing, transporting and storage of samples, and any errors in these processes will result in a false negative.
2. The mutation of sequence related to primers or probes used in this kit may cause false-negative results.
3. Cross-contamination during sample processing may lead to false positive, and the FAM channel detection results of the negative control showed an amplification curve.

PRECAUTIONS

1. The test is manually operated. Experimental personnel who perform this test should have received professional training in gene amplification or

molecular biology diagnostics and be qualified for relevant experimental operations. There should be reasonable biosecurity precautions and protective procedures in the laboratories. The test should only be performed in laboratories that follow safety practices according to the applicable Biosafety Regulations in Microbiological and Biomedical Laboratories.

2. The whole detection process should be carried out in three areas: the first area is for reagent preparation. The second area is for specimen processing and reaction system preparation. The third area is for amplification, fluorescence detection and results analysis. Instruments, equipment and lab coats should be used independently in each area to prevent contamination.
3. In the testing process, should always take care to avoid RNase contamination, wear disposable gloves without fluorescent substances (Frequent replacement is recommended), use the disposable thin-walled 200μL PCR tube (or 96-well PCR plate with optical film) and pipette tips with filter. Never touch the reaction tube directly with bare hands.
4. The handling of Clinical Specimens should be performed in the biosafety cabinet to ensure the safety of laboratory staff and prevent environmental pollution. Harmful and/or toxic specimens and reagents in the experiment should be properly placed and stored, and in charge by an assigned person. Waste should be disposed properly in special containers. Lab bench, equipment such as operator's stations, pipettes, centrifuges, and PCR thermocyclers etc., should be regularly wiped and disinfected with 1.0% sodium hypochlorite and/or 70% ethanol. Laboratory room, ultra-clean bench should be treated with an ultraviolet lamp regularly and after each experiment.
5. Before the experiment, reagents should be fully thawed, mixed well, and centrifuged for a few seconds to bring down all the liquid to the bottom of the centrifuge tubes. When preparing the reaction solution, attention should be paid to: mixing all liquids on the vortex mixer, not blowing with the pipette to avoid bubbles, and centrifuging the reaction mixture solution for a few seconds. Use the kit before the expiration date and do not combinate the reagents with different batch numbers.

Manufacturing date and expiration date: view on label

INDEX OF SYMBOLS

	Consult Instructions for Use	Σ	Contain <n> tests	EC REP	Authorized Representative in the European Community
IVD	In vitro diagnostic medical device		Use-by date	-25℃ -15℃	Temperature limit -25 to -15℃
REF	Catalogue #	LOT	Lot Number	CN	Country of manufacture
	Manufacture Date		Manufacturer	UDI	Unique device identifier
	Keep dry		Keep away from sunlight	CE	CE conformity marking

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Effective Date: 2022-06-02

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变更历史

版本号	生效日期	本次变更原因，依据及详细变更内容
0.0	2022-05-23	初始版本
1.0	2022-05-25	更新说明书排版(标识、抽提描述、去除PCR空白、注意事项、局限性描述、增加采样方式与保存标题等)，修改单词语句错误。
2.0	2022-06-02	增加阴性质控品，更新病毒简称，更新PCR程序，增加血浆采集描述和病毒背景资料。