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Nucleic Acid Testing

Size	Kit	REF
48 tests	A	PCRL0101A
	B	PCRL0101B
96 tests	A	PCRL0102A
	B	PCRL0102B

AutoMolec Monkeypox

Key to Graphical Symbols Used

LOT	batch code		use by
	manufacturer	Σ	contains sufficient for <n> tests
IVD	*in vitro* diagnostic medical device		temperature limitation
REF	catalogue number		consult instructions for use
EC REP	authorized representative in the European Community		date of manufacture

EC REP

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CE IVD

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Contact your local dealers for all product related questions in your local language

Intended use

This AutoMolec Monkeypox is based on real-time PCR test intended for the qualitative detection of monkeypox virus gene in serum and lesion exudate specimen from individuals.

Summary

Monkeypox virus is a double stranded DNA virus. Similar with smallpox, it is a kind of zoonosis classified as a virus in the family Poxviridae. Usually monkeypox virus is transmitted to humans through animals such as rodents and primates, but the transmission can also occur between people. It may develop symptoms such as fever, rash, lymphadenopathy, muscle soreness, trembling and fatigue. The infection is usually diagnosed by methods like virus isolation, nucleic acid diagnosis and so on. The main diagnosis methods of monkeypox infection include virus isolation and nucleic acid diagnosis.

This product is only used for the medical institutions. It is used for clinical reference only and cannot be used as the only standard for the clinical diagnosis. It is recommended that a comprehensive analysis of the condition be carried out in combination with the patient's clinical presentation and other laboratory tests.

Measurement Principle

The primers and probes, which are aimed at the conserved gene region of monkeypox virus gene, combined with Mixes to perform amplification based on real-time PCR.

Human DNA is tested as internal control, the extraction and amplification process is monitored by detecting whether the internal control is normal to avoid false negative.

Materials provided

Component		48 tests	96 tests	Kit
Reagent strip	Mix 1	1.0mL	2.0mL	A
	Mix 2	1.0mL	2.0mL	
	Proteinase K	1.5mL	3.0mL	
Q1		1.0mL×4	1.0mL×8	B
Q2		1.0mL×4	1.0mL×8	

- Mix 1

Buffer contains probes, bifunctional DNA polymerase, uracil-DNA glycosylase (UDG) and dNTP.

- Mix 2

Buffer contains primers and Manganese ion.

- Proteinase K

Buffer contains proteinase K.

- Q1

The negative control contains pseudoviruses, which include the internal control sequences of this kit.

- Q2

The positive control contains pseudoviruses, which include the target sequences and internal control sequences of this kit.

Assay Analyzers on which the kit can be used

- AutoMolec 3000
- AutoMolec 3000S
- AutoMolec 1600

- AutoMolec 1600S

The AutoMolec Monkeypox assay is performed on the automated instrument System-AutoMolec system, which consisting of a nucleic acid extraction/purification unit, and an amplification and detection unit.

Materials Required but not Provided

1. AutoMolec System
2. Nucleic Acid Extraction & Purification Reagent
3. Tip tray and PCR tube
4. Virus preservation tube (including guanidine salt for inactivation, lesion exudate only)

Warnings and Precautions

1. For professional use only. For *In Vitro* Diagnostic Use.
2. Follow the instruction for use carefully. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this instruction for use.
3. Handle the potentially contaminated materials and wastes safely according to local requirement.
4. Some reagents contain preservatives, such as ProClin 300®, may cause sensitization by skin contact, which must be avoided to contact with skin. If any reagent came into contact with the skin or mucous membrane, wash directly and disinfect the contacted area. This material and its container must be disposed in a safe way. If swallowed, seek medical advice immediately and show this container. All samples and post-use kits shall be treated as potentially infectious substances, and disposed in accordance with local government and national regulations.
5. Do not smoke, drink, eat or use cosmetics in the working area.
6. Wear protective clothing and disposable gloves when dealing with samples and reagents. Wash hands after operations.
7. Use caution when handling patient samples to prevent cross contamination. Use of disposable pipettes or pipette tips is recommended.
8. Conduct the assay away from bad ambient conditions. e.g. ambient air containing high concentration corrosive gas such as sodium hypochlorite acid, alkaline, acetaldehyde and other high concentration corrosive gases, or containing dust.
9. Do not use reagents beyond the labeled expiry date. When storing the kit, be certain the reagent strip is securely sealed and store it at 2-8 ºC.
10. Do not mix or use components from kits with different batch codes.
11. Avoid foam formation in all reagents and samples.
12. Do not substitute any reagent in this kit with those from other manufacturers.
13. When any damage to the protective packaging is observed, do not use the kit.
14. Any serious incident shall be reported to manufacturer and competent authority of the Member State in which user and/or patient is established.
15. As the assay involves the extraction of viral DNA and PCR amplification, be careful to avoid contamination of the reagent. Regularly perform negative control test to monitor the contamination of amplified products.
16. After each experiment, clean the experiment table thoroughly with 0.5% sodium hypochlorite freshly prepared.
17. The improper procedures in the process of transportation and using, such as storage, sample collection, sample process, may affect the performance of the kit. Please follow the operations in instructions.
18. Due to the sampling methods of swabs and characteristics of the infection, false negative results may be caused by the insufficient collected sample. The results should be determined combining with clinical diagnostic information. Retest if it was necessary.
19. The equipments and operators in clinical laboratories should follow the requirements of local government.
20. Dead volume should be considered during the process of sample preparation, which should be referred to the insert of AutoMolec system for more details.
21. If non-human-derived sample was tested, the result of internal control is not recommended as a reference.

Storage

1. Store the kit at 2-8ºC. When stored as directed, all reagents are stable until the expiration date.
2. After opening, the kit should be stored at 2-8ºC for no more than 14 days.
3. Do not freeze. Avoid strong light.

Sample

1. Serum or lesion exudate could be used for this assay

2. Collect samples in accordance with correct medical practices:
   Serum: Collect samples in accordance with correct medical practices (non-heparin).
   Lesion exudate: Wipe the exudate (3-4 times) from the lesion with a sterile swab, transfer it immediately transfer into an virus preservation tube containing guanidine salt, finally seal the tube closely for the following tests.
3. For optimal results, inspect all samples for bubbles. Remove bubbles with a tip prior to analysis. Use a new tip for each sample to prevent cross contamination.

Sample storage

Samples used for virus isolation and nucleic acid testing should be tested as soon as possible. Samples can be stored at 2-8 ºC for 24 hours. Samples for long-time storage should be stored at -70ºC or lower. Avoid repeated freeze-thaw cycles.

Measurement Procedure

1. **Check the consumable materials**
- Verify adequate volume of consumable materials is present prior to running the test.
- Refer to the AutoMolec system's operation manual.

2. **Load the kit**
- Load the kit to the appropriate position of the AutoMolec system.

3. **Order tests**
- Place 600μL sample in each tube on the AutoMolec system supporting sample rack.
- Load the sample rack and refer to the corresponding AutoMolec system operating manual for testing.
- All the processes of nucleic acid extraction, purification and amplification are completed by AutoMolec system automatically, please refer to the corresponding operation manual for more details

4. **Quality control**

It is recommended to conduct quality control in the following situations:
- Use of each batch of test or kit every 24 hours.
- Change of the kit lot

Each laboratory shall establish an acceptable range suitable for the laboratory according to its own conditions to ensure proper test performance. It should be performed according to the laboratory regulations if each laboratory needs more frequent quality control.

Measurement Results

Save the results after reactions completed, results will be analyzed by the instrument automatically.

One or more targets may cause amplification inhibition of internal control (IC) or other targets. When one or more target viruses were detected, the result of IC can be disregarded.

Possible results and corresponding interpretations are attached below:

Target	Result	Report Interpretation
Monkeypox	Not detected	No Monkeypox DNA detected
	Detected	Monkeypox DNA present
	Indeterminate	Presence or absence of Monkeypox cannot be determined. Repeat assay with same sample or, if possible, new sample.
Invalid	Invalid	Presence or absence of Monkeypox cannot be determined. Repeat assay with same sample or, if possible, new sample.

Limitations of the Procedure

1. This assay is intended as an aid for the clinical diagnosis. Conduct this assay in conjunction with clinical examination, patient's medical history and other test results.

2. The contamination rate may be reduced by the use of UDG, but cross contamination between samples can only be avoided by management of laboratories and strict compliance with this insert.
3. The change of the target sequence caused by mutation or other reasons may lead to a false negative result.
4. Results may be affected by the quality of sample collection, processing, transportation and storage.
5. If the results are inconsistent with clinical evidence, additional testes are suggested.

Performance Characteristics

1. Analytical Sensitivity

Limit of Detection references were assayed. Monkeypox DNA was detected in S, and the LOD of this assay should not be higher than 800 copies/mL.

2. Relative Agreement

Positive reference agreement rate:

Internal positive references were assayed. Monkeypox DNA was detected in P.

Negative reference agreement rate:

Internal negative references were assayed, Monkeypox DNA was not detected.

3. Measurement Precision

Internal precision references were assayed; the CV of tested Ct values of Monkeypox were all ≤5%.

Literature References

1. Longo MC, Berninger MS and Hartley JL. 1990. Use of uracil DNA glycosylase to control carry-over contamination in polymerase chain reactions. Gene 93:125-128.

2. Laboratory biosafety manual-Third edition. World Health Organization: Geneva,2004.

3.Clinical and Laboratory Standards Institute (CLSI). Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline-Third Edition. CLSI Document M29-A3 Wayne, PA: CLSI, 2005.