

White Paper

Comprehensive Solution for Monkeypox Testing



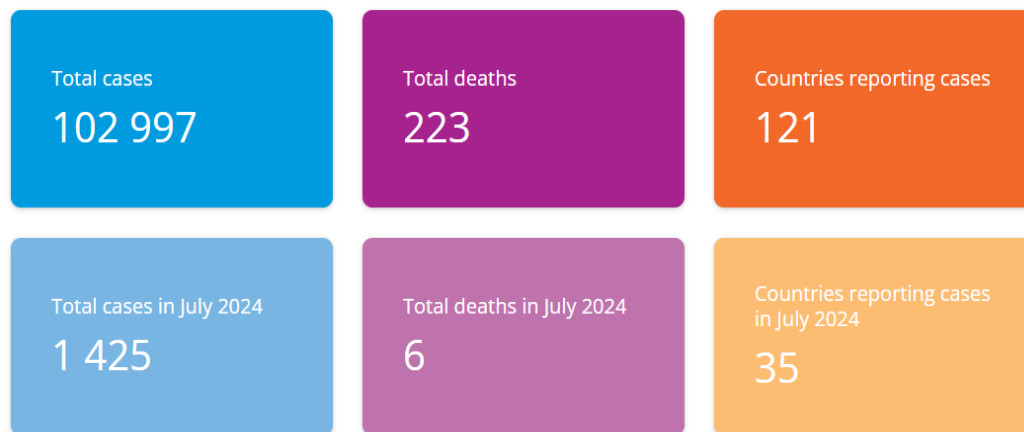
White Paper: Comprehensive Solution for Monkeypox Testing

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White Paper: Comprehensive Solution for Monkeypox Testing

Since May 2022, the monkeypox virus epidemic has occurred in many countries such as the UK, Portugal, Spain, Australia, Germany and France, which arouse a great deal of public attention. On 14 August 2024, the World Health Organization once again declares mpox(monkeypox) outbreak a public Health Emergency of International Concern (PHEIC)", with the same level as polio and covid-19.

Data as updated monthly; from 01 January 2022 to 31 July 2024



Source: https://worldhealthorg.shinyapps.io/mpx_global/

Until 31 July 2024, the global confirmed cases of monkeypox have reached 102,997 and it seems the reported cases tend to grow continuously. With the upsurge of monkeypox in the Democratic Republic of the Congo (DRC) and a growing number of countries in Africa.

What is Monkeypox?

Monkeypox is a smallpox-like, sporadic acute infectious disease caused by the monkeypox virus. Monkeypox virus is an animal-derived virus that belongs to the Orthopoxviridae family with the variola virus. At present, due to the mutation of the virus, it is subdivided into the Monkeypox Virus Clade One (I) and the Monkeypox Virus Clade Two (II). The Monkeypox Virus Clade One (I) is more virulent, with a fatality rate of 10%, while the Monkeypox Virus Clade Two (II) has a lethality rate of 1%.

Monkeypox is resistant to drying and low temperatures and can survive for several months on soil, crusts, and clothing. The virus is heat sensitive and can be inactivated by heating to 56°C for 30 minutes or 60°C for 10 minutes. It can be inactivated by ultraviolet rays and general disinfectants, and it is sensitive to sodium hypochlorite, chloroxymol, glutaraldehyde, formaldehyde, and paraformaldehyde.

How is Monkeypox Spread?

Monkeypox virus is a zoonotic disease, and it is mainly spread by animals. Humans are infected by bites or close contact with animals that carry the virus and are spread through blood, body fluids, and pollutants.

Human-to-human transmission can be caused by close contact with respiratory secretions, skin lesions, or recently contaminated objects of an infected person. Transmission through respiratory droplets typically requires prolonged face-to-face contact, putting health workers, family members, and other close contacts of active cases at greater risk. This may reflect decreased immunity in all communities due to the cessation of smallpox vaccination.

Monkeypox virus can also be transmitted from mother to fetus through the placenta (which can cause congenital monkeypox) or through close contact during and after birth. Monkeypox is not a sexually transmitted disease, but close physical contact is a well-known risk factor for transmission, which include sexual contact.

Current research suggests that the population is generally susceptible, but as mentioned above, the monkeypox virus and smallpox virus belong to the same viral family, so the smallpox vaccine is also effective against this virus. But since the global eradication of the smallpox virus in the 1980s, vaccination has stopped.

Person to Person Transmission

- Spread by direct contact with a contagious rash, scab, or bodily fluids;
- Prolonged face-to-face contact or close physical contact (such as kissing, hugging, or sexual intercourse); respiratory secretions;
- Contact with items (such as clothing or bed sheets) that have a contagious rash or bodily fluids;
- Pregnant women transmit the virus to the fetus through the placenta.

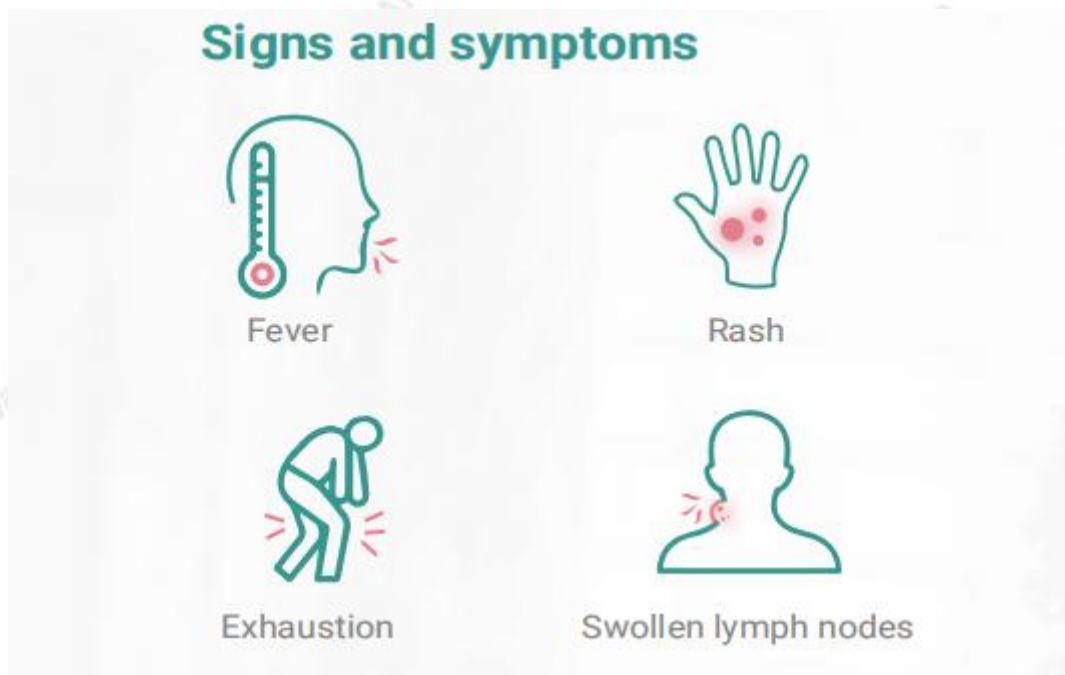
Animal-to-human Transmission

- A person is scratched or bitten by an animal;
- Preparing or eating meat;
- Use products from infected animals.

What are the Symptoms of monkeypox?

The clinical symptoms of monkeypox are very similar to smallpox but a milder symptoms, usually presenting swollen lymph nodes. The incubation period of the disease is generally 3-17 days.

What are the stages of Monkeypox?



Incubation Period: The incubation period of monkeypox is 3-17 days. During the incubation stage, symptoms may not appear and the patient may feel fine. The illness commonly lasts 2-4 weeks. The initial health of the person and the exposure route may affect the severity of the illness.

Precursor Period: People with monkeypox virus infection may present early onset symptoms such as fever, headache, sore throat, and cough, most patients appear with lymph nodes.

Rash Stage: The rash is the most typical symptom of monkeypox, most monkeypox cases onset with a fever, and are accompanied by chills, headache, swollen lymph nodes, muscle pain, joint pain, weakness, and fatigue. The rashes tend to concentrate on the face and extremities, they also appear on the oral mucosa, palms and soles, genitalia, conjunctiva, and cornea. The lesions progress through four phases macular, papular, vesicular, to pustular before scabbing over and desquamation.



Source: https://www.who.int/health-topics/monkeypox#tab=tab_1

Shedding Stage: It takes about 2-4 weeks from the onset to the scab falling off. After the scab falls off, it can leave erythema or pigmentation, or even a scar, which can last for several years. Once all scabs fall off, the person is no longer contagious.

How to Prevent and Treat Monkeypox?

The monkeypox virus mainly transmits through close contact with an infected person, animal or materials contaminated by the monkeypox virus. Here are the monkeypox prevention steps:

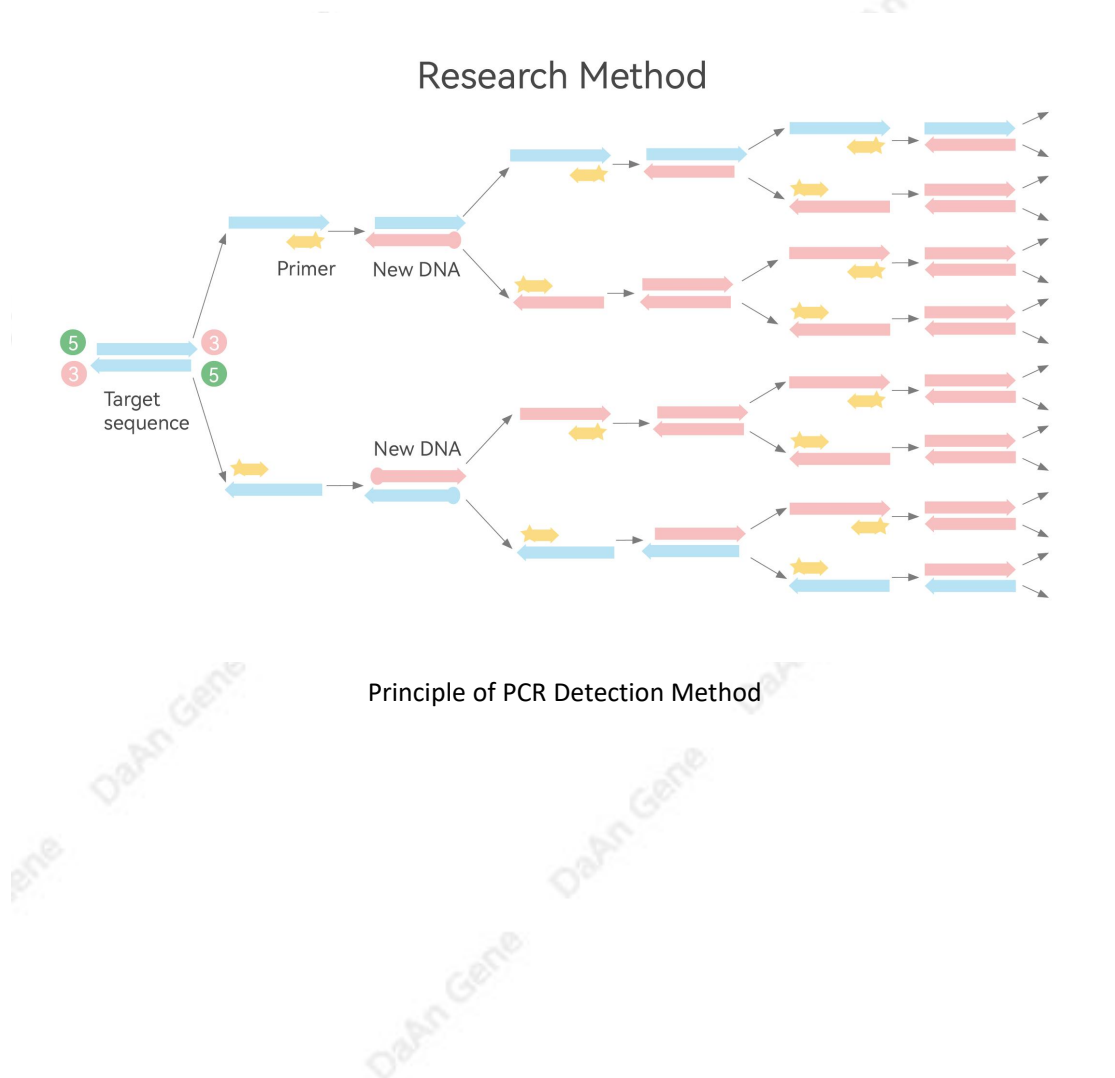
- Avoid skin-to-skin contact with someone who has monkeypox-like rashes
- Avoid touching the materials that monkeypox patient has used, or the objects contaminated by the monkeypox virus
- Keep healthy people away from the monkeypox patient.
- Avoid touching animals that may carry the virus, such as monkeys and rodents.
- Keep your hand clean, wash your hand with soap and sanitizer

Smallpox and monkeypox are caused by orthopoxviruses, so the smallpox vaccine is considered effective to prevent monkeypox virus infection, and the doctor may prescribe smallpox antiviral drugs to treat monkeypox. Currently, monkeypox has no specific approved treatment, monkeypox is a self-limiting disease, and the treatment of monkeypox majorly aims at supporting the body and relieving the symptoms.

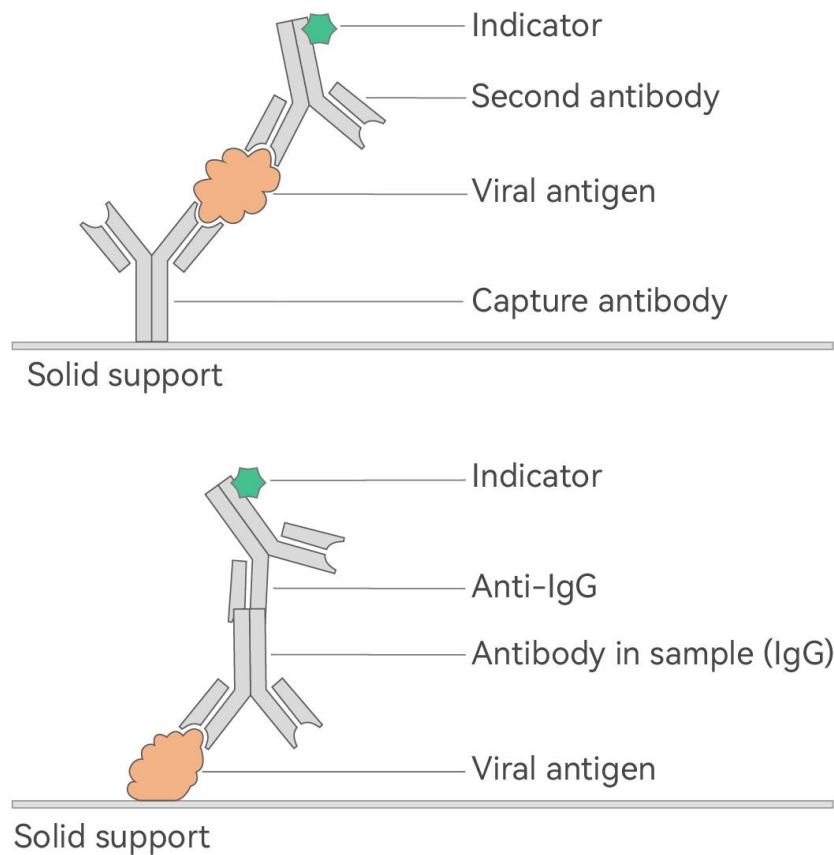
Principle of Laboratory Detection of Monkeypox Virus

Monkeypox detection methods are mainly divided into two categories: virus PCR detection, virus antigen and antibody detection.

PCR test method of monkeypox virus: Based on a specific sequence of monkeypox virus genes, specific primers, and fluorescent probes designed to target the highly conserved coding regions of the monkeypox virus gene for PCR amplification. The principle carries out through amplifying different fragment sizes and restriction endonuclease digestion of different length fragments of domain amplification fragments. PCR tests can be used for monkeypox infection rapid laboratory tests and early clinical diagnosis.



Monkeypox Virus Antigen/Antibody Test: Immunoassay can use for both antigen and antibody detection. However, antigen cross-reaction between monkeypox virus and poxvirus will decrease the specificity of detection, so the monkeypox virus cannot identify accurately. Antigen/antibody detection commonly use for epidemiological investigation, which has the merits of rapid results and simple procedures. In acute and convalescent periods, serum antibodies raised by 4 times can apply in the diagnosis of monkeypox virus infection. But it can only be used as an auxiliary diagnosis in the middle and late stages of the disease.



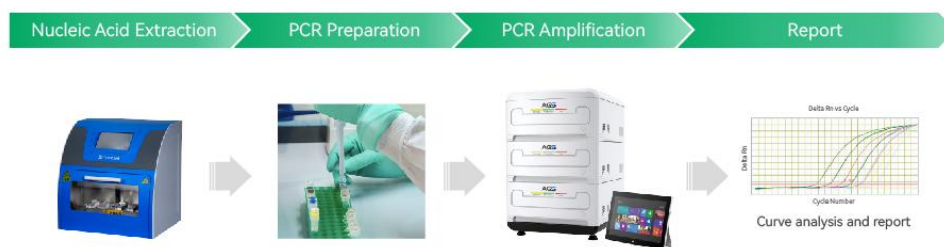
Principle of Immune Detection Method

Daan Gene Detection Kit for Monkeypox Virus DNA (PCR-Fluorescence Probing)

WHO recommended in *Laboratory testing for the monkeypox virus (Interim guidance)* for using specific real-time PCR or poxvirus general test methods should be used preferentially to detect suspected monkeypox virus sample. The laboratory confirmation of suspected monkeypox infection should base on a real-time polymerase chain reaction (PCR) testing method to detect the monkeypox virus-specific DNA sequences. PCR technology is the preferred method for monkeypox detection due to its high accuracy and sensitivity. Skin lesion specimens are recommended for diagnostic confirmation of MPXV, including swabs of rashes exudate and lesion surface, lesion crusts, and roof swabs from multi-lesion.

Daan Gene's Comprehensive Solution for Monkeypox Virus Testing

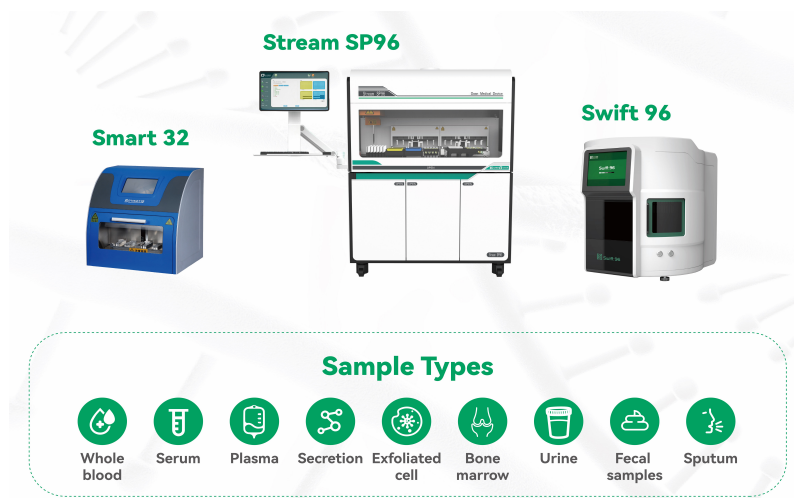
Daan Gene monkeypox PCR detection kit has obtained CE, NMPA and MHRA certifications. Our product utilizes real-time fluorescent PCR technology, which has been recommended as the gold standard for detecting monkeypox by WHO.



Daan Gene's Nucleic Acid Extraction Solution

Before the target gene sequence being amplified, the sample from suspicious patients should be purified, we call it as nucleic acid extraction. Nucleic acid extraction is the process of purification of RNA/DNA for samples using a combination of physical and chemical methods, which are the crucial procedure for many downstream molecular biology research. Daan Gene's

nucleic acid extraction system and nucleic acid extraction kit can extract and purify of nucleic acid in a sample of human body in laboratory environment with high efficiency.



Daan Gene's Monkeypox Virus Detection Kit

Polymerase chain reaction (PCR) is the preferred laboratory test given its accuracy and sensitivity which suggested by WHO. Confirmation of monkeypox virus infection is based on nucleic acid amplification testing (NAAT), using real-time or conventional polymerase chain reaction (PCR) is preferred for detection of unique sequences of viral DNA.



- ◆ **Reliable:** Based on WHO recommended diagnosis method: real-time polymerase chain reaction (PCR)
- ◆ **High Specificity:** Highly conservative region of Monkeypox virus gene coding region
- ◆ **High Accuracy:** Involved endogenous internal to monitor the whole NAAT procedure from sampling to PCR result
- ◆ **Universal:** Compatible with mainstream real-time fluorescent PCR system

Daan Gene's PCR Amplification Solution

Daan Gene's PCR Detection System combines multi-model design and multi-fluorescence channel detection features to provide outstanding performance and reliable results. It can provide accurate analysis of up to 144 nucleic acid samples (RNA/DNA) simultaneously for a wide range of applications, such as immunology, human genome engineering, forensic medicine, clinical diagnosis of viruses, tumors and hereditary diseases, etc.



AGS8830 Real-Time PCR
Detection System



Lava 96 Real-time PCR Detection
System



AGS4800 Real-time PCR System

Daan Gene's Capabilities

Founded in 1993 and headquartered in Guangzhou, China, Daan Gene is in the front ranks among world's molecular diagnosis companies with its expertise in many core businesses. Apart from developing new diagnostic test kits, automatic extractors and real-time PCR systems, its objectives include producing core raw material, CRMs and setting up labs to perform clinical analyses for hospitals and individuals.

Daan Gene's innovative molecular diagnostic solutions have helped millions of patients all over the world. Besides molecular diagnostic technology, it is also committed to immunological diagnostic, biochemical technologies and POCT. Daan Gene has set up multiple product lines to make a comprehensive layout in the IVD industry.

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Contact Us

Daan Gene Co., Ltd.

CHINA (Headquarters)

Address: No.19, Xiangshan Road, Science Park, High & New Technology Development District, Guangzhou, Guangdong, P.R. China

Telephone: : +86-20-32290789-5225

Fax: +86-20-32068352

Email: marketing@daangene.com

Website: <https://en.daangene.com/>

Canada Office

Address: #413-4538 Kingsway Burnaby, BC V5H 4T9, Canada

Telephone: +16044517588

Fax: +604451.7587

Email: gbai@daangene.net

Colombia Office

Address: Cl 93 No.16 46 Of 702, Bogotá D.C.

Telephone: +57 3103940417

Email: alonso.zheng@daangene.net

Daan Gene Co., Ltd.

Address: No.19, Xiangshan Road, Science Park, High & New Technology Development District, Guangzhou, Guangdong, P.R. China

Email: marketing@daangene.com

Website: <https://en.daangene.com/>