IVD CE

SYNTHGENE

For professional and in vitro diagnostic use only.

Monkeypox Virus Antigen Rapid Test Kit

【Product name】
Monkeypox Virus Antigen Rapid Test Kit

【Packaging specification】
1 test/bag, 1/5/10/25/50 test(s)/kit

【Intended use】
The product is used for the qualitative detection of monkeypox virus antigen in human rash exude, nasal swab, and oropharyngeal swab.

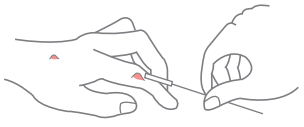
【Testing principle】
This product uses colloidal gold immunochromatography combined with double antibody sandwich principle to detect monkeypox virus antigens in human rash exude, nasal swab, and oropharyngeal swab. During the test, the specimen is dropped into the sample well, and then the specimen is chromatographed under the capillary effect. If the specimen contains monkeypox virus, a colored band will appear in the test area (T), indicating a positive result for monkeypox virus. If the specimen does not contain the corresponding substance to be tested, there will be no colored band in the test area (T), indicating a negative result. A colored band appears in the quality control area (C) regardless of whether the corresponding substance to be tested is present in the specimen. The color band in the quality control area (C) is the standard to determine whether there are enough specimens and whether the chromatographic process is normal, and also serves as the internal control standard of the test.

【Main components】
1. Test pad, individually packaged in aluminum foil bag (1 piece/bag, 1/5/10/25/50 piece(s)/kit)
2. Extraction tube with buffer (1 piece/bag, 1/5/10/25/50 piece(s)/kit)
3. Instruction manual (1copy/bag, 1copy/kit)

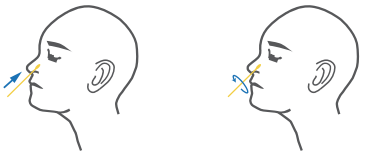
【Optional components】
□ Medical waste bag (1 piece/bag, 1/5/10/25/50 piece(s)/kit)
□ Swab (1 piece/bag, 1/5/10/25/50 piece(s)/kit)
Note: The components in different batch kits are not interchangeable.

【Storage conditions and validity】
Storage conditions: The product should be stored in a dry place at 2-30°C protected from light, and do not freeze.
Validity period: 24 months.
The reagent should be used as soon as possible within 1 hour after the aluminum foil bag is opened; it is recommended to use it immediately after opening under high temperature and high humidity conditions.

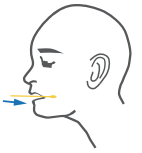
【Sample requirements】
1. This test kit is suitable for sample types of human rash exude, nasal swab, and oropharyngeal swab.
2. The swab for collecting the sample is a plastic rod swab with nylon flocking/absorbent cotton/polyester fiber tip.
3. Sample collection
3.1 Rash exudates
Step 1: Wipe the swab back and forth 6 times with slight force on the ulcerated skin.
Step 2: Immerse the swab head into the extraction tube with buffer provided with the kit.



3.2 Nasal swab
Step 1: When collecting samples, first blow the nose with toilet paper, carefully unpack the nasal swab, and avoid touching the swab head.
Step 2: Raise the head of the subject slightly, hold the swab in one hand and slowly insert the swab head into one nostril 1-1.5 cm backward along the bottom of the lower nasal passage (for subjects aged 2-14 years, insert the swab 1 cm deep into the nostril). Rotate it at least 4 times (the duration is not less than 15 seconds), and then use the same swab to repeat the same operation for the other nasal cavity.
Step 3: Immerse the swab head into the extraction tube with buffer provided with the kit.



3.3 Oropharyngeal swab
Step 1: Raise the head of the subject slightly, the mouth is opened wide, and an "ah" sound is issued to expose the pharyngeal tonsils on both sides.
Step 2: Insert the swab over the base of the tongue, and wipe the pharyngeal tonsils on both sides of the subject with slight force back and forth at least 3 times, and then wipe up and down the posterior pharyngeal wall at least 3 times.
Step 3: Immerse the swab head into the extraction tube with buffer provided with the kit.



4. Sample Storage
The virus sampling solution or the buffer provided by this kit should be used as soon as possible after sample collection, and the processed samples should be tested as soon as possible within 6 hours.
The specimens can be stored for 3 days at 2-8°C. For long-term storage, specimens should be stored below -20°C.

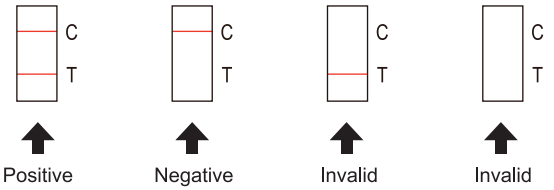
Note: The sampling method will affect the test results. It is recommended that the sampling personnel operate according to the requirements of the instructions.
During the sampling process, the contamination of the sampling swab should be avoided, and it should be tested immediately after sampling.

【Test method】
1. Preparation before testing
1.1 Please read the instruction manual carefully, check whether the reagents are within the validity period, and check whether the components of the kit are missing or damaged.
1.2 Return the reagents and samples to room temperature before testing.
1.3 Clean or disinfect your hands.
2. Sample processing
2.1 Remove the sealing film from the extraction tube.
2.2 Insert the sampled swab into the extraction tube, immerse the swab in the buffer, and rotate and mix for at least 30 seconds. Meantime, squeezing the swab head with your hand from the outer wall of the extraction tube for at least 5 times.
2.3 Squeeze the buffer from the swab head through the outer wall of the extraction tube with your hand, and take out the swab.
2.4 Put the squeezed swab into a medical waste bag.
2.5 Cover the extraction tube for later use.
3. Testing
3.1 Tear open the aluminum foil bag along the incision site, take out the test strip and place it on a horizontal, dry surface.
3.2 Slowly add 3 drops (about 75 μL) of the treated sample buffer to the sample well nd start timing.
3.3 Interpret the result within 10 minutes, and the result is valid within 30 minutes.
3.4 All used consumables, test cards and other wastes should be placed in medical waste bags and properly disposed of in accordance with relevant national regulations.
3.5 Wash or disinfect your hands again.
Note:Please interpret the results within the specified time, and interpreting less or more than this time may lead to wrong results.

【Interpretation of test results】
Positive: A colored band in the quality control area (C) and a colored band in the test area (T), indicating the specimen contains monkeypox virus antigens.
Note: The colored bands in the test area (T) may appear in different shades of color. However, within the specified observation time, no matter the color of the colored band is dark or light, even if there is only a very weak colored band, it should be judged as a positive result. If you suspect monkeypox virus infection, please report it immediately and seek medical treatment according to the regulations.

Negative: Only one colored band appears in quality control area (C), and there is no colored band appears in test area (T). Negative results indicated that monkeypox virus antigen is not detected in the specimen.
Note: A negative result cannot completely rule out the possibility of infection. Follow-up treatment should be carried out in accordance with local epidemic prevention and control policies. If necessary, it is recommended to go to the hospital for further examination.

Invalid: There is no colored band appears in the quality control area (C), the result is considered to be invalid.
Note: Invalid results may be caused by improper operations or the deteriorated reagent beyond the expiration date. In any case, it should be retested. If the problem persists, stop using this batch of products immediately and contact with your local supplier.



【Limitations of test methods】

1. This product is only used for in vitro diagnosis of human rash exudate, nasal swab, and oropharyngeal swab samples. The test results are for clinical reference only and should not be used as the only basis for clinical diagnosis and treatment. Clinical management of patients should combine with the symptoms, signs, medical history, other laboratory tests, treatment response and epide-miological information. It is recommended to retest suspicious samples at intervals.
2. This product only provides qualitative detection of monkeypox virus in samples and cannot be used for quantification. If you need to detect the specific content of a certain index, please use relevant professional instruments.
3. The accuracy of the test is affected by the sample collection process. Any mistakes in the sample collection and storage process can lead to false negative results. If cross-contamination occurs during sample processing, false positive results may occur. Avoid high temperature and direct sunlight.
4. This product is used for preliminary screening. Due to the limitation of detection methodology, the possibility of monkeypox virus infection cannot be ruled out for a negative result. It needs to be combined with other test results and comprehensive clinical judgment to make an accurate diagnosis.

【Performance characteristics】

Use the enterprise reference product for testing, and the results should meet the requirements of the reference product.
1. Negative coincidence rate: The enterprise negative reference products (N1-N10) are used for testing, and the results are all negative.
2. Positive coincidence rate: The enterprise positive reference products (P1-P10) are used for testing, and the results are all positive.
3. Minimum detection limit: The enterprise minimum detection limit reference products (S1, S2, and S3) are used for testing. S1 should be positive, S2 can be positive or negative, and S3 is negative.
4. Repeatability: The enterprise repeatability reference products (R1 and R2) are tested for 10 times respectively, and the test results of R1 and R2 are both positive, and there is no difference in color rendering.
5. Inter-batch difference: 3 different batches of kits are used to detect the enterprise repeatability reference products R1, R2. R1, R2 are all positive, and there is no difference in color rendering.
6. Specificity:
6.1 Interfering substances: The test results of this kit are not affected by mucin, blood (human), Sanhuang tablets, Niuhuangjiedu tablets, Pudilan anti-inflammatory oral liquid, watermelon frost spray, Kaihoujian spray, histamine hydrochloride, loratadine, cetirizine, acyclovir, oseltamivir, ribavirin, levofloxacin, azithromycin, ceftriaxone, meropenem, acetaminophen, aspirin, tobramycin, vitamins A, etc.
6.2 Cross-reaction: This test reagent do not cross-react with the following substances within a certain range: Staphylococcus aureus, Streptococcus pyogenes, Pseudomonas aeruginosa, Candida albicans, Propionibacterium, Diphtheroids, Varicella-Zoster Virus, Rubella Virus, Herpes Simplex Virus-1/-2, human herpes virus 6, human herpes virus 7, human herpes virus 8, measles virus, enterovirus, Treponema pallidum, dengue virus, smallpox virus (pseudovirus), vaccinia virus, mouse pox virus, Molluscum contagiosum virus, Turner pox virus (pseudovirus), Yaba virus (pseudovirus), and novel coronavirus.

【Precautions】

1. Please read the instruction manual carefully before use, and carry out the test operation in strict accordance with the kit instructions.
2. Pay attention to safety measures during operation, such as wearing gloves.
3. This product is a one-time use in vitro diagnostic product, please do not reuse it.
4. If the aluminum foil bag is found to be damaged, do not use it. Use the test pad as soon as possible after opening the foil bag.
5. The temperature has a great influence on the test results. It should be tested at room temperature.
6. Do not mix test cards and sample diluents from different batches.
7. This reagent does not contain any pathogens, but wastes such as reagents, swabs, extraction tubes and samples after testing must be treated as potential infectious substances and should be properly handled in accordance with the relevant regulations.

【References】

[1] Ye Fei, Song Jingdong, Zhao Li, Zhang Yi, Xia Lianlian, Zhu Lingwei, Ren Jiao, Wang Wenling, Wu Guizhen, Tian Houwen, Tan Wenjie. Molecular and serological tests confirmed a case of monkeypox virus infection in Sierra Leone, West Africa in 2017[J]. Chinese Journal of Zoonoses, 2019, 35(06): 535-538.

[2] Guan Qianqian. Preparation and identification of monkeypox virus-specific monoclonal antibodies [D]. Chinese Center for Disease Control and Prevention, 2017.

[3] Lv Qinfeng, Zheng Wei, Wu Zhonghua, Luo Peng, He Lei, Xu Qi, Li He. Study on the detection method of monkeypox virus LAMP [J]. China Journal of Hygiene Inspection, 2013, 23(05): 1170 -1173.

[4] Li Yana. Research progress on human transmission of monkeypox virus and its detection methods [J]. Medical Review, 2009, 15(18): 2800-2802.

LABEL INTRODUCE FOR USER

Abbreviation	Explanation	Abbreviation	Explanation
IVD	In vitro diagnostic medical device	LOT	Batch code
Σ	Contains sufficient for<n>tests		Date of manufacture
	Manufacturer		Use-by date
EC REP	Authorized representative in the European Community	2℃ 30℃	Temperature limit: 2~30℃
CE	CE Marking		Keep away from sunlight
REF	Catalogue number		Keep dry
	Consult instructions for use		Do not re-use
	Biological risks		Do not use if package is damaged

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EC REP

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GUARANTEE AND TECHNICAL SUPPORT

If invalid message repeats or need technical support,please contact Synthgene Medical Technology Co., Ltd. Customer Service and Support Center.

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