Mpox disease Emergency Use Listing Procedure (EUL) for IVDs
Product: EasyNAT Monkeypox Virus Assay
EUL Number: MPXV-13201-208-00
Outcome: Accepted.

The EUL process is intended to expedite the availability of in vitro diagnostics needed in public health emergency situations and to assist interested UN procurement agencies and Member States in determining the acceptability of using specific products in the context of a Public Health Emergency of International Concern (PHEIC), based on an essential set of available quality, safety, and performance data. The EUL procedure includes the following:

- Quality Management Systems Review and Plan for Post-Market Surveillance: a desktop review of the manufacturer's Quality Management System documentation and specific manufacturing documents.
- Product Dossier Review: assessment of the documentary evidence of safety and performance. This evaluation of limited scope is to verify critical analytical and performance characteristics.

The EasyNAT Monkeypox Virus Assay, with product code U202028-20, CE-Mark regulatory version manufactured by Ustar Biotechnologies (Hangzhou) Ltd., Bldg 1,2 & 4, 611 Dongguan Road, Binjiang District, 310053, Hangzhou, Zhejiang Province, PEOPLE'S REPUBLIC OF CHINA, was listed as eligible for WHO procurement on 9 May 2025.

Intended use:

According to the claim of intended use from Ustar Biotechnologies (Hangzhou) Ltd., Inc., *"The EasyNAT Monkeypox Virus Assay is an automated, invitro nucleic acid amplification test used to qualitatively detect the DNA of monkeypox virus clade I and clade II (including Ib) in lesion swabs specimens from individuals suspected of monkeypox virus infection by their healthcare provider. This kit can be used as an aid in the clinical diagnosis of monkeypox virus infections. The kit is designed for laboratory professional use."*

Validated specimen type:
Human lesion swabs (of acute pustular or vesicular rash from individuals suspected of mpox) collected using Nylon flocked swabs by a healthcare provider.

Test kit contents:

Component	Number of tests and product code (20 T/kit, U202028-20)
Cartridge	20
Positive Control	1 tube
Negative Control	1 tube
Instructions for Use (IFU)	1

Items required but not provided:

- Nucleic Acid Amplification and Detection Analyzer (Manufacturer: Ustar
- Biotechnologies (Hangzhou) Ltd.), EasyNAT System, with Software Version 1 or later.
- Flocked swab and viral transport media (VTM/UTM).
- Calibrated precision pipettes.
- Filtered sterile pipette tips.

Storage:
The reagents must be stored at 2–8 °C until the expiration date provided on the label.

Shelf-life upon manufacture:
The shelf-life is currently assigned 12 months dating.

Warnings/limitations:

Please refer to the IFU attached to this report.

Product dossier assessment

Ustar Biotechnologies (Hangzhou) Ltd. submitted a product dossier for the EasyNAT Monkeypox Virus Assay in alignment with the Instructions and requirements for Emergency Use Listing (EUL) Submission: In vitro diagnostics detecting Monkeypox virus nucleic acid (PQDx_457). The WHO reviewed the information provided in the dossier.

The risk-benefit assessment conclusion was acceptable.

Quality Management Systems Review

To establish eligibility for WHO procurement, Ustar Biotechnologies (Hangzhou) Ltd. was asked to provide up-to-date information about the status of its quality management system.

Based on the WHO's review of the submitted quality management system documentation, Ustar Biotechnologies (Hangzhou) Ltd., Inc., provided sufficient information to fulfil the requirements described in the Instructions and requirements for EUL Submission: In vitro diagnostics detecting Monkeypox virus nucleic acid (PQDx_457).

The quality management system assessment conclusion was acceptable.

Plan for Post-Market Surveillance

Post-market surveillance, including monitoring all customer feedback, detecting and acting on adverse events, product problems, non-conforming goods and processes is a critical component of minimising the potential harm of an IVD listed for emergency use.

The following post-EUL activities are required to maintain the EUL status:
1. Notification to WHO of any planned changes to a prequalified product, in accordance with "*WHO procedure for changes to a WHO prequalified in vitro diagnostic" (document number PQDx_121*)[1]; and
2. Post-market surveillance activities, in accordance with "*WHO guidance on post-market surveillance of in vitro diagnostics" (ISBN 978 92 4 150921 3)*[2].

Ustar Biotechnologies (Hangzhou) Ltd. is also required to submit an annual report summarising sales data and all complaints. Certain complaints and changes to the product must be notified immediately to WHO, as per the above-mentioned documents. The sales data will serve as denominator data to guide the frequency of re-inspection.
The manufacturer has committed to ensuring that post-emergency use listing safety, quality, and performance monitoring activities are in place, which are in accordance with WHO guidance on post-market surveillance of in vitro diagnostics.

Scope and duration of procurement eligibility

The EasyNAT Monkeypox Virus Assay, with product code U202028-20, manufactured by Ustar Biotechnologies (Hangzhou) Ltd., is eligible for WHO procurement for 12 months from the day of listing. The assay detects the monkeypox virus DNA clade I and clade II (including clade Ib). This listing does not infer that the product meets WHO prequalification requirements and does not mean that the product is listed as WHO-prequalified.

As part of the ongoing requirements for listing as eligible for WHO procurement, Ustar Biotechnologies (Hangzhou) Ltd. must engage in post-market surveillance activities to ensure that the product continues to meet safety, quality, and performance requirements. Ustar

[1] https://iris.who.int/bitstream/handle/10665/251915/WHO-EMP-RHT-PQT-2016.01-eng.pdf;jsessionid=830C82950055325AF37A0A8302BE4623?sequence=1

[2] https://www.who.int/publications/i/item/9789240015319

Biotechnologies (Hangzhou) Ltd., Inc., is required to notify WHO of any complaints, including adverse events related to the use of the product, within 10 days.

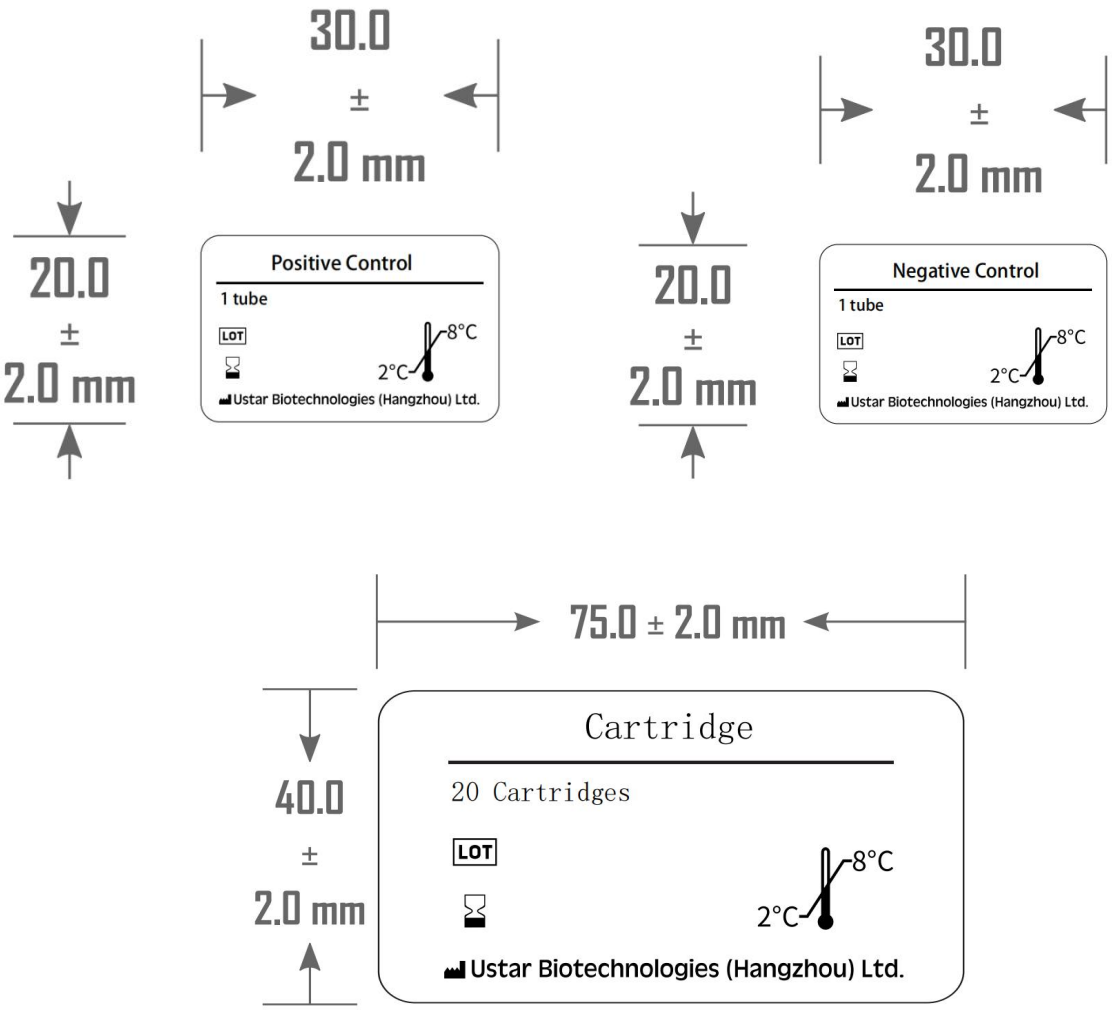
WHO reserves the right to rescind eligibility for WHO procurement if additional information on the safety, quality, and performance during post-market surveillance activities and if new data becomes available to WHO that changes the risk-benefit balance.

Labelling

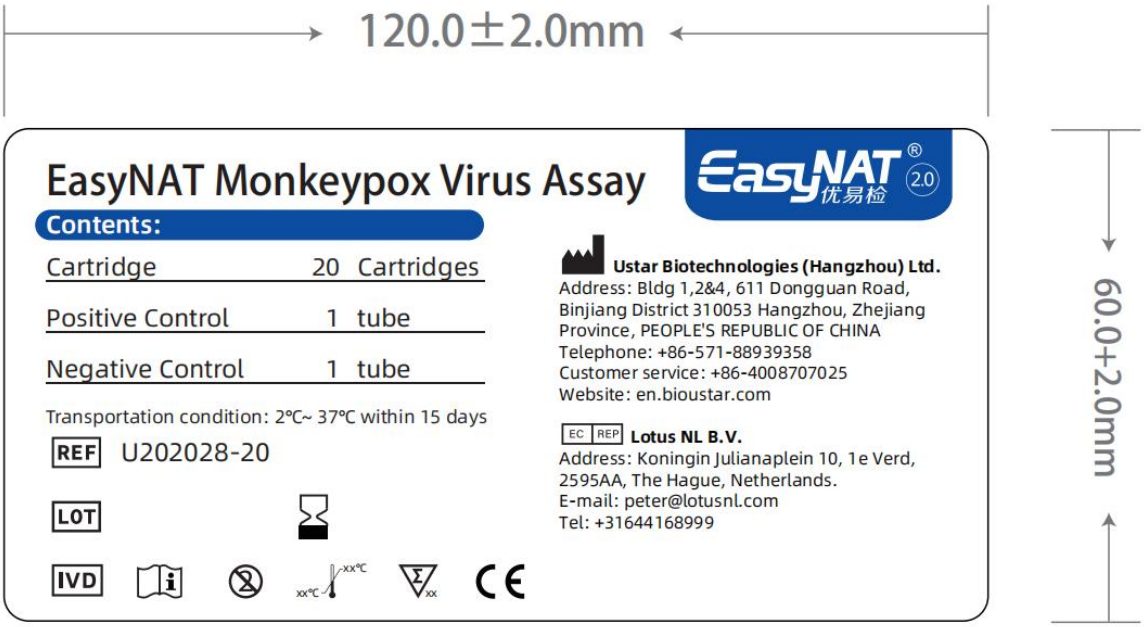
1. **Labels**
2. **Instructions for use**

1.0 Labels

1.1 Components Labels



1.2 Label of Outer Package

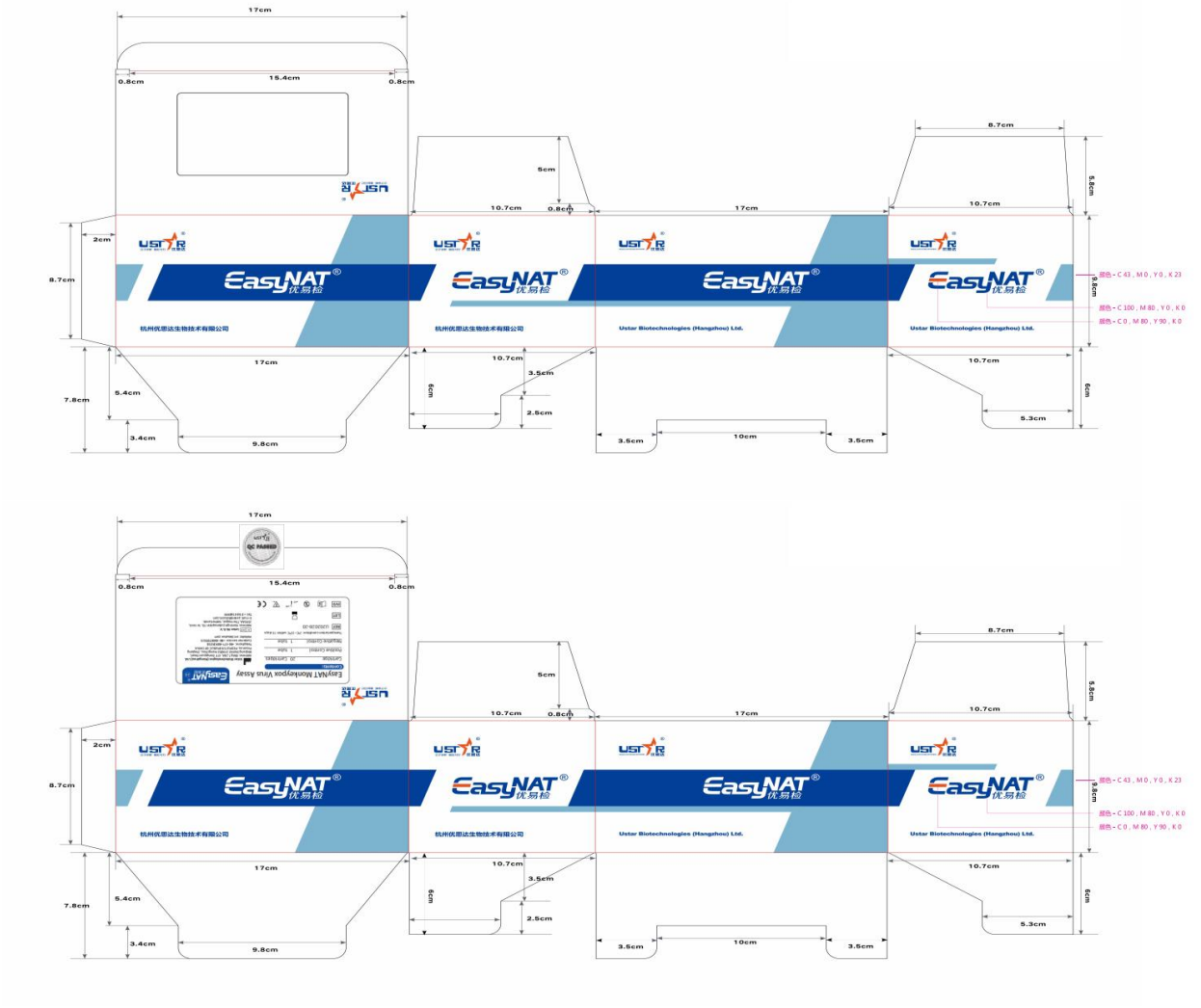


1.3 Label of QC Passed

Square：35mm × 35 mm
Circle: 30mm × 30 mm

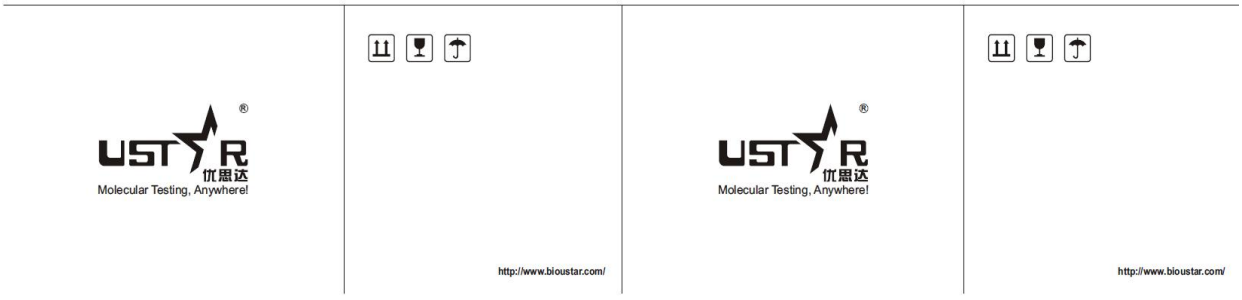
1.4 Outer Package

Size of outer package box: 170mm ×110mm×100mm



1.5 Shipping Package

Size of shipping package box:



2.0 Instructions for Use[3]

[3] English version of the IFU was the one that was assessed by WHO. It is the responsibility of the manufacturer to ensure correct translation into other languages.

EasyNAT Monkeypox Virus Assay

Instructions for Use

CE IVD

1 PRODUCT NAME
EasyNAT Monkeypox Virus Assay

2 SPECIFICATION
20 tests/kit, Product Code: U202028-20

3 INTENDED USE
The EasyNAT Monkeypox Virus Assay is an automated, *in vitro* nucleic acid amplification test used to qualitatively detect the DNA of monkeypox virus clade I and clade II (including Ib) in lesion swabs specimens from individuals suspected of monkeypox virus infection by their healthcare provider. This kit can be used as an aid in the clinical diagnosis of monkeypox virus infections. The kit is designed for laboratory professional use.

4 SUMMARY AND EXPLANATION
The EasyNAT Molecular Diagnostic Test is a qualitative test run on the EasyNAT® System for the detection of Monkeypox Virus (MPXV) DNA in lesion swabs specimens. Internal Control (human β-actin gene) is included in the cartridge to monitor the test process. The EasyNAT Molecular Diagnostic Test includes External positive and negative control material and may be used for quality control.

5 MATERIALS PROVIDED

S/N	Materials	Specification	Quantity	Main Components
1	Cartridge	1 test/cartridge	20 cartridges	Specific primers and probe deoxyribonucleoside triphosphate (dNTP), DNA polymerase and all buffers required are prefilled in the cartridge
2	Positive Control	1.2 mL/tube	1 tube	With target sequence
3	Negative Control	1.2 mL/tube	1 tube	Without target sequence
4	Instructions for Use	1 pcs/kit	1 pcs	/

Note:
1. Do not mix the materials from different kit lots.
2. Materials required but not provided:
2.1 Nucleic Acid Amplification and Detection Analyzer (Manufacturer: Ustar Biotechnologies (Hangzhou) Ltd.), EasyNAT® System, with Software Version 1 or later.
2.2 Flocked swab and viral transport media (VTM/UTM).
2.3 Calibrated precision pipettes.
2.4 Filtered sterile pipette tips.

6 WARNING AND PRECAUTIONS

6.1 General
- For *in vitro* diagnostic use.
- For professional use only.
- Pathogenic microorganisms, including hepatitis viruses and Human Immunodeficiency Virus, may be present in clinical specimens. Treat all biological specimens, including used cartridges, as if capable of transmitting infectious agents. Because it is often impossible to know which might be infectious, all biological specimens should be treated with standard precautions. Guidelines for specimen handling are available from the U.S. Center for Disease Control and Prevention and the Clinical and Laboratory Standards Institute[1][2].
- Follow your institution's safety procedures for working with chemicals and handling biological samples.
- Biological specimens, transfer devices, and used cartridges should be considered capable of transmitting infectious agents requiring standard precautions. Follow your institution's environmental waste procedures for proper disposal of used cartridges and unused reagents. These materials may exhibit characteristics of chemical hazardous waste requiring specific national or regional disposal procedures. If national or regional regulations do not provide clear direction on proper disposal, biological specimens and used cartridges should be disposed per WHO [World Health Organization] medical waste handling and disposal guidelines.
- In the event of a serious incident involving the product, please inform Ustar and report to the competent authority where the user and/or the patient is located.

6.2 Assay/Reagent
6.2.1 Testing
- Each single-use cartridge is used to process one test. Do not reuse processed cartridges.
- Ensure that the work area and the required items are regularly disinfected with 1% sodium hypochlorite, 75% alcohol or ultraviolet light.
- Carry out laboratory quality control in accordance with local regulations to avoid false positive results caused by laboratory contamination.
- Manage protective gloves, clothing *etc.* used in the test separately to avoid introduction of contamination and errors in the test results.
- Do not squeeze the middle and lower parts of the Cartridge when operating.
- Keep the QR code of the Cartridge (located on the cap) is clean, clear and not scribbled or covered to ensure the QR code can be read.
- Operate in strict accordance with this Instructions for Use. Do not load the cartridge into the instrument module before entering the sample information.
- The Positive Control, if applicable, should be added after all samples and the Negative Control have been loaded.
- Centrifuge the Positive Control before opening the cap, and keep the time of opening as short as possible.
- Do not open the module door of the applicable instrument during the test.
- Do not open the cap of used cartridges.

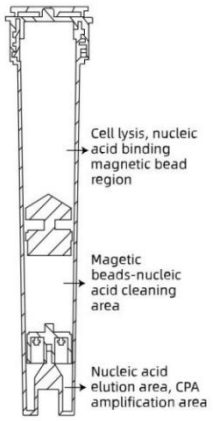
6.2.2 Result Viewing
- Upon completion of the test, the results will be displayed and saved automatically by the instrument. Check previous test results in the View window of the instrument.

6.2.3 Operation
- Take protective measures as required when handling samples.
- If the reagent enters your eyes or mouth, or irritates your skin, rinse immediately with plenty of water and seek medical advice if necessary.
- Ensure that there is no liquid or other adherents on the outer wall of the cartridge before loading it on the instrument.

6.2.4 Precautions for Use
- Store the kit under the storage conditions specified in this Instructions for Use.
- Remove only the required amount of reagents for testing to avoid product deterioration, and store the remaining ones under the specified storage conditions.
- Do not use the Positive Control for any other purpose (e.g. dilution or addition to specimens) except as specified in this Instructions for Use to avoid contamination of the test environment.
- Do not use reagents or cartridges that have passed the expiration date.
- Do not mix reagents from different batches. Do not refill reagents.
- Do not use a cartridge that has damaged or leaked.

6.2.5 Disposal
Dispose of used cartridge as medical waste in accordance with local, regional, national, and/or international regulations.

7 PRINCIPLE OF THE PROCEDURE



In this assay, the cartridge is equipped with multiple hydrophobic separation layers to isolate the lysis buffer, wash buffer and reaction reagents. The specimens are chemically lysed in extraction buffer at high temperature to release the nucleic acids under the heating control of the external instrument. An external magnetic field provided by the instrumentallows the nucleic acid samples to pass through different layers. Finally, the nucleic acids are eluted in the cartridge legs where the amplification reaction occurs. Thus, it enables fully automatic "all-in-one" nucleic acid analysis in which the lysis, binding, washing, elution and amplification reaction are completed in a closed cartridge.

The Cartridge is pre-loaded with nucleic acid purification and elution reagents and cross-priming amplification (CPA)[3] reagents. The assay contains two amplification system to detect two different conserved regions of F3L-F4L gene of monkeypox virus. To run a test, the operator only needs to add the sample to the cartridge. Under the control of applicable instrument, the DNA in the sample are extracted and purified automatically. The purified DNA are mixed with CPA reagent in the cartridge, which are heated by the instrument for isothermal amplification. Meanwhile, the fluorescence probe specifically binds to the DNA template in the primer amplification region and amplifies to produce fluorescence signal. The instrument collects the real-time fluorescence signal and analyzes the changes to report the test result automatically.

The assay also includes reagent for the detection of an internal control (IC) that is composed of a CPA system for specific detection of endogenous gene fragments to monitor the extraction, purification or amplification reactions.

8 STORAGE AND HANDLING
- Storage: at 2℃~8℃, ≤+ 80% RH.
- Shelf life: 12 months.
- Transportation: at ambient temperature (2℃~37℃) within 15 days, allow brief periods at 40℃.
- Use the Cartridge for testing immediately after opening the cap and adding the sample. If not, store the cartridge at 2℃~8℃ and test within 8 hours.

9 SPECIMEN COLLECTION, TRANSPORT, AND STORAGE
This kit has been validated for testing lesion swabs specimens. Sample collection, transportation, and storage were performed completely according to the 'Guidelines for Collecting and Handling Specimens for Mpox Testing'[4] from CDC.

9.1 Specimen Collection
Use a sterile swab to wipe the exudate with slight force for at least 3 times. Put the swab sample in the tube, break the swab stick off near the tip to permit tightening of the cap. Place the tube in a tube stand.

9.2 Specimen Storage
Collected samples should be sent for testing as soon as possible. Samples which can be tested within 7 days should be stored at 2℃~8℃; If they cannot be tested within 7 days, they should be stored for up to 30 days at -20℃ or lower. Freeze and thaw no more than 3 times.

9.3 Specimen Transport
Ship specimens on dry ice, if available. Do not ship specimens at 25℃~40℃.

10 APPLICABLE INSTRUMENT
Nucleic Acid Amplification and Detection Analyzer (EasyNAT® System) produced by Ustar Biotechnologies (Hangzhou) Ltd.. The laboratory should be equipped with a 110V~220V power supply and a stable worktable. The system could be run at 5~40℃ and 25~90% relative humidity.

11 PROCEDURE
Note: The test should be performed by a trained professional. Please operate in strict accordance with the steps below.
11.1 Specimen Testing
Before testing, if the sample is stored at -20°C or below, transfer it to 2~8°C until completely thawed, then proceed with the test.
11.1.1 Preparing the Cartridge
Add 200 μL of sample to the Cartridge. Reset the cartridge cap and shake to mix well for subsequent testing (paraffin may float but will not affect following steps).
11.1.2 Starting the Test
Note: This section lists the basic steps for running the test. For detailed instructions, see the operator manual of the applicable instrument.
(1) Enter cartridge information: Scan the QR code on the cap of the Cartridge prepared according to Section 11.1.1. Using the QR code, the system automatically loads the cartridge information and the amplification detection program MPXV0. If the QR code on the cartridge does not scan, then enter the information manually by tapping ***[Scan QR code on the cartridge]*** on the touch screen of the applicable instrument.
(2) Enter sample information: Scan the sample barcode. Using the barcode, the system automatically loads the sample information. If scanning fails, then enter the information manually by tapping Scan the sample barcode on the screen of the applicable instrument.
(3) Start test: Load the cartridge into the instrument module. Close the module door. Tap ***[Start]*** on the touch screen of applicable instrument. The test will run with a countdown displayed on the screen.The total test duration is about 29 minutes.
11.1.3 Viewing Results
Upon completion of the test, the results will be displayed and saved automatically. For more detailed instructions on how to view the results, see ***INTERPRETATION OF RESULTS***.
11.2 Quality Control Testing
(1) Add 200μL of Positive Control or Negative Control to the Cartridge, and screw the cap tightly.
(2) Follow the steps described in ***PROCEDURE***Section 11.1.2 and 11.1.3.

Note: Prior to initial use of any new instrument or new lot of the reagent, both positive and negative control tests shall be performed.

Note:

(1) In case of a positive result from the negative control, please decontaminate the testing environment and repeat the test. If the issue persists, contact customer service of the manufacturer.

(2) For invalid control results (positive and/or negative), make sure follow the IFU. If the issue persists, repeat the test in an alternate well. If the problem continues, contact customer service of the manufacturer.

12 CUT-OFF VALUE

Upon completion of the test, the results are reported automatically by the applicable instrument. The results of MPXV0 and IC are displayed respectively.

In the amplification area, FAM fluorescence reports MPXV results (MPXV0l/MPXV0r), and CY5 fluorescence reports internal control results (ICl/ICr).

If the Tt value of MPXV0 is shown as N/A, and the Tt value for IC ≤24, test result for MPXV is 'Negative'.

If the Tt value of MPXV0 ≤24, test result for MPXV is 'Positive'.

If the Tt value of IC is shown as N/A, test result for IC is 'Negative'.

If the Tt value of IC≤24, test result for IC is 'Positive'.

13 INTERPRETATION OF RESULTS

Table 1. EasyNAT Monkeypox Virus Assay Results and Interpretation

Tt Value				Result	Interpretation
MPXV0l	MPXV0r	ICl	ICr		
≤24	≤24	≤24	≤24	POSITIVE	Monkeypox Virus was detected in the sample.
≤24	≤24	≤24	N/A		
≤24	≤24	N/A	≤24		
≤24	≤24	N/A	N/A		
≤24	N/A	≤24	≤24		
≤24	N/A	≤24	N/A		
≤24	N/A	N/A	≤24		
≤24	N/A	N/A	N/A		
N/A	≤24	≤24	≤24		
N/A	≤24	≤24	N/A		
N/A	≤24	N/A	≤24		
N/A	≤24	N/A	N/A		
N/A	N/A	≤24	≤24	NEGATIVE	No Monkeypox Virus was detected in the sample, and the IC testing met the acceptance criteria.
N/A	N/A	≤24	N/A		
N/A	N/A	N/A	≤24		
N/A	N/A	N/A	N/A	INVALID	The IC testing did not meet the acceptance criteria, and it was uncertain whether Monkeypox Virus was in the sample.
N/A and no amplification curve				NO RESULT	Insufficient data are collected to produce a test result.

14 Retest

14.1 Reasons to Repeat the Assay

If any of the following test results occur, retest with a new Cartridge.

- An INVALID result indicates that the sample was not properly processed, CPA test reagent was inhibited, or the sample was inadequate.
- A NO RESULTS indicates that insufficient data were collected. For example, the operator stopped a test that was in progress.
- Abnormal results of external quality control (Positive Control and Negative Control) were reported. For example, a positive result reported on the Negative Control indicates that the experimental environment may be contaminated.

14.2 Retesting Conditions

- For an INVALID result, perform a negative control test in the same well, while testing the same sample at a 3-fold dilution in another well. If the negative control is normal but the diluted sample still yields invalid results, re-sampling is required. If the re-sampled specimen still produces invalid results, contact customer service of the manufacturer.
- For A NO RESULTS, the sample should be reloaded and re-tested.

15 Quality Control

Each test includes an Internal Quality Control and External Quality Control.

- **Internal Control**

Internal Control (IC) is used to ensure that sample collection, processing is adequate and to monitor amplification reagent failure or instrument malfunction.

The IC is not required in an analyte positive sample, and should meet the acceptance criteria in an analyte negative sample, otherwise the test result is invalid.

- **External Control**

The Positive Control is used to monitor amplification reagent failure or instrument malfunction. Negative Control is used to monitor reagent or the environmental contamination. The test result of Positive Control should be 'POSITIVE', while the test result of Negative Control should be 'NEGATIVE'.

- **Metrological Traceability**

The metrological traceability of values is assigned to control materials by dPCR (digital PCR).

16 LIMITATIONS

- Test results from this assay are for clinical reference only. Results from the assay should be interpreted in conjunction with patients' symptoms, signs, medical history, other laboratory data and therapeutic effects for treatment or other patient management decisions.
- The detection of Monkeypox Virus is contingent upon the viral load in the sample. False-negative results may occur due to patient-related factors (e.g., presence, type, and duration of symptoms), improper sample collection methods (e.g., inadequate collection, transportation, or handling), infection stage (e.g., samples collected too early or too late during the illness), and/or the presence of interfering substances.
- Mutations or other changes within the regions of the genomes covered by the primers and/or probes in the assay may result in false negative results.
- Other unverified interfering substances or amplification inhibitors may lead to false negative results.
- False-positive results may arise from contamination during specimen preparation or handling, or cross-contamination among patient specimens.

17 PERFORMANCE CHARACTERISTICS

17.1 Trueness

Trueness of the assay was 100%, and results showed that:

Negative commercial reference panels: All negative for MPXV.

Positive commercial reference panels: All positive for MPXV.

17.2 Analytical Sensitivity (Limit of Detection (LoD))

The limit of detection (LoD) of the EasyNAT Monkeypox Virus Assay is 200 copies/mL for MPXV.

17.3 Analytical Specificity

17.3.1 Cross-Reactivity

Potential cross-reactivity was assessed in silico by calculating the % homology of the genomic sequence of organisms including:

Acinetobacter calcoaceticus, Bacteroides fragilis, Buffalopox virus, Camelpox virus, Candida albicans, Chlamydia trachomatis, Corynebacterium diphtheriae, Corynebacterium jeikeium, Cowpox virus, Ectromelia virus, Enterococcus faecalis, Escherichia coli, HSV1, HSV2, Homo sapiens, HPV, Lactobacillus, Mycoplasma genitalium, Mycoplasma pneumoniae, Neisseria gonorrhoeae, Orf virus, Pseudomonas aeruginosa, Staphylococcus aureus, Staphylococcus epidermidis, Streptococcus agalactiae, Streptococcus Group C, Streptococcus Group G, Streptococcus mitis, Streptococcus pyogenes, Treponema pallidum, Trichomonas vaginalis, Trichophyton rubrum, Vaccinia virus, Varicella-zoster virus, Variola virus, Cutibacterium acnes, Dengue Virus, Human Herpesvirus 6/7/8, Measles morbillivirus, Tanapox Virus, Yaba virus, Molluscum contagiosum virus, Rubella Virus, Enterovirus, Human Genomic DNA. All organisms listed are predicted to not cross-react with this assay.

17.3.2 Exogenous and Endogenous Interfering Substances

Positive and negative samples were prepared in pooled negative sample and tested in the presence of potentially interfering substances including: Pooled negative matrix, Abrevea, Acyclovir, Albumin, Blood/EDTA, Mucin, Hydrocortisone cream, Benadryl cream/ointment, Carmex, Casein, Lanacane, KY Jelly, Douche, Neosporin, Female urine, Male urine, Feces, Seminal fluid, Zinc Oxide ointment, Vagisil cream, Cornstarch. All materials listed are not cross-react with this assay.

17.4 Clinical Performance

Performance characteristics of the EasyNAT Monkeypox Virus Assay were determined in a clinical study. The positive percent agreement of the test kit was 98.70%; the negative percent agreement was 100%, the overall percent agreement was 99.34%.

18 The summary of safety and performance

Intended users and patients can log in to the European database on medical devices (Eudamed) to request the summary of safety and performance (SSP) of the device or contact the manufacturer to obtain it.

19 REFERENCE

1. Centers for Disease Control and Prevention. Biosafety in microbiological and biomedical laboratories. (refer to latest edition).
2. CLSI Publication M29. Protection of laboratory workers from occupationally acquired infections; Approved Guideline. (refer to latest edition).
3. Xu G, Hu L, Zhong H, et al. Cross priming amplification: mechanism and optimization for isothermal DNA amplification. Sci. Rep. 2012;2:246.
4. http:www.cdc.gov/poxvirus/mpox/clinicians/prep-collection-specimens.html.

20 EXPLANATION OF SYMBOLS

IVD	*In vitro* diagnostic medical device		Do not re-use
	Temperature limit		Consult instructions for use
	Contains sufficient for <n> tests		Manufacturer
	Use-by date	LOT	Batch code
	Biological risks	REF	Catalogue number
	Do not use if package is damaged	EU REP	Authorized representative in the European Union
CE	CE Marking		

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21 INSTRUCTION VERSION AND MODIFICATION DATE

Approved on May 9, 2022. Version: A/0

Revised on October 18, 2024. Version: B/0

Revised on May 4, 2025. Version: B/1