Mpox disease Emergency Use Listing Procedure (EUL) for IVDs
Product: RADIONE Mpox Detection Kit
EUL Number: MPXV-13227-214-00
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 RADIONE Mpox Detection Kit, with product code RP001, Rest of the World regulatory version manufactured by KH Medical Co., Ltd., located at 181, 201 Jinwiseo-ro, Jinwi-myeon, Pyeongtaek-si, Gyeonggi-do, 17712, Republic of Korea, was listed as eligible for WHO procurement on 6 March 2025.

Intended use:

According to the claim of intended use from KH Medical Co., Ltd., "*The RADIONE Mpox virus Detection Kit is an in vitro diagnostic medical device, based on Real-time PCR technology, for the qualitative detection of Monkeypox virus (MPXV) including Clade 1, Clade 2, and Orthopox Generic Strain, in human skin lesion or swab specimens obtained from patients with signs and symptoms of Mpox.*
The kit is intended to aid in the diagnosis of Monkeypox virus infection. It is designed for use by trained healthcare professionals and laboratory personnel in clinical laboratories and point-of-care (POC) settings. The test is performed using the RADIONE point-of-care molecular diagnostic system, which automates nucleic acid extraction, amplification, and detection, requiring minimal manual intervention."

Validated specimen type:
Human skin lesion swabs collected using the NS-1 Swab Applicator (Cat. No. UTNS-1C) and immediately transferred into the validated transport medium (Noble Biosciences Clinical Virus Transport Medium, 3 mL).

Test kit contents:

Component	Number of tests and product code (24 T/k), (RP001)
Pre-filled PCR Tube	4 well-strip tube x 24 EA
Instructions for Use	1 EA

Items required but not provided:

- RADIONE instrument (Cat No. KM009 / S/W ver. nT01V1.0.14.34),
- RADIONE Universal DNA/RNA Extraction Kit (KP001),
- (includes the Extraction Cartridge),
- Cartridge Holder (provided with the equipment),
- Disposable powder-free gloves,
- Noble Biosciences Clinical Virus Transport Medium with NS-1 Swab Applicator (Cat No. UTNS-1C, standard nylon-flocked swab with a breakpoint),
- calibrated pipettes and sterile filter tips,
- RADIONE Mpox Positive control (Cat No. RP001-PC),
- Mini centrifuge (<4000rpm).

Storage:
The test kit must be stored at -25°C to -15°C.

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

Warnings/limitations:

Please refer to the Instructions for Use attached to this public report.

Product dossier assessment

KH Medical Co., Ltd. submitted the product dossier for the RADIONE Mpox Detection Kit 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, KH Medical Co., 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, KH Medical Co., Ltd 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].

KH Medical Co., 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 RADIONE Mpox Detection Kit, with product code RP001, manufactured by KH Medical Co., Ltd., is eligible for WHO procurement for 12 months from the day of listing. The assay detects the monkeypox virus nucleic acid, including Clade 1, Clade 2, and Orthopox Generic Strain. This listing does not infer that the product meets WHO prequalification requirements and does not mean

[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

that the product is listed as WHO-prequalified. As part of the ongoing requirements for listing as eligible for WHO procurement, KH Medical Co., Ltd. must engage in post-market surveillance activities to ensure that the product continues to meet safety, quality, and performance requirements. KH Medical Co., Ltd 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.

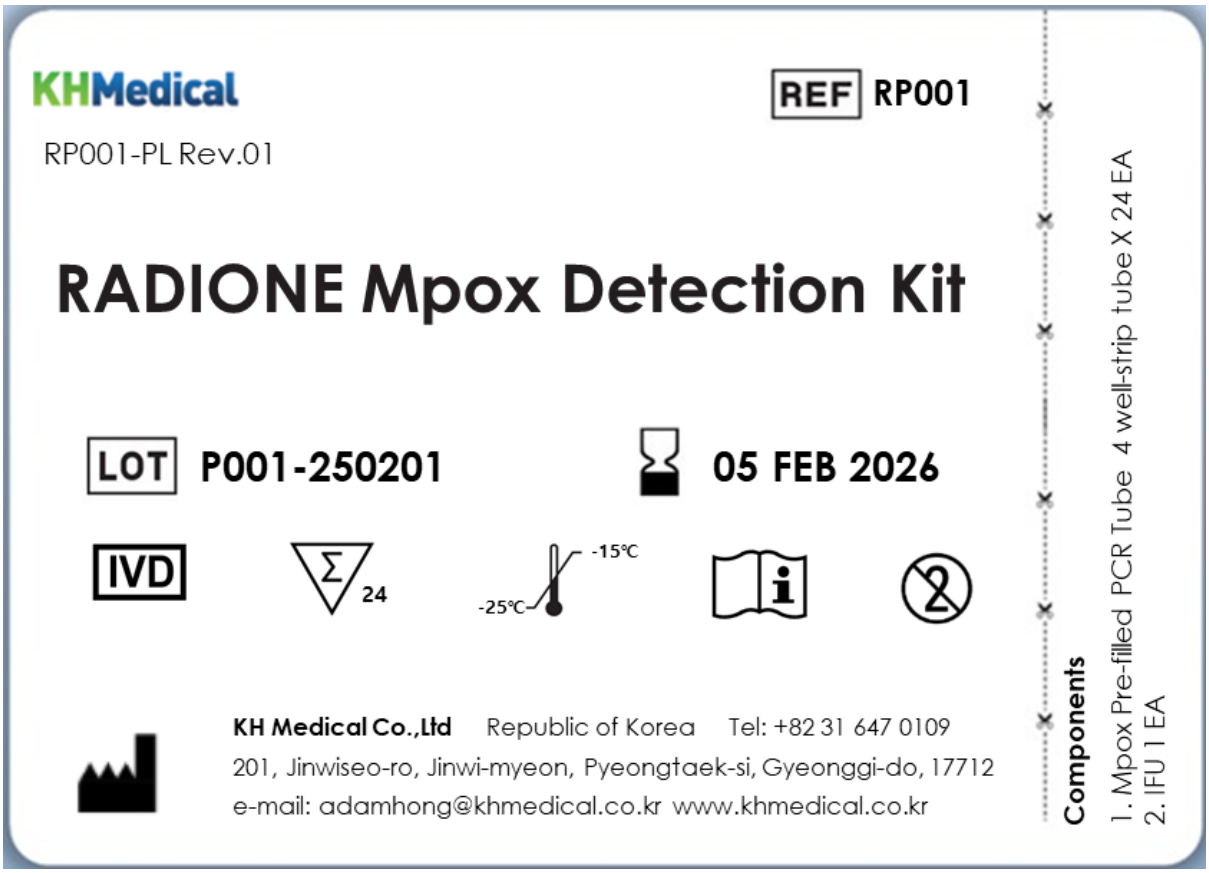
Labelling

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

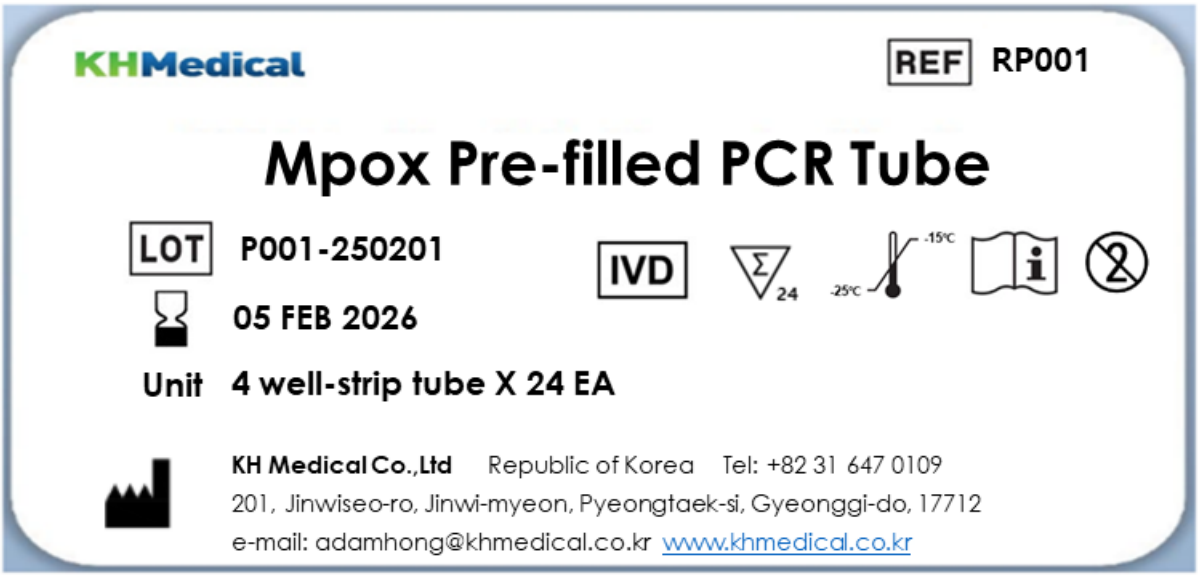
1.0 Labels

1.1 Packaging box

1.2 Box label



1.3 Aluminum Pouch label



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.

KHMedical

IVD | REF RP001

RADIONE Mpox Detection Kit

This instruction must be read carefully prior to use. Reliability of assay results cannot be guaranteed if there is any deviation from the instructions

1. Intended use

The RADIONE Mpox virus Detection Kit is an in vitro diagnostic medical device, based on Real-time PCR technology, for the qualitative detection of Monkeypox virus (MPXV) including Clade 1, Clade 2, and Orthopox Generic Strain, in human skin lesion or swab specimens obtained from patients with signs and symptoms of Mpox.

The kit is intended to aid in the diagnosis of Monkeypox virus infection. It is designed for use by trained healthcare professionals and laboratory personnel in clinical laboratories and point-of-care (POC) settings. The test is performed using the RADIONE point-of-care molecular diagnostic system, which automates nucleic acid extraction, amplification, and detection, requiring minimal manual intervention.

2. Principle of RADIONE system

2.1 System Overview

The RADIONE system is a fully automated Point-of-Care (POC) molecular diagnostic device that integrates nucleic acid extraction, amplification, and detection using real-time PCR technology. This enables rapid and accurate detection of MPXV DNA. The system is designed to significantly reduce the need for manual intervention. Users are only required to load samples and reagents, while the system independently carries out nucleic acid extraction, amplification, and detection to ensure reliable and efficient results.

The kit must be used together with the RADIONE Universal DNA/RNA Extraction Kit (KP001) on the RADIONE instrument (KM009), as they are designed to work in combination to ensure accurate results.

2.2 Principles of the procedure

The RADIONE Mpox Detection Kit is designed to detect Monkeypox virus (MPXV) DNA and differentiate between Clade 1, Clade 2, and Orthopox Generic Strain. The detection process relies on specific primers and probes that target conserved regions of the MPXV genome. The D14L gene is used for Clade 1a detection, while an intact region of the D14L gene is targeted for Clade 1b. The J2L gene serves as the target for Clade 2. This detection is performed using the TaqMan probe method, ensuring high specificity and sensitivity for MPXV detection.

The kit operates based on real-time PCR technology with fluorescence-based detection. The detection process begins with nucleic acid extraction, which is performed using the RADIONE Universal DNA/RNA Extraction Kit (KP001). This kit contains essential buffers, including lysis, washing, and elution buffers, which ensure effective viral RNA/DNA extraction. After extraction, the PCR amplification process begins. The master mix used in this step includes Taq DNA Polymerase for amplification, dNTPs for DNA synthesis, magnesium chloride buffer for enzyme function optimization, and fluorescent probes for real-time detection.

The RADIONE instrument (KM009) automates the testing process by integrating various functions. The system then performs automated nucleic acid extraction through a magnetic bead-based extraction system, which facilitates sample lysis, washing, and elution. Finally, the instrument carries out PCR amplification and fluorescence-based detection to confirm the presence of MPXV DNA.

To ensure accurate testing, the kit incorporates an Internal Control (IC), which monitors the entire testing workflow, from nucleic acid extraction to detection. The IC targets the human GAPDH gene using specific primers and a probe included in the master mix. By detecting the human GAPDH gene, the IC verifies the presence of human DNA in the sample, ensuring proper sample collection and confirming successful nucleic acid extraction. This allows for the identification of potential issues, such as improper specimen collection or extraction failures, which could otherwise compromise test accuracy.

The RADIONE system includes built-in software that automatically interprets results based on pre-programmed threshold values. The software analyzes real-time PCR fluorescence curves to determine whether a sample is positive, negative, or invalid. The system is designed to require minimal user intervention, as it automatically generates and displays the final results.

Regarding specimen handling, the kit has been validated for use with skin lesion swabs, which must be collected using the NS-1 Swab Applicator (Cat. No. UTNS-1C) and immediately transferred into the validated transport medium (Noble Biosciences Clinical Virus Transport Medium, 3 mL) to maintain nucleic acid stability.

3. Precautions and Warning

1) This assay needs to be carried out by trained personnel.
2) Please wear disposable gloves when handling.
3) When the control value is out of the expected range (see **"11. Quality Control"**), it is indicative of instability or deterioration of the Kit.
4) Do not use the Kit after its expiration date.
5) Follow standard precautions for infectious waste management. All patient specimens and positive controls should be considered to be potentially infectious and handled with precautions.
6) Do not eat, drink, smoke, apply cosmetics or handle contact lenses in areas where reagents and human specimens are handled.
7) Handle all specimens considering them infectious and follow safe laboratory procedures.[1]
8) Specimen processing should be performed in accordance with national biological safety regulations.
9) Dispose of used Kit reagents and human specimens according to local, state, and federal regulations.
10) Do not reuse disposable materials after use.
11) Do not pool reagents from different lots or from different Kits of the same lot.
12) All reagents must be brought to room temperature before use if stored frozen.
13) Use only swab specimens collected from human skin lesions as indicated in the IFU.
14) Store the product at -25°C to -15°C to maintain stability.
15) Follow good laboratory practices to avoid contamination of reagents, including the use of aerosol-resistant tips, designated workspaces, and regular decontamination of surfaces.

4. Kit Components (Included in the Kit)

The RADIONE Mpox Detection Kit is designed to provide 24 tests per kit and includes the following components:

• Pre-filled PCR Tubes: 4 well-strip tubes x 24 EA (sufficient for 24 tests)
• Instructions for Use (IFU)

Component	Unit
Pre-filled PCR Tube	4 well-strip tube X 24 EA
Instructions for use	1 EA

Note: The Extraction Cartridge is not included in this kit. It is provided separately as part of the RADIONE Universal DNA/RNA Extraction Kit (KP001).

5. Materials Required but Not Provided

The following materials are required to perform the assay but are not included in the kit:

- RADIONE instrument(Cat No. KM009 / S/W ver. nT01V1.0.14.34)
- RADIONE Universal DNA/RNA Extraction Kit (KP001) (includes the Extraction Cartridge)
- Cartridge Holder(provided with the equipment)
- Disposable powder-free gloves
- Noble Biosciences Clinical Virus Transport Medium with NS-1 Swab Applicator (Cat No. UTNS-1C, standard nylon-flocked swab with a breakpoint)
- calibrated pipettes and sterile filter tips

6. Instruments and materials Available, but not provided

- RADIONE Mpox Positive control(Cat No. RP001-PC)
- Mini centrifuge (<4000rpm)

7. Storage

- All components should be stored at -25°C to -15°C upon arrival.
- Exposure time at Room temperature (25°C) should not exceed 60 minutes.
- Freeze-thaw cycles should not exceed 5 times.

8. Specimen collection, transportation and storage

- The RADIONE Mpox Detection Kit should use lesion swab samples collected in 3 mL of Noble Biosciences Clinical Virus Transport Medium with NS-1 Swab Applicator (Cat No. UTNS-1C)
- For safe use of the collection device, refer to the manufacturer's manual.
- For Mpox diagnostics, collect lesion samples using sterile synthetic swabs. Refer to the CDC Mpox Specimen Collection Guidelines[2] for detailed recommendations on proper collection and handling techniques. Once collected, promptly transfer the swabs into the Transport medium to ensure optimal sample preservation.
- Skin lesion samples collected in the transport medium is stable up to 7 days at 2°C to 8°C.

9. Preparation of Reagents & Specimen

9-1 Preparation of Reagents

- Before starting the assay, all reagents must be brought to room temperature (15°C - 25°C) for at least 10 minutes if stored frozen.
- Once thawed, briefly spin down the Pre-filled PCR tubes using a Mini Centrifuge at 4000 rpm for 10 seconds to collect any condensation and ensure uniform reagent distribution.

9-2 Preparation of specimens

- If specimens are stored in refrigeration, allow them to reach room temperature before processing (approximately 10 minutes at 15°C - 25°C).
- Mix specimens thoroughly by vortexing the tube for a few seconds to ensure homogeneity before applying to the extraction cartridge.

10. Batch Processing and Cross-Contamination Prevention

10-1 Batch Processing

- Prepare all required specimens and reagents in advance, ensuring the correct quantity for the intended batch size.
- Label and verify each specimen carefully before starting the processing steps to prevent mix-ups.
- Once all specimens are prepared, immediately load them into the RADIONE instrument and start the run to minimize potential degradation.

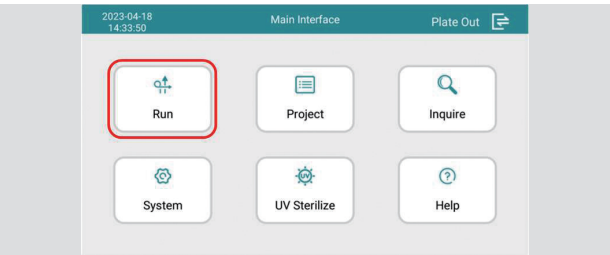
10-2 Cross-contamination Prevention[3]

- Keep the sample preparation area separate from the RADIONE operation area to prevent contamination.
- Change gloves frequently: Replace gloves whenever moving between work areas or handling a new specimen to avoid cross-contamination.
- Once all specimens are prepared, immediately load them into the RADIONE instrument and start the run to minimize potential degradation.
- Disinfect work surfaces: After each test, clean workstations and equipment thoroughly using 10% bleach or RNase remover to eliminate potential contaminants.

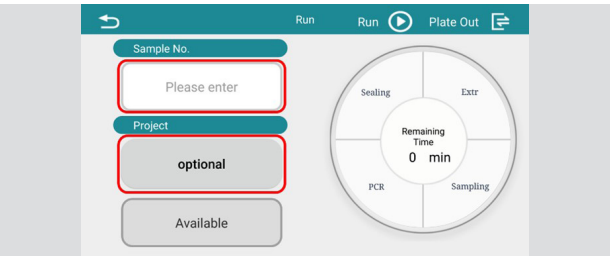
11. Test Procedure

11-1 Equipment and software setup

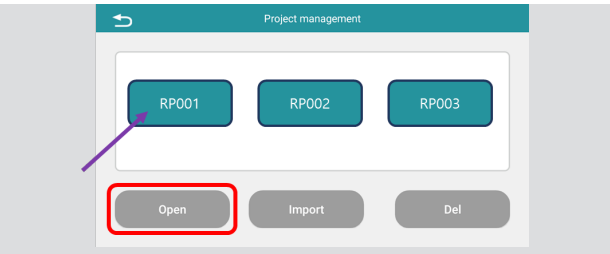
1) Turn on the RADIONE instrument.
2) Enter the username and password to log in.
3) Touch the **"Run"** button



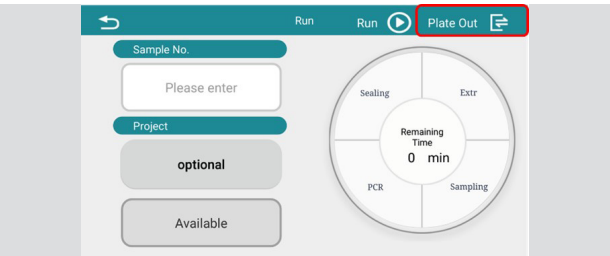
4) Enter the sample No. and touch the **"Optional"** button.



5) Select the **"RP001"** button and touch the **"open"** button

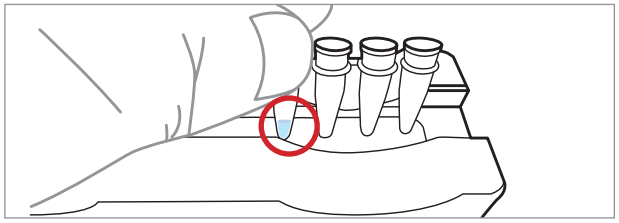


6) Touch the **"Plate Out"** button to open the door



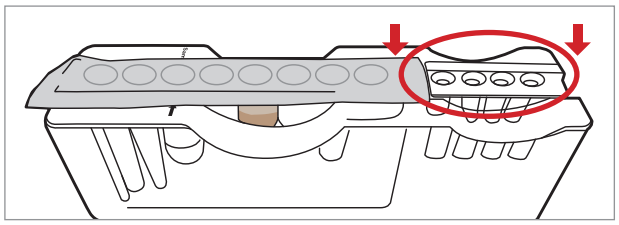
11-2 Cartridge & PCR reagent setup

1) Remove the cap from the pre-filled PCR tube and place it on the Cartridge Holder.

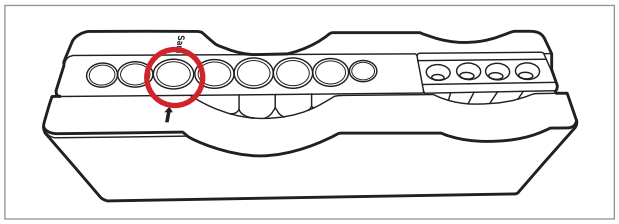


Note: Make sure that the PCR tube containing the reagent is placed in the first compartment.

2) Prepare the extraction cartridge and ensure that the PCR connector attached to the cartridge is securely fixed to the PCR tube by pushing it.

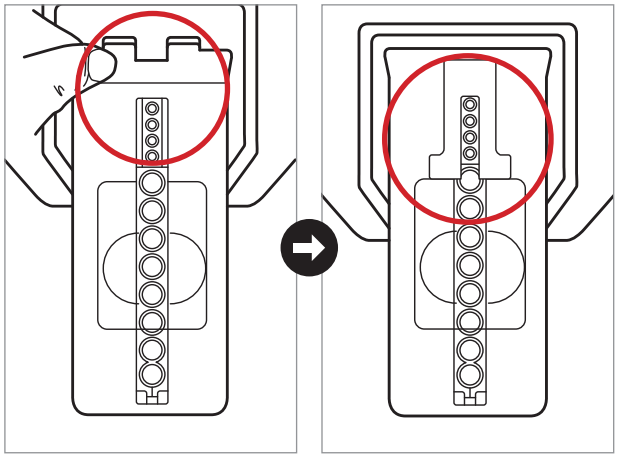


3) Remove the lid of the extraction cartridge and add 200 µl of the sample into the sample compartment indicated on the Cartridge Holder



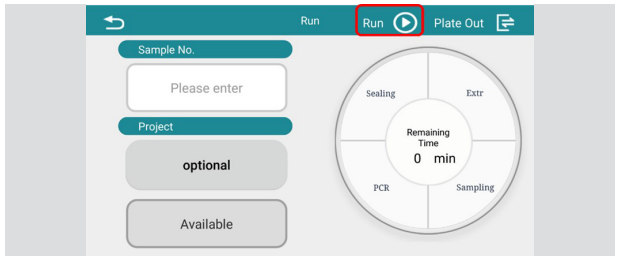
11-3 Load the cartridge and Run

1) Open the PCR tube depressor, insert the prepared cartridge, and close the PCR tube depressor.



2) Touch the **"Plate In"** button to close the door

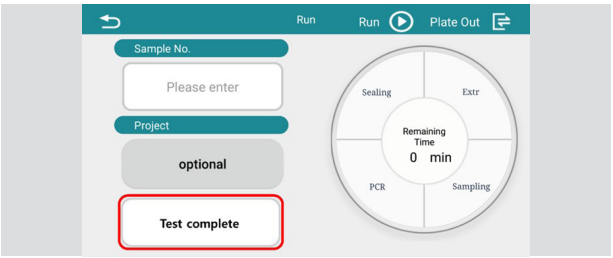
3) Touch the **"RUN"** button to start the test



12. Result Check and Interpretation

12-1 Result check

1) Touch **"Test complete"** from the screen in order to check the Test result when it is completed



2) Touch **"Test complete"** from the screen in order to check the Test result when it is completed

3) Amplified positive samples are marked as **"P,"** and non-amplified samples are marked as **"N."** You can also check the Ct values.

12-2 Test interpretation

1) Test interpretation of RADIONE Mpox Detection Kit is described as below

Case	Target: Clade 2 (FAM)	Target: Clade 1 (VIC)	Target: Orthopox Generic (ROX)	Target: IC (Cy5)	Result
1	≤40	-	≤40	≤40 or -	Clade 2 Strain Positive
2	≤40	-	-	≤40 or -	Clade 2 Strain Positive
3	-	≤40	-	≤40 or -	Clade 1 Strain Positive
4	-	≤40	≤40	≤40 or -	Clade 1 Strain Positive
5			≤40	≤40 or -	Orthopoxvirus positive*
6	-	-	-	≤40	Negative
7	>40 or -	>40 or -	>40 or -	>40 or -	Invalid **
8	≤40	≤40	≤40 or -	≤40 or -	Invalid ***

* Re-tests are recommended for the positive result of Orthopox virus Generic only amplification. Also clinical correlation is recommended.

** Results are invalid. Re-test is required. If the same result is obtained during re-test, other additional confirmatory tests can be performed

*** Results are invalid. A re-test is required. If the same result is obtained during the re-test, there may be an issue with sample storage or collection, so please refer to '14. Troubleshooting"

13. Quality Control

By using the Mpox Positive Control Kit (RP001-PC) provided by the manufacturer, users can periodically verify the performance of the reagents or check for any functional issues. For detailed instructions on how to use the control materials, please refer to the IFU provided with the control kit. Additionally, users can verify the absence of contamination in the reagents by using an NTC (No Tem-plate Control), which is a solution free of MPXV DNA. Please note that NTC is not provided separately, and it is recommended to use a contamination-free PBS solution for this purpose.

13-1 Preparation of Reagents

- Before starting the assay, all reagents must be brought to room temperature (15°C - 25°C) for at least 10 minutes if stored frozen.
- Once thawed, briefly spin down the Pre-filled PCR tubes using a Mini Centrifuge at 4000 rpm for 10 seconds to collect any condensation and ensure uniform reagent distribution.

13-2 Preparation of Positive control or No template control

- If control reagent are stored in refrigeration, allow them to reach room temperature before processing (approximately 10 minutes at 15°C - 25°C).
- Mix specimens thoroughly by vortexing the tube for a few seconds to ensure homogeneity before applying to the extraction cartridge.

13-3 Test Procedure

- The Control reagent should be treated the same as a patient specimen and tested following the procedures outlined in Section 11: Test Procedure.

13-4 QC result analysis

- The kit performance is considered valid if the Ct value obtained after instrument operation falls within the acceptable range provided in the table below.
- If the Ct value falls outside the acceptable range, the kit is considered invalid and should not be used.

Control	Clade 2 (FAM)	Clade 1 (VIC)	Orthopox Generic (ROX)	IC (Cy5)
NTC	No Ct or Ct>40	No Ct or Ct>40	No Ct or Ct>40	No Ct or Ct>40
PC	25≤Ct≤32	25≤Ct≤32	25≤Ct≤32	25≤Ct≤32

14. Test Limitations

1) Performance of the Kit has been established in skin lesion or swab specimens from symptomatic individuals suspected of Monkeypox.
2) This Kit is a qualitative test and does not provide the quantitative value.
3) All users, analysts, and any person reporting diagnostic results should be trained to perform this procedure by a competent instructor. They should demonstrate their ability to perform the test and interpret the results prior to performing the assay independently.
4) Negative results do not preclude Monkeypox Virus and should not be used as the sole basis for treatment or other patient management decisions.
5) Detection of viral DNA may not indicate the presence of infectious virus or that virus is the causative agent for clinical symptoms.
6) False positive results may happen from cross-contamination between patient samples, specimen mix-up and/or DNA contamination during product handling.
7) False-negative results may arise from:
   · Improper sample collection
   · A sample at concentrations near or below the limit of detection of the test.
   · Degradation of the viral DNA during specimen transport and/or storage.
   · Failure to follow the Instructions for Use provided
8) This assay has been validated using skin lesion swab specimens collected with the NS-1 Swab Applicator (Cat. No. UTNS-1C) and transported in Noble Biosciences Clinical Virus Transport Medium (3 mL). The use of other swab materials or transport media has not been validated and may affect assay performance

15. Performance characteristics

Analytical sensitivity (Limit of Detection)

In order to determine limit of detection (LOD) of RADIONE Mpox Detection Kit, a tentative LOD is established with several diluted concentrations using synthesized DNA. After a tentative LOD is established, the claimed LOD was established with 24 replicates of diluted concentrations spanning tentative LOD.

· **Claimed LoD:** 800 copies/㎖

Target	Copies/㎖
Clade 2	(95% CI: 600 -800)
Clade 1	(95% CI: 600 -800)
Orthopox Generic Strain	(95% CI: 600 -800)

· **Cut off Value**

A Ct value of 40 was set as the cut-off of RADIONE Mpox Detection Kit.

Cross Reactivity

RADIONE Mpox Detection Kit did not cross-react with any of 21 pathogens. IPC was all detected 20~35 Ct range.

No.	Reference	Cat. No.	Pathogen	Result
0-1			NTC	Not detected
0-2			Positive control	Target detected
1	NCCP	15882	Streptococcus pneumoniae	Not detected
2	NCCP	72002	Legionella pneumophila	Not detected
3	NCCP	72026	Bordetella pertussis	Not detected
4	NCCP	72006	Pseudomonas aeruginosa	Not detected
5	NCCP	72077	Mycobacterium tuberculosis	Not detected
6	ATCC	29342DQ	Mycoplasma pneumoniae	Not detected
7	NCCP	43193	Adenovirus	Not detected
8	NCCP	43252	Dengue virus serotype 1	Not detected
9	NCCP	43248	Dengue virus serotype 2	Not detected
10	NCCP	43256	Dengue virus serotype 3	Not detected
11	NCCP	43257	Dengue virus serotype 4	Not detected
12	NCCP	43280	Zika virus	Not detected
13	Vircell	MBC100	Yellow Fever Virus	Not detected
14	NCCP	43230	Influenza A virus (H3N2)	Not detected
15	NCCP	43231	Influenza A virus (H1N1)	Not detected
16	NCCP	43232	Influenza B virus (Yamagata)	Not detected
17	NCCP	43238	Respiratory Syncytial virus A	Not detected
18	NCCP	43239	Respiratory Syncytial virus B	Not detected
19	NCCP	43214	human Coronavirus NL63	Not detected
20	NCCP	43261	SFTS virus	Not detected
21	NCCP	43326	SARS-CoV-2	Not detected

Interfering test

RADIONE Mpox Detection Kit does not have any interference with following interfering substances.

No.	Interfering Substances	Concentrations	Interference
1	Bilirubin	30 mg/dL	No interference
2	Hemoglobin	2 g/dL	No interference
3	Triglyceride	1 g/dL	No interference

16. Clinical performance evaluation

1) Introduction

This clinical validation study was conducted at the Institut National de Recherche Biomedicale (INRB) in Kinshasa, Democratic Republic of Congo, to evaluate the kit's performance against the FDA Emergency Use Listed (EUL) GeneXpert Mpox detection kit.

The study took place between September and October 2024, utilizing skin lesion swab samples collected from suspected Mpox patients between April and August 2024. Performance metrics such as sensitivity, specificity, and overall diagnostic accuracy were assessed.

2) Study Design and Methods

A total of 148 skin lesion swab samples were collected, with 127 evaluable samples included in the final analysis.

- 45 positive samples (confirmed by GeneXpert)
- 103 negative samples (confirmed by GeneXpert) were included in the study. However, 21 samples were deemed invalid due to presumed issues with sample quality or improper storage, leaving 82 evaluable negative samples for the final analysis.

3) Result

Out of 45 positive samples, 43 were correctly identified as positive by the RADIONE Mpox Detection Kit. Additionally, all 82 evaluable negative samples were confirmed as negative, demonstrating the high accuracy of the test.

		FDA cleared method		
		Positive	Negative	Total
RADIONE Mpox Detection Kit	Positive	43	0	43
	Negative	2	82	84
	Total	45	82	127

- **PPA (Sensitivity):** 95.6% (43/45) [95% CI: 85.2 – 99.2]
- **NPA (Specificity):** 100% (82/82) [95% CI: 95.6 – 100]

17. Troubleshooting

- When no signal appears for any target:
  This Kit includes an Internal Control (IC) to verify the presence of human DNA. The sensitivity of the IC is strategically adjusted to ensure amplification occurs only when a sufficient amount of human DNA is present. This design helps prevent false negatives caused by low target DNA levels due to improper sample collection or storage.
  If no signal appears for any target while the IC also fails to amplify, the sample may not contain enough human DNA for reliable detection. In such cases, recollect the specimen and repeat the test with a new cartridge to ensure accurate results.
- When the No Template Control (NTC) shows amplification:
  The NTC is included in every test to monitor for contamination. If the NTC shows amplification, possible causes include cross-contamination during sample handling or reagent contamination. If this occurs, take the following actions:
  1. Repeat the test using fresh reagents and new pipette tips.
  2. Check for contamination in the working environment, including surfaces, pipettes, and other laboratory equipment.
  3. Ensure proper handling procedures to prevent cross-contamination, such as processing positive and negative samples separately and using dedicated pipettes for each reagent.
  4. If contamination persists, contact technical support for further assistance.

For any other technical issues, please contact **adamhong@khmedical.co.kr**

18. Bibliography

1) WHO, Laboratory biosafety manual, 4th edition

2) CDC, Guidelines for Collecting and Handling Specimens for Mpox Testing https://www.cdc.gov/mpox/hcp/diagnosis-testing/collecting-specimens.html

3) CLSI. MM03—Molecular Diagnostic Methods for Infectious Diseases. 3rd ed., 2015.

19. Description of Symbol Used

Symbol	Description	Symbol	Description
REF	Catalogue number		Consult instruction for use
LOT	Lot number	-25°C -15°C	Storage at -25°C to -15°C
	Use by date		Manufacturer
Σ	Contains sufficient for tests	IVD	In vitro diagnostic Medical Device

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