Mpox disease Emergency Use Listing Procedure (EUL) for IVDs
Product: Monkeypox Virus Nucleic Acid Detection Kit (Fluorescence PCR)
EUL Number: MPXV-13330-248-00
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 Monkeypox Virus Nucleic Acid Detection Kit (Fluorescence PCR), with product code HWTS-0T071C, Rest-of-World regulatory version manufactured by Jiangsu Macro & Micro-Test Med-Tech Co., Ltd, located at Juegang Street Rudong County, 226499 Nantong City, People's Republic of China, was listed as eligible for WHO procurement on 27 October 2025.

Intended use:

According to the claim of intended use from Jiangsu Macro & Micro-Test Med-Tech Co., Ltd, *"The assay is in vitro diagnostic medical device in the format of nucleic acid test using fluorescent PCR method.*
The assay is intended for in vitro qualitatively detecting nucleic acids of monkeypox virus (MPVX) clade I (including Ib) and clade II in human lesion swab specimens from individuals with signs and symptoms consistent with MPXV infection], including those requiring differential diagnosis. Results of the kit could be as an aid in the clinical diagnosis of MPXV infection.
Human lesion swabs (of acute pustular or vesicular rash from individuals suspected of mpox) by a healthcare provider were validated by the kit.

The kit is designed specifically for MPVX rather than orthopoxviral in general through manual operation for professional use only in a laboratory setting for in vitro diagnosis use."

Validated specimen type:

Human lesion swabs (of acute pustular or vesicular rash) collected using flocked swabs (i.e. Virus Sampling Kit (MT0301-1, Yocon)).

Test kit contents:

Type of reagent	*Product code (HWTS-0T071C) (50 Tests/kit)*
MPXV Reaction Buffer	1mL/vial
MPXV Positive Control	600µL/vial
MPXV Blank Control	600µL/vial

Items required but not provided:

- Extraction reagent: Type I and Type II-1 of Macro & Micro-Test Viral DNA/RNA Kit (HWTS-3017),
- Sample preservation solution:
  - Virus Sampling Kit (MT0301-1, Yocon),
  - Sample Collecting, Mailing & Shipping Kit (HWTS-3002, Macro & Micro-Test),
  - UTM Universal Transport Medium (Copan P/N 3C064N, Copan).
- 1.5mL of DNase/RNase-free centrifuge tube,
- DNase/RNase-free Tips,
- desktop centrifuge,
- desktop oscillation mixer,
- magnetic rack,
- thermostatic metal bath.

Validated PCR Systems

- Applied Biosystems 7500 Real-Time PCR Systems (Software version: Real-Time PCR Software v2.4 or 7500 Software v2.0.5),
- SLAN-96P Real-Time PCR Systems (Hongshi Medical Technology Co., Ltd.) (Software version: SLAN 8.2.2)

Storage:
The test kit must be stored at below -18 ℃.

Shelf-life upon manufacture:
The shelf life is currently assigned a 12-month dating period.

Warnings/limitations:

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

Product dossier assessment

Jiangsu Macro & Micro-Test Med-Tech Co., Ltd submitted the product dossier for the Monkeypox Virus Nucleic Acid Detection Kit (Fluorescence PCR) 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, JIANGSU MACRO & MICRO-TEST MED-TECH 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, JIANGSU MACRO & MICRO-TEST MED-TECH 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 conclusion of the quality management system assessment 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 "*Reportable changes to WHO prequalified and emergency use listed in vitro diagnostics*"[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].

JIANGSU MACRO & MICRO-TEST MED-TECH 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.

[1] https://iris.who.int/handle/10665/381373

[2] https://iris.who.int/handle/10665/337551

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 Monkeypox Virus Nucleic Acid Detection Kit (Fluorescence PCR), with product code HWTS-0T071C, manufactured by JIANGSU MACRO & MICRO-TEST MED-TECH CO., LTD, is eligible for WHO procurement for 12 months from the day of listing. The assay detects nucleic acid from monkeypox virus, including clades clade Ib and clade II. 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, JIANGSU MACRO & MICRO-TEST MED-TECH CO., LTD must engage in post-market surveillance activities to ensure that the product continues to meet safety, quality, and performance requirements. JIANGSU MACRO & MICRO-TEST MED-TECH CO., LTD is required to notify WHO of any serious reportable 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 review

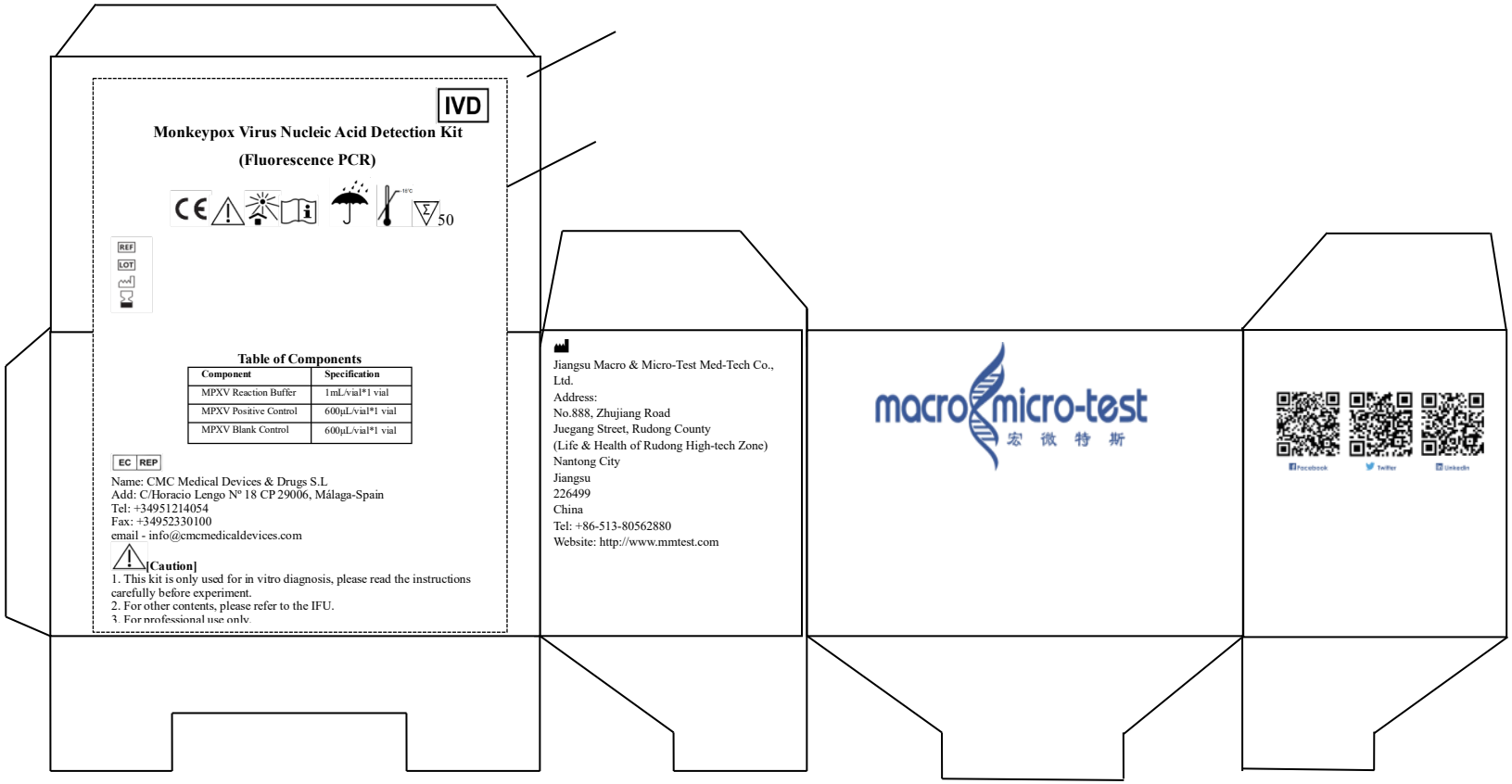
The labelling submitted for Monkeypox Virus Nucleic Acid Detection Kit (Fluorescence PCR) was reviewed by WHO staff and external technical experts appointed by WHO. The review evaluated the labelling for clarity and consistency with the information submitted in the product dossier, alignment with international guidance and standards, and suitability for the intended users and settings in WHO Member States, including low- and middle-income countries.

The table below provides traceability of the labelling documents reviewed during the assessment, including document titles, version numbers, approval dates, and control identifiers.

Controlled Labelling References

Document Type	Document Title	Version / Revision	Date Approved	Controlled Document No.
Outer box artwork	[Labels and packing template-MPXV PCR kit_v1.1]	[v1.1]	[2025-09-19]	[HWTS-STP-TZ/BZ-MPXV-W]
Pouch / Device label	[Labels and packing template-MPXV PCR kit_v1.1]	[v1.1]	[2025-09-19]	[HWTS-STP-TZ/BZ-MPXV-W]
Reagent bottle labels	[Labels and packing template-MPXV PCR kit_v1.1]	[v1.1]	[2025-09-19]	[HWTS-STP-TZ/BZ-MPXV-W]
Instructions for Use (IFU)	Instructions for use of MPXV PCR kit_v1.3	[v1.3]	[2025-09-19]	[HWTS-STP-IFU-MPXV-W]

Labels



IVD

Monkeypox Virus Nucleic Acid Detection Kit

(Fluorescence PCR)

50

REF

LOT

Table of Components

Component	Specification
MPXV Reaction Buffer	1mL/vial*1 vial
MPXV Positive Control	600μL/vial*1 vial
MPXV Blank Control	600μL/vial*1 vial

EC REP

Name: CMC Medical Devices & Drugs S.L
Add: C/Horacio Lengo Nº 18 CP 29006, Málaga-Spain
Tel: +34951214054
Fax: +34952330100
email - info@cmcmedicaldevices.com

[Caution]

1. This kit is only used for in vitro diagnosis, please read the instructions carefully before experiment.
2. For other contents, please refer to the IFU.
3. For professional use only.

Jiangsu Macro & Micro-Test Med-Tech Co., Ltd.
Address:
No.888, Zhujiang Road
Juegang Street, Rudong County
(Life & Health of Rudong High-tech Zone)
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226499
China
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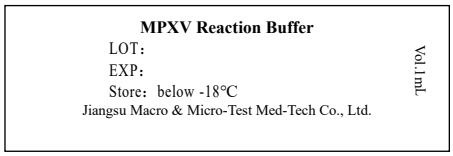
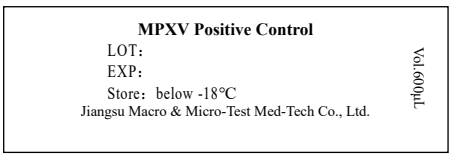
Website: http://www.mmtest.com

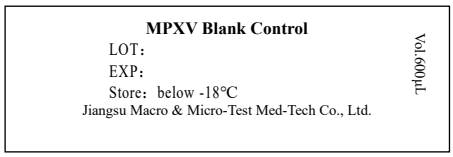
macro micro-test 宏 微 特 斯

Facebook Twitter LinkedIn

Components label







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.

CE IVD

Monkeypox Virus Nucleic Acid Detection Kit (Fluorescence PCR)

Instructions for Use

For Emergency Use Only

FOR PROFESSIONAL USE ONLY

For *In Vitro Diagnostic Use* Only

Jiangsu Macro & Micro-Test Med-Tech Co., Ltd.

Table of Contents

[Product Name]

Monkeypox Virus Nucleic Acid Detection Kit (Fluorescence PCR)

[Packaging Size]

50 tests/kit

[Intended Use]

The assay is in vitro diagnostic medical device in the format of nucleic acid test using fluorescent PCR method.

The assay is intended for in vitro qualitatively detecting nucleic acids of monkeypox virus (MPVX) clade I (including Ib) and clade II in human lesion swab specimens from individuals with signs and symptoms consistent with MPXV infection [1], including those requiring differential diagnosis. Results of the kit could be as an aid in the clinical diagnosis of MPXV infection.

Human lesion swabs (of acute pustular or vesicular rash from individuals suspected of mpox) by a healthcare provider were validated by the kit.

The kit is designed specifically for MPVX rather than orthopoxviral in general through manual operation for professional use only in a laboratory setting for in vitro diagnosis use.

[Test Principles]

This kit adopts fluorescent probe real-time PCR technology to select two specific conservative regions of MPXV, F3L gene and B7R gene, to design specific primers and probes, where the F3L gene probe 5' is labeled with FAM reporter and the probe 3' is labeled with BHQ1 quencher, the B7R gene probe 5' is labeled with VIC/HEX reporter and the probe 3' is labeled with BHQ1 quencher. During the PCR amplification process, specific primers and probes bind to their respective target sequences. When the Taq enzyme encounters the probe bound to the target sequence, the reporter and the quencher are separated by 5' end exonuclease activity, so that the fluorescence monitoring system can receive the fluorescence signals, that is, every time a DNA chain is amplified, a fluorescent molecule is formed, achieving complete synchronization between the accumulation of fluorescent signals and the formation of PCR products. At the same time, endogenous internal control, which serves as quality control, is introduced to avoid false negative detection.

Introduce an endogenous internal control into the system and select the commonly used housekeeping gene β-actin to monitor the entire process and avoid false negative detection.

[Main Components]

S/N	Component	Specification (50 tests/kit)	Quantity	Component Description
1	MPXV Reaction Buffer	1mL/vial	1 vial	Amplification reaction reagent, primers and probes of MPXV F3L and B7R, and primers and probes of internal control, etc.

2	MPXV Positive Control	600μL/vial	1 vial	Mixture of MPV F3L gene pseudo virus, MPXV B7R gene pseudo virus and internal control plasmids
3	MPXV Blank Control	600μL/vial	1 vial	DNase/RNase free H_2O

Note: Components in the kits from different batches cannot be mixed or interchanged.

Reagents need but not provided:

Extraction reagent: Type I and Type II-1 of Macro & Micro-Test Viral DNA/RNA Kit (HWTS-3017)

Sample preservation solution: Virus Sampling Kit (MT0301-1, Yocon), Sample Collecting, Mailing & Shipping Kit (HWTS-3002, Macro & Micro-Test), UTM® Universal Transport Medium™, (Copan P/N 3C064N, Copan)

Consumables need but not provided: 1.5mL of DNase/RNase-free centrifuge tube, DNase/RNase-free Tips, desktop centrifuge, desktop oscillation mixer, magnetic rack, thermostatic metal bath.

[Warnings and Precautions]

1. For in vitro diagnostic use (IVD).

2. For emergency use only.

3. Results of the kit is for clinical reference only and should not be used as the sole basis of clinical diagnosis, treatment and other patient management decisions. Clinical correlation with patient history and other diagnostic information is necessary to determine patients' infection status under the Guideline for the Diagnosis and Treatment of Monkeypox and the Monkeypox Prevention and Control Plan [1].

4. Positive results are indicative of the presence of MPXV nucleic acids. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected might not be the definite cause of disease. Negative results with this device do not preclude MPXV (clade I/II) infection.

5. All samples intending for the kit should be considered potential infectious. Sample operations, including collection, storage, transportation and testing should be handled accordingly using good laboratory procedures as outlined in Regulations on the Management of Clinical Gene Amplification Laboratories in Medical Institutions and other relevant molecular biology laboratory requirements [2,3,4]. Properly personal protection measures such as PPE should be taken.

6. The assay is validated only for lesion swab specimens. Performance of the kit was not established with other sample types.

7. Do not eat, drink, smoke, apply cosmetics or handle contact lenses in areas where reagents and human specimens are handled.

8. False positive and false negative results could be caused by poor specimen quality, improper sample operations (including collection, transportation, or laboratory processing), and limitation of the testing technology. The operator should understand the principles of the procedures, including its performance limitations, in advance of

operation to avoid potential mistakes.

9. Amplification technologies such as PCR are sensitive to accidental introduction of PCR product from previous amplification reactions. Incorrect results could occur if either the clinical samples or the real-time reagents used in the amplification step become contaminated by accidental introduction of amplification product (amplicon). Workflow in the laboratory should proceed in a unidirectional manner.

1) Maintain separate areas for assay setup and handling of nucleic acids.
2) Always check the expiration date prior to use. Do not use expired reagent. Do not substitute or mix reagent from different kit batches or from other manufacturers.
3) Change aerosol barrier pipette tips between all manual liquid transfers.
4) During preparation of samples, compliance with good laboratory techniques is essential to minimize the risk of cross-contamination between samples, and the inadvertent introduction of nucleases into samples during and after the extraction procedure.
5) Maintain separate, dedicated equipment (e.g., pipettes, microcentrifuges) and supplies (e.g., microcentrifuge tubes, pipette tips) for assay setup and handling of extracted nucleic acids.
6) Wear a clean lab coat and powder-free disposable gloves (not previously worn) when setting up assays. Change gloves between specimens and whenever contamination is suspected.
7) Keep reagent and reaction tubes capped or covered as much as possible.
8) The kit should be transported and stored at low temperature. The kit should be fully dissolved and shaked evenly, then centrifuge briefly prior to operation. Avoid unnecessary repeated freezing and thawing.
9) Do not open the reaction tubes/plates post amplification to avoid contamination with amplicons.
10) Work surfaces, pipettes, and centrifuges should be cleaned and decontaminated with cleaning products such as 10% bleach, “DNAZap™” or “RNase AWAY™” to minimize risk of nucleic acid contamination. Residual bleach should be removed using 70% ethanol.
11) The consumables that have touched the control materials (such as tips), tubes with PCR amplification products, samples and the residual components of the kit should be disinfected or sterilized before disposal.

10. Dispose unused/used reagents and human samples according to local, state, and federal regulations.

11. When a serious incident has occurred (e.g. repeated failure of the assay or increased rate of invalid test results), please contact the manufacturer and/or the local regulatory authority.

[Storage Conditions and Shelf-life]

The kit should be stored below -18℃ and the shelf life is 12 months. The number of opening and repeated freeze-thaw should be no more than 4 cycles. It can be transported for no more than 5 days below -18℃.

See the packaging label for the production date, batch number and expiration date.

[Applicable Instruments]

Applied Biosystems 7500 Real-Time PCR Systems (Software version: Real-Time PCR Software v2.4 or 7500 Software v2.0.5)

SLAN-96P Real-Time PCR Systems (Hongshi Medical Technology Co., Ltd.) (Software version: SLAN 8.2.2)

[Requirements for Samples]

1. Sample collection

1.1 Using a sterile swab apply firm pressure to the lesion and swipe the swab back and forth at least 2-3 times before rotating the swab and repeating using the other side of the swab. If the lesion ruptures while swabbing, ensure to collect the lesion fluid.

1.2 Remove and place the swab into the tube containing 3 mL of viral transport medium (VTM/UTM). Break swab at the indicated break line and cap the specimen collection tube tightly.

2. Storage

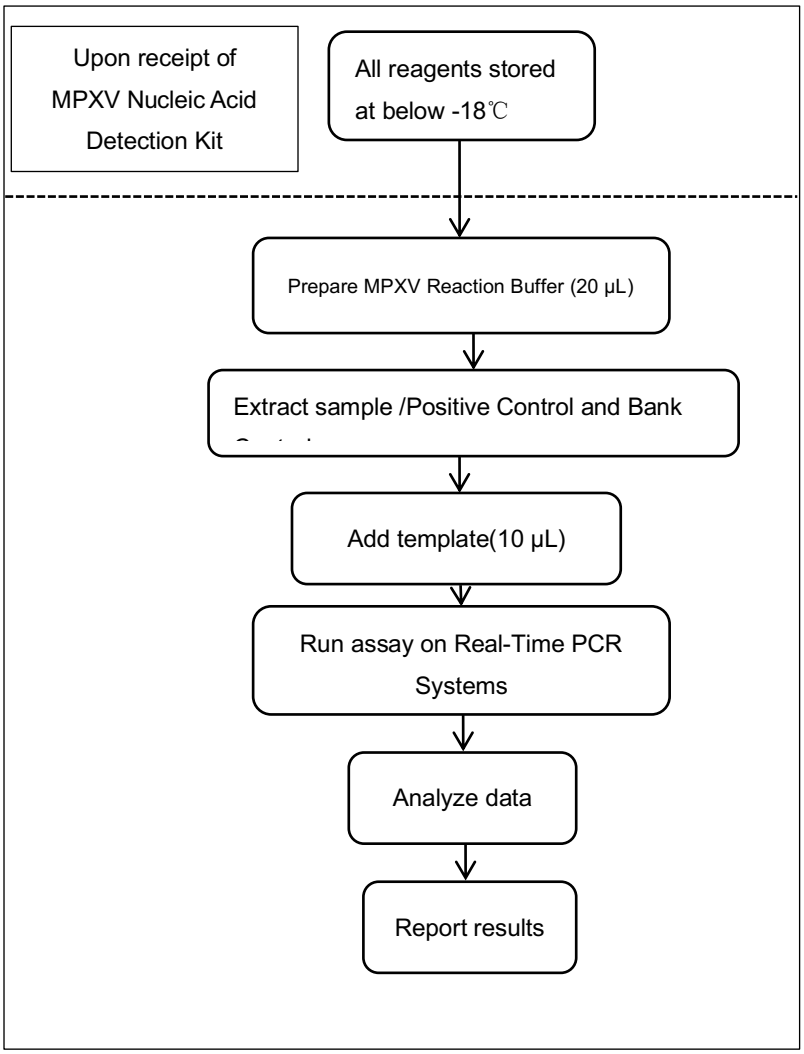
The samples to be tested should be stored at 2-8°C for no more than 5 days, stored below -18°C for no more than 4 months, and stored below -70°C for no more than 24 months. The samples should be avoided from repeated freezing and thawing (no more than 4 cycles). The shipping with dry ice should not exceed 5 days.

The extracted sample nucleic acid should be stored below -18℃ for no more than 4 months. The shipping with dry ice should not exceed 5 days. The repeated freezing and thawing should not be more than 4 cycles.

[Test Procedures]

The brief test flow chart is shown as **Figure 1.**

Figure 1. Summary of Preparation and Testing Process



Please read the operation procedures carefully before operation.

1. Reagent preparation

1.1 Place the MPXV Reaction Buffer at room temperature, and after the reagents are fully thawed, shake evenly and centrifuge briefly for later use.

1.2 Calculate the number of reactions to be prepared, N (N = number of samples + 1 tube of blank control + 1 tube of positive control). Based on the number of reactions needed N, aliquot 20 μ L of MPXV Reaction Buffer to the PCR reaction tubes, press the tube caps tightly and transfer to the sample processing area. The remaining MPXV Reaction Buffer should be frozen below -18℃ immediately after use.

2. Sample processing

Recommended extraction reagent: Type I and Type II-1 Macro & Micro-Test Viral DNA/RNA Kit (HWTS-3017).

The extraction should be conducted in strict accordance with the instructions for use. The extracted sample volume is 200μL and the recommended elution volume is 80μL.

Note: The positive control and blank control should be extracted in parallel. When handling the positive control, please take precautions to avoid contamination of the specimen sample. Failure to take proper precautions when handling the positive control could result in a false positive result.

3. Adding the samples

Add 10μL each of the blank control, the extracted DNA of samples, as well as the positive control in sequence separately to the prepared fluorescent quantitative PCR reaction tubes, press the tube caps tightly and centrifuge briefly.

4. PCR amplification

4.1 Create and Run an Experiment on Applied Biosystems 7500 Real-time PCR Instrument (Real-Time PCR Software v2.4 or 7500 Software v2.0.5)

1) Launch Applied Biosystems 7500 Real-time PCR Instrument by double clicking on the 7500 Software icon on the desktop.

2) A new window should appear, click **Log in as Guest** to log in anonymously.

3) Choose the **New Experiment** to start an experiment (**see Figure 2**)

Figure 2. Home Window

4) Set up the **Experiment Properties**. Fill in or select (see **Figure 3**):

a. Experiment name: ***your own customized choice***

b. Barcode (optional): *leave blank or your choice*

c. Username (optional): ***leave blank or your name***

d. Comments (optional): ***leave blank or your choice***

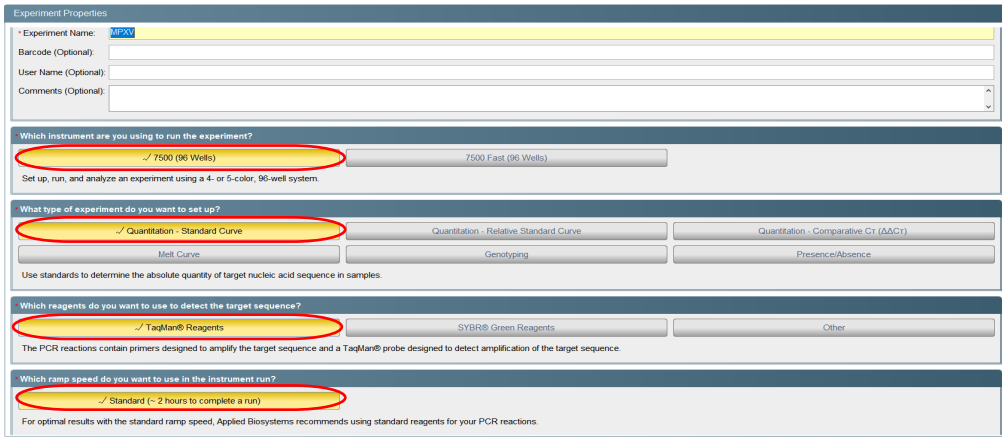
e. Which instrument are you using to run the experiment: **7500 (96-wells)**

f. What type of experiment do you want to set up: **Quantitation-Standard Curve**

g. Which reagents do you want to use to detect the target sequence: **TaqMan® Reagents**

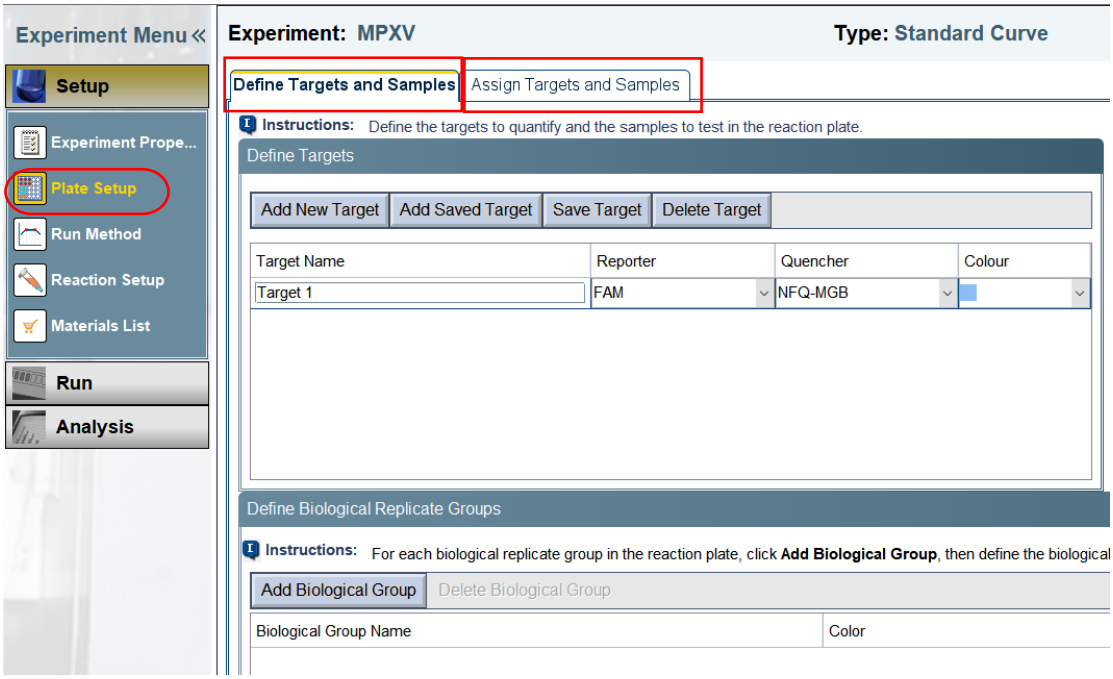
h. Which ramp speed do you want to use in the instrument run: **Standard (~2 hours to complete a run)**

Figure 3. Experiment Properties Window (For 7500 Real-time PCR Systems)



5)After making selections click **Plate Setup** at the left side of the window. Then the **Define Targets and Samples** and **Assign Targets and Samples** will appear as below (see **Figure 4**).

Figure 4. Plate Setup



6) Define targets (see **Figure 5**). Fill in or select:

a. Target Name: ***1***

b. Reporter: **FAM**

c. Quencher: **None**

d. Color: *to change the color of the detector indicator, do the following:*

□Click on the color square to reveal the color chart

□Select a color by clicking on one of the squares

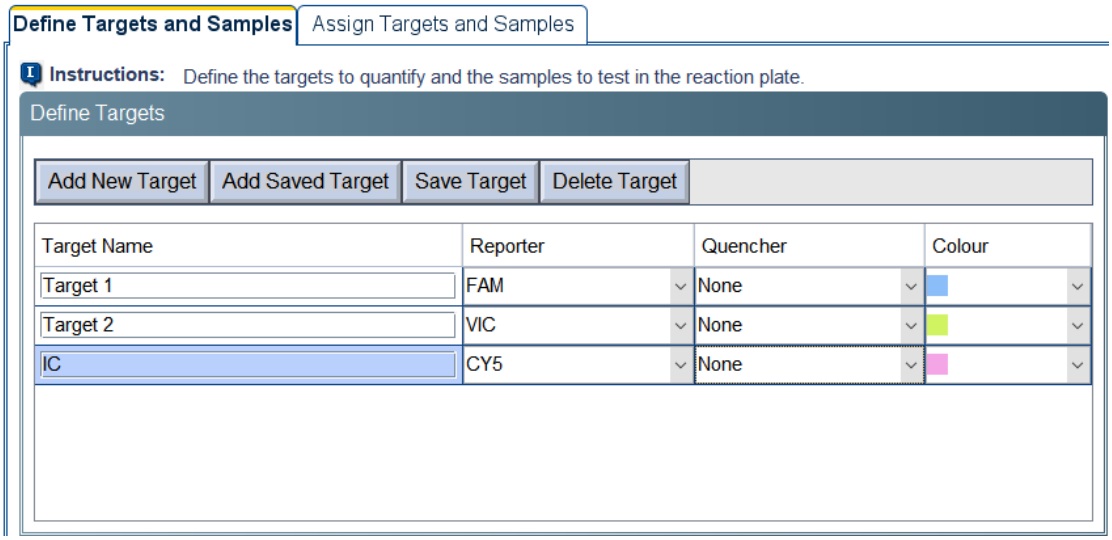
e. When necessary to add a new target or delete an exited target, click **Add New Target** or **Delete Target**.

7) Repeat Step 6 for each target in **Define Targets** window.

Name	Reporter	Quencher	Corresponding Gene
1	FAM	None	MPXV F3L gene
2	VIC/HEX	None	MPXV B7R gene
IC	CY5	None	IC

'Target 1' represents 'MPXV F3L gene' and 'Target 2' represents 'MPXV B7R gene'.

Figure 5. Define Targets



8) Define Samples (see **Figure 6**). Fill in or select:

a. Sample Name: ***Your Choice***

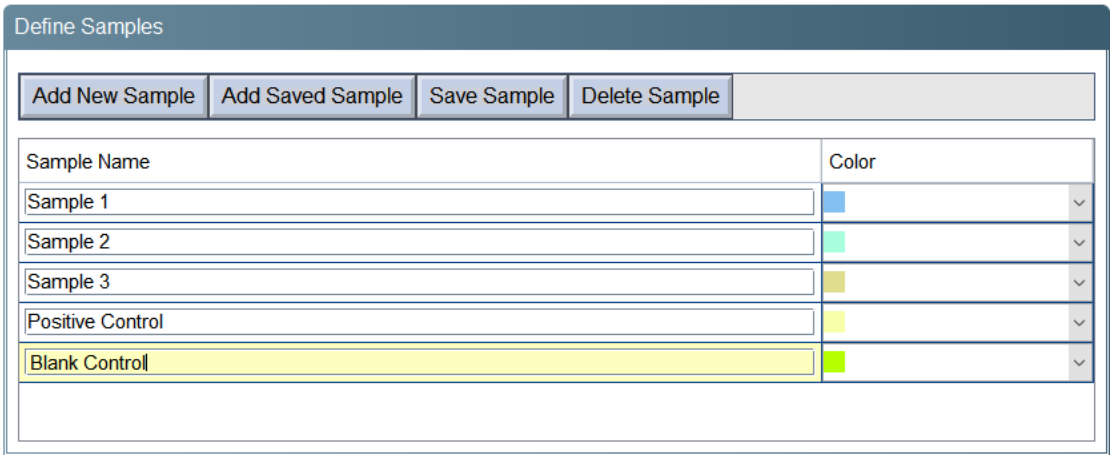
b. Color: *to change the color of the detector indicator do the following:*

□Click on the color square to reveal the color chart

□Select a color by clicking on one of the squares

c. When necessary to add a new sample or delete an exited sample, click **Add New Sample** or **Delete Sample**.

Figure 6. Define Samples



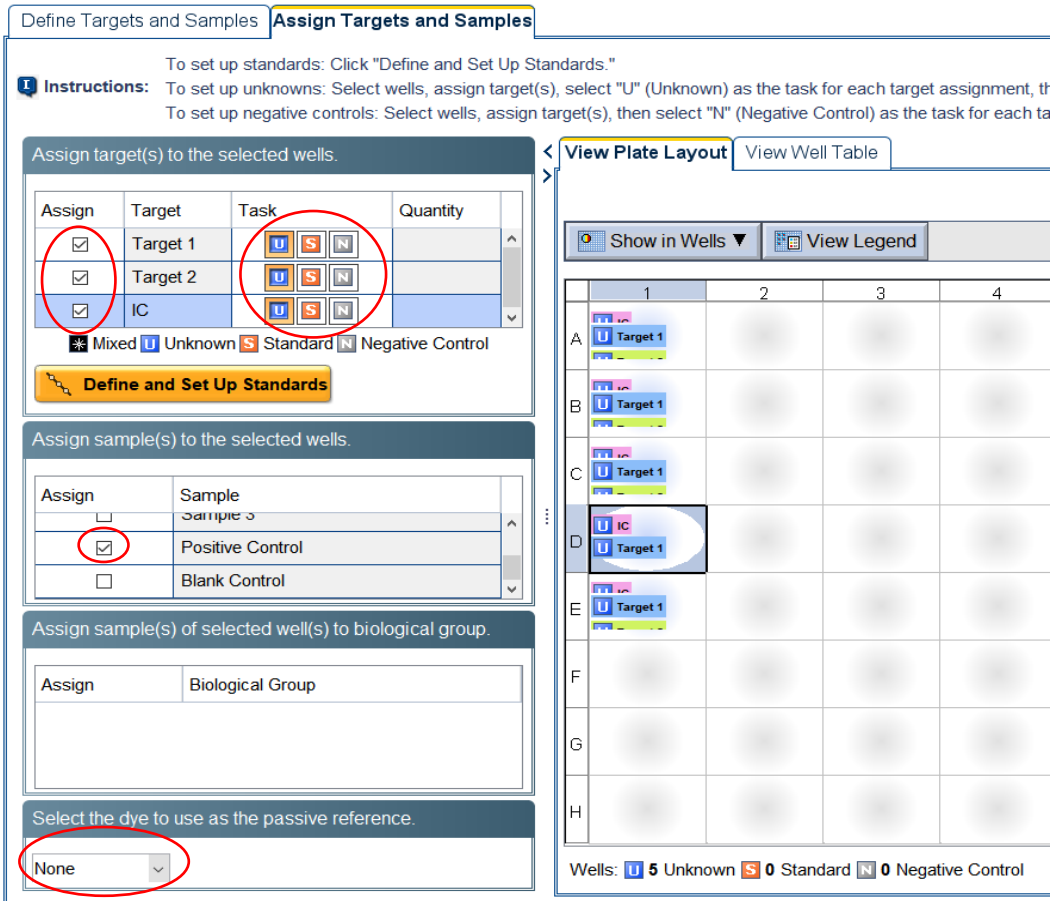
9) Click **Assign Targets and Samples** (see **Figure 7**) to layout samples.

a. Assign target(s): Select wells and assign the four targets including 'MPXV F3L gene/MPXV B7R gene/IC'. Then specify the reaction well under **Task** tab (S means a standard while U represents an unknown sample and N is a negative control).

b. Assign sample(s): Select wells and assign sample.

c. Select the dye: **None**

Figure 7. Assign Targets and Samples



10) After finishing **Plate Setup**, proceed to **Run Method** (see **Figure 8**) in the **Experiment Menu**.

a. Reaction Volume Per Well: ***30***

b. In First Holding Stage, Set to **2 min** at **50°C**.

c. In First Holding Stage, Set to **1 min** at **95°C**.

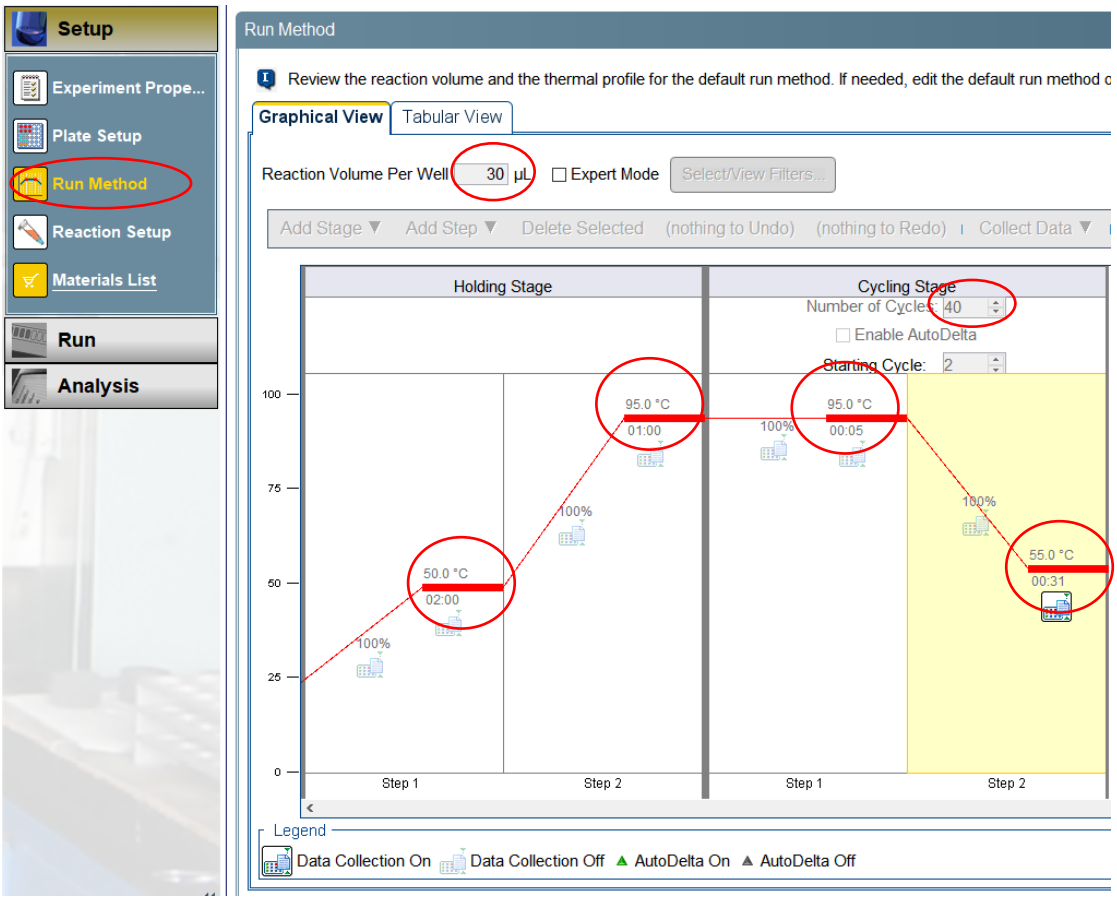
d. In Cycling Stage, Step 1 set to **5 sec** at **95°C.**

e. In Cycling Stage, Step 2 set to **31 sec** at **55°C**.

f. In Cycling Stage, Numbers of Cycles should be set to **40.**

g. The icon under the time in Step 2 of Cycling Stage should be highlighted to indicate data collection.

Figure 8. Define Run Method



11) Before proceeding, the run file must be saved; from the main menu, select **File,** then **Save As**.

Save in appropriate run folder designation.

12) Turn on ABI 7500 Real-time PCR Instrument.

13) Load the plate into the plate holder in the instrument. Ensure that the plate is properly aligned in the holder.

14) Once the run file is saved, click **Start** button. *Note: The run should take approximately 1 hour to complete.*

Data Analysis

1) Once the run has completed, select the **Analysis** tab at the upper left corner of the software.

2) Select the Amplification Plot tab to view the raw data (see **Figure 9**).

3) Start by highlighting all samples from the run; to do this, click on the upper left hand box **(a)** of the sample wells (see **Figure 10**). All the growth curves should appear on the graph.

4) On the top of the window **(b)**, the **Plot Type** drop down selection should be set to **Δ Rn vs Cycle**. The **Graph Type** drop down selection should be set to **Linear (c)**.

5) Select **1** from **(d)** the Target drop down menu, using the downward arrow.

Note: Please note that each target is analyzed individually to reflect different performance profiles of target.

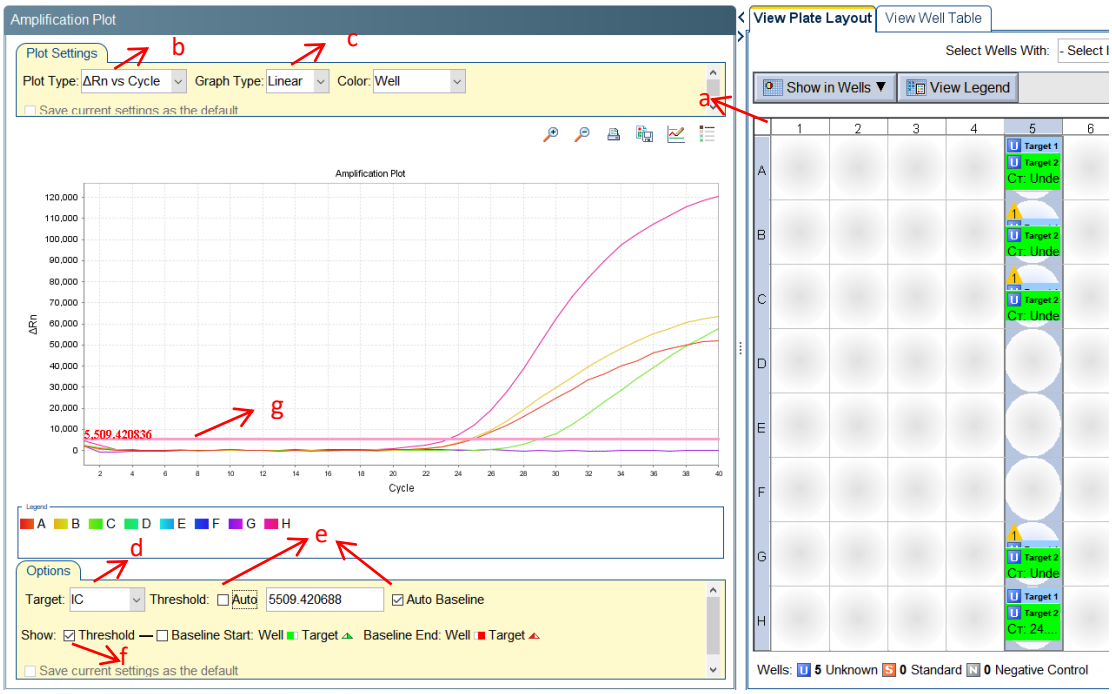
6) Cancel the check of **Auto** in **Threshold (e)**.

Note: Do not cancel the check of **Auto Baseline**.

7) Add the check of **Threshold** in **Show (f)**.

8) Using the mouse, click and drag the blue threshold line **(g)** until it lies within the exponential phase of the fluorescence curves.

Figure 9. Amplification Plot Window



9) Click the **Reanalyse** button in the upper right corner of the window.

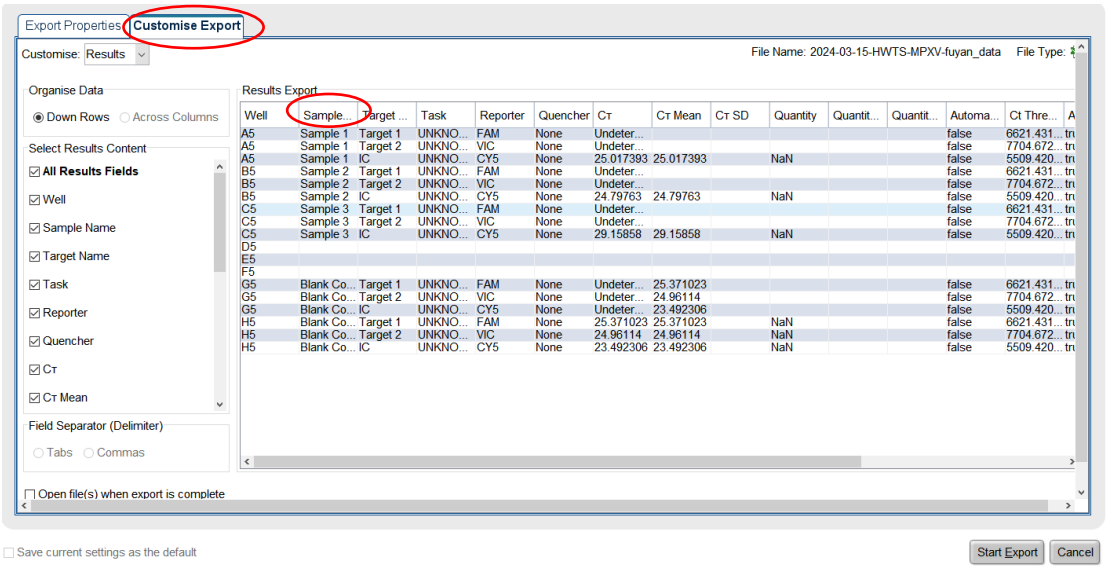
10) Repeat Steps 5-9 to analyze results generated for each set of markers (i.e. 1, 2, 3, etc).

11) Save analysis file by selecting **File**, then **Save As** from the main menu.

12) After completing analysis for each of the markers, click the **Export** tab, then the **Export Data** screen (see **Figure 10**) will appear. Select **Customise Export** to display the Ct values (see **Figure 10**).

13) To filter report by sample name in ascending or descending order, simply click on **Sample Name** in the table.

Figure 10. View Well Table



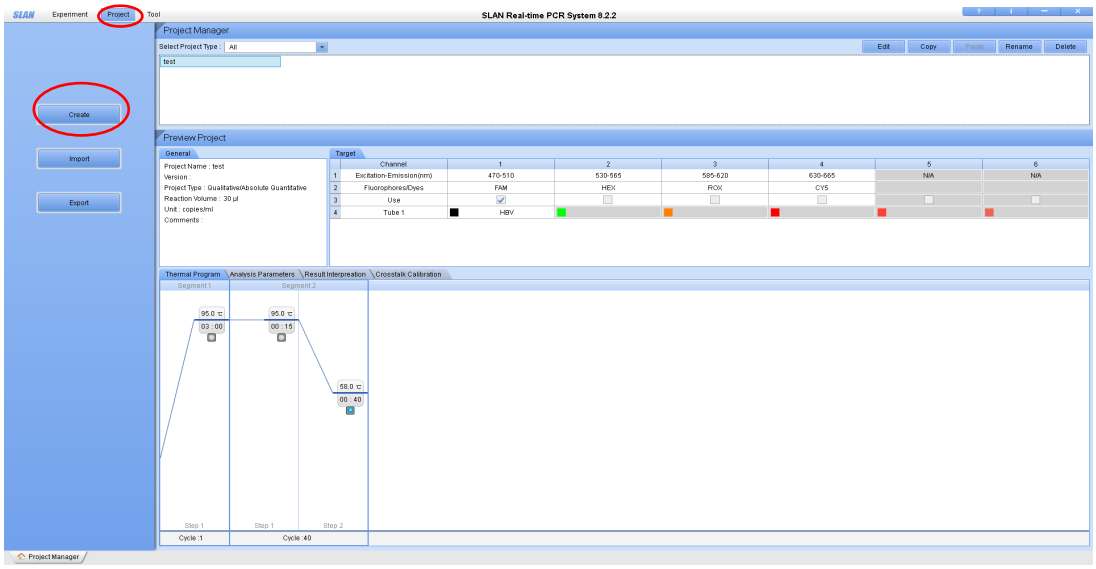
4.2 Create and Run an Experiment on SLAN-96P Real-Time PCR Systems (Hongshi Medical Technology Co., Ltd.) (Software version: SLAN 8.2.2)

1) Launch SLAN-96P Real-Time PCR Systems Software icon on the desktop.

2) Set up the reaction program

a. Click *Project*, click *Create* to create the reaction program (see Figure 11)

Figure 11. Reaction Program

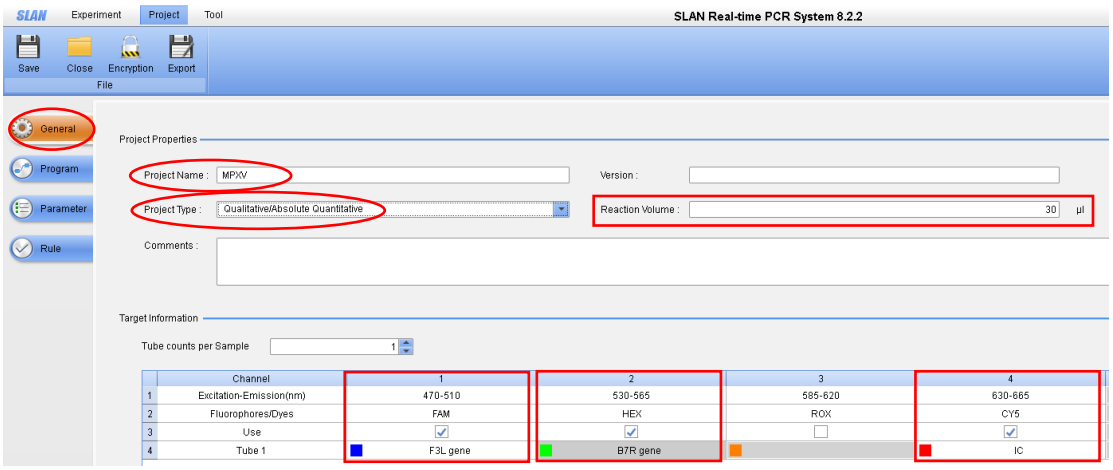


b. Click **General** to enter the reaction program naming and fluorescence channel selection page (see **Figure 12**).

- Name the reaction program. Users can name it according to personal habits.
- Choose ***Qualitative Absolute quantitative*** model in ***Project Type***.
- Reaction system **30µL**
- Fluorescence channel settings

Channel	Excitation-Emission(nm)	Fluorophoresi/Dyes	Use	Tube1
1	470-510	FAM	☑	MPXV F3L gene
2	530-565	VIC/HEX	☑	MPXV B7R gene
4	630-665	CY5	☑	IC

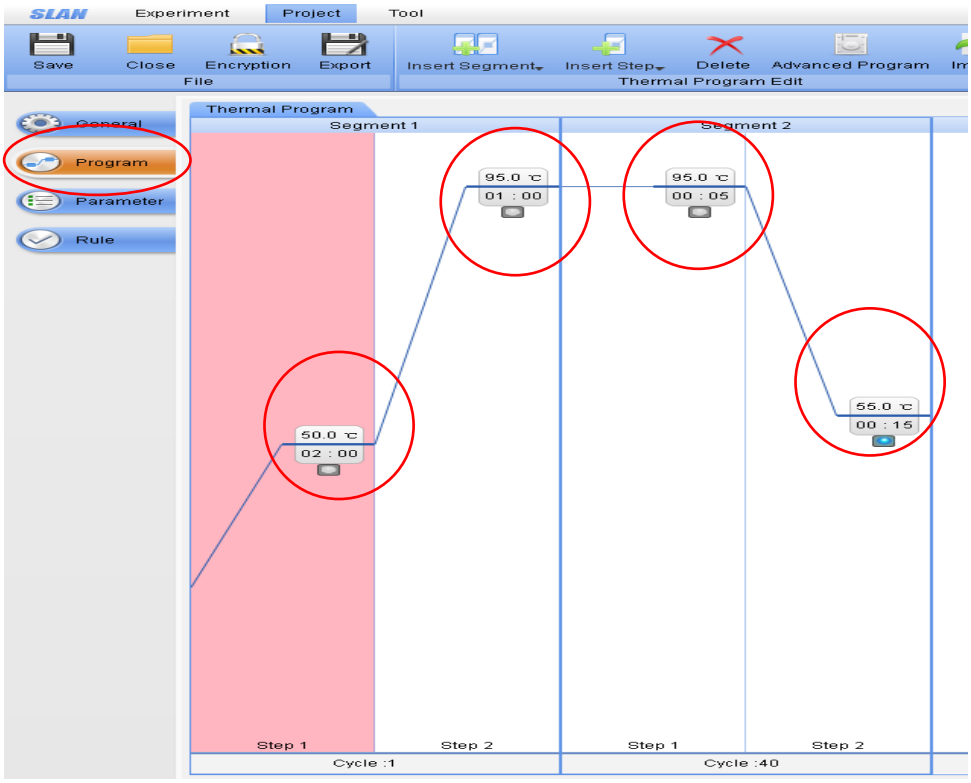
Figure 12. Reaction Program Information Setting



c. Click ***Program*** to set the reaction program (see **Figure 13**).

- In Segment 1 Stage, Set to **2 min** at **50°C**.
- In Segment 1 Stage, Set to **1 min** at **95°C**.
- In Segment 1 Stage, Numbers of Cycles should be set to **1.**
- In Segment 2 Stage, Step 1 set to **5 sec** at **95°C.**
- In Segment 2 Stage, Step 2 set to **15 sec** at **55°C**.
- In Segment 2 Stage, Numbers of Cycles should be set to **40.**

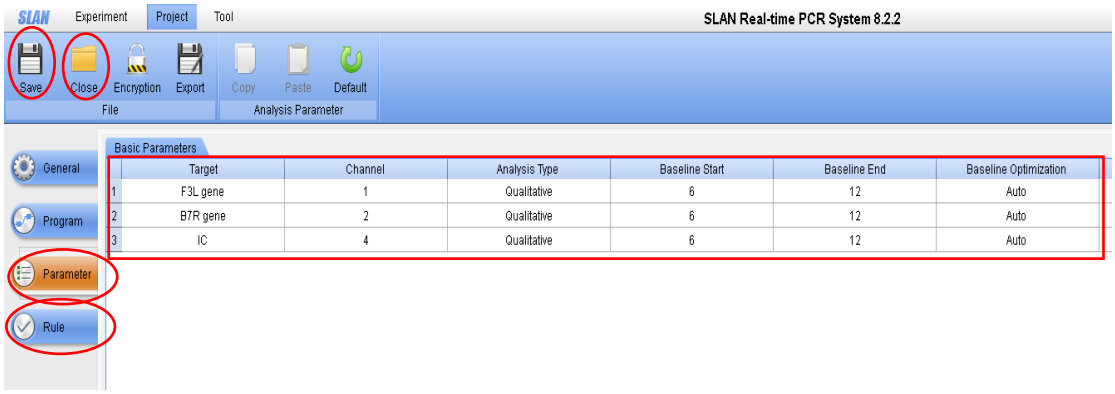
Figure 13. Reaction Program Setting



d. There is no need to set ***Parameter*** and ***Rule***, just use the default form (see **Figure 14**).

e. After the settings are completed, click ***Save*** to save the reaction program, and click ***Close*** to complete the reaction program settings (see **Figure 14**).

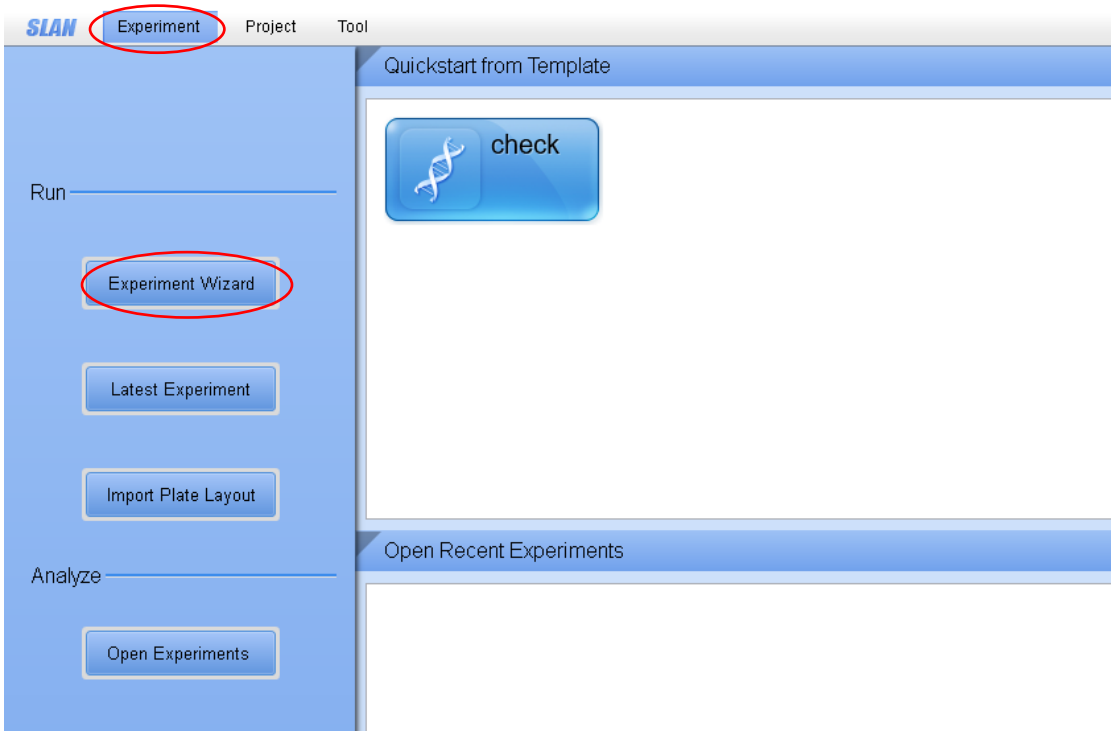
Figure 14. *Parameter, Rule* and *Save* Page



3) Experiment setting

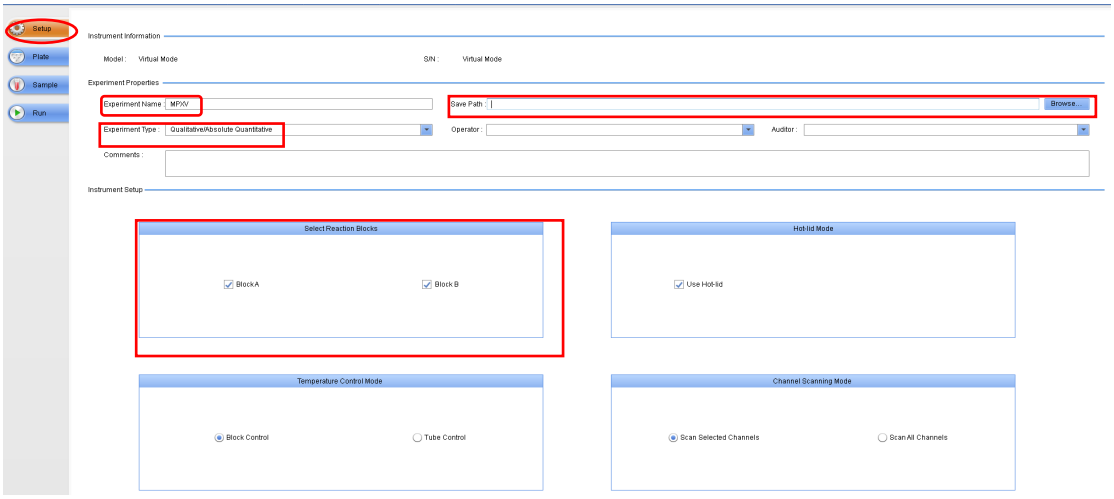
a. Select *Experiment*, click *Experiment wizard* to create the experiment (see Figure 15).

Figure 15. Experiment Page



b. Click ***Setup*** and name the experiment. Save the information in ***Save Path***, ***Experiment Type*** and ***Select Reaction Block*** (See **Figure 16**).

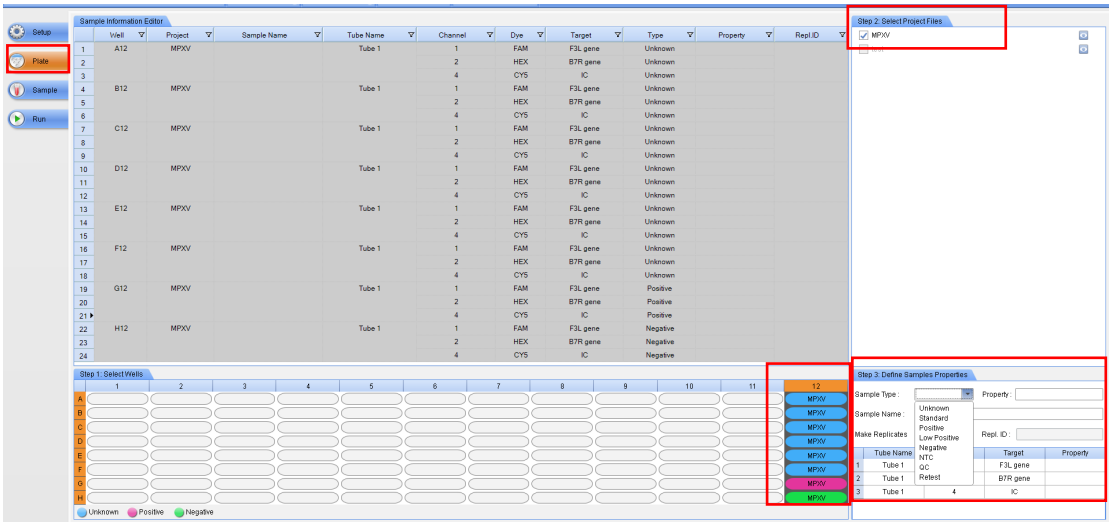
Figure16. Setup



c. Click ***Plate***,edit the plate (see **Figure 17**).

- Step 1 Choose the reaction plate
- Step 2 Choose the test project
- Step 3 Label the reaction well according to the needs. ***Unknown*** represents unknown samples, ***Positive*** represents positive control, and ***Negative*** represents blank control.

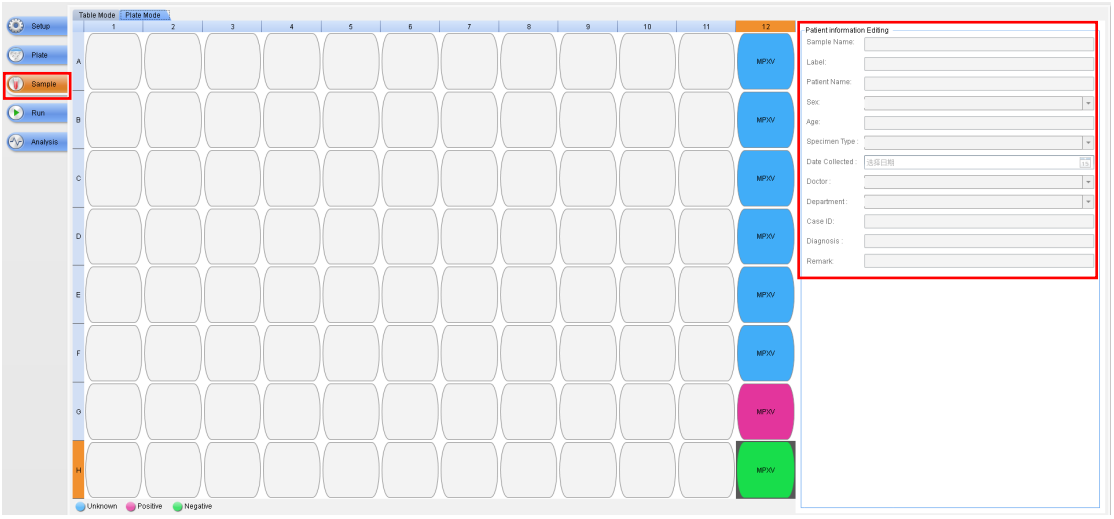
Figure 17. Plate Edit



d. Click **Sample** to edit the sample information (see **Figure 18**).

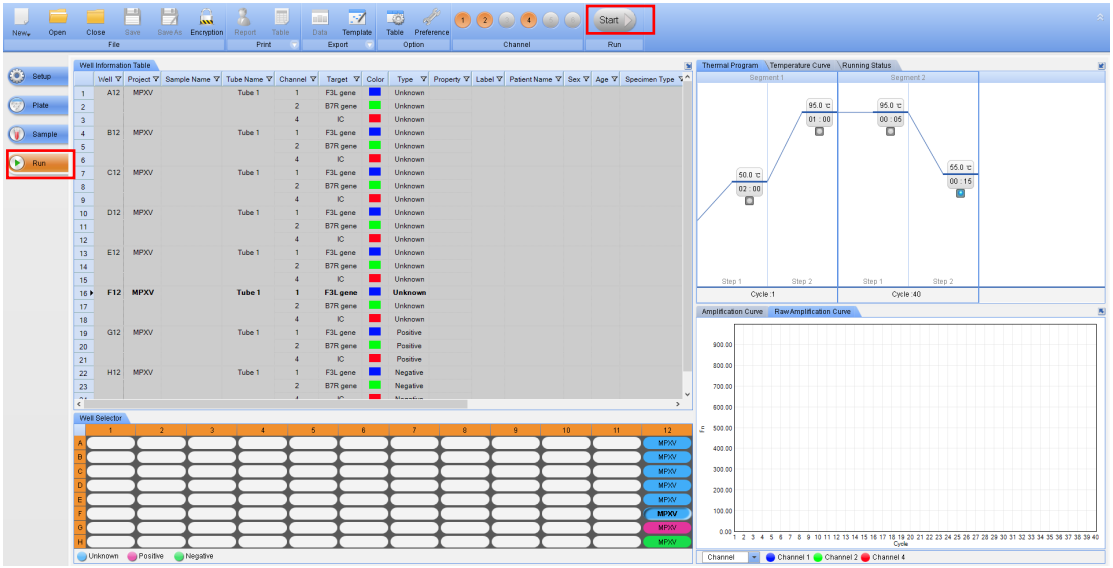
- Set sample information according to experimental requirements.

Figure 18. Sample Information



e. Click ***Run*** to enter the experiment run page. Click ***Start*** to start the experiment (see **Figure 19**).

Figure 19. Experiment Run

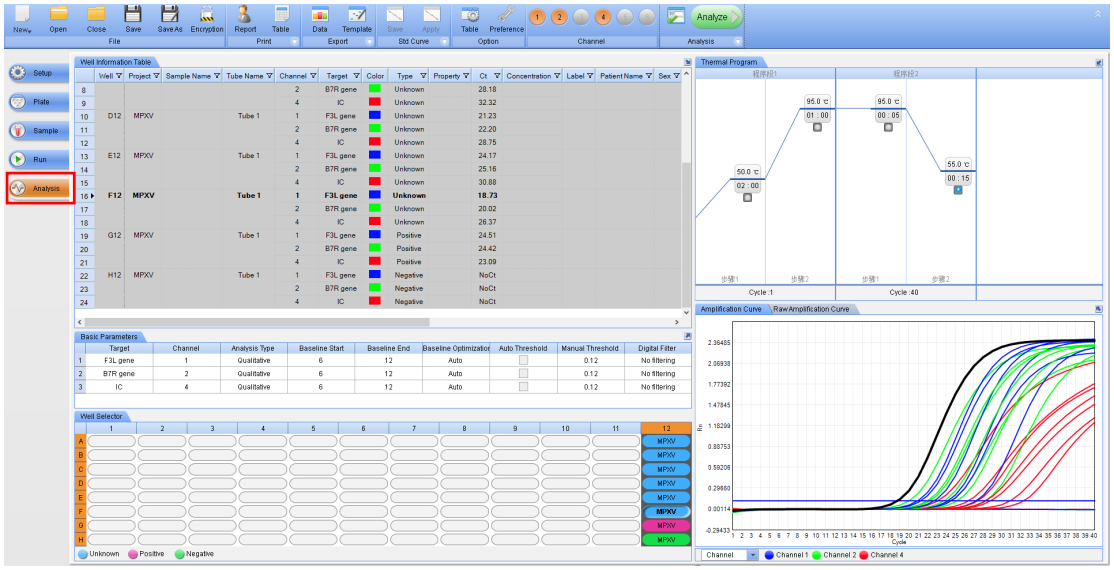


Data Analysis

1) Once the run has completed, **Click Analysis to analyze the results (see Figure 20).**

- Baseline setting: The starting points of baseline should be set as 6 and the ending as 12.
- Threshold setting: The threshold of each channel should be set separately. In setting the threshold for a channel, change the configuration of 'baseline optimization' in 'basic parameter' from automatic to manual. Then, manually adjust the threshold line, so that the threshold line just exceeds highest point of amplification curve (random noise curve) of each channel of the normal blank control.

Figure 20. Result Analysis



[Quality Control]

(1) Blank Control: No Ct is detected in the FAM and VIC/HEX, and Ct>35 or no Ct is detected in the CY5 channel.

(2) Positive Control: There are obvious amplification curves with Ct≤35 detected in the FAM, VIC/HEX and CY5 channels.

The above requirements must be met simultaneously in the same run of test. Otherwise the test should be invalid and retested.

[Cut-off Value]

The critical value of kit detection is analyzed by ROC curve analysis and percentile method. The cut-off values of this kit for detecting MPXV F3L gene and B7R gene are determined as Ct≤38. The cut-off value of internal control is Ct≤35.

[Interpretation]

IF the test was valid through assessing the quality control matrix including positive control, blank control and internal reference in testing specimen, the testing results of specimen for Mpox should be interpreted as follows.

S/N	FAM (F3L gene)	VIC/HEX (B7R gene)	CY5 (Internal Control)	Result Interpretation
1	Ct≤38	Ct≤38	Any	MPXV positive
2	Ct≤38	Ct>38 or no Ct	Any	It is recommended to retest the sample.

3	Ct>38 or no Ct	Ct≤38	Any	If Ct≤38 is detected in the retest of both targets or Ct≤38 is still retested for any single target, it is determined as MPXV positive. If Ct>38 is detected in the retest of both targets, it is determined as MPXV negative.
4	Ct>38 or no Ct	Ct>38 or no Ct	Ct≤35	MPXV negative
5	Ct>38 or no Ct	Ct>38 or no Ct	Ct>35 or no Ct	It is recommended to re-extract and test the sample. Or recollect sample to test.

Note: Obvious amplification curves are all required in the FAM and VIC/HEX channels with Ct≤38 detected and in the CY5 channel with Ct≤35 detected.

[Limitations]

(1) Results of the kit is for clinical reference only. It should not be used as the sole basis of clinical diagnosis while interpreted in combination with the patient's clinical manifestations and other laboratory test findings.

(2) The assay was validated only for human lesion swab specimens while performance with other specimen types has not established.

(3) The assay was to detect MPXV (Clade I/II) but not differentiate between Clade I and Clade II.

(4) The variola virus used in the cross-reactivity studies was a pseudo virus.

(5) False positive results could be caused potentially by cross-contamination of samples during transportation or processing, aerosols such as PCR products or contaminated consumables and equipment used in the experiment. Good laboratory procedures as outlined in Regulations on the Management of Clinical Gene Amplification Laboratories in Medical Institutions and other relevant molecular biology laboratory requirements should be performed. Properly personal protection measures such as PPE should be taken.

(6) False negative results could be caused by improper operations in sample collection, transportation, storage and processing, low viral load in the testing sample, mutation in target sequence of MPVX or sequence changes caused by other reasons, and other unverified interference factors or PCR inhibitors.

(7) Clinical performance of the kit was evaluated using clinical samples of MPXV Clade II and contrived samples of MPXV Ib from pseudo-virus respectively.

(8) Inclusivity of the kit was validated through wet-laboratory test using clinical samples of MPXV Clade II and samples from pseudo-virus of MPXV Ib and through bioinformatic analysis of MPXV sequences from GISAID databases.

[Performance Characteristics]

Limit of Detection (LoD)

The LoD is defined as the lowest amount of analyte detectable in a sample at which 95% replicates positive, and it was determined by probit analysis.

Use the MPXV negative samples to dilute the MPXV positive samples into 7 concentration gradients for detection, starting with 2000 copies/mL. Each dilution was extracted in 20 replicates. Samples were then tested with Monkeypox Virus Nucleic Acid Detection Kit (Fluorescence PCR).

A probit regression with SPSS Software was performed and the LoD value was determine for 95% positive. The test results refer to Table 1-2.

Table 1 Positive Rate of MPXV Samples (F3L/B7R Gene)

Monkeypox Concentration (Copies/mL)	Detection rate (Positive/replicates)	
	F3L Gene	B7R Gene
2000	100.00% (20/20)	100.00% (20/20)
1000	100.00% (20/20)	100.00% (20/20)
500	100.00% (20/20)	100.00% (20/20)
250	100.00% (20/20)	100.00% (20/20)
125	55.00% (11/20)	60.00% (12/20)
65	35.00% (7/20)	40.00% (8/20)
25	0.00% (0/20)	0.00% (0/20)

Table 2. Statistics of Probability Values of detection limit of MPXV

Target	Monkeypox Concentration (Copies/mL)		
	95% LOD by Probit	Lower 95% CI	Upper 95% CI
F3L gene	195.984	159.340	284.298
B7R gene	187.595	152.255	274.266

Based on above results, the LoD of the Kit was determined to be 200copies/mL (F3L gene and B7R).

Take 200 copies/mL as the LoD. Dilute the positive samples of each target of MPXV to 200 copies/mL. Each dilution was extracted in 20 replicates. Three batches of Monkeypox Virus Nucleic Acid Detection Kit (Fluorescence PCR) were used for detection on different fluorescence PCR instruments. The results showed that the positive rates of each target are less than 95%. The results showed that the LoD of each target of the kit is 200 copies/mL. The statistical results are shown in Table 3.

Table 3. Validated LoD of Three Batches of Test Kits on Applicable Instruments

Target	ABI7500 (positive/tests)	SLAN-96P (positive/tests)

	Batch 1	Batch 2	Batch 3	Batch 1	Batch 2	Batch 3
F3LTarget (200Copies/mL)	20/20 (100%)	20/20 (100%)	20/20 (100%)	20/20 (100%)	20/20 (100%)	20/20 (100%)
B7R Target （200Copies/mL）	20/20 (100%)	20/20 (100%)	20/20 (100%)	19/20 (95%)	20/20 (100%)	20/20 (100%)

Precision

Intra-lot/inter-lot and intra-day precision

On the same day, use three batches of test kits to test sample 1 (P1, 20×LoD), sample 2 (P2, 2×LoD) and sample 3 (negative sample). Each sample was tested 20 times, and the intra-batch, inter-batch and intra-day coefficients of variation were calculated to evaluate the intra-batch, inter-batch and intra-day precision.

The test results show that the intra-batch/inter-batch and intra-day precision of P1 and P2 are less than 5%, and the negative coincidence rate of negative samples is 100%. The test statistical results are shown in Table 5-7.

Table 5. Test Results of Intra-lot/Inter-lot and Intra-day Precision by 3 Batches of Kits (Sample 1)

Test Item	Gene (Channel)	ABI7500			SLAN-96P		
		Batch 1	Batch 2	Batch 3	Batch 1	Batch 2	Batch 3
Sample 1(n=20)	F3L (FAM)	0.52%	0.61%	0.56%	1.43%	1.45%	1.60%
	B7R(VIC/HEX)	0.55%	0.76%	0.74%	0.84%	0.74%	0.58%
Sample 1(n=60)	F3L (FAM)	0.76%			1.51%		
	B7R(VIC/HEX)	0.99%			0.72%		

Table 6. Test Results of Intra-lot/Inter-lot and Intra-day Precision of 3 Batches of Kits(Sample 2)

Test Item	Gene (Channel)	ABI7500			SLAN-96P		
		Batch 1	Batch 2	Batch 3	Batch 1	Batch 2	Batch 3
Sample 2(n=20)	F3L (FAM)	1.99%	1.63%	1.41%	1.86%	3.11%	2.95%
	B7R(VIC/HEX)	1.32%	1.39%	1.72%	1.47%	1.90%	2.36%
Sample 2(n=60)	F3L (FAM)	1.82%			2.66%		
	B7R(VIC/HEX)	1.58%			1.93%		

Table 7. Test Results of Intra-lot/Inter-lot and Intra-day Precision of 3 Batches of Kits (Negative Sample)

Test Item	Gene (Channel)	ABI7500			SLAN-96P		
		Batch 1	Batch 2	Batch 3	Batch 1	Batch 2	Batch 3
Sample 3 (n=20)	F3L (FAM) Coincidence rate	100%	100%	100%	100%	100%	100%
	B7R	100%	100%	100%	100%	100%	100%

	(VIC/HEX) Coincidence rate						
	IC(CY5) Coincidence rate	100%	100%	100%	100%	100%	100%
Sample 3 (n=60)	F3L (FAM) Coincidence rate	100%			100%		
	B7R (VIC/HEX) Coincidence rate	100%			100%		
	IC(CY5) Coincidence rate	100%			100%		

Inter-day precision

The same operator used three batches of the kits to test sample 1 (P1, 20×LoD), sample 2 (P2, 2×LoD) and sample 3 (negative sample), respectively. The tests were conducted twice a day for 20 consecutive days. Each sample was tested in 3 replicates, and the inter-day coefficient of variation was calculated to evaluate the inter-day precision.

The test results showed that the inter-day precision of P1 and P2 was less than 5%, and the negative coincidence rate was 100%. The test statistical results are shown in Table 8.

Table 8 Inter-day Precision of Three Batches

Test Item	Gene (Channel)	SLAN-96P			ABI7500		
		Batch 1	Batch 2	Batch 3	Batch 1	Batch 2	Batch 3
Sample 1 (n=120)	F3L (FAM)	1.70%	2.04%	1.73%	1.57%	1.73%	1.90%
	B7R (VIC/HEX)	1.12%	1.19%	1.23%	1.15%	1.44%	1.68%
Sample 2 (n=120)	F3L (FAM)	3.30%	3.35%	1.73%	3.26%	3.47%	3.50%
	B7R (VIC/HEX)	2.24%	2.30%	1.23%	2.17%	2.07%	2.53%
Sample 3 (n=120)	F3L (FAM) Coincidence rate	100%	100%	100%	100%	100%	100%
	B7R (VIC/HEX) Coincidence rate	100%	100%	100%	100%	100%	100%
	IC(CY5) Coincidence rate	100%	100%	100%	100%	100%	100%

Multi-operators and multi-sites precision

Select two locations. Two operators used the same batch of kits to test sample 1 (P1, 20×LoD), sample 2 (P2, 2×LoD) and sample 3 (negative sample) on different fluorescence PCR instruments at two sites on the same day. Each sample was tested in 20

replicates, to evaluate the precision between different operators and different sites.

The results showed that the precision of P1 and P2 are less than 5.0%. The negative coincidence rate is 100%. The test statistical results are shown in Table 9-12.

Table 9. Precision Test Results between operators and between labs on ABI7500 (1)

Test Item	Gene (Channel)	Operator 1		Operator 2	
		Site 1	Site 2	Site 2	Site 1
Sample 1 (n=20)	F3L (FAM)	1.10%	0.51%	0.60%	0.55%
	B7R (VIC/HEX)	0.58%	0.65%	0.75%	0.55%
Sample 2 (n=20)	F3L (FAM)	3.56%	1.42%	1.66%	2.01%
	B7R (VIC/HEX)	1.35%	1.73%	1.38%	1.33%
Sample 3 (n=20)	F3L (FAM) Coincidence rate	100%	100%	100%	100%
	B7R (VIC/HEX) Coincidence rate	100%	100%	100%	100%
	IC(CY5) Coincidence rate	100%	100%	100%	100%

Table 10. Precision Test Results between operators and between labs on ABI7500(2)

Test Item	Gene (Channel)	Between operators		Between labs	
		Site 1	Site 2	Operator 1	Operator 2
Sample 1 (n=40)	F3L (FAM)	0.85%	0.57%	0.57%	0.59%
	B7R(VIC/HEX)	0.67%	0.96%	0.99%	0.60%
Sample 2 (n=40)	F3L (FAM)	3.56%	1.66%	3.56%	1.42%
	B7R(VIC/HEX)	1.35%	1.38%	1.35%	1.73%
Sample 3 (n=40)	F3L (FAM) Coincidence rate	100%	100%	100%	100%
	B7R (VIC/HEX) Coincidence rate	100%	100%	100%	100%
	IC(CY5) Coincidence rate	100%	100%	100%	100%

Table 11. Precision Test Results of between operators and between labs on SLAN-96P (1)

Test Item	Gene (Channel)	Operator 1		Operator 2	
		Site 1	Site 2	Site 1	Site 2
Sample 1 (n=20)	F3L (FAM)	0.77%	0.63%	1.07%	1.07%
	B7R (VIC/HEX)	0.45%	0.38%	0.55%	0.55%
Sample 2 (n=20)	F3L (FAM)	4.00%	2.80%	3.80%	2.91%
	B7R (VIC/HEX)	4.20%	2.54%	4.26%	2.31%

Sample 3 (n=20)	F3L (FAM) Coincidence rate	100%	100%	100%	100%
	B7R (VIC/HEX) Coincidence rate	100%	100%	100%	100%
	IC(CY5) Coincidence rate	100%	100%	100%	100%

Table 12. Precision Test Results of between operators and between labs on SLAN-96P (2)

Test Item	Gene (Channel)	Between operators		Between labs	
		Site 1	Site 2	Operator 1	Operator 2
Sample 1 (n=40)	F3L (FAM)	0.66%	1.14%	0.77%	1.32%
	B7R(VIC/HEX)	0.61%	0.81%	0.86%	0.59%
Sample 2 (n=40)	F3L (FAM)	2.50%	1.47%	2.50%	1.45%
	B7R(VIC/HEX)	2.72%	1.41%	2.72%	0.91%
Sample 3 (n=40)	F3L (FAM) Coincidence rate	100%	100%	100%	100%
	B7R (VIC/HEX) Coincidence rate	100%	100%	100%	100%
	IC(CY5) Coincidence rate	100%	100%	100%	100%

Analytical Specificity (Cross-reactivity)

The analytical specificity was evaluated by testing the cross-reactivity of a panel of 36 kinds of different pathogens. The organisms selected were clinically relevant organisms, common skin flora or laboratory contaminants, or microorganisms. Each organism was tested with 3 batches of Monkeypox Virus Nucleic Acid Detection Kit (Fluorescence PCR) on different fluorescence PCR instruments.

The results showed that no false positive samples were detected for 36 different pathogens by the kit. The test results are shown in Table 13.

Table 13. Results of Analytical Specificity

Pathogens	ABI7500			SLAN-96P		
	Batch 1	Batch 2	Batch 3	Batch 1	Batch 2	Batch 3
Variola virus (smallpox)	-	-	-	-	-	-
Molluscum contagiosum virus	-	-	-	-	-	-
Vaccinia virus	-	-	-	-	-	-
Cowpox virus	-	-	-	-	-	-
Ectromelia (mousepox) virus	-	-	-	-	-	-
Camelpox virus	-	-	-	-	-	-
Buffalopox	-	-	-	-	-	-
Parapox virus	-	-	-	-	-	-

HSV-1	-	-	-	-	-	-
HSV-2	-	-	-	-	-	-
Varicella-zoster virus	-	-	-	-	-	-
Streptococcus mitis	-	-	-	-	-	-
Staphylococcus aureus	-	-	-	-	-	-
Staphylococcus epidermidis	-	-	-	-	-	-
Streptococcus pyogenes	-	-	-	-	-	-
Pseudomonas aeruginosa	-	-	-	-	-	-
Trichophyton rubrum	-	-	-	-	-	-
Corynebacterium jeikeium	-	-	-	-	-	-
Candida albicans	-	-	-	-	-	-
Human Genomic DNA	-	-	-	-	-	-
Lactobacilllus species	-	-	-	-	-	-
Escherichia coli	-	-	-	-	-	-
Acinetobacter calcoaceticus	-	-	-	-	-	-
Bacteroides fragilis	-	-	-	-	-	-
Enterococcus faecalis	-	-	-	-	-	-
Streptococcus Group C	-	-	-	-	-	-
Streptococcus Group G	-	-	-	-	-	-
Corynebacterium diptheriae	-	-	-	-	-	-
Neisseria gonorrhoeae	-	-	-	-	-	-
Chlamydia trachomatis	-	-	-	-	-	-
Mycoplasma pneumoniae	-	-	-	-	-	-
Mycoplasma genitalium	-	-	-	-	-	-
Human papilloma virus (HPV)	-	-	-	-	-	-
Trichomonas vaginalis	-	-	-	-	-	-
Treponema pallidum	-	-	-	-	-	-

Note: '–' means negative for target F3L gene or B7R gene.

Interfering Substances

The potentially interfering substances were spiked into samples with concentration of MPXV near the LoD of the kit. All samples were then tested with Monkeypox Virus Nucleic Acid Detection Kit (Fluorescence PCR) in 3 replicates. Testing results of samples containing potentially interfering substances were compared to samples containing no spiked interfering substance, no false positive or false negative observed.

All tested interfering substance of said concentrations showed no influence on the performance of Monkeypox Virus Nucleic Acid Detection Kit (Fluorescence PCR).

Table 14. Results of Interfering Substances

Substance/Class	Description/Active Ingredient	Substance Level	Positive/tests		Interference at Concentration (Yes/No)
			Negative Sample	Positive Sample	

Control	Negative matrix	/	0/3	3/3	/
Acyclovir	Antiviral medication	7mg/mL	0/3	3/3	No
Albumin	Protein	≥2.2mg/mL	0/3	3/3	No
Benadryl cream/ointment*	Diphenhydramine (antihistamine)	5%(w/v)	0/3	3/3	No
Benzocaine containing local anesthetic	Benzocaine containing local anesthetic	5%（v/v)	0/3	3/3	No
Blood/EDTA	Blood (human)	5%（v/v)	0/3	3/3	No
Casein	Milk protein	25mg/mL	0/3	3/3	No
Cornstarch	Cornstarch	2.5mg/mL	0/3	3/3	No
Docosanol containing cold sore treatment	Docosanol containing cold sore treatment	5%（v/v)	0/3	3/3	No
Douche	Benzalkonium chloride	7%(w/v)	0/3	3/3	No
Feces	Feces(human)	0.22%(w/v)	0/3	3/3	No
Female urine	Female urine(human)	10%（v/v)	0/3	3/3	No
Hydrocortisone cream	Hydrocortisone cream	7%(w/v)	0/3	3/3	No
Lidocaine containing cream	Lidocaine containing cream	7%(w/v)	0/3	3/3	No
Lubricant	KY Jelly	7%(w/v)	0/3	3/3	No
Male urine	Male urine(human)	10%（v/v)	0/3	3/3	No
Mucin	Purified Mucin protein	60 μg/mL	0/3	3/3	No
Neosporin	Bacitracin, neomycin, and polymixin b	5% (w/v)	0/3	3/3	No
Petrolatum containing lip	Vaseline	7%(w/v)	0/3	3/3	No
Seminal fluid	Seminal fluid(human)	7%（v/v)	0/3	3/3	No
Zinc Oxide ointment	Zinc oxide	7% (w/v)	0/3	3/3	No

Inclusivity

(1) Inclusivity of the kit was validated using 7 clinical samples of MPXV Clade II collected by Shenzhen People's hospital from patients from different regions of China and 3 samples prepared from synthesized pseudoviruses of MPXV Clade I (reference genome：MN702444.1). These samples were tested by the kit with results met requirements in LOD (95% detectable) and repeatability (CV<5%) for both F3L and B7R.

(2) GISAID database was accessed in May 2024 and 2005 MPXV sequences including 30 sequences of clade Ia, 21 sequences of Clade Ib, and 1954 sequences of clade II were downloaded and analyzed bioinformatically against the sequences of

primers/probes of the kit. No mutation was identified for both F3L and B7R.

Clinical Performance evaluation

Performance of the investigational kit in testing MPXV Clade II was evaluated in six clinical centers with 548 clinical samples enrolled, including 214 positive samples and 334 negative samples. Comparing to sequencing, clinical performance of the kit was summarized in terms of Positive Percent Agreement (PPA) and Negative Percent Agreement (NPA) as Table 15 below.

Table 15. Result summary of clinical trial

Investigational Kit	Comparator (Sequencing)		Total	Positive percent agreement (95%CI)	Negative percent agreement (95%CI)	Overall percent agreement (95%CI)
	Positive	Negative				
Positive	212	2	214	100.00% [98.22%-100.00%]	99.40% [97.86%-99.84%]	99.64% [98.68%-99.90%]
Negative	0	334	334			
Total	212	336	548			

Kappa: 0.9923.

Clinical performance of the kit in testing MPXV Clade 1b was evaluated using 43 contrived samples from synthesized pseudo-viruses comparing to sequencing with PPA about 100% (95%CI: 91.78%, 100.00%).

[Symbol Description]

Symbols	Definition
	IN VITRO DIAGNOSTIC MEDICAL DEVICE
	CE MARK
	KEEP AWAY FROM SUNLIGHT
	KEEP DRY
	UPPER LIMIT OF TEMPERATURE
	CONSULT INSTRUCTIONS FOR USE
	BATCH CODE
	CATALOGUE NUMBER

	USE-BY DATE
	DATE OF MANUFACTURE
	MANUFACTURER
	SUFFICIENT FOR <N> TESTS
	CAUTION
	AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY

[References]

1 National Health Commission of China. Technical guidance for Mpox prevention and control (2022 version). 27 June 2022.

2 Centers for Disease Control and Prevention. Biosafety in microbiological and biomedical laboratories. (refer to latest edition).

3 CLSI Publication M29. Protection of laboratory workers from occupationally acquired infections; Approved Guideline. (refer to latest edition).

4 World Health Organization. Interim guidance, Diagnostic testing for the monkeypox virus (MPXV), 10 May 2024.

[Manufacturer Information]

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EC REP

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[Approval and Revision Dates of IFU]

Version No.	Release Date	Description of Revision
V1.0	2024-08-29	Initial version
V1.1	2025-05-10	1 Updated Precautions and warnings on any potential false results. 2 Clarified the extraction kit for the device. 3 Added notes in laboratory procedures to avoid any potential cross-contamination.
V1.2	2025-08-05	Clarified the applicable extraction kit of Type II-1 of Macro & Micro-Test Viral DNA/RNA Kit (HWTS-3017)
V1.3	2025-09-19	Revised the IFU in context and formats according to the review comments from WHO.