

qcLAMP-Mini Platform

A platform for performing real-time quantitative colorimetric loop-mediated isothermal amplification (qcLAMP).



Praecis Dx Ltd

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Warranty and Responsibility

All products are tested under rigorous quality management processes by the Manufacturer. The Manufacturer guarantees to ensure the quality of the product during the warranty period. If there are any issues related to the quality of the product, please contact your local distributor.

Manufacturer warrants that the qcLAMP-Mini Platform will conform to its specifications and performance for a period of 24 months after its shipment date from the Seller. Non-compliance with the warnings and precautions, as well as the product instructions, during the usage of the qcLAMP-Mini Platform, will result in the loss of warranty.

The warranty does not cover issues that result from:

- a) Servicing, fixing, or replacing the product, not authorized by PraecisDx Ltd
- b) External causes such as accident, abuse, misuse or problems with electrical power and
- c) Missing or altered service tags or serial numbers.

Enquiries and customer service

For any further information of inquiries for the product please send us an e-mail at (info@praecisdx.com).

1. Intended Use

The PraecisDx qcLAMP-Mini Platform is a testing device for nucleic acid amplification and detection using real-time quantitative colorimetric loop-mediated isothermal amplification (qcLAMP). It enables rapid detection of bacterial, viral or fungal contaminants in a range of settings including veterinary, environmental and food processing.

For further information relating to use of the test reagents, please see the PraecisDx UTI-Dx kit insert.

2. Product Description

The qcLAMP-Mini platform has a small footprint, is lightweight and runs with low power (5V, 2.4 A).

The device connects via Bluetooth to a smartphone or tablet operating either an Android or iOS based application.

The qcLAMP-Mini employs a mini digital camera for monitoring real-time colour changes of LAMP reagents (provided separately) during a colourimetric LAMP amplification process. The camera collects non-calibrated images at predefined time intervals every 10 seconds and automatically extracts the red, green, and blue (RGB) channel values. Colour change is expressed as colour index units (pixels) on the Y-axis of a real-time curve that is displayed on the screen of a smart device connected by Bluetooth (smart device not included).

The instrument can analyse up to six individual samples simultaneously and the colour index units are visualised as curves displayed in real time on the connected smart device. The user can automatically send the data to a registered email account for remote analysis or directly from the smartphone application.

Before using the instrument for the first time it needs to connect to a smart device via Bluetooth. Prior to using qcLAMP-Mini for the first time, two simple steps are required (detailed descriptions of how to do this are given in section 8 of this instruction leaflet):

- Download the PraecisDx app to your smart device
- Register the instrument with the app, this is achieved using your smart device camera to scan the QR code supplied with the qcLAMP-Mini (for convenience, the same QR code is displayed on the underside of the instrument and also on its packaging). This only needs to be done once on receipt of the qcLAMP-Mini. The benefit of this approach is that multiple instruments can be registered to a single smart device.

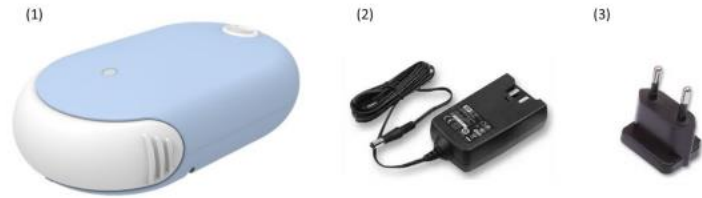
In a similar manner, the UTI-Dx kit also uses a QR code to register the kit with the PraecisDx app. This simple process needs to be performed when starting a new kit, and the relevant QR code is attached to the test kit packaging

2. Product Dimensions

Size:	18.1cm x 10.7cm x 5.2cm.
Weight :	300 g.
Moving parts:	None

3. Package Contents

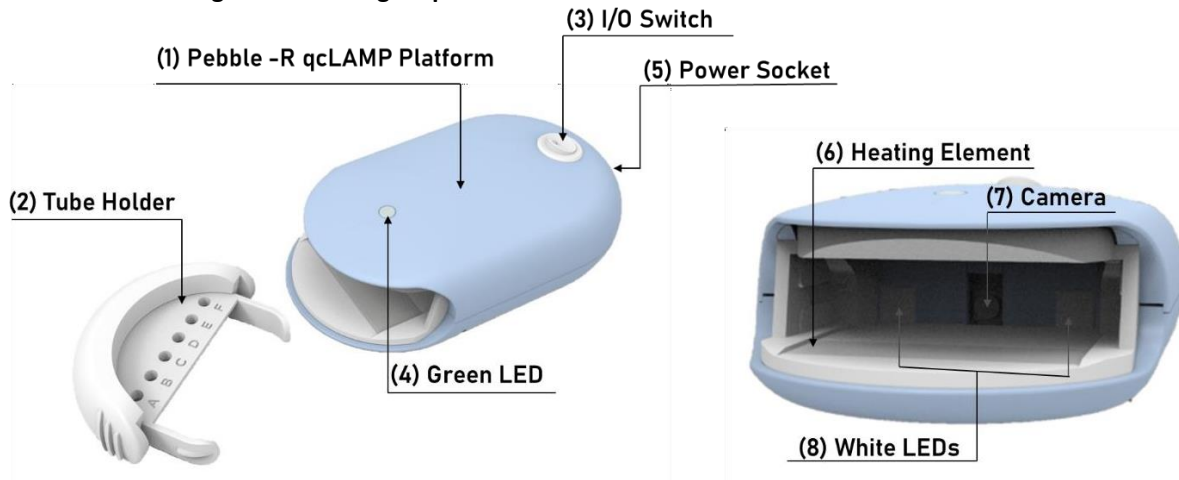
- 1 x qcLAMP-Mini device
- 1 x AC/DC power supply unit
- 1 x power plug (EU, US or UK plug)



3.1 Component Parts

Label	Description	Function
1	qcLAMP-Mini Platform	Main body of the device
2	Sample Tuber Holder	Removable part that accepts the vials
3	On/off Switch	Main power switch
4	Green LED Light	Switched on when system is running a test
5	Power Socket	Plugs to the power-supply, with a 5 V DC
6	Heating Element	Heats the vials
7	Camera	Records the pixels of the color-change in the vials
8	White LED Lights	Illuminates the chamber

4. Storage and Handling Requirements



Keep dry. Do not expose to water.
Refer to your box and the bottom of your device for the storage conditions for your device.
Operate at room temperature (optimum range: 22°C to 27°C, functional range: 20°C to 30°C)
Humidity 0% to 75% humidity.
Do not refrigerate or freeze.

5. Disposal Information

- All plastic parts are 100% recyclable.
- Packaging box is 100% recyclable.
- The qcLAMP-Mini device should be disposed of as electronic equipment according to all local, state, country, and federal regulations.

6. Additional Materials and Equipment Required but not Included.

Equipment

- Android (**compatible with v6.0 to v14.0**) based smart device (mobile phone or tablet). It is recommended to have a minimum of 4Gb RAM. iOS is upcoming, and this IFU will be updated upon its release.
- Fixed volume 20 ul micropipette and appropriate disposable tips.
- Latex gloves and appropriate PPE for handling biological samples

Consumables

- PraecisDx UTI-Dx test kit. Please see instructions for use supplied with the kit.

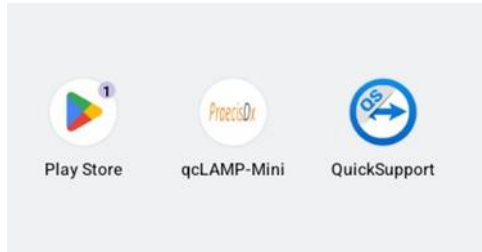
7. Warnings and Precautions

- For professional use only.
- Not intended to be used by individuals for self-testing.
- Local guidelines on biosafety should be followed in all circumstances.
- The instrument should be operated in an appropriately equipped facility by trained personnel.
- The equipment has been designed and tested to CISPR 11 Class A.
- The device is neither water-resistant nor waterproof.
- Always place the device on a flat surface.
- Use only compatible kits, consumables and equipment that meets the specifications provided by PraecisDx Ltd.
- Make sure you have a strong Bluetooth connection to avoid unexpected termination of the device's operation.
- Ensure you have a strong and secure internet connection, to avoid connection loss with the cloud service.
- Handle with care. If not, parts could detach, dislocate, or deform. In such cases, please contact your Distributor (see section 13.2).
- Do not disassemble the qcLAMP-Mini device as it might result in performance issues.
- Do not touch or move either the camera or camera lens. Sensitivity can be significantly reduced.
- Post amplification qcLAMP reaction tubes **must not be opened** to avoid contamination with DNA amplicons, which could result in false positive results.
- Dispose of the used tubes as biological waste.
- Non-compliance with these warnings and precautions may result in permanent malfunction of the system.
- Between runs, it is suggested to leave approximately a 10 min time-space. During this time keep the tube holder out of the chamber of qcLAMP-Mini Platform.

8. Initial Instrument Setup and Connection to Smart Device

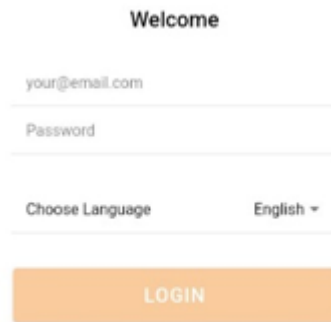
- 8.1 Check that the original packaging is intact and not damaged, and that the blue security seal is intact. If there are signs of damage, contact your local distributor.
- 8.2 Assemble the power unit with the socket adaptor relevant to your local power supply.
- 8.3 Insert the power cable into the socket at the back of the qcLAMP-Mini illustrated as (5) in section 3.1.

8.4 Open either Google Play Store (Android) or App Store (iOS) and search for the Praecis qcLAMP-Mini app:

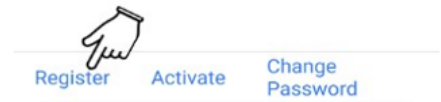


8.5 Open the app and you will see the welcome page where you will be asked to select your preferred language.

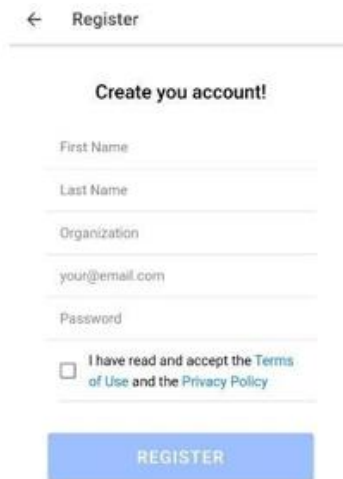
Note: You do not need to enter your email address or password at this stage.



8.6 On the next page, locate the “Register” option at the bottom of the screen and select this:



8.7 You will then be prompted to fill in your account details. Once you hit “Register” a verification code will be sent to your email address



8.8 To verify your account, click on the “Activate” button at the bottom of the screen



8.9 At this point you enter the Activation code that was just sent to your email address and then click on “Verify”. You will then be redirected to the login page.

Activation

Activate your account!

your@email.com

Activation code

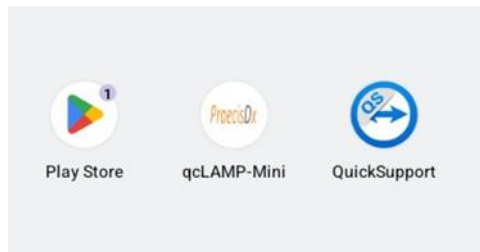
VERIFY

9. Powering up the qcLAMP-Mini and Pairing it with Your Smart Device

9.1 Switch the device on via the power button (illustrated as (3) in section 3.1).

Note. Please wait approximately two to three minutes (2-3 min) for the system to boot in order to be detected via Bluetooth. If it is the first time that you turn on the system, you should wait for 5-6min.

9.2 Return to your smart device and restart the PraecisDx qcLAMP-Mini app. Ensure that the Bluetooth facility on your smart device is switched on.



9.3 Now, login using your previously selected email address and password.

Login

Welcome

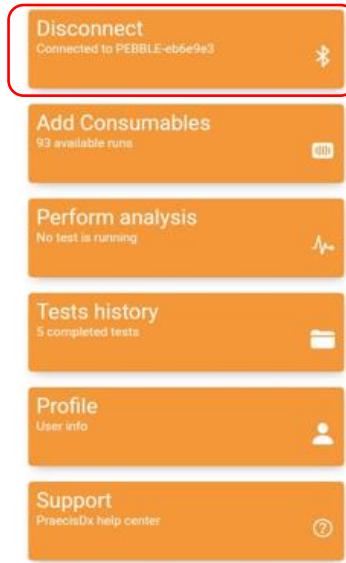
test@test.com

.....

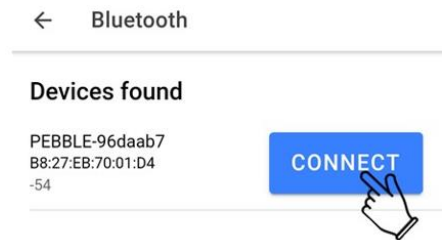
Choose Language English ▾

LOGIN

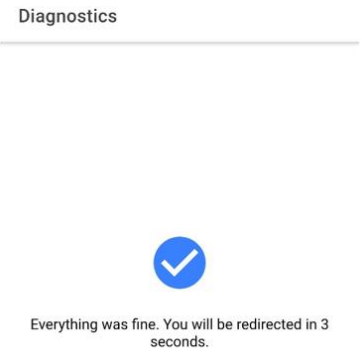
This will then open the app main page. Select the first option to connect the instrument to your smart device via Bluetooth:



9.4.a The app will then automatically search for the qcLAMP-Mini, and when found will display the its serial number as shown in the following example. Select the “Connect” button and your smart device will pair with the qcLAMP-Mini.



9.4.b The instrument will then automatically perform a short internal self-check and will then display the following screen to confirm all internal processes are working correctly. Should this screen fail to appear, please or contact your local PraecisDx distributor.



9.4 If you are setting up the instrument for the first time, it will be necessary to assign the qcLAMP-Mini to your smart device by completing one more simple step. Once assigned, you will no longer be required to perform this step. Assignment is achieved by using the camera on your smart device to scan the QC code that is displayed on the packing exterior or on the base of the instrument. Both are the same, so you can use either. You will be prompted to scan QR codes by this screen.

Device is not assigned yet. Using the button below, please scan the code of the device to continue.



Below are images of the QC codes located on the packaging exterior and on the base of the qcLAMP-Mini:



At this point, the qcLAMP-Mini is now fully set up and you can control all tests via the paired smart device.

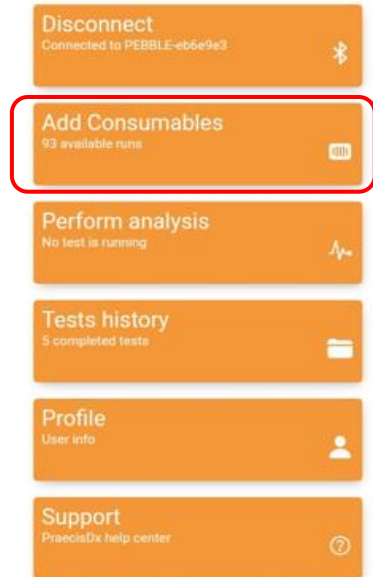
10. Assigning UTI-Dx Kits to the qcLAMP-Mini and Running Tests

10.1 Assigning UTI-Dx Test Kit Runs. Go to the home page of the qcLAMP-Mini app and select “Add Consumables”.

A pop-up window will appear to scan the QR code located on the back the kit package.

Your smart-device will ask to allow qcLAMP-Mini application to take pictures and record video via a popup window.

To use the application, permissions must be allowed.



10.2 Use the camera on your smart device to scan the QR attached to the kit pouch.

This will only need to be done once per kit. It will automatically add 62 sample runs.

When you receive a new kit you will need to scan the QR code by following the same process.




11. Performing a Test. – Please Refer to the UTI-Dx Kit Insert for Detailed Use of the Samples and Reagents

Select the “Perform Analysis” tab on the app home page. Four windows will then open in sequence. The first enables you to enter the number of samples being run. For a full UTI-Dx test run, you should select “6”:

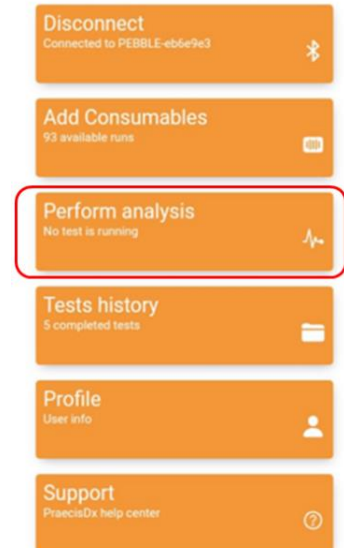
Step - 1/4

Set number of samples

Number of samples 

NEXT

CANCEL



When you select “Next” the app will prompt you to select the reagent kit details which were entered by scanning the kit QR code during section 10 of this instruction manual.


The screen will show the kit reference and the number of tests remaining from that kit, as follows: Check the circle to confirm the kit being used and then select “Next”

Step - 2/4

Select consumable

Name

4559 available runs
ID: Z7XW90PGHSBYJ3F11ECM

NEXT 

CANCEL


The next window allows you to enter the test parameters, these should be entered as follows:


Step 3/4

Set parameters

Temperature (°C) 77

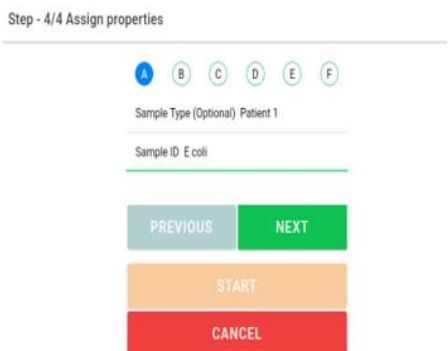
Time (min) 35

Colorimetric dye HNB 

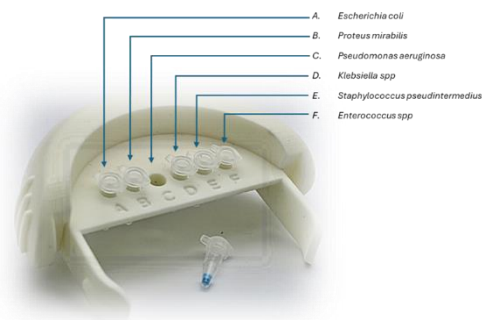
CONFIRM 

CANCEL

Select “Confirm” to enter the test parameters and to move to the final window, which allows you to enter the patient reference information and also to define which bacterial species is being detected in each of the six test positions A to F.



These are designated in the kit Instructions as indicated in the Image shown on right. The patient ID is entered into the “Sample Type” line, and each bacterial species is entered into the “Sample ID” line. If you wish, you can simply enter the corresponding species letter into this line. Select “Next” to move onto the following organism.



When all the information has been entered, and the urine samples have been added to the tubes and placed into the correct position in the sample holder, insert the sample holder into the qcLAMP-Mini and select “Start” to initiate the test run.

The qcLAMP-Mini will indicate that the test is running by illuminating the green light on top of the instrument.



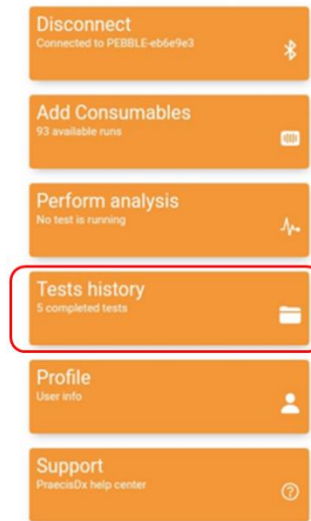
The instrument will then incubate the samples for 35 minutes and will simultaneously transmit the data curves to your smart device for all six samples in real time. The curves will be displayed on your smart device as they emerge. Once the run is complete, the green light on top of the instrument will switch off.

Please note,

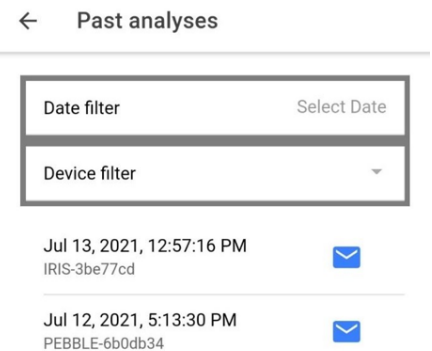
- **Do not remove the sample holder from the qcLAMP-Mini before the run is completed as indicated by the green light.**
- **Do not move the instrument when it is running.**
- **Ensure that your smart device is close to the instrument to ensure a strong Bluetooth connection, otherwise, data may be lost.**
- **Once the run is complete, remove the sample tubes from the instrument and discard them into clinical waste. Under no circumstances open the tubes after the run, there is a risk of the amplified DNA contaminating the instrument resulting in incorrect results.**
- **When removing the sample holder do not touch the heating element (item 6 in section 3.1 of this manual) since it reaches high temperatures and could result in burn injury.**

12. Data Retrieval

When a run is completed, there results are stored on your smart device and can be accessed by selecting the “Test History” tab on the app home page.



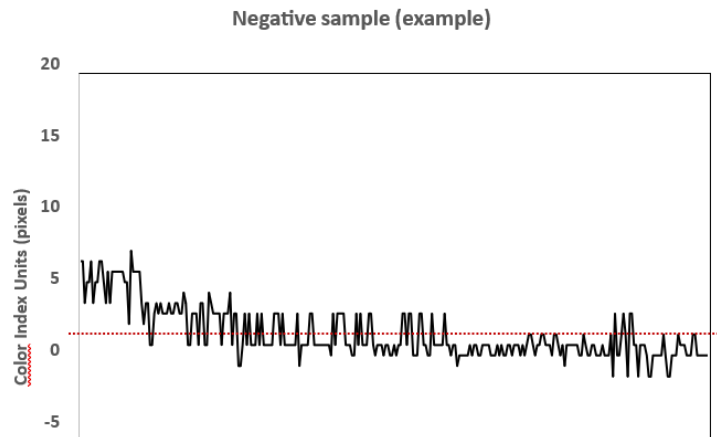
Selecting this tab opens a new window which allows you to retrieve data directly by reference to the test date. Additionally, you may have the results sent directly to your email address in a CSV format. This allows you to perform additional analysis by exporting the results to Excel or by transferring the data to your practice database. It also allows you to provide remote access to the data to other colleagues located in different premises,



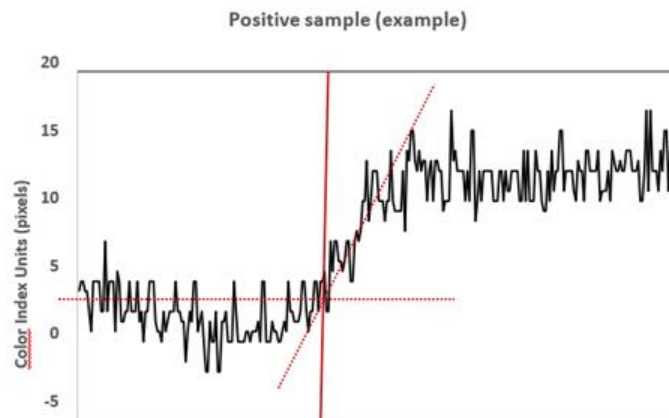
13. Data Interpretation.

For a detailed description of how the data is analyzed and interpreted by the qcLAMP-Mini, please refer to the UTI-Dx test kit manual.

In summary, as the LAMP reaction develops in the qcLAMP-Mini, the amplification of the target species DNA results in a colour change from the LAMP reagents. If the sample is negative for the target organism, no colour change will occur, and the resulting curve produced during the incubation period will be flat.



A positive sample will show development of the colour index during the incubation period.



14. Cleaning Instructions

In case of contamination, use gentle surface decontaminants such as 10% bleach (1:10 dilution of commercial 5.25-6.0% sodium hypochlorite) or equivalent to disinfect reaction chamber and tube holder of the system.

- Please be careful while cleaning. Do not touch the camera or camera lens.
- Ensure the tube holder is dry before loading onto the device.
- Do not use ethanol at the outer parts of the device, as it may cause the loss of colour intensity.

15. Contact Information.

Your local distributor is:



16. Technical Support.

In the first instance, please contact your local distributor. They will transfer your questions directly to the Praecis Dx Technical Support Team.