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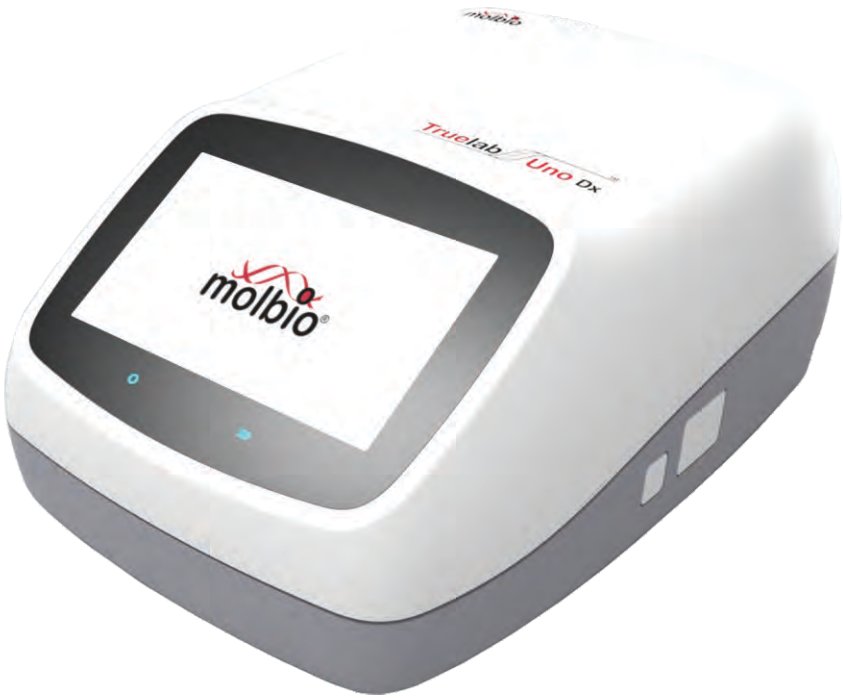
Truelab® Uno Dx

Real Time Quantitative micro PCR Analyzer



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User Manual

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Preface

I. Contact Addresses

Molbio Diagnostics Private Limited
Registered Office: Plot No. L-46, Phase II D,
Verna Industrial Estate,
Verna, Goa - 403 722, INDIA.

II. Warranty

Warranty Information would be specified in the warranty certificate. Contact your Molbio representative for further information. Normally the instrument would be under warranty for a period of 12 Months from the date of Installation or 14 Months from the date of Invoice whichever is earlier. Post warranty services are also available from Molbio.

III. Trademarks

Truelab® / Truenat® / Trueprep® / Truepet® are trademarks of Molbio Diagnostics Private Limited

IV. Intended Use

The **Truelab® Uno Dx** Real Time Quantitative micro PCR Analyzer is intended for performing real time PCR as well as real time RT-PCR of target nucleic acids derived from a broad variety of human pathogens using the **Truenat®** disease specific micro PCR chips. It is an *In Vitro* Diagnostics (IVD) device meant for professional use only.

V. Preamble

Before starting the PCR testing on the **Truelab® Uno Dx Real Time Quantitative micro PCR Analyzer** it is important to read this USER MANUAL thoroughly and completely. All instructions contained in this manual need to be adhered to and non-adherence may lead to serious damage to the equipment.

VI. Usage of the Truelab® User Manual

The USER MANUAL at the outset introduces the fundamentals of PCR and real time PCR, the concepts of Ct and multiplexing in PCR. It then gives the overview of the **Truelab® Uno Dx Real Time Quantitative micro PCR Analyzer** and its specifications and thereafter proceeds to guide the USER through the friendly software on how to perform the PCR assay using the **Truenat®** micro PCR chip on the **Truelab® Uno Dx Real Time Quantitative micro PCR Analyzer.**

VII. Conventions Used in this Manual

This manual uses certain conventions that make it easier for you to differentiate types of instructions.

Note for customers: Any serious incident that has occurred in relation to the device shall be reported to the Molbio Diagnostics Private Limited and the competent authority of the Member State in which the user and/or the patient is established.

Text Conventions:

Text Convention	Usage
Numbered Lists	Numbered Lists indicate that the steps need to be performed according to the numbering.
Bold Text	When found within a numbered list or explanatory section, Bold Text is used to indicate an object that the user interacts with, which can be a physical object or an object on the software interface. For instance **Touchscreen**, **Power Button** and **AC Adapter** are references to physical objects. **Send** and **OK** are references to objects on the software interface.

Note Conventions:

You will see three types of notes in this manual. Each has a symbol and a particular type of textual formatting to indicate what type of note it is.
The table below details their use, along with the associated symbol.

Symbol	Text Formatting and Usage
Note	***This is a note.*** A note communicates information that cannot be included as part of a procedural list, but is useful for the user to understand what he is doing in a certain section or to understand the relevance of a particular section or instruction.
Important:	***This is an Important Note.*** An important note communicates important information that cannot be included as part of a procedural list, but is integral for the user to read and understand.
Caution: ⚠	***This is a Cautionary Note.*** A cautionary note is placed before or after any instruction or section that may cause damage to the device or invalidate the test results if performed, or if performed incorrectly. It is also used to communicate general precautions and things to avoid.

1 Introduction

Thank you for the purchase of **Truelab® Uno Dx Real Time Quantitative micro PCR Analyzer.** The **Truelab® Uno Dx** is a revolutionary portable and battery-operated PCR analyzer. It enables fast, accurate and reliable near-care disease testing. It is easy to use and requires minimal training.

This is the User Guide for the **Truelab® Uno Dx Real Time Quantitative micro PCR Analyzer**. It provides detailed instructions for the use of all the **Truelab® Uno Dx's** available functions, as well as additional information about its technical specifications, a brief introduction to the concept of PCR and a glossary.

1.1 Polymerase Chain Reaction (PCR)

The Polymerase Chain Reaction, invented in 1983 by Kary Mullis, is a technique of amplifying DNA that has found widespread use among professionals and researchers involved with analysis of nucleic acids due to its high reliability, speed and sensitivity.

Since Deoxyribonucleic Acid (DNA) is unique to each species and individual, it is currently the most reliable identifier for any living organism, from microbes to humans. Using the PCR method, even the smallest amounts of DNA can be amplified for further analysis. For example, it can be used to amplify even the smallest trace of an infectious bacterium or virus from a biological specimen.

The process involves amplifying a specific piece of DNA in a sample using an enzyme called DNA polymerase and periodic cycling of temperature, which anneals and splits strand, respectively. With each round of annealing and splitting, the amount of nucleic acid doubles leading to an exponential amplification of the starting trace nucleic acid in a short amount of time.
For instance, a typical PCR reaction that runs for thirty-five cycles, at 100% efficiency, will give you:

$$2^{35} = 34 \text{ billion copies}$$

The amplified DNA is then analyzed separately so that it can be identified.

1.2 Real-time PCR

Real-time PCR is a variant of the regular PCR method. It has several advantages over regular PCR that has made it the PCR method of choice. A Real-time Polymerase Chain Reaction involves simultaneously amplifying and detecting the target DNA during every cycle, thus generating accurate information about the presence of the target DNA and its quantity in each reaction, thus removing the need to analyze the post-PCR product separately.
The **Truelab® Uno Dx Real Time Quantitative micro PCR Analyzer** is a Real-time PCR-based system.

1.3 Understanding Cycle Threshold (Ct Value)

In any Real-time PCR, a positive reaction is detected by the accumulation of the amplicon and hence of the fluorescence signal. After PCR, each amplification curve is defined by its threshold cycle (Ct) number. The Ct can thus be defined as the number of cycles required for the fluorescence signal to cross the threshold (exceeding the background signal of the system). Ct levels are inversely proportional to the amount of target DNA (or cDNA) in the sample. So lower the Ct level greater is the amount of target nucleic acids in the sample.

Definitions:

1. Baseline: defined as the first few cycles of the PCR reaction where the fluorescent signal is almost unchanged.
2. Threshold: used to determine the Ct value in a real time quantitative analysis is a value of the fluorescence that is significantly higher than the baseline, falling in the region of the exponential amplification.
3. Ct (Cycle threshold): is defined as the number of cycles required for the fluorescent signal to cross the threshold.

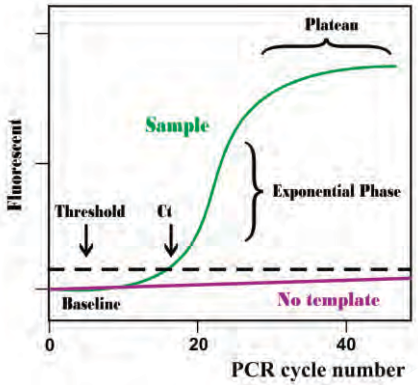


Figure 1 : Model of a real-time PCR amplification plot

Note: Cycle threshold (Ct) is a relative measure of the concentration of the target in the PCR reaction. Many factors besides the concentration of the target impact the value of the Ct. Therefore Ct values from PCR reactions run under different conditions or obtained using different PCR machines and/or reagents cannot and should not be compared.

2 Setting Up the Truelab® Uno Dx Real Time Quantitative micro PCR Analyzer

2.1 Contents

The standard **Truelab® Uno Dx** package contains the following components:

- One **Truelab® Uno Dx Real Time Quantitative micro PCR Analyzer** (REF 603021001)
- One AC Adapter to power the **Truelab® Uno Dx** (REF 603060001)
- One **Truelab®** Antenna (Black) for cellular connectivity (REF 603080001)
- One **Truelab®** Microtube Stand (REF 603070001)
- One **Truepet®** SPA fixed volume precision micropipette (REF 604070006)
- One **Truepet®** Pipette stand (REF 604080001)
- One **Truelab® micro PCR Printer** (REF 603050001)
- One **Truelab® micro PCR Printer** user manual
- One **Truelab® Uno Dx Real Time Quantitative micro PCR Analyzer** user manual

2.2 Materials required but not provided with the analyzer

1. **Trueprep® AUTO v2** Universal Cartridge Based Sample Prep Device (REF 603042001) with accessories
2. Also required additionally are: **Trueprep® AUTO** MTB Sample Pre-treatment Pack (REF 60204AS05 / 60204AS20 / 60204AS25 / 60204AS50 / 60204AS100 / 60204AS200), **Trueprep® AUTO** Universal Sample Pre-treatment Pack (REF 60205AB05 / 60205AB20 / 60205AB25 / 60205AB50 / 60205AB100 / 60205AB200), **Trueprep® AUTO** Transport Medium for Swab Specimen Pack (REF 60206TS05 / 60206TS20 / 60206TS25 / 60206TS50 / 60206TS100 / 60206TS200), **STABILYSE®** Prep Free (REF 90101PF05 / 90101PF20 / 90101PF25 / 90101PF50 / 90101PF100 / 90101PF200), **Trueprep® AUTO** Universal Cartridge Based Sample Prep Kit (REF 60203AR05 / 60203AR25 / 60203AR50 / 60203AR100 / 60203AR200) or **Trueprep® AUTO v2** Universal Cartridge Based Sample Prep Kit (REF 60207AR05 / 60207AR25 / 60207AR50 / 60207AR100 / 60207AR200),**Truenat®** disease specific real time micro PCR test kit, **Truenat®** Positive Control Kit, powder free disposable gloves, waste disposal container with lid.

2.3 Installation Requirements

2.3.1 Installation Precautions

- Do not install the **Truelab® Uno Dx** next to instruments that may cause vibrations or electromagnetic interference. Please keep the **Truelab® Uno Dx** at least one meter away from other instruments or equipment.
- Do not store the instrument in the path of direct sunlight or use it close to any radiating or heating apparatus, such as a conventional oven, hot plate or infrared lamp.
- Do not store the **Truelab® Uno Dx** in an atmosphere of potentially explosive liquids, vapors and gas.
- Always place the **Truelab® Uno Dx** on a flat surface in an upright position.

2.3.2 Environmental Requirements

The **Truelab® Uno Dx** has been designed to operate safely and reliably within the following environment specifications:

- Estimated operating temperature (between 15°C to 40°C) at Relative Humidity (RH) between 10% to 80% (non-condensing)
- Estimated storage temperature (between 5°C to 45°C) at Relative Humidity (RH) between 10% to 90% (non-condensing)
- The unit should be stored on a flat, dry surface.

2.3.3 Limitations of use

- Device is not rated for water and dust IP rating.
- Device will not perform reliably at temperature above 40° C.
- Wired connectivity (LAN) option is not available.
- Do not move the analyzer while a test is in progress.
- For each test, be sure to follow the instruction in the assay-specific package insert, which specifies the test requirement.

2.4 Installing the Truelab® Uno Dx

The **Truelab® Uno Dx** should be positioned on the workspace / tabletop / workbench in an upright position.

Caution:

⚠ ***The Truelab® Uno Dx should not be moved when a test is in progress. Attempting to do so may interfere with its functioning and compromise test results.***

At the time of installation, service personnel from Molbio will set up a user profile for the laboratory on the **Truelab® Uno Dx** and designate the head of the health center or any other authority assigned for the purpose as the “Power User”, who has access to certain special administrative features on it that regular users do not.

2.4.1 Power Users

There is only one designated Power User for each Analyzer. Power users can:

- Edit or change laboratory details, such as laboratory name and location
- View results of tests conducted by any user
- Generate and send log files
- Create new user ID
- Delete user
- Reset a user's password
- Transfer results to server
- Update Profiles and the Truelab® Software

Multiple User ID's can be created by the Power User for Regular Users to log in and run tests on the **Truelab® Uno Dx**. These additional users will not have power user privileges mentioned above.

2.4.2 Regular Users

Regular users can:

- Run tests
- Print the results
- View previous results of tests run using their User ID
- Generate and send log file
- Transfer results to server

Important:
Regular users do not have access to all the administrative features of the Analyzer that are accessible to the Power User.

3 Specifications of the Truelab® Uno Dx Real Time Quantitative micro PCR Analyzer

The **Truelab® Uno Dx** is a portable, battery-operated Real time PCR Analyzer. It houses a touchscreen for user interaction, a sliding chip tray for the **Truenat®** microchip, optical detection systems and electronic components that control all aspects of the system.

3.1 General Specifications

Truelab® Uno Dx real time quantitative micro PCR analyzer	
Principle	Patented real-time micro PCR
Optics	Fluorescence, Three Wavelength
Speed	40 cycles of PCR/35 minutes
Interface	Wi-Fi, 3G, Bluetooth
Calibration	Auto-calibration
Memory	20,000 test results
Operating environment	Temperature: 15-40°C, RH: 10 -80%
Display	5" Capacitive Touch screen TFT-LCD
Printer	External 2" Bluetooth Thermal Printer
Power	Rechargeable Lithium Ion Battery Pack: 7.4V; 8.7 Ah Input to AC/DC adaptor: Single Phase 100-240V; 50/60Hz; 1000 mA Output from AC/DC adaptor: 10 V; 4500mA; 45VA. If the input specifications in your country do not meet the above requirements, please contact your local Molbio representative
Weight	~1.5 kgs
Size	248 mm x 185 mm x 112 mm

"**Truelab® Uno Dx** complies with the emission and immunity requirements described in IEC 61326 series".
This equipment has been designed and tested to CISPR 11 Class B.

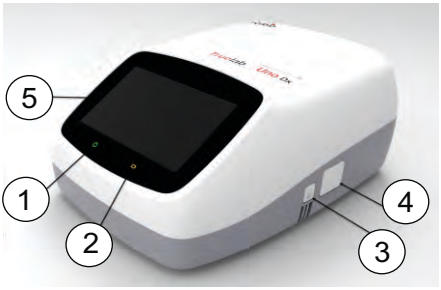
3.2 Shipping

The **Truelab® Uno Dx** is shipped as part of the **Truelab® Real Time micro PCR Workstation** (Cat no. 623010001) or as a standalone system (Cat no. 603021001).

4 Using the Truelab® Uno Dx Real Time Quantitative micro PCR Analyzer

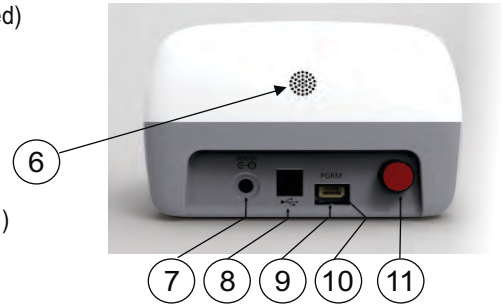
4.1 Introduction

4.1.1 Interacting with the Truelab® Uno Dx



1. ON / In use LED
2. Low Power / Charging LED
3. Eject Point
4. Chip Tray
5. Touchscreen display

6. Exhaust (Not to be blocked)
7. Charging Port
8. Dual USB Port
9. Sim card tray
10. Program port
11. Power Button (ON / OFF)



12. Bump-on
13. Air vents

Figure 2 : Illustration of Truelab® Uno Dx

4.1.1.1 Connecting the GSM antenna before Use

Before using the **Truelab® Uno Dx**, you should check the Analyzer's GSM antenna is attached. This antenna is required for data connectivity using SIM card.
To do this,

4.1.1.1.1 Straighten the GSM antenna.

4.1.1.1.2 Place the GSM antenna on the connector as shown in Figure 3

Figure 3: GSM Antenna insert direction

4.1.1.1.3 Slowly rotate clockwise till resistance is felt as shown in Figure 3

4.1.1.1.4 Twist the GSM antenna at 90 degrees as shown in Figure 4 and avoid placing objects in three to four centimetres around the GSM antenna for better reception.

Figure 4: GSM Antenna Position

To remove the GSM antenna for transportation or storage straighten it first and then slowly rotate anti clock wise until it loosens.

Caution:

⚠ Do not apply excessive force as it may damage or effect the performance of network reception.

The **Truelab® Uno Dx** is operated using the touch-sensitive screen. You can use your fingers to operate it. The **Chip Tray** holds the disposable, disease-specific **Truenat® chips**
You can either run the analyzer using battery power or use it with the power cable plugged in.

4.1.2 Checking Battery Status before Use

Before using the **Truelab® Uno Dx** on battery, you should check if the Analyzer is sufficiently charged. To do this,

4.1.2.1 "Press the **Power Button** for 2-3 seconds to switch ON the Analyzer"

The green **Power LED Indicator** will glow.

If the Analyzer battery is low, the amber **Low Battery LED Indicator** will also glow.

Boot-up screen will load in about 30 seconds and Login screen will load in another 20 seconds.

Figure 5: The Boot-up Screen

4.1.2.2 Check the **Battery Status Icon** on the Login Screen

a) A battery icon and numeric percentage indicator is visible in the top right corner

b) An exclamation mark will be visible on the battery status icon if battery is low. A system message will also appear indicating battery is low. This message will remain on the screen for 5 seconds. After 5 seconds, the battery icon with exclamation mark will be visible on the top left corner

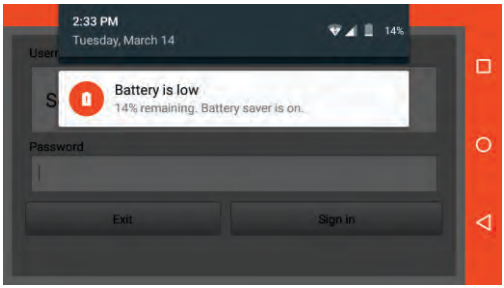


Figure 6: Home Screen with Low Battery Alert System Message

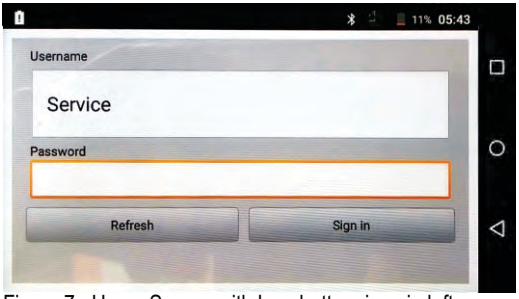


Figure 7 : Home Screen with Low battery icon in left corner

4.1.2.3 If the **Low Battery LED Indicator** and/or the **Battery Status Icon** indicate low battery charge, you can either use the **Truelab® Uno Dx** with the **AC Adaptor** or you can charge it and wait for it to finish before using it on battery power. (See the next section, 4.1.3, "Charging/Using the **Truelab® Uno Dx** with the AC Adaptor").

Note:

- *The Battery Status Icon can be seen in the Login Screen. It can also be seen once you've logged in and attempt to begin a test*
- *If the battery charge is too low to perform a test, the Analyzer will alert you with a system message to plugin the charger before it lets you select and confirm a test profile.*
- *Use only the provided AC Adaptor to charge or power to **Truelab® Uno Dx***

4.1.3 Charging/Using the Truelab® Uno Dx with the AC Adaptor

4.1.3.1 Plug in the **Truelab® AC Adaptor** to the **Charging Port** of the **Truelab® Uno Dx** Analyzer

4.1.3.2 Plug in the other end of the **AC Adaptor** to a wall socket

4.1.3.3 Switch ON the wall socket

4.1.3.4 When the **Truelab® Uno Dx** is charging, the blue **Charging LED Indicator** will glow, and the **Low Battery LED Indicator** will go off if it was glowing.

4.1.3.5 You can now use the **Truelab® Uno Dx** with the AC Adapter (Proceed to Section 4.2) Charging the Analyzer will take ~4 hours. When the charging is complete, the **Charging LED Indicator** will stop glowing.

4.2 Starting the Truelab® Uno Dx

Note:

An on-screen keyboard will appear every time you click on a textbox requiring text input. This is also operated using fingers.

4.2.1 Starting the Truelab® Application

Tap the **Truelab® Uno Dx Application Icon,** this will open the **Truelab®** Login Screen.

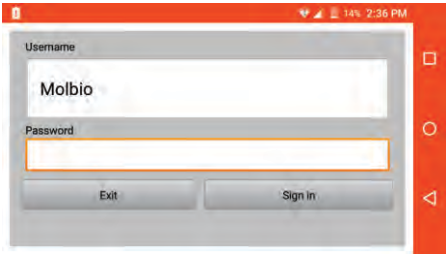


Figure 8 : Login Screen

4.2.2 Logging In

You will need to log in to the application using the appropriate user name. To log in,

4.2.2.1 Tap the **User Name Bar** in the **Login Screen**, This will open a drop-down menu to select the User Name

4.2.2.2 Select the user name from the list displayed.

Note: The user name "Molbio" is just used here as an example. The user name is definable by the customer.

4.2.2.3 Tap the **Password text box** You will be prompted with an On-Screen keyboard.

4.2.2.4 Type the password with the on-Screen keyboard.

4.2.2.5 Select the ✓ button on the on-Screen keyboard.

4.2.2.6 Tap **Sign In.** This will open the **Status Screen.**
Test Bay Status:
The **Status Screen** will show one bay to run the test.
Tap on the Bay to enter the **Profiles Screen.**

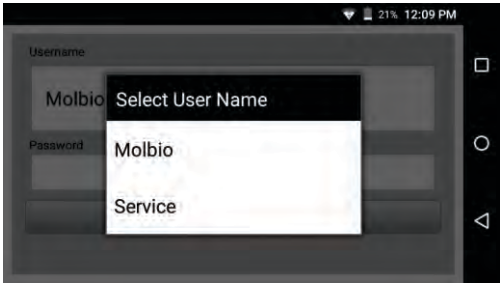


Figure 9: User ID Selection

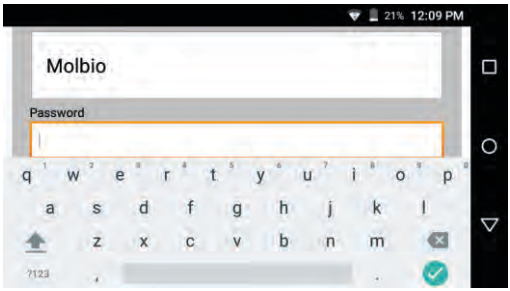


Figure 10: The Login Screen, with the On-screen Keyboard

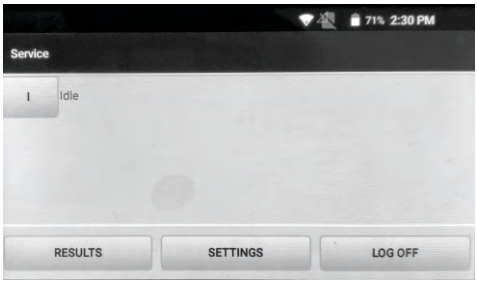


Figure 11: Status Screen

4.2.3 Profiles and Sample Details

The **Profiles Screen** will list out all available disease profiles that you can choose from. A profile contains preset PCR parameters for that particular test.

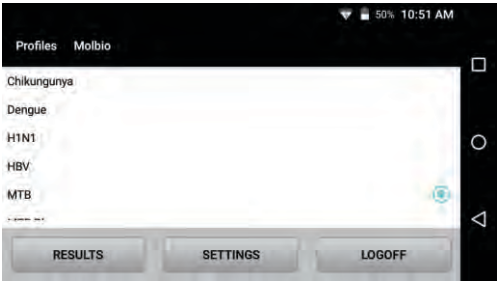


Figure 12: The Profiles Screen

To choose a profile,

4.2.3.1 Tap on the profile of your choice from the list.
You will be prompted with a message asking you if you would like to proceed with your choice.

Note: *The profile used as an example in this manual is "MTB".*

4.2.3.2 Tap the "**Proceed"** Button on this pop-up as shown in Figure 10.
The **Sample Details Form** will be displayed.

Note: *Selecting the Cancel button will take you back to the profiles screen*

4.2.3.3 If battery charge is too low to perform a test, the Analyzer will display a prompt that says the battery is low. You are required to plugin the charger before the Analyzer will let you begin a test.

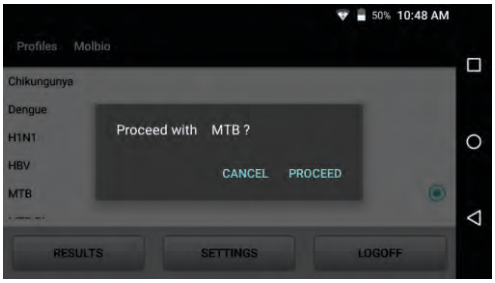


Figure 13: Profile Confirmation Prompt

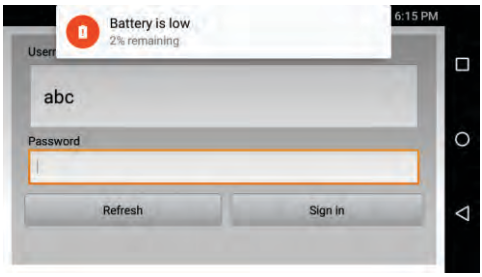


Figure 14: Low Battery Alert before confirmation of profile

4.2.3.4 Fill in the **Sample Details Form** with the details of the test using the on-screen keyboard

4.2.3.5 Only patient ID field is mandatory, patient name will be automatically captured same as patient ID.

By default Gender will be selected as Male & Age/YOB will be zero if not entered manually.

Choose the appropriate sample type from the drop-down menu.

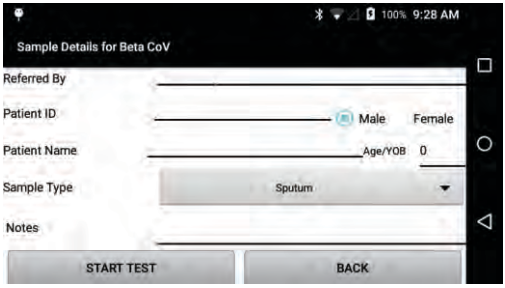


Figure 15 : Filling in the Sample Details From

Important:

- ***Enter the details carefully, this screen will not be accessible again once the chip has been loaded.***
- ***The Patient Name is mandatory; you will be prompted by the Analyzer if you have not filled it in.***
- ***It is recommended to enter details in all fields.***

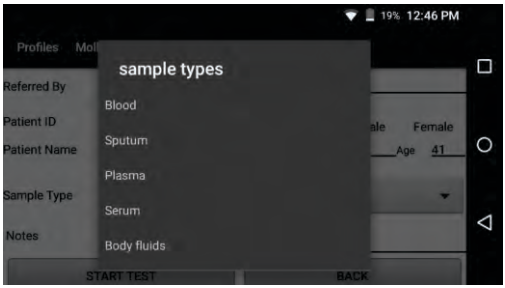


Figure 16 : Sample type selection

Note:
This data will be saved along with test results when the test has finished and can be viewed whenever you like. (See section 4.7 "Viewing Saved Test Results")

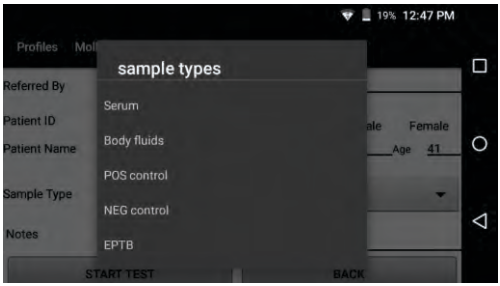


Figure 17 : Sample menu expanded

4.2.3.6 When you have completed the **Sample Details Form**, Press the **"Start Test" Button** at the bottom of the screen. You will be prompted to load the test chip with the message "**Please Load Sample**".

4.2.3.7 The sample now needs to be loaded onto the **Truenat®** Chip. Proceed to the next section for instructions on loading the **Truenat®** chip.

Important:
Do not select the Done Button in this prompt till you have finished loading the test chip and pushing the chip tray back in fully (as detailed in Section 4.3)

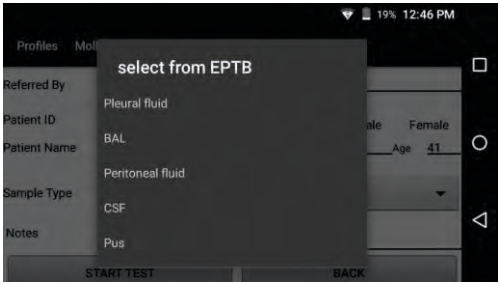


Figure 18 : Sample type sub-menu

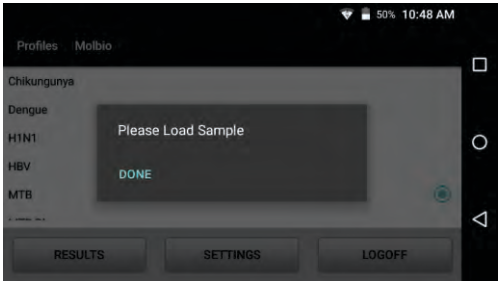


Figure 19 : Prompting the User to load the Sample

4.3 Loading the Truenat® chip

4.3.1 Accessing the Chip Tray

4.3.1.1 Press the **Eject** button.
This will eject the **Chip Tray.** The location of the **Eject Button** is shown in Figure 2.

4.3.1.2 Pull out the chip tray gently till all six **tray pins** are exposed

4.3.2 Placing the Chip on the Chip Tray

4.3.2.1 Place a new **Truenat® chip** on to the Chip Tray by lowering the chip onto the chip tray.

Important : Make sure you have placed the chip correctly onto the tray.

a) **The chip's registration holes should be placed properly onto all the tray pins.**

b) **The reaction well should face upwards.**

Figure 21 below shows the correct placement of the chip, with the reaction well facing upwards and to the right side and the chip being placed on the tray pins properly.

Incorrect placement of the Chip will prevent the tray from being pushed back in fully

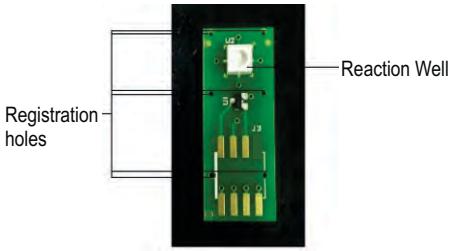


Figure 20 : The **Truenat®** Chip

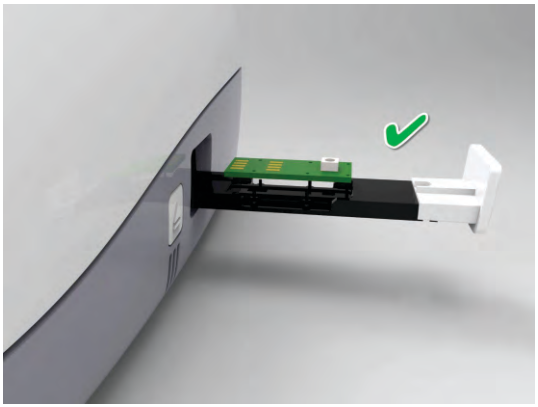


Figure 21 : The **Truenat®** Chip being placed correctly onto the Chip Tray

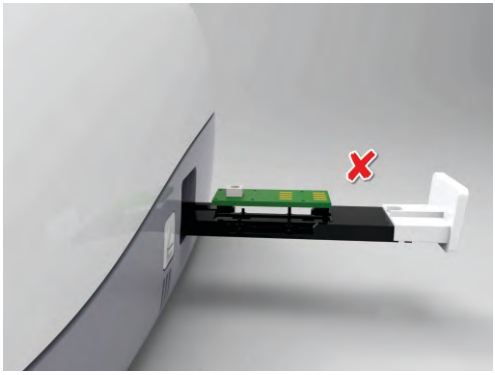


Figure 22 : An Example of Incorrect Chip Placement

4.3.3 Loading the Sample onto the Chip

4.3.3.1 After the Chip has been properly placed onto the **Chip Tray,**

Pipette six (6) µl of the purified nucleic acid from **ECT tube** (from **Trueprep® AUTO/AUTO v2** Universal Cartridge based Sample Prep Kit) into the microtube. Allow it to stand for 30-60 seconds to get a clear solution.

⚠ Do not mix it by tapping, shaking or by reverse pipetting. Using the same filter barrier tip, pipette out six (6) µl of this clear solution and dispense into the center of the **reaction** well of the chip.

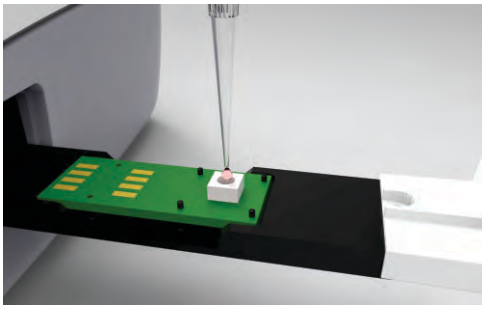


Figure 23 : Loading the Sample onto the Chip

Note:

a) A 6µl **Truepet®** SPA fixed volume Precision micropipette is provided with your **Truelab®** workstation.

Important:

a) Do not touch the bottom of the reaction well with the pipette tip.
b) Do not touch the reaction well with your hand.
c) Ensure that the elute has been pipetted out fully into the center of the reaction well.
d) Ensure that there is no spillage of the elute from or around the reaction well.

4.3.3.2 Gently push the **Chip Tray** back into place
Figure 24 (below) shows a summary of the **Truenat®** loading procedure. When the chip has been loaded correctly, proceed to section 4.4.

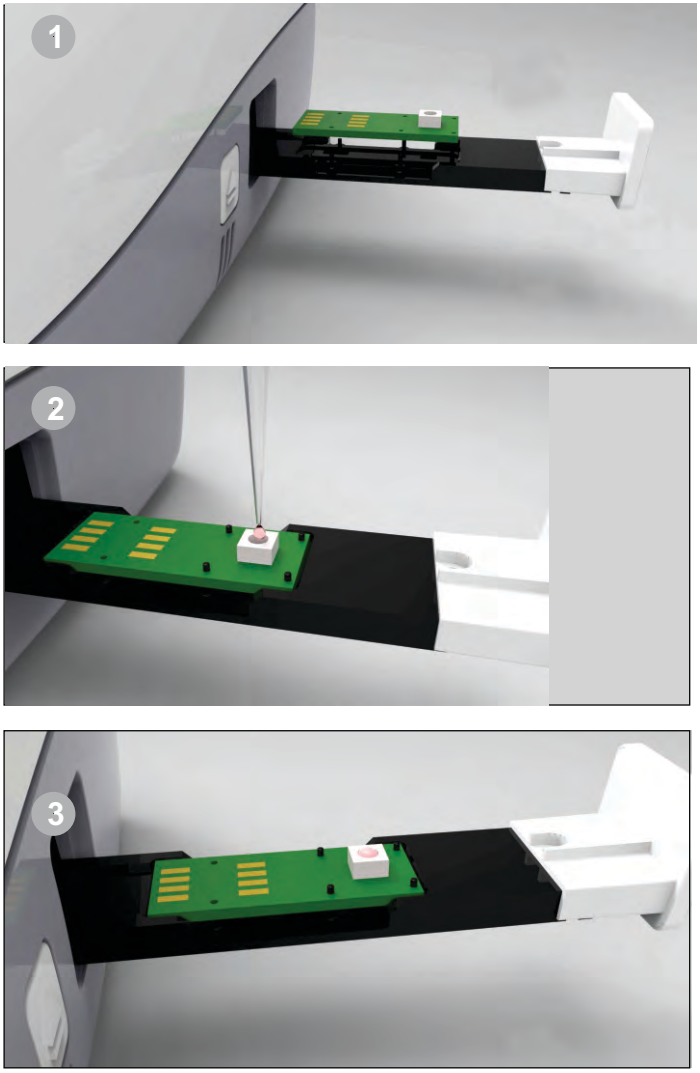


Figure 24 : A Summary of the **Truenat®** Chip Loading Procedure

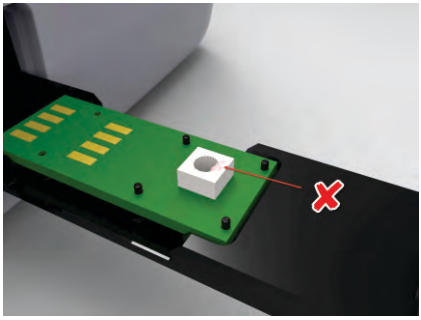


Figure 25 : Incorrect Sample Loading, Showing Spillage of the Elute Around the Reaction Well

4.4 Starting the Test

4.4.1 Starting the Test

After completing the **Truenat®** chip loading procedure and pushing the chip tray back inside,

4.4.1.1 Select "Done" at the "Please Load Sample" prompt. You will be prompted with the message "Initializing, please Wait".

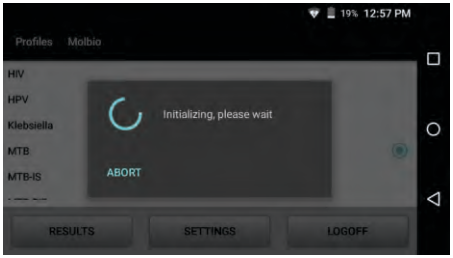


Figure 26 : Initialization screen

4.4.1.2 Wait for the Analyzer to finish initializing. If you wish to Abort the test at this point, please press Abort. This option is available for a brief period of 2 seconds. If the test is aborted within this 2 second window, the chip will remain un-used and the back to the profiles screen will appear. User can choose a profile and enter patient details once again.

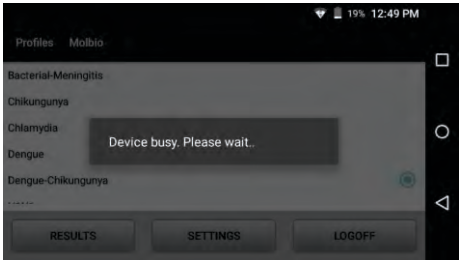


Figure 27 : System message when Abort is pressed during initialization

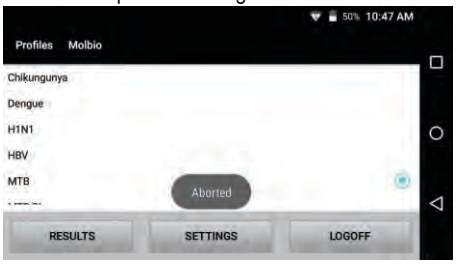


Figure 28 : Prompt message confirming that test is aborted

4.4.1.3 When it has finished initializing, the In-use LED Indicator on the **Truelab® Uno Dx** micro PCR Analyzer will glow Red and the Test Status Screen will appear. This indicates that the test has started.

Caution:
⚠ Do not attempt to switch off the Analyzer once the chip has been loaded and the test has started.

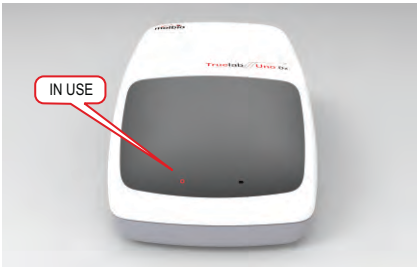


Figure 29: The Red In-Use LED Indicator glowing

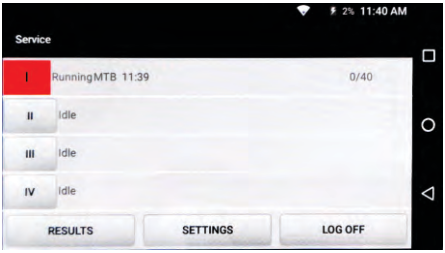


Figure 30: In-use screen

4.4.2 System Messages

Before the test begins, the Analyzer will check all system parameters,including the **Truenat®** chip. If there are any errors, the Analyzer will alert you with a pop-up message. The alerts you may receive are as follows:

4.4.2.1 **Loaded Truenat® Chip and Selected Test Profile do not match**

If you loaded the wrong **Truenat®** disease-specific chip for the profile you selected, an error message will be displayed and the test will not be started. If this happens, start the procedure again and ensure that the **Truenat®** chip you are loading matches the profile. Figure 30 shows this error

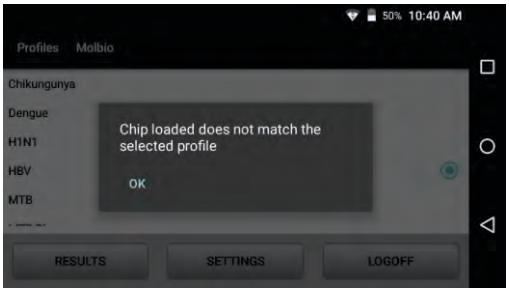


Figure 31: Error in matching inserted **Truenat®** Chip to chosen Test Profile

message. Pressing the OK button in the pop-up error message will take you back to the Profiles Screen so that you can start again.	

4.5 During the Test

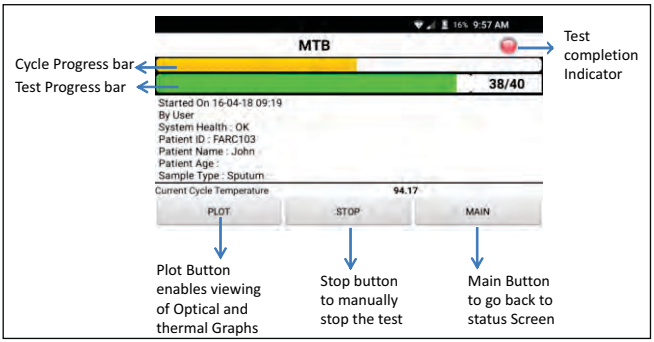


Figure 32: The Test Status Screen

The **Test Status Screen** lets you monitor the progress of your current test.

- The Green **Test Progress Bar** at the top of the **Test Status Screen** indicates the total progress of the test, along with the current cycle number. For instance, in the Screen shot above, the current cycle is 38, out of the total number of 40 cycles.
- The Yellow **Cycle Progress Bar** is the topmost bar on the **Test Status Screen** and indicates the progress of the current cycle.
- The **Test Details**, including patient details, sample type, system health, battery level and current cycle temperature are detailed in the **Test Details Bar.**
- The **Red Test Completion Indicator** on **the Test Status Screen** will turn **green** when the test is complete.

You can also view the Thermal and Optical graphs during the test.

Note: *The screen will go blank (stand-by mode) after every minute of inactivity. This is done to conserve battery. If you want to see the screen after it has gone blank, double tap on the screen. Refrain from waking up the screen unnecessarily as this will drain the battery.*

4.5.1 Viewing the Thermal Graph

4.5.1.1 Tap the **Plot Button** on the Test Screen

4.5.1.2 Select **Temperature** to view the thermal graph

Note:

The number in the right corner, here "92.94", indicates what temperature the reaction well is at. The graph changes as the cycles progress.

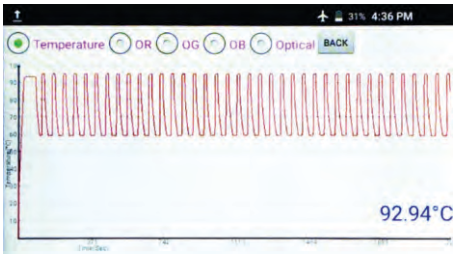


Figure 33: The Temperature Graph

4.5.2 Viewing the Optical Graph

4.5.2.1 Tap the **Plot Button** on the **Test Screen**

4.5.2.2 Select **Optical** to view the Optical Graph

Note:

The fluorescence measure in the optical graph is in arbitrary units. The graph changes as the number of cycles increases. The number in the right corner, here "38", indicates which cycle is ongoing.

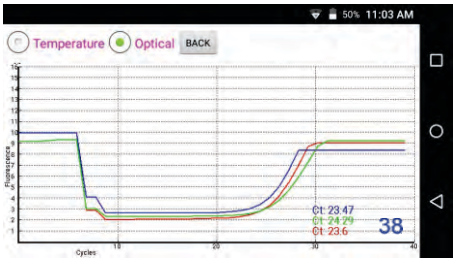


Figure 34: The Optical Graph

4.5.3 Stopping the Test

Caution:

⚠ Stopping the test will make the current chip unusable. To do the test again, you will have to use a new chip and start the process from the beginning. This Function can be used to stop the reaction if the optical graph shows clear steep slope for test and IC graphs.

If you want to stop the test,

4.5.3.1 Tap the **Stop** Button at the bottom of the **Test Status Screen.**
A pop-up will be displayed asking you to confirm that you want to stop the test.

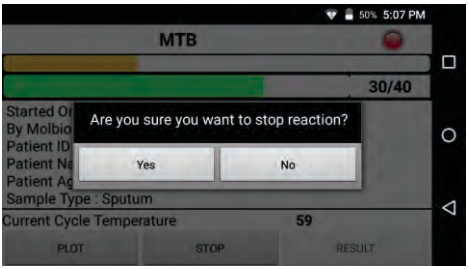


Figure 35: Test Stop Confirmation

4.5.3.2 Tap Yes in the confirmation pop-up to stop the test
The Test Status screen will be displayed.

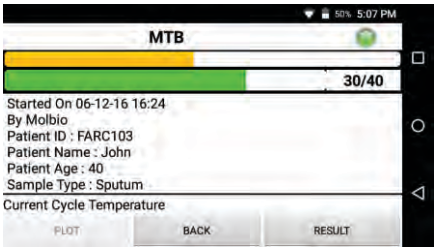


Figure 36: The Test Status Screen after Stopping the Test

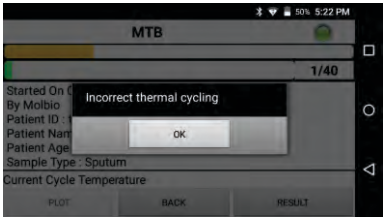
4.5.3.3 In the **Test Status Screen**,
to view the results screen for test results, Tap **Result**.
To go back to the **Profiles Screen**, Tap **Back**.

4.5.4 System Messages

In rare circumstances, the following errors may occur during the test.
When one of these errors occurs, you will be prompted by the Analyzer with a pop-up message.

4.5.5 Test Completion

The test stops automatically when it is complete. When the test is done, the red In-use LED indicator on the **Truelab® Uno Dx** will turn green and you will hear a beep.

System Message: "Incorrect Thermal Cycling" **When it Occurs:** During the test	**Reason:** Cycle temperature out of range from normal operation range. **Solution:** Please repeat the test using a fresh chip. If the problem persists, please contact Molbio support.	 Figure 37: Incorrect thermal cycling error
System message "Probe Check Failed" **When it Occurs:** During the test	**Reason:** Low/high volume loaded in reaction well, liquid spilled outside reaction well or chip exposed to light for long periods of time. **Solution:** Please repeat the test using a fresh chip.	 Figure 38: Probe check failed error

4.6 After the Test

4.6.1 **Viewing the Test Results,** you can view the Test results by tapping the Result button, which will open the results screen. The results screen shows you the input details, chip details and test results.

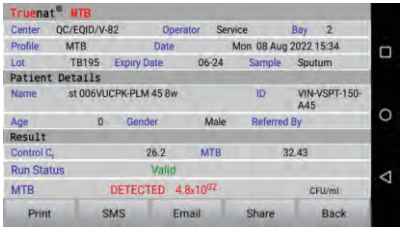


Figure 39: The Test Results Screen

4.6.1.1 Incase of any error encountered after completion of the test, you can run the same test by tapping the Repeat button. Sample details are not required to be entered in Sample details form.

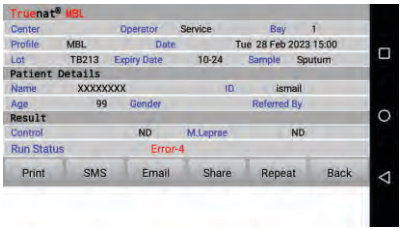


Figure 40: The Test Results Screen with repeat option

4.6.2 **Printing the Results**

Note:

- An external Bluetooth printer is provided with the **Truelab®** Workstation.
- Results can be sent wirelessly through SMS and/or Internet (3G/2G or Wi-Fi) to other devices and servers if it was configured to do so during installation. For further details or activation of this feature, contact Molbio Support.

Figure 41: The **Truelab®** micro PCR Printer

4.6.2.1 To print the results of the test, Click the **Printer Power Button** on the left side of **Truelab®** micro PCR Printer The blue Power LED will blink, this indicates that the Printer is switched ON.

Figure 42: The Power Button on the front side of the Printer

4.6.2.2 Wait for at least ten seconds

4.6.2.3 Tap the **Print Button** in the **Results Screen** of your **Truelab® Uno Dx**. The Bluetooth printer will print out the test results.

4.6.2.4 Switch off the printer when printing has finished by pressing the **Printer Power Button.**

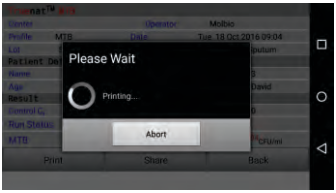


Figure 43: Message Displayed before the System begins Printing

4.6.3 Sharing the results via Bluetooth

4.6.3.1 Tap the Share Button in the Results Screen of your **Truelab® Uno Dx.**

4.6.3.2 A pop-up will appear list of available Bluetooth devices will appear. Select the device which you want to transfer the result to.

4.6.3.3 To share the multiple results, go to Results > select Export option > repeat procedure mentioned in 4.6.3.2.

Results will be exported in CSV format

Note: Ensure regular backup of patient data

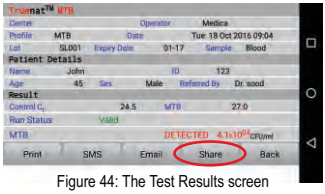


Figure 44: The Test Results screen

Figure 45 A: Choose Bluetooth device screen

Figure 45 B: Export option for result transfer

4.6.4 Emailing the results

Configuration for custom SMTP server address

Note: *Email setup is a one time activity and might require IT personnel involvement.*

Procedure : Goto Settings > Application > Email

Enter email address and password
Enter SMTP server address (supports only SSL enabled due to security reasons)
Enter SMTP server adress, default is 465.
Click Save.

Figure 46 A: Settings screen in Truelab device

Figure 46 B: SMTP configuration screen

4.6.4.1 Tap on Email button on the Result screen of your **Truelab® Uno Dx**

4.6.4.2 A pop-up will appear which will ask you to enter the email ID you want to send the result to.

Note: If result is to be sent to multiple email IDs, separate the email ids with a comma (,)

4.6.4.3 Tap on 'Result' in the pop-up to email the results to the email IDs entered. Once the Email is sent, pop-up will be displayed as "Email sent successfully

Note: Ensure regular backup of patient data

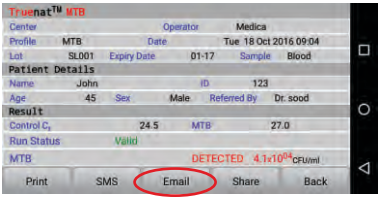


Figure 47 A: The Test results screen

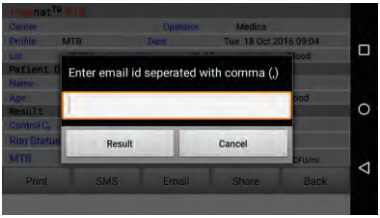


Figure 47 B: Email pop-up on results screen

Figure 48: Email sent successfully cofirmation

4.6.5 SMSing the results

4.6.5.1 Tap the SMS Button in the Results Screen of your **Truelab® Uno Dx.**

4.6.5.2 A pop-up will appear which will ask you to enter the mobile number you want to send the result to. For sharing of results by SMS within India, please enter the 10 digit mobile number.

Note: If sending to a number outside of India, please enter the country code followed by the mobile number.

4.6.5.3 Tap on 'Send' in the pop-up to SMS the results to the phone number entered.

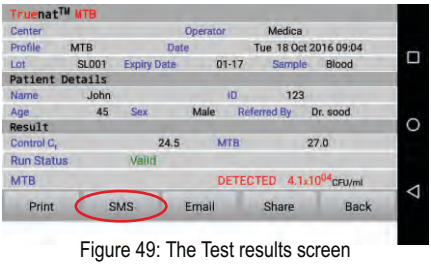


Figure 49: The Test results screen

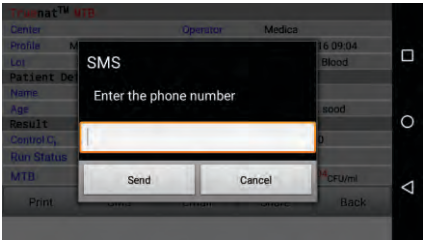


Figure 50: Pop-up to send SMS

4.6.6 Language translation

If you want to share the results in other language, English, Czech, French & Russian options are available. Go to Home page > Settings > Tap on LAN & Select the required language.

Log off the device & Log in again & repeat procedure as per 4.6.4 and 4.6.5

Thermal printing & Email will be partially translated in the selected language

Note: Ensure regular backup of patient data

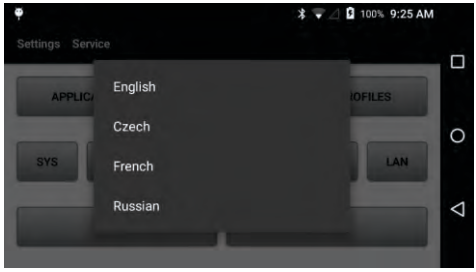


Figure 51: Language selection screen

4.6.7 Removing the Chip

After ensuring that the Analyzer is switched off,

4.6.7.1 Push the **Eject Button**
This will eject the **Chip Tray**

4.6.7.2 Take the **Truenat® Test Chip** off the **chip tray**

4.6.7.3 Discard the chip into a waste disposal container having freshly prepared 0.5% sodium hypochlorite solution

4.6.7.4 Push the **Chip Tray** back into place

4.6.8 Logging Out/Starting a New Test

- Tapping the **Back** button in the **Test Results Screen** will re-open the **Profiles Screen**
  At this point, you can begin a new test by choosing a new profile.
- You can also logout of the **Truelab® Uno Dx** by Tapping the **Log off** button in the **Profiles Screen.**

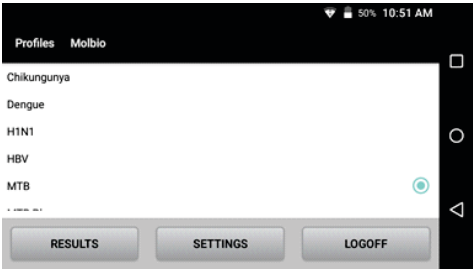


Figure 52: The Profiles Screen

Note:

- *If you leave the touchscreen switched ON without **using** it, it will **automatically switch** to Sleep Mode after a minute. When you want to perform another test, double tap the screen to switch it ON again.*
- *If you had logged off before leaving the screen idle, you will have to login again.*

4.7 Viewing Saved Test Results

Results and details of previously performed tests can be viewed at any time. You cannot browse saved test results when a test is currently in progress.

Note:

- *Unless you are a Power User (see Section 2.3, "Installation of the **Truelab® Uno Dx**", for details) you will only be able to view tests that were performed using your designated user ID.*
- *Only the last 60 days of results are displayed, for results older than that use the search function*

4.7.1 To view previous test results

4.7.1.1 Double tap the **touchscreen** and login (See section 4.2) This will open the **Status Screen.**

4.7.1.2 At the **Status Screen,** tap the **Results** Button at the bottom of the screen. The **Test Results List** will be displayed.

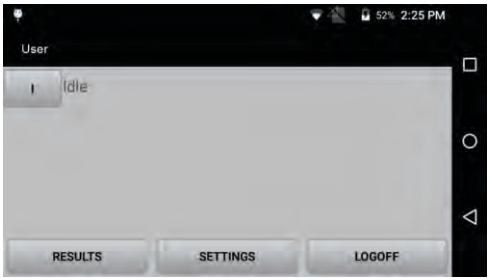


Figure 53: The Status Screen

4.7.1.3 Tap the test result you want to view (Your selection will be indicated by a green dot to the right of the test name).

Note:
To scroll through the list,

4.7.1.3.1 Touch and hold down your finger on the touchscreen.

4.7.1.3.2 Swipe upwards or downwards on the screen till you see the test result you want to view.

Note :

- *The results are named automatically by the Analyzer in the format "profile-date-time-patient:ID". For example, in figure 44, the last result in the list named "MTB-RIF on 2016-11-18 09-34-22 Patient:GARC107", indicates it was a test using the MTB-RIF profile that was performed on the 18th of November 2016 at 9:34 AM for sample with Patient ID GARC107.*
- *By default, the most recently run test result will be on the top.*
- *If you want to search specifically by Patient Name or Test Name or Referred by fields, use the search function to find what you are looking for.*

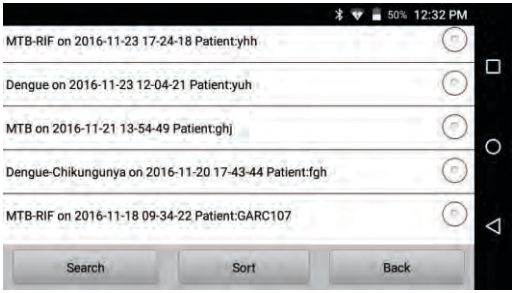


Figure 54: The Results List

4.7.1.4 The Graph Screen will be displayed.

- To view the Temperature Profile, select **Temperature**
- To view the Optical Plot, select **Optical**
- To view the Test Result, select **Result**

Your current selection will be indicated by a green dot to the left of the appropriate title.

Note:

*The Test Result can be printed by switching ON the **Truelab**® micro PCR Printer and then clicking the Print button on the Test Results screen.*

4.7.2 Search Saved Results

Saved results can also be searched based on the following fields:

- Test Name
- Patient Name
- Referred By
- Date & Time (YYYY-year, MM-month, DD-day and HH-hour, MM-minutes, SS-seconds.)

To search for saved results,

4.7.2.1 Double tap the **touchscreen** and login (See section 4.2) This will open the **Profiles Screen.**

4.7.2.2 At the **Profiles Screen,** tap the **Results** Button at the bottom of the screen. This will open the **Test Results List.**

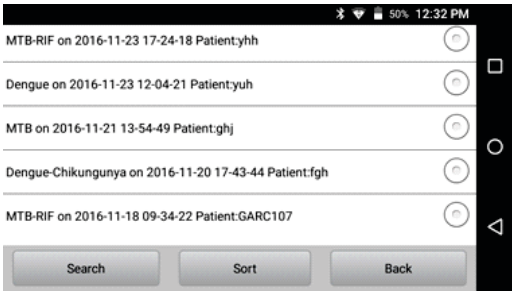


Figure 55: The Profiles Screen

4.7.2.3 Tap the **Search** Button You will be prompted with a pop-up display with the following search options.

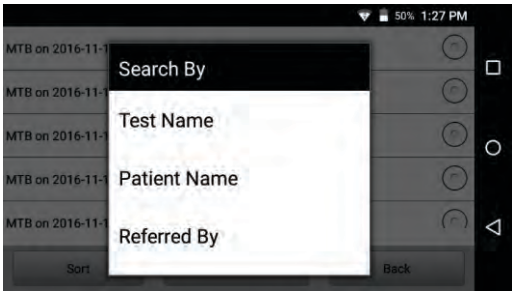


Figure 56: Selecting the Parameter to Search By

4.7.2.4 Tap the field you want to search based on (In the screenshot, the parameter is Test Name) You will be prompted with a text box.

4.7.2.5 Fill in the text box with what the information you wish to search.

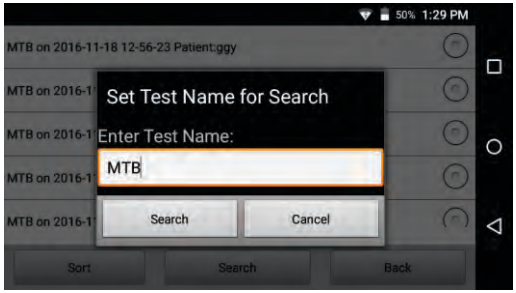


Figure 57: Searching By Name

4.7.2.6 Tap the **Search** button on the pop-up to initiate the search.
When the search is complete, a list of previous test results will be displayed.

Figure 58: Options available after search feature is used

4.7.2.7 Tap the result you want to view to open the **Test Results Screen.**

Note:

- *Refer to section 4.7.1, "Viewing Previous Test Results", from 4.7.1.3 to 4.7.1.5 for instructions on viewing results.*
- *Refer to section 4.6.3, "Printing the Results", if you want to print a particular result from your search.*

4.7.2.8 Tap Sort to sort the results that appear after you press the Search button. You can sort by name, which will arrange the results in ascending order based on the search parameter chosen (Test Name, Patient Name, Referred By, Date).

4.7.2.9 Tap Clear to go back to the Results list.

4.7.2.10 Tap **Back** to go back to the Profiles Screen.

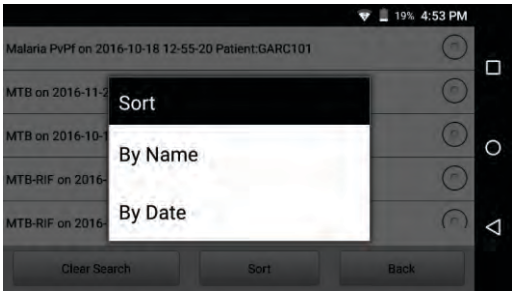


Figure 59: Sort feature for results that appear after a search

Note:
In this section, the parameter used to search by is "Test Name". The pop-up textbox is similar for the "Referred by" and "Patient Name" searches.
However, if you search by date, the pop-up will be a text box with "From" and "To" fields to enter the range of the search. Clicking on each of these textboxes will display another pop-up to select the date (as shown in figure 57), where you use the "+" and "-"buttons on the pop-up to change each parameter of the date

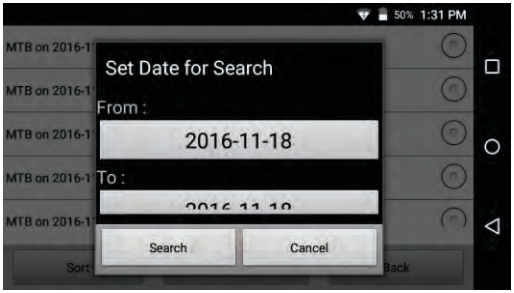


Figure 60: Pop-up to enter the Date into each Text Box

Figure 61: The From and To Fields filled-in

4.7.3. Sorting Test Results

On the results screen, the list of results can be sorted based on:

- Name
- Date

To sort the list of results,

4.7.3.1 Switch on the **Touch screen** and log in this will open the **profile Screen.**

4.7.3.2 At the **Profiles Screen,** tap the **Results** Button at the bottom of the screen This will open the **Test Results List.**

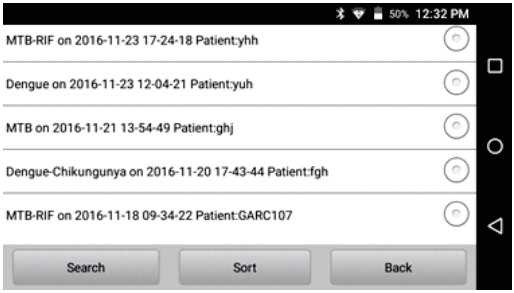


Figure 62: The Profiles Screen

4.7.3.3 Tap the **Sort** Button
This will prompt you with the following options to sort by

- By Name
- By Date

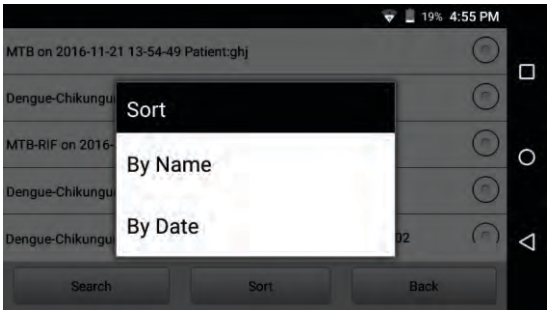


Figure 63: Test Results Sorting Options

4.7.3.4 Tap your option of choice to select it.
This action will sort all results based on that field in ascending order.

Note:
To view the list in descending order, repeat steps 4.7.3.3 to 4.7.3.4 after it has been sorted ascending order, and a pop-up will be displayed confirming the action .

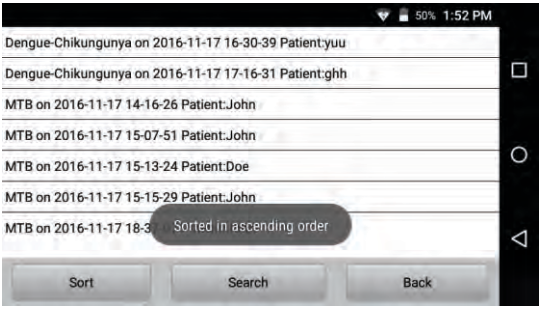


Figure 64: Tests Sorted by Name in Ascending Order

5 Power User Features

Important:

- ***The features detailed in this section can only be accessed by power users (see Section 2.3, "Installing the Truelab® Uno Dx" for details on power users and regular users). If you attempt to access these features as a regular user, you will simply receive an error message.***
- ***In order to use the features in this section, you must log in to the Truelab® using the power user ID.***
- ***You can use the back button to go back to the previous screen or to cancel a pop-up or prompt.***

5.1 Logging In as the Power User

5.1.1 Open the **Truelab® Uno Dx** Applications.

5.1.2 Click on the **User Name** box.
This will open a drop-down menu.

5.1.3 Select the power user ID that was created for you at the time of installation.

5.1.4 Type the password for this ID in the **Password** text box.

5.1.5 Tap the **Login** Button.

Note:
If you have forgotten the password for your power user account, please contact Molbio support.

5.2 Creating a New User

Note:
You cannot create another Power User. New users will only be regular users

5.2.1 Login as the power user (refer to previous section, 5.1, "Logging In as the Power User", for details) This will open the **Status Screen.**

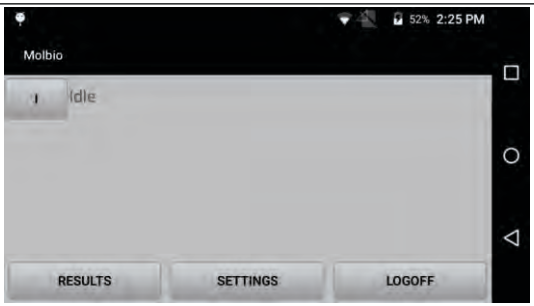


Figure 65: The Status Screen

5.2.2 Tap **Settings** in the **Status Screen.** This will open the **Settings Screen.**

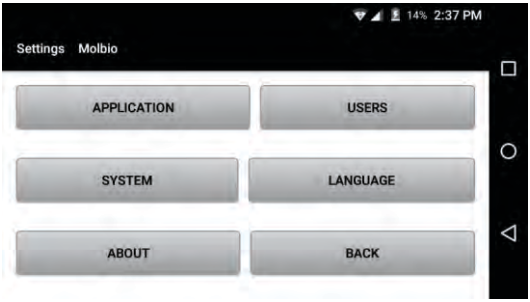


Figure 66: The Settings Screen

5.2.3 Tap the **Users Icon**. This will open the **User Settings Screen**, which will show a list of all user IDs registered on the **Truelab® Uno Dx**.

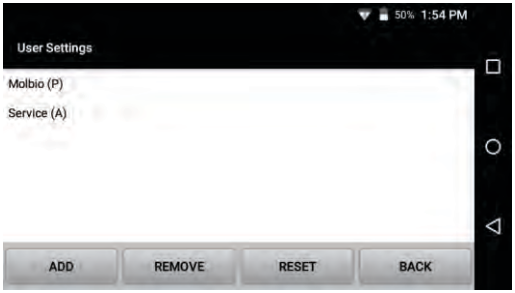


Figure 67: The User Settings Screen

5.2.4 Tap the **Add** button in the **User Settings Screen.** This will open the **Add User Form**.

5.2.5 Fill in the details of the **Add User Form.** You will have to fill in the user name and password. You will have to re-type the same password in the **Confirm Password Text Box.**

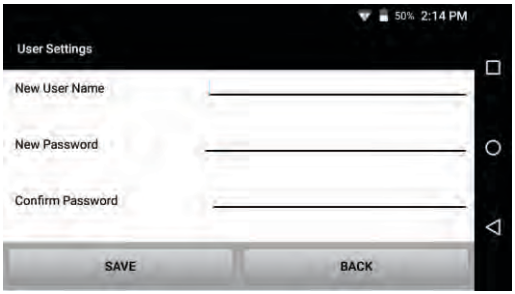


Figure 68: Add User Form

Note:

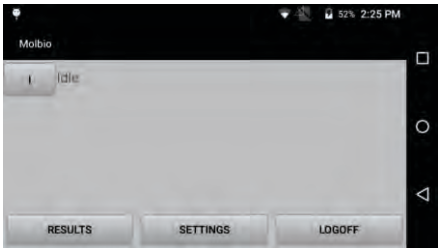
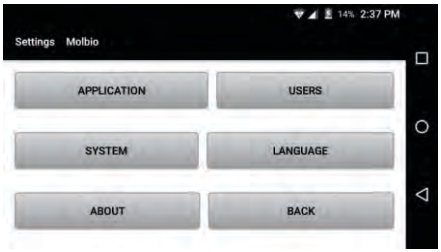
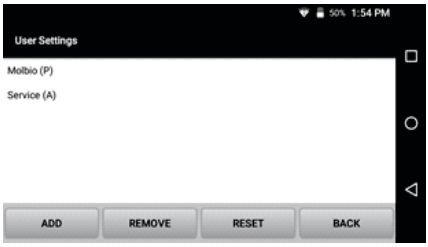
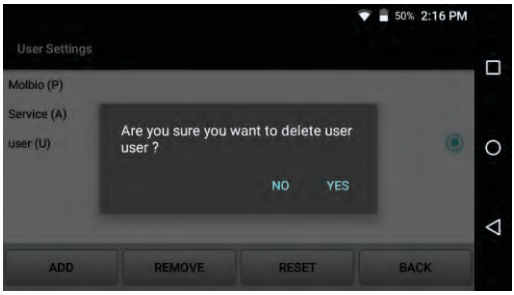
You can type in any user name of your choice.

5.2.6 Tap **Save** when you've entered all the details to create the new user. This user will now appear in the **User Settings Screen** and the **Truelab® Login Screen**

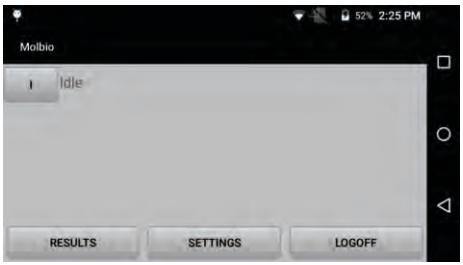
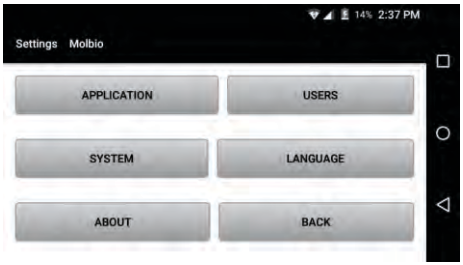
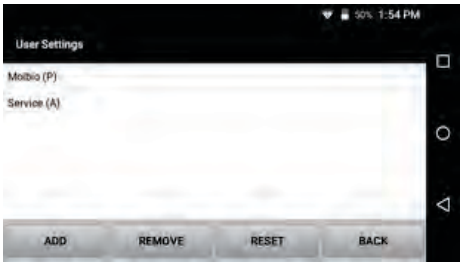
5.3 Deleting a User

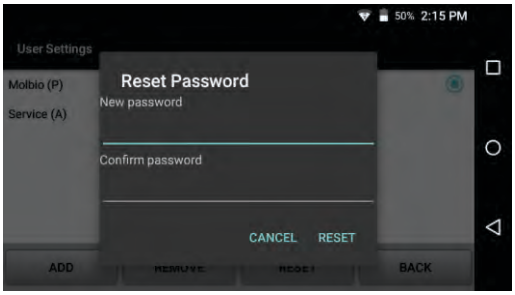
Deleting a particular user name will remove that user name from:

- The drop-down menu in the **Truelab® Uno Dx Login Screen**
- The user list in the **User Settings Page**

5.3.1 Login as the power user (refer to previous section, 5.1, “Logging In as the Power User”, for details) This will open the **Status Screen.**	 Figure 69: The Status Screen
5.3.2 Tap **Settings** in the **Status Screen.** This will open the **Settings Screen.**	 Figure 70: The Settings Screen
5.3.3 Tap the **User Settings** Icon. This will open the **User Settings Screen**, which will show a list of all users.	 Figure 71: The User Settings Screen
5.3.4 Select the user you want to delete by tapping on that particular **User Name.** 5.3.5 Tap the **Remove** Button You will be prompted to confirm that you want to delete the user. 5.3.6 Tap the **Yes** Button on this prompt to delete the user you selected.	 Figure 72: User Deletion Conformation Prompt

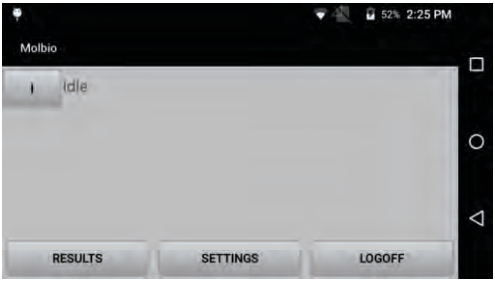
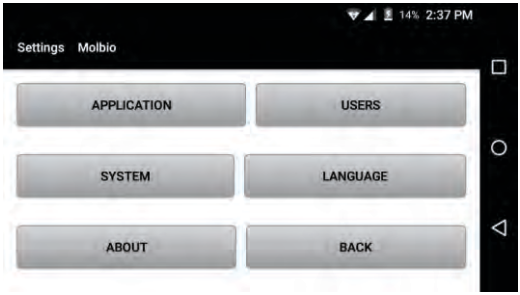
5.4 Resetting the Password

5.4.1 Login as the Power User This will open the **Status Screen.**	 Figure 73: The Status Screen
5.4.2 Tap **Settings** in the **Status Screen.** This will open the **Settings Screen.**	 Figure 74: The Settings Screen
5.4.3 Tap the **User Settings** Icon This will open the **User Settings Screen.**	 Figure 75: The User Settings Screen
5.4.4 Tap on the **User Name** whose password you would like to change. 5.4.5 Tap **Reset** This will open the Password Reset Form. 5.4.6 Fill in the New password in the appropriate text box.	

5.4.7 Retype the new password in the **Confirm Password Text Box.** 5.4.8 Tap the **Reset** Button to reset the password to the new one you just typed.	 Figure 76: Password Reset Form

5.5 Changing Lab Details

The **Truelab® Uno Dx** allows a power user to edit the lab name and location that has been recorded on the system.

To edit the Lab Name and Lab Location, 5.5.1 Login as Power User This will open the **Status Screen**	 Figure 77: The Status Screen
5.5.2 Tap the **Settings** button in the **Status Screen.** This will open the **Settings Screen.**	 Figure 78: The Settings Screen

5.5.3 Tap the **Application Icon** in the **Settings Screen** This will open the **App Settings Screen.**

5.5.4 Tap on the text boxes next to **Lab Name** and **Lab Location** This will display an on-screen keyboard which can be used to type in the details. Enter Email ID and Password in the text boxes provided. Enter the SMTP server and SMTP Port no 465 by default. (For above mentioned details contact IT team of respective dept) This is to allow test results from the Analyzer to be emailed. The Analyzer is capable of sharing results via email using gmail account credentials. It is recommended to create a new gmail account for the specific purpose of emailing results from the Analyzer, rather than using a pre-existing account. Two factor authentication for this gmail account should be disabled. To assure result integrity, it is recommended that the same gmail account should not be used for any other purpose.

*Note: Do not change any other details in this page as this will affect some features of the **Truelab**® Uno Dx. Press the "Default" Icon*

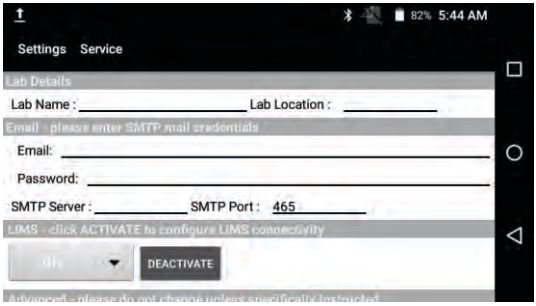


Figure 79: The Application Icon

in the Server IP section if accidentally changed. This will restore the settings.

5.5.5 Select **Save** when you are finished.
A pop-up message confirming that the new Lab name and location have been saved will be displayed.

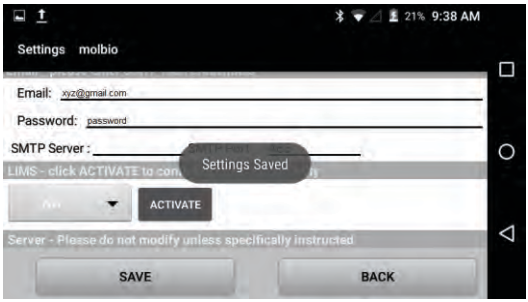


Figure 80: Confirmation of saved changes to app settings

5.6 Updating the Truelab® Uno Dx

The analyzer will prompt the user with a system message when a new update is available.

5.6.1 Login as Power User
This will open the **Status Screen.**

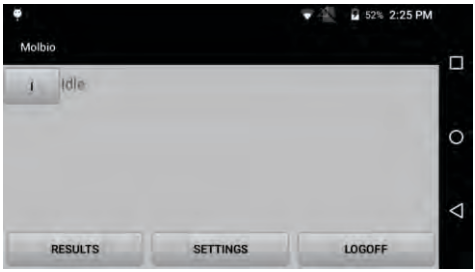


Figure 81: The Status Screen

5.6.2 Tap the **Settings** button in the **Status Screen**
This will open the **Settings Screen.**

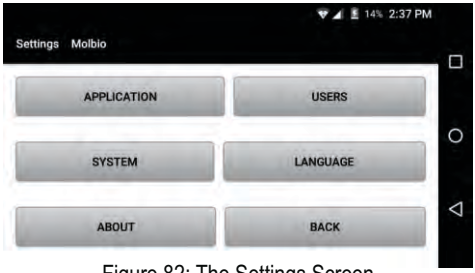


Figure 82: The Settings Screen

5.6.3 Tap the **About** Icon in the **Settings Screen.**
This will open the **About Screen.**

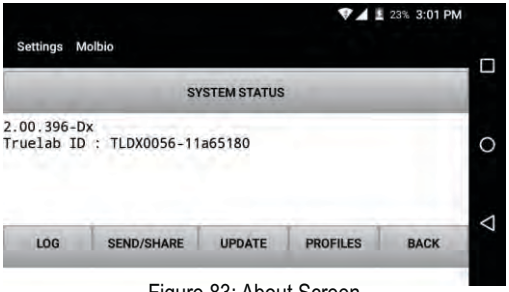


Figure 83: About Screen

5.6.4 Tap **Update**
The **Truelab® Uno Dx** will connect to the server and automatically check for new versions of the software. If it finds a new version,the Analyzer will automatically download and install the new version. The progress of the download is visible on screen. On completion of the download, an installation will be automatically initiated and will be completed in 5-10 seconds and the login screen will be displayed. Please login as usual to proceed.

Note:
The following message will be displayed if the system software is already up to date: "Latest Version Installed. No Update available"

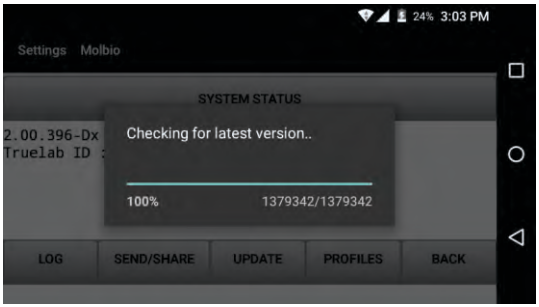
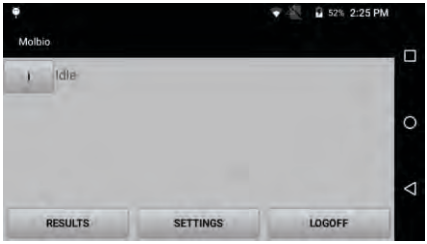
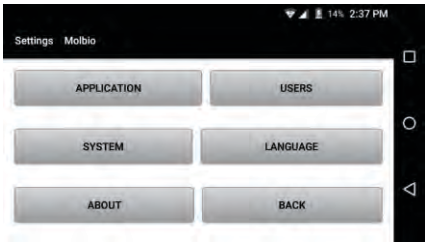
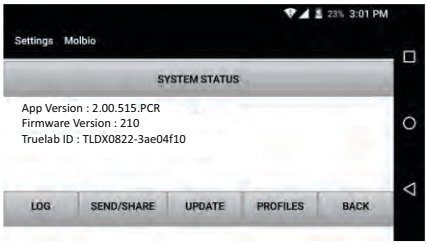


Figure 84: The System Message when Checking for Updates

5.6.5 This will display an Installation progress bar. Note: If login screen does not appear after 10 seconds, please press Home button. If you are unable to login, please contact Molbio support.	 Figure 85: Installation Progress Screen

5.7 Updating Disease Profiles

5.7.1 Login as Power User This will open the **Status Screen.**	 Figure 86: The Status Screen
5.7.2 Tap the **Settings** button in the **Status Screen** This will open the **Settings Screen.**	 Figure 87: The Settings Screen
5.7.3 Tap the **About** Icon in the **Settings Screen.** This will open the **About Screen.**	 Figure 88: About Screen

5.7.4 Tap **Profiles** in the **About Screen.**
This will begin the update process. A confirmation message will be displayed when the update process is complete.

Note:

The message "Latest Version Installed" will be displayed if the profiles are already up to date .

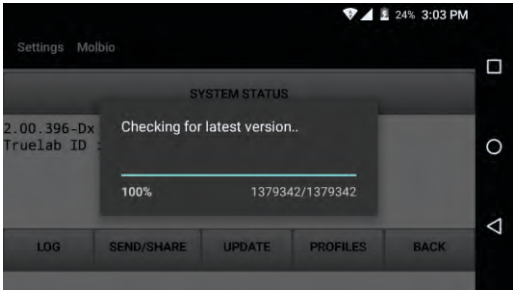


Figure 89: The System message when checking for updates

6 Generating and Transmitting Log Files

The **Truelab® Uno Dx** automatically records data within the system whenever it encounters an error. A log file, which is file containing information about the error, can be generated by the user so that it can be sent to Molbio Support for troubleshooting. All support requests from the user to Molbio Support should be accompanied by the log file generated after the incident has been reported to occur. It is strongly suggested that the user generates a log file immediately every time there is any undesirable behavior or event during the working with the **Truelab® Uno Dx.**

Important:

If a test is in progress when the error occurs, create the log file before beginning the next test.

Log files can be sent to Molbio support using one of the following methods:

- The Internet

  The **Truelab® Uno Dx** micro PCR Analyzer is capable of connecting to Wi-Fi / 3G network

  Note:

  These features are configured during installation.

- Via Bluetooth to the nearest computer/mobile phone

  The log file should be sent to Molbio support with the **Truelab® Uno Dx** micro PCR Analyzer ID (in use) and nature of incident.

6.1 Creating a Log File

6.1.1 **Login,** this will open the **Status Screen.**

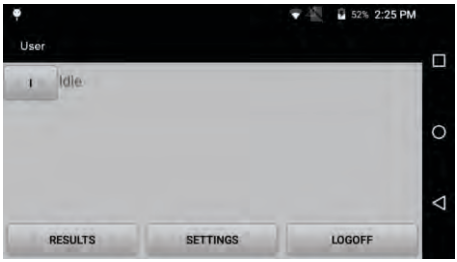


Figure 90: The Status Screen

6.1.2 Tap the **Settings** button in the **Status Screen.** This will open the **Settings Screen.**

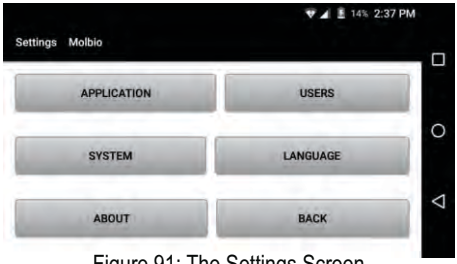


Figure 91: The Settings Screen

6.1.3 Tap the **About** Icon in the **Settings Screen.** This will open the **About Screen.**

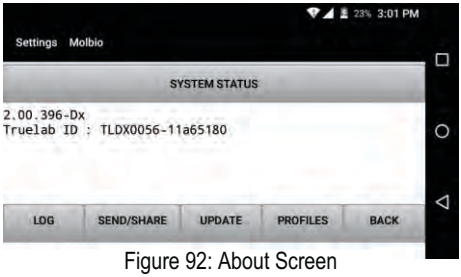


Figure 92: About Screen

6.1.4 Tap the **Log** icon in the **About Screen.** The **Truelab® Uno Dx** will now create a log file and prompt you with a success message when it has finished.

Note:

- *If the log file creation fails, please contact Molbio Support.*
- *Log files are automatically named and created, in the format: "log-date-time".*

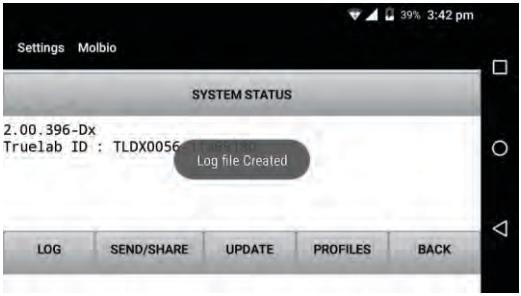


Figure 93: Log file creation confirmation

6.2 Sending Log files to the server using Wi-Fi / 3G

If the **Truelab® Uno Dx** is connected to a Wi-Fi or 3G network, you can send the Log file and Support Request to Molbio Support directly.

Note:
If the **Truelab® Uno Dx** is not configured to work with Wi-Fi / 3G or if a Wi-Fi / 2G network is unavailable, see section 6.3 “Sending Log Files to other devices (Mobile / PC) equipped with Bluetooth”.

To send log files using 3G / Wi-Fi,

6.2.1 Login, this will open the **Status Screen.**

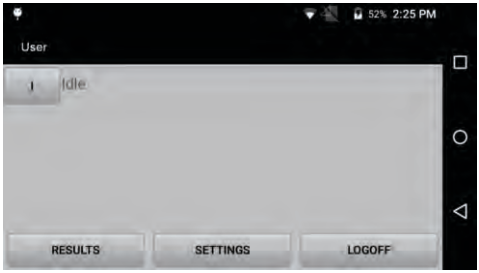


Figure 94: The Status Screen

6.2.2 Tap the **Settings** button in the **Status Screen.**
This will open the **Settings Screen.**

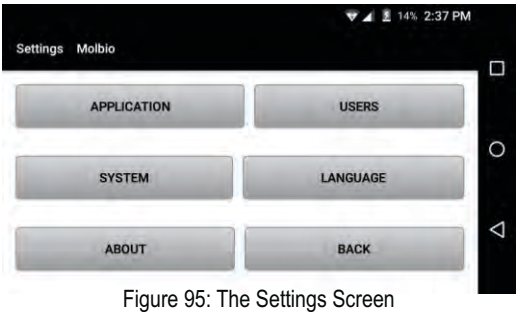


Figure 95: The Settings Screen

6.2.3 Tap the **About** Icon in the **Settings Screen.**
This will open the **About Screen.**

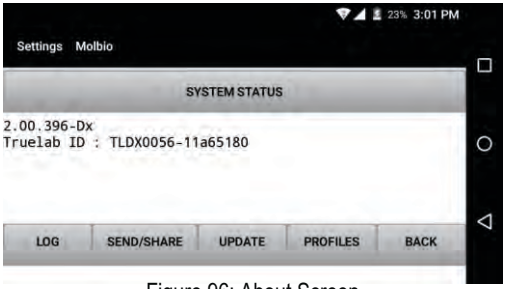


Figure 96: About Screen

6.2.4 Tap the **Send/Share Button**
This will display a pop-up with the options “Log File” and “Data File”.

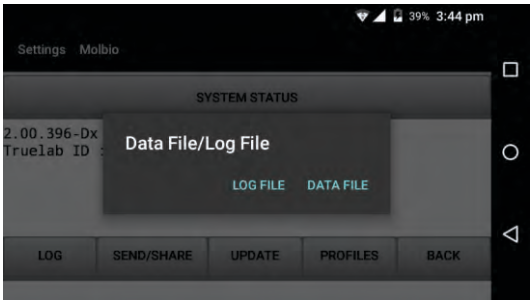


Figure 97: Pop-up for selection of Log File or Data file

6.2.5 Tap **Log File**
A list of available log files will be displayed.

Note:
Select the correct log file to send.
Log files are named automatically when they are created, in the format: “log-date-time”.

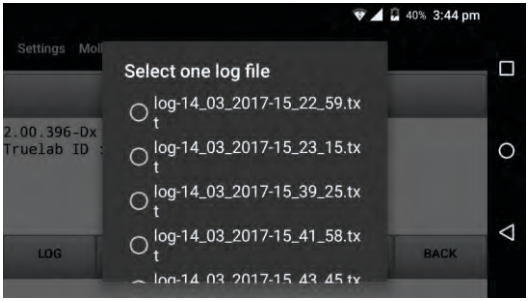


Figure 98: Log file selection

6.2.6 Tap the log file you want to send from the list to select it.
This will display a pop-up with the options “Send” and “Share”.

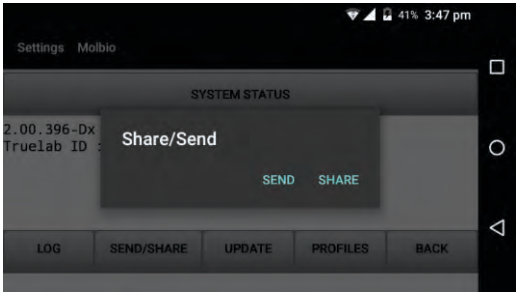


Figure 99: Pop-up for selecting send or share

6.2.7 Tap **Send**
This will send the file to the Molbio Server. A progress bar will be displayed on the screen and the message "File Sent" will be displayed when the process is complete.

Note:
*If the file was not sent, it will alert you with a pop-up. If the problem does not resolve itself on re-trying the procedure, or if the **Truelab® Uno Dx** alerts you with a system error message, please contact Molbio Support*

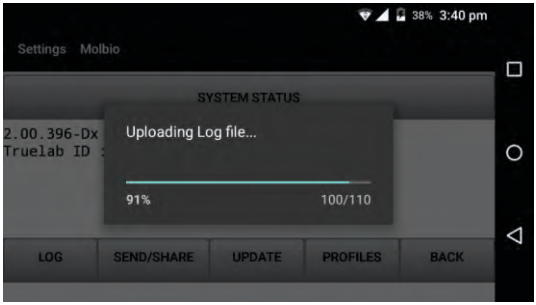


Figure 100: Log file upload status

6.3 Sending Log Files to other devices (Mobile / PC) equppied with bluetooth

If the **Truelab® Uno Dx** is not connected to a Wi-Fi Network, you can use the Bluetooth functionality to send the log file to the nearest computer or mobile phone with a working Wi-Fi connection.
Once the file is sent, you can use that device to send the log file and support request to Molbio Support.

6.3.1 Login, this will open the **Status Screen.**

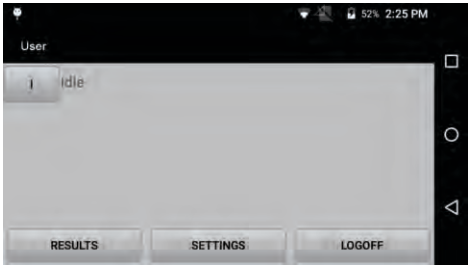


Figure 101: The Status Screen

6.3.2 Tap the **Settings** button in the **Status Screen.**
This will open the **Settings Screen.**

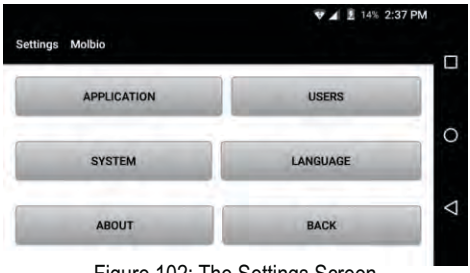
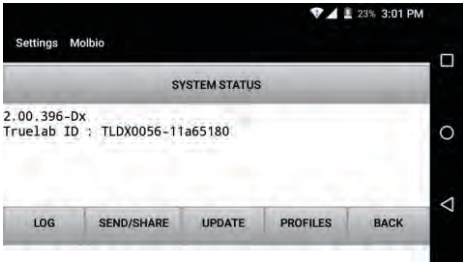
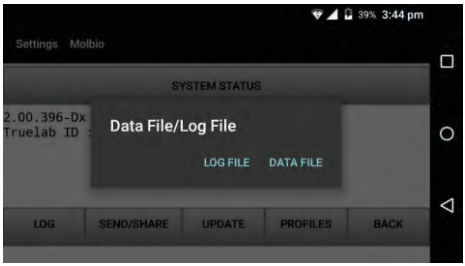
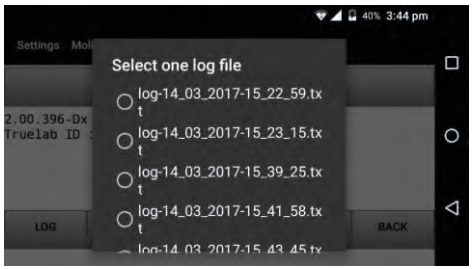
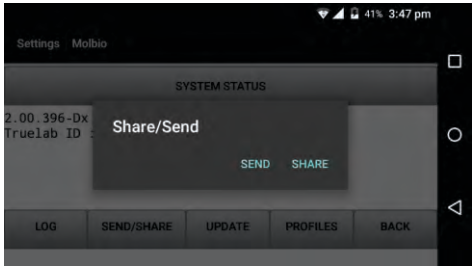


Figure 102: The Settings Screen

6.3.3	Tap the **About** Icon in the **Settings Screen.** This will open the **About Screen.**	 Figure 103: About Screen
6.3.4	Tap the **Send/Share Button .** This will display a pop-up with the options “Log File” and “Data File”.	 Figure 104: Pop-up for selection of Log file or Data file
6.3.5	Tap **Log File** A list of available log files will be displayed.	 Figure 105: Log file List
6.3.6	Tap the log file you want to send from the list to select it (Your selection will be indicated by a green dot next to the log file name). This will display a pop-up with the options “Send” and “Share”.	 Figure 106: Pop-up for selection of Send or Share option

6.3.7 Tap **Share** in the Pop-up Message.

6.3.8 This will display the **Bluetooth Devices** List, which is a list of all available Bluetooth devices that the **Truelab® Uno Dx** can connect to.

6.3.9 Tap on the name of the device you want to send the file to.
This will send the file to the device and display the message “File Sent” when complete.

Note:

- *Check the recipient device to verify that log file is received successfully.*
- *If the file was not sent, it will alert you with a pop-up. If the problem does not resolve itself on re-trying the procedure, or if the **Truelab® Uno Dx** alerts you with a Bluetooth Error message, please contact Molbio Support.*

6.3.10 On completion , please send it to customer support via e-mail.

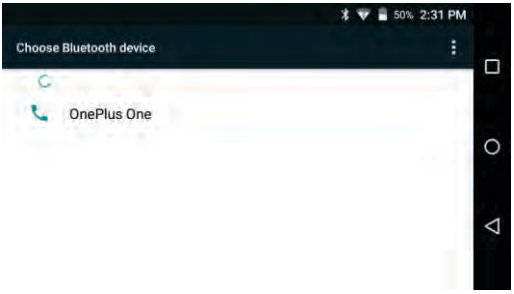


Figure 107: Bluetooth Devices List for transmitting log files

7 Sending the Data File

You can send data files (test data) to an external agency or server using a 3G or Wi-Fi connection, if this feature was configured during installation.

To send the Data File,

7.1 Login as Power User
This will open the **Status Screen.**

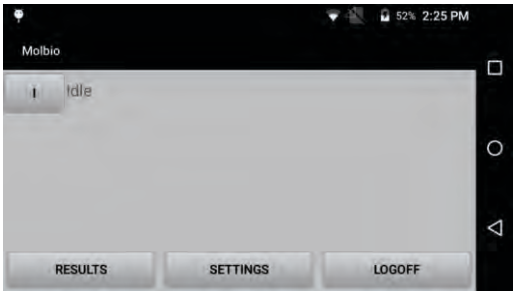


Figure 108: The Status Screen

7.2 Tap the **Settings** button in the **Status Screen.** This will open the **Settings Screen.**

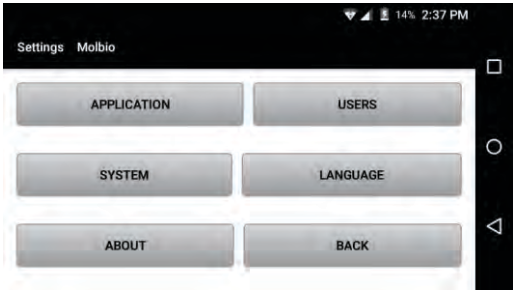


Figure 109: The Settings Screen

7.3 Tap the **About** Icon in the **Settings Screen.** This will open the **About Screen.**

7.4 Tap the **Send / Share Button** This will display a pop-up with the options "Log File" and "Data File".

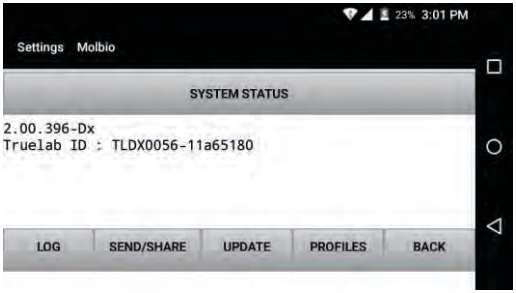


Figure 110: About Screen

7.5 Tap **Data File** The **Truelab® Uno Dx** will display an upload status bar, and display a pop-up confirmation message when it is finished.

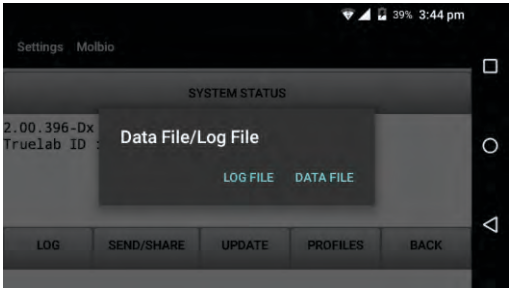


Figure 111: Pop-up for selection of Log file or Data file

7.6 Tap **OK** in the pop-up message.

Note:

- *If the file was not sent, it will alert you with a pop-up. If the problem does not resolve itself on re-trying the procedure, or if the **Truelab® Uno Dx** alerts you with a Bluetooth Error message, please contact Molbio Support.*

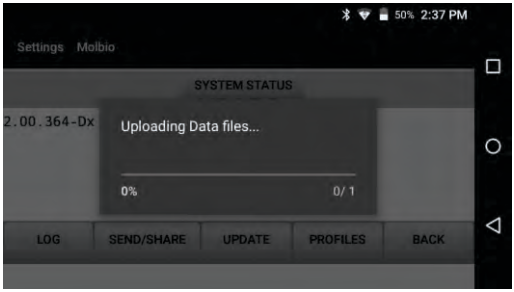


Figure 112: Data file upload progress

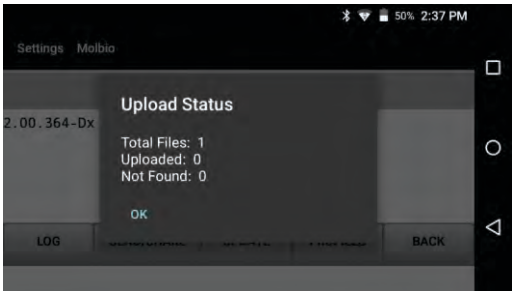


Figure 113: Upload status of data file

8 System Settings

This section provides information about the connectivity (Wi-Fi, Cellular, Bluetooth), date & time settings, etc. Connectivity helps to facilitated over the air updates, results sharing and remote diagnosis.

8.1 Connecting the Analyzer to Wi-Fi Networks

8.1.1 Switching ON Wi-Fi

8.1.1.1 Tap the Settings button in the Profiles Screen. This will open the Settings Screen

8.1.1.2 Tap the 'System' button

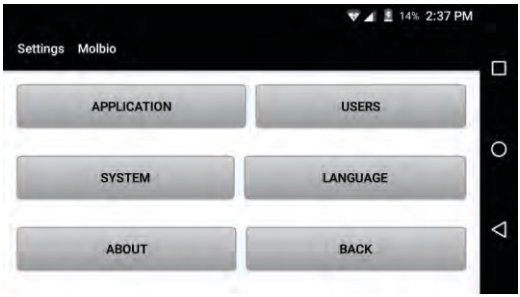


Figure 114: The Settings Screen

8.1.1.3 This will open the System Settings Screen.
Tap on Wi-Fi.

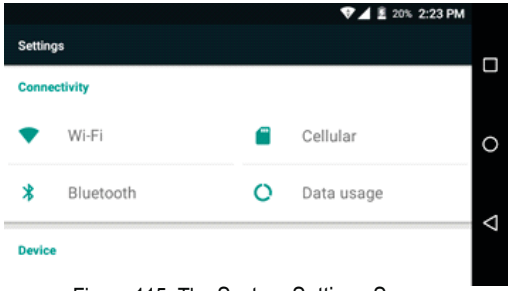


Figure 115: The System Settings Screen

8.1.1.4 Drag the slider handle to the right to turn ON Wi-Fi. The list of available Wi-Fi networks will appear. Choose the network you want to connect to.

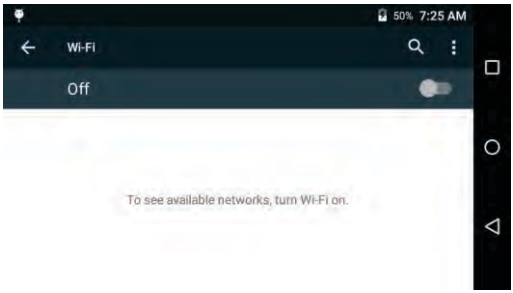


Figure 116: Wi-Fi Settings Screen

8.1.2 Configuring chosen Wi-Fi network

8.1.2.1 Once you tap on the network name, a pop-up will appear where you can configure and set up the connection. Scroll down and select advanced options to configure the IP settings.

8.1.2.2 Check with your network and router administrators if your network IP settings Dynamic or Static. If Dynamic, choose DHCP

If you choose the Protocol as Static IP, you will be prompted to enter an IP address.

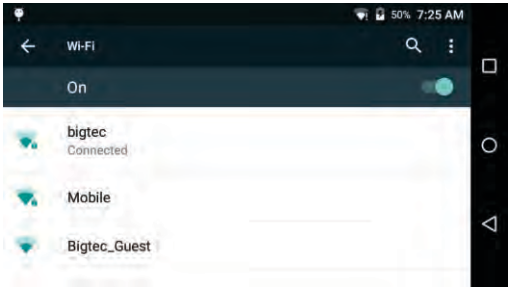


Figure 117: Connecting to desired Wi-Fi network

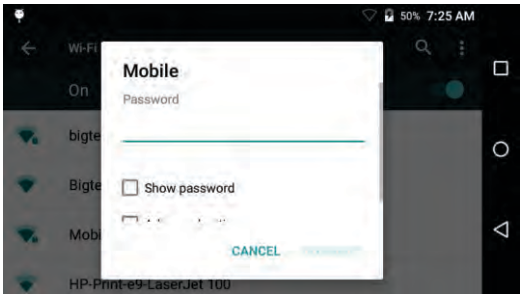


Figure 118: Enter the password

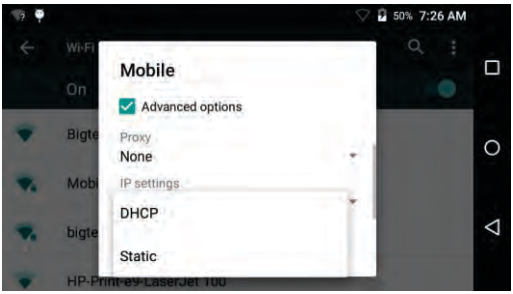


Figure 119: Wi-Fi advanced setting option for Dynamic or Static

8.1.2.3 Enter the password for the chosen Wi-Fi network and press 'Connect'.

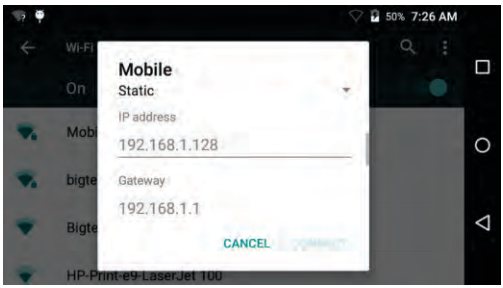


Figure 120: Display screen for static network

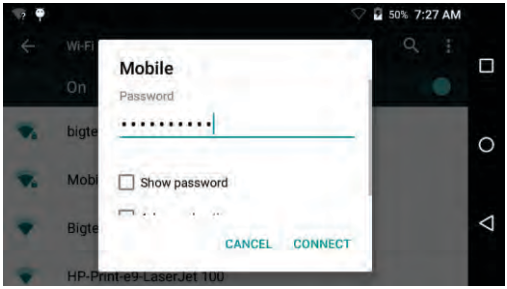


Figure 121: Enter the password

8.2 Cellular connectivity

Truelab® Uno Dx is equipped with a cellular modem for 3G connectivity. This can be used where a wifi network is not preferred or available for connectivity. Please note a SIM card with valid data plan is required.

8.2.1 Inserting and removing SIM

The slim slot is situated at the rear next to the power button. The slot accepts one micro SIM.

Figure 122: Sim Slot for SIM card and direction for SIM Insertion

8.2.1.1. To insert the SIM, make sure **Truelab® Uno Dx** is switched off. Gently insert the SIM with the contacts side facing up words as shown in the above image. The SIM will lock in slot with a soft click sound.

8.2.1.2. To remove the SIM, make sure **Truelab® Uno Dx** is switched off. Gently push the SIM, it will unlock and come out a quarter length, Pull it out completely using two fingers.

8.2.2. Checking connectivity: After login screen is displayed, **Truelab® Uno Dx** will register to the network in about 2 minutes. If the network coverage is low, this may take another 90 seconds. Once registered the signal will be displayed next to the battery icon along with a status of data connection. If data connection is successfully initiated, a small 3G symbol is displayed along with the signal triangle (in case 3G network is not available and is connected to a 2G network, symbol 'E' or 'G' may appear). Typically this happens at the same time as the registration completion. **Truelab® Uno Dx** will be auto configured for data connection on first boot after a SIM change. If a different operator is chosen on a roaming SIM, rarely, this auto-configuration may not work. In this case, the data connectivity symbol 3G, E or G) symbol may not appear. Please

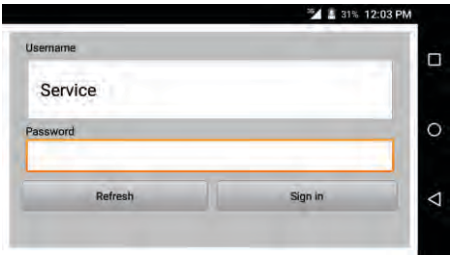


Figure 123: Selection of User Name

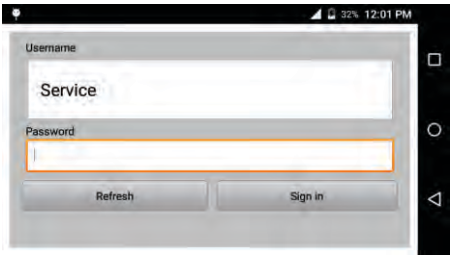


Figure 124: Enter the password Screen

refer 8.2.5 for manual data connection configuration.

8.2.3. Choosing operators: If you are using a roaming SIM and would like to select a preferred operator, it can be done so.

8.2.3.1. Login as power user, tap on 'Settings', 'System'. On the system settings screen, tap on 'Cellular'.Tap on Cellular Networks and choose 'Network Operators', this will trigger search for available network operators in coverage. This may take a few minutes time. On completion, a list of providers will be displayed. Choose the preferred provider by tapping the respective name. Successful registration displays a message 'Registered on network' and will display the previous menu. In case of unsuccessful attempt, please repeat the process, and make sure you are selecting a valid provider for the SIM card inserted. If you are un sure of which provider to select, please tap 'Choose automatically' in 'Available network' screen. You can also cancel on going network search by pressing back button (triangle shape) in the navigation bar present on right hand side of the screen.

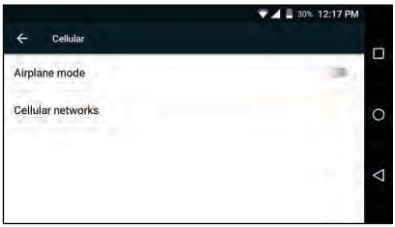


Figure 125: Cellular Screen

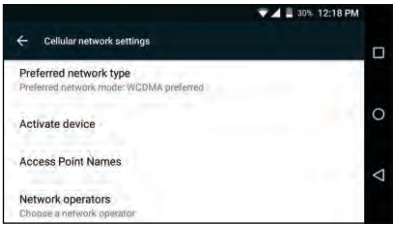


Figure 126: Cellular network Settings

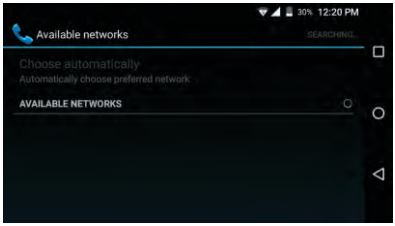


Figure 127: Search for available network

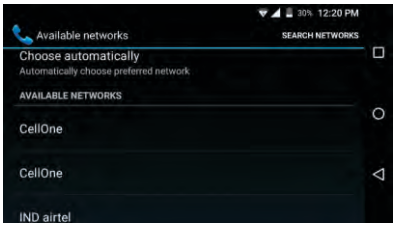


Figure 128: Screen with available network displayed for selection

8.2.4. **Network type selection:** By default **Truelab® Uno Dx** is configured to work on 3G mode. In this mode, if there are no 3G signal coverage, network will automatically switch to 2G mode to ensure connectivity. If you wish to choose the type manually, follow these steps. It is advised to leave this settings unchanged,ie in 3G mode (WCDMA Preferred).

8.2.4.1 . On Cellular network settings, tap 'Preferred network type', Below options would listed:

1. GSM/WCDMA auto - 2G/3G automatic. **Truelab®** Uno Dx chooses which ever best available.
2. WCDMA only. 3G/2G mode only, if there is no 3G coverage, network connect to 2G.
3. GSM only. 2G mode only, will not connect to a 3G network.
4. GSM/WCDMA Preferred - 2G/3G auto with preference to 3G mode.

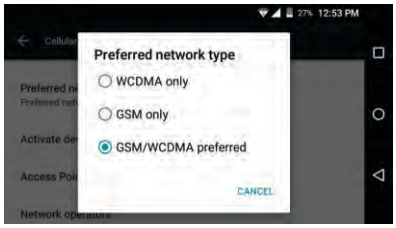


Figure 129: Pop-up Screen for selection of Preferred network type

8.2.5. Access point names configuration. Access point names(or APN in short) are the pointers which allow **Truelab® Uno Dx** to initiate a data connection once a network is registered. The APN will be different for every service provider. APNs are configured automatically on first boot after every SIM

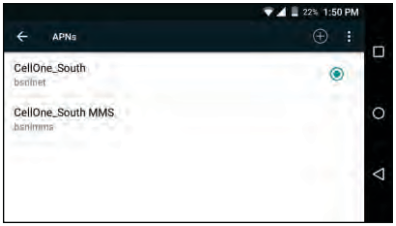


Figure 130: Access point names Screen

change and no manual configuration is required. However, a manual configuration may be required at times when a roaming SIM is used and provider is choose manually. Go to APNs screen by tapping 'Access Point Names' on Cellular network settings. A restart (switch off and switch back on) may be necessary if a new APN is created manually.

8.2.5.1. Reset to provider default APN: Tap on three dot menu on the top right hand side, and choose 'Reset to default'.

8.2.5.2. Edit existing APN: Enter 'Edit access point' by tapping the APN from the list. You can do one of the following three
a. Edit fields. - To save the modified fields, from the three dot menu on right hand side top, choose 'Save'
b. Discard modification - from the three dot menu on right hand side top, choose 'Discard'
c. Delete APN - Delete the APN by choosing 'Delete APN'

8.2.5.3 . Create new APN. To manually add APN for a manually roaming provider, from the APNs screen tap on '+' symbol on top right hand side. Enter desired name in 'Name' field, and enter the remaining fields with the values provided by the network provider.Once finished, please tap on the three dot menu and choose

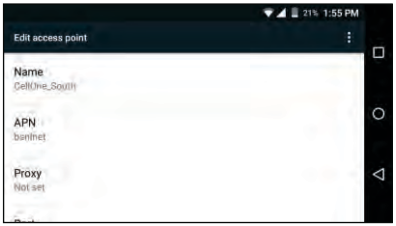


Figure 131: Edit access pint Screen

'Save'. Please note other APNs to be deleted before creating a new one in case of choosing a provider manually for roaming SIM.

8.2.5.4. To go back to default APNs , delete all available APN and repeat step 8.2.5.1(ie reset to service provider default).

8.2.5.5 To check the network connectivity go to home page > settings > About > NETWORK STATUS.
Network status shall be displayed

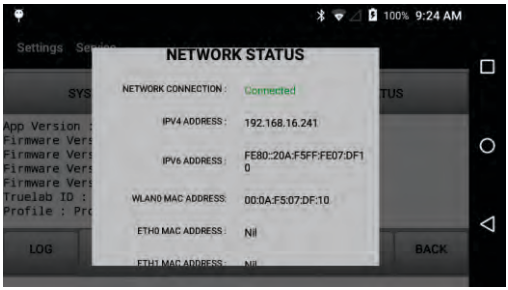


Figure 132: Network status screen

8.3 Bluetooth connectivity

8.3.1 Switching ON Bluetooth

8.3.1.1 Tap the Settings button in the Profiles Screen. This will open the Settings Screen.

8.3.1.2 Tap the ' System' button.

8.3.1.3 This will open the System Settings Screen. Tap on Bluetooth.

8.3.1.4 Drag the slider handle to the right to turn ON Bluetooth. The list of available devices will appear. Choose the device you want to pair with.

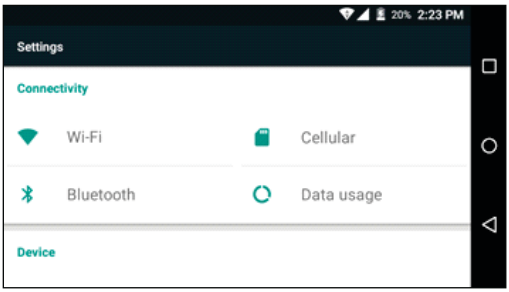


Figure 133: System setting screen

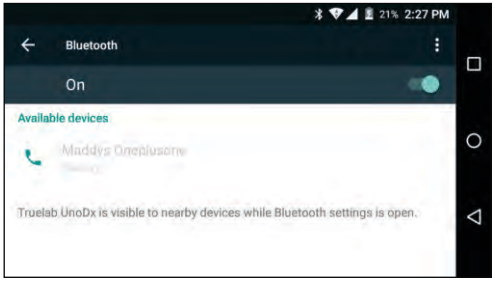


Figure 134: List of Bluetooth connection for available devices

8.3.2 Pairing Instructions

8.3.2.1 A pop-up will appear with the pairing code. Press 'Pair'

8.3.2.2 If pairing is successful, the device will appear under the paired devices list.

8.3.2.3 To sever the connection, tap on the device name and press 'Forget' on the pop-up that appears.

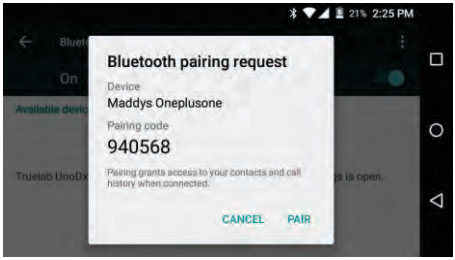


Figure 135: Pop-up for Bluetooth pairing request

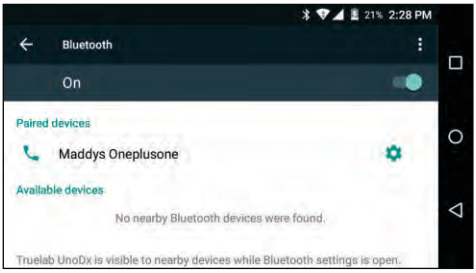


Figure 136: Paired devices list

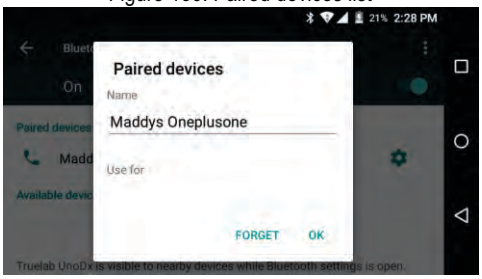


Figure 137: Pop-up for paired device

8.4 Date and Time settings

8.4.1 Tap the Settings button in the Profiles Screen. This will open the Settings Screen.

8.4.2 Tap the ' System' button.

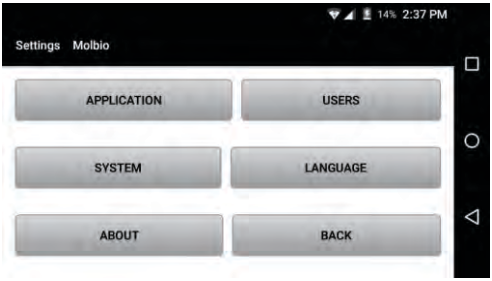


Figure 138: The Settings Screen

8.4.3 Scroll down to bottom to the 'Device' section. Tap on 'Date & time'.

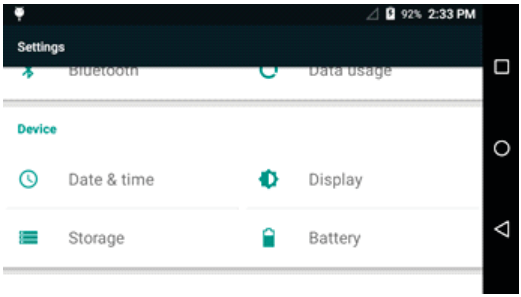


Figure 139: Date & Time selection under Settings Screen

8.4.4 If the Analyzer has 3G / Wi-Fi functioning, it can get the date and time from the internet or from the cellular network.To manually select date and time, drag the slider handle to the left. This will activate the 'Set date' and 'Set time' fields.

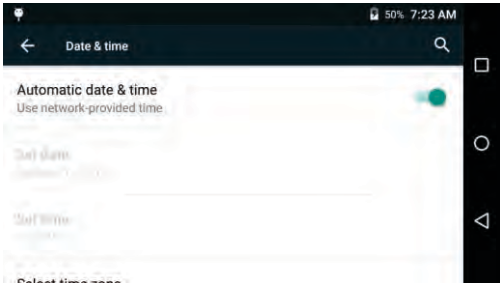


Figure 140: Date & Time Screen

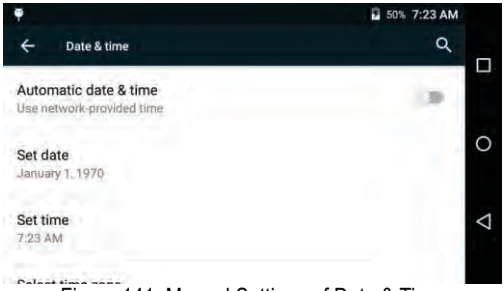


Figure 141: Manual Settings of Date & Time

8.4.5 Press 'Set date'. A pop-up will appear that allows you to select the date. Press 'OK' after selecting the date.

8.4.6 Press 'Set time'. A pop-up will appear that allows you to select the time. Press 'OK' after setting the time.

Note: If the Analyzer is switched off and un-used for 30 days or more, please set the date and time before use. The Analyzer will not allow the user to start a test if the date and time are incorrect.

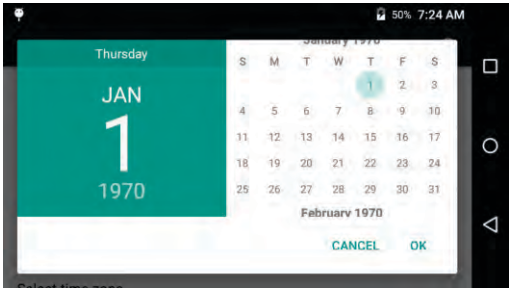


Figure 142: Pop-up to Set Date

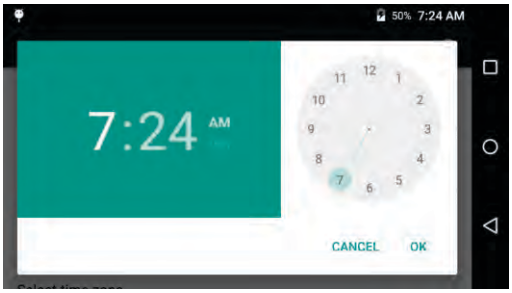


Figure 143: Pop-up to Set Time

8.5 Display settings

8.5.1 Tap the Settings button in the Profiles Screen. This will open the Settings Screen.

8.5.2 Tap the 'System' button.

8.5.3 Scroll down to bottom to the 'Device' section. Tap on 'Display'.

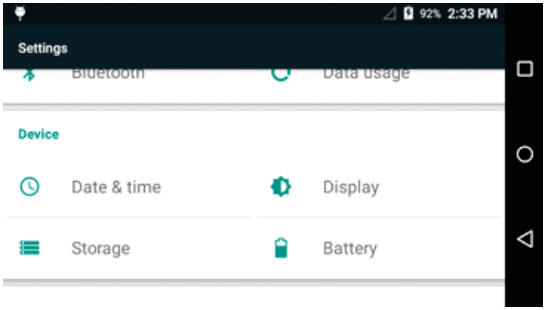


Figure 144: Device Settings Screen to select Display

8.5.4 To adjust screen brightness, select 'Brightness level' and adjust the brightness as desired.

8.5.5 To change the time after which the screen goes to sleep, select 'Sleep' and choose the desired setting.

8.5.6 To change the font size of the text on the screen, select 'Font size' and choose the desired size.

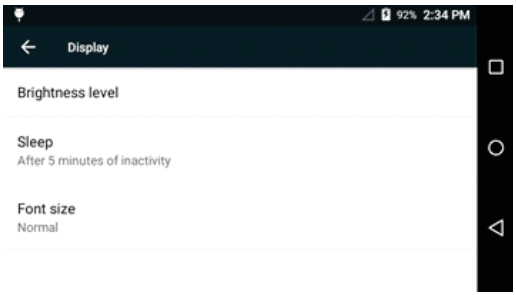


Figure 145: Display Screen

8.6 Storage status

8.6.1 Tap the Settings button in the Profiles Screen. This will open the Settings Screen.

8.6.2 Tap the ' System' button.

8.6.3 Scroll down to bottom to the 'Device' section. Tap on 'Storage'.

8.6.4 The status bar shows how much space is used and how much is available, which is also reflected in the text below. If the available space is 50MB or less, please contact Molbio Support for backup of your test results.

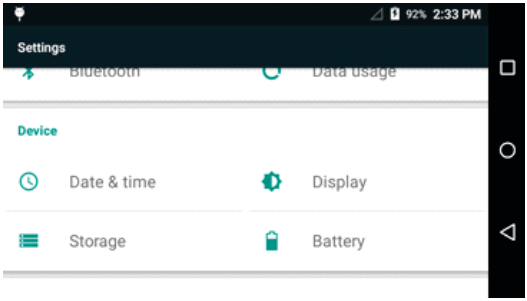


Figure 146: Settings Screen to select storage

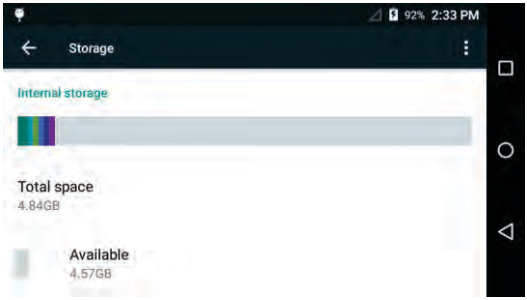


Figure 147: Screen to show Storage Status/Storage Screen

8.7 Battery status

8.7.1 Tap the Settings button in the Profiles Screen. This will open the Settings Screen.

8.7.2 Tap the 'System' button.

8.7.3 Scroll down to bottom to the 'Device' section. Tap on 'Battery'.

8.7.4 The text and graph indicate % charge of the battery and whether the battery is being charged or not.

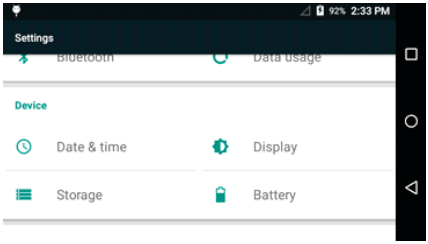


Figure 148: Settings Screen to select Battery option

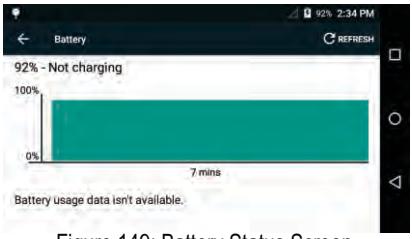


Figure 149: Battery Status Screen

9. Switching off the Analyzer

9.1 Normal Shutdown

9.1.1 To switch off the Analyzer, press the Power Button for 2-3 seconds.

9.1.2 Tap 'OK' in the pop-up that appears on the screen to proceed with shut down.

9.2 Forced shutdown

9.2.1 If the device is not responding during regular use (when a test is not in progress), pressing the Power Button for ~7 seconds will cause a force shut down of the device.

Caution:

⚠ If a force shut down is performed for any reason, the device may take 3-4 minutes to boot up when switched on again.

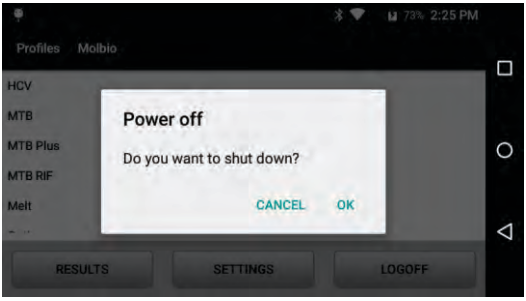


Figure 150: Pop-up Screen for Power off

10. Maintaining the Truelab® Uno Dx

10.1 Maintenance

The **Truelab® Uno Dx** will prompt you in case of hardware malfunction or errors encountered when performing a test. Refer to the "System Messages and Troubleshooting" section on how to resolve common errors or contact Molbio support.

10.2 Cleaning instructions

- If required, wipe the exterior of the **Truelab® Uno Dx** micro PCR Analyzer with a dry, lint-free cloth ensuring that no fibrous material adheres to the surface of the Analyzer.
- Do not spill water or any other solution on the surface of the Analyzer.
- If a spill or leak occurs in the work area surrounding the Analyzer, wipe the exterior of the **Truelab® Uno Dx** micro PCR Analyzer with cloth or tissue dipped in 0.5% solution of sodium hypochlorite.
- Wipe the exterior of the **Truelab® Uno Dx** micro PCR Analyzer with cloth or tissue dipped in 0.5% solution of sodium hypochlorite once every 4 weeks and/or when the Analyzer is transferred to a different work space.

10.3 Disposal of Instrument

Do not dispose off the Instrument as unsorted Municipal waste. Contact Molbio for the collection of Instrument.

11. Safety

11.1 Cleaning & decontamination

1. If hazadous materials are spilled onto the instrument, the instrument should be appropriately decontaminated.
2. Using cleaning or decontamination methods other than those recommended by Molbio may compromise the safety or quality of the instrument.
3. For the protection of others, ensure that the instrument is properly decontaminated prior to having the instrument serviced at your facility or before sending the instrument for repair, maintenance or disposal.

11.2 Moving the installed equipment

1. If you decide to move the instrument after it has been installed, do not attempt the same without consulting Molbio support.

11.3 General Biohazard

Biological samples such as tissues, blood fluids, and blood of humans have the potential to transmit infectious diseases. Wear appropriate protective clothing, and gloves.

11.4 Waste disposal of Consumables

All laboratory hardware used for a PCR assay including **Truenat®** micro PCR chips, micropipette tips etc., are to be safely disposed of by using the following method:

1. Submerge all of the materials in a freshly prepared 0.5% solution of sodium hypochlorite for 30 minutes.

2. Dispose as biological waste as per the applicable laws in your region.

11.5 Protection from hazards related to device battery

For the battery cell, chemical materials are stored in a hermetically sealed metal or metal laminated plastic case, designed to withstand temperatures and pressures encountered during normal use. As a result, during normal use, there is no physical danger of ignition or explosion and chemical danger of hazardous materials' leakage.

However, if exposed to a fire, added mechanical shocks, decomposed, added electric stress by miss-use, the gas release vent will be operated. The battery cell case will be breached at the extreme, hazardous materials may be released. Moreover, if heated strongly by the surrounding fire, acid gas may be emitted.

11.6 Truelab® Uno Dx complies to below list of standards

Sr.No	Standard/Reference ID	Title of Standard/Regulation
1	ISO 14644-5:2004	Clean rooms and associated controlled environments -Part 5:Operations
2	IEC 61000-4-15	Power line Flicker Test
3	IEC 1000-3-2	Power Frequency Harmonics Emission Test
4	IEC 61000-4-8	Power Frequency Magnetic Field Immunity test
5	IEC 61000-4-2:2008	Electrostatic discharge immunity
6	IEC 61000-4-3:2010	Radio-frequency, electromagnetic field immunity
7	IEC 61000-4-4:2012	Electrical fast transient /burst immunity
8	IEC 61000-4-6:2013	Immunity to conducted disturbance, induced by RF fields
9	IEC 61000-4-8:2009	Power frequency magnetic field immunity
10	IEC61000-4-11:2004	Voltage dips and short interruptions
11	IEC 61000-3-2:2009	Harmonic current emission
12	IEC 61000-3-3: 2008	Voltage fluctuation and flicker

12. System Messages and Troubleshooting

The following section details some errors you may encounter while using the **Truelab® Uno Dx** real time quantitative micro PCR Analyzer, and provides you with the reason for the error and possible solutions to it. If the error you encounter is not mentioned in this section, please contact Molbio support.

This section describes how to view system information, which may be required to provide to Molbio Support when a service request is sent.

Tap the Settings button in the Profiles Screen. This will open the Settings Screen.

Tap the 'About' button.

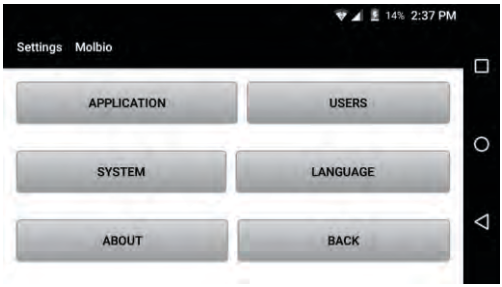


Figure 151: The Settings Screen

This will open the About Settings Screen. Tap on the ' System Status' button that runs across the upper portion of the screen.

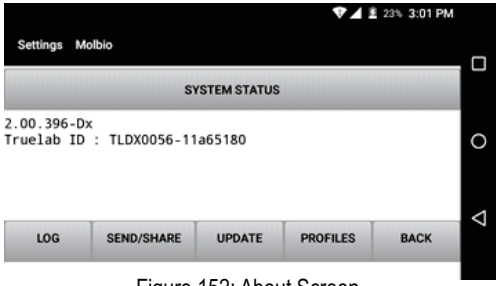


Figure 152: About Screen

This will take you to the System Status screen where status of various sub-systems is accessible and the model / version numbers of the device and software are available. Scroll down to all the fields.

Figure 153: The System Status Screen

Tap on the first tab 'Status' to go to access the status information of various sub-systems.

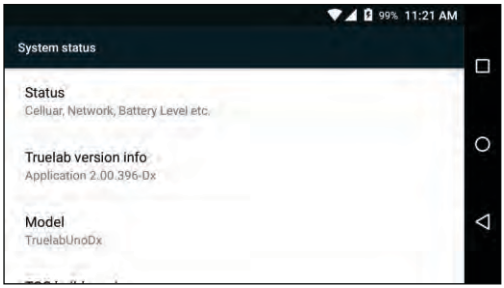


Figure 154: The System Status Screen with sub-systems

If there are issues with connectivity that you are reporting to Molbio Support, tap on 'SIM Status' tab. This takes you to the SIM Status screen where details on the cellular network and signal strength are available.

Figure 155: Status Screen for SIM status option

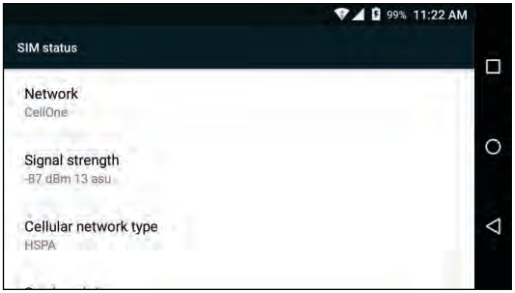
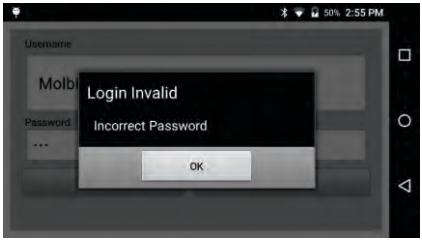
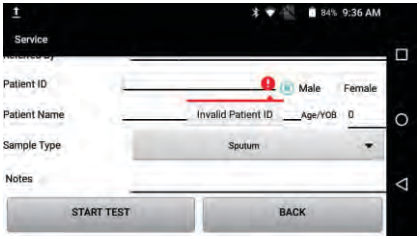
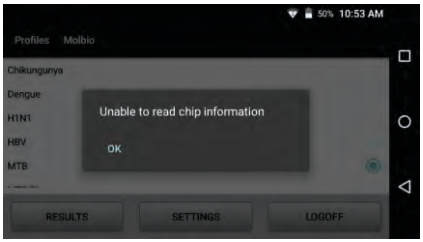
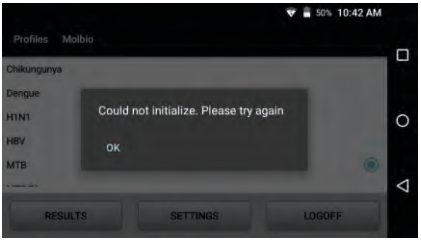
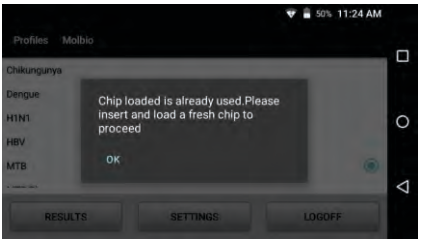
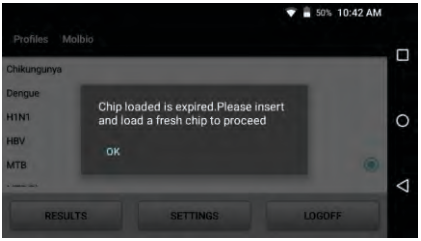
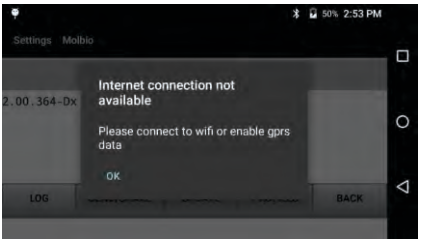
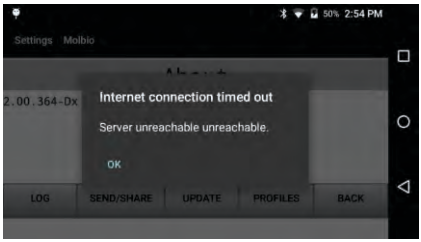
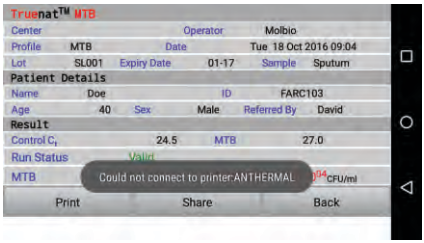
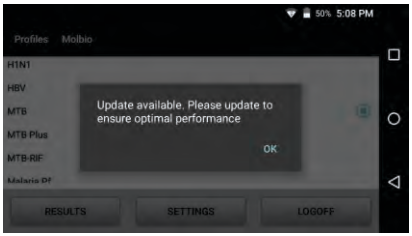
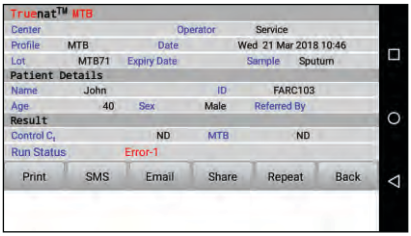
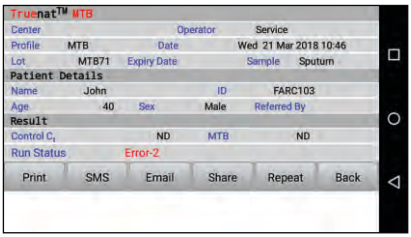


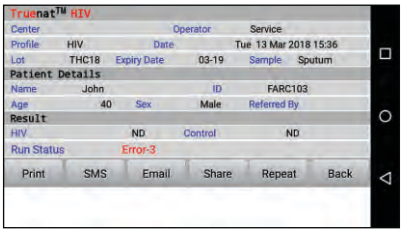
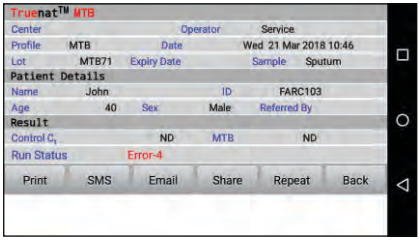
Figure 156: SIM Status Screen

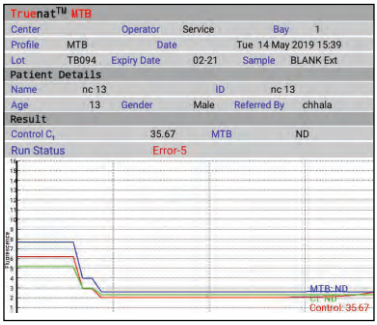
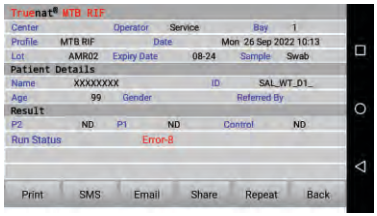
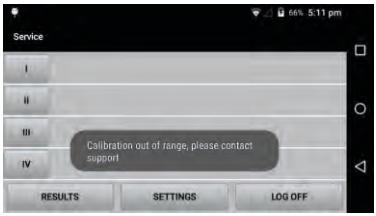
Description	Reason for Error and Possible Solution	Screenshot of Error
Login attempt failure, with system message "Login Invalid, Incorrect Password"	**Reason:** The password you entered was incorrect. **Solution:** • Tap the **OK** Button This will take you back to the login screen • Re-enter the correct password (password is case-sensitive)	 Figure 157: Login invalid prompt
System message "Invalid Patient ID" in Sample Details Screen.	**Reason:** The "Patient ID" field in the Sample Details Form is blank. This field is mandatory. **Solution:** You need to fill in mandatory information to continue with the test.	 Figure 158: Sample Details Screen
System Message "Unable to read chip information"	**Reason:** The Analyzer was unable to read chip memory. **Solution:** 1. Tap 'OK' on the Read Error Prompt. 2. Check if chip was loaded properly into the tray. If so, remove the chip and select the profile from Profile screen and repeat the steps. 3. Load a different chip or the same chip in case not loaded before. If the same message reappears, please contact Molbio support team.	 Figure 159: Chip information read error

Description	Reason for Error and Possible Solution	Screenshot of Error
System Message " Could not initialize. Please try again"	**Reason:** The system was unable to establish an internal connection. **Solution:** Please attempt the test again. Contact Molbio support team if the problem persists.	 Figure 160: Initialization error
System Message "Chip is already used", after completing **Truenat®** chip loading procedure	**Reason:** You have loaded a used chip in the Chip Tray. **Solution:** Please use a fresh chip.	 Figure 161: Used chip alert
System Message "Chip loaded is expired", after completing **Truenat®** chip loading procedure	**Reason:** You have loaded an expired chip in the Chip Tray. **Solution:** Please use a fresh chip.	 Figure 162: Expired Chip Alert
System Message: "Internet connection not available	**Reason:** You are not connected to a 3G / Wi-Fi connection because you are not in range of the signal. **Solution:** Move the device to within range of the Wi-Fi signal. If the problem persists, contact Molbio Support.	 Figure 163: Internet connection status

Description	Reason for Error and Possible Solution	Screenshot of Error
System Message: "Internet connection timed out"	**Reason:** The Analyzer could not connect to the Molbio Support Server. **Solution:** Contact Molbio Support	 Figure 164: Molbio Support Server Status
System Message: "Could not connect to printer"	**Reason:** The Analyzer was unable to successfully initiate Bluetooth pairing with the printer. **Solution:** Always switch ON the printer and wait at least ten seconds before selecting the print button on the results screen. If this does not solve this issue, please contact Molbio Support.	 Figure 165: Printer connection status
System message: "Update available. Please update to ensure optimal performance."	**Reason:** The Analyzer found a system update that needs to be installed **Solution:** Install the update as per instructions mentioned in Section 5.6	 Figure 166: Update available alert

Description	Reason for Error and Possible Solution	Screenshot of Error
Error 1- Thermal Cycling error	**Reason:** This error usually occurs when the Test chip is faulty. This error is displayed when the thermal cycling does not happen. **Solution:** Please attempt the test Again without entering patient data by pressing Repeat button. Contact Molbio's support team if the problem persists.	 Figure 167: Error 1 Screen Status
Error 2- Test stopped Manually	**Reason:** This error is displayed when the user has manually stopped the ongoing test and the analyzer does not have sufficient run time to compute data. **Solution:** Please attempt the test Again.	 Figure 168: Error 2 Screen Status

Description	Reason for Error and Possible Solution	Screenshot of Error
Error 3- Incorrect optical profile	**Reason:** This error is displayed when there is a deviation in the expected optical profile due to reduction in reaction volume in the chip during the course of reaction. **Solution:** Please attempt the test again without entering patient data by pressing Repeat button. Contact Molbio's support team if the problem persists.	 Figure 169: Error 3 Screen Status
Error 4- Runtime Error	**Reason:** This error is displayed when run data capture/analysis is incomplete. **Solution:** Please attempt the test again without entering patient data by pressing Repeat button. Contact Molbio's support team if the problem persists	 Figure 170: Error 4 Screen Status

Description	Reason for Error and Possible Solution	Screenshot of Error
Error 5- Probe check Error	**Reason:** This error is displayed in the event of low initial signal due to insufficient mastermix dispensed onto the chip. **Solution:** Please attempt the test again without entering patient data by pressing Repeat button. Contact Molbio's support team if the problem persists.	 Figure 171: Error 5 Screen Status
Error 8- Control Probe Error	**Reason:** This error is displayed if the Control Probe T_m (melting temperature) is not detected or out of specified range **Solution:** Repeat the run with same elute using another chip. Contact Molbio support team if the problem persists.	 Figure 172: Error 8 Screen Status
Temperature Calibration Error	**Reason:** Temperature calibration value of any bay is out of range, to prevent users from starting a test, no further runs are allowed. Pop up will be displayed as "Calibration out of range, please contact support" **Solution:** Contact Molbio support.	 Figure 173: Temperature Calibration Screen Status

13 Glossary

Absolute quantification:

An assay used to quantitate unknown samples by interpolating their quantity from a standard curve (as in the determination of the viral copy number).

Amplicon:

The amplified sequence of DNA obtained by the PCR process. This is also called the “PCR product”.

Amplification Plot:

The plot of cycle number versus fluorescence signals which correlates with the initial amount of nucleic acid during the exponential phase of the PCR.

Baseline:

The initial cycles of the PCR during which there is little change in fluorescence signal (usually cycles 3 to 15).

Ct (threshold cycle):

Threshold cycle reflects the the cycle number at which the fluorescence signal generated within the reaction crosses the threshold. It is inversely correlated to the logarithm of the initial copy number. The Ct assigned to a particular sample thus reflects the point during the reaction at which a sufficient number of amplicons have accumulated. It is also sometimes called the crossing over (Cp) point.

Dynamic Range:

The range of initial template concentrations over which accurate Ct values are obtained. If endogenous control is used for ΔCt quantitation method, dynamic ranges for sample and control should be comparable. In absolute quantitation interpolation within this range is accurate but extrapolation beyond the dynamic range should be avoided. The larger the dynamic range the greater is the ability to detect samples with both high and low copy number in the same run.

Internal Positive Control (IPC):

An exogenous control that is characterized by spiking DNA at a known concentration into each sample. This serves to distinguish between true target negatives from PCR inhibition and also monitor the presence of inhibitors in the template. Most commonly IPC is added to the PCR master mix to determine whether inhibitors are present in the master mix. Alternatively it can be added at the point of sample collection or prior to sample nucleic acid extraction to monitor sample stability and extraction efficiency in addition to presence of any inhibitors in the master mix..

Template:

The nucleic acid sample used to amplify the target sequence is called the template.

Threshold:

Usually 10X the standard deviation of Rn for early PCR cycles (background activity). The threshold should be set in the region associated with an exponential growth of the PCR product (which may be easier in the log view of the amplification plot) and not as high as the linear or plateau sections of the

curve. It should be above the highest baseline signal level. It is assigned for each run to calculate the Ct or Cp value for each amplification. It may be necessary to have separate different Ct thresholds for each dye used in the reaction.

Y – Intercept:

Ina standard curve the value of y (Ct) where the curve crosses the y-axis at X=1 copy or 3.08 picogram of DNA equivalent template. The y-intercept value corresponds to the Ct value for a single copy of the target molecule. The value of around 40 indicates good sensitivity of the assay. Ct values greater than 40 are encountered if PCR efficiency is lower than 100%.

(Glossary adapted from "Glossary of real time PCR terms" by M.Tevfik Dorak, MD. PhD.)

14. References

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Symbol keys

Symbols	Description of Symbol key
IVD	In Vitro Diagnostic medical device
	Keep away from sunlight
REF	Catalogue number
	Caution
EC REP	Authorised Representative in the European Community
SN	Serial number
CE	CE mark
	Consult Instructions for use
	Manufacturer
	The WEEE (Waste Electrical and Electronic Equipment) symbol
	Electrostatic Sensitive Device
	Non-sterile
	Device for near-patient testing
UDI	Unique Device Identifier

Symbol keys

Symbols	Description of Symbol key
	This Way Up
	Medical Electronic Rush
	Fragile, handle with care
	Keep Dry
	Fully automatic operation
	Portable
	Rapid sample prepping
	Mains / rechargeable battery powered
	Truenat® microchip based
	Real Time PCR Techonology
	GPS compatible
	Cellular compatible
	Wi-Fi compatible
	Bluetooth compatible
	Stacking limit by number
	Direct current

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