CE

IVD

Trueprep® AUTO v2

Universal Cartridge Based Sample Prep Device

REF 603042001

UDI 8908007989972

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

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

IV. Intended Use

The **Trueprep® AUTO v2** Universal Cartridge Based Sample Prep Kit works with **Trueprep® AUTO v2** Universal Cartridge Based Sample Prep Device and is used for extraction and purification of nucleic acids from a wide range of biological specimens. It is an *in vitro* Diagnostics (IVD) device meant for professional use in near-patient, laboratory or any healthcare settings, by healthcare professionals or any user appropriately trained by a representative of Molbio Diagnostics.

V. Preamble

Before starting the nucleic acid extraction on the **Trueprep® AUTO v2 Universal Cartridge Based Sample Prep Device** 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 Trueprep® AUTO v2 User Manual

This user manual is intended to guide the USER through the installation, operation, and maintenance of the **Trueprep® AUTO v2 Universal Cartridge Based Sample Prep Device**, ensuring optimal performance and reliable results. It also provides the specifications of the device utilized in nucleic acid extraction, followed by a description of any encountered errors.

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 **Power Button** and **AC Adapter** are references to physical objects. **Exit** 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

1.1 The Trueprep® AUTO v2 Universal Cartridge Based Sample Prep Device

Testing for infectious diseases by detecting the pathogens nucleic acids using nucleic acid amplification methods is a highly specific and sensitive diagnostic tool. Molbio's **Truelab®** micro PCR System is a nucleic acid amplification platform that works on Real Time Polymerase Chain Reaction (PCR) technology that enables near patient diagnosis through disposable, disease specific micro PCR chips and a portable, automated **Truelab®** Real Time micro PCR analyzer.

The PCR process necessitates the extraction and purification of nucleic acids from clinical specimens to free it from potential PCR inhibitors. The **Trueprep® AUTO v2 Universal Cartridge Based Sample Prep Device** together with **Trueprep® AUTO/AUTO v2 Universal Cartridge Based Sample Prep Kit** provides an easy method of nucleic acid extraction and purification.

Trueprep® AUTO v2 Universal Cartridge Based Sample Prep Device is light weight and portable and operates on mains and/or re-chargeable battery. It is capable of performing upto 16 sample extractions with one recharge and is fully automatic, with minimal hands on time.

The cartridge based extraction process is quick, reliable, and efficient and does not require highly skilled personnel to carry out the extraction process. All the waste from processing of the sample is contained within the cartridge dump area thus posing no risk from potentially bio-hazardous material.

The device has a universal protocol and can work with all kinds of samples such as sputum, BAL, whole blood, serum, plasma, tissue, stool, urine, CSF, pleural fluid, lymph node aspirate, pus, peritoneal fluid, saliva, swab specimens and culture specimen.

1.2 Principle

The **Trueprep® AUTO v2** is an electromechanical system pre-programmed to sequentially heat, mix and add reagents to the contents of the cartridge placed in the cartridge holder and has a 2 - line LCD screen that displays the status.

Specimen pre-treated with lysis reagent is added to the sample chamber of the cartridge which is then placed in the cartridge holder of the device. Sample processing is initiated upon pressing the start button on the device, through an automatic pre-programmed process wherein nucleic acids released by chemical and thermal lysis of cells bind to the proprietary matrix in the matrix chamber. In subsequent steps, the captured nucleic acids are washed with buffers to remove the PCR inhibitors and finally eluted from the matrix using the elution buffer. At the end the cartridge is automatically ejected and the elute containing purified nucleic acids is then collected from the elute chamber for further analysis.

2 Installation

2.1 Installation Precautions

- Do not install the **Trueprep® AUTO v2** next to instruments that may cause vibrations or electromagnetic interference.
- Do not store the **Trueprep® AUTO v2** 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 **Trueprep® AUTO v2** in an atmosphere of potentially explosive liquids, vapors and gas.
- Always place the **Trueprep® AUTO v2** on a flat surface in an upright position.

2.2 Environmental Requirement

The **Trueprep® AUTO v2** has been designed to operate safely within the following environment Specifications:

- Estimated operating temperature (between 15°C to 45°C) at Relative Humidity (RH) between 10% to 90% (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.

3 Specifications

Trueprep® AUTO v2 Universal Cartridge Based Sample Prep Device	
Principle	Proprietary matrix-based extraction
Operation	Fully automatic
Display screen	2 line alphanumeric LCD
Power	Rechargeable Lithium Ion Battery Pack 7.4 V, 9600 mAh External AC/DC adaptor: Input 1.5A, 100/240V, 50/60 Hz; Output 10V, 4.5A
Weight	2.75 kgs
Size	215 x 235 x 115 mm
Software	Proprietary firmware
Operating environment	Temperature 15 - 45°C, RH: 10 -90%

"**Trueprep® AUTO v2** complies with the emission and immunity requirements described in IEC 61326 series".

4 Precautions

- Check for Low Battery before using the **Trueprep® AUTO v2** (see section 7.1)
- Insert and remove the cartridge gently from the holder, use of excessive force could damage it.
- Do not spill liquids inside the cartridge holder
- Do not perform an extraction in the presence of reactive vapours (e.g., from sodium hypochlorite, acids, alkalis or aldehydes) or dust.

5 Materials Required

5.1 Contents

- **Trueprep® AUTO v2** Universal Cartridge Based Sample Prep Device (REF603042001)
- AC Adapter (SMPS) with power cord to power (REF 603060001) - 1 No.
- **Trueprep®** replaceable tray for cartridge holder (REF603090001) - 25 Nos.
- **Trueprep®** cartridge stand (REF603100001) - 1 No.
- **Trueprep®** reagent pack holder (REF603160001) - 1 No.
- **Trueprep® AUTO v2** plug-in connector for 25T reagent bottle (REF604090001) - 1 No.
- **Trueprep® AUTO v2** Universal Cartridge Based Sample Prep Device User manual - 1 No.

5.2 Materials required but not provided with Device

Trueprep® AUTO v2 Universal Cartridge Based Sample Prep Device compatible with :

Trueprep® AUTO Universal Cartridge Based Sample Prep Kit (REF 60203AR05 / 60203AR25 / 60207AR50 / 60203AR100 / 60203AR200) / **Trueprep® AUTO v2** Universal Cartridge Based Sample Prep Kit (REF 60207AR05 / 60207AR25 / 60207AR50 / 60207AR100 / 60207AR200) consisting of:

- Universal Reagent Pack (5/25/50/100/200 tests)
- Universal Cartridge Pack (5/25/50/100/200 Nos.)
- Disposable transfer pipette graduated (5x3 ml/25x3 ml/50x3 ml/100x3 ml/200x3 ml)
- Package insert (1 No.)

6. The Trueprep® AUTO v2 Universal Cartridge Based Sample Prep Device

6.1A Top Panel View

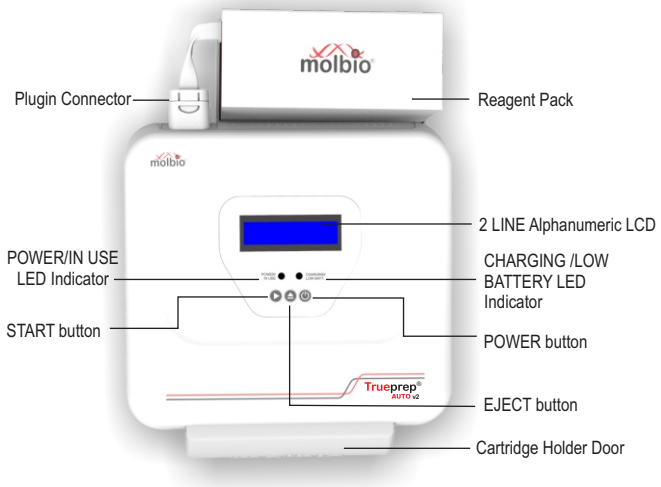

Figure 1 : The **Trueprep® AUTO v2** top view, with cartridge holder shown in the front panel

- The **Power** button switches on and switches off the **Trueprep® AUTO v2**
- The **Eject** button opens the cartridge holder

- The **Start** button is used to begin sample processing
- The Power/In Use LED Indicator will glow when the **Trueprep® AUTO v2** is switched on and when it is in use.

i) It will glow red and blink continuously when the **Trueprep® AUTO v2** is switched on and waiting for user input

ii) It will glow red continuously when it is in use

- The Charging/Low Battery LED Indicator will glow when the **Trueprep® AUTO v2** battery is low and when it is being charged using the power cable.

i) It will glow red when the battery is low and needs to be charged

ii) It will glow blue when the **Trueprep® AUTO v2** is being charged

6.1B Back Panel View

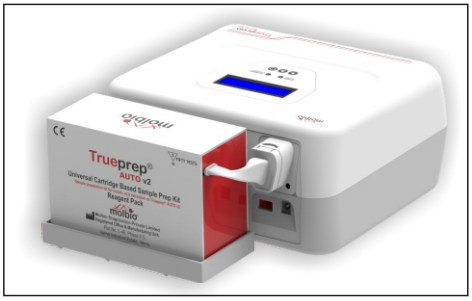

Figure 2: The **Trueprep® AUTO v2** device Back panel with reagent pack of the **Trueprep® AUTO v2** Universal Cartridge Based Sample Prep Kit

6.2 The Cartridge

Samples are processed on disposable, single-use cartridges that are inserted into the cartridge holder. These cartridges come pre-loaded with Internal Positive Control and only require the addition of pre-treated sample to the sample chamber for processing on the **Trueprep® AUTO v2** device.

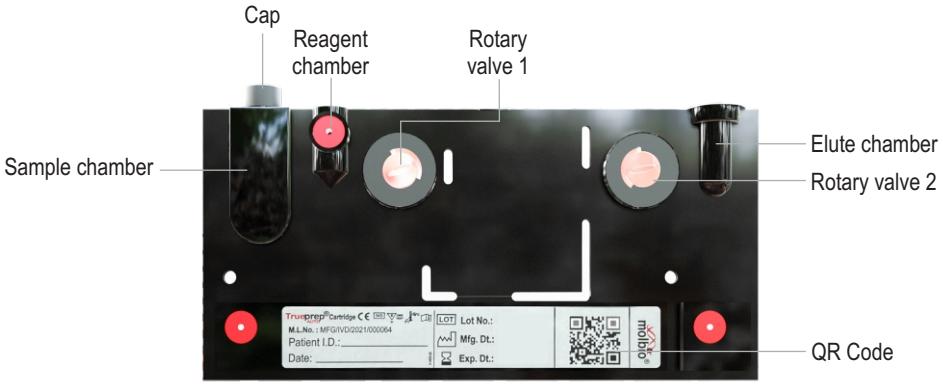

Figure 3: Disposable **Trueprep® AUTO** cartridge for sample processing

7 Using the Trueprep® AUTO v2 Universal Cartridge Based Sample Prep Device

7.1 Charging/Using the Trueprep® AUTO v2 with the AC Adapter

7.1.1 Press the **Power** button to switch on the **Trueprep® AUTO v2**

7.1.2 Low battery

- If the battery charge is low, you will see the above alert message
- The Charging/Low Battery LED Indicator will glow red and you will also hear a beeping sound. The **Trueprep® AUTO v2** device can not begin a new run if the battery is low.

Fig 4: Low battery LED glowing red

7.1.3 If the battery charge is full or sufficient to carry out a run, the Charging/Low Battery LED Indicator will stay off. You may proceed to use **Trueprep® AUTO v2** on battery charge.
For charging or to use **Trueprep® AUTO v2** on mains, connect the **AC Adapter** to the **Charging Port** on the right side of the back panel of the device.

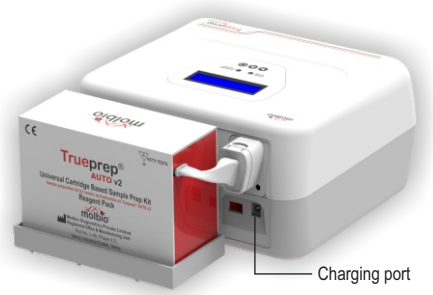

Figure 5: The charging port in right hand side of the back panel of the **Trueprep® AUTO v2**

7.1.4 Connect the other end of the AC Adapter to a mains socket.

7.1.5 Switch on the mains power.

7.1.6 You can now proceed to use the **Trueprep® AUTO v2** using the mains power. If the **Trueprep® AUTO v2** is being charged, the charging LED Indicator will glow blue. Charging takes ~3-4 hours (overnight). When charging is complete, the charging LED Indicator will go off. When this happens, please disconnect the AC Adapter unless it is being used to power the device.

Figure 6: The Blue Charging LED Indicator Glowing

7.2 Plugging in the reagent bottle pack of 25T or reagent pack of 50T

7.2.1 Plugging in the Reagent Bottle Pack of 25 T packsize:

1. Before starting a run for the first time, plug in the colour coded reagent bottles from the **Trueprep® AUTO** Sample Prep Kit Reagent Pack into the back panel of the device, matching the colour of the cap on the panel with the colour of the reagent bottle cap in the kit using provided Plug-in connector with coloured caps (Figure 7). Discard the reagent bottle cap once the bottle is plugged in.
2. Ensure that the tubing is fully immersed in the liquid upto the bottom of the reagent bottle.

3. A set of bottles is sufficient for 25 tests.
4. The device will prompt when 25 tests have been completed and the bottles have to be replaced by following manual buffer resetting procedure as per Point No. 7.2.5.1.

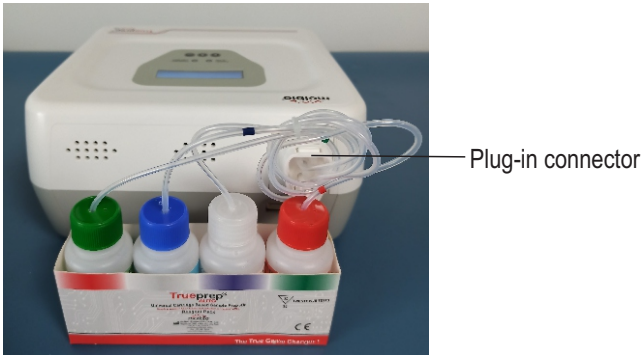

Figure 7: The **Trueprep® AUTO v2** Back Panel, with tubing and caps for plugging in reagent bottles from the Reagent Pack of 25T pack size of the **Trueprep® AUTO** Universal Cartridge Based Sample Prep Kit

7.2.2 Plugging in the reagent pack of 50T pack size:

1. Before starting a run for the first time, plug in the reagent pack from the **Trueprep® AUTO v2** Sample Prep Kit to the backside of the device (Figure 8). Discard the used reagent pack in a proper manner.
2. The device will prompt when 50 tests have been completed and the reagent pack have to be replaced by following buffer resetting procedure as per Point No. 7.2.5.1 or 7.2.5.2.

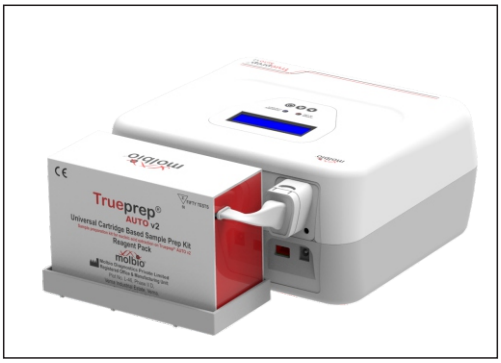

Figure 8: The **Trueprep® AUTO v2** device Back Panel with Reagent Pack (50T) of the **Trueprep® AUTO v2** Universal Cartridge Based Sample Prep Kit

7.2.5 Buffer Resetting Procedure

When buffer count is completed (buffer count=25/50), the device will prompt for changing Reagent pack and resetting buffer count.

7.2.5.1 When QR code scanning disabled:

Following will be displayed on screen alternatively, once buffer count reaches 25/50.

Press Start and Eject button together, buffer count will reset to zero and following will be displayed.

7.2.5.2 When QR code scanning enabled:

Following will be displayed on screen alternatively, once buffer count reaches 50.

Press Eject, insert Reagent Reset Card provided with the new Reagent pack, close the tray and press start. Once the buffer count has reset to zero, following will be displayed on screen.

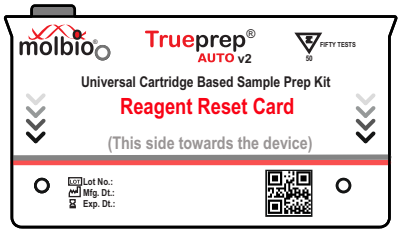

Figure 9: Reagent Reset Card for 50 Tests pack size

7.3 Switching ON/OFF the Trueprep® AUTO v2

7.3.1 Press the **Power** button to switch on the **Trueprep® AUTO v2**. You will be prompted with the message 'Buffer Count'.

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7.3.2 Later you will be prompted with the message for

7.3.3 Press the Power button, when following screen will be displayed, release the power button.

The device will turn off automatically within 30 seconds.

7.4 Placing the Cartridge in the device and starting the run

Important: Only use the cartridge provided in the corresponding sample prep kits.

7.4.1 Press the **Eject** button to open the cartridge holder. You will be prompted with the message

Figure 10: The cartridge holder opened after eject button is pressed

7.4.2 Take a cartridge out of the cartridge pouch from the **Trueprep® AUTO/AUTO v2** Universal Cartridge Based Sample Prep Kit cartridge pack. The pouch also contains one Elute Collection Tube (ECT) for use at the end of extraction. Place the cartridge, after adding pre-treated sample (sample + lysis reagent) into the sample chamber (see procedure in corresponding **Truenat®** pack insert), in the cartridge holder. Note the orientation of the cartridge is to be placed in picture below.

⚠ ***Caution: Placing the cartridge in the wrong orientation will cause the cartridge holder to remain open, and the cartridge will not be inserted in the device***

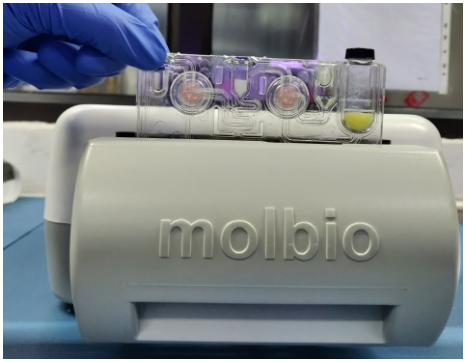


Figure 11: Cartridge being placed in cartridge holder

7.4.3 Push the cartridge holder gently inwards to close it shut. Press the Start Button to proceed. This is the start of the **Trueprep® AUTO v2** sample preparation process. After reading the QR code of Cartridge Extraction process starts. If the QR code is read then the same cartridge cannot be reused. The reagents from the bottle/pouch in the back will be automatically added to the cartridge based on the pre-programmed protocol.

Figure 12: Cartridge placed in cartridge holder in correct orientation

7.4.4 Once the process is completed the device will give a beep sound with display message as below

The device will automatically eject the cartridge holder. Take out the cartridge and place it on the cartridge stand. Pierce the seal of elute chamber and aspirate out the entire elute into Elute collection

tube (ECT) using Disposable transfer pipette provided in the cartridge pack.

Remove the cartridge soon after the completion of Extraction, else there is a chance of Elute getting evaporated and the Final volume becoming Lesser.

7.4.5 Discard the cartridge as per the instructions in Section 8.3.

7.4.6 Tray replacement

Cartridge holder contains one middle Replaceable tray as shown in Figure 13. Steps for replacement of Replaceable tray are as follows:

Step 1: Removal of the tray:

Remove the Replaceable tray from cartridge holder as shown in the Figure 14.

Step 2: Placement of the tray:

2a. Place the Replaceable tray in cartridge holder as shown in Figure 15.

i. Inspect the Replaceable tray in the cartridge holder.
ii. If there are liquids spilled in the tray, take out the tray and discard as per the instructions in Section 8.3.
iii. Clean the cartridge holder with 70% Isopropyl Alcohol (IPA) as described in Section 8.3.
iv. Replace the removed tray with a new tray and close the cartridge holder. (25 Replaceable trays are provided with the **Trueprep® AUTO v2** device. More trays, if required, can be ordered from Molbio).

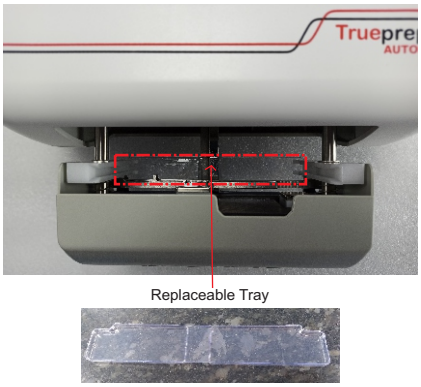


Figure 13: Replaceable tray in cartridge holder

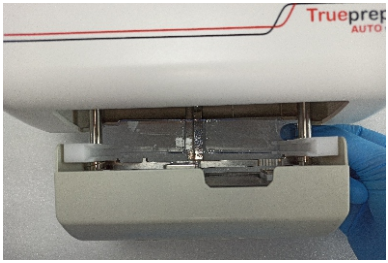


Figure 14: Removal of Replaceable Tray from cartridge holder

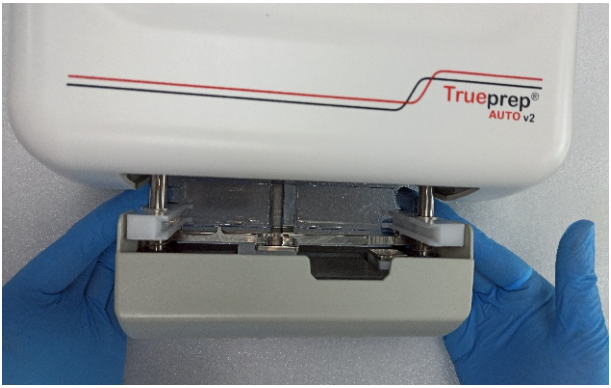
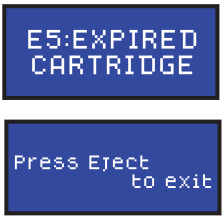
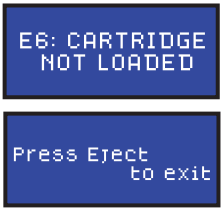
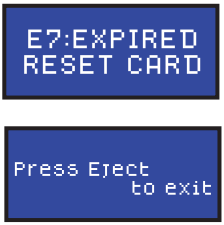


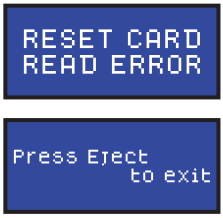
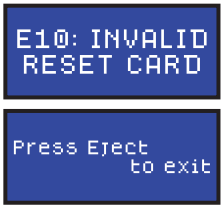
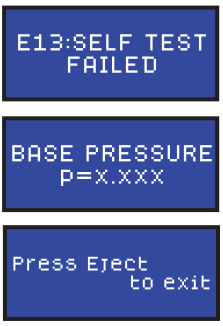
Figure 15: Replacement of discarded Replaceable tray with new

8 Errors, Alerts and Maintenance

8.1 Error Messages

Error Code	Display message	Error Type	Description
E1	E1:CARTRIDGE VALVE ERROR Press Eject to exit	Cartridge Errors	The Screen displays the error message "E1:CARTRIDGE VALVE ERROR" and instruction "Press Eject to exit" alternatively. **Solution:** Contact Molbio's support team
E2	E2:CARTRIDGE ERROR Press Eject to exit		The Screen displays the error message "E2:CARTRIDGE ERROR" and instruction "Press Eject to exit" alternatively. **Solution:** Contact Molbio's support team
E3	E3:CARTRIDGE CLOGGED Press Eject to exit		The Screen displays the error message "E3:CARTRIDGE CLOGGED " and instruction "Press Eject to exit" alternatively. **Solution:** Contact Molbio's support team

Error Code	Display message	Error Type	Description
E4		Cartridge Errors	The Screen displays the error message "E4:USED CARTRIDGE" and instruction "Press Eject to exit" alternatively. **Solution:** Use new cartridge
E5			The Screen displays the error message "E5: EXPIRED CARTRIDGE" and instruction "Press Eject to exit" alternatively. **Solution:** Check the Expiry Date of cartridge
E6			The Screen displays the error message "E6:CARTRIDGE NOT LOADED" and instruction "Press Eject to exit" alternatively. **Solution:** Contact Molbio's support team
E7		Reagent Pack Errors and Warnings	The Screen displays the error message "E7:EXPIRED RESET CARD" and instruction "Press Eject to exit" alternatively. **Solution:** Check the Expiry Date
E8			The Screen displays the error message "E8:USED RESET CARD" and instruction "Press Eject to exit" alternatively. **Solution:** Use new Reset card

Error Code	Display message	Error Type	Description
E9		Reagent Pack Errors and Warnings	The Screen displays the error message "E9: RESET CARD READ ERROR" and instruction "Press Eject to exit" alternatively. **Solution:** Contact Molbio's support team
E10			The Screen displays the error message "E10:INVALID RESET CARD" and instruction "Press Eject to exit" alternatively. **Solution:** Contact Molbio's support team
E11		Device Errors and warnings	The Screen displays the error message "E11:RTD-L ERROR" Note: This is for Lysis Heater **Solution:** Contact Molbio's support team
E12			The Screen displays the error message "E12:RTD- E ERROR" Note: This is for Elution Heater **Solution:** Contact Molbio's support team
E13			The Screen displays the error message "E13: SELF TEST FAILED" current base pressure value and instruction "Press Eject to exit" alternatively. **Solution:** Check for any rubber stuck to the Dump Nozzles (D1 & D2)
W1			The Screen displays the alert message "W1:SBC NOT RESPONDING" for 2 seconds. **Solution:** Contact Molbio's support team

Code	Display message	Error Type	Description
W2		Device Errors and warnings	The Screen displays the alert message “W2:UNABLE TO READ CARTRIDGE” for 2 seconds **Solution:** Contact Molbio’s support team
W3			The Screen displays the alert message “W3:BATTERY LOW! CONNECT CHARGER” until charger is connected.
E14	 	Cartridge Errors	The Screen displays the error message "E14: CARTRIDGE ERROR (ELUTION) " and instruction "Press Eject to Exit" alternatively. **Solution:** Contact Molbio's support team.
E15	 		The Screen displays the error message "E15: CARTRIDGE CLOGGED (ELUTION) " and instruction "Press Eject to Exit" alternatively. **Solution:** Contact Molbio's support team.

8.2 User Menu

8.2.1 Accessing Menu

- Press and hold ‘Start Button’ and ‘Power Button’ on the **Trueprep® AUTO v2**. Firmware Version and Total run status counts will be displayed on the screen as given below.

- Release both the buttons, when following is displayed.

- In the menu, the first line of LCD display shows different function options. The second line displays navigating options for next (>: Eject Button) and back (< : Start Button). The 'Power Button' allows selection of currently displayed item.

8.2.2 Exiting User Menu

- Navigate to and select following item to exit from the menu.

Note: *Shutdown is disabled in menu; in order to shutdown the device, user must exit from menu and press Power Button.*

8.2.3 Flushing Procedure

- Replace Reagent Pack for 25T or 50T with Distilled water, using provided Plug-in connector.
- Select "Flush" menu and once it is selected tray will be ejected. Following screens will toggle with 2 seconds interval.

- Insert cartridge and press start, the flushing process will begin.
- The cartridge will be ejected once flushing is completed, following will be displayed on screen and device will go back to menu.

- Press Power button to exit without flushing.

8.3 Maintenance

8.3.1 Disposal of consumables

Discard the used cartridges, Replaceable trays, reagent bottles and other consumables in 0.5% Sodium Hypochlorite. Let the items remain submerged in the solution for 30 minutes and then dispose as per the medical waste guidelines in your region.

8.3.2 Cleaning

The surface of the device should be cleaned using freshly prepared 0.5% Sodium Hypochlorite solution and a clean cloth or tissue. This should be done once everyday and/or when the device is moved to a different work space.

8.3.3 Spills

If you notice a spill in the Replaceable tray placed in the cartridge holder, dispose the tray. Clean the insides of the cartridge holder with clean cloth or tissue or swab dipped in 70% Isopropyl Alcohol (IPA). Wait for 5 minutes before inserting a new Replaceable tray into the holder.

8.3.4 Disposal of Instrumentation

Do not Dispose off Instrument as unsorted municipal waste. Contact Molbio for collection of instrument.

9. Safety

9.1 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.

9.2 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.

10. References

1. Nasir A., Rita C.P.R., Alexandre D.T.C., et al. (2017) Current Nucleic Acid Extraction Methods and Their Implications to Point-of-Care Diagnostics. BioMed Research International. 1-13.

2. Ruihua T., Min L., Xueyan Y., et al. (2022) Comparison of paper-based nucleic acid extraction materials for point-of-care testing applications. Cellulose. 29: 2479–2495.

3. Xing S., Anne M.C. (1999) Cellulose as a Matrix for Nucleic Acid Purification. Analytical Biochemistry 267: 415–418.

4. Vijayalakshmi J., Surekha A., Renuka D.A., et al. (2019) Truenat - A Novel Diagnostic Tool for Rapid Detection of Mycobacterium Tuberculosis and Rifampicin Resistance in Pulmonary Samples. Int.J.Curr.Microbiol.App.Sci 8(10): 1-9.

5. Gomathi N.S., Manjula S., Urvashi B.S., et al. (2020) Multicentric validation of indigenous molecular test Truenat™ MTB for detection of Mycobacterium tuberculosis in sputum samples from presumptive pulmonary tuberculosis patients in comparison with reference standards. Indian J Med Res. 152: 378-385.

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
	Device for near-patient testing
UDI	Unique Device Identifier
	This Way Up
	Medical Electronic Rush

Symbol keys

Symbols	Description of Symbol key
	Fragile, handle with care
	Keep Dry
	Fully automatic operation
	Portable
	Rapid sample prepping
	Mains / rechargeable battery powered
	Stacking limit by number
	Direct current
	Temperature range
	Humidity limitation

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