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Trueprep™ AUTO



Universal Cartridge based
Sample Prep Device



REF 603041001

User Manual

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1. Introduction

1.1 The Trueprep™ AUTO 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™** microPCR 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 microPCR chips and a portable, automated **Truelab™** Real Time microPCR 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 Universal Cartridge Based Sample Prep Device** together with **Trueprep™ AUTO Universal Based Sample Prep Kit** provides an easy method of nucleic acid extraction and purification.

Trueprep™ AUTO 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 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, Whole blood, Serum, Plasma, tissue, stool and other body fluid samples and swabs and culture specimen.

1.2 Principle

The **Trueprep™ AUTO** 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** next to instruments that may cause vibrations or electromagnetic interference.

Do not store the **Trueprep™ AUTO** 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** in an atmosphere of potentially explosive liquids, vapors and gas.

Always place the **Trueprep™ AUTO** on a flat surface in an upright position.

2.2 Environmental Requirement

The **Trueprep™ AUTO** has been designed to operate safely within the following environment specifications:

Room temperatures (between 15°C to 45°C)

Relative Humidity (RH) between 10% –90% (non-condensing)

The unit should be stored on a flat, dry surface.

3 Specifications

Trueprep™ AUTO Device	
Principle	Proprietary matrix-based extraction
Operation	Fully Automatic
Display Screen	2 line alphanumeric LCD
Power	Rechargeable Lithium Ion Battery Pack 7.4 V, 11.6 Ah External AC/DC adaptor: Input 1.5A, 100/240V, 50/60 Hz; Output 10V, 4.5A
Weight	2.9 kgs
Size	215 x 235 x 115 mm
Software	Proprietary firmware
Operating environment	Temperature 15 - 45°C, RH: 10 -90%

4 Precautions

Check for Low Battery before using the **Trueprep™ AUTO** (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 Universal Cartridge Based Sample Prep Device (REF603041001)
 AC Adapter (SMPS) with power cord to power (1No.)
 User Manual (1No.)
 Replaceable tray for cartridges holder (25 nos.)
 Cartridge Stand (1No.)
 Bottle holder tray (1No.)

5.2 Materials Required but not provided with Device

Trueprep™ AUTO Universal Cartridge Based Sample Prep Device compatible with :

Trueprep™ AUTO Universal Cartridge Based Sample Prep Kit (REF60203AR25) consisting of

Universal Reagent Pack (25 tests)
 Universal Cartridge Pack (25 nos.)
 Disposable transfer pipette graduated (25 x3ml)
 Package insert (1 No.)

6 The Trueprep™ AUTO

6.1A Top View



Figure 1 : The **Trueprep™ AUTO** Top View, with cartridge holder shown in the front panel.

The **Power** button switches on and switches off the **Trueprep™ AUTO**
 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** is switched on and when it is in use.

- i) It will glow red and blink continuously when the **Trueprep™ AUTO** 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** 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** is being charged

6.1B Back View



Figure 2: The **Trueprep™ AUTO** Back Panel, with tubing and caps for plugging in reagent bottles from the Reagent Pack of the **Trueprep™ AUTO** 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**.

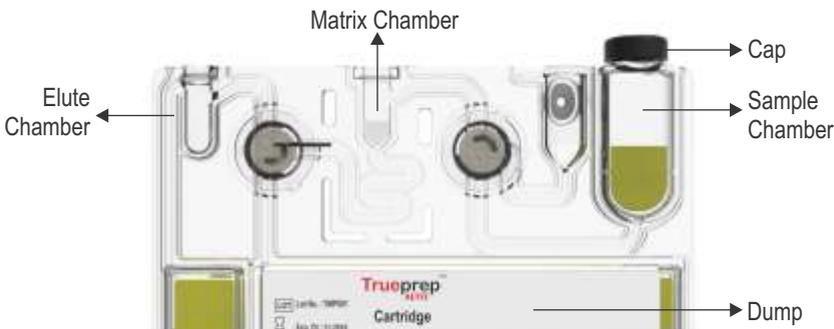


Figure 3: Disposable **Trueprep™ AUTO** cartridge for sample processing

Using the Trueprep™ AUTO

7.1 Charging/Using the Trueprep™ AUTO with the AC Adapter

7.1.1 Press the **Power** button to switch on the Trueprep™ AUTO

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 device will not let you begin a 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 on battery charge. For charging or to use Trueprep™ AUTO on mains, connect the **AC Adapter** to the **Charging Port** on the right side of the back panel of the device.

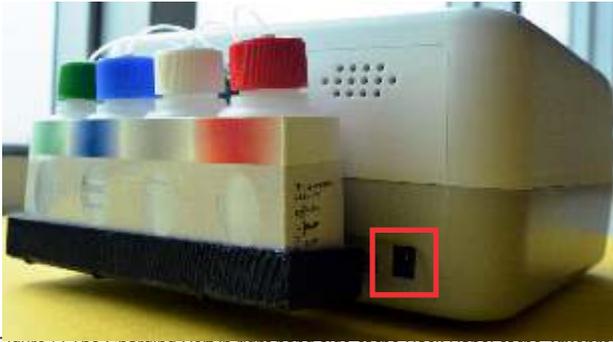


Figure 5: The Charging Port in right hand side of the Back Panel of the Trueprep™ AUTO

- 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 using the mains power. If the Trueprep™ AUTO is being charged, the charging LED Indicator will glow blue. Charging takes ~9-10 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 Charging LED Indicator is Glowing

7.2 Plugging in the reagent bottles

- 7.2.1 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. Discard the reagent bottle cap once the bottle is plugged in
- 7.2.2 Ensure that the tubing is fully immersed in the liquid upto the bottom of the reagent bottle.
- 7.2.3 A set of bottles is sufficient for 25 tests.
- 7.2.4 The device will prompt when 25 tests have been completed and the bottles have to be replaced.



Figure 7: Reagent bottles with tubing fully immersed in liquid

7.3 Switching On the Trueprep™ AUTO

7.3.1 Press the **Power** button to switch on the **Trueprep™ AUTO**. You will be prompted with the message.

TRUEPREP AUTO

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

INSERT CARTRIDGE



Figure 8: The cartridge holder opened after eject button is pressed

7.4.2 Take a cartridge out of the Cartridge Pouch from the Trueprep™ AUTO 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



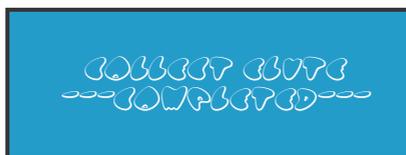
Figure 9: Cartridge being placed in cartridge holder

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** sample preparation process. The reagents from the bottles in the back will be Automatically added to the cartridge based on the pre-programmed protocol.



Figure 10: 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. Collect 50µL of the elute from the elute

chamber of the cartridge into the Elute Collection Tube (ECT) provided in the cartridge pouch using the Truepet™ Precision 50µL Micropipette.

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

7.4.6 Tray replacement

- 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 Extra trays are provided with the Trueprep AUTO device. More trays, if required, can be ordered from Molbio).

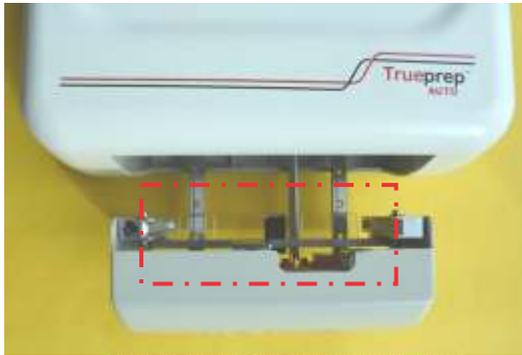


Figure 11: Replacable tray in cartridge holder



Figure 12: Tray removal from cartridge holder



Figure 13: Replacement of discarded tray with new tray

8 Errors, Alerts and Maintenance

8.1 Error Messages

Error Message	Description	Reason for Error and Solution
	<p>The Screen displays the error message "Cartridge Not Loaded"</p>	<p>Reason: No cartridge is inserted or cartridge orientation is wrong.</p> <p>Solution: Please ensure cartridge is loaded and is in the correct orientation.</p>
	<p>The Screen displays the error message "VALVE ERROR"</p>	<p>Reason: Cartridge valve are damaged.</p> <p>Solution: Please start afresh with a new cartridge</p>
	<p>The Screen displays the error message "CARTRIDGE CLOGGED PRESS EJECT"</p>	<p>Reason: The cartridge is clogged because the specimen used is too thick.</p> <p>Solution: Please start afresh with a new cartridge</p>

	<p>The Screen displays the error message “CARTRIDGE ERROR PRESS EJECT”</p>	<p>Reason: There is a leak in the cartridge.</p> <p>Solution: Check for spillage in the tray below the cartridge in the cartridge holder. If necessary, replace the tray (refer 7.4.6). Please start afresh with a new cartridge</p>
	<p>The Screen displays the error message “RTD ERROR”</p>	<p>Reason: The heater is not working.</p> <p>Solution: Contact Molbio Support.</p>
	<p>The Screen displays the error message “Self Test Failed, Press Eject”</p>	<p>Reason: This error message appears when the device is powered on because the pressure from previous run is not released.</p> <p>Solution: Press Eject. When the cartridge holder opens, close it gently.</p>

8.2 Alert Messages

	<p>The screen displays the alert message “Battery Low !, Connect Charger”</p>	<p>Reason: This alert appears when the battery is low and the charger needs to be plugged in. The device cannot start a run when the battery is low</p>
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		<p>Solution: Connect the charger and wait for the device to finish charging or operate it on mains</p>
	<p>The Screen toggles between 2 displays “Change reagent pack and Reset” and “By Pressing Start & Eject SW”</p>	<p>Reason: The reagent bottles have been used up.</p> <p>Solution: Remove the used up reagent bottles and discard as per the pack insert. Plug in a new Trueprep™ AUTO Reagent Pack as shown in Section 7.2. Re-set the counter by pressing Start and Eject buttons together.</p>

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 every 4 weeks 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% Iso Propyl Alcohol (IPA). Wait for 5 minutes before inserting a new tray into the holder.

8.3.4 Disposal of Instrumentation

Do not Dispose off Instrumentation as unsorted municipal waste. Contact **Molbio** for collection of instrumentation.

Symbol keys

Symbols	Description of Symbol key
	In Vitro Diagnostic medical device
	Keep away from sunlight
	Catalogue number
	Authorised Representative in the European Community
	Serial number
	Temperature limitation
	Consult Instructions for use
	Manufacturer
	The WEEE (Waste Electrical and Electronic Equipment) symbol

Symbol keys

Symbols	Description of Symbol key
	This Side Up
	Medical Electronic Rush
	Do Not Stack
	Fragile
	Keep Dry
	Fully automatic operation
	Portable
	Rapid sample prepping
	Mains / rechargeable battery powered
	Trueprep™ AUTO Universal Cartridge Based Sample Prep Kit



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