



# Trueprep<sup>®</sup> AUTO

## Universal Cartridge Based Sample Prep Kit

Sample preparation kit for nucleic acid extraction on Trueprep<sup>®</sup> AUTO

### 1. INTENDED USE

Trueprep<sup>®</sup> AUTO Universal Cartridge Based Sample Prep Kit (REF 60203AR05 / 60203AR25 / 60203AR50 / 60203AR100) works with Trueprep<sup>®</sup> AUTO Universal Cartridge Based Sample Prep Device and is used for extraction and purification of nucleic acids from a wide range of biological specimens.

### 2. INTRODUCTION

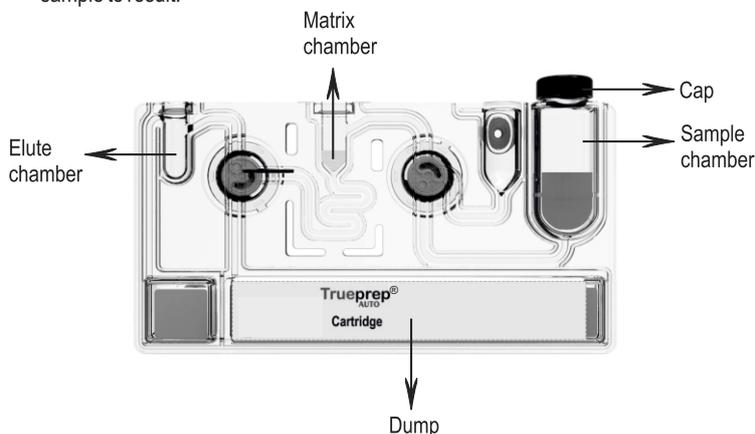
Testing for infectious diseases by detecting the pathogens nucleic acids using nucleic acid amplification methods is a highly specific and sensitive diagnostic tool. Molbio's Truelab<sup>®</sup> Real Time Micro PCR System is a nucleic acid amplification platform that works on real time Polymerase Chain Reaction (PCR) technology that enables near patient diagnosis through disposable, disease specific micro PCR chips and a portable, automated Truelab<sup>®</sup> Real Time 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<sup>®</sup> AUTO Universal Cartridge Based Sample Preparation Device together with Trueprep<sup>®</sup> AUTO Universal Cartridge Based Sample Prep Kit provides an easy and automated method of nucleic acid extraction and purification.

Trueprep<sup>®</sup> AUTO Universal Cartridge Based Sample Prep Device is light weight, portable and operates on mains and/or re-chargeable battery. It is capable of 16 sample extractions with one recharge and has a simple, user friendly automatic operation. Trueprep<sup>®</sup> AUTO Universal Cartridge Based Sample Prep Kit contains cartridges and reagents for purification of nucleic acids from biological specimen. The entire process of extraction and purification of nucleic acids is completely automatic and takes about 20 minutes.

### 3. PRINCIPLE OF THE TEST

Trueprep<sup>®</sup> AUTO Universal Cartridge Based Sample Prep Kit protocol uses a proprietary matrix enclosed in a cartridge to purify nucleic acids from clinical samples. The cartridge also contains pre-loaded Internal Positive Control (IPC). The IPC is a full process control that undergoes all the processes the specimen undergoes, from extraction to amplification, thereby validating the analysis from sample to result.



The pre-treated sample (refer corresponding Truenat<sup>®</sup> pack insert) is added to the sample chamber of the cartridge. The cartridge is then placed in the Trueprep<sup>®</sup> AUTO Universal Cartridge Based Sample Prep Device for processing. DNA/RNA from the sample are bound by the matrix and inhibitors present in sample are washed out. At the end of processing the bound DNA/RNA is eluted and collected in elution chamber. All the waste generated in the process is contained within the dump region of cartridge. The elute is transferred to the Elute collection tube (ECT). Six microliters of the elute is then transferred to Truenat<sup>®</sup> chips for further analysis on the Truelab<sup>®</sup> Real Time PCR analyzer.

### 4. PACK SIZE

REF	60203AR05	60203AR25	60203AR50	60203AR100
	5T	25T	50T	100T

### 5. MATERIALS PROVIDED

A. The Reagent Pack contains the following:

1. Reagents:

No.	Contents	Purpose
1.	Wash Buffer A	To wash inhibitors from the sample-GREEN CAP
2.	Wash Buffer B	To wash inhibitors from the sample-BLUE CAP
3.	Elution Buffer	To elute nucleic acids-WHITE CAP
4.	Priming Waste	To purge residual liquid from tubing-RED CAP

2. Reagent Reset Card-1 No. (Applicable for Trueprep<sup>®</sup> AUTO v2 Users only)

B. The Cartridge Pack contains the following:

No.	Contents	Purpose
1.	Cartridge	Cartridges containing immobilized internal control (IPC) for extraction
2.	Elute collection tube (ECT)	Capped tubes for collection and storage of extracted nucleic acids
3.	Elute collection tube (ECT) Label	To label Elute collection tube (ECT)
4.	Disposable Transfer Pipette	To pierce the seal of elute chamber and to transfer extracted nucleic acids from elute chamber of cartridge into the Elute collection tube (ECT)

C. Disposable Transfer Pipettes (graduated) - 3 ml

D. Package Insert

### 6. STORAGE AND STABILITY

Trueprep<sup>®</sup> AUTO Universal Cartridge Based Sample Prep Kits are stable for two (2) years from the date of manufacture if stored between 2°C to 40°C. They are also stable for one (1) month at temperatures up to 45°C. Avoid exposure to light.

### 7. MATERIALS REQUIRED BUT NOT PROVIDED WITH THE KIT

Truelab<sup>®</sup> Real Time micro PCR Workstation (REF623010001 / 633010001 / 643010001 / 653010001) consisting of,

1. Trueprep<sup>®</sup> AUTO Universal Cartridge Based Sample Preparation Device (REF 603041001).
2. Truelab<sup>®</sup> Uno Dx / Truelab<sup>®</sup> Duo / Truelab<sup>®</sup> Quattro Real Time micro PCR Analyzer (REF 603021001 / 603022001 / 603023001).
3. Truelab<sup>®</sup> micro PCR Printer (REF 603050001).
4. Trueprep<sup>®</sup> Cartridge Stand (REF603100001)
5. Trueprep<sup>®</sup> Bottle holder tray (REF603110001)
6. Trueprep<sup>®</sup> Replaceable tray for cartridge holder (REF603090001)
7. Powder free disposable gloves, waste disposal container with lid.

### 8. TYPE OF SPECIMENS, HANDLING AND STORAGE

#### Specimen Collection & Storage:

1. The intended clinical specimen depends on the test to be conducted and is specified in the package insert of the test (Refer disease specific Truenat<sup>®</sup> pack insert).
2. Specimen should be collected as per standard practice and must either be processed immediately or stored frozen at -20°C. Frozen samples must be brought to room temperature before starting sample processing.
3. Samples need to be first pre-treated (Refer Trueprep<sup>®</sup> AUTO MTB Sample Pre-treatment Pack and Trueprep<sup>®</sup> AUTO Universal Sample Pre-treatment Pack packinsert) before starting extraction procedure as explained in section 13 below. Sample pre-treatment decontaminates the specimen and makes it ready for extraction.

### 9. SAFETY PRECAUTIONS

1. For *in vitro* diagnostic use only.
2. Bring all reagents and specimen to room temperature (15 - 30°C) before use.
3. Do not use kit beyond expiry date.
4. Carefully read the User Manuals, package inserts and Material Safety Data Sheets (MSDS) of all the components of the Truelab<sup>®</sup> Real Time micro PCR System before use.
5. All materials of human origin should be handled as though potentially infectious.
6. Do not pipette any material by mouth.
7. Do not eat, drink, smoke, apply cosmetics or handle contact lenses in the area where testing is done.
8. Use protective clothing and wear disposable gloves when handling samples and while performing extraction.

### 10. PROCEDURAL PRECAUTIONS

1. Do not exchange kit components from different lots.
2. Check all packaging before using the kit. Damage to the packaging does not prevent the contents of the kit from being used. However, if the outer packaging is damaged the user must check that components of the kit are intact before

using them.

- Do not perform the assay in the presence of reactive vapors (e.g. from sodium hypochlorite, acids, alkalis, or aldehydes) or dust.
- All pipetting steps should be performed with utmost care and accuracy. Cross-contamination between reagents and samples may invalidate results.
- Separate filter barrier tips should be used to pipette separate reagents.
- It is mandatory to only use the ECT provided in the Cartridge Pouch of the kit.

## 11. CLEANING AND DECONTAMINATION

- Spills of potentially infectious material should be cleaned up immediately with absorbent paper tissue and the contaminated area should be decontaminated with disinfectants such as 0.5% freshly prepared sodium hypochlorite [10 times dilution of 5% sodium hypochlorite (household bleach)] before continuing work.
- Sodium hypochlorite should not be used on an acid-containing spill unless the spill-area is wiped dry first. Materials used to clean spills, including gloves, should be disposed off as potentially bio-hazardous waste e.g. in a bio-hazard waste container.

## 12. DISPOSAL AND DESTRUCTION

- Submerge the used cartridge and disposable transfer pipette in freshly prepared 0.5% sodium hypochlorite solution for 30 minutes before disposal as per the standard medical waste disposal guidelines.
- Disinfect the solutions and/or solid waste containing biological samples before discarding them according to local regulations.
- Samples and reagents of human and animal origin, as well as contaminated materials, disposables, neutralized acids and other waste materials must be discarded according to local regulations after decontamination by immersion in a freshly prepared 0.5% of sodium hypochlorite for 30 minutes (1 volume of 5% sodium hypochlorite for 10 volumes of water).
- Do not autoclave materials or solutions containing sodium hypochlorite.
- Chemicals should be handled in accordance with Good Laboratory Practice and disposed off according to the local regulations.

## 13. EXTRACTION PROCEDURE

- Put on a fresh pair of latex gloves.
- Before using the **Trueprep® AUTO** Universal Cartridge Based Sample Prep Device for the first time, plug-in the bottles from the reagent pack into the back of the device. Ensure that the cap colour of the bottles matches the caps attached to the tubing.
- Take a new cartridge from the **Trueprep® AUTO** Universal Cartridge Based Sample Prep Kit, label the patient ID, date, in the space provided on the Cartridge label and place the cartridge in the cartridge stand provided with the **Trueprep® AUTO** Universal Cartridge Based Sample Prep Device.
- Perform sample pre-treatment as per sample type (refer disease specific **Truenat®** pack insert) and transfer the entire content of the bottle with pre-treated sample using disposable transfer pipette (graduated-3ml) into the sample chamber of the cartridge.
- Switch ON the **Trueprep® AUTO** Universal Cartridge Based Sample Prep Device and press EJECT button.
- Place the cartridge into the device, gently close the door and press START.
- The device performs all the steps automatically.
- Meanwhile, mention the patient ID, date, in the space provided on the Elute collection tube (ECT) label provided in the Cartridge pouch and affix the label to the Elute collection tube, present in the Cartridge pouch.
- The process is concluded by a beep sound from the device and automatic ejection of cartridge. 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.
- ⚠ Dispose off the cartridge as mentioned under "Disposal & Destruction".
- Inspect the replaceable tray in the cartridge holder. If there are liquids spilled in the tray, take out the tray and discard as per the instructions in Section 8.3 of user manual of **Trueprep® AUTO** Universal Cartridge Based Sample Prep Device.
- Switch off **Trueprep® AUTO** Universal Cartridge Based Sample Prep Device.
- Clean any liquid spills, if any, according to section "Cleaning and decontamination".
- Proceed to analysis (refer **Truelab® Uno Dx/Duo/Quattro** manual).

## 14. STORAGE OF THE EXTRACTED NUCLEIC ACID

The extracted nucleic acids collected in the Elute Collection Tube (ECT) can be stored at 4°C for upto 24 hours or at -20°C for upto one (1) year.

## 15. PROCEDURE TO CONNECT A NEW REAGENT PACK (APPLICABLE FOR TRUEPREP® AUTO v2 USERS ONLY)

**To connect a new reagent pack for 5T / 25T / 50T / 100T:**

After completion of 05 / 25 / 50 / 100 extractions, the **Trueprep® AUTO v2** device will prompt to "change the reagent pack" and "Insert Reagent Reset Card & Start" on the

screen alternatively. Follow the below mentioned procedure.

- Turn off the **Trueprep® AUTO v2** and disconnect the power adapter.
- Disconnect the adaptor caps and tubings from the old reagent bottles and discard the bottles safely.
- Take a new Reagent pack, Open it and take out the reagent reset card given for 5T / 25T / 50T / 100T.
- Connect the new reagent bottles to the adaptor caps one-by-one as per colour coding.
- Turn on the device.
- Use "Eject" button to open the tray and insert the new Reset Card, as indicated on it.
- Close the tray and press "Start"
- It will display "New Reagent Pack registered" and ejects the Reagent Reset Card.
- The buffer count will be reset and **Trueprep® AUTO v2** is now ready for extraction with the new Reagent Pack.

## 16. SPECIAL PRECAUTIONS

- Do not re-use the Cartridge.
- Ensure that the cartridge is never removed from the **Trueprep® AUTO** Universal Cartridge Based Sample Prep Device during extraction procedure.
- Take out the cartridge immediately after the completion of extraction from the device as there are chances of evaporation due the heat generated by the heater plate of the device and place it on the cartridge stand provided along with the device.
- Do not move the **Trueprep® AUTO** Universal Cartridge Based Sample Prep Device during run.
- Check if the low-battery indicator is glowing before starting a test. If yes please plug-in the charger before starting extraction.

## 17. TROUBLE SHOOTING

Refer user manual of **Trueprep® AUTO** Universal Cartridge Based Sample Prep Device.

## 18. REFERENCES

- Ana R.H., Laura N., Steffen Z., et al. (2021) A microfluidic cartridge for fast and accurate diagnosis of Mycobacterium tuberculosis infections on standard laboratory equipment. *Lab Chip*. 21;1540–48.
- JinSeok K., Chinsung P., Jangwon L., et al. (2017) Automated Nucleic Acids Purification from Fecal Samples on a Microfluidic Cartridge. *BioChip J.* 1-9.
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- Siun C & Beow C.Y. (2009) DNA, RNA, and Protein Extraction: The Past and The Present. *J. biotechnol. Biomed.* 1-10.
- Robert L., Janet T., Elizabeth S., et al. (2022) Practical Guide to Specimen Handling in Surgical Pathology. College of American pathologists. 10; 1-71.
- Peipei L., Menghang L., Dongmei Y., et al. (2021) Solid-Phase Extraction Methods for Nucleic Acid Separation. A Review. *J. Sep. Sci.* 1-35.

## SYMBOL KEYS

 Consult instructions for use	 IVD In vitro Diagnostic Medical Device. Not for medicinal use.	 Temperature Limitation	 REF Catalogue Number	 For single use only	 This Way Up	 Manufacturer
 Date of Manufacture	 Date of Expiry	 LOT Batch Number / Lot Number	 Caution	 Contains sufficient for <n> tests	 EC REP Authorised Representative in the European Community	



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