



## Universal Cartridge Based Sample Prep Kit

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

### 1. INTENDED USE

**REF** Trueprep<sup>®</sup> AUTO Universal Cartridge Based Sample Prep Kit (REF 60203AR05 / 60203AR25 / 60203AR50 / 60203AR100 / 60203AR200) 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.

**Trueprep<sup>®</sup> AUTO Universal Cartridge Based Sample Prep Kit** contains single use extraction cartridges and reagents 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.

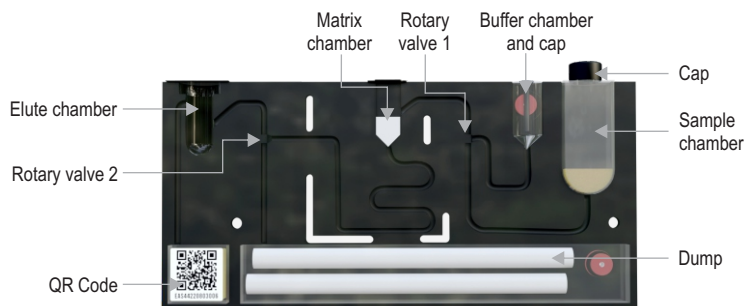
### 2. INTRODUCTION

Testing for infectious diseases by detecting the pathogens nucleic acids using nucleic acid amplification methods is a highly specific and sensitive diagnostic tool. **Truenat<sup>®</sup>** point-of-care real time 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 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<sup>®</sup> AUTO Universal Cartridge Based Sample Prep 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 nuclease-free 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 cartridge from the **Trueprep<sup>®</sup> AUTO Universal Cartridge Based Sample Prep Kit** contains pre-loaded Internal Positive Control (IPC), composed of known concentration of Positive Control DNA, trehalose, PBS buffer and amaranth dye, which is co-extracted along with sample nucleic acids, thereby validating the process from extraction to PCR run.



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 Mastermix tube for further analysis on the **Truenat<sup>®</sup>** chips and **Truelab<sup>®</sup>** Real Time micro PCR Analyzer.

### 4. PACK SIZE

REF	60203AR05	60203AR25	60203AR50	60203AR100	60203AR200
5T	25T	50T	100T	200T	

### 5. MATERIALS PROVIDED

- The Reagent Pack contains the following:
  - 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

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

- 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)

- Disposable Transfer Pipettes (graduated) - 3 ml
- Package Insert

### 6. STORAGE, HANDLING AND STABILITY

- Trueprep<sup>®</sup> AUTO Universal Cartridge Based Sample Prep Kit** is 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 sunlight.
- Do not open the cartridge pouch and reagent pack until ready to test.
- Do not use the cartridge pouch if torn.
- Do not use cartridge pouches and reagent packs that have passed the expiration date.

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

- REF** **Truelab<sup>®</sup> Real Time micro PCR Workstation** (REF 623010001 / 633010001 / 643010001 / 653010001) consisting of,
- Trueprep<sup>®</sup> AUTO/AUTO v2 Universal Cartridge Based Sample Prep Device** (REF 603041001 / 603042001)
  - Truelab<sup>®</sup> Uno Dx / Truelab<sup>®</sup> Duo / Truelab<sup>®</sup> Quattro Real Time micro PCR Analyzer** (REF 603021001 / 603022001 / 603023001).
  - Truelab<sup>®</sup> micro PCR Printer** (REF 603050001).
  - Trueprep<sup>®</sup> cartridge stand** (REF 603100001)
  - Trueprep<sup>®</sup> bottle holder tray** (REF 603110001)
  - Trueprep<sup>®</sup> replaceable tray for cartridge holder** (REF 603090001)
  - Also required additionally are: **Trueprep<sup>®</sup> AUTO Universal Sample Pre-treatment Pack** (REF 60205AB05 / 60205AB20 / 60205AB25 / 60205AB50 / 60205AB100 / 60205AB200), **Trueprep<sup>®</sup> AUTO MTB Sample Pre-treatment Pack** (REF 60204AS05 / 60204AS20 / 60204AS25 / 60204AS50 / 60204AS100 / 60204AS200) for MTB samples, **Trueprep<sup>®</sup> AUTO Transport Medium for Swab Specimen Pack** (REF 60206TS05 / 60206TS20 / 60206TS25 / 60206TS50 / 60206TS100 / 60206TS200) for swab specimens, disease specific **Truenat<sup>®</sup> Chip-based Real Time PCR Test**, powder free disposable gloves, waste disposal container with lid and sodium hypochlorite.

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

#### Specimen Collection & Storage:

- 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).
- 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.
- 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

- For *in vitro* diagnostic use only.
- Bring all reagents and specimen to room temperature (15 - 30°C) before use.
- Do not use kit beyond expiry date.
- Carefully read the user manuals, package inserts and Material Safety Data Sheets (MSDS) of all the components of the **Truelab<sup>®</sup>** system before use.
- Good laboratory practices are recommended to avoid contamination of specimens or reagents
- All materials of human origin should be handled as though potentially infectious.
- Do not pipette any material by mouth.

8. Do not eat, drink, smoke, apply cosmetics or handle contact lenses in the area where testing is done.
9. Use protective clothing and wear disposable gloves when handling samples and while performing extraction.
10. Do not substitute assay components / reagents with any other components / reagents.
- ⊗ 11. Each single-use cartridge is used to process one test. Do not reuse cartridge.

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

## 11. CLEANING AND DECONTAMINATION

1. 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.
2. 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

1. 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.
2. Disinfect the solutions and/or solid waste containing biological samples before discarding them according to local regulations.
3. 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).
4. Do not autoclave materials or solutions containing sodium hypochlorite.
5. Chemicals should be handled in accordance with good laboratory practice and disposed off according to the local regulations.

## 13. EXTRACTION PROCEDURE

1. Put on a fresh pair of latex gloves.
2. Before using the **Trueprep<sup>®</sup> 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.
3. Take a new cartridge from the **Trueprep<sup>®</sup> 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<sup>®</sup> AUTO** Universal Cartridge Based Sample Prep Device.
- ⓘ 4. Perform sample pre-treatment as per sample type (refer disease specific **Truenat<sup>®</sup>** 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.
5. Switch ON the **Trueprep<sup>®</sup> AUTO** Universal Cartridge Based Sample Prep Device and press EJECT button.
6. Place the cartridge into the device, gently close the door and press START.
7. The device performs all the steps automatically.
8. 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.
9. 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.
10. 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.
11. ⚠ Dispose off the cartridge as mentioned under "Disposal & Destruction".
12. 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 8.4 of user manual of **Trueprep<sup>®</sup> AUTO** Universal Cartridge Based Sample Prep Device.
13. Switch off **Trueprep<sup>®</sup> AUTO** Universal Cartridge Based Sample Prep Device.
14. Clean any liquid spills, if any, according to section "Cleaning and Decontamination".
- ⓘ 15. Proceed to analysis (refer **Truelab<sup>®</sup> Uno Dx/Duo/Quattro** manual).

## 14. PROCEDURE TO CONNECT A NEW REAGENT PACK (APPLICABLE FOR TRUEPREP<sup>®</sup> AUTO v2 USERS ONLY)

### To connect a new reagent pack for 5T / 25T / 50T / 100T / 200T:

After completion of 05 / 25 / 50 / 100 / 200 extractions, the **Trueprep<sup>®</sup> 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.

1. Turn off the **Trueprep<sup>®</sup> AUTO v2** and disconnect the power adapter.
2. Disconnect the adaptor caps and tubings from the old reagent bottles and discard the bottles safely.
3. Take a new reagent pack, open it and take out the reagent reset card given for 5T / 25T / 50T / 100T / 200T.
4. Connect the new reagent bottles to the adaptor caps one-by-one as per colour coding.
5. Turn on the device.
6. Use "Eject" button to open the tray and insert the new reset card, as indicated on it.
7. Close the tray and press "Start"
8. It will display "New Reagent Pack registered" and ejects the reagent reset card.
9. The buffer count will be reset and **Trueprep<sup>®</sup> AUTO v2** is now ready for extraction with the new reagent pack.

## 15. SPECIAL PRECAUTIONS

- ⊗ 1. Do not re-use the cartridge.
2. Ensure that the cartridge is never removed from the **Trueprep<sup>®</sup> AUTO** Universal Cartridge Based Sample Prep Device during extraction procedure.
3. 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.
4. Do not move the **Trueprep<sup>®</sup> AUTO** Universal Cartridge Based Sample Prep Device during run.
5. Check if the low-battery indicator is glowing before starting a test. If yes please plug-in the charger before starting extraction.

## 16. TROUBLE SHOOTING

- ⓘ Refer user manual of **Trueprep<sup>®</sup> AUTO** Universal Cartridge Based Sample Prep Device.

## 17. REFERENCES



















1. 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.
2. JinSeok K., Chinsung P., Jangwon L., et al. (2017) Automated Nucleic Acids Purification from Fecal Samples on a Microfluidic Cartridge. *BioChip J.* 1-9.
3. Cleaning/Disinfection SOP for Research Laboratories for Mitigating DNA Contamination. Boston University, Environmental Health and Safety, 2021.
4. Siun C & Beow C.Y. (2009) DNA, RNA, and Protein Extraction: The Past and The Present. *J. biotechnol. Biomed.* 1-10.
5. Robert L., Janet T., Elizabeth S., et al. (2022) Practical Guide to Specimen Handling in Surgical Pathology. College of American pathologists. 10; 1-71.
6. Peipei L., Menghang L., Dongmei Y., et al. (2021) Solid-Phase Extraction Methods for Nucleic Acid Separation. A Review. *J. Sep. Sci.* 1-35.

**Note:** Any serious incident that has occurred in relation to the kit 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.

## 18. REVISION HISTORY

Section	Description of the changes
Throughout	Symbols are added as per regulatory requirements
1	Intended use is updated.
2	Introduction is updated to add "Trueprep <sup>®</sup> AUTO Universal Cartridge Based Sample Prep Kit contains 'nuclease free' cartridges"
3	Principle of kit is updated to add 1) Add content of the kit 2) Cartridges images is updated 3) Updated to "Six microliters of the elute is the transferred to Mastermix tube for further analysis on the Truenat <sup>®</sup> chips and Truelab <sup>®</sup> Real Time PCR analyser."
5	Materials provided is updated.
6	Storage and stability is updated to storage handling and stability.
7	MATERIALS REQUIRED BUT NOT PROVIDED WITH THE KIT is updated.
9	Safety Precautions are updated.
18	Added Revision History table
Symbol keys	Symbols keys are updated

**SYMBOL KEYS**

 Consult instruction for use	 In vitro Diagnostic Medical Device	 Batch number/ Lot number	 Catalogue number	 Unique Device Identifier	 This way up	 Manufacturer	 Caution	 Non sterile
 Contains sufficient for <math>\leftrightarrow</math> tests	 Temperature limitations	 Date of manufacture	 Date of expiry	 For single use only	 Keep dry	 Keep away from sunlight	 Authorised Representative in European Community	 Device for near-patient testing



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