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Trueprep® AUTO v2

Universal Cartridge Based Sample Prep Kit

Sample preparation kit for nucleic acid extraction on Trueprep® AUTO v2

1. INTENDED USE

Trueprep® AUTO v2 Universal Cartridge Based Sample Prep Kit (REF 60207AR05 / 60207AR25 / 60207AR50 / 60207AR100) 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.

2. INTRODUCTION

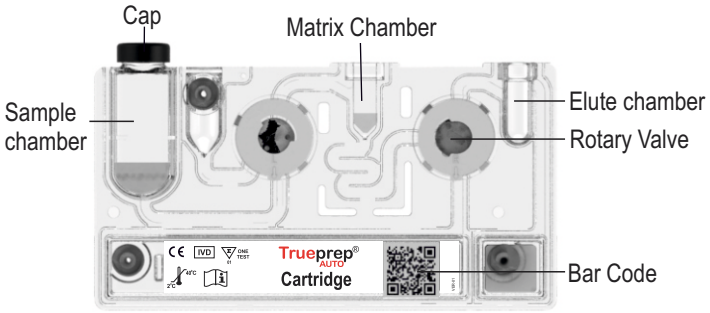
Testing for infectious diseases by detecting the pathogens nucleic acids using nucleic acid amplification methods is a highly specific and sensitive diagnostic tool. **Molbio's Truelab®** Real Time Micro PCR System is a nucleic acid amplification platform that works on real time Polymerase Chain Reaction (PCR) technology that enables near patient diagnosis through disposable, disease specific micro PCR chips and a portable, automated **Truelab®** 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® AUTO v2** Universal Cartridge Based Sample Preparation Device together with **Trueprep® AUTO v2** Universal Cartridge Based Sample Prep Kit provides an easy and automated method of nucleic acid extraction and purification.

Trueprep® AUTO v2 Universal Cartridge Based Sample Prep Device is light weight, portable and operates on mains and/or re-chargeable battery. It is capable of up to 16 sample extractions with one recharge and has a simple, user friendly automatic operation. **Trueprep® AUTO v2** 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® AUTO v2 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®** pack insert) is added to the sample chamber of the cartridge. The cartridge is then placed in the **Trueprep® AUTO v2** 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®** chips for further analysis on the **Truelab®** Real Time PCR analyzer.

4. PACK SIZE

REF	60207AR05	60207AR25	60207AR50	60207AR100
Σ	5T	25T	50T	100T

5. MATERIALS PROVIDED

A. The Reagent Pack contains the following reagents

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

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. Reagent Reset Card-1 No.
E. Package Insert

6. STORAGE AND STABILITY

Trueprep® AUTO v2 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® Real Time micro PCR Workstation (REF623010001/633010001/643010001/653010001) consisting of,

1. **Trueprep® AUTO v2** Universal Cartridge Based Sample Preparation Device (REF 603042001).
2. **Truelab® Uno Dx/Truelab® Duo/Truelab® Quattro** Real Time micro PCR Analyzer (REF 603021001/603022001/603023001).
3. **Truelab®** micro PCR Printer (REF 603050001).
4. **Trueprep®** Cartridge Stand (REF 603100001)
5. **Trueprep®** Reagent Pack holder (REF 603160001)
6. **Trueprep®** Replaceable tray for cartridge holder (REF 603090001)
7. **Trueprep®** Plug-in connector for flush (REF 604090001)
8. 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®** 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® AUTO** MTB Sample Pre-treatment Pack, **Trueprep® AUTO** Universal Sample Pre-treatment Pack and **Trueprep® AUTO** Transport Medium for Swab Specimen 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® 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.
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.
7. If **Trueprep® AUTO v2** device is to be kept idle for more than 10 days, carry out flushing protocol. Refer user manual of **Trueprep® AUTO v2** Universal Cartridge Based Sample Prep Device for the Flush protocol and follow as per the given procedure.

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® AUTO v2** Universal Cartridge Based Sample Prep Device for the first time, plug in the Reagent pack to plugin connector of Device (Refer Section 14 to connect a new reagent pack).
3. Take a new cartridge from the **Trueprep® AUTO v2** 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 v2** Universal Cartridge Based Sample Prep Device.
4. 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.
5. Switch ON the **Trueprep® AUTO v2** Universal Cartridge Based Sample Prep Device and press EJECT button and the door will partially open.
6. Open the door and place the cartridge into the device, gently close the door and press START button.
7. The device performs all the steps automatically after reading the QR code printed on the Cartridge. Refer **Trueprep® AUTO v2** Universal Cartridge Based Sample Prep Device Manual for any error related to QR code reading.
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 cartridge and Disposable transfer pipette 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 8.3 of user manual of **Trueprep® AUTO v2** Universal Cartridge Based Sample Prep Device.
13. Switch off **Trueprep® AUTO v2** Universal Cartridge Based Sample Prep Device.
14. Clean liquid spills, if any, according to section “Cleaning and decontamination”.
15. Proceed to analysis (refer disease specific **Truenat®** pack insert and **Truelab® Uno Dx/Duo/Quattro** manual).

14. PROCEDURE TO CONNECT A NEW REAGENT PACK:

1. Turn off the **Trueprep® AUTO v2** and disconnect the power adapter.
2. Disconnect the used reagent pack, close connector with the cap and discard safely.
3. Take a new reagent pack and peel off the protective wrap. Take out the reset card.
4. Keep the new pack on the tray of **Trueprep® AUTO v2**, with "This side up" arrow pointing upward and facing away from the device.
5. Hold the reagent pack's connector upward and remove the cap. Plug-in the connector into the socket of **Trueprep® AUTO v2**. Ensure it is properly connected.
6. Turn on the device.
7. Use “Eject” button to open the door and insert the new Reset Card, as indicated on it.
8. Close door and press ‘Start”.
9. It will display "New Reagent Pack registered" and ejects the Reagent Reset Card.
10. The buffer count will be reset and **Trueprep® AUTO v2** is now ready for extraction with the new Reagent Pack.

⚠ Do not keep the connector down after removing its protective cap. Reagents may flow out. Connect immediately to device socket.

15. SPECIAL PRECAUTIONS

1. Do not re-use the Cartridge.
2. Ensure that the cartridge is never removed from the **Trueprep® AUTO v2** 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® AUTO v2** 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® AUTO v2** 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.
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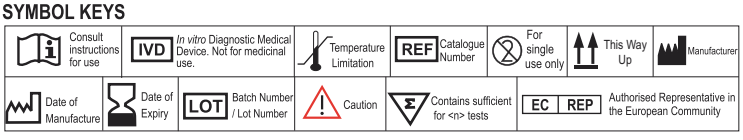
4. Siun C & Beow C.Y. (2009) DNA, RNA, and Protein Extraction: The Past and The Present. *J. biotechnol. Biomed.* 1-10.
5. Robert L., Janet T., Elizabeth S., et al. (2022) Practical Guide to Specimen Handling in Surgical Pathology. College of American pathologists. 10; 1-71.
6. Peipei L., Menghang L., Dongmei Y., et al. (2021) Solid-Phase Extraction Methods for Nucleic Acid Separation. A Review. *J. Sep. Sci.* 1-35.

SYMBOL KEYS



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