Universal Sample Pre-treatment Pack

Universal Sample pre-treatment pack for Non MTB samples

1. INTENDED USE
Trueprep™ AUTO Universal Sample Pre-treatment Pack (REF 60205AB05/60205AB20) is used to pre-treat the samples such as whole blood/serum/plasma/urine/stool/swab specimen/other body fluids before proceeding for extraction and purification of nucleic acids using Trueprep™ AUTO Universal Cardi•x Based Sample Prep Kit and Trueprep™ AUTO Universal Cardi•x Based Sample Prep Device.

2. INTRODUCTION
Trueprep™ AUTO Universal Sample Pre-treatment pack is an add-on pack containing reagents to pre-treat patient sample such as human blood/serum/plasma/urine/stool/swab specimen/other body fluids before proceeding for extraction and purification of nucleic acids using the Trueprep™ AUTO Universal Cardi•x Based Sample Prep Device and Trueprep™ AUTO Universal Cardi•x Based Sample Prep Kit. Processed sample is subjected for further Real Time PCR analysis on disease specific Truenat™ chip (except for Truenat™ MTB/Truenat™ MTB Plus chip) for the quantitative/semiquantitative/qualitative detection and diagnosis of appropriate disease.

NOTE: Truelab™ Uno / Truelab™ Uno Dx / Truelab™ Duo / Truelab™ Quattro /Trueprep™ AUTO/ Trueprep™ / Truenat™ are all registered trademarks of Molbio Diagnostics (P) Limited.

The Trueprep™ AUTO Real Time micro PCR Analyzer is protected by the following patents and patents pending: IN 2312/CHE/2007, WO 2009/047805 and corresponding claims of any foreign counterpart(s) thereof.

3. PRINCIPLE OF THE TEST
Disease specific Truenat™ chips require purified nucleic acids from patient's samples. These samples tend to have high levels of PCR inhibitors. Hence it is necessary to digest complex specimen to release the bacterial/virus, concentrate to get better yields and also discard potentially inhibitory substances.

The Trueprep™ AUTO Universal Sample pretreatment pack employs a reagent to achieve above objectives and to enable further extraction and purification of the target DNA/RNA using Trueprep™ AUTO Universal Cardi•x Based Sample Prep Device together with Trueprep™ AUTO Universal Cardi•x Based Sample Prep Kit. Sample Pre-treatment decontaminates the specimen and makes it ready for storage/transportation/extraction.

4. CONTENTS OF THE Trueprep™ AUTO Universal Sample Pre-treatment Pack
A. Lysis buffer.
B. Disposable transfer pipette (graduated).
C. Packinsert

5. STORAGE AND STABILITY
Trueprep™ AUTO Universal Sample Pre-Treatment Pack is stable for two (2) years from the date of manufacture if stored between 2-4°C. It is also stable for one (1) month at temperatures up to 45°C. Avoid exposure to light or elevated temperatures (above recommended levels). Do not freeze.

6. MATERIALS REQUIRED BUT NOT PROVIDED WITH THE KIT
Truelab™ Real Time micro PCR Workstation (REF 613010001/62301001/633010001/643010001) consisting of
1. Trueprep™ AUTO Universal Cardi•x Based Sample Prep Device (REF 603041001)
2. Trueprep™ Uno / Trueprep™ Uno Dx / Trueprep™ Duo / Trueprep™ Quattro Real Time micro PCR Analyzer (REF F603021001/603022001/603023001).
3. Trueprep™ micro PCR Printer (REF 603050001).
4. Trueprep™ SPA fixed volume precision micropipette - 6 µl (REF 604070006).
5. Trueprep™ Microtube Stand (REF 603070001).

Also required additionally are: Truenat™ Universal Control Kit (REF 601100008), DNase and RNase-free pipette tips with filter barrier, which may also be procured from Molbio, Powder free disposable gloves, nylon flock swab and waste disposal container with lid.

7. SAMPLE PROCESSING PROCEDURE
Sample must be pre-treated using Trueprep™ AUTO Universal Sample Pre-treatment pack as follow:
A. Protocol for Whole Blood, Plasma and serum:
Transfer 250µl of whole blood collected in EDTA anticoagulant or 500µl of plasma collected in EDTA anticoagulant/specimen using the transfer pipette provided into the lysis buffer tube provided and mix well after tightly closing the cap.
B. Protocol for Urine:
Collect about 10 ml of first flow of urine (ensuring atleast 2 hours gap from last urination) in a urine collection cup. Transfer 1 ml from the cup to the lysis buffer tube and mix well after tightly closing the cap. Dispose off urine collection cup as per the section on “Disposal and Destruction” (Section 11).
C. Protocol for Swab specimen:
Refer to the package insert of Trueprep™ AUTO Transport Medium for Swab Specimen Pack for collection and preparation of swab specimen. Transfer the entire content from the Transport Medium for Swab Specimen Tube into the lysis buffer tube and mix well after tightly closing the cap. Dispose off the Transport Medium for Swab Specimen Tube as per the section on “Disposal and Destruction” (Section 11).
D. Protocol for Stool:
Transfer 150 mg of Stool sample using a nylon flock swab into the lysis buffer tube. Mix the swab contents by vortexing for 1 minute. Allow the contents of tube to settle at room temperature for 5 minutes. Transfer 2 ml of the clear suspension to Cartridge for further procedure. Note: Ensure that while transferring the suspension to Cartridge no particulate matter is transferred. Dispose off nylon flock swab as per the section on “Disposal and Destruction” (Section 11).

8. SAFETY PRECAUTIONS
1. For in vitro diagnostic use only.
2. Bring all reagents to specimen to room temperature (20°C - 30°C) before use.
3. Do not use kit beyond expiry date.
4. Carefully read the User Manuals of Trueprep™ AUTO Universal Cardi•x Based Sample Prep Device and Trueprep™ AUTO Universal Cardi•x Based Sample Prep Kit. (Refer to the User Manual of Trueprep™ AUTO Universal Cardi•x Based Sample Prep device and the package insert of Trueprep™ AUTO Universal Cardi•x Based Sample Prep kit for details).
5. Do not pipette any material by mouth.
6. Do not eat, drink, smoke, apply cosmetics or handle contact lenses in the area where testing is done.
7. Use protective clothing and wear disposable gloves when handling samples and while performing sample extraction.

9. 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 vapours (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.

10. PROCEDURAL LIMITATIONS
1. Optimal performance of this test requires appropriate specimen collection, handling, storage and transport to the test site.
2. Though very rare, mutations within the highly conserved regions of the target genome where the Truenat™ assay primers and/or probe bind may result in the under-quantitation of or a failure to detect the presence of the concerned pathogen.
3. The instruments and assay procedures are designed to minimize the risk of contamination by PCR amplification products. However, it is essential to follow good laboratory practices and ensure careful adherence the procedures specified in this package insert for avoiding nucleic acid contamination from previous amplifications, positive controls or specimens.
4. A specimen for which the Truenat™ assay reports “Not Detected” cannot be concluded to be negative for the concerned pathogen. As with any diagnostic test, results from the Truenat™ assay should be interpreted in the context of other clinical and laboratory findings.
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 biohazard waste container.

12. DISPOSAL AND DESTRUCTION
1. Submerge the used content such as transfer pipette, pipette tips, nylon flocked swab, Sample pre-treatment tube, Transport Medium for Swab Specimen Tube, lysis buffer tube, urine collection cup etc. 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 contaminated fluid or 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.