CE

Trueprep® AUTO

Transport Medium for Swab Specimen Pack

Medium for Collection, Decontamination and Transport of Swab Specimen for Trueprep® AUTO

1. INTENDED USE

REF **Trueprep® AUTO** Transport Medium for Swab Specimen Pack **(REF 60206TS05 / 60206TS20 / 60206TS25 / 60206TS50 / 60206TS100 / 60206TS200)** is intended for use with clinician-collected endocervical, vaginal, anorectal, nasal and throat swab specimens. The transport media is used as a medium for collection, decontamination and transport of various types of swabs specimens before proceeding for pre-treatment using Lysis buffer, extraction and purification of nucleic acids using **Trueprep® AUTO/AUTO v2** Universal Cartridge Based Sample Prep Kit and **Trueprep® AUTO/AUTO v2** Universal Cartridge Based Sample Prep Device. The transport medium will keep the nucleic acids of the respective organism intact thus maintaining the integrity of the nucleic acids. The medium does not maintain the viability of the microorganism. The collection and transport medium ensures for the safe collection and transport of the microorganisms which includes bacteria and viruses from the site of collection to the testing centre. **Trueprep® AUTO** Transport Medium for Swab Specimen Pack contains single-use lysis buffer tube 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

One of the major requirements when handling microorganisms is for the safe collection and transport of the sample specimens to the testing centres. **Trueprep® AUTO** Transport Medium for Swab Specimen contains the necessary reagents to inactivate the micro organism so that it is safe to handle. **Trueprep® AUTO** Transport Medium facilitates in the complete release of the sample containing the microorganisms from the swab specimen. The **Trueprep® AUTO** Transport Medium for Swab Specimen Pack is an add-on pack containing reagents for collection, decontamination and transport of various swabs specimens before proceeding for pre-treatment using Lysis buffer from **Trueprep® AUTO** Universal Sample Pre-treatment Pack, extraction and purification of nucleic acids using the **Trueprep® AUTO/AUTO v2** Universal Cartridge Based Sample Prep Device and **Trueprep® AUTO/AUTO v2** Universal Cartridge Based Sample Prep Kit. Processed sample is subjected for further Real Time PCR analysis on disease specific **Truenat®** chip for the semi-quantitative detection and diagnosis of appropriate disease.

NOTE : Truelab® / Truenat® / Trueprep® / Truepet® all are trademarks of Molbio Diagnostics Private Limited.

The Truelab® Real Time micro PCR Analyzer is protected by the following patents and patents pending: IN 2313/CHE/2007 (Patent No. 281573), WO 2009/047804 and corresponding claims of any foreign counterpart(s) thereof.

The Truenat® micro PCR chip 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®** test requires inactivation and purification of the nucleic acids from the microorganisms prior to the step of PCR. The swab specimens collected for the testing of these infectious microorganisms will be entangled with the tissues of patient from whom the sample is collected. These micro organisms must be freed from the swab samples so that their nucleic acids are available for purification on the **Trueprep® AUTO/AUTO v2** Universal cartridge based sample prep device. These samples tend to have high levels of PCR inhibitors. Hence it is necessary to release the bacteria/virus, to concentrate and to obtain better yields thus discarding potentially inhibitory substances. The **Trueprep® AUTO** Transport Medium for Swab Specimen Pack employs a reagent to achieve above objectives to enable efficient extraction and purification of the target DNA/RNA using **Trueprep® AUTO/AUTO v2** Universal Cartridge Based Sample Prep Device using **Trueprep® AUTO/AUTO v2** Universal Cartridge Based Sample Prep Kit. Sample Pre-treatment decontaminates the specimen and makes it ready for storage / transportation / extraction.

4. CONTENTS OF THE Trueprep® AUTO Transport Medium for Swab Specimen Pack

A. Transport Medium for Swab Specimen Tubes (contains transport medium).
B. Packinsert

REF	60206TS05	60206TS20	60206TS25	60206TS50	60206TS100	60206TS200
Σ	5T	20T	25T	50T	100T	200T

5. STORAGE, HANDLING AND STABILITY

+2°C +40°C **Trueprep® AUTO** Transport Medium for Swab Specimen Pack is stable for two (2) years from the date of manufacture if stored between 2-40°C. It is also stable for one (1) month at temperatures upto 45°C. Avoid exposure to sunlight or elevated temperatures (above recommended levels). Do not freeze.

6. MATERIALS REQUIRED BUT NOT PROVIDED WITH THE KIT

REF **Truelab®** Real Time micro PCR Workstation (REF 623010001 / 633010001 / 643010001 / 653010001) consisting of

1. **Trueprep® AUTO/AUTO v2** Universal Cartridge Based Sample Prep Device (REF603041001/603042001).
2. **Truelab® Uno Dx/Truelab® Duo/Truelab® Quattro** Real Time micro PCR Analyzer (REF603021001/603022001/603023001).
3. **Truelab®** micro PCR Printer (REF 603050001).
4. **Truepet®** SPA fixed volume precision micropipette - 6 µl (REF 604070006).
5. **Truelab®** Microtube Stand (REF 603070001).
6. Also required additionally are: **Trueprep® AUTO** Universal Cartridge Based Sample Prep Kit (REF60203AR05 / REF60203AR25 / REF60203AR50 / REF60203AR100 / REF60203AR200) or **Trueprep® AUTO v2** Universal Cartridge Based Sample Prep Kit (REF60207AR05 / REF60207AR25 / REF60207AR50 / REF60207AR100 / REF60207AR200), **Trueprep® AUTO** Universal Sample Pre-treatment Pack (REF60205AB05 / REF60205AB20 / REF60205AB25 / REF60205AB50 / REF60205AB100 / REF60205AB200), **Truenat®** disease specific real time micro PCR test kit **Truenat®** Positive Control Panel, disease specific **Truenat®** Chip-based Real Time PCR Test, Powder free disposable gloves and waste disposal container with lid.

7. SAMPLE PROCESSING PROCEDURE

Various types of swab specimens must be collected as per standard procedures using a sample specific swab (Kindly refer **Truenat®** disease specific package insert for type of swab).

Nasal/Throat Swab specimen:

Swab specimen must be collected as per standard procedures using a standard nylon flocculated oropharyngeal & nasopharyngeal swabs. Insert the swab with specimen into the Transport Medium for Swab Specimen Tube provided and mix well by repeatedly twirling the swab in the buffer solution. Gently break the handle of the nylon swab at the break point, leaving the swab containing the specimen in the Transport Medium for Swab Specimen Tube. Tightly close the cap of the Transport Medium for Swab Specimen Tube. ⚠ Dispose off the remaining part of the swab after use, as per the section on "Disposal and Destruction" (Section 12).

Cervical/Vaginal/Anorectal Swab specimen:

Swab specimen must be collected as per standard procedures using a standard nylon flocculated cervical swabs. Insert the swab with specimen into the Transport Medium for Swab Specimen Tube provided and mix well by repeatedly twirling the swab in the buffer solution. After mixing, squeeze out the excess liquid from the swab by pressing it a few times against the inside wall of the tube. Tightly close the cap of the Transport Medium for Swab Specimen Tube. ⚠ Dispose off the swab as per the section on "Disposal and Destruction" (Section 12).

Nucleic acid extraction: Transfer 500 µL from the Transport Medium for Swab Specimen Tube into the Lysis Buffer Tube from **Trueprep® AUTO** Universal Sample Pre-treatment Pack for further procedure with the **Trueprep® AUTO/AUTO v2** Universal Cartridge Based Sample Prep Device and **Trueprep® AUTO/AUTO v2** Universal Cartridge Based Sample Prep Kit (Refer to the User Manual of **Trueprep® AUTO/AUTO v2** Universal Cartridge Based Sample Prep device and the package inserts of **Trueprep® AUTO** Universal Sample Pre-treatment Pack and **Trueprep® AUTO/AUTO v2** Universal Cartridge Based Sample Prep Kit for details). Remaining sample can be stored at 4°C in case the sample has to be repeated. ⚠ Dispose off the Transport Medium for Swab Specimen Tube as per the section on "Disposal and Destruction" (Section 12).

8. SAFETY PRECAUTIONS

IVD +20°C +30°C

1. For *in vitro* diagnostic use only.
2. Bring all reagents and specimen to room temperature (20°C - 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 Quantative 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 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. 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.

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 swab, Transport Medium for Swab Specimen Tube 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 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. SPECIFIC PERFORMANCE CHARACTERISTICS

Inactivation efficacy of the Swab Collection Media and Lysis Buffer containing human clinical specimens spiked with SARS CoV-2 tissue culture fluid specimens

500µl Swab collection media containing nasal swab/throat swab (NS/TS) specimens spiked with 100µl of SARS-CoV (undiluted) tissue culture fluid specimen was incubated at room temperature for 5 minutes. Buffer control samples were taken as normal cell culture media added to the 2 respective lysis buffers processed and observed for the presence of cytopathic effect (CPE) till five post-infection days (PID). Two blind passages were given to confirm virus propagation. The SARS-CoV-2 RNA was monitored at each passage by real-time RT-PCR to check the multiplication of the virus.

Conclusion: Virus spiked Swab Collection Media and lysis buffer showed that it is capable of inactivating the virus / clinical samples containing viral particles with 100% efficiency as is evident as no cytopathic changes was observed in vitro cell culture and the negative results by SARS CoV-2 real-time RT-PCR.

14. REFERENCES

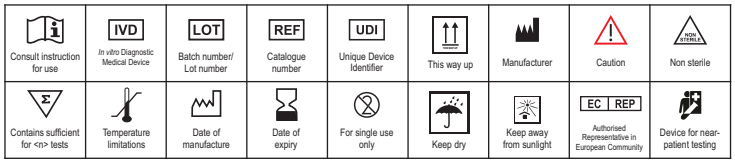
1. Julian D., Katherine G., Thomas T., et al. (2011) Evaluation of Swabs, Transport Media, and Specimen Transport Conditions for Optimal Detection of Viruses by PCR. J. Clin. Microbiol. 50(3): 1064-65.
2. David V.B., C. Mee L., Stuart T., et al. (2020) Evaluation of Commercially Available Viral Transport Medium (VTM) for SARS-CoV-2 Inactivation and Use in Point-of-Care (POC) Testing. Viruses. 12: 1-11.
3. Natalie N.K., Aniqa S., Gordon R., et al. (2020) Evaluation of Nasopharyngeal Swab Collection Techniques for Nucleic Acid Recovery and Participant Experience: Recommendations for COVID-19 Diagnostics. Open Forum Infectious Diseases. 1-6.
4. Lara F.B.H., Sarah H.A., Michele R.H., et al. (2016) Self-collection of vaginal swabs for human papillomavirus screening among women in temporary residential programs. Am J Obstet Gynecol. 214(4): 546–47.
5. Haguenoer K., Sengchanh S., Gaudy-Graffin C., et al. (2014) Vaginal self-sampling is a cost-effective way to increase participation in a cervical cancer screening programme: a randomised trial. British Journal of Cancer. 111: 2187–2196.
6. Min L., Qianyuan L., Jun Z., et al. (2020) Value of swab types and collection time on SARS-COV-2 detection using RT-PCR assay. Journal of Virological Methods. 286: 1-5.
7. Cleaning/Disinfection SOP for Research Laboratories for Mitigating DNA Contamination. 2021. Boston University.

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.

15. REVISION HISTORY

Section	Description of the changes
Throughout	Symbols are added as per IVDR requirements
1	Intended use is updated
3	Principle of the test is updated to add "the Trueprep® AUTO/AUTO v2 universal cartridge sample prep device."
5	Storage and stability is updated to storage,handling and stability
6	Section is updated
7	Sample Processing Procedure is updated
10	Section is revised
15	Added Revision History table
Symbol keys	Symbol keys are updated

SYMBOL KEYS



Molbio Diagnostics Private Limited

Registered Office and Manufacturing Unit - I:
Plot No. L-46, Phase II D, Verna Industrial Estate, Verna, Goa - 403 722, INDIA
Manufacturing Unit - II:
Plot No. L-42, Phase II B, Verna Industrial Estate, Verna, Goa - 403 722, INDIA
www.molbiodiagnostics.com
Email: sales@molbiodiagnostics.com (Sales Enquiries)
customersupport@molbiodiagnostics.com (Feedback and Customer Support)
EC REP Qarad EC-REP BV, Pas 257, 2440 Geel, Belgium

TPATM/1024/V-06
English - October 2024