Truenat®

CDI

Chip-based Real Time PCR Test for *Clostridium difficile*

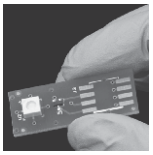
1. INTENDED USE

Truenat® CDI (601620005 / 601620020 / 601620025 / 601620050 / 601620100 / 601620200) is a Chip-based Real Time Polymerase Chain Reaction (PCR) test for the semi-quantitative detection and diagnosis of *Clostridium difficile* infections in stool samples. **Truenat® CDI** runs on the **Truelab®** Real Time Quantitative micro PCR Analyzers. **Truenat® CDI** is an *in vitro* diagnostics test meant for professional use only.

2. INTRODUCTION

Clostridium difficile, also known as *Clostridioides difficile* (CDI or C-diff), is a common nosocomial pathogen and a major cause of infectious diarrhea in hospitalized patients. *Clostridium difficile* infection is spread by bacterial spores found within feces. Surfaces may become contaminated with the spores with further spread occurring via the hands of healthcare workers.

Although *Clostridium difficile* is commonly regarded as a healthcare-associated infection, majority of infections are acquired outside of hospitals, where medications and recent history of diarrheal illnesses (e.g. laxative abuse or food poisoning due to Salmonellosis) are thought to drive the risk of colonization. Risk factors for infection include antibiotic or proton pump inhibitor use, hospitalization, other health problems, and older age. The infections occur in all areas of the world. About 453,000 cases occurred in the United States in 2011, resulting in 29,000 deaths. Global rates of the disease have increased in recent years. The bacterium was discovered in 1935 and found to be disease-causing in 1978. The pathogenicity of *Clostridium difficile* is mainly mediated by two exotoxins: toxin A (TcdA) and toxin B (TcdB). The toxin can cause severe diarrhea and life-threatening colitis. In children, the most prevalent symptom of a *Clostridium difficile* is watery diarrhea with at least three bowel movements a day for two or more days, which may be accompanied by fever, loss of appetite, nausea, and/or abdominal pain. Those with a severe infection also may develop serious inflammation of the colon and have little or no diarrhea. Complications may include pseudo membranous colitis, toxic megacolon, perforation of the colon, and sepsis. Diagnosis is by stool culture or testing for the bacteria's DNA or toxins.



The tests to diagnose *Clostridium difficile* comprises of cytotoxicity assay, Toxin ELISA and Stool tests. Stool leukocyte measurements and stool lactoferrin levels also have been proposed as diagnostic tests, but may have limited diagnostic accuracy. Testing of stool samples by real-time polymerase chain reaction is able to detect *Clostridium difficile* very effectively than above described methods. However, molecular tests such as PCR have so far been restricted to centralized reference laboratories as they require skilled manpower and elaborate infrastructure. Also the turnaround time for results could take a few days to weeks leading to high losses to follow-up.

The **Truelab®** Real Time micro PCR System enables decentralization and near patient diagnosis and detection of *Clostridium difficile* by making real time PCR technology rapid, simple, robust and user friendly and offering "sample to result" capability even at resource limited settings. This is achieved through a combination of lightweight, portable, mains/ battery operated **Truelab®** Real Time micro PCR Analyzer and **Trueprep® AUTO/AUTO v2** Universal Cartridge Based Sample Prep Device and room temperature stable **Truenat® CDI** micro PCR chips and **Trueprep® AUTO/AUTO v2** Universal Cartridge Based Sample Prep Kits so that even the peripheral laboratories with minimal infrastructure and minimally trained technician can easily perform these tests routinely in their facilities and report PCR results in less than an hour. Moreover, with these devices PCR testing can also be initiated in the field level, on site.

Truenat® CDI is a disposable, room temperature stable, micro PCR test with dried $MgCl_2$ in reaction well and freeze dried PCR reagents in microtube for performing Real Time PCR test for *Clostridium difficile* and runs on the **Truelab®** Real Time Quantitative micro PCR Analyzers. It requires only six (6) µL of purified DNA to be added to the reaction well for the analysis. The intelligent chip also carries test and batch related information. The **Truenat® CDI** chip also stores information of used chips to prevent any accidental re-use of the chip.

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

The Truelab® Real Time micro PCR Analyzer is protected by the following patents and patents granted: IN 2313/CHE/2007 (Patent No. 281573), WO2009/047804 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

Truenat® CDI works on the principle of Real Time Polymerase Chain Reaction (PCR) based on Taqman chemistry. The DNA from the patient sample is first extracted using **Trueprep® AUTO/AUTO v2** Universal Cartridge Based Sample Prep Device and **Trueprep® AUTO/AUTO v2** Cartridge Based Sample Prep Kit. The **Truenat® CDI** chip is placed on the chip tray of the **Truelab®** Real Time micro PCR Analyzer. Six (6) µL of the purified DNA is then dispensed using the provided micropipette and tip into the microtube containing freeze dried PCR reagents and allowed to stand for 30-60 seconds to get a clear solution. ⚠ No mixing by tapping, shaking or by reverse pipetting should be done. Six (6) µL of this clear solution is dispensed into the reaction well of the **Truenat® CDI** chip and the test is started. A positive amplification causes the dual labeled fluorescent probes in the **Truenat® CDI** chip to release the fluorophores in an exponential manner which is then captured by the built-in opto-electronic sensor and displayed as amplification curve on the analyzer screen, on a real time basis during the test run. The Cycle threshold (Ct) is defined as the number of amplification cycles required for the fluorescent signal to cross the threshold (i.e. exceed the background signal). Ct levels are inversely proportional to the amount of target nucleic acid in the sample. (i.e the lower the Ct level the greater is the amount of target nucleic acid in the sample). In the case of negative samples, amplification does not occur and a horizontal amplification curve is displayed on the screen during the test run. At the end of the test run, *Clostridium difficile* "DETECTED" or "NOT DETECTED" result is displayed and in positive cases, semi-quantitative result is also displayed on the screen. Based on the detection of the internal positive control (IPC), the validity of the test run is also displayed. The IPC is a full process control that undergoes all the processes the specimen undergoes – from extraction to amplification there by validating the test run from sample to result. Absence of or shift of IPC Ct beyond a pre-set range in case of negative samples invalidates the test run. While IPC will co-amplify in most positive cases also, in some specimen having a high target load, the IPC may not amplify, however the test run is still considered valid. The results can be printed using the **Truelab®** micro PCR printer or transferred to the lab computer/or any remote computer via Wifi network or 3G/GPRS network. Upto 20000 results in **Truelab® Uno Dx/Duo/Quattro** can be stored on the analyzer for future recall and reference.

4. TARGET SELECTION

The gene chosen for **Truenat® CDI** codes for the *Clostridium difficile* toxin B protein.

5. CONTENTS OF THE Truenat® CDI KIT

A. Individually sealed pouches, each containing
   1. **Truenat® CDI** micro PCR chip.
   2. Microtube with freeze dried PCR reagents.
   3. DNase & RNase free pipette tip.
   4. Desiccant pouch

B. Package Insert.

REF	601620005	601620020	601620025	601620050	601620100	601620200
Σ	5T	20T	25T	50T	100T	200T

6. CONTENTS OF THE Trueprep® AUTO Universal Sample Pre-treatment Pack

A. Lysis buffer.
B. Disposable transfer pipette (graduated).
C. Package Insert.

REF	60205AB05	60205AB20	60205AB25	60205AB50	60205AB100	60205AB200
Σ	5T	20T	25T	50T	100T	200T

7. STORAGE AND STABILITY

Truenat® CDI chip is stable for two (2) years from the date of manufacture if stored between 2-30°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.

Trueprep® AUTO Universal Sample Pre-treatment 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. Do not freeze.

8. MATERIALS REQUIRED BUT NOT PROVIDED WITH THE KIT

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 (REF 603021001/603022001/603023001).
3. **Truelab®** micro PCR Printer (REF 603050001).
4. **Truepet®** SPA fixed volume precision micropipette - 6 µl (REF 604070006).
5. **Truelab®** Microtube Stand (REF 603070001).

Also required additionally are: **Trueprep® AUTO** Universal Sample Pre-treatment Pack (REF60205AB05 / REF60205AB20 / REF60205AB25 / REF60205AB50 / REF60205AB100 / REF60205AB200), **Trueprep® AUTO** Universal Cartridge Based

Sample Prep Kit (REF60203AR05 / REF60203AR25 / REF60203AR50 / REF60203AR100) or **Trueprep® AUTO v2** Universal Cartridge Based Sample Prep Kit (REF60207AR05 / REF60207AR25 / REF60207AR50 / REF60207AR100), Nylon flocked swabs, Powder free disposable gloves, waste disposal container with lid.

9. SPECIMEN PREPARATION FOR EXTRACTION WITH Trueprep® AUTO/AUTO v2

Stool specimen:

For Solid stool specimens: Transfer solid stool sample (approximately 100-150 mg) using an appropriate disposable swab / spatula / wooden applicator stick into the lysis buffer tube. Dispose of the used swab/spatula/wooden applicator stick as per the section on "Disposal and Destruction" (Section 17). Mix the contents of the lysis buffer by vortexing for 1 minute. Allow the contents of the tube to settle at room temperature for 5 minutes.

For Watery stool specimens: Transfer 150 µL of the watery stool specimen using a suitable micropipette / Pasteur pipette into the lysis buffer tube. Dispose off the used pipette tip / Pasteur pipette as per the section on "Disposal and Destruction" (Section 17). Mix the contents of the lysis buffer by vortexing for 1 minute. Allow the contents of the tube to settle at room temperature for 5 minutes. ⚠ Dispose off the used swab / spatula / Wooden applicator stick / pipette tip / Pasteur pipette as per the section on "Disposal and Destruction" (Section 17). (Refer to package insert of **Trueprep® AUTO** Universal Sample Pre-treatment Pack for details).

Sample Storage and Transportation:

Sample Pre-treatment decontaminates the specimen and makes it ready for storage/ transportation/ extraction. The specimen in this form is stable for up to three (3) days at 40ºC and one (1) week at 30ºC.

Nucleic acid extraction: Transfer (1.5 to 2 ml) of the clear suspension to cartridge using the transfer pipettes provided with **Trueprep® AUTO/AUTO v2** Universal Cartridge Based Sample Prep Kit. Ensure that no particulate matter is transferred from the suspension in the lysis buffer to the cartridge. Dispose of lysis buffer tube and transfer pipette after use, as per the section on "Disposal and Destruction" (Section 17). Carry out further extraction procedure with the **Trueprep® AUTO/AUTO v2** Universal Cartridge Based Sample Prep Device. (Refer to the User Manual of **Trueprep® AUTO/AUTO v2** Universal Cartridge Based Sample Prep Device and the package insert of **Trueprep® AUTO/AUTO v2** Universal Cartridge Based Sample Prep Kit for details).

10. SAFETY PRECAUTIONS

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

11. PROCEDURAL PRECAUTIONS

1. Check all packages 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 confirm that individual components of the kit are intact before using them.
2. Do not perform the test in the presence of reactive vapours (e.g. from sodium hypochlorite, acids, alkalis or aldehydes) or dust.
3. While retrieving the **Truenat® CDI** micro PCR chip, microtube and the DNase and RNase free pipette tip from the pouch, ensure that neither bare hands nor gloves that have been used for previous tests run are used.

12. 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 to 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.

13. 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.

14. TEST PROCEDURE

(Please also refer the **Truelab®** Real Time Quantitative micro PCR Analyzer user manual).

1. Switch on the **Truelab®** Analyzer.
2. Select user and enter password.
3. For **Truelab® Uno Dx**, select the test profile for "CDI" to be run from the Profiles Screen on the Analyzer screen. For **Truelab® Duo/Quattro**, select the Bay (Idle1/2) for **Duo** and (Idle1/2/3/4) for **Quattro** from the Status Screen to view the Profiles Screen. Select the test profile for "CDI" to be run from the Profiles Screen on the Analyzer screen.
4. Enter the patient details as prompted in the **Truelab®** Analyzer screen.
5. Press Start Reaction.
6. For **Truelab® Uno Dx,** Press the eject button to open the chip tray. For **Truelab® Duo/Quattro**, the chip tray opens automatically on tapping the "Start Reaction" button.
7. Open a pouch of **Truenat® CDI** and retrieve the micro PCR chip, microtube and DNase & RNase free pipette tip.
8. Place the **Truenat® CDI** chip on the chip tray without touching the white reaction well. The reaction well should be facing up and away from the Analyzer. Gently press the chip to ensure that it has seated in the chip tray properly.
9. Place the microtube containing freeze dried PCR reagents in the microtube stand provided along with the **Truelab®** Real Time micro PCR workstation **after ensuring that white pellet of dried PCR reagents remains at the bottom of the microtube.** Remove the microtube cap and dispose it off as per the section on "Disposal and Destruction" (Section 17). Using the filter barrier tip provided in the pouch, pipette out six (6) µL of the purified DNA from the Elute Collection Tube into the microtube. Allow it to stand for 30-60 seconds to get a clear solution. ⚠ Do not mix it by tapping, shaking or by reverse pipetting. Using the same filter barrier tip, pipette out six (6) µL of this clear solution and dispense into the centre of the white reaction well of the **Truenat® CDI** chip. Take care not to scratch the internal well surface and not to spill elute on the outside of the well. Dispose off the microtip as per the section on "Disposal and Destruction" (Section 17).
10. For **Truelab® Uno Dx,** slide the chip tray containing the **Truenat® CDI** Chip-based Real Time PCR test loaded with the sample into the **Truelab®** Analyzer. Press Done on the "Please Load Sample" Alert message. For **Truelab® Duo/Quattro**, select "YES" at the Please load Sample prompt. Chip tray will close automatically and the reaction will start.
11. Read the result from the screen.
12. After the reaction is completed, for **Truelab® Uno Dx,** push the Eject button to eject the chip tray. For **Truelab® Duo/Quattro**, tap the "Open/Close Tray" button to eject the chip tray.
13. Take out the **Truenat® CDI** Chip-based Real Time PCR test at end of the test and dispose it off as per the section on "Disposal and Destruction" (Section 17).
14. Turn on **Truelab®** micro PCR printer and select print on the screen for printing out hard copy of the results. Test results are automatically stored and can be retrieved any time later. (Refer to the **Truelab®** Analyzer manual).
15. Switch off the **Truelab®** Analyzer.

15. RESULTS & INTERPRETATIONS

Two amplification curves are displayed on the **Truelab®** Analyzer screen to indicate the progress of the test. Both the target and the internal positive control (IPC) curves will take a steep, exponential path when the fluorescence crosses the threshold value in case of positive samples. The Cycle threshold (Ct) will depend on the number of target nucleic acids in the sample. The curve will remain horizontal throughout the test duration and the IPC curve will take an exponential path in case of negative samples. In case the IPC curve remains horizontal in a negative sample, the test is considered as Invalid. At the end of the test run, the results screen will display "DETECTED" for Positive result or "NOT DETECTED" for Negative result. The result screen would also display the microbial load as "HIGH (Ct<20)","MEDIUM (20≤Ct<25)", "LOW (25≤Ct<30)" or " VERY LOW (Ct≥30)" for positive specimen. The result screen also displays the validity of the test run as "VALID" or "INVALID". Invalid samples have to be repeated with fresh specimen from the sample preparation stage. *While IPC will co-amplify in most positive cases also, in some specimen having a high target load, the IPC may not amplify, however the test run is still considered valid.

16. QUALITY CONTROL PROCEDURES

To ensure that the **Truelab®** Real Time micro PCR Analyzer is working accurately, run known PCR positive and negative samples from time to time.

17. DISPOSAL AND DESTRUCTION

1. Submerge the used **Truenat® CDI** chip, microtube, microtube cap, transfer pipette, pipette tips, lysis buffer tube, nylon flock swab 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.

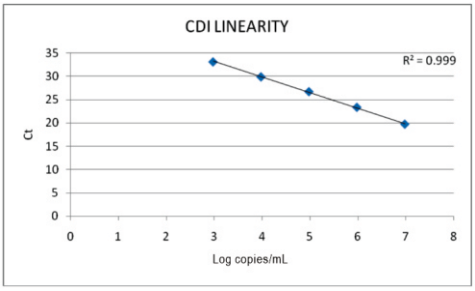
18. SPECIFIC PERFORMANCE CHARACTERISTICS

Analytical Exclusitivity (Primer specificity): The following microorganisms were evaluated in *silico* from the NCBI database using the NCBI nucleotide blast and primer blast tools to determine for potential cross-reactivity in the **Truenat® CDI** assay. Results obtained showed no cross reactivity of the **Truenat® CDI** test with the listed organisms.

Organism	**Organism**
Acinetobacter anitratus	Adenovirus
Candida albicans	Cytomegalovirus
Chlamydia trachomatis	Hepatitis B virus
Enterobacter cloacae	Hepatitis C virus
Salmonella enteric	Human Immunodeficiency virus
Staphylococcus aureus	Epstein-Barr virus
Streptococcus mutans	Herpes Simplex virus
Escherichia coli	Simian virus
Gardnerella vaginalis	Human Papillomavirus
Yersinia enterocolitica	
Trichomonas vaginalis	
Enterococcus faecalis	
Mycobacterium tuberculosis	
Klebsiella pneumoniae	
Mycobacterium bovis	

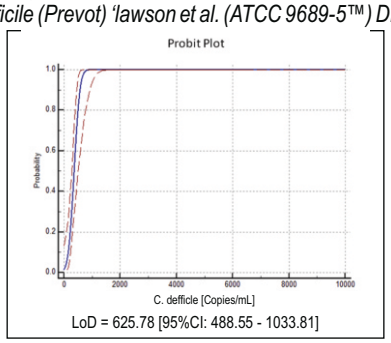
Linearity:

The linearity analysis was performed according to CLSI Guidelines. Serial dilutions of *Clostridoides difficile (Prevot)' lawson et al. (ATCC 9689-5™) DNA* 9.50E+06 to 9.50E+02 copies/mL was made and nucleic acids were extracted on **Trueprep® AUTO** Universal Cartridge Based Sample Prep Device in triplicates for each dilution followed by PCR on **Truelab®** Real Time micro PCR analyzer using **Truenat® CDI** test. The assay is found to be linear over 5 orders of magnitude (from 9.50E+06 to 9.50E+02 copies/mL) for CDI DNA from ATCC.



Limit of detection (LoD):

The LoD was determined by making dilutions of *Clostridioides difficile (Prevot) lawson et al. (ATCC 9689-5™) strain DNA* and performing nucleic acid extractions on **Trueprep® AUTO** Universal Cartridge Based Sample Prep Device for each of the dilution 10 times followed by followed by PCR on **Truelab®** Real Time micro PCR analyzer using **Truenat® CDI** test. Probit analysis of the data was used to determine the concentration of the DNA with 95% probability of detection. The LoD was found to be 625.78 copies/mL for *Clostridoides difficile (Prevot) 'lawson et al. (ATCC 9689-5™) DNA.*



Robustness:

Potential sample carryover within the **Truenat® CDI** test was evaluated by testing alternate Positive followed by Negative samples. The numbers of samples run were 20 Positives and 20 Negatives. The results showed no carryover contamination. The **Truenat® CDI** test did not exhibit any detectable carry over between Positive and Negative PCR runs.

Reproducibility:

The purpose of this study is to compare the functional performance of the **Truenat® CDI** assay using three different titres of samples on **Truelab®** Real Time micro PCR analyzer. High, Medium and low titre samples were extracted on **Trueprep® AUTO** Universal Cartridge Based Sample Prep Device and tested among three different users (Inter user), on three different devices (Inter device) and on 5 consecutive days (Inter day) to check the variability. Mean %CV values for all titres has been calculated for Inter User (1.79), Inter day (1.54) and Inter Device (2.51) which were in the accepted range of ≤15% CV for **Truenat® CDI** assay.

Precision:

Precision was tested by performing **Truenat® CDI** assay with extracted DNA of High, Medium and Low titres for five consecutive days. Every day PCR for each titre DNA was run in triplicates. The %CV values obtained for High titre (2.91), Medium titre (3.08) and low titre (1.92) were within the accepted range of ≤15% CV for **Truenat® CDI** assay.

Clinical validation:

A panel of 30 stool samples comprising of 20 negative and 10 positive specimens were tested on three different manufacturing lots of **Truenat® CDI** assay at Ramaiah Medical College Hospital Laboratory, Bangalore against the HELINI Clostridium difficile Real-time PCR Kit as the reference test.

	HELINI Clostridium difficile Real-time PCR Kit		
	Positive	Negative	Total
Truenat® CDI Positive	10	0	10
Truenat® CDI Negative	0	20	20
Truenat® CDI Total	10	20	30

With the consideration of above data, **Truenat® CDI** test performed consistently in this study with observed sensitivity of 100% and specificity of 100% in comparison with HELINI Clostridium difficile Real-time PCR reference kit and the inter lot variation data obtained was within the accepted range of ≤15% CV for **Truenat® CDI** test.

19. REFERENCES

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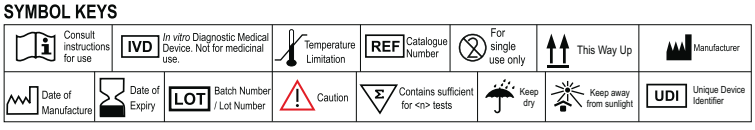
SYMBOL KEYS



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