## 10. PERFORMANCE DATA
### Internal Evaluation
Standard ATCC cultures as recommended by CLSI were used for validation. These cultures were tested simultaneously both on MICROPRO™ AST and on standard Kirby-Bauer antibiotic testing using Mueller Hinton-Agar plate. The expected Susceptibility results as depicted by CLSI against these reference cultures were compared with the results obtained with MICROPRO™ AST susceptibility test Panel Kit. The results were also compared with standard Kirby-Bauer antibiotic testing using Mueller Hinton-Agar plate.

- **Result:** MICROPRO™ AST showed 100.67% correlation with both CLSI and Kirby-Bauer antibiotic testing methods.

### External Evaluation
Conducted in Goa Medical college, Bambolim Goa. A total of 100 specimen were tested simultaneously both on MICROPRO™ AST and on standard Kirby-Bauer antibiotic testing using Mueller Hinton-Agar plate.

- **Result:** MICROPRO™ AST showed 97.6% correlation with Kirby-Bauer antibiotic testing method.

### Stability Validation
Stability studies were performed on all the components of MICROPRO™ AST Susceptibility test Panel Kit at three different temperatures: at 2-8°C for 2 years, at Room temperature for 1 year and at 37°C for a period of 30 days.

- **Result:** The variations in results were found to be within the acceptable range against time periods.

### Precision Validation
Repeatability and Reproducibility tests were performed with actual samples and control ATCC cultures recommended by testing. Same sample was inoculated in five different kits simultaneously both on and on standard Kirby-Bauer antibiotic testing using Mueller Hinton-Agar plate. The expected Susceptibility results as depicted by CLSI against these reference cultures showed 100% correlation with both CLSI and Kirby–Bauer antibiotic testing methods.

- **Result:** The variations in results were found to be within the acceptable range against time periods.

## 11. Antibiotic list in MICROPRO™ AST Susceptibility test Panel Kits:

### A. MICROPRO™ AST Susceptibility Test Panel Kit-UTI
- **Ampicillin** Ceftriaxone
- **Tobramycin** Amoxicillin-Cloxacillin Acid
- **Amikacin** Cefazolin
- **Ciprofloxacin** Ceftazidime
- **Gentamicin** Levofloxacin
- **Levofloxacin** Nitrofurantoin
- **Nitrofurantoin** Norfloxacin
- **Norfloxacin** Tetracycline
- **Tetracycline** Trimethoprim/Sulfamethoxazole
- **Trimethoprim/Sulfamethoxazole** Ticarcillin/Cilavulanic acid

### B. MICROPRO™ AST Susceptibility Test Panel Kit-GN
- **Ampicillin** Cefazolin
- **Tobramycin** Amoxicillin-Cloxacillin Acid
- **Amikacin** Cefazolin
- **Ciprofloxacin** Ceftazidime
- **Gentamicin** Levofloxacin
- **Levofloxacin** Nitrofurantoin
- **Nitrofurantoin** Norfloxacin
- **Norfloxacin** Tetracycline
- **Tetracycline** Trimethoprim/Sulfamethoxazole
- **Trimethoprim/Sulfamethoxazole** Ticarcillin/Cilavulanic acid

### C. MICROPRO™ AST Susceptibility Test Panel Kit-GP
- **Ampicillin** Tigocephalin
- **Tobramycin** Aztreonam
- **Amikacin** Cefotin
- **Ciprofloxacin** Clindamycin
- **Nitrofurantoin** Gentamicin
- **Levofloxacin** Chloramphenicol
- **Nitrofurantoin** Penicillin
- **Oxacillin** Perocillin
- **Tobramycin** Dorsycine
- **Ampicillin** Tigecycline
- **Norfloxacin** Nitromycin
- **Tetracycline** Dorosilvne
- **Trimethoprim/Sulfamethoxazole** Nettymycin
- **Ticarcillin/Cilavulanic acid** Lamiplam

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**Note:** The antibiotics list mentioned here is for test kit for UTI, GN and GP organisms.

**MICROPRO™ AST System** will generate test results based on recommended antibiotics as per CLSI.

### 12. REFERENCES
2. CLSI M100S.  
3. CLSI M100S.  
4. CLSI M100S.  
5. CLSI M100S.  
6. CLSI M100S.  
7. CLSI M100S.  
8. CLSI M100S.  
9. CLSI M100S.  
10. CLSI M100S.

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**1. INTENDED USE**
**MICROPRO™ AST** is a system intended for Antimicrobial Susceptibility Testing of most pathogens involved in UTI, GI, ENT, CNS, Blood etc. in less than five hours.

**2. INTRODUCTION**
An important task for the clinical microbiology laboratory is the performance of antimicrobial susceptibility testing of significant bacterial isolates. The goals of testing are to detect possible drug resistance in common pathogens and to assure susceptibility to drugs of choice for particular infections. The most commonly used conventional methods include the disk diffusion method. Later generation testing methods include broth microdilution which include the use of rapid and sensitive instruments.

In general, current testing methods provide accurate detection of antimicrobial resistance. Use of instrument can standardize the reading of end points and often produce susceptibility test results in a shorter period. Sensitive optical detection systems allow detection of even subtle changes in bacterial growth.

**3. WORKING PRINCIPLE**
The **MICROPRO™ AST** system is based on three basic steps:
- Inoculum preparation (≈ 1 McFarland std. 0.5) in Mueller Hinton Broth-CA.
- Selecting the required **MICROPRO™ AST** Test Panel Kit and loading the inoculum.
- Detection of Susceptibility based on growth measured by Turbidimetry Analyzer.

**4. STORAGE AND STABILITY**
- Store the **MICROPRO™ AST** Test Panel Kit at 2-8˚C before use.
- Carefully read the User Manual and package inserts.

**5. MATERIAL REQUIRED BUT NOT PROVIDED WITH THE KIT**
- Computer with rs232 port, Windows OS (XP and above) for installation of MICROPRO™ AST Data calculation and reporting software, Minicompatible power supply (UPS), Bacteriological Incubator (at 37 - 35˚C), Printer for printing results. Pipette Tips (200 μl, 10 μl per test).
- Marker Pen, Tissue Paper, 70% IPA, Bactericidal Handrub, Gloves and Masks.

**6. PRECAUTIONS**
(a). For laboratory use only. (b). Bring all reagents and specimen to room temperature (20 - 30˚C) before use. 
(c). Do not use the kits beyond expiry date. 
(d). Carefully read the User Manual and package inserts before use. 
(e). Take Universal Precautions. All human body fluids should be treated as potentially infectious. 
(f). Always be prepared for any accidental spillage. 
(g). In case of accidental spillage clean the area thoroughly and wipe with 70% IPA at least three times. 
(h). Use a Bactericidal Handrub before and after test procedure. 
(i). Visually examine the broth, reagents and other components to ensure there is no physical damage, microbial contamination, discoloration, precipitation, evaporation or any signs of deterioration. 
(j). If any of these is observed, do not use these reagents and contact Service provider immediately.
7. SYSTEM CONTENTS

5. SYSTEM CONTENTS

A) Micropro-AST Installation Pack

1. MICROPRO® AST Analyzer

- Analyzer for Reading AST microplates

2. McFarland Standard (0.5)

- Cuvettes with McFarland standards for inoculum preparation

3. Susceptibility test Panel Tray with tray cover

- Tray to place susceptibility test panels while testing

4. Multichannel Micropipette (12 Channel, fixed 200 uL)

- Micropipette for dispensing inoculum into Test Panel

5. Gamma Sterile tips (200 uL)

- Gamma Sterile Filter-tips in a tipbox

6. Analyzer accessories

- User Manual, power cable, RS-232 cable, touch-pen, pen bracket, fuse, lamp, mouse dust cover etc.

B) Reagent Packs

1. MICROPRO®AST Susceptibility test Panel-UTI

- Two Susceptibility Panels with 22 Antibiotics

2. MICROPRO®AST Susceptibility test Panel - GN (20 TESTS)

- Three Susceptibility Panels with 30 Antibiotics

3. MICROPRO®AST Susceptibility test Panel- GP (20 TESTS)

- Three Susceptibility Panels with 25 Antibiotics

4. MICROPRO®AST Inoculum Preparation Kit (20 TESTS)

- For Inoculum Preparation
  - Ready to use broth for culture growth

5. MICROPRO®AST Accessories Kit (20 TESTS)

- a) Sterile Loop
  - b) Sterile Dropper
  - c) Sterile Reservoir

B. Incubation and Preparation:

1. Susceptibility Test Panels and place them on the table.

2. From MICROPRO®AST Accessories Kit retrieve the required number of Sterile reservoirs corresponding to the number of samples to be tested. Retrieve the inoculated Mueller Hinton Broth-CA vial and pour the entire inoculum in a sterile reservoir.

3. Using the Multichannel Fixed Volume Micropipette (12 Channel, 200 uL) and tips in a tipbox provided, transfer 2 drops of inoculum to the Normal Saline vials provided with the Installation pack. Close the Vials. Discard the tips and the Reservoir. Do the same for all the samples.

4. For Gram Positive samples select MATERIAL SUSCEPTIBILITY test Panel Kit - GP and for Gram-Negative samples select MATERIAL SUSCEPTIBILITY test Panel Kit - GN.

5. From the recommended MICROPRO®AST Inoculum Preparation Kit, retrieve the required number of Normal Saline vials and Mueller Hinton Broth-CA vials corresponding to the number of samples to be tested and place them on a flat clean table top.

6. Write Patient IDs / Names in the space indicated on both the vials. Do it for all the samples.

7. From MICROPRO®AST Accessories Kit retrieve the required number of Sterile Loop and Sterile Droppers corresponding to the number of samples to be tested.

8. For samples tested with MICROPRO®AST BCS, after completing Biochemical Identification tests about 1 ml of broth will remain in MICROPRO®AST Barcoded Cuvette (A). Centrifuge the cuvettes at RCF of 5000 g for 10 minutes at room temp. Allow the pellet to be observed. Discard the supernatant carefully to avoid spilling the cuvette and retain the pellet.

9. No such preparation is needed for Plate cultures.

10. For UTI cultures MICROPRO®AST Susceptibility test Panel Kit - UTI is recommended.

11. For UTI cultures MICROPRO®AST Susceptibility test Panel Kit - UTI is recommended.

12. For UTI cultures MICROPRO®AST Susceptibility test Panel Kit - UTI is recommended.

13. For UTI cultures MICROPRO®AST Susceptibility test Panel Kit - UTI is recommended.

14. Three Susceptibility Panel strips (B,C or B,C,D), one by one to all the two or three strips. Use the same set of tips to dispense inoculum to all the vials. Discard the tips and the Reservoir. Do the same for all the samples.

Note: It is recommended to use one tray for sample, as it will avoid accidental cross-contamination and ensure easy handling while testing. Leave at least 2 to 3 rows on the top while placing the strips, to avoid environmental contamination and unwanted faster drying.

D). Initiate test in MICROPRO®AST Analyzer:

15. Note down the Patient IDs / Names, the corresponding Test-ID Codes and the row positions (for e.g. 1A, 1B, 1C etc.) in the register or daily work sheet provided. Do it for all the samples.

16. Retrieve the inoculated Mueller Hinton Broth-CA vial and pour the entire inoculum in a sterile reservoir. Mix well; then, inject the inoculated Mueller Hinton Broth-CA vial and pour the entire inoculum in a sterile reservoir.

17. After the test is initiated, the tray covers on MICROPRO®AST Susceptibility Test Panel Trays and place them in a Bacteriological Incubator (at 37 °C).

18. Twenty recommended incubation time is at least 5 hours for Gram negative and UTI cultures. For Gram Positive cultures extra 2-3 hours of incubation will be required, which will be instructed by the Software.

19. However it can be incubated further overnight if required by the particular organism.

20. Recommended incubation time is at least 5 hours for Gram negative and UTI cultures. For Gram Positive cultures extra 2-3 hours of incubation will be required, which will be instructed by the Software.


22. After the recommended time interval, check whether incubation status is complete. MICROPRO®AST Analyzer / Software User Interface utilizes algorithm and tells the status and further action required. Refer Help section in MICROPRO®AST Software User Interface installed in the computer.

23. After incubation is over, MICROPRO®AST Software Interface calculates the results as Susceptible, Intermediate or Resistant against each antibiotic and recommends antibiotics with priority as well. Refer Help section in MICROPRO®AST Software User Interface in the computer.

24. A print out of the sample result with the printer attached to the computer.