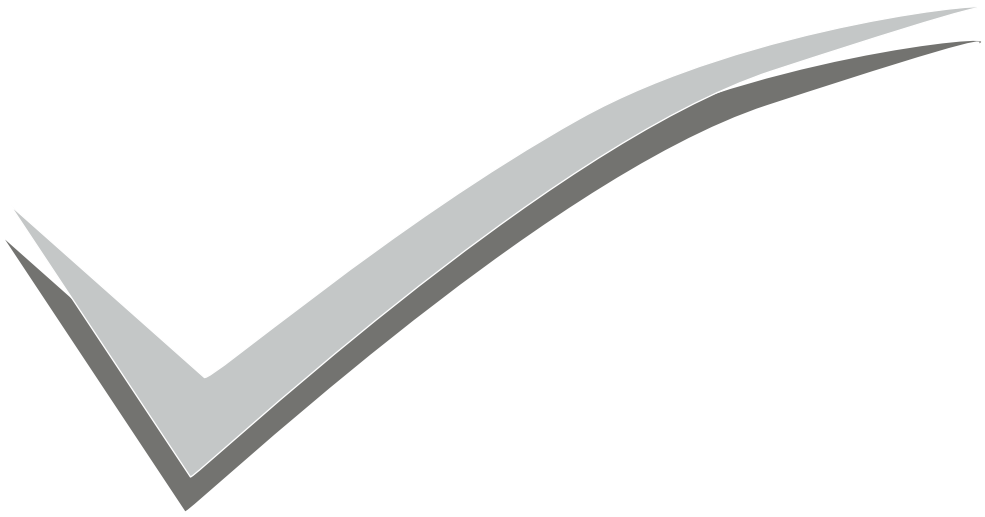
CE

ISO 13485:2003

Performance Evaluations



MICROPRO BCS

Broth Culture System for Detection, Ennumeration and Identification of UTI

Performance Evaluations

CE

ISO 13485:2003

INDEX

MICROPRO BCS

Broth Culture System for Detection, Ennumeration and Identification of UTI

Scientific Report

Comparative evaluation of MICROPRO™ Broth Culture System (BCS) with the conventional Solid plate culture method for the detection of Urinary tract infection in hospital based clinical patient samples

Abstract:

Objective:

(1)To assess the performance of MICROPRO™ BCS, a spectrophotometric/turbidimetric based assay for the detection, enumeration and identification of Urinary Tract infection, with clinical patient samples

(2) To compare the performance of MICROPRO™ BCS with the current gold standard, the solid plate culture method.

Study methods

A total of 110 clinical patient urine specimens were collected from a reputed Hospital in India, and analyzed for Urinary Tract infections using MICROPRO™ BCS and the Plate Culture Technique.

.

Results

MICROPRO™ BCS yielded a Positive Predictive Value of 100%. The positive samples identified by MICROPRO™ BCS were in total agreement with the Plate Culture Technique.

Out of the 76 negative samples, MICROPRO™ BCS identified all the negative samples, however plate culture could identify only 70 negative samples, six were reported as mixed infection/ contamination by the plate culture method.

Both MICROPRO™ BCS and plate culture method detected the remaining 20 samples as mixed infection/ contamination cases.

Conclusion

An overall agreement of 95% was observed in the results obtained by MICROPRO™ BCS and the gold standard Plate Culture Technique for UTI detection in clinical patient specimens. The positive specimens were accurately identified by the MICROPRO™ ID kit.

Background:

Urinary tract infections (UTIs) are considered to be the most common bacterial infection. UTI accounts for nearly 7 million physician visits and 1 million emergency department visits, resulting in 100,000 hospitalizations. Urinary tract infection (UTI) is also the most common hospital-acquired infection, accounting for 40% of all hospital-acquired infections. More than 80% of these infections are attributable to use of an indwelling urethral catheter.

Accurate diagnosis depends on both the presence of symptoms and a positive urine culture which is the gold standard followed by identification of the organism by antibiogram, the entire process takes atleast 48 hours before arriving at a definite conclusion.

MICROPRO™ Broth Culture System (BCS) an assay system based on spectrophotometric/turbidimetric method detects, enumerates and identifies most urinary pathogens within 5 hours thereby expediting diagnosis for accurate and effective treatment.

Study Method:

A comparative evaluation of MICROPRO™ BCS and the conventional Plate culture technique was performed at Goa Medical College and Hospital, Bambolim, Goa in the month of January 2014. A total of 110 unknown clinical urine samples were used for the evaluation.

The evaluation parameters and prerequisites were as follows:

(1)The samples to be used for evaluation were freshly collected in the morning.

(2) The samples collected were used for inoculation (in Micropro Broth media and plates) within 2 hours.

(3) If samples were collected from patients who were on medication or antibiotics that could affect urinalysis results, the same was noted down.

(4) The samples were inoculated in MICROPRO™ BCS Broth Culture Cuvettes (A & B) and plates simultaneously. The time difference was not more than 15 minutes.

Procedure:

(1) Patient ID / Gender / Age / Ward details etc. were noted down.

(2) Samples once received were inoculated in MICROPRO™ Broth Culture media (A & B) as well as on the solid culture plates.

(3) For plating: MacConkey Agar without CV, NaCl and with 0.5% Sodium Taurocholate as well as Blood Agar plates were used.

(4)For detection: After an incubation of 4 hours MICROPRO™ BCS detects positive or negative samples. Same was noted down in Urine Analysis Result sheet. Plates were incubated overnight for detection. Once result detected the same was noted down.

(5)For enumeration: After 4 hours of incubation MICROPRO™ BCS enumerates positive samples in terms of cfu/ml. Same was noted down. Once plate count is received after overnight incubation it was noted down.

(6)For Identification: For positive samples MICROPRO™ (Biochemical) ID Kit identifies 8 major pathogens in 25 minutes which contribute to about 97% of UTI cases. The identified pathogens were noted down. Similarly, for plate culture, Identification was done on CLED or chromogenic media. The identified pathogens were noted down.

Evaluation Results:
The results of the evaluation are presented in the following table

Samples	MICROPRO™ BCS	Plate Culture
Positive Samples	14	14
Negative Samples	76	70
Contamination/	20	26
Total	110	110

As observed in the table.
(1)Fourteen positive samples were identified by both MICROPRO™ BCS and plate culture method indicating that there is 100% correlation between MICROPRO™ BCS and plate culture method for positive samples.
These positive samples had a colony count of 10^4 to 10^8 cfu/ml, data confirmed by the Hospital.
(2)Seventy-six negative samples were detected by MICROPRO™ BCS as compared to 70 negative samples Identified by Plate Culture Technique.
(3)MICROPRO™ BCS detected 20 samples as Mixed Infection or Contamination whereas Plate Culture Technique identified 26 samples as Mixed Infection or Contamination, including the six negative samples. All the 76 negative samples had a colony count less than10^4 cfu/ml.
The positive samples were further analyzed by MICROPRO™ ID Kit, which consists of a series of biochemical tests for the presumptive identification of Causative UTI Pathogen.
The results given below have also been confirmed by the Hospital.

Pathogens	Number of cases detected
E.coli	05
E. faecalis	03
Proteus.spp.	02
S.pyogenes	01
Klebsiella pneumonia	02
S. aureus	01

Discussion:
Most of the UTI are caused by the eight common urinary pathogens that account for approximately 97% of infections. The primary pathogen involved is *Escherichia coli*. The fairly common secondary pathogens are *Enterococcus faecalis, Klebsiella pneumoniae, Proteus mirabilis, Proteus spp., Pseudomonas aeruginosa, S. pyogenes and S.aureus*.

From the evaluation it is observed that
(1) MICROPRO™ BCS yielded a Positive Predictive Value of 100%. And from the positive samples,
(2)MICROPRO™ID kit correctly identified the causative organisms.
(3) MICROPRO™ BCS showed an excellent correlation with the plate culture method.

MICROPRO™ Broth culture system ensures that entire process of detection and identification of Urinary Tract infections can be achieved in 5 hours therefore expediting the process of diagnosis and treatment of Urinary tract infections.

References:
(1). Practical Medical Microbiology, Mackie and MacCartney, Vol 2, 13 th ed, Churchill Livingston 1989, Edited by J,G Collee Duguid, A.G. Fraser, B.P. Marmion. (2). Detection, Prevention and Management of Urinary Tract infections, C.M Kunin, 4th Edition, 1987, (3). McPherson RA, Ben-Ezra J. Basic examination of urine. In: McPherson RA, Pincus MR, eds. (Henry's Clinical Diagnosis and Management by Laboratory Methods.) 22nd ed. Philadelphia, PA: Elsevier Saunders; 2011:chap 28. (4). Hooton TM, Bradley SF, Cardenas DD, et al. Diagnosis, prevention, and treatment of catheter-associated urinary tract infection in adults: 2009 International Clinical Practice Guidelines from the Infectious Diseases Society of America. Clin Infect Dis. 2010; 50(5):625-663. (5). Ban KM, Easter JS. Selected urologic problems. In: Marx JA, Hockberger RS, Walls RM, et al, eds. Rosen's Emergency Medicine: Concepts and Clinical Practice. 7th ed. Philadelphia, Pa: Mosby Elsevier; 2009: chap 97. (6). Dean AJ, Lee DC. Bedside laboratory and microbiologic procedures. In: Roberts JR, Hedges JR, eds. Clinical Procedures in Emergency Medicine. 5th ed. Philadelphia, Pa: Saunders Elsevier; 2009:chap 68. (7). MacFaddin, Jean F. "Biochemical Tests for Identification of Medical Bacteria." Williams & Wilkins, 1980, pp 173 – 183. (8). Bachoon, Dave S., and Wendy A. Dustman. Microbiology Laboratory Manual. Ed. Michael Stranz. Mason, OH: Cengage Learning, 2008. Exercise 15, "Normal Flora of the Intestinal Tract" Print. (9). Bergey's Manual of Systematic Bacteriology, Vol. 1. Baltimore, Williams and Wilkins, 1984. (10). Nicola F1, Centorbi H, Bantar C, Smayevsky J, Bianchini H., Utility of pyrrolidonyl-arylamidase detection for typing Enterobacteriaceae and non-fermenting Gram-negative bacteria, Rev Argent Microbiol. 1995 Oct-Dec;27(4):204-9. (11). Gordon J, McLeod JW. Practical application of the direct oxidase reaction in bacteriology. J Pathol Bacteriol 1928; 31:185-90. (12). Koneman EW, Allen SD, Janda WM, Schreckenberger PC, Winn WC Jr. Color atlas & textbook of diagnostic microbiology. 5th ed. Philadelphia: JB Lippincott, 1997. (13). L Essers and K Radebold, Rapid and reliable identification of Staphylococcus aureus by a latex agglutination test. J Clin Microbiol. Nov 1980; 12(5): 641–643. (14). Kloos, W.E. and P.B. Smith. Staphylococci. 1980. Manual of Clinical Microbiology, 3rd ed. E.H. Lennette, A. Balows, W.J. Hausler, Jr. and J.P. Truant, ed. ASM, Washington, D.C. (15). Finegold, S.M. and E.E. Sweeney. 1961. New Selective and Differential Medium for Coagulase-Positive Staphylococci Allowing Rapid Growth and Stain Differentiation. J. Bacteriol.; 81:636-641. (16). Data on file: Microxpress (P) Ltd.

Scientific Report

Multi-centric evaluation of MICROPRO™ Broth Culture System (BCS), a quick and reliable system for detection and identification of Urinary tract infections (UTI)

Abstract:

Objective:

(1) To evaluate the performance of MICROPRO™ Broth Culture System, a spectrophotometric/ turbidimetric system for the detection and identification of Urinary Tract infections (UTI), extensively at the field level.

(2) To compare its performance with the conventional method generally preferred by the Microbiologists and Pathologists, the Solid plate culture (SPC) method.

Study methods

Two hundred and sixty- four samples in total were used for the evaluations performed in 10 different states in India covering north, south, east, west and central India, involving 53 microbiologists/ pathologists, in the year 2015.

The reagents MICROPRO™ BCS bearing Lot No. AA1 and MICROPRO™ ID Lot No. MIDO6161 were used in the evaluations and the performance was compared with the conventional gold standard, the Solid plate culture (SPC) method.

Results

Out of the total 264 urine samples used for the evaluation, 98 samples were detected as True UTI positives by MICROPRO™ BCS immediately after four hours of incubation and 101 samples by the Solid plate culture after overnight incubation. The two false negative cases by MICROPRO™ BCS were identified as *Staphylococcus haemolyticus* and *Providencia spp*. Statistically these rare samples account for less than 1% of cases (2 out of 264 in our study).

The True negatives, 159 samples in all were detected by both the methods.

Most of the UTI positive samples were identified accurately by the MICROPRO™ ID Kit in less than 30 minutes and the results are comparable to the conventional identification technique.

Conclusion

In the pan India performance evaluation of MICROPRO™ BCS carried out in the year 2015, MICROPRO™ BCS showed 97% correlation with the conventional Plate culture technique for the detection and identification of Urinary tract infection.

Background:

Urinary Tract Infections (UTIs) are associated with multiplication of organisms in the urinary tract. It is a serious health problem affecting millions of people each year. The common uropathogen identified in patients with UTI include enteric gram-negative bacteria, with *E. coli* being the most common followed by *Proteus mirabilis*, *Klebsiella,* and *Enterococcus*. In complicated UTIs, in addition to *E. coli*, there is a higher prevalence of *Pseudomonas*, *Enterobacter species*, *Klebsiella* and *Enterococcus*. Other aerobic gram-negative bacteria of the Enterobacteriaceae family include *Citrobacter* and *Salmonella.*

The diagnosis of a urinary tract infection therefore involves detection and identification of the pathogen in the presence of clinical symptoms.

The pathogen is detected by urine culture, either by Broth culture method or Solid plate culture, using midstream urine.

MICROPRO™ BCS is a broth culture assay system based on spectrophotometric/turbidimetric method and can detect as well as enumerate the Urinary tract pathogens in 4 hours. The detected UTI pathogen can then be identified using MICROPRO™ ID kit. The MICROPRO™ ID system, based on the biochemical method of analysis, identifies most of the Urinary tract pathogens detected by the Solid plate culture method or the Broth culture method in less than twenty-five minutes.

Study Method: A Pan India evaluation of MICROPRO™ Broth Culture System (BCS) was performed at various Microbiology and Pathology clinics in the east, west, north, central and south India involving a total of 53 microbiologists/pathologists.

Samples used for the evaluation:

A total of 264 fresh clean catch, midstream, morning voided samples were collected and used for testing within 2-3 hours.

MICROPRO™ BCS reagents used for the evaluation:

Following are the lot details of the MICROPRO™ BCS reagents used in the all India evaluation

MICROPRO™ BCS kit	Lot. No. AA1
MICROPRO™ ID kit	Lot No. MIDO6161

Procedure:

The test procedure, as mentioned in the packinsert of MICROPRO™ BCS and MICROPRO™ ID system was followed in the pan India evaluation along with the conventional Solid plate culture method (SPC) and the culture identification method.

Summary of the Results- Pan India

Table 1: Detection of UTI Samples

UTI culture method	Total No. of Samples	Positive samples	False positive	Negative samples	False negative	Mixed infection
Micropro BCS	264	98	0	159	2	05
Plate culture	264	101	0	159	0	04

(2) Table 2: Identification of Positive UTI Samples

Pathogens	MICROPRO™ ID	Conventional Identification
E.coli	59	58
E. faecalis	06	06
S. pyogenes	03	03
P. mirabilis	00	00
Proteus.spp	01	01
P.aeruginosa	07	08
Citrobacter spp.	03	03
Klebsiella pneumoniae	04	04
Staph group	11	11
S. haemolyticus	00	01
Providencia	00	01
Candida	00	02
Yeast	00	01
Total	94	99
Unidentified	4	2

Discussion:

(1) A total of 264 fresh clean catch, midstream, morning voided samples were collected for the pan India evaluation. These fresh samples were used for testing with MICROPRO™ BCS and Standard Plate Culture technique within 3 hours of collection .

(2) Out of the total 264 samples, 98 samples were detected as true positives and 159 samples as true negatives by MICROPRO™ BCS within 4 hours of incubation. With Solid plate culture method after overnight incubation, 101 samples were detected as true positives and 159 samples as true negatives. Refer Table 1. There is a 97% correlation in the detection of positive cases between MICROPRO™ BCS and Solid plate culture.

(3) Samples detected negative by MICROPRO™ BCS were found to have plate count less than 10*3 cfu/ml .

(4)Two cases of false negative was observed with MICROPRO™BCS, (Refer Zone wise details **Location: Karnataka**) which were detected as positive by Solid plate culture (SPC) after 48 hours of incubation; These two cases were found to be *Staphylococcus haemolyticus* and *Providencia spp*. Statistically these rare samples account for less than 1% of cases (2 out of 264 in our case).

(5)Further all the UTI positive samples were identified using MICROPRO™ID Kit within 30 minutes. The results were confirmed by the conventional identification method preferred by the respective Microbiologists and Pathologists in the laboratories in India .

(5) Out of 98 positive samples 59 (60%) were identified as *E. coli* along with rest of the cultures by MICROPRO™ BCS whereas 58 of 101 positive cases (57%) were identified as *E. coli* using Solid plate culture technique (SPC). Refer Table 2.

(6) Five mixed infection cases were correctly identified by MICROPRO™ ID kit where a mixed biochemical profile was generated. Only four mixed infection cases were identified with conventional Plate Culture technique.

(7) One out of the five mixed infection case showed the growth of both *E. coli* and *pseudomonas* in MICROPRO™ ID Kit whereas SPC identified it as positive case with only pseudomonas growth.

(8) MICROPRO™ BCS detected positive infection in three fungal cases (Refer Zone wise details **Location : Kerala**) but couldn't identify them, because fungal identification kit is not available. But the same was detected and identified with solid plate culture (SPC) after 2-3 days of incubation.

(9) SPC technique could not identify one sample with *E. coli*, detected by MICROPRO™ BCS . **Location : Kerala**

(10) One sample which was detected as borderline infection in both SPC and MICROPRO™ BCS remain unidentified by both the identification methods .**Location : Kerala**

(11)Overall,when MICROPRO™ BCS results were compared to SPC results, 96-97 % correlation was observed between the two techniques.

Detailed Zone wise data is provided in following sheets.

Location: Karnataka

Customer Details:

1. Dr. Kavitha, HOD Microbiology, Anand Diagnostics
2. Dr. Sri Kara Mallya, Professor & HOD of Department of Microbiology, Medical College, Mangalore
3. KMC Hospital, Mangalore

MICROPRO™ **Reagent used:**

MICROPRO™ BCS kit	Lot. No. AA1
MICROPRO™ ID kit	Lot No. MIDO6161

Results

(1) Detection of UTI Samples

UTI culture method	Total Samples	Positive samples	False positive	Negative samples	False negative	Mixed infection
Micropro BCS	39	22	0	13	02	02
Plate culture	39	24	0	13	0	02

Scientific Report

(2) Identification of Positive UTI Samples

Pathogens	MICROPRO™ ID	Conventional Method
E.coli	12	12
E. faecalis	02	02
S. pyogenes	0	0
P. mirabilis	0	0
Proteus.spp (vulgaris)	01	01
P.aeruginosa	02	02
Citrobacter spp.	0	0
Klebsiella pneumoniae	02	02
Staph group	03	03
S. haemolyticus	0	01
Providencia	0	01
Total	22	24

From the above evaluation

With MICROPRO™ BCS, two false negative cases were observed, which were detected as positive by plate culture after 48 hours of incubation. These were identified as *Staphylococcus haemolyticus and Providencia spp.* which are rare species that account for less than 1% of the cases.

Location: Gujarat

Customer Details:

1. Mr. Paresh R. Kapopara, Advance Diagnostics
2. Dr. Manish Patel, HOD Microbiology, Smimer Hospital, Surat
3. Dr. Frenil Munim, MD Microbiology, SRL Diagnostics Abha Laboratory, Surat
4. Dr. Hetal Wala, MD Microbiology, Sanket Metropolis, Vadodara
5. Dr. Dharmendra Patel, MD Microbiology, Bankers Heart Hospital, Vadodara

MICROPRO™ **Reagent used:**

MICROPRO™ BCS kit	Lot. No. AA1
MICROPRO™ ID kit	Lot No. MIDO6161

Results

(1) Detection of UTI Samples

UTI culture method	Total Samples	Positive samples	False positive	Negative samples	False negative	Mixed infection
Micropro BCS	03	01	0	02	0	0
Plate culture	03	01	0	02	0	0

(2) Identification of Positive UTI Samples

Pathogens	MICROPRO™ ID	Conventional Method
E.coli	0	0
E. faecalis	01	01
S. pyogenes	0	0
P. mirabilis	0	0
Proteus.spp (vulgaris)	0	0
P.aeruginosa	0	0
Citrobacter spp.	0	0
Klebsiella pneumoniae	0	0
Total	01	01

Location: Rajasthan

Customer Details:

1. Dr. Rajesh, Reliable Diagnostics, Jaipur
2. Dr. Ashok Kumar, Goyal Hospital, Jodhpur
3. Dr. Rashmi Sharma, Govind Diagnostics Clinic, Jodhpur
4. Dr. Manish, Reliable Diagnostics Center, Jodhpur
5. Dr. Chetan Jain, Amit X-ray & Lab, Jodhpur
6. Dr. Yogesh Singh, Dr. B Lal Chemical Laboratory, Pvt. Ltd., Jaipur

MICROPRO™ **Reagent used:**

MICROPRO™ BCS kit	Lot. No. AA1
MICROPRO™ ID kit	Lot No. MIDO6161

Scientific Report

Results

(1) Detection of UTI Samples

UTI culture method	Total Samples	Positive samples	False positive	Negative samples	False negative	Mixed infection
Micropro BCS	18	09	0	09	0	0
Plate culture	18	09	0	09	0	0

(2) Identification of Positive UTI Samples

Pathogens	MICROPRO™ ID	Conventional Method
E.coli	06	06
E. faecalis	02	02
S. pyogenes	0	0
P. mirabilis	0	0
Proteus.spp	0	0
P.aeruginosa	0	0
Citrobacter spp.	0	0
Klebsiella pneumoniae	0	0
Staph group	01	01
Total	09	09

Location: Pune

Customer Details:

1. Dr. Alka Karmarkar, Micro Find Diagnostics, Sanjeevan Hospital
2. Dr. Vikas Mandleeha, Shraddha Pathology Laboratory
3. Dr. Madhumanti Abhyankar, Golwikar Metropolis Health Services Pvt. Ltd.
4. Dr. Satav Pathology Lab
5. Dr. Maithli Kavthekar, Sahydri Hospital
6. Dr. Sampada Patwardhan, Deenanth Mangeshkar Hospital

MICROPRO™ **Reagent used:**

MICROPRO™ BCS kit	Lot. No. AA1
MICROPRO™ ID kit	Lot No. MIDO6161

Results

(1) Detection of UTI Samples

UTI culture method	Total Samples	Positive samples	False positive	Negative samples	False negative	Mixed infection
Micropro BCS	21	11	0	09	0	01
Plate culture	21	11	0	09	0	01

(2) Identification of Positive UTI Samples

Pathogens	MICROPRO™ ID	Conventional Method
E.coli	10	10
E. faecalis	0	0
S. pyogenes	0	0
P. mirabilis	0	0
Proteus.spp	0	0
P.aeruginosa	0	0
Citrobacter spp.	01	01
Klebsiella pneumoniae	0	0
Staph group	0	0
Total	11	11

Location: East

Customer Details:

1. Dr. J. Jena, KIMS
2. Dr. Pratima Saikai, GNRC, Dispur, Guwahati, Assam
3. Dr. Rajumoni Sharma, Nalbari Materinity Hospital, Assam
4. Dr. Deborati Dey, Merina Hospital, Thana Road, Jalpaiguri
5. Dr. Arunava Sarkar, Neotia Hospital, Uttarayan, Siliguri
6. Mr. Sujit Chakrobarty, Orchid Diagnostic, Jalpaguri
7. Dr. Savantani Endow Dutta, Merina Hospital, Thana Road, Jalpaiguri
8. Dr. Kumar, Burnpur Hospital, Asansol
9. Dr. Hari Das Majee, Avishkar Diagnostic, Asansol
10. Mr. Sandeep, Millenium Diagnostic Center, Asansol
11. Jyoti Pathology Laboratory, Jorhat
12. Dr. Kalyan Kumar Baruch, M. D. Pathology, Patholab, Jorhat

Scientific Report

MICROPRO™ **Reagent used:**

MICROPRO™ BCS kit	Lot. No. AA1
MICROPRO™ ID kit	Lot No. MIDO6161

Results

(1) Detection of UTI Samples

UTI culture method	Total Samples	Positive samples	False positive	Negative samples	False negative	Mixed infection
Micropro BCS	70	13	0	56	0	01
Plate culture	70	13	0	56	0	01

(2) Identification of Positive UTI Samples

Pathogens	MICROPRO™ ID	Conventional Method
E.coli	07	07
E. faecalis	0	0
S. pyogenes	0	0
P. mirabilis	0	0
Proteus.spp	0	0
P.aeruginosa	01	01
Citrobacter spp.	01	01
Klebsiella pneumoniae	0	0
Staph group	04	04
Total	13	13

Location: Uttar Pradesh

Customer Details:

1. Dr. S. S. Soni, Doctors X-Ray & Pathology, Kanpur
2. Dr, Mamta Barthwal, Indira Diagnostic Center, Lucknow
3. Dr. Parvati, Upadhyaya, Regency Hospital, Kanpur
4. Dr. Richa Mishra, SGPGI, Lucknow
5. Dr. Dimple K. Sinha, Medilab Pathology, Faizabad
6. Dr. Sujatha, Rama Medical College, Kanpur
7. Dr. Vikas Mishra, Paliwal Diagnostics, Kanpur
8. Dr. Arun Gupta, Gian Pathology, Kanpur
9. Dr. Abhijeet Singh, Sadbhawana Hospital, Lucknow
10. Dr. S. N. Ameen, Sarkar Diagnostics, Lucknow
11. Dr. R. K. Rastogi, Modern Pathology, Lucknow
12. Dr. V. K. Gupta, Deoki Hospital, Lucknow

MICROPRO™ **Reagent used:**

MICROPRO™ BCS kit	Lot. No. AA1
MICROPRO™ ID kit	Lot No. MIDO6161

Results

(1) Detection of UTI Samples

UTI culture method	Total Samples	Positive samples	False positive	Negative samples	False negative	Mixed infection
Micropro BCS	41	16	0	25	0	0
Plate culture	41	16	0	25	0	0

(2) Identification of Positive UTI Samples

Pathogens	MICROPRO™ ID	Conventional Method
E.coli	11	11
E. faecalis	0	0
S. pyogenes	01	01
P. mirabilis	0	0
Proteus.spp	0	0
P.aeruginosa	02	02
Citrobacter spp.	01	01
Klebsiella pneumoniae	0	0
Staph group	01	01
Toral	16	16

Location: Madhya Pradesh

Customer Details:

1. Dr. Rashmi Nichlani, S V Diagnostic Centre, Bhopal
2. Dr. I. P. Singh, Kasturba Hospital, Bhopal
3. Dr. Rajendra Tantuye, Nidan Pathology, Bhopal

MICROPRO™ **Reagent used:**

MICROPRO™ BCS kit	Lot. No. AA1
MICROPRO™ ID kit	Lot No. MIDO6161

Scientific Report

Results

(1) Detection of UTI Samples

UTI culture method	Total Samples	Positive samples	False positive	Negative samples	False negative	Mixed infection
Micropro BCS	21	06	0	15	0	0
Plate culture	21	06	0	15	0	0

(2) Identification of Positive UTI Samples

Pathogens	MICROPRO™ ID	Conventional Method
E.coli	03	03
E. faecalis	0	0
S. pyogenes	02	02
P. mirabilis	0	0
Proteus.spp	0	0
P.aeruginosa	01	01
Citrobacter spp.	0	0
Klebsiella pneumoniae	0	0
Staph group	0	0
Totsl	06	06

Location: Chennai

Customer Details:

1. Dr. Arivarasan, Bose Clinical Lab & X-Rays, Madurai
2. Dr. Kavipriya, MD Microbiology, Apollo KH Hospital, Melvisharam

MICROPRO™ **Reagent used:**

MICROPRO™ BCS kit	Lot. No. AA1
MICROPRO™ ID kit	Lot No. MIDO6161

Results

(1) Detection of UTI Samples

UTI culture method	Total Samples	Positive samples	False positive	Negative samples	False negative	Mixed infection
Micropro BCS	16	06	0	10	0	0
Plate culture	16	06	0	10	0	0

(2) Identification of Positive UTI Samples

Pathogens	MICROPRO™ ID	Conventional Method
E.coli	04	04
E. faecalis	0	0
S. pyogenes	0	0
P. mirabilis	0	0
Proteus.spp	0	0
P.aeruginosa	0	0
Citrobacter spp.	0	0
Klebsiella pneumoniae	0	0
Staph group	02	02
Totsl	06	06

Location: Hyderabad

Customer Details:

1. Krishna Imaging and Diagnostics Pvt. Ltd.

MICROPRO™ **Reagent used:**

MICROPRO™ BCS kit	Lot. No. AA1
MICROPRO™ ID kit	Lot No. MIDO6161

Results

(1) Detection of UTI Samples

UTI culture method	Total Samples	Positive samples	False positive	Negative samples	False negative	Mixed infection
Micropro BCS	2	0	0	2	0	0
Plate culture	2	0	0	2	0	0

Discussion:
As there were no positive samples in the above evaluation no identification test was required to be performed.

Location: Kerala

Customer Details:
1. Mr. Shiju, Lab In Charge, KIMS Alshifa, Ootty Road Perinthalmanna

MICROPRO™ **Reagent used:**

MICROPRO™ BCS kit	Lot. No. AA1
MICROPRO™ ID kit	Lot No. MIDO6161

Results
(1) Detection of UTI Samples

UTI culture method	Total Samples	Positive samples	False positive	Negative samples	False negative	Mixed infection
Micropro BCS	30	13	0	16	0	1
Plate culture	30	14	0	16	0	0

(2) Identification of Positive UTI Samples

Pathogens	MICROPRO™ ID	Conventional Method
E.coli	5	4
E. faecalis	1	1
S. pyogenes	0	0
P. mirabilis	0	0
Proteus.spp	0	0
P.aeruginosa	1	2
Citrobacter spp.	0	0
Klebsiella pneumoniae	2	2
Staph group	0	0
Candida	0	2
Yeast	0	1
Total	9	12
Unidentified	4	2

Discussion:
MICROPRO™ BCS could detect three fungal cases but could not identify them as fungal identification kit is not available. But the same was detected and identified with Solid plate culture (SPC) after 2-3 days of incubation.

- SPC could not identify one sample with *E. coli*, whereas MICROPRO™ BCS could.
- One sample found with borderline infection in both SPC and MICROPRO™ BCS remain unidentified in both.
- One sample identified as mixed infection with growth of both *E. coli* and *pseudomonas* in MICROPRO™ BCS whereas SPC identified it as positive case with only pseudomonas growth.

Location: Maharashtra

Customer Details:
1. Mrs. Moghe, Pathologist, Kanakavali, Maharashtra

MICROPRO™ **Reagent used:**

MICROPRO™ BCS kit	Lot. No. AA1
MICROPRO™ ID kit	Lot No. MIDO6161

Results
(1) Detection of UTI Samples

UTI culture method	Total Samples	Positive samples	False positive	Negative samples	False negative	Mixed infection
Micropro BCS	3	1	0	2	0	0
Plate culture	3	1	0	2	0	0

(2) Identification of Positive UTI Samples

Pathogens	MICROPRO™ ID	Conventional Method
E.coli	1	1
E. faecalis	0	0
S. pyogenes	0	0
P. mirabilis	0	0
Proteus.spp	0	0
P.aeruginosa	0	0
Citrobacter spp.	0	0
Klebsiella pneumoniae	0	0
Staph group	0	0
Totsl	1	1

References:

(1). Practical Medical Microbiology, Mackie and MacCartney, Vol 2, 13 th ed, Churchill Livingston 1989, Edited by J,G Collee Duguid, A.G. Fraser, B.P. Marmion. (2). Detection, Prevention and Management of Urinary Tract infections, C.M Kunin, 4th Edition, 1987, (3). McPherson RA, Ben-Ezra J. Basic examination of urine. In: McPherson RA, Pincus MR, eds. (Henry's Clinical Diagnosis and Management by Laboratory Methods.) 22nd ed. Philadelphia, PA: Elsevier Saunders; 2011:chap 28. (4). Hooton TM, Bradley SF, Cardenas DD, et al. Diagnosis, prevention, and treatment of catheter-associated urinary tract infection in adults: 2009 International Clinical Practice Guidelines from the Infectious Diseases Society of America. Clin Infect Dis. 2010; 50(5):625-663. (5). Ban KM, Easter JS. Selected urologic problems. In: Marx JA, Hockberger RS, Walls RM, et al, eds. Rosen's Emergency Medicine: Concepts and Clinical Practice. 7th ed. Philadelphia, Pa: Mosby Elsevier; 2009: chap 97. (6). Dean AJ, Lee DC. Bedside laboratory and microbiologic procedures. In: Roberts JR, Hedges JR, eds. Clinical Procedures in Emergency Medicine. 5th ed. Philadelphia, Pa: Saunders Elsevier; 2009:chap 68. (7). MacFaddin, Jean F. "Biochemical Tests for Identification of Medical Bacteria." Williams & Wilkins, 1980, pp 173 – 183. (8). Bachoon, Dave S., and Wendy A. Dustman. Microbiology Laboratory Manual. Ed. Michael Stranz. Mason, OH: Cengage Learning, 2008. Exercise 15, "Normal Flora of the Intestinal Tract" Print. (9). Bergey's Manual of Systematic Bacteriology, Vol. 1. Baltimore, Williams and Wilkins, 1984. (10). Nicola F1, Centorbi H, Bantar C, Smayevsky J, Bianchini H., Utility of pyrrolidonyl-arylamidase detection for typing Enterobacteriaceae and non-fermenting Gram-negative bacteria, Rev Argent Microbiol. 1995 Oct-Dec;27(4):204-9. (11). Gordon J, McLeod JW. Practical application of the direct oxidase reaction in bacteriology. J Pathol Bacteriol 1928; 31:185-90. (12). Koneman EW, Allen SD, Janda WM, Schreckenberger PC, Winn WC Jr. Color atlas & textbook of diagnostic microbiology. 5th ed. Philadelphia: JB Lippincott, 1997. (13). L Essers and K Radebold, Rapid and reliable identification of Staphylococcus aureus by a latex agglutination test. J Clin Microbiol. Nov 1980; 12(5): 641–643. (14). Kloos, W.E. and P.B. Smith. Staphylococci. 1980. Manual of Clinical Microbiology, 3rd ed. E.H. Lennette, A. Balows, W.J. Hausler, Jr. and J.P. Truant, ed. ASM, Washington, D.C. (15). Finegold, S.M. and E.E. Sweeney. 1961. New Selective and Differential Medium for Coagulase-Positive Staphylococci Allowing Rapid Growth and Stain Differentiation. J. Bacteriol.; 81:636-641. (16). Data on file: Microxpress (P) Ltd.

Scientific Report

Performance validation of the different batches of MICROPRO™ Broth Culture System (BCS), a spectrophotometric/turbidimetric method for the detection of Urinary Tract infections against solid plate culture method.

Abstract:

Objective:
To validate the performance of MICROPRO™ BCS using sterile urine spiked with bacterial suspension of known concentration (cfu/ml) and comparing with the plate culture system, numerically correlation.

Study method
Five hundred and sixty-eight fresh samples were prepared for the validation study involving 16 R&D batches and 3 Commercial batches of MICROPRO™ Broth Culture System (BCS).
The study was conducted from March 2015 to December 2015.
For every evaluation, fresh urine samples were collected from healthy people and tested for infection or contamination via plating method. Sterile urine samples were retained and stored aseptically. The samples were then spiked with the dilutions of ATCC cultures prepared as per McFarland standards. The final bacterial concentration attained in the samples was in the range of 10*4 – 10*7 cfu/ml. The bacterial culture dilutions thus prepared were tested as samples and evaluated on both MICROPRO™ BCS and Plate culture technique.
Further the growth in MICROPRO™ BCS cuvettes were then identified using MICROPRO™ ID (Biochemical) Kit and that on the plate culture by the conventional identification method.

Result and Conclusion
Out of the total 568 samples used for the study, MICROPRO™ Broth Culture System (BCS) yielded 553 (97.3%) correct results and Solid Plate culture (SPC) yielded 556 (97.9%) correct results and correlated numerically.
The ATCC spiked urine samples were accurately identified (100%) by MICROPRO™ ID and the conventional identification technique.

Background:
MICROPRO™ Broth Culture System (BCS) an assay system based on spectrophotometric/turbidimetric method detects, enumerates and identifies most urinary pathogens within 5 hours.
The current globally acknowledged gold standard for detection, diagnosis and treatment of UTI's remains the standard plate culture method followed by the antibiogram. This entire process takes atleast 48 hours for a treatment decision.
MICROPRO™ Broth Culture System (BCS) based on a simple procedure can be adapted by most laboratories and can expedite the process of detection, identification and treatment of Urinary tract infection cases.
The performance of MICROPRO™ Broth Culture System (BCS) was validated over the period, from March 2015 to December 2015 using urine spiked with bacterial suspension of known concentration (cfu/ml) and the results compared with the plate culture method. The details of the validation report is complied as follows.

Procedure:
A total of 16 R&D batches and 3 Commercial batches of MICROPRO™ BCS manufactured in the year 2015 were validated for their performance using freshly collected sterile urine samples spiked with bacteria of known concentration.

(1) As a part of the test procedure freshly collected urine samples were checked for infection or contamination by the plating method.

(2) The sterile urine samples were then retained, stored aseptically and used in the evaluation.

(3) McFarland Standards were prepared for the eight ATCC cultures as per Table No. 1.

(4) The bacterial cultures were then serially diluted in the sterile urine aliquots as mentioned below to yield a final bacterial concentration in urine as mentioned in Table No. 1.

100 µl of 10*8 cfu/ml bacterial standard + 900 µl of Sterile Urine = 1 ml of 10*7 cfu/ml bacterial suspension

100 µl of 10*7 cfu/ml bacterial suspension + 900 µl of Sterile Urine = 1 ml of 10*6 cfu/ml bacterial suspension

100 µl l of 10*6 cfu/ml bacterial suspension + 900 µl of Sterile Urine = 1 ml of 10*5 cfu/ml bacterial suspension

100 µl of 10*5 cfu/ml bacterial suspension + 900 µl of Sterile Urine = 1 ml of 10*4 cfu/ml bacterial suspension

Table No 1.

Sr. No.	Cultures	McFarland/cfu/ml	Final Conc range. of Bacteria-spiked Urine
1.	*E. coli*	0.5/ 10*8 cfu/ml	10*4 – 10*7 cfu/ml
2	*E. faecalis*	0.5/ 10*8 cfu/ml	10*4 – 10*7 cfu/ml
3.	S. *pyogenes*	0.5/ 10*8 cfu/ml	10*4 – 10*7 cfu/ml
4.	*P. mirabilis*	0.5/ 10*8 cfu/ml	10*4 – 10*7 cfu/ml
5.	*P. vulgaris*	0.5/ 10*8 cfu/ml	10*4 – 10*7 cfu/ml
6.	*P. aeruginosa*	0.5/ 10*8 cfu/ml	10*4 – 10*7 cfu/ml
7.	*C. freundii*	0.5/ 10*8 cfu/ml	10*4 – 10*7 cfu/ml
8.	*K. pneumoniae*	0.5/ 10*8 cfu/ml	10*4 – 10*7 cfu/ml

(5) The bacterial culture dilutions (10*4 ,10*5, 10*6,10*7) so prepared were tested as samples and evaluated on both MICROPRO™ BCS and Plate culture.
(6) MICROPRO™ BCS results were obtained after 4 hours of incubation.
(7)Plate culture results were obtained after overnight incubation.
(8) All tests were performed in duplicates.

Note: Plates where contamination was observed during the procedure, the corresponding MICROPRO™ BCS results were not considered.
This protocol was repeated regularly with each lot of MICROPRO™ BCS manufactured.

Evaluation Data:
Following is the collated data of testing
(1) 16 R & D lots
Period of testing: March 2015 to June 2015

Date of testing	No.of Samples
12/03/2015	16
14/03/2015	16
15/03/2015	16
17/03/2015	16
20/03/2015	16
24/03/2015	16
27/03/2015	16
31/03/2015	16

Date of testing	No.of Samples
02/04/2015	40
17/04/2015	40
04/05/2015	40
20/05/2015	40
04/06/2015	40
10/06/2015	40
17/06/2015	40
26/06/2015	40

Note:
(1) For the period from March 2015 and June 2015, R&D lots were tested before starting commercial batch production.
(2) In the month of March 2015, 16 samples were used for testing i.e.,one positive and one negative for each of the 8 UTI cultures. For positive sample, only one dilution with the lowest value 10*4 was used to check for sensitivity of the kit . A total of 8 positive and 8 negative samples were tested.
(3) From April onwards, 40 samples were used for testing, 4 positives (10*4 ,10*5, 10*6, 10*7dilutions) and one negative for each of the 8 UTI cultures was used in the evaluation. A total of 32 positive and 8 negative samples were tested.

(2) 3 Commercial lots
Period of testing: June 2015 to December 2015

Date of testing	MICROPRO BCS Batch No	No.of Samples
25/06/2015	AA1	40
27/08/2015	AA2	40
18/12/2015	AA3	40

Results- UTI detection

Samples	Cultures	Bacteria - Spiked Urine	No. of Samples	Micropro™ BCS Result	Plate Culture Result
A1	*E. coli*	Negative control	19	19	18
A2		10*4 cfu/ml	19	19	19
A3		10*5 cfu/ml	11	11	11
A4		10*6 cfu/ml	11	11	11
A5		10*7 cfu/ml	11	11	11
B1	*E. faecalis*	Negative control	19	18	18
B2		10*4 cfu/ml	19	19	19
B3		10*5 cfu/ml	11	11	11
B4		10*6 cfu/ml	11	10	10
B5		10*7 cfu/ml	11	11	11
C1	*S. pyogenes*	Negative control	19	19	19
C2		10*4 cfu/ml	19	19	19
C3		10*5 cfu/ml	11	11	10
C4		10*6 cfu/ml	11	07	06
C5		10*7 cfu/ml	11	08	09
D1	*P. mirabilis*	Negative control	19	19	19
D2		10*4 cfu/ml	19	19	19
D3		10*5 cfu/ml	11	11	11
D4		10*6 cfu/ml	11	11	11
D5		10*7 cfu/ml	11	10	11
E1	*P. vulgaris*	Negative control	19	18	18
E2		10*4 cfu/ml	19	19	19
E3		10*5 cfu/ml	11	11	11
E4		10*6 cfu/ml	11	11	11
E5		10*7 cfu/ml	11	11	11
F1	*P. aeruginosa*	Negative control	19	19	19
F2		10*4 cfu/ml	19	19	19
F3		10*5 cfu/ml	11	10	11
F4		10*6 cfu/ml	11	11	11
F5		10*7 cfu/ml	11	11	11
G1	*C. freundii*	Negative control	19	19	19
G2		10*4 cfu/ml	19	19	19
G3		10*5 cfu/ml	11	10	11
G4		10*6 cfu/ml	11	11	11
G5		10*7 cfu/ml	11	11	11
H1	*K. pneumoniae*	Negative control	19	19	19
H2		10*4 cfu/ml	19	17	19
H3		10*5 cfu/ml	11	11	11
H4		10*6 cfu/ml	11	11	11
H5		10*7 cfu/ml	11	11	11
TOTAL			568	553	556

Discussion- UTI detection
A total of 568 known positive and negative samples were tested with both the techniques.

1. MICROPRO™ BCS yielded 553 (97.3%) correct results and Plate Culture technique yielded 556

(97.9%) correct results.

2. Three Negative samples yielded as positive due to contamination of controls itself during the procedure.
3. Contamination was obtained with positive samples in Plate culture also, but due to low cfu (<100cfu/ml) have been neglected.
4. With *E. faecalis,* (10*6 cfu/ml), one out of 11 samples showed lower concentration of 10*3 – 10*5 cfu/ml in MICROPRO™ BCS and the same sample on Plate Culture showed the count less than 10*5 cfu/ml
5. With *S. pyogenes*, (10*6 cfu/ml), Four out of 11 samples showed lower concentration of 10*3 – 10*5 cfu/ml in MICROPRO™ BCS and five out of 11 samples showed less than 10*4 cfu/ml in Plate Culture.
6. With *S. pyogenes*, (10*7 cfu/ml), Three out of 11 samples showed lower concentration of 10*3 – 10*5 cfu/ml in MICROPRO™ BCS and two out of 11 samples showed less than 10*5 cfu/ml in Plate Culture.
7. With *P. aeruginosa* and *C. freundii* both, (10*5 cfu/ml), one out of 11 samples showed lower concentration of 10*3–10*5 cfu/ml in MICROPRO™ BCS, the results were fine in Plate Culture.
8. With *K.pneumoniae*, (10*4 cfu/ml), Two out of the 19 samples showed higher concentration of 10*5 - 10*5 cfu/ml in MICROPRO™ BCS and the results were fine in Plate Culture.

UTI Identification Procedure

Following Incubation, the growth in MICROPRO™ BCS cuvettes (A & B) were identified using MICROPRO™ ID (Biochemical) Kit which showed standard biochemical profile as shown in table below

Result Interpretation of wells						Positive result in wells	UTI Pathogens Test Conclusion
W1 (Catalase Test)	W2 (VP Test)	W3 (PYR Test)	W4 (Oxidase Test)	W5 (TDA Test)	W6 Indole Test)		
Bubbles	-	-	-	-	Pink ring	1 & 6	***E. coli***
-	Light to Dark Pink	Dark cherry red	-	-	-	2 & 3	***Enterococcus faecalis***
-	-	Dark cherry red	-	-	-	3	***Streptococcus pyogenes***
Bubbles	-	-	-	Light to Dark Brown	-	1 & 5	***Proteus mirabilis***
Bubbles	-	-	-	Light to Dark Brown	Pink ring	1 ,5 & 6	***Proteus spp.***
Bubbles	-	-	Blue to Purple	-	-	1 & 4	***Pseudomonas aeruginosa***
Bubbles	-	Dark cherry red	-	-	-	1 & 3	***Citrobacter spp.***
Bubbles	Light to Dark Pink	-	-	-	-	1 & 2	***Klebsiella pneumoniae***

Similarly, post incubation the plate cultures were subjected to conventional identification methods as in the following table

Sr. No	Cultures	Gram Character	Motility	Morphology	Other	Result
1	*E. coli*	Gram negative negative bacilli	Motile	Dry flat Lactose fermenting with bile precipitation colonies on MacConkey agar with Crystal Violet, NaCl and 0.15% bile salt	IMVIC reaction Methyl Red +ve Citrate –ve	Complies
2	*E. faecalis*	Gram positive cocci in pairs	Non-motile	Tiny deep pink Lactose fermenting colonies on MacConkey agar with 0.5% sodium taurocholate	Growth on bile esculin agar with positive bile esculin hydrolysis test	Complies
3	*S. pyogenes*	Gram positive cocci in pairs	Non-motile	Pin point colonies with wide zone of beta hemolysis on blood agar	Sensitive to bacitracin 0.04 unit	Complies
4	*P. mirabilis*	Gram negative bacilli	Motile	Non-Lactose fermenting colonies on MacConkey agar with Crystal Violet, NaCl and 0.15% bile salt	Swarming on blood agar Urease +ve	Complies
5	*P. vulgaris*	Gram negative bacilli	Motile	Non-Lactose fermenting colonies on MacConkey agar with Crystal Violet NaCl and 0.15% bile salt	Swarming on blood agar Urease +ve	Complies
6	*P. aeruginosa*	Gram negative bacilli	Motile	Non-Lactose fermenting irregular colonies on MacConkey agar with Crystal Violet, NaCl and 0.15% bile salt	Growth on Cetrimide agar with bluish green pigmentation	Complies
7	*C. freundii*	Gram negative bacilli	Motile	Lessmucoid Lactose fermenting colonies on MacConkey agar with Crystal Violet, NaCl and 0.15% bile salt	-----	Complies
8	*K. pneumoniae*	Gram negative bacilli	Motile	Mucoid Lactose fermenting colonies on MacConkey agar with Crystal Violet,	IMVIC reaction Methyl Red-ve Citrate +ve Urease +ve	Complies

Results - UTI identification

Samples	Cultures	Bacteria - Spiked Urine	No. of Samples	Micropro™ BCS Result	Plate Culture Result
A2	*E. coli*	10*4 cfu/ml	19	19	19
A3		10*5 cfu/ml	11	11	11
B2	*E. faecalis*	10*4 cfu/ml	19	19	19
B3		10*5 cfu/ml	11	11	11
C2	*S. pyogenes*	10*4 cfu/ml	19	19	19
C3		10*5 cfu/ml	11	11	10
D2	*P. mirabilis*	10*4 cfu/ml	19	19	19
D3		10*5 cfu/ml	11	11	11
E2	*P. vulgaris*	10*4 cfu/ml	19	19	19
E3		10*5 cfu/ml	11	11	11
F2	*P. aeruginosa*	10*4 cfu/ml	19	19	19
F3		10*5 cfu/ml	11	10	11
G2	*C. freundii*	10*4 cfu/ml	19	19	19
G3		10*5 cfu/ml	11	10	11
H2	*K. pneumoniae*	10*4 cfu/ml	19	17	19
H3		10*5 cfu/ml	11	11	11

Discussion- UTI identification

1. Identification of positive Samples with MICROPRO™ ID and Plate Culture technique yielded 100% correlation with known samples.
2.. Those samples which showed lower concentration (cfu/ml) than known standards, also yielded correct biochemical profile.
3. With *S. pyogenes* (10*4 cfu/ml) which is the lowest limit, 2 hours of extra incubation helps in yielding better biochemical profile.

Conclusion:

MICROPRO™ BCS yielded 97.3% correct results in comparison with Plate Culture technique which demonstrated 97.9% accuracy when tested with sterile urine spiked with bacterial suspension of known concentration (cfu/ml) and both the techniques correlated numerically.

Further identification of UTI cultures with MICROPRO™ ID and conventional identification methods yielded 100% correlation with known samples.

References:

(1). Practical Medical Microbiology, Mackie and MacCartney, Vol 2, 13 th ed, Churchill Livingston 1989, Edited by J,G Collee Duguid, A.G. Fraser, B.P. Marmion. (2). Detection, Prevention and Management of Urinary Tract infections, C.M Kunin, 4th Edition, 1987, (3). McPherson RA, Ben-Ezra J. Basic examination of urine. In: McPherson RA, Pincus MR, eds. (Henry's Clinical Diagnosis and Management by Laboratory Methods.) 22nd ed. Philadelphia, PA: Elsevier Saunders; 2011:chap 28. (4). Hooton TM, Bradley SF, Cardenas DD, et al. Diagnosis, prevention, and treatment of catheter-associated urinary tract infection in adults: 2009 International Clinical Practice Guidelines from the Infectious Diseases Society of America. Clin Infect Dis. 2010; 50(5):625-663. (5). Ban KM, Easter JS. Selected urologic problems. In: Marx JA, Hockberger RS, Walls RM, et al, eds. Rosen's Emergency Medicine: Concepts and Clinical Practice. 7th ed. Philadelphia, Pa: Mosby Elsevier; 2009: chap 97. (6). Dean AJ, Lee DC. Bedside laboratory and microbiologic procedures. In: Roberts JR, Hedges JR, eds. Clinical Procedures in Emergency Medicine. 5th ed. Philadelphia, Pa: Saunders Elsevier; 2009:chap 68. (7). MacFaddin, Jean F. "Biochemical Tests for Identification of Medical Bacteria." Williams & Wilkins, 1980, pp 173 – 183. (8). Bachoon, Dave S., and Wendy A. Dustman. Microbiology Laboratory Manual. Ed. Michael Stranz. Mason, OH: Cengage Learning, 2008. Exercise 15, "Normal Flora of the Intestinal Tract" Print. (9). Bergey's Manual of Systematic Bacteriology, Vol. 1. Baltimore, Williams and Wilkins, 1984. (10). Nicola F1, Centorbi H, Bantar C, Smayevsky J, Bianchini H., Utility of pyrrolidonyl-arylamidase detection for typing Enterobacteriaceae and non-fermenting Gram-negative bacteria, Rev Argent Microbiol. 1995 Oct-Dec;27(4):204-9. (11). Gordon J, McLeod JW. Practical application of the direct oxidase reaction in bacteriology. J Pathol Bacteriol 1928; 31:185-90. (12). Koneman EW, Allen SD, Janda WM, Schreckenberger PC, Winn WC Jr. Color atlas & textbook of diagnostic microbiology. 5th ed. Philadelphia: JB Lippincott, 1997. (13). L Essers and K Radebold, Rapid and reliable identification of Staphylococcus aureus by a latex agglutination test. J Clin Microbiol. Nov 1980; 12(5): 641–643. (14). Kloos, W.E. and P.B. Smith. Staphylococci. 1980. Manual of Clinical Microbiology, 3rd ed. E.H. Lennette, A. Balows, W.J. Hausler, Jr. and J.P. Truant, ed. ASM, Washington, D.C. (15). Finegold, S.M. and E.E. Sweeney. 1961. New Selective and Differential Medium for Coagulase-Positive Staphylococci Allowing Rapid Growth and Stain Differentiation. J. Bacteriol.; 81:636-641. (16). Data on file: Microxpress (P) Ltd.

For further information contact :

TULIP DIAGNOSTICS (P) LTD

Gitanjali, Tulip Block, Dr. Antonio Do Rego Bagh, Alto Santacruz, Bambolim Complex Post Office, Goa - 403202, INDIA.

Tel.: +91 832 2458546-50 **Fax :** +91 832 2458544 **E-mail :** sales@tulipgroup.com **Website :** www.tulipgroup.com