Antech's *FIRST*ract™ rapid urine culture demonstrates excellent performance and high sensitivity and specificity in comparison to standard urine culture results.

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INTRODUCTION

Bacterial culture has been the gold standard for the growth, detection, and identification of bacteria in veterinary urine samples since its inception and currently remains the clinical diagnostic test of choice in veterinary medicine. Unfortunately, plating, inoculation, and waiting for bacteria to grow visible colonies is very time-consuming. The turn-around time for actionable results is not ideal for veterinary patients suffering from signs consistent with a urinary tract infection. Veterinarians may prescribe empirical antibiotics for symptomatic relief of a pet's discomfort prior to knowing if an infection exists. In this paper, we will demonstrate a novel approach for accelerated and improved detection of bacteria in urine cultures. Verifying the presence or absence of bacteriuria in a urine sample will facilitate appropriate antibiotic usage, decrease the development of antimicrobial resistance and promote a One Health approach to optimal patient care.

Antech's *FIRST*ract™ employs automated technology to rapidly grow and assess bacteriuria, delivering urine culture results in hours, not days. The *FIRST*ract™ test uses a patented light scattering technology to monitor accelerated bacterial replication activity from the inoculum, providing real-time growth curves yielding rapid detection of bacteria in urine samples. This test is the first automated assay for quick urine culture with highly sensitive and specific results. The identification of positive or negative bacterial growth using *FIRST*ract™ methodology is clinically advantageous over using standard culture alone since it provides rapid and clinically actionable results.

*FIRST*ract™ utilizes 500 μL of urine, inoculated into a proprietary culture broth optimized for aerobic bacterial pathogen growth, and incubated in a controlled setting for up to 5 hours. Samples are maintained in aseptic vials with pierceable hermetic seals that considerably reduce potential contamination. During the analysis, samples are incubated at a controlled temperature and continuously mixed, minimizing sedimentation, flotation, and growth abnormalities.

Interference from erythrocytes, leukocytes, and dead cells is minimized by obtaining an initial baseline reading of turbidity. The amount of light scatter through the inoculum is then measured every 5 minutes using spectrophotometry. An exponential increase in turbidity that is consistent with the presence of viable bacteria in the patient urine sample is then reported as positive growth.

STUDY DESIGN

Comparison of Conventional Urine Culture and Antech's *FIRST*ract™ Urine Test

A total of 565 urine samples without any chemical preservatives were submitted for culture and antibiotic testing. The samples were divided into 2 aliquots. The first aliquot was assayed by *FIRST*ract™ urine culture analysis and the second aliquot was assayed for bacteria by conventional culture methods.

All analyzers for this study were maintained per the manufacturers' instructions, and all laboratory assays followed established standard operating procedures.

PRECISION ANALYSIS, *FIRST*ract™ URINE CULTURE

A total of four urine samples were selected from conventional cultures. Each of the four samples was run ten times on *FIRST*ract™ on the same day, and qualitative results from *FIRST*ract™ were compared to those from standard urine culture.

DATA ANALYSIS AND CALCULATIONS

Collation and calculations were performed using a commercially available spreadsheet program (Microsoft Excel). All statistical and method comparison analyses were performed using a commercially available statistical software program (EP Evaluator, Data Innovations).

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RESULTS

Conventional culture results compared to Antech's *FIRST*ract™ test

Of the 565 urine samples analyzed in this study, 346 samples were negative for bacteria via the standard urine culture technique. Of those 346 negative urine samples, 325 were negative on *FIRST*ract™, while 21 urine samples produced positive results. A total of 219 urine samples were positive for bacteria via the standard urine culture technique, of which 213 produced positive results on *FIRST*ract™, while 6 samples had negative results. The summary of the results obtained with the different methods is shown in Table 1. Sensitivity, specificity and overall accuracy as well as positive and negative predictive values are summarized in Table 2.

Table 1. Correlation Data

	CONVENTIONAL CULTURE		
***FIRST*ract™**		POSITIVE	NEGATIVE
	Positive	213	21
	Negative	6	325

Table 2. Key Statistics from Correlation Studies

PERCENTAGE		CONFIDENCE INTERVAL
Sensitivity	97.26%	94.13% to 98.99%
Specificity	93.93%	90.87% to 96.20%
Positive Predictive Value	91.03%	87.01% to 93.89%
Negative Predictive Value	93.96%	91.14% to 95.88%
Accuracy	95.22%	93.12% to 96.83%

Patient and Urine Characteristics

Of these 565 urine samples, 423 (74.9%) were from canines, 141 (24.9%) were from felines, and 1 (0.2%) was from a rabbit. 261 (46.2%) samples were collected by cystocentesis, 233 (41.2%) samples were collected by unknown methods, 39 samples (6.9%) were collected by free catch or natural void, 31 (5.5%) samples were collected by catheterization, and 1 sample (0.2%) was collected via exam table-top. Finally, a distribution table of urine specific gravity results for the 565 urine samples is reported in Figure 1.

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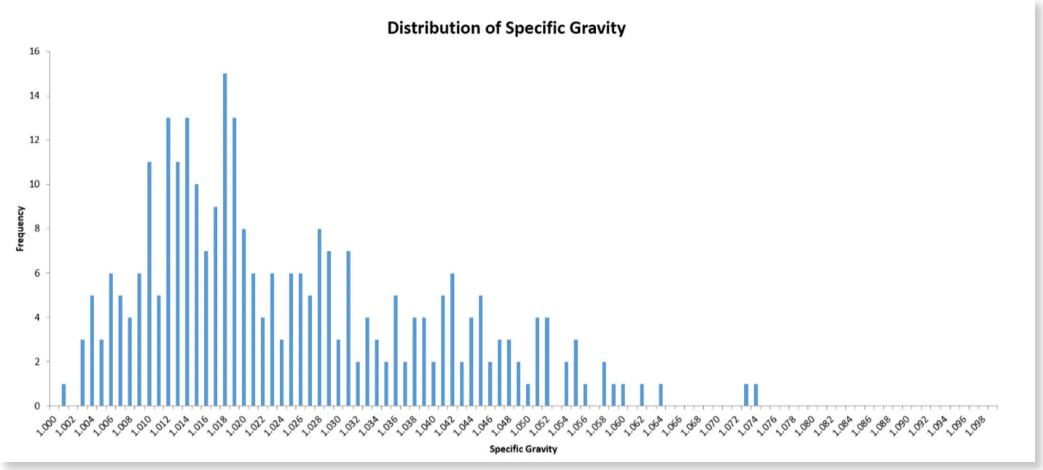
Figure 1. Distribution of Specific Gravity of the Samples Used in the Antech UBS Correlation Study



PRECISION ANALYSIS FOR *FIRST*RACT™

In the precision analysis study, all replicates of the samples used in the *FIRST*ract™ precision analysis matched the results obtained by standard urine culture with a reproducibility of 100% based on 10 replicates.

DISCUSSION

Performance characteristics assessed included sensitivity, specificity, positive predictive value, negative predictive value, and accuracy. These performance characteristics can aid in the clinical interpretation of results relative to standard culture. As demonstrated, the *FIRST*ract™ methodology is highly sensitive and specific. Occasional false positives may occur, however the clinician will receive a final report using standard culture methodology in these instances. Most importantly, false negatives are rare providing the clinician with assurance of timely recognition of an infection.

*FIRST*ract™ will yield a positive or negative result within 24 hours of submission; significantly faster than the standard urine culture method that takes 48 to 72 hours for a final result. Clinical signs such as hematuria, dysuria or pollakiuria are consistent with a urinary tract infection and are common in veterinary medicine, and the need for rapid identification of bacteria in a sample is critical to providing accurate and timely treatment. The use of antibiotics based on clinical suspicion is non-judicious in this age of increasing antibiotic resistance. This practice has been an issue for clinicians who want to provide treatment in a timely manner to their patients. *FIRST*ract™ will yield an accurate result of the presence or absence of bacteriuria in less than 24 hours, allowing veterinarians to make timely and appropriate treatment decisions.

TURBIDITY

Due to the light scattering technology of *FIRST*ract™, samples demonstrating a high degree of turbidity, such as samples with significant hematuria or pyuria, can cause interference and impact results. An initial baseline reading of turbidity is assessed on each urine sample, which will flag any excessively turbid samples that may impact result accuracy. This baseline turbidity assessment ensures that only live bacteria are detected while minimizing the impact of potentially interfering substances such as erythrocytes and leukocytes. Of the 565 urine samples assessed in this correlation study, 30 (5.3%) were determined to be excessively turbid. These *FIRST*ract™ results will be reported as having excessive turbidity and standard urine culture and sensitivity results will still be reported.

Study limitations included the known limitations of traditional urine culture testing and the lack of patient information needed to stratify results by gender, reproductive status, and age. Future investigations should include additional patient demographics.

CONCLUSION

In conclusion, results show that Antech's *FIRST*ract™ test is a valuable and accurate assay for the rapid detection of bacteria in veterinary urine samples. *FIRST*ract™ results are available in hours, providing veterinarians with an expedited confirmation of the presence or absence of bacteriuria. This will allow veterinarians to make well informed treatment plans in a shorter amount of time and promote good practices that support antimicrobial stewardship.

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