Evaluation of the **Vivalytic one Analyser** for detecting **uropathogenic bacteria** and **antimicrobial resistances** in urine samples of urological patients

P1083

J. Hartmann[1,2], M. Fritzenwanker[1,3], C. Imirzalioglu[1,3], T. Hain[1,3], F. Wagenlehner[1,2]

[1]German Center for Infection Research (DZIF). Partner Site Giessen-Marburg-Langen, Campus Giessen, Giessen, Germany

[2]Clinic for Urology, Pediatric Urology and Andrology, Justus Liebig University Giessen, Germany

[3]Institute of Medical Microbiology, Justus Liebig University Giessen, Germany

Background

The **Vivalytic Urinary tract infection** (UTI) test, currently under development, represents a qualitative PCR-based microarray test able to detect twenty-one specific uropathogenic bacteria and seven associated antimicrobial resistance genes in a **point-of-care** (POC) setting in four steps within 146 minutes.

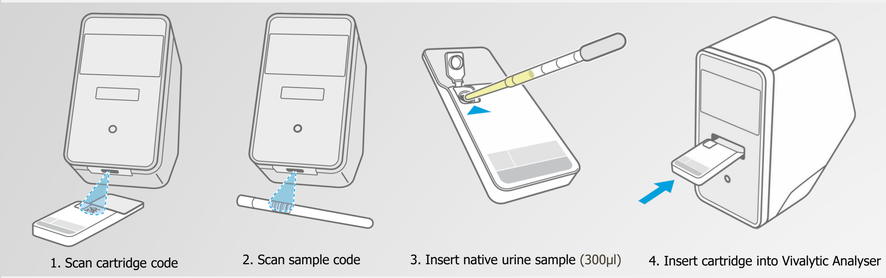


Figure 1: Source: Bosch

Questions

--› What is the diagnostic accuracy of the Vivalytic UTI assay compared to standard-of-care diagnostics?

--› Does sample transport influence the pathogen and resistance detection rate, of the Vivalytic UTI assay?

Methods

In September 2023, we performed the Vivalytic UTI test on 126 consecutive urine samples of urological patients in the University Hospital of Giessen, Germany.

We **preselected** the urine samples for bacteriuria by screening with urine flow cytometry (UFC).

➛ **UFC cut-off ≥70 bacteria/µl.**

We performed the Vivalytic UTI POC test **twice:**
(1) Urological department; **before transport**
(2) Microbiological laboratory; **after transport.**
Results were compared to standard urine culture and antibiotic sensitivity testing according to EUCAST; after transport of urine specimen.

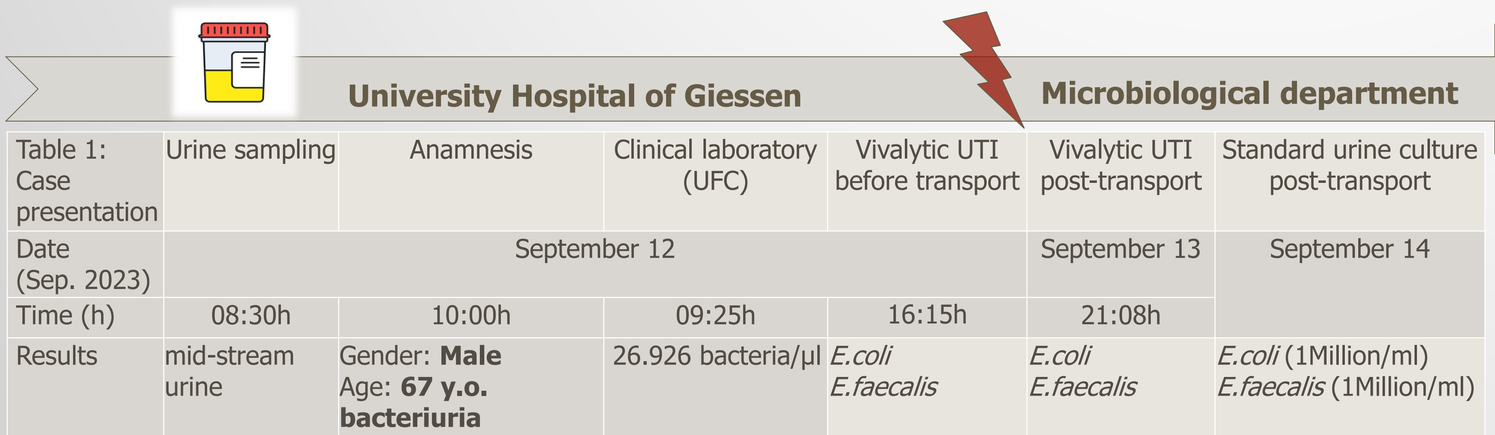


Table 1: Case presentation	Urine sampling	Anamnesis	Clinical laboratory (UFC)	Vivalytic UTI before transport	Vivalytic UTI post-transport	Standard urine culture post-transport
Date (Sep. 2023)	September 12				September 13	September 14
Time (h)	08:30h	10:00h	09:25h	16:15h	21:08h	
Results	mid-stream urine	Gender: **Male** Age: **67 y.o.** **bacteriuria** AB treatment: **Yes**	26.926 bacteria/µl	*E.coli* *E.faecalis*	*E.coli* *E.faecalis*	*E.coli* (1Million/ml) *E.faecalis* (1Million/ml)

Selected 126 urine samples of urological patients

The selected urine samples included native mid-stream urine (88.1%), and catheterized urine (11.9%) from 51 female and 75 male patients with an average age of 62.9 years.

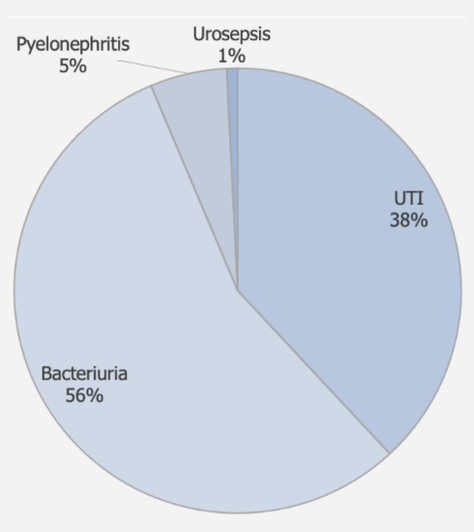


Figure 2: Suspected infections (bacteriuria, UTI, Pyelonephritis, Urosepsis)

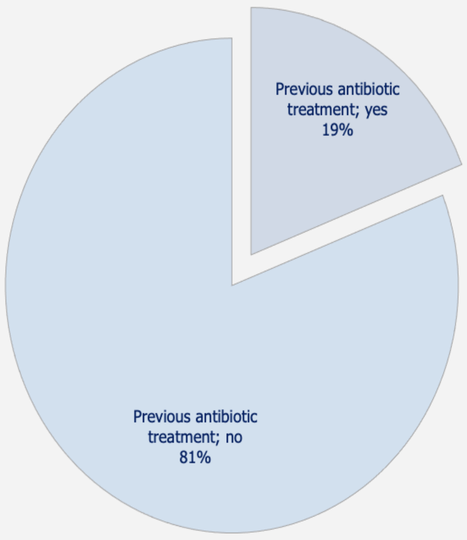


Figure 3: Previous antibiotic treatment (yes/no)

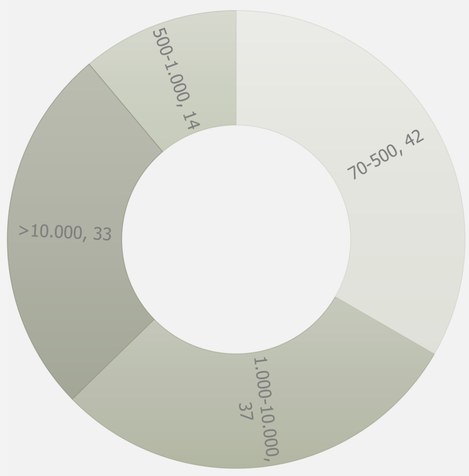


Figure 4: Urine flow cytometry ranges from 70 to 91.195 bacteria/µl

Results

Positive test: one/more uropathogenic species and/or antimicrobial resistance genes detected. Positive test results at the POC before transport (80.95%, 221 pathogen total) compared to after transport (78,57%, 184 pathogen total).

Negative test: no species and/or antimicrobial resistance gene detected.

Invalid test: partial/complete absence of human cellular material. Retesting necessary.

Figure 5: Positive, negative, invalid/lost test results after evaluation of 126 urine samples tested by the Vivalytic UTI test and compared to standard urine culture

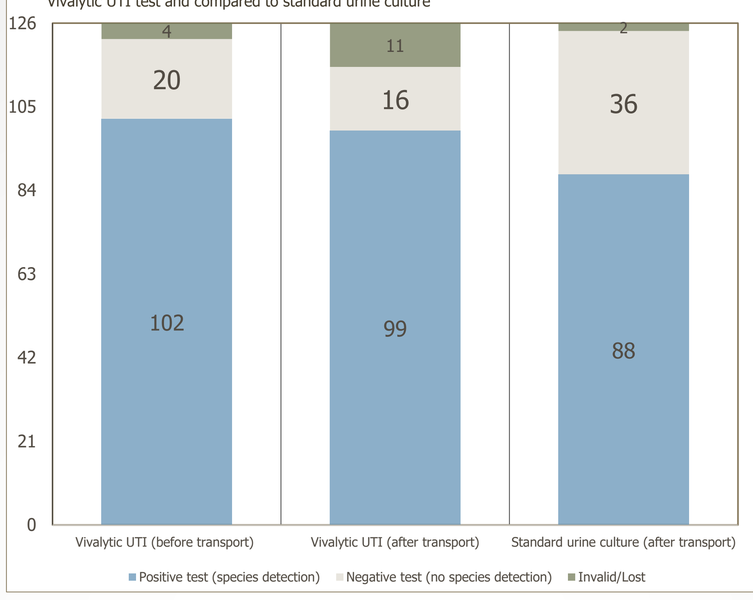
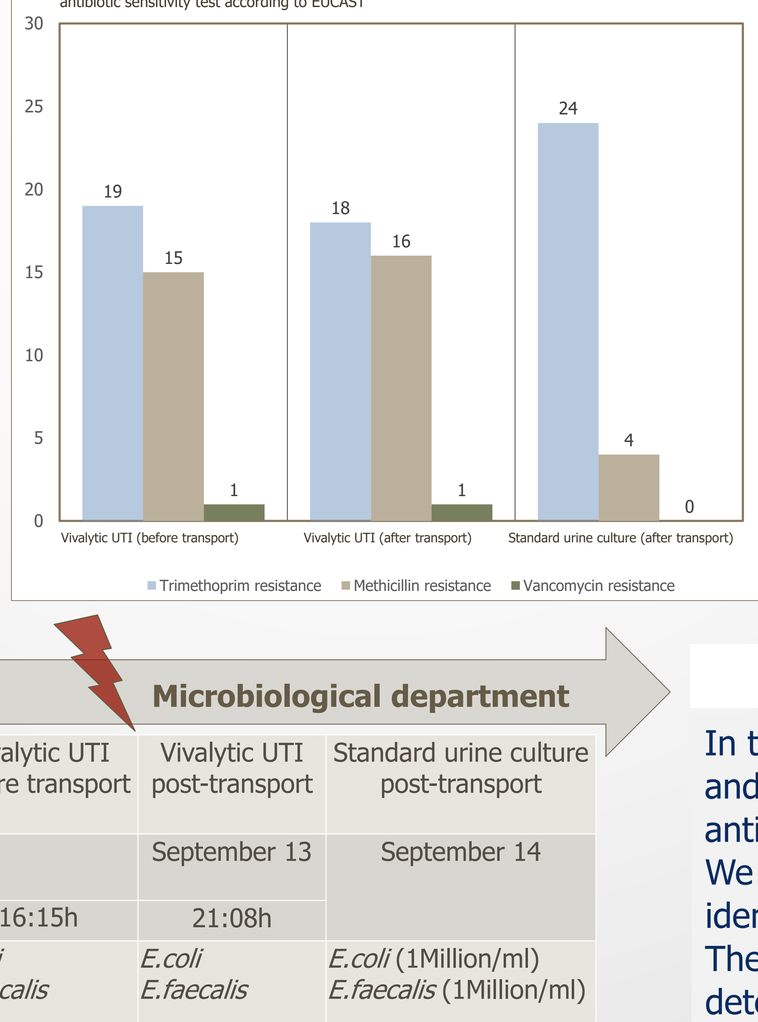


Figure 6: Antibiotic resistance gene detection by using the Vivalytic UTI test compared to standard antibiotic sensitivity test according to EUCAST



Graphs & Tables

The Vivalytic UTI test detected **nineteen** species, **sixteen** reached a diagnostic accuracy ≥90.27% with negative predictive values ≥93.67%.

The most frequently found uropathogenic bacteria for complicated UTIs were;
Escherichia coli, Enterococcus faecalis, Proteus spp., Pseudomonas aeruginosa, and Klebsiella pneumoniae.

Figure 7: Most common found uropathogenic bacteria by using Vivalytic UTI test (before, after transport) compared to standard urine culture

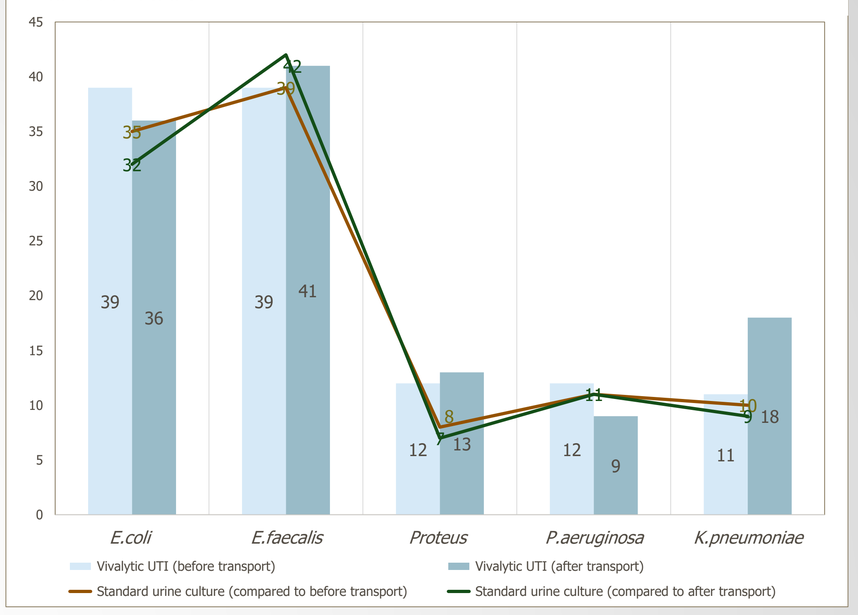


Table 2: N-detection rate with proportion (%), SE-Sensitivity, SP-Specificity, ACC-Accuracy in %

Comparison Vivalytic UTI test results to standard urine culture and antibiotic sensitivity test (before transport)						Comparison Vivalytic UTI test results to standard urine culture and antibiotic sensitivity test (after transport)					
Most common uropathogens before transport	N (%)	UFC range bacteria/µl	SE	SP	ACC	Most common uropathogens after transport	N (%)	UFC range bacteria/µl	SE	SP	ACC
E.coli	39 (17.65)	102-74567	94.29	92.77	93.22	*E.coli*	36 (19.57)	102-91165	90.62	91.36	91.15
E.faecalis	39 (17.65)	114-60473	87.18	93.67	91.35	*E.faecalis*	41 (22.28)	114-60473	88.10	94.37	92.04
Proteus spp.	12 (5.43)	475-29994	100.0	96.36	96.61	*Proteus spp.*	13 (7.07)	475-2994	100.0	94.83	95.12
P.aeruginosa	12 (5.43)	180-30706	90.91	98.13	97.46	*P.aeruginosa*	9 (4.89)	458-30706	72.73	99.02	96.46
K.pneumoniae	11 (4.97)	201-44830	90.00	98.15	97.46	*K.pneumoniae*	18 (9.78)	201-60473	88.89	90.38	90.27
Antimicrobial resistance genes before transport						Antimicrobial resistance genes after transport					
Trimethoprim	19	(54.29)	62.50	93.1	84.15	Trimethoprim	18	(51.43)	68.18	95.00	87.80
Methicillin	15	(42.86)	50.00	83.33	81.71	Methicillin	16	(45.71)	100.0	83.54	84.15
Vancomycin	1	(2.86)	/	98.78	/	Vancomycin	1	(2.86)	/	98.78	/

The antimicrobial resistance gene detection rate reached a higher accuracy after transport (≥84.15%) compared to POC-testing before transport (≥81.71%), except for Vancomycin resistance.

Conclusion

In this study, the Vivalytic UTI test displayed high sensitivity and specificity in identifying uropathogenic bacteria and antibiotic resistance markers.
We observed a higher degree of concordant pathogen identification at the POC, before transport (p=0.0336).
The transport of urine samples influenced the pathogen detection rate and antibiotic susceptibility testing of the Vivalytic UTI analyser.

Limitations of the Vivalytic UTI test

➛ A negative test result does not exclude the presence of specific pathogens:
(1) *Aerococcus urinae, Enterococcus hirae, Hafnia alvei*, and *Staphylococcus lugdunensis* not part of the Vivalytic UTI test panel, detected by Standard urine culture only (19%).
(2) Pathogen present in urine sample at levels below sensitivity.

➛ A positive test does not necessarily imply the presence of viable bacterial cells.

➛ Invalid test results in 9.5% before transport, 11.1% after transport.

➛ No quantitative test results available.

Acknowledgments

This study was supported by the team of the urological and microbiological department, we especially thank B. Schneider and F. Meis for excellent technical support.