among adult women of reproductive age and evaluate the appropriateness of empirical treatment.

Methods. Non-pregnant women between the age of 20 and 49 years who presented with vaginal discharge were prospectively enrolled in a teaching hospital since Oct 2018. Vaginal swabs were collected for determination of Nugent score, culture for *Trichomonas vaginalis* (TV) and *Candida* species, and multiplex polymerase chain reaction (PCR) for BV, VVC and TV. Demographics, symptoms, physical findings, and the empirical treatment were recorded.

Results. From Oct 2018 to May 2020, 172 women were included (median age, 37 years). The prevalence of laboratory confirmed BV, VVC, and TV was 21.5% (n=37), 20.3% (35), and 0.6% (1), respectively. Ten (5.8%) women had concurrent BV and VCC. Among 38 women who had bacterial vaginosis or trichomoniasis, only 8 (21.1%) received metronidazole empirically while more than half (11/19, 57.9%) of women who received metronidazole empirically did not have laboratory-confirmed bacterial vaginosis or trichomoniasis. Among 35 women who had candidiasis, 10 (28.6%) received antifungal agents. Antifungal agents were prescribed to more than two thirds (21/31, 67.7%) of women who did not have laboratory confirmed candidiasis. Overall, 58.7% (101/172) of empirical treatment was deemed optimal. Multiplex PCR test has an overall diagnostic accuracy of 86.0% (148/172) as compared to the composite gold standard.

Conclusion. The empirical treatment for vaginal discharge syndrome is suboptimal. Better diagnostic assays have a potential to improve clinical patient care.

Disclosures. **All Authors**: No reported disclosures

1220. Disruption of the Body Temperature Circadian Rhythm in Hospitalized Patients

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Session: P-55. New Approaches to Diagnostics

Background. The circadian rhythm is believed to offer survival advantage with dysregulation being linked to immune response deficiencies and metabolic derangements. Diurnal temperature variation exists in humans, yet its preservation during illness is not well understood. Herein we present an analysis of diurnal body temperatures among hospitalized patients, with a focus on infectious versus non-infectious diagnoses.

Methods. Temperatures measured within 1/2 hour of 8am, 12pm, 4pm, 8pm, 12 am, and 4am from 16,245 hospitalized patients were analyzed using descriptive statistics and t-tests.

Results. Although we found a diurnal pattern when analyzing the ensemble of temperatures from all patients (Figure 1), stratified by measurement site (oral, axillary, temporal, and tympanic), the through-to-peak difference was only 0.2F (0.1C), while previously reported diurnal difference in healthy volunteers was 1.9 °F (1.06 °C). Data from the core body temperature sites monotherm and rectal did not show any diurnal pattern. The peaks in body temperature occurred at 8 pm for all patients, regardless of age, which is similar to healthy people. However, the minimum body temperature was shifted to later times compared with healthy people (6am or 2 hours before rising in health) – for young patients (age 20-30 years, N=1285) the through was at 8am and for elderly patients (age 70-80 years, N=1736), it was at 12pm (Figure 2). Analysis of body temperature of individual patients showed that less than 20% of patients exhibited diurnal variation and among those showing variation, the trend was present only on the minority of hospitalization days (Table 1). Interestingly, the presence or absence of an infectious process did not influence the proportion of patients showing diurnal variation.

Figure 1

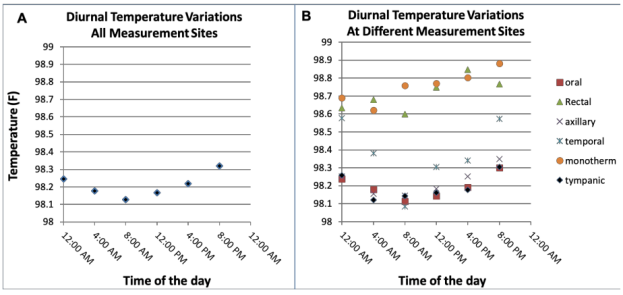

Figure 2

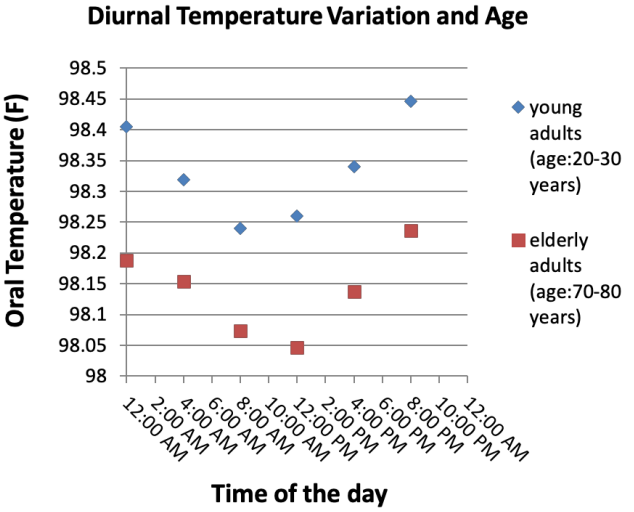

Table 1

		diurnal trend present	no diurnal trend	% with diurnal trend
no infection	ACS rule out	1	6	14
	AAA	0	2	0
	suicidal ideation	1	1	50
total no infection		***2***	***9***	***18***
infection present	abdominal abscess	1	4	20
	pneumonia	0	3	0
total infection present		***1***	***7***	***13***

Conclusion. Hospitalization is associated with disruption in the circadian rhythm as reflected by patients' body temperature, with shifting of the diurnal variation curve and blunting of the temperature range both in the ensemble and on the individual level. The trend is not influenced by having an infection. However, since core body temperatures tend to be the measurement site of choice in the ICU setting, we suspect that further obliteration of the diurnal rhythm occurs with more severe disease.

Disclosures. **All Authors**: No reported disclosures

1221. Evaluation of the FilmArray® Global Fever Panel

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Session: P-55. New Approaches to Diagnostics

Background. Acute Febrile Illness (AFI) is caused by a diverse set of pathogens. The FilmArray Global Fever (GF) Panel, developed by BioFire Defense in collaboration with the U.S. Department of Defense and NIAID, uses an automated, multiplex nested PCR system to evaluate whole blood samples for multiple pathogens simultaneously in under an hour.

Methods. BioFire Defense conducted analytical performance studies to show sensitivity (LoD), inclusivity, and specificity (exclusivity), and a prospective clinical study to evaluate the positive percent agreement (PPA) and negative percent agreement (NPA) of the GF Panel. The results of these studies will be reported in two submissions to the US FDA.

Results. The analytical performance demonstrated the ability to accurately detect multiple pathogens, including Category A biothreat pathogens. Eleven locations around the world tested 1,865 specimens on the GF Panel. The rate of positive detections was 35% (652/1865), with *Plasmodium* spp. accounting for the majority of positives (53.4%, 348/652) and dengue virus the second most (40.5%, 264/652). Other detected pathogens include *Leptospira* spp., West Nile virus, Zika virus, *Leishmania* spp., Crimean-Congo hemorrhagic fever virus, and chikungunya virus. Twenty-eight (28) specimens had more than one detected pathogen (4.3% of positive specimens). Comparator testing consisted of in-house developed PCR assays followed by bidirectional sequencing. PPA between GF Panel and comparator testing ranged between 92.7-100%, and the NPA ranged between 99.3-100%. In all cases, discrepancies coincided with analytes that were near the limit of detection of the GF Panel and comparator assays. When the GF Panel result was compared to site-specific malaria testing, the PPA ranged between 94.7-100% and the NPA ranged between 43.3-100%. Analysis of the NPA suggests that the GF Panel is more sensitive than microscopy, producing "discrepancies" for this comparison. The wide range in NPA between sites could be due to variation in microscopy technique; the GF Panel eliminates such variation because it is fully automated.

Conclusion. The results show that the FilmArray GF Panel could aid in rapid and actionable AFI diagnosis caused by multiple, sometimes co-occurring, pathogens.

Disclosures. Jared R. Helm, PhD, BioFire Defense (Employee) Brian Jones, PhD, BioFire Defense, LLC (Employee, own stock) Corike Toxopeus, PhD, BioFire Defense, LLC. (Employee, stock owner) David S. Rabiger, PhD, BioFire Defense (Employee) Mark Gurling, PhD, BioFire Defense, LLC (Employee) Olivia Jackson, n/a, BioFire Defense (Employee) Marissa Burton, BS Biology, Biomerieux, Inc. (Shareholder) Cynthia Andjelic, PhD, BioFire Defense (Employee, Other Financial or Material Support, Own stocks) Cynthia L. Phillips, PhD, BioFire Defense (Employee, Scientific Research Study Investigator, Shareholder)BioFire Defense (Employee, Scientific Research Study Investigator, Shareholder)

1222. Fosfomycin Susceptibility Testing using the new ETEST® FO

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Background. Fosfomycin (FO) is a bactericidal antibiotic with a broad spectrum of activity against a wide range of Gram-positive and Gram-negative bacteria. Oral FO is mainly used in the treatment of urinary tract infections, particularly those caused by *E. coli* and *E. faecalis*. In order to determine MICs to FO, the ETEST® FM is already available but the reading can be difficult especially with *E. coli*. To resolve this issue, a new ETEST® with FO, called ETEST® FO, has been developed (not FDA cleared, yet). The purpose of this study is to compare this new strip to the agar dilution reference method (AD) on a panel of *E. coli* and *E. faecalis*.

Methods. A total of 39 isolates comprising 20 *E. coli* (ESBL or CPE) and 19 *E. faecalis* (VRE or VSE) were tested by ETEST® FO and Agar dilution. The isolates were sub-cultured on Columbia agar plates supplemented with 5% sheep blood before testing. After incubation, suspensions of the isolates were prepared in 0.85% saline. These suspensions were used to inoculate both AD and ETEST® plates. Results were read after 16-20 hours incubation at 35°C +2°C in ambient air. Following CLSI QC guideline, 4 QC organisms were tested. Results were analyzed using the FDA/CLSI breakpoints for FO (S < 64µg/mL, I=128 µg/mL, R> 256 µg/mL). Performance was evaluated using FDA performance criteria, essential agreement (EA, ≥ 90%), category agreement (CA, ≥ 90%), major error rate (ME, ≤3.0%) and very major error rate (VME, ≤2.0%).

Results. All the QC strains MICs were within the CLSI ranges. For the panel results, see the table below:

Performance for ETEST® FO on *E. coli* and *E. faecalis*

Species	EA	CA	Very Major Error Rate	Major Error Rate	Minor Error Rate
Overall (39)	97.4% (38/39)	97.4% (38/39)	0% (0/2)	0.0% (0/37)	2.6 % (1/39)
E. faecalis (19)	100% (19/19)	94.7% (18/19)	NA (No R)	0.0% (0/19)	5.2% (1/19)
E. coli (20)	95.0% (19/20)	100% (20/20)	0% (0/2)	0.0% (0/18)	0% (0/20)

Conclusion: This first and preliminary study shows that ETEST® FO can potentially meet the FDA acceptance criteria and could be a valuable tool for determining FO MIC for *E. coli* harboring various resistance mechanisms and *E. faecalis* including VRE. Moreover, in comparison with the current ETEST FM strip, this new strip brings a real reading improvement and resolve the issue for E. coli. The clinical study phase will determine the product's performance.

Disclosures. Marion Pompilio, BioMérieux (Employee) Gilles Zambardi, biomerieux (Employee)

1223. Impact of Helicobacter pylori Infection on Duodenal Microbial Community Structures and Microbial Metabolic Pathways

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Session: P-55. New Approaches to Diagnostics

Background. Recent reports suggest that *Helicobacter pylori* infection causes extragastric diseases. However, the onset mechanisms of these diseases have not been fully elucidated, and the factors involved in the onset of these extragastric diseases remain obscure.

Methods. Forty-seven (20 male, 27 female) subjects who underwent gastric cancer screening were enrolled. Aspirated duodenal fluid samples were collected from the descending duodenum. Samples were analyzed by 16S rRNA gene amplicon sequencing to investigate whether the duodenal microbiota and microbial biofunctions were affected by *H. pylori* infection.

Results. Thirteen subjects were *H. pylori* positive while 34 were negative. We observed 1404 bacterial operational taxonomic units from 23 phyla and 253 genera. In the *H. pylori* positive group, we observed higher abundance of *Proteobacteria* and lower abundance of *Actinobacteria* and *TM7* than in the *H. pylori* negative group. The abundance of 10 genera differed significantly between the *H. pylori* positive and negative groups. Aspects of microbiota in the *H. pylori* positive group were significantly influenced by 12 taxa primarily belonging to *Gammaproteobacteria*, compared with those in the *H. pylori* negative group. Microbial functional annotation collated using the Kyoto Encyclopedia of Genes and Genomes Orthology database showed that 12 microbial metabolic pathways were significantly affected by *H. pylori* infection.

Conclusion. 1. *pylori* infection disrupted the normal bacterial communities in the duodenum and changed aspects of the commensal microbial functions primarily by upregulating the metabolic pathways. This may be one of the principal factors in the development of extragastric diseases.

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