The diagnosis of acute respiratory infection (ARI) in patients and was elevated in 50.0%. In the remaining patients, PCT was not available for one patient with viral infection (see tables). Serum CRP was not available for 4 of the patients included (14%) and elevated with respect to the final diagnosis.

Methods. We prospectively enrolled patients presenting to the emergency department (ED) with dermatologic lower extremity complaints that involved visible erythema. Using a thermal imaging camera, the maximum temperature value (Tmax) for the affected area of skin and corresponding area on an unaffected limb were captured. The Tmax gradient between the affected and unaffected limb was calculated. Gold standard diagnosis (cellulitis versus pseudocellulitis) was determined by consensus of a blinded, multidisciplinary physician review panel (two infectious disease, two dermatologists and two emergency medicine). Differences in temperature variables (Tmax and Tmax gradient) between cellulitis and pseudocellulitis were compared using t-tests.

Results. The sample included 204 participants, 59% male with an average age of 57 years. Based on expert panel consensus diagnosis, 92 (45%) of the participants had cellulitis. The cellulitis group had an average Tmax of 33.2°C and 30.2°C for affected and unaffected skin respectively, which was a significant difference of 2.9°C (p < 0.001). The difference in the Tmax gradients between patients with cellulitis and pseudocellulitis was 2.08°C (p < 1.46; p < 0.001).

Conclusion. This represents the largest validation study of skin surface temperature differences between cellulitis and pseudocellulitis. Significant difference in temperature gradients between cases of cellulitis and pseudocellulitis suggests thermal imaging could be a useful diagnostic adjunct that can help differentiate these conditions. Such a modality could be particularly helpful in the ED setting where providers must balance diagnostic uncertainty with antimicrobial stewardship principles. Future work will identify the best performing temperature variables and determine optimal cutoff values for use in diagnostic algorithms.

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Table 1. Results for Viral Infection

| Viral Infection | FebriDx Result | Present | Absent | Total |
|-----------------|----------------|---------|--------|-------|
| Positive        | 13             | 0       | 13     |
| Negative        | 1              | 14      | 17     |
| Total           | 14             | 14      | 28     |
| Sensitivity (95% CI) | 91.67% (61.52 - 99.79%) |
| Specificity (95% CI) | 100% (79.41-100.00%) |

FebriDx Performance when compared to Clinical Diagnosis

Conclusion. FebriDx demonstrated a higher accuracy for differentiating bacterial vs. viral infection in an immunocompromised cohort than single biomarkers CRP and PCT. FebriDx demonstrated a high diagnostic accuracy to differentiate viral from bacterial infection in patients with chronic immunosuppressive conditions in a real-world setting and had better performance than standalone CRP and PCT to distinguish viral and bacterial ARI in immunocompromised patients.

Disclosures. Catalina Suarez-Cuervo, MD, Lemos Diagnostics (Employee)

1035. Manufacturing Processes of SER-109, a Purified Investigational Microbiome Therapeutic, Reduce Risk of Transmission of Emerging and Undetected Infections in Donor Stool

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Background. Fecal microbiota transplantation (FMT) is vulnerable to emerging pathogens due to reliance on donor screening for risk mitigation. These concerns were highlighted by dual FDA safety alerts regarding FMT transmission of bacterial pathogens, which were recognized in hindsight only after hospitalizations and deaths. The FDA also warned of potential risk of SARS-CoV-2 transmission, leading to quarantine of FMT in March 2020, two months after COVID-19 was reported on US soil. Conversely, our development program for SER-109, an oral investigational microbiome therapeutic, was prospectively designed to inactivate organisms of concern, while purifying the hardy Firmicutes spores. We evaluated whether the manufacturing processes for SER-109 inactivate model organisms, including a coronavirus with gastrointestinal tropism, and a representative Gram-negative bacterium.

Methods. Model organisms were selected based on biologic suitability, detectability, and laboratory safety. Porcine Epidemic Diarrhea Virus (PEDV, a coronavirus) was selected to model SARS-CoV-2. Quantitation used a Vero cell tissue culture infection dose (TCID50) assay. For E. coli, a rifampin-tolerant Salmonella enterica was selected and quantitated with MacConkey lactose agar plus rifampicin. Spiking experiments into representative fecal suspensions were completed to measure inactivation of model organisms. Log-reduction factors (LRF) were calculated based on the drop in organism titer during inactivation. Hold controls in non-ethanolic test matrices were used to purify the hardy Firmicutes spores. We evaluated whether the manufacturing processes for SER-109 inactivate model organisms, including a coronavirus with gastrointestinal tropism, and a representative Gram-negative bacterium.

Results. In 70% v/v ethanol, PEDV was inactivated by more than 4.2 log10 (to limit of detection, LOD) within 4 minutes (Fig1). In 50% v/v ethanol, S. enterica was inactivated by more than 6.5 log10 (to LOD) within 30 seconds (Fig2). Figure 1. Inactivation of Porcine Epidemic Diarrhea Virus (PEDV), log10 reduction factor (LRF) versus time

Average of two experiments shown. Also shown is the maximum achievable inactivation based on the limit of detection (LOD).

Figure 1. Inactivation of Porcine Epidemic Diarrhea Virus (PEDV), log10 reduction factor (LRF) versus time

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