Conclusion. Within an immunocompromised patient population, differences in organism identification between three commercially available RDT panels did not impact theoretical antibiotic prescribing.

Disclosures. **J. Kristie Johnson, PhD, D(ABMM)**, **GenMark** (Speaker's Bureau) **Kimberly C. Claeys, PharmD**, **GenMark** (Speaker's Bureau)

1025. Prediction of Intravenous Immunoglobulin Resistance and Coronary Artery Dilatation in Kawasaki Disease: a Multicenter Study from Oman

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Session: P-58. New Approaches to Diagnostics

Background. Prediction of intravenous immunoglobulin (IVIG) resistance and coronary artery dilatation continues to be a challenge in the management of Kawasaki disease. Significant differences exist among different populations.

Methods. Children < 13 years of age who presented to the two main tertiary care hospitals in Oman (Royal Hospital and Sultan Qaboos University Hospital) between 2008 and 2019 with a diagnosis of Kawasaki disease were included. Diagnosis was confirmed and clinical, laboratory and echocardiography data was systematically collected and checked for accuracy. The primary outcome was the presence of IVIG resistance or coronary artery dilatation at the 6-week follow-up. Bivariate analysis was used to identify significant predictors of the primary outcome, followed by multivariable logistic regression to determine independent predictors. The Muscat Index of Kawasaki disease Severity (MIKS) score was created based on the results.

Results. 156 children with Kawasaki disease were included. Median age was 2.1 years (IQR 0.9-3.8), and 64% were males. All patients received IVIG, 26 (17%) received steroids, and one received infliximab. Coronary dilatation was identified in 41 (26%) patients on initial echocardiogram, and 26 (18%) at the 6-week follow-up visit. Variables significantly associated with the primary outcome were age ≤15 months (P=0.031), hemoglobin (P=0.009), WBC count (P=0.002), absolute neutrophil count (P=0.006), and CRP ≥150 mg/L (P=0.015). These variables in addition male gender (P=0.058), ALT >80 IU/L (P=0.10) and serum sodium (P=0.10), were entered into multivariable logistic regression. A predictive model based on CRP ≥150 mg/L (LR=2.2, P=0.049), male gender (LR=2.1, P=0.095) and WBC (LR=1.1, P=0.017) resulted, and it was used as basis for the MIKS score (Table 1). The MIKS score performed favorably to the Kobayashi score in its sensitivity to predict the primary outcome and its separate components (Table 2). Combining the MIKS score with other high-risk criteria had a sensitivity of 95% in predicting the primary outcome and a specificity of 56%.

Table 1. Calculation of the Muscat Index of Kawasaki disease Severity (MIKS) score

Criteria	Score
C-reactive protein ≥150 mg/L	2
WBC	
≥13.5 x10^9/L	1
≥19 x10^9/L	3
Male gender	2
Maximum score	7

Table 2. Sensitivity, specificity and P value for the Kobayashi, MIKS, and combined high risk criteria in predicting IVIG resistance, coronary dilatation at 6 weeks, separately or in combination, among patients with Kawasaki disease. MIKS: Muscat Index of Kawasaki disease Severity. *High risk: presence of coronary artery dilatation on initial echocardiogram or age <1>

	IVIG resistance			Coronary dilatation at 6 weeks			IVIG resistance or coronary dilatation at 6 weeks		
	Sens.	Spec.	P value	Sens.	Spec.	P value	Sens.	Spec.	P value
Kobayashi ≥4	53%	78%	0.014	38%	75%	0.22	40%	78%	0.054
MIKS ≥4	72%	69%	0.001	62%	69%	0.006	65%	74%	<0.001
High risk* or Kobayashi ≥4	83%	51%	0.010	89%	56%	<0.001	85%	60%	<0.001
High risk* or MIKS ≥4	100%	47%	<0.001	92%	50%	<0.001	95%	56%	<0.001

Conclusion. The MIKS score predicts IVIG resistance and coronary artery dilatation in Kawasaki disease in our setting, with favorable performance compared to the Kobayashi score.

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

1026. Following the Hoof Prints: Detecting *Coxiella* and *Brucella* infections with A Plasma-based Microbial Cell-Free DNA Next-generation Sequencing Test

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Session: P-58. New Approaches to Diagnostics

Background. *Coxiella burnetii* and *Brucella spp*. are zoonotic bacterial pathogens responsible for Q fever and Brucellosis, respectively. Both pathogens have a global distribution and Brucellosis is the most common zoonosis in the world. However, the CDC reports only 80-120 cases of human brucellosis and ~150 cases of acute Q fever annually. The diagnosis of these infections can be limited by: (1) their difficulty to culture; (2) the insensitivity and nonspecificity of serology; (3) the clinical overlap with other infections; and (4) the unreliability of epidemiological exposure history for these zoonoses. Unbiased microbial cell free DNA (mcfDNA) next-generation sequencing (NGS) offers a potential solution to overcome these limitations.

Methods. The Karius Test™ (KT) developed and validated in Karius's CLIA certified/CAP accredited lab in Redwood City, CA detects mcfDNA in plasma. After mcfDNA is extracted and NGS performed, human reads are removed, and remaining sequences are aligned to a curated database of > 1500 organisms. McfDNA from organisms present above a statistical threshold are reported and quantified in molecules/µL (MPM). KT detections of *Coxiella* and *Brucella* were reviewed from August 2017 - present; clinical information was obtained with test requisition or consultation upon result reporting.

Results. KT detected 8 cases of *Coxiella burnetii* (1735 MPM +/- 3000) and 5 cases of *Brucella melitensis* (avg 296 MPM +/- 223) (Table 1), representing approximately 1-2% of all detections in the US during this period. All of the Coxiella detections were in adults (100% male) with 5 cases of fever of unknown origin, 2 cases of culture-negative endocarditis and one case of endovascular graft infection. *Brucella* detections occurred in 3 adults and 2 children (60% male), 3 with exposure to unpasteurized dairy and included 3 cases of spine infection (2 vertebral osteomyelitis, 1 epidural abscess).

Table 1. *Coxiella burnetii* and *Brucella melitensis* detections by the Karius Test™

Case	Age	Sex	IC	Exposure	Clinical Context	Karius Test Result	MPM (RI<10)
1	Adult	M	No	No	Endovascular graft infection	*Coxiella burnetii*	8,262
2	Adult	M	No	Livestock	Fever of Unknown Origin	*Coxiella burnetii*	776
3	Adult	M	No	No	Fever of Unknown Origin	*Coxiella burnetii*	202
4	Adult	M	No	Livestock	Fever of Unknown Origin	*Coxiella burnetii*	2,468
5	Adult	M	No	No	Fever of Unknown Origin	*Coxiella burnetii*	165
6	Adult	M	No	No	Fever of Unknown Origin	*Coxiella burnetii*	217
7	Adult	M	No	No	Culture-negative native valve endocarditis	*Coxiella burnetii*	53
8	Adult	M	No	No	Culture-negative prosthetic valve endocarditis	*Coxiella burnetii*	Not available*
9	Pediatric	M	No	Unpasteurized dairy	Fever of Unknown Origin	*Brucella melitensis*	Not available^
10	Adult	F	No	Unpasteurized dairy	Vertebral osteomyelitis and bacteremia	*Brucella melitensis*	569
11	Adult	M	No	Unpasteurized dairy	Epidural abscess	*Brucella melitensis*	374
12	Pediatric	F	Unknown	Unknown	Not obtained	*Brucella melitensis*	182
13	Adult	M	No	No	Vertebral osteomyelitis	*Brucella melitensis*	59

MPM: Molecules per microliter; RI: Reference interval which denotes the 97.5th %tile of the MPM for each microbe in a cohort of 684 healthy subjects; IC: Immunocompromised
*Initial version of the test that did not offer quantification ^Sample did not meet minimum sequencing depth requirements for quantification

Conclusion. Open-ended, plasma-based mcfDNA NGS provides a rapid, non-invasive test to diagnose diverse clinical manifestations of zoonotic infections such as Q fever and Brucellosis against competing broad differential diagnoses. Furthermore, these cases highlight the potential of the KT to diagnose infections caused by fastidious/unculturable pathogens with cryptic clinical presentations.

Disclosures. **Nicholas R. Degner, MD, MPH, MS**, **Karius Inc.** (Employee, Shareholder) **Ricardo Castillo-Galvan, MD MPH**, **Karius Inc.** (Consultant) **Jose Alexander, MD, D(ABMM), FCCM, CIC, SM, MB(ASCP), BCMAS**, **Karius** (Employee) **Aparna Arun, MD**, **Karius** (Employee) **Ann Macintyre, DO**, **Karius, Inc.** (Employee) **Bradley Perkins, MD**, **Karius, Inc.** (Employee) **Asim A. Ahmed, MD**, **Karius, Inc.** (Employee) **Matthew Smollin, PharmD**, **Karius, Inc.** (Employee)

1027. Earlier Is Better: Progress Toward Decreased Time to Optimal Therapy and Improved Antibiotic Stewardship for Gram-positive Bloodstream Infections Through Use of GenMark Dx ePlex system

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Session: P-58. New Approaches to Diagnostics

Background. The ePlex BCID Gram-Positive (GP) panel utilizes electrowetting technology to detect the most common causes of GP bacteremia (20 targets) and 4 antimicrobial resistance (AMR) genes in positive blood culture (BC) bottles. Rapid detection of intrinsic vancomycin resistance and acquired resistance genes (*mecA, mecC, vanA, vanB*) enables early optimization of antimicrobial therapy whereas early detection of common contaminants is expected to decrease unnecessary antibiotic utilization and hospitalizations.

Methods. In this prospective study, aliquots of BC bottles with GP bacteria detected on Gram stain (GS) (n=101) received standard of care (SOC) culture and antimicrobial susceptibility testing (AST). Additionally, samples were evaluated with the BCID-GP panel but only SOC results were reported in the EMR and available to inform clinical decisions. Patients were excluded if the sample was a subsequent culture in a persistent episode of bacteremia (n=17) or if the assay failed (n=4). Chart review

was performed to evaluate the expected impact of the BCID-GP panel on the time to organism identification, AST results, and optimization of antimicrobial therapy.

Results. A total of 80 patients were included in the final analysis (Table 1). *S. epidermidis* was the most common bacteria identified, followed by *S. aureus*, and other coagulase-negative staphylococci. Thirty-nine patients with staphylococci (48.8%) had the *mecA* gene detected and 2 patients with *E. faecium* had the *vanA* gene detected. The BCID-GP panel saved a mean of 24.4 hours (h) to identification and 48.3h to susceptibility testing compared to standard methods across all patients. In 38 patients (47.5%), the BCID-GP panel result could have enabled an earlier change in antibiotic therapy. Table 2 highlights opportunities to optimize antimicrobial therapy 53.4h earlier for 16 (20%) patients with organisms expressing AMR genes, 29.2h earlier for 8 (10%) patients infected with organisms, such as streptococci, with very low resistance rates, and to stop antimicrobial therapy 42.9h earlier for 14 (17.5%) patients with contaminated blood cultures.

Table 1. Patient demographics and co-morbidities.

Variable	Total (N=80)
Age (Mean)	54.1
Male – No. (%)	43 (53.8)
Race/Ethnicity – No. (%)	
• White	43 (53.8)
• Black	35 (43.8)
• Hispanic/Latino	2 (2.5)
Immunosuppression – No. (%)	
• Solid malignancy	6 (7.5)
• Hematologic malignancy	4 (5)
• SOT	7 (8.9)
• HSCT	3 (3.8)
• Other	4 (5)
Diabetes – No. (%)	32 (40)
Cardiovascular disease – No. (%)	26 (32.5)
Chronic lung disease – No. (%)	11 (13.8)
CKD – No. (%)	12 (15)
ESRD – No. (%)	7 (8.8)
Cirrhosis – No. (%)	3 (3.8)
IVDU – No. (%)	1 (1.3)
Mechanical ventilation – No. (%)	15 (18.8)
ECMO – No. (%)	1 (1.3)
Trauma at time of admission – No. (%)	8 (10)
Burn at time of admission – No. (%)	1 (1.3)
Pitt Bacteremia Score (Mean)	2.46

Table 2. Time of antibiotic change and time saved.

Potential change to antibiotics	No. of patients	Mean time saved (hours)
Stop for earlier ID of contaminant species	14	42.9
Change GP antibiotic based on presence or absence of resistance gene	16	53.4
Change GP antibiotic based on earlier ID of *Streptococcus*	8	29.2

Conclusion. The BCID-GP panel could have enabled earlier optimization or stopping of antibiotics in many patients with significant time savings compared to standard laboratory methods.

Disclosures. **Todd P. McCarty, MD**, **Cidara** (Grant/Research Support)**GenMark** (Grant/Research Support, Other Financial or Material Support, Honoraria for Research Presentation)**T2 Biosystems** (Consultant) **Sixto M. Leal, Jr., MD, PhD**, **Abnova** (Grant/Research Support)**AltImmune** (Grant/Research Support)**Amplyx Pharmaceuticals** (Grant/Research Support)**Astellas Pharmaceuticals** (Grant/Research Support)**CNINE Dx** (Grant/Research Support)**GenMark Diagnostics** (Grant/Research Support, Other Financial or Material Support, Honoraria-Research Presentation)**IHMA** (Grant/Research Support)**IMMY Dx** (Grant/Research Support)**JMI/Sentry** (Grant/Research Support)**mFluiDx Dx** (Grant/Research Support)**SpeeDx Dx** (Grant/Research Support)**Tetraphase Pharmaceuticals** (Grant/Research Support)

1028. Performance and Patient Acceptability Evaluation of the Chembio DPP® HIV-Syphilis Assay in an Emergency Department

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Session: P-58. New Approaches to Diagnostics

Background. Emergency departments (EDs) serve as sentinel settings for diagnosing sexually transmitted infections (STIs), including HIV and syphilis. We aimed to assess performance and patient acceptability of a point-of-care (POC) test, the Chembio Dual Path Platform (DPP®) HIV-Syphilis Assay, in an urban ED in Baltimore.

Methods. 170 patients were enrolled via convenience sampling from Oct 2019 – March 2020 and Jan 2021 – June 2021. Patients eligible were < 70 yrs, men who have sex with men, pregnant without care, had STI concerns, or history of drug use. Subjects received standard of care (SOC) HIV and syphilis testing under institutional laboratory algorithms. Subjects were then tested with the finger-stick POC test and completed a survey, both before and after the POC test to assess subjects' attitudes about the POC test.

Results. Comparing the SOC and POC results, 165/170 (97.1%) were test concordant. 3 syphilis POC results were false negative, but reported successful treatment over 10 years prior to enrollment (treponemal antibody remains after treatment). 1 HIV result was false negative and 1 was false positive. Overall the sensitivity and specificity of the HIV POC test were 96.8% (95%CI: 83.3%, 99.9%) and 99.3% (95% CI: 96.1%, 100%), and for syphilis were 85.7% (95%Cl: 63.7%, 97.0%) or 100% (95%CI: 81.5%, 100%), if excluding 3 persons having been successfully treated, and 100% (95% CI: 97.6%, 100%) respectively.

The pre-test survey found 67% and 77% of participants were comfortable with a finger-stick test and agreed the POC test result would be as good as the SOC test result, which increased to 96% and 86% in the post-test, respectively, ($p < 0.05$). At post-test, 86% reported they would feel confident to perform this test at home and 81% would use it at least once per year if it were available. 97% reported they were more likely to seek treatment if receiving a positive result during their ED visit and 91% reported it would reduce their stress/anxiety if receiving a negative test result in the ED.

Conclusion. Our findings demonstrated satisfactory performance and high patient acceptability of the Chembio DPP® HIV-Syphilis Assay. Given the test is FDA approved, implementation studies are needed to determine whether adoption of this POC test will benefit patients and be consistent with ED workflows.

Disclosures. **Richard E. Rothman, PhD, MD**, **Chem bio** (Grant/Research Support)

1029. Torus Synestia Nucleic Acid Analysis Platform for Fast, High Multiplex Analysis of Nucleic Acids With Single-Nucleotide Discrimination Level

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Session: P-58. New Approaches to Diagnostics

Background. Nucleic acid amplification testing (NAAT) is an essential tool both for biomedical research and for clinical molecular diagnostics. Currently, there are multiple NAAT platforms available, each offering certain performance and utility advantages and disadvantages as compared to each other. Next generation NAAT platforms aim to deliver increased target detection sensitivity and specificity, low limits of target detection, quantitative high multiplex target capacity, rapid time to results, and simple sample-to-answer workflow.

Methods. Here we describe the Torus Synestia System, a NAAT platform capable of rapid, highly multiplexed amplification and detection of both DNA and RNA targets. The platform comprises a small, portable (~ 2kg) amplification and detection device and a disposable single-use cartridge housing a PCR amplification chamber with an integrated label-free microarray for real-time data acquisition and interpretation. The platform offers a 30-min turnaround time with a detection limit of 10 DNA/RNA molecules per assay and single nucleotide discrimination.

Results. We demonstrate the Synestia System performance and utility with three distinct molecular applications: 1) detection of 20 genetic loci and 30 single nucleotide polymorphisms in human genomic DNA; 2) detection and genotyping of 43 unique bacterial species associated with human urinary tract infections; and 3) detection and profiling human respiratory viral pathogens including SARS-CoV-1/2, seasonal coronaviruses, Influenza A/B, and human respiratory syncytial viruses. In addition, the single-nucleotide specificity of our label-free microarray probes allowed for robust identification and discrimination of newly emerging SARS-CoV-2 lineages, such as B.1.1.7 (a.k.a. UK), B.1.351 (a.k.a. South African), P.1 (a.k.a. Brazilian), and B.1.617 (a.k.a. Indian).

Conclusion. The Torus Synestia System has broad applicability in both clinical and research environments. We are confident that the Torus Synestia System will revolutionize syndromic diagnostics at the point of care (PoC) and lead to improved response times during future epidemic and pandemic pathogen outbreaks.

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

1030. Chasing the Long Tail of Infectious Diseases: Detecting *Capnocytophaga canimorsus* and *Pasteurella multocida* Infections with A Plasma-based Microbial Cell-Free DNA Next Generation Sequencing Test

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