Results. Regardless of the angle considered, the classic analysis—which measured the percentages of lymphocytes, monocytes, and neutrophils—did not distinguish outcomes (A). In contrast, non-overlapping patterns generated by the PRS differentiated 3 (left, vertical, and right) groups of patients (B). One subset was only composed of survivors (B). The remaining subsets included the highest oxygenation requirements (B). At least two immunologically interpretable, multi-cellular indicators distinguished the 3 data subsets with statistically significant differences \((C, \ p \leq 0.05)\). Survivors (the left subset) showed lower N/L and/or higher M/L ratios than non-survivors (the vertical subset, C). Therefore, PRS partitioned the data into subsets that displayed both biological and significant differences. Because it offers visually explicit information, clinicians do not require a specialized training to interpret PRS-generated results.

CBCs vs. outcomes - Software-analyzed CBCs vs. outcomes

Conclusion. (1) Analysis of blood leukocyte data predicts MOR and 30-d mortality. (2) Real time PRS analysis facilitates personalized medical decisions. (3) PRS measures two dimensions rarely assessed: multi-cellularity and dynamics. (4) Even with very small datasets, PRS may achieve statistical significance. (5) Larger COVID+ infected cohort is being analyzed for potential commercialization.

Disclosures. Claudia R. Libertin, MD, Gilead (Grant/Research Support)

365. Assessing Provider Utilization of COVID-19 Inflammatory Marker Trends in Hospitalized Patients and Implications in Optimizing Value-Based Care During a Pandemic
Praveen Subramanian, DO1; Lucy Stun, PharmD1; Nathan Babr, MD1; Lewis Satterwhite, M.D.1; Maharsi Bhakta, M.D.1; Wissam El Atrouni, MD1; Fred Flapp, MD, PhD1; Jessica Newman, DO1; 1University of Kansas Medical Center, Kansas City, Kansas; The University of Kansas Medical Center, Kansas City, Kansas
Session: P-15. COVID-19 Diagnostics

Background. Numerous inflammatory markers may serve a role in prognostication of patients hospitalized with COVID-19. Early in the pandemic, our health system created an admission order set which included daily d-dimer, C-reactive protein (CRP), lactate dehydrogenase (LDH), and ferritin. Given more available outcomes data, limiting standing order of studies that do not affect daily management could result in significant cost savings to the health system without adverse patient outcomes. The purpose of this study was to determine ordering and utilization patterns of inflammatory markers by physicians caring for patients hospitalized with COVID-19 infections.

Methods. An anonymous 10-question survey was distributed to 125 physicians (Infectious Diseases, Hospitalist, Pulmonary and Critical Care faculty). Responses were tallied and values greater than 50% were identified as the majority of the surveyed group.
Conclusions. Of the markers studied, both d-dimer and CRP were considered useful by most respondents. LDH and ferritin were used less frequently and were not considered as useful in guiding medical decision making. Discontinuation of standing daily LDH and ferritin orders is believed to have potential to result in cost savings to the health care system with no adverse patient outcomes.

Disclosures. All Authors: No reported disclosures

366. Abbott BinaxNOW Rapid Antigen Test Performance in Detecting SARS-CoV-2 Infections in a COVID-19 Outbreak Among Horse Racetrack Workers

Krishna Surasi, MD, MPH; Kristin J. Cummings, MD, MPH; Carl V. Hanson, PhD; Mary Kate Morris, PhD, MPH; Maria Salas, MPH; David Seftel, M.D., M.B.A.; Lisa M. Ortiz, MD, MPH, MS; Ruwan Thilakaratne, MPH; Cameron Stainken, MD; Debra Wadford, PhD; Centers for Disease Control and Prevention, Berkeley, California; California Department of Public Health, Richmond, California; Golden Gate Fields Medical Clinic, San Francisco, California; City of Berkeley, Berkeley, California; UCSF, San Francisco, California

Session: P-15. COVID-19 Diagnostics

Background. Rapid antigen tests (e.g., Abbott’s BinaxNOW) are cheaper and faster than nucleic acid amplification tests (e.g., real-time reverse transcription polymerase chain reaction [RT-PCR]) for SARS-CoV-2 infection, with variable reported sensitivity. A horse racetrack in California experienced a COVID-19 outbreak among staff in May 2020. The goal was to evaluate the sensitivity, specificity, LR+ and LR- of the BinaxNOW test in detecting SARS-CoV-2 infections in the workplace outbreak.

Methods. Between November 25–December 22, 2020, anterior nasal swabs were collected from racetrack staff for six rounds of paired BinaxNOW and RT-PCR tests. BinaxNOW tests were interpreted according to manufacturer instructions. RT-PCR was performed at the state public health lab using the ThermoFisher TaqPath COVID-19 Combo Kit. Staff with positive results on either test were isolated and removed from subsequent testing. Viral cultures were attempted on specimens with cycle threshold (Ct) > 30.

Results. Overall, 769 paired results from 342 staff were analyzed. Most were of Hispanic ethnicity (62.0%) and ages ranged from 18 to 92 years (median 52). BinaxNOW performance compared to RT-PCR (95% CI) was as follows: positive percent agreement (PPA) 43.3% (34.6%–52.4%); negative percent agreement (NPA) 100% (99.4%–100%); positive predictive value (PPV) 100% (93.5%–100%); negative predictive value 89.9% (87.5%–90.2%). Among 127 RT-PCR-positive specimens, those with paired BinaxNOW-positive results (n = 55) had a lower mean Ct value than those with paired BinaxNOW-negative results (n = 72) (17.8 vs. 28.5) (p < 0.001). In dual positive pairs, median time from specimen collected to RT-PCR result reported was 4 days (range 1-6), compared to the 15-minute BinaxNOW reporting time. Of 100 Ct < 30 specimens, 51 resulted in positive virus isolation, 45 (88.2%) of which were BinaxNOW-positive.

Conclusions. High PPA and PPV support immediate isolation of BinaxNOW-positive individuals, while low PPA supports confirmatory testing following BinaxNOW-negative results. BinaxNOW performed better in paired specimens with lower Ct value and positive viral cultures, which could suggest that among RT-PCR-positive specimens, those that are BinaxNOW-negative may be less likely to contain infectious virus than those that are BinaxNOW-positive.

Disclosures. David Seftel, M.D., M.D., M.B.A., Enable Biosciences, Inc (Board Member, Employee, Scientific Research Study Investigator, Shareholder)

367. Role of Conventional Biomarker for Prediction of Chest CT-confirmed COVID-19 Pneumonia

Monprasit Haripradungkij, MD; Twareegrunt Sripongboonsrit, MD, MSc; Chulabhorn Hospital, HBB Princess Chulabhorn College of Medical Science, Chulabhorn Royal Academiy, Bangkok, Thailand, Lak si, Krueng Thep, Thailand

Session: P-15. COVID-19 Diagnostics

Background. The coronavirus disease 2019 (COVID-19) has a wide range of severity. Chest computed tomography (CT) had high sensitivity and specificity to identify COVID-19 pneumonia. However, chest CT was not available in almost all hospitals in pandemic settings, including developed countries. This study is to evaluate the potential role of conventional inflammatory biomarkers to predict COVID-19 pneumonia.

Methods. All 155 RT-PCR-confirmed COVID-19 patients were evaluated for pneumonia by chest CT from April 10, 2021 to May 3, 2021 in the outpatient unit, a Thai university hospital. The inflammatory biomarkers were evaluated the sensitivity, specificity, LR+, LR- and ROC to predict COVID-19 pneumonia.

Results. Of all 155 patients, pneumonia was diagnosed by chest CT in 117 patients. The pneumonia patients had a median (IQR) age of 38 (30, 55) years old. The BMI was higher in pneumonia than mild illness in 25.5 (22.0, 29.5) and 22.9 (19.4, 26.9) kg/m², respectively (p<0.001). In univariate analysis, serum high-sensitivity C-reactive protein (hsCRP), lactate dehydrogenase (LDH), ferritin, total lymphocyte count (TLC), and albumin were associated with pneumonia, but the only hsCRP demonstrated association by multivariate analysis. The area under the ROC curves (AUC) was 0.82, 0.74, 0.68, 0.38, and 0.37 in hsCRP, LDH, ferritin, TLC, and albumin, respectively. The optimal cut-off level for hsCRP to diagnose COVID-19 pneumonia was 2.00 mg/L, given sensitivity, specificity, LR+, LR- of 81.9%, 70.3%, 2.75, and 0.26 respectively (Figure 1 and Table 1).

Disclosures. All Authors: No reported disclosures

Table 1. Demonstrated sensitivity, specificity, LR+, and LR- for each specific cut-off value of hsCRP

| Cut-off for hsCRP (≥ mg/L) | Sensitivity (%) | Specificity (%) | LR+ | LR- |
|---------------------------|----------------|----------------|-----|-----|
| 1.90                      | 81.9           | 64.9           | 2.33| 0.28|
| 1.95                      | 81.9           | 67.6           | 2.53| 0.27|
| 2.00*                     | 81.9           | 70.3           | 2.75| 0.26|
| 2.05                      | 80.2           | 70.3           | 2.70| 0.29|
| 2.10                      | 80.2           | 70.3           | 2.70| 0.28|

*Indicated optimal cut-off value for hsCRP to predict chest CT-confirmed pneumonia.

ROC Curve of hsCRP to Diagnose of COVID-19 Pneumonia

This figure shows ROC curve for hsCRP to diagnose chest CT-confirmed COVID-19 pneumonia. The area under the ROC curve is 0.82. The optimal cut-off value for hsCRP is 2.00 given sensitivity of 81.9% and specificity of 70.3%.

Conclusion. The hsCRP was the conventional biomarker that had an excellent performance in predicting COVID-19 pneumonia lead to early anti-SARS-CoV-2 treatment. This study demonstrated the potential role of hsCRP combined with clinical assessment in negative chest X-rays to replace chest CT in a high burden COVID-19 country during pandemic situations.

Disclosures. All Authors: No reported disclosures

368. Performance Characteristics of Sequencing Assays for Identification of the SARS-CoV-2 Viral Genome

 Danny Antaki, PhD; Mara Couto-Rodriguez, MS; Tong Liu, na; Kristin Butler, MS; Esteban Toro, PhD; Bryan Hoglund, BS; Xavier O. Jirau Serrano, BS; Joseph Barrows, MS; Bradley A. Connor, M.D.; Christopher Mason, PhD; Niamh B. O'Hara, PhD; Dororthy Nagy-Szakal, MD; Twisti Bioscience, South San Francisco, California; Biotia, New York, New York; Weill Cornell Medicine, New York, New York

Session: P-15. COVID-19 Diagnostics

Background. As the SARS-CoV-2 (SCV-2) virus evolves, diagnostics and vaccines against novel strains rely on viral genome sequencing. Researchers have gravitated towards the cost-effective and highly sensitive amplicon-based (e.g. ARTIC) and hybrid capture sequencing (e.g. SARS-CoV-2 NGS Assay) to selectively target the SCV-2 genome. We provide an in silico model to compare these 2 technologies and present data on the high scalability of the Research Use Only (RUO) workflow of the SARS-CoV-2 NGS Assay.

Methods. In silico work included alignments of 383,656 high-quality genome sequences belonging to variant of concern (VOC) or variant of interest (VOI) isolates (GISAID). We profiled mismatches and sequencing dropouts using the ARTIC V3 primers, SARS-CoV-2 NGS Assay probes (Twist Bioscience) and 11 synthesized viral sequences containing mutations and compared the performance of these assays using clinical samples. Further, the miniaturized hybrid capture workflow was optimized and evaluated to support high-throughput (384-plex). The sequencing data was processed by COVID-DX software.

Results. We detected 101,432 viruses (27%) with > 1 mismatch in the last 6 base pairs of the 3’ end of ARTIC primers; of these, 413 had > 2 mismatches in one primer. In contrast, only 38 viruses (0.01%) had enough mutations (> 10) in a hybrid capture probe to have a similar effect on coverage. We observed that mutations in ARTIC primers led to complete dropout of the amplicon for 4/11 isolates and diminished coverage in additional 4. Twist probes showed uniform coverage throughout with little to no dropouts. Both assays detected a wide range of variants (> 99.9% coverage at 5X depth) in clinical samples (CT value < 30) collected in NY (Spring 2020-Spring 2021). The distribution of the number of reads and on target rates were more uniform among specimens within amplicon-based sequencing. However, uneven genome coverage and primer dropouts, some in the spike protein, were observed on VOC/VOI and other isolates highlighting limitations of an amplicon-based approach.