**Session:** P-13. COVID-19 Diagnostics

***Background:*** The management of the COVID-19 pandemic is hampered by the long delays associated with laboratory PCR testing. In hospitals this leads to poor patient flow and nosocomial transmission and so rapid, accurate diagnostic tests are urgently required. The aim of this study was to evaluate the clinical impact and real-world diagnostic accuracy of molecular point-of-care testing (mPOCT) for COVID-19 in hospital.

***Methods:*** We performed a prospective, interventional, non-randomised, controlled study of mPOCT for COVID-19 in adults presenting to hospital with suspected COVID-19. Patients were tested using the QIAstat-Dx SARS-CoV-2 at the point-of-care with results delivered to clinical and infection control teams. Control patients were tested using the PHE Rdrp reference assay. The Primary outcome measure was time to result and secondary outcome measures included infection control outcomes and measures of diagnostic accuracy.

***Results:*** Between 20th March and 29th April 2020 500 patients were tested by POCT and 555 controls, who were tested with laboratory PCR, were identified. Overall 33% were positive for SARS-CoV-2. Median time to results with POCT was 1.7 (1.6 to 1.9) hours versus 21.3 (16.0 to 27.9) hours in the control group (difference of 19.6 hours, 95%CI 19.0 to 20.3; p< 0.0001). Median time to arrival in definitive clinical area (COVID-19 positive or negative ward) was 8.0 (6.0 to 15.0) hours in the POCT group versus 28.8 (23.5 to 38.9) hours in the control group, p< 0.0001. Median time to enrolment into other COVID-19 clinical trials was 1.5 (1 to 3) days in the POCT versus 3.0 (2 to 5) days in the control group, p< 0.0001. Sensitivity of the POCT was 99.4% and specificity was 98.3%. The sensitivity of the laboratory PHE reference RdRp assay was 87.2% and specificity was 98.9%.

***Conclusion:*** mPOCT was associated with a large reduction in time to results and improvements in infection control measures and patient flow, compared with laboratory PCR. In addition, patients were recruited onto other clinical trials more rapidly with POCT. The QIAstat-Dx SARS-CoV-2 panel had high diagnostic accuracy for the detection of COVID-19 compared to laboratory PCR. Resources should be urgently made available to support the widespread implementation of mPOCT in hospitals, in preparation for the second wave.

***Disclosures:*** **Tristan William. Clark, BM MRCP DTM&H MD**, **BioFire Diagnostics** (Other Financial or Material Support, Equiptment and consumables for the purposes of research)**BioMerieux** (Other Financial or Material Support, Equipment and consumables for the purposes of research)**Qiagen** (Other Financial or Material Support, Discounted Equipment and consumables for the purposes of research)

**416. Comparative Analytical Assessment of PCR Mastermixes for Detection of SARS-CoV-2 using the CDC Diagnostic Test and the LightMix Modular Test on the cobas® z 480 Analyzer**

Steven Cagas, PhD[1]; Stephen McCune, BS[1]; Pedro Rodriguez, Ph.D[2]; Ray Hein, PhD[1]; John Osiecki, PhD[1]; Nicole Robinson, Ph.D[2]; Chris L. McGowin, PhD[1]; [1]Roche Diagnostics Corp, Indianapolis, Indiana; [2]Roche Diagnostics Corporation, Indianapolis, CA

**Session:** P-13. COVID-19 Diagnostics

***Background:*** The novel severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is a betacoronavirus responsible for the ongoing global pandemic and associated respiratory disease. Rapid development and implementation of molecular diagnostic testing solutions has been imperative to meet the enormous and urgent public health needs, and remains a key component of the US emergency response. Nucleic acid amplification tests (NAATs), with emergency use authorization (EUA) by the FDA, have been subject to significant supply chain shortages. This study aims to comparatively assess several commercially available substitutive mastermix reagents for the CDC SARS-CoV-2 EUA test and the TIB Mol Biol LightMix Modular (RUO) test.

***Methods:*** Positive control material included with each testing kit was used directly as DNA template for all manually assembled reactions and comparative evaluation. Additionally, these tests were evaluated similarly using the cobas omni Optimization kit, the first step in assessing suitability on the cobas® omni Utility Channel for high-volume user-defined molecular testing on the fully automated cobas® 6800/8800 Systems. All PCR was performed per the manufacturer's instructions using the User Defined Workflow (UDF; open channel) on the cobas® z 480 analyzer.

***Results:*** Robust amplification of the commercial control material was observed with each mastermix for all gene targets within the CDC and LightMix tests. Modest but significant (ANOVA, p< 0.05) target-specific Ct-value impacts were observed among the mastermixes assessed in this study. Using the cobas® omni optimization kit, Ct values for each target within the CDC and LightMix tests were consistently and significantly lower (ANOVA, p< 0.05) than the comparator mastermixes.

***Conclusion:*** Each mastermix may be a useful alternative to the recommended mastermix for SARS-CoV-2 detection. Additionally, these findings suggest the CDC and LightMix tests may be adapted for fully-automated, high-throughput testing on the 6800/8800 Systems.

***Disclosures:*** Steven Cagas, PhD, Roche Diagnostics Corp (Employee) Stephen McCune, BS, Roche Diagnostics Corp (Employee) Pedro Rodriguez, Ph.D, Roche Diagnostics Corp (Employee) Ray Hein, PhD, Roche Diagnostics Corp (Employee) John Osiecki, PhD, Roche Diagnostics Corp (Employee) Nicole Robinson, Ph.D, Roche Diagnostics Corp (Employee) Chris L. McGowin, PhD, Roche Diagnostics Corp (Employee)

**417. Comparative Assessment of Multiple SARS-CoV-2 Antibody and Neutralization Assays from Blood Samples in COVID-19 Infected Patients.**

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**Session:** P-13. COVID-19 Diagnostics

***Background:*** The severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2, COVID-19) has caused a world-wide pandemic. Diagnosis is usually made by an RT-PCR test from a respiratory sample. A number of tests are available for antibody detection or assessment, including rapid, enzyme immunoassays (EIA) and neutralization. However, characterization of the antibody immune response is not well documented and the clinical significance of COVID antibodies remains largely unknown. In addition, comparison of results across different assay formats using identical samples has not been rigorously studied, making clinical interpretation of serologic tests difficult.

Assessment of multiple SARS-CoV-2 antibody and neutralization assays from blood samples in COVID-19 infected patients

| Patient Information | | Rapid Test | Rapid Test | Rapid Test | ELISA | ELISA | ELISA | Test name | | | | Binding Inhibition Plate Assay |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Chembio DPP® COVID-19 IgM/IgG System | SD BIOSENSOR STANDARD™ Q COVID-19 IgM/IgG Duo Test | BTNX Rapid Response™ COVID-19 IgG/IgM Test Cassette | BIORAD Platelia SARS-CoV-2 Total Ab | EUROIMMUN Anti-SARS-CoV-2 ELISA (IgG) | EUROIMMUN Anti-SARS-CoV-2 ELISA (IgA) | | | | | GenScript SARS-CoV-2 Surrogate Virus Neutralization Test |
| | | Nucleocapsid Protein (NP) antigen | SARS-CoV-2 recombinant protein | SARS-CoV-2 antigens | SARS-CoV-2 nucleocapsid antibodies (IgM/IgA/Ab | Recombinant structural protein of SARS-CoV-2 | Recombinant structural protein of SARS-CoV-2 | Test Target (from package insert or communication from | | | | Recombinant antigen to S protein targets |
| | | Interpretation | Interpretation | Interpretation | Interpretation | Interpretation | Interpretation | | | | | Interpretation |
| Patient Number | Days Ab Testing after first recorded RT-PCR+ | Chembio | SD Biosensor | BTNX | Biorad: IgM, IgG, IgA | Euroimmun IgG | Euroimmun IgA | IgG/IgM Assays Tested | IgG and/or IgM Agreement | Total Assays Tested | Total Agreement | GenScript Binding Inhibition ACE2 receptors |
| | | No EUA | No EUA | No EUA | EUA | EUA | No EUA | | | | | No EUA |
| 1 | 4 | Negative | Positive | | Positive | Negative | Negative | 4 | 50% | 5 | 60% | Positive |
| 1 | 8 | Positive | Positive | Positive* | Positive | Positive | Negative | 5 | 100% | 6 | 83% | Positive |
| 1 | 14 | Positive | Positive | | Positive | Positive | Negative | 4 | 100% | 5 | 80% | Positive |
| 1 | 18 | Positive | Positive | | Positive | Positive | Negative | 4 | 100% | 5 | 80% | Positive |
| 1 | 26 | Positive | Positive | | Positive | Positive | Negative | 4 | 100% | 5 | 80% | Positive |
| 1 | 42 | Positive | Positive | Positive* | Positive | Positive | Negative | 5 | 100% | 6 | 83% | Positive |
| 2 | 8 | Negative | Negative | | Equivocal | Negative | Negative | 4 | 75% | 5 | 66% | Negative |
| 2 | 20 | Positive | Positive | Positive | Positive | Positive | Positive | 5 | 100% | 6 | 100% | Positive |
| 2 | 48 | Positive | Positive | Positive | Positive | Positive | Positive | 5 | 100% | 6 | 100% | Positive |
| 3 | -3 | Negative | Negative | Negative | Negative | Negative | Negative | 5 | 100% | 6 | 100% | Negative |
| 3 | 2 | Negative | Negative | Negative | Negative | Negative | Negative | 5 | 100% | 6 | 100% | Negative |
| 4 | 18 | Positive | Positive | | Positive | Positive | Positive | 4 | 100% | 5 | 100% | Positive |
| 4 | 29 | Positive | Positive | Positive | Positive | Positive | Positive | 5 | 100% | 6 | 100% | Positive |
| 4 | 46 | Positive | Positive | Positive | Positive | Positive | Positive | 5 | 100% | 6 | 100% | Positive |
| 5 | 2 | Positive | Negative | Negative | Negative | Negative | Positive | 5 | 80% | 6 | 66% | Negative |
| 5 | 7 | Negative | Negative | Negative | Equivocal | Negative | Positive | 5 | 80% | 6 | 66% | Negative |
| 6 | 0 | Negative | Negative | Negative | Negative | Negative | Negative | 5 | 100% | 6 | 100% | Negative |
| 6 | 13 | Negative | Negative | | Equivocal | Negative | Negative | 4 | 75% | 5 | 80% | Negative |
| 6 | 28 | Positive* | Positive | | Positive | Positive | Negative | 4 | 100% | 5 | 80% | Positive |
| 7 | 0 | Negative | Negative | Negative | Negative | Negative | Negative | 5 | 100% | 6 | 100% | Negative |
| 7 | 5 | Positive | Positive | Positive | Positive | Positive | Positive | 5 | 100% | 6 | 100% | Positive |
| 7 | 5 | Positive | Positive | | Positive | Positive | Positive | 4 | 100% | 5 | 100% | Positive |
| 8 | 4 | Positive | Positive | Positive | Positive | Positive | Positive | 5 | 100% | 6 | 100% | Positive |
| 8 | 15 | Positive | Positive | Positive | Positive | Positive | Positive | 5 | 100% | 6 | 100% | Positive |
| 9 | 0 | Negative | Negative | Negative | Negative | Negative | Negative | 5 | 100% | 6 | 100% | Negative |
| 9 | 6 | Positive | Positive | | Positive | Positive | Positive | 4 | 100% | 5 | 100% | Positive |
| 10 | 0 | Negative | Negative | | Negative | Negative | Negative | 4 | 100% | 5 | 100% | Positive |
| 10 | 4 | Negative | Negative | | Negative | Negative | Negative | 4 | 100% | 5 | 100% | Positive |
| 11 | 23 | Positive | Positive | | Positive | Positive | Positive | 4 | 100% | 5 | 100% | Positive |
| 11 | 31 | Positive | Positive | | Positive | Positive | Positive | 4 | 100% | 5 | 100% | Positive |
| 13 | 6 | Positive | Positive | | Positive | Positive | Positive | 4 | 100% | 5 | 100% | Positive |
| 13 | 7 | Positive | Positive | | Positive | Positive | Positive | 4 | 100% | 5 | 100% | Positive |
| 14 | 5 | Positive | Positive | | Positive | Positive | Positive | 4 | 100% | 5 | 100% | Positive |
| mean | 13.5 | | | | | | | 4.5 | 96% | 5.5 | 91% | |

***Methods:*** 1–5 serial (total 33) serum or plasma samples from 14 patients who were positive for SARS-CoV-2 by EUA authorized RT-PCR assays from nasopharyngeal specimens where tested with the following COVID-19 antibody tests: LFA rapid tests (Chembio DPP IgM/IgG, SD Biosensor Standard IgM/IgG, BTNX Rapid Response IgM/IgG), and EIA tests (BioRad Platelia SARS-CoV-2 Total antibody-IgG/IgM/IgA, EuroImmun SARS-CoV-2 IgG, and EuroImmun SARS-CoV-2 IgA). See Table 1 for results and EUA. Results were recorded as positive, negative, or equivocal. Additionally, antibody neutralization was assessed on matched samples.

***Results:*** Mean age of SARS-CoV-2 positive patients was 73 years (range 65–89), 11/14 had symptoms, all were male and hospitalized (6 ICU), and 3 died. Average number of days serum was collected after RT-PCR positivity was 13.5 days (range -3 to 46 d). BTNX assay was only tested on 16 samples. Among all assays, total concordance of results was 91%. When only IgG/IgM or total antibody assays were considered, concordance of results was 96% (Table). IgA specific results were discordant in 9/33 (27%) of samples compared to other assays. Two patients were negative in all assays in serial samples collected within one week of PCR positivity. Antibody neutralization was detected, but not from all samples.

***Conclusion:*** In general, there was good agreement among antibody detection assays. Neutralization may reflect disease outcome. The study was limited by the number of positive samples and patient number, and at the time specificity was not addressed for all the assays.

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

**418. Comparison of the Abbott SARS-CoV-2 IgG and DiaSorin LIASON SARS-CoV-2 S1/S2 IgG Antibody Assays**

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**Session:** P-13. COVID-19 Diagnostics

***Background:*** The Abbott Laboratories SARS-CoV-2 IgG assay and the DiaSorin LIASON SARS-CoV-2 S1/S2 IgG assay are both chemiluminescent immunoassays that

qualitatively detect IgG antibodies against SARS-CoV-2 antigens. The Abbott assay detects IgG against the viral nucleocapsid (N) protein, while the DiaSorin assay uses antigen derived from the viral spike (S) protein. Here we evaluate the performance of these two assays at our institution.

***Methods:*** 45 patient samples (serum or plasma) were tested for anti-SARS-CoV-2 IgG by both the Abbott and DiaSorin assays. The samples were previously characterized at a national reference laboratory using the Abbott assay or by an in-house PCR-based test for SARS-CoV-2 RNA. Samples yielding discordant results across platforms were further tested using the EUROIMMUN Anti-SARS-CoV-2 ELISA (IgG) assay at the reference laboratory.

***Results:*** 22 samples tested negative for SARS-CoV-2 by the reference lab Abbott assay, and 23 tested positive by the same reference lab test (n = 13) or by an in-house PCR-based test (n = 10). The 22 samples characterized as negative again tested negative by both the Abbott (in-house) and DiaSorin assays (100% NPA). Among the 23 samples characterized as positive, all 23 tested positive by the Abbott assay (100% PPA), while only 15 tested positive by the DiaSorin assay (65% PPA). For each of the 8 discordant cases, samples were further tested by EUROIMMUN assay, which targets the S protein; 7 of the 8 samples tested negative by this assay, in agreement with the DiaSorin test results. Thus, for the discordant cases, testing for IgG against N (in-house and reference lab Abbott assays) gave positive results, while testing for IgG against S (DiaSorin and EUROIMMUN assays) mostly gave negative results.

***Conclusion:*** These findings highlight the importance of the differences between various SARS-CoV-2 antibody tests, and providers should be aware of the specific antigenic target(s) in each test. Selection of a specific assay may depend on the need to assess past exposure to SARS-CoV-2 (for which a nucleocapsid target may be more sensitive) or to detect neutralizing antibodies (for which a spike target may be more relevant). This also has implications for disease surveillance as reliance on anti-spike antibodies alone may underestimate infection prevalence.

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

**419. Diagnostic Utility of a Ferritin to Procalcitonin Ratio to Differentiate Patients with COVID-19 from Those with Bacterial Pneumonia**

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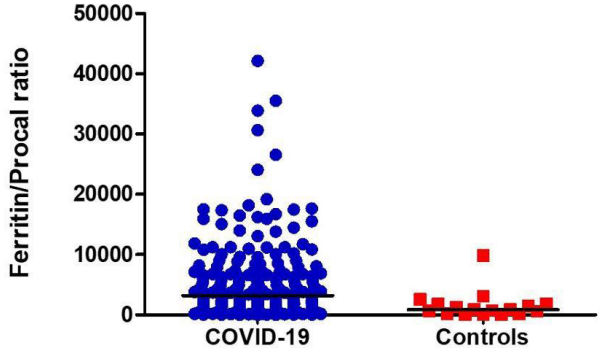
**Session:** P-13. COVID-19 Diagnostics

***Background:*** Accurate, rapid, inexpensive biomarkers are needed to differentiate COVID-19 from bacterial pneumonia, allowing effective treatment and antibiotic stewardship. We hypothesized that the ratio of ferritin to procalcitonin (F/P) reflects greater viral activity and host response with COVID-19 pneumonia, while bacterial pneumonia would be associated with less cytolysis (lower ferritin) and more inflammation (higher procalcitonin), thus a lower F/P ratio.

***Methods:*** We conducted a retrospective study of adult patients admitted to a single University hospital in the US through May 2020, during the COVID-19 pandemic. We compared F/P ratio of patients diagnosed with COVID-19 or bacterial pneumonia, excluding patients with COVID-19 and bacterial co-infections. In a logistic regression, we controlled for age, sex, body mass index (BMI), diabetes (DM), and hypertension (HTN). We used a receiver operating characteristic analysis to calculate the sensitivity and specificity of F/P values for the diagnosis of COVID-19 versus bacterial pneumonia.

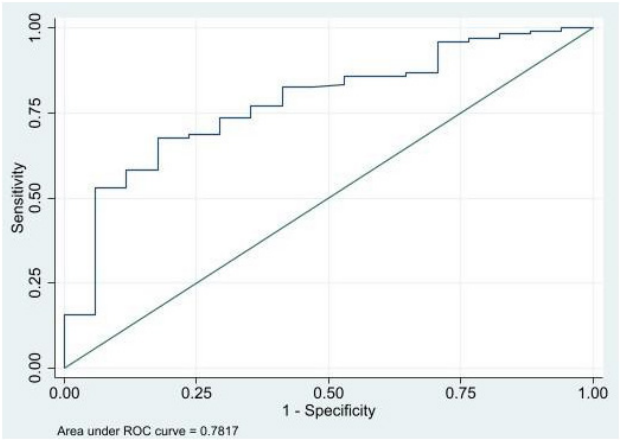
***Results:*** Of 218 patients with COVID-19 and 17 with bacterial pneumonia, COVID-19 patients were younger (56 vs 66 years, p=0.04), male (66% vs 24%, p=0.009), had higher BMI (31 vs 27 kg/m$^2$, p=0.03), and similar rates of HTN (59% vs 45%, p=0.3) and DM (32% vs 18%, p=0.2). The median F/P ratio was significantly higher in patients with COVID-19 (3195 vs 860, p=0.0003, Figure 1). An F/P ratio cut-off of ≥ 1250 generated a sensitivity of 78% and a specificity of 59% to correctly classify a COVID-19 case (Figure 2). When adjusted for age, gender, BMI, DM, and HTN, a ratio ≥ of 1250 was associated with significantly greater odds of COVID-19 versus bacterial pneumonia (OR: 4.9, CI: 1.5, 16.1, p=0.009).

Figure 1. Ferritin to Procalcitonin Ratios of patients with COVID-19 and patients with Bacterial Pneumonia (controls).




Black line represents medians. P=0.0003

Figure 2. Receiver Operating Characteristic Analysis of Ferritin to Procalcitonin Ratio Cut-off Values Predicting COVID-19 Diagnosis.




***Conclusion:*** We observed an elevated F/P ratio in patients with COVID-19 compared to those with bacterial pneumonia. A F/P ratio ≥ 1250 provides a clinically relevant increase in pre-test probability of COVID-19. Prospective studies evaluating the discriminatory characteristics of F/P ratio in larger cohorts is warranted.

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

**420. Diagnostic Utility of Chest CT scan for COVID-19, in the Early Stage of the Pandemic in Brooklyn, New York**

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**Session:** P-13. COVID-19 Diagnostics

***Background:*** Diagnosis of coronavirus disease 2019 (COVID-19) in the early weeks of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) pandemic in New York City posed unique challenges. Due to inadequate testing availability and long turnaround times, decisions on which patients to isolate were problematic. With sensitivity comparable to reverse transcription polymerase chain reaction (RT-PCR), the absence of ground glass opacities (GGOs) on chest CT scan was useful to rule out COVID-19. We evaluated the specificity of chest CT scan findings for COVID-19 along with other clinical and laboratory findings.

***Methods:*** A retrospective chart review was done of 182 adult patients who were tested for SARS-CoV-2 by RT-PCR and underwent a chest CT scan while admitted to Maimonides Medical Center between March 1 to 23, 2020. Cases were defined as those with a positive RT-PCR result or who were treated for COVID-19. Negative cases were defined as those with negative RT-PCR and an alternative diagnosis confirmed by an ID physician. Beyond March 23, almost all newly admitted patients were isolated.

***Results:*** There were 111 COVID-19 positive and 71 COVID-19 negative patients. Of the COVID-19 patients, 61% were male and 39% female, 56% white, 20% Hispanic, 14% black, 9% Asian, 36% Jewish, 35% had diabetes mellitus (DM), 50% had hypertension and 42% had cardiovascular disease. Clinical symptoms, signs, and laboratory values for COVID-19 positive and negative groups were not significantly different. COVID-19 patients had significantly higher BMI (p = 0.001). On chest CT scan, bilateral or unilateral, peripheral distribution and lower lobar GGOs were over 80% specific for COVID-19. The frequency of GGOs was significantly higher when chest CT scans were done during the second week of illness compared to the first week (p = 0.0195). Jewish patients were associated with higher rates of death (p = 0.0475) and underlying DM was associated with higher rates of ARDS, AKI, intubation, ICU admission and death (p < 0.05) compared to other demographic and comorbid groups.

***Conclusion:*** Chest CT scan is an important component in the diagnostic process for patients with suspected COVID-19 infection, especially during the second week of symptoms. The findings may aid clinical decisions in the setting of a second surge of SARS-CoV-2.

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

**421. If at first you do not succeed…. Repeat SARS-COV2 PCR testing**

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**Session:** P-13. COVID-19 Diagnostics

***Background:*** Nucleic Acid Amplification Tests (NAATs) of nasopharyngeal specimens (NPS) have become standard for diagnosis of SARS-COV2. IDSA guidelines suggest repeat testing after 24–48 h when initially negative and clinical suspicion persists. We characterized patients from whom initial NPS were NAAT-negative, but