Methods. Karius Test™ (KT) developed and validated in Karius’s CLIA-certified/CAP accredited lab, detects mcfDNA from plasma. mcfDNA is extracted, NGS performed, human sequences removed and remaining sequences aligned to a curated pathogen database of > 1500 organisms. Organisms present above a statistical threshold are reported and quantified. For > 85% of tests the time to result reporting is the next day from sample receipt. KT results were reviewed from November-2018 to May-2021 for detections of HHV6A and HHV6B. The comparative incidence of HHV6A and HHV6B detections, their age distributions and their quantitative viral concentration in molecules/μL (MPM) were assessed.

Results. KT detected 322 cases of HHV6; 10% (n=32) were HHV6A and 90% (n=290) HHV6B (Table 1). KT had a higher relative abundance in children (with a distribution into adolescence) compared to adults (Figure 1). The average HHV6A MPM was 860 (range 27 - 10,472); the average HHV6B MPM was 3,361 (range 21 - 131,518).

Table 1. Summary of HHV-6 Detections

| Virus variant | # of detections | MPM (60 < 100) mean/median | MPM range | Interquartile range | MPM SD |
|---------------|-----------------|-----------------------------|-----------|---------------------|---------|
| HHV6A         | 32              | 850/191                     | 25.8 - 10,472 | 661.35              | +/- 2,017 |
| HHV6B         | 290             | 3,361/379                  | 21 - 131,518 | 1,707.55            | +/- 10,850 |

Figure 1. Distribution of HHV6A and HHV6B by Age Group

Conclusion. The distribution of the HHV6 variants detected through KT shows an overwhelming 91% predominance of HHV6B to HHV6A. The application of mcfDNA metagenomic sequencing for open-ended detection, variant determination and quantification of HHV6 provides more specific resolution than serological and PCR methods. KT may lend important insights into the association of specific HHV6 variants with clinical syndromes affecting vulnerable populations.

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674. Evaluation of the Access Bio CareStart™ Rapid SARS-CoV-2 Antigen Test in Asymptomatic Individuals Tested at a Community Mass-testing Program in Western Massachusetts

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Session: P-31. Diagnostics: Virology

Background. Point-of-care antigen-detecting rapid diagnostic tests (RDTs) to detect Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) represent a scalable tool for surveillance of active SARS-CoV-2 infections in the population. Data on the performance of these tests in real-world community settings will be paramount for their implementation to combat the COVID-19 pandemic.

Methods. We evaluated the performance characteristics of the CareStart™ COVID-19 Antigen Test (CareStart) in a community testing site in Holyoke, Massachusetts. We compared CareStart to a SARS-CoV-2 reverse transcriptase quantitative polymerase chain reaction (RT-qPCR) reference, both using anterior nasal swab samples. We calculated the sensitivity, specificity, and the expected positive and negative predictive values at different SARS-CoV-2 prevalence estimates.

Results. We performed 666 total tests on 591 unique individuals. 573 (86%) were asymptomatic. There were 52 positive tests by RT-qPCR. The sensitivity of CareStart was 49.0% (95% Confidence Interval [CI]: 34.8 - 63.4) and specificity was 99.5% (95% CI: 98.5 - 99.9). Among positive RT-qPCR tests, the median cycle threshold (Ct) was significantly lower in samples that tested positive on CareStart. Using a Ct less than or equal to 30 as a benchmark for positivity increased the sensitivity of the test to 64.9% (95% CI: 47.5 - 79.8).

Performance characteristics of CareStart test results benchmarked against the RT-qPCR gold standard (excluding undetermined results).

Examples of images of Carestart rapid test showing variable band intensities.

Conclusion. Our study shows that CareStart has a high specificity and moderate sensitivity. The utility of RDTs, such as CareStart, in mass implementation should prioritize use cases in which a higher specificity is more important, such as triage tests to rule in active infections in community surveillance programs.

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675. Crimean-Congo Hemorrhagic Fever Beyond Ribavirin: A Systematic Review

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Results. We gathered a total of 10 studies, which included 4 therapeutic plasma exchange (TPE), 2 corticosteroids, 2 IVIG, and 1 with convalescent plasma (CP).

TPE in one study showed decreased mortality rate and increased efficacy in patients with severe CCHF. While the other study reported pulmonary embolism related to the use of TPE. Nevertheless, the patients had good outcome in the end. Two case reports used TPE plus ribavirin and supportive measures. Both were discharged home and recovered without sequel. Corticosteroids were found to be beneficial in one study where the case fatality rate was lower with the addition of corticosteroids to ribavirin in severely ill patients (p=0.0014). In a case series of six patients, who received the combination in early stages of the disease had good clinical outcomes with improved survival. IVIG was shown to increase platelet counts in two studies. In the first study, platelet counts increased above 150,000/mL in 8.5 +/- 2.5 days. While in the other study the normalization of platelets was seen in 4 - 4.8 days, with no significant difference (P = 0.49). In addition, there was a decrease in the duration of symptoms but there was no statistically significant difference in mortality rates (P = 0.171). CP treatment showed a survival rate of 86% in treated patients. CP was more useful in high-risk patients, defined as having a viral load of 10^4 copies or more. The main limitations of the studies were the small size and heterogeneity among the outcomes of the studies.

Conclusion. TPE, CP, IVIG, and corticosteroids were effective in improving the clinical outcomes of patients. The use of these treatments beyond ribavirin should be explored in future studies.

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676. Impact of Stratified Testing Algorithm Utilizing Rapid Testing and Polymerase Chain Reaction (PCR) Tests for Viral Infections

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Session: P-31. Diagnostics: Virology

Background. In 2017, the multiplex respiratory viral panel (RVP) test was the only test available for patients (pts) with respiratory symptoms in our emergency department (ED). In 2018, the more rapid influenza/respiratory syncytial virus (Flu/RSV) test was incorporated in a stratified testing algorithm (STA) – depending on clinical features and physician discretion, pts underwent either Flu/RSV or RVP. We analyzed the STA impact by comparing data between winters of 2017 and 2018.

Methods. In a retrospective, single-center cohort study in suburban NY, admitted pts 218 years diagnosed with viral infections (by either test) were included. We excluded pts diagnosed at another hospital, admitted to intensive care or observation (< 24 hours) units and pts with missing data. Data was collected through electronic medical chart review.

Primary outcomes were clinical evaluation time [time between triage and test order]; laboratory-turnaround (lta) time (between order and result); ED length of stay (EDLOS) [between admit order and bed assignment]. Secondary outcomes included isolation time (between result to start of isolation precautions), treatment time (between result to influenza treatment). Outcome differences were assessed using Chi-Square and Mann-Whitney rank sum tests for categorical and continuous variables, respectively.

Results. 734 pts were included in the study [368 in 2017; 366 in 2018]. Median age was 72 years and 55.9% were female. After implementing the STA, EDLOS was significantly lower [Table 1], with no significant differences in other parameters. lta times were slightly higher after implementation [25 minutes (2017) vs 29 minutes (2018)].

Table 1. Differences in clinical and laboratory turnaround times among patients admitted with viral infections in winters of 2017 and 2018

|                      | Winter of 2017 | Winter of 2018 |
|----------------------|----------------|----------------|
| Clinical evaluation time | 26.5+/-11.5 | 26+/-10.5 |
| Laboratory turnaround time | 15.4+/-4.5 | 19.4+/-7.5 |
| EDLOS | 253+/-112 | 246+/-93.5 |
| Time to isolation | 141+/-50.5 | 169+/-52.5 |
| Time to treatment | 126+/-30.5 | 129+/-33.5 |

Conclusions. A stratified diagnostic algorithm may have reduced EDLOS, but without significant differences in other outcomes. A higher lta time might have been due to testing constraints, heterogeneous pt populations or other confounders. Prospective studies will help assess the real-world impact of such algorithms.

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677. Compliance and Performance Characteristics of Subject Collected Versus Health-care Worker Collected Nasal Swabs for Respiratory Viral Surveillance

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Background. Self-collection of mid-nasal swabs (SCNS) at home is a convenient alternative to health-care worker-collected nasal swabs (HCWC) for determining the pathogen-specific epidemiology of influenza-like illness (ILI). We evaluated the