LITERATURE REVIEW SARS-CoV 2 Diagnostics

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WHO TO TEST (CDC Recommendation update 8/22/2021)

- People with symptoms of COVID-19.
- People who have had close contact (within 6 feet for >15 minutes) with someone with confirmed or suspected COVID-19.
  - Those who are fully vaccinated should get tested 3-5 days following exposure.
  - Those who are not vaccinated should be tested as soon as possible, and, if negative, should test 3-5 days since initiating exposure or as soon as any symptoms appear..
- People who are not fully vaccinated and are prioritized for expected community screening.
- People who have been asked or referred to be tested by their school, workplace, healthcare provider, or health department.

NUCLEIC ACID AMPLIFICATION e.g., PCR (test for active infection)

- CDC recommends against repeat testing for at least 3 months after a positive test.
- Increasing testing frequency has shown to have a positive effect on cases averted over 100 days. Pooled testing has been identified as a way to increase testing frequency and efficiency while also reducing costs.
- PCR testing has the lowest false negative rate on day 8 post-SARS-CoV 2 exposure for people who are asymptomatic.
- PCR sensitivity ranges from 42%-98.8% with a meta-analysis pooled sensitivity of 89%; there are patients who have positive PCR tests after already testing negative, demonstrating increased sensitivity with repeated testing.
- Variables in PCR detection sensitivity include disease state, sample type and technique, and test manufacturer.
- Positive PCR may not reflect transmissible infection as reliably as a positive viral culture, PCR can detect non-infectious viral fragments
- Pooled testing, which has been utilized by other countries, has the potential to save time, money, and increase efficiency compared to individual testing, but may have diminished returns if prevalence is above 10%.
- Several combination tests that test for SARS-CoV 2, influenza A, and influenza B simultaneously have received FDA EUA such as the CDC flu SC2 Multiplex Assay and Xpert Xpress SARS-CoV-2/Flu/RSV tests.

ANTIGEN TESTING (test for active infection, detects viral proteins)

- Results are ready in minutes, but antigen tests have lower sensitivity and specificity, also seen in influenza rapid tests.
- Guidelines from the Infectious Diseases Society of America (IDSA) provide diagnostic recommendations:
  - Symptomatic individuals should be tested with NAAt rather than antigen tests
  - Asymptomatic individuals at risk for exposure should be tested with a single NAAT over a single rapid antigen test
  - Asymptomatic individuals at risk for exposure should be tested with a single NAAT over two consecutive rapid antigen tests
  - Single or repeat rapid antigen testing versus no testing for asymptomatic indivduals is dependent on the circumstances
- Concerns about some rapid antigen tests' high false positive rate has led to some questions regarding its utility, particularly in asymptomatic individuals. Those with positive tests who are asymptomatic with low suspicion of COVID-19 should have a follow up nucleic acid amplification test to confirm positivity.
- Rapid antigen testing devices (such as PANBIO COVID-19 Ag rapid tests) may be beneficial as a mass screening test, when RT-PCR assays are not or insufficiently available, in particular in symptomatic patients and patients with high viral loads.
- The QuickNavi™-COVID19 Ag showed high specificity and appropriate sensitivity for the detection of SARS-CoV-2 in symptomatic patients.

SEROLOGY (test for past infection, detects antibodies)

- The CDC has recommended that serologic testing should not be used to establish absence or presence of SARS-CoV 2 infection.
- The Infectious Diseases Society of America lists 3 indications for serology:1) evaluation of patients with a high clinical suspicion when RT-PCR is negative *and* two weeks have passed since symptom onset; 2) assessment of multisystem inflammatory syndrome in children; 3) serosurvellance
- The most reliable EUA approved commercial testing kits include: Abbott ARCHITECT SARS-CoV-2 IgG, Roche Elecsys Anti-SARS-CoV-2 Pan-Ig, Siemens Healthcare Diagnostics Dimension EXL SARS-CoV-2 IgG (CV2G), and Siemens Healthcare Diagnositcs Dimension Vista SARS-CoV-2 IgG (COV2G).
- A rapid and reliable saliva-based test for COVID-19 antibodies, the CoVAb, has been developed as an alternative to the standard blood test
- Symptomatic patients are more likely to test positive for IgM; In acute infection, IgG levels are significantly higher in symptomatic.

STATUS OF TEXAS

- As of October 22nd, 2021, San Antonio/Bexar County has a percent positivity test rate of 1.9%.
- Many Texas health insurers and health maintenance organizations are waiving copayments, deductibles and coinsurance for COVID-19 testing; a list of participating insurance companies are listed here: https://www.opic.texas.gov/coronavirus
- There are currently over 90 testing sites in Bexar county with 21 of them being drive-thru testing or walk up (PCR)–they can be found here: https://covid19.sanantonio.gov/What-YOU-Can-Do/Testing#TestingLocation