TIP SHEET: Using the Abbott ID Now Rapid Molecular Test for COVID-19

April 22, 2020

The Abbott ID Now Rapid Molecular Test for COVID-19 is the first in-house lab testing available to MemorialCare. It has been available within MemorialCare for about two weeks, and there remains some confusion about its proper use in testing.

- The Abbott ID Now test utilizes a nucleic acid molecular detection method similar to their influenza A and B tests. This is typically a highly accurate methodology with a documented sensitivity of 93.2% for influenza A, 97.2% for Influenza B and a specificity of about 99% for both.
- The Abbott test comes with its own swab, which is thicker than the usual nasopharyngeal swab used for standard PCR testing. The swab supplied with the kit is intended for use in the anterior nares or in the oropharynx. In the nares, it should be inserted about 1 inch into the side with the most drainage, to the level of the turbinates, and needs to be coated with mucus for the test to be accurate. The same swab should then be used to swab the contralateral side. **Swabbing a dry nose increases the likelihood of a false negative test. Oropharyngeal testing** is intended to pick up drainage from the nasopharynx above, and unless there is significant anterior nasal mucus production, **is the preferred route of testing**. The Epic order defaults to the oropharyngeal source. Throat swabbing should include swabbing the posterior pharynx, tonsils, and other inflamed areas. The swab should not contact the tongue, cheeks, or teeth.
- Concerns have been raised about potentially poor sensitivity of the Abbott test. A study performed at the Cleveland Clinic, not yet published, evaluated five different molecular testing technologies, including the Abbott ID Now test. Of 239 samples, the Cleveland Clinic study found the Abbott test correctly identified 85.2%, and missed 14.8%, yielding a sensitivity of 85.2%.
- In our paired validation study testing simultaneous samples with Abbott and Quest technologies, MemorialCare's lab also found a combined sensitivity of 85%.
- In determining the accuracy of the test, sensitivity and specificity are just part of the equation. Prevalence of disease in the community and degree of clinical suspicion, i.e. pre-test probability, are hugely important. The lower the prevalence of the disease in a tested population, the greater the negative predictive value or "NPV" of a negative test (i.e., the more likely it is that a negative result is **truly** negative).
    - If the true sensitivity of the Abbott test is 85%, and one obtains a negative test in a patient who is felt to have a high likelihood of COVID-19 based on clinical presentation (say, hypothetically, 50% likelihood), then the NPV in this case

would be 86.8%; put differently, there would be a 13.2% chance that this was a false negative.
    - In the Emergency Department, where about 10% of patients with symptoms have been testing positive (even using the Quest PCR test), the NPV of the Abbott test would be 98.3%; thus, even in this symptomatic group, the false negative rate is less than 1 out of 50 negative tests.
    - Contrast that with an asymptomatic patient, in whom the likelihood of COVID-19 is much lower. If one assumes a likelihood of disease in an asymptomatic patient of 2 to 5% (likely an overestimate in California, even given our limited knowledge of disease prevalence), the NPV would range from 99.2 to 99.7%. Thus, the likelihood of a false negative in this case would be only 0.8 to 0.3%.
- Note that as the pre-test likelihood (prevalence) drops, so does the positive predictive value (PPV); that is, the likelihood of a false positive progressively rises. **All of these calculations are shown in table form at the end of this Tip Sheet.**
- Based on these concepts derived from Bayesian logic, **following up a negative Abbott test with another test only makes sense if you have a very high level of clinical suspicion (there is a high pre-test probability) of COVID-19 disease**. In such a case, it would be appropriate to follow up the negative Abbott test with a PCR-based test, either through Quest, or utilizing one of the PCR methodologies that our clinical labs will soon have available. Ordering a follow-up PCR test for a patient **not** at high pretest probability of COVID-19 is not medically reasonable and consumes a precious resource that is in limited supply (nasopharyngeal testing swabs and reagents).
- In order to allow for the proper follow-up testing of a potentially falsely negative Abbott test in a patient at high pretest probability of disease, a **new Epic order** is being generated that is specifically intended for follow-up PCR testing. The ordering physician must certify that the test is being ordered because the patient is felt to be at high pretest probability of COVID-19 disease. Specifically, this excludes such retesting in asymptomatic patients, who by definition are not at high pretest probability. Because of the limited availability of nasopharyngeal swabs, and because the in-house PCR testing will be limited, ordering of this test will be audited to ensure it is being used properly.

Group 1: Patients at High Pre-Test Probability based on classic presentation (N=200)			**Prevalence =50%**
	COVID+ (n=100)	COVID - (n= 100)	
Test +	True Positive = 85	False Positive = 1	Positive Pred. Value =98.8%
Test -	False Negative =15	True Negative = 99	**Negative Predictive Value = 86.8%**
	Sensitivity = 85%	Specificity = 99%	

Group 2: Patients with Initial Positive Symptom Questionnaire at Triage (N=200)			**Prevalence =10%**
	COVID+ (n=20)	COVID - (n= 180)	
Test +	True Positive = 17	False Positive = 2	Positive Pred. Value =89%
Test -	False Negative =3	True Negative = 178	**Negative Predictive Value = 98.3%**
	Sensitivity = 85%	Specificity = 99%	

Group 3: Asymptomatic patients with Low Clinical Pre-test Probability (N=200)			**Prevalence = 5%**
	COVID+ (n=10)	COVID - (n= 190)	
Test +	True Positive = 8.5	False Positive = 2	**Positive Pred. Value =81 %**
Test -	False Negative 1.5	True Negative =188	**Negative Pred. Value =99.2%**
	Sensitivity = 85%	Specificity = 99%	

Group 4: Asymptomatic Patients at Very Low Clinical Pre-test Probability (N=200)			**Prevalence = 2%**
	COVID+ (n=4)	COVID - (n= 196)	
Test +	True Positive = 3.4	False Positive = 2	**Positive Pred. Value =63 %**
Test -	False Negative =.6	True Negative =194	**Negative Pred. Value =99.7%**
	Sensitivity = 85%	Specificity = 99%	