

Requirements for diagnostics in primary care; a clinicians' view



Dr Nick Karr is the founder and CEO at Citra Urgent Care (formerly known as Sinai Urgent Care), where he also works as a practicing physician. Citra operates 5 centres in the Dallas metro area, which have provided more than 100,000 point-of-care molecular tests since the start of the COVID-19 pandemic. Here he provides us his experience of how a molecular diagnostic test needs to perform in order to work well in primary care.



Background

The past year has taught me the importance of not just testing in general, but rather of the right kind of testing. The COVID-19 pandemic has been a case study on the critical importance of testing and what's more, it's provided an education to the public regarding the different types of tests available

- Patients are now much more familiar with the different types of tests used to diagnose infections, namely antigen and PCR.
- They also have much better knowledge of the superiority of PCR, in terms of accuracy.

While in-clinic PCR does provide the assurance of same day results that you don't get when labs are sent out, even a 30 minute turnaround is too long to expect patients to wait.

So what is the right kind of test?

Fast

Ideally less than 10 minutes, but for sure under 15.

- This speed gets us results with enough time to actually discuss them with the patient during their visit. This is critical because it allows the provider to make treatment decisions with the patient while they are present, as opposed to having to call them after they leave to discuss treatment plans.
- It also helps in the event that there are errors with the sample and the patient has to be retested. With a sub-10min test you can do so while they are present, versus having to call them to ask them to return.

Reducing the time until the test provides results also leads to improved efficiency.

- Increasing the time between when the lab technician receives the sample and when the test produces results leads to an increase in the number of errors, including.
 - Confusing of samples.
 - Incorrectly uploading test results to the wrong patient's chart.
- The ability to run a faster (sub 10 minute) test also allows you to turn the rooms over quicker, should patients want to stay for the results.

Accurate

Antigen testing, while fast, lacks the sensitivity and specificity needed to make definitive treatment decisions. The ideal test should have greater than 95% sensitivity and specificity.

Reasonable price

Commercial payors are offering less and less for test reimbursement, for example United Health Group is reimbursing below the cost of current tests. A \$10-20 test allows for at least some revenue to be generated from the test.

CLIA Waived

Most clinics are authorized only to provide waived testing so it's of the utmost importance that a test in the office would need to be CLIA waived



Conclusion

Any diagnostic test designed for use in urgent and primary care must be CLIA waived, below \$20 cost to the clinician, and provide results in under 10 minutes. To provide the confidence necessary to make a definitive diagnosis sensitivity and specificity must be greater than 95%.

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