Luminex

White Paper

Respiratory Infection Testing Requires Flexible, Cost-Effective Diagnostics

The uncertainties of flu season serve as a stark reminder of the challenges faced in testing for respiratory infections. Whether it's flu or another respiratory pathogen, there is significant overlap of symptoms, making it difficult for labs to hone in on a diagnosis without tedious serial testing or large syndromic panel tests that may not be covered by insurance. Clinical teams also have to be prepared for drastic changes in demand for these tests. In the 2017-2018 flu season, clinical labs in the U.S. tested more than 1.2 million specimens for influenza, according to the Centers for Disease Control and Prevention.[1]

Molecular testing has been a major boon for respiratory infection testing. PCR-based tests are now widely accepted as the gold standard method, allowing labs to step away from the more time-consuming serology tests and tissue cultures.[2] With molecular assays, labs can generate results more quickly for the greatest impact on patient care. In addition to helping physicians select the most appropriate treatment for each patient, this shift has also had important implications for reducing the unnecessary use of antibiotics.

But embracing molecular diagnostics is not enough to help clinical labs manage the vagaries of respiratory testing. From seasonal changes in demand and different needs for certain patient situations to reimbursement uncertainty and the possibility of evolving practice guidelines, the most critical requirement in any clinical lab is flexibility. The ideal solution for respiratory testing allows laboratorians to rapidly scale capacity up or down, choose which pathogens to test for, and carefully manage costs. Lab directors and managers interested in streamlining their respiratory infection testing pipelines must consider a number of clinical, operational, and economic factors.

Clinical Considerations

Different laboratory settings require different algorithms for respiratory testing. The patient population is a key element: for example, testing choices for primarily healthy young adults are quite different from those for elderly or immunocompromised patients. Patients who have traveled to areas of the world where other respiratory infections are endemic also require special attention, as their testing needs will be distinct. Depending on the patient demographics, clinical labs may want to narrow respiratory testing just to flu and respiratory syncytial virus, or broaden it out to include a range of other possibilities.

During flu season — especially an unexpectedly severe season such as the 2017-2018 winter — the approach may shift. Labs in areas with high flu rates might choose to adopt an influenza-only assay since so many of their cases will be explained by flu pathogens. Ideally, follow-up testing for samples that come back negative for flu would happen quickly and with minimal additional cost.

Operational Factors

For many types of testing, the capacity issue is as simple as reference labs needing high-volume solutions while small, local labs need lower-volume options. But for some respiratory infections, the seasonal fluctuations are so large that even low-volume labs have to be able to accommodate significant testing spikes with very little notice. Labs with robust pipelines that can handle both stat and batch testing are best equipped for meeting this challenge without suffering a potentially catastrophic backlog of assays. Diagnostic solutions that facilitate variable throughput sample processing help labs manage their highest and lowest periods of demand without having to make major workflow changes.

Another operational factor is in test selection. To meet diverse testing needs, labs often offer an assortment of overlapping small and large panels, as well as expensive send-out tests for pathogens not covered by other options. This cobbled-together approach introduces unwanted challenges in managing test choice and turnaround time.

> **"The good thing is that if you do really run this one target and then they (physicians) want to know more, you can just release. You're not going back to that sample and retesting. You have that information still at your fingertips. That's awesome."**
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> - Cynthia Stewart , Bridgeport Hospital, Member of the Yale New Haven Health System

Economic Elements

Palmetto's 2018 local coverage determination detailing a decision to limit reimbursement for large, panel-based respiratory testing has put clinical lab teams in a difficult situation.[3] Syndromic testing for certain high-risk patients — immunocompromised, elderly, etc. — is a very effective way to return useful information to physicians in a medically relevant time frame. But some payers, like Palmetto, have adopted guidelines that discourage this type of approach.

In this environment, labs have to balance fiscal constraints with necessary performance and pathogen coverage as they strive to provide the best data possible for physicians and their patients. Here, too, flexibility helps labs achieve this balance. Assays that offer the choice of targeted or syndromic testing enable lab teams

to customize their diagnostic approach on a case-by-case basis. This flexibility will be even more critical as payers continue to move toward value-based reimbursement.

"You can flex into different configurations and build custom panels that best fit your testing needs," says Margie Morgan at Cedars-Sinai Medical Center, where her lab offers three versions of the VERIGENE® RP *Flex* Panel, Flu A/B with RSV, the full panel and just *Bordetella*. **"We created three *Flex* panels that work best for our patient population. These targeted panels are clinically relevant and reasonably priced."**

VERIGENE® RP *Flex*: The Flexible Solution

The VERIGENE® Respiratory Pathogens *Flex* Test (RP *Flex*) is an automated, multiplexed, flexible nucleic acid test for the identification of viruses and bacteria that most commonly cause respiratory infections.[4] VERIGENE RP *Flex* is a single panel of 16 viral and bacterial targets addressing the full spectrum of respiratory testing needs in a cost-effective manner. While the entire panel is run for each sample, laboratorians choose which results to view and pay only for those selected. Any combination of targets can be chosen for an individual sample at the time of test ordering. Additional results not initially reported after test completion can be reflexed instantly at an extra cost without running another test. Importantly, the VERIGENE RP *Flex* returns results quickly; hands-on time to run the assay is less than five minutes and run time is less than two hours.

For example, during the height of flu season, lab teams can run the VERIGENE RP *Flex* test and start by unmasking only the influenza results. For many patients, this will be sufficient to explain respiratory symptoms and costs will be minimized. But in cases where flu A/B results are negative and more information is needed, the clinician can ask the lab to unmask other results. This can happen immediately since the panel does not have to be rerun; the answers are ready to be viewed if needed. In all cases, labs only pay for the targets that were reported.

This method offers labs the utmost flexibility, allowing teams to begin with the most likely pathogens and expand to less common culprits only when needed. Labs can also select subsets of the test as options for healthcare providers, such as a bacterial panel, a viral panel, or a flu/RSV-only panel. This gives lab managers great control over their test menus without having to find new assays or adopt send-out testing.

User Experience

In the two years that VERIGENE RP *Flex* has been available, many clinical labs have adopted the test and reported on their experience with it.

At the 2017 Clinical Virology Symposium, Dr. Yvette McCarter, a clinical microbiology lab director from UF Health Jacksonville, reported that her lab had saved more than $95,000 in respiratory testing during the prior year by switching to this test.[5] The approach allowed McCarter to handle flu and *Bordetella* testing as well as broad-panel viral testing on the same instrument.

At the 2016 meeting of the Association for Molecular Pathology, Dr. Kevin McNabb from the New Hanover Regional Medical Center in North Carolina described his lab's implementation of the VERIGENE RP *Flex* respiratory panel.[6] The test was chosen because it covered all relevant viral and bacterial targets and was cost-effective. The lab's molecular testing team now relies on this test during low-demand seasons; McNabb estimated that it would save the facility about $65,000 annually.

Conclusion

Testing for respiratory infections is not conducive to a one-size-fits-all assay. It requires even more flexibility than other microbiology testing areas because of the spikes in demand associated with the seasonality of flu. Clinical labs have dynamic needs for respiratory testing, and these needs can only be addressed with a highly flexible solution that accommodates dramatic swings in volume as well as a shifting reimbursement landscape. Optimal assays and platforms will allow clinical lab teams to adjust quickly for factors such as season, patient demographics, and acceptable cost.

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