Questions on Respiratory Multiplex Panel Testing

Respiratory infections are common and may significantly affect the immunocompromised or young. The impact of respiratory illness may include inability to meet responsibilities at home or work, potential inappropriate use of antibiotics, and possible hospitalization. Nucleic acid amplification tests (NAATs) that first appeared for human immunodeficiency virus (HIV) in the 1980s were also used for Chlamydia trachomatis and now have been adopted for use with respiratory pathogens. Studies indicate detection of respiratory pathogens via molecular or NAAT testing, may detect multiple pathogens from a single sample more often than other methods. Studies also indicate infections in the elderly are more frequent and more severe with distinct features concerning clinical presentation. Diagnosis of infections in elderly patients is often complicated by atypical presentation or lack of classical symptoms of infection such as fever or localized pain. Atypical clinical presentation along with lack of fever may result in delayed diagnosis leading to a delay in treatment of elderly patients. The respiratory NAAT studies have shown validity for specific tests with clinical significance yet to be determined. The Coverage Advisory Committee (CAC) is convened to review the clinical evidence and answer the following questions to provide advice about the quality of the evidence for respiratory multiplex panel testing.

Voting Questions

For each voting question, please use the following scale identifying your level of confidence with a score of 1 being low or no confidence and a score of 5 representing high confidence.

1	—	2	—	3	—	4	—	5
Low Confidence				Intermediate				High Confidence

1. What confidence do you have that there is sufficient data to demonstrate the accuracy and reliability of these panels?
    a. Are there significant differences between the panels?

2. What confidence do you have in the literature regarding clinical validity (clinical sensitivity, specificity, positive predictive value, negative predictive value) of these panels?
    a. Does the literature show clinical validity differences between the panels? If so, discuss the implications.

3. In general, are there patient circumstances listed below for which only certain panels should be ordered?
    a. Consider circumstances such as: severity, time duration of symptoms, hypoxemia, infiltrates, hospitalization; environmental factors such as recent travel, local or regional outbreaks.
    b. Does the literature indicate it is appropriate to test all patients suspected of having a respiratory tract infection?

        i. What characteristics does the literature speak to regarding when/who to test?
    c. What level of false negative rate does the literature show for these panels?
        i. What are the implications?

4. How confident are you of the recommendation in #3? Rate and discuss your answer.

5. Based on the evidence, should restrictions for ordering these panels, if any, be considered for patient groups?
    a. immuno-compromised patients
    b. immuno-competent patients

6. How confident are you that the literature demonstrates patient outcome data is sufficient for clinical decision-making for these panels?

7. Is the evidence generalizable to the Medicare population?

8. In summary, does the literature show the advantages outweigh the disadvantages of these panels?

9. Does the need exist for additional evidence to answer risk/benefit questions not addressed in the current literature?