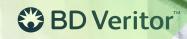


The Value of Rapid Antigen Testing

DR. AMESH ADALJA, MD

Disclosure

Dr. Amesh Adalja received paymentfrom Becton, Dickinson andCompany for this presentation.



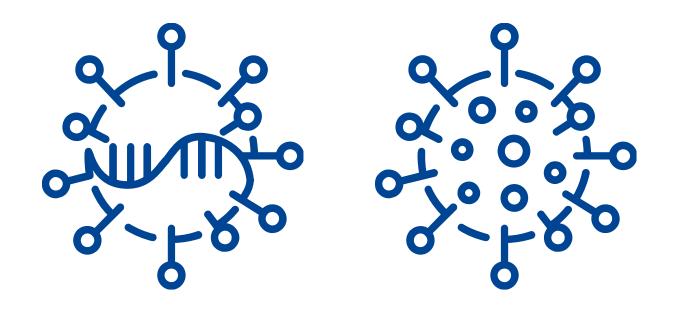
Learning Objectives

- Explain the overall value and differences between molecular and antigen testing
- Discuss the respiratory disease state and the recent tripledemic in the US
- Describe the benefit of combination rapid antigen testing during respiratory seasons

Testing is Critical

SO IS CHOOSING THE RIGHT TESTING MODALITY

Molecular and Antigen tests are commonly used to diagnose patients with active upper respiratory infections.¹



Molecular Test

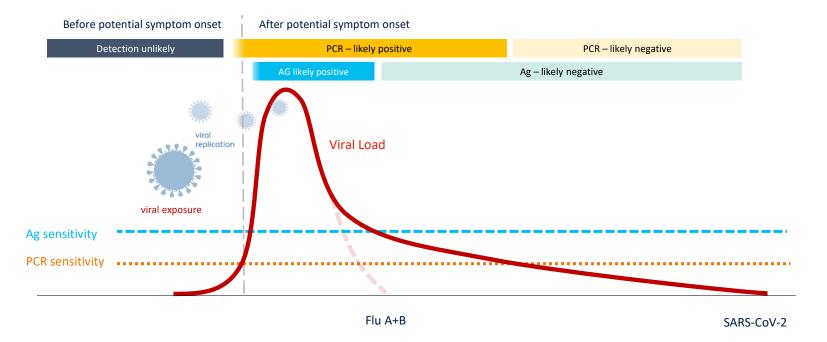
Antigen Test

Overview: Molecular vs. Antigen testing

	Molecular (Laboratory)	Antigen (POC, At-Home)
Other Names	PCR, NAAT ¹	Rapid test ¹
Tests for	Viral genetic material (RNA) ¹	Specific proteins of the virus ¹
Sample Type	Usually collected from nose or throat ¹	Usually collected from nose or throat ¹
Personnel Required	Samples can be self or provider-collected, but lab personnel required to perform testing ¹	Collection and testing can be performed independently or by HCPs (e.g. SCV2 at-home tests) ¹
Processing Time	~2-3 hours ¹	~15-30 minutes ¹
Result Communication Time	~24-48 hours plus transport time ¹	Immediately ¹
Accuracy (sensitivity)	Highly sensitive, gold standard ¹	Less sensitive than molecular, especially in those without symptoms ¹
Window of Detection	Up to 90 days post-symptom onset ¹	Usually 5-7 days post-symptom onset ¹ (usually when most infectious)
Confirmatory Test Required?	No ¹	Serial testing and/or follow-up PCR confirmatory testing required if negative ¹

When to test symptomatic patients for COVID-19 and Influenza

PROGRESSION OF VIRAL INFECTION 2,3,4



Different tests are appropriate at different times and for different objectives. Selecting the appropriate test depends on several criteria:^{2,3,4}

What's the testing objective?

- What's the patient's condition and potential exposure?
- What's the patient care setting and access to a lab?

How quickly do you need an answer?

References:

Sethuraman N, Jeremiah SS, Ryo A. Interpreting Diagnostic Tests for SARS-CoV-2. JAMA (v0.1)
 Q., Liu, B., Deng, H. et al. Antibody responses to SARS-CoV-2 in patient (v0.1)
 Mina Michael J. et al. Rethinking Covid-19 Test Sensitivity - A Strategy for Containment N (v0.1)
 Goyal A et al. Viral load and contact heterogeneity predict SARS-CoV-2 transmission and super-spreading events

Rapid Antigen Testing

BUILT FOR THE DEMANDS OF TODAY

With its shorter turnaround time, ability to accurately detect active infection, ease-of-use, and results delivered at the point-of-care or at-home, antigen testing is well-suited for early diagnosis and intervention:⁶



Rapid results support immediate diagnosis and patient management^{1,6}

Same day convenience reduces patient and care wait times and loss to follow up⁶



No prescription required for athome antigen tests¹



No medical professional required for sample collection or for testing for at-home antigen tests¹



Clinically validated and trusted⁶



Cost-effective to support frequent testing scenarios such as serial testing⁶



Expands access to testing^{1,6}



Condition	Time of year	Treatment(s)	Us disease burden
COVID-19	 Still being understood¹ Expected to become seasonal, like influenza²² 	 Antivirals (Remdesivir, Paxlovid, Molnupiravir)¹⁸ Immune Modulators (Olumiant and Actemra)¹⁸ 	 104M+ confirmed cases¹⁶ 6.1M+ admissions¹⁶ 1.1M+ deaths¹⁶
Influenza A & Influenza B	 Flu activity typically peaks between Dec and Feb¹² Atypical flu transmission has been reported all over the world after the COVID-19 pandemic²⁰ 	 Antivirals (Tamiflu, Relenza, Peramivir, and Baloxavir marboxil)⁹ 	 9M-41M cases per year¹² 140k-710k hospitalizations per year¹² 12k-52k deaths per year¹²
Respiratory Syncytial Virus (RSV)	 Peaks late-December to mid-February¹⁴ 	 No treatment in most cases, typically self- limiting¹³ 	 2.1M outpatient visits per year in children <5¹⁴ 235k hospitalizations per year¹⁴ 6k-10k deaths in adults 65+ per year¹⁴
Group A Strep	 Cases occur year-round, but more commonly in winter and spring¹⁵ 	 First Line abx's: Penicillin V & Amoxicillin¹⁵ If PCN allergic: Erythromycin & Cephalexin¹⁵ 	 5.2M+ outpatient visits annually¹⁵ >2.8 million antibiotic Rx's annually for persons aged 0-64 years¹⁵

Key Takeaways:

Several highly contagious respiratory infections cocirculate during fall/winter months.

Each have different approved treatments and plans of care.

Rapid and accurate diagnosis at the POC allows quicker and more effective treatment intervention.

Why test? Similar Presentation & Symptoms

Condition	Molecular (Laboratory)	
COVID-19 ¹⁰	Fever/chills, cough, shortness of breath or difficulty breathing, muscle or body aches, headache, new loss of taste or smell, sore throat, congestion or runny nose, nausea or vomiting, and diarrhea	
Influenza A and Influenza B ¹⁰	Fever/chills, cough, sore throat, runny or stuffy nose, muscle or body aches, headaches, fatigue, vomiting, and diarrhea	
Respiratory Syncytial Virus (RSV) ¹³	Fever, runny nose, decreased appetite, coughing, sneezing, and shortness of breath	
Streptococcal Pharyngitis ¹⁵	Fever/chills, sore throat, headache, nausea, scarlatiniform rash and vomiting	
Allergic Rhinitis ⁷	Sneezing, runny nose, congestion, itchy and watery eyes, headache, post-nasal drip, and scratchy throat	
Common Cold ⁸	Sneezing, runny nose, congestion, sore throat, coughing, fever, and post-nasal drip.	





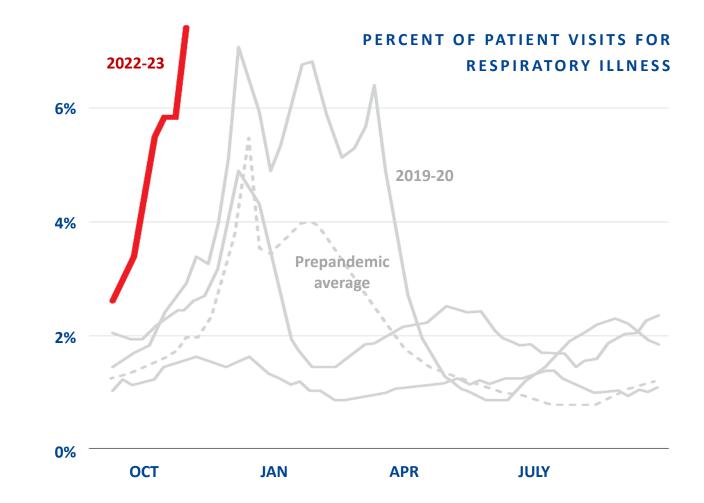
Overlapping symptom



Condition-specific symptom

2022-2023 U.S. Tripledemic

- The 2022-2023 "Tripledemic" (SARS-CoV-2, Flu, RSV) overwhelmed the U.S. healthcare system much earlier than expected last year²⁷
- ~40% of U.S. adults reported someone in their household became infected with one of the 3 viruses²⁵
- Co-infections are possible and evidence suggests they can lead to more severe disease in hospitalized patients²⁶



Multi-analyte Antigen Testing During Respiratory Season

POTENTIAL BENEFITS OF COMBO TESTING 17,19,21

- More efficient and convenient provider and patient workflows (1 sample, 1 test, 3 results)
- Increased diagnostic confidence
- More targeted treatment (decreased risk of inappropriate abx use)
- Ability to detect co-infections
- Increase patient satisfaction (faster TTR, more confidence behind provider diagnosis)
- Conservation of healthcare resources and supplies

What the experts are saying...

- "Given overlap between influenza and symptoms of mild/moderate COVID-19, systematic testing for SARS-CoV-2 and influenza will be needed during the upcoming influenza season" (Flannery et al., 2021)¹⁹
- "A fast and convenient differential diagnosis between COVID-19 and influenza has significant clinical value" (Li et al., 2021)²¹
- "...treatments for COVID-19 and influenza are very different, and misdiagnosis could result in treatment delay and unnecessary wastage of medical resources" (Li et al., 2021)²¹

Summary & Key Takeaways

BENEFITS OF POC RAPID ANTIGEN TESTING

- Increased diagnostic confidence given significant symptom overlap between infections (multi-analyte testing capabilities)^{19, 21}
- Decreases risks of unnecessary and/or inappropriate prescribing (antibiotics & antivirals)²³
- Increased patient convenience (receive evaluation, testing, and treatment in one visit)^{1, 19, 21}
- Helps to further mitigate community transmission 1,19,21,24
- Can promote faster initiation of antiviral therapies (e.g. Tamiflu, Paxlovid)²⁴
- Easy to use and low training requirements²⁴

BD, the BD Logo and BD Veritor are trademarks of Becton, Dickinson and Company or its affiliates. © 2023 BD. All rights reserved. (BD-90378 2172-US-0523 June 2023)





BD Veritor[™] Plus System

A COMPREHENSIVE ANTIGEN TESTING PORTFOLIO



*In the USA, these products have not been FDA cleared or approved but have been authorized by FDA under an Emergency Use Authorization for use by authorized laboratories; use by laboratories certified under the CLIA, 42 U.S.C. §263a, that meet requirements to perform moderate, high, or waived complexity tests. The products are authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation. *The BD Veritor[™] System for Rapid Detection of SARS-CoV-2 has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens; the BD Veritor[™] System for Rapid Detection of SARS-CoV-2 & Flu A+B has been authorized only for the detection of proteins from SARS-CoV-2, influenza A and influenza B, not for any other viruses or pathogens; and, in the USA, the emergency use of these products is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.



REFERENCES

- Centers for Disease Control and Prevention. (n.d.-c). Covid-19 testing: What you need to know. <u>https://www.cdc.gov/coronavirus/2019-</u> <u>ncov/symptomstesting/testing.html#:~:text=There%20are%20two%20main%20types,often%20performed%2</u> Oin%20a%20laboratory.2011
- 2. Sethuraman N, Jeremiah SS, Ryo A. Interpreting Diagnostic Tests for SARS-CoV-2. JAMA (V0.1)
- 3. Q., Liu, B., Deng, H. et al. Antibody responses to SARS-CoV-2 in patient (v0.1)
- 4. Mina Michael J. et al. Rethinking Covid-19 Test Sensitivity A Strategy for Containment N (v0.1)
- 5. Goyal A et al. Viral load and contact heterogeneity predict SARS-CoV-2 transmission and super-spreading events
- 6. Kendall EA:Arinaminpathy N:Sacks JA:Manabe YC: Dittrich S:Schumacher SG:Dowdy, DW; (n.d.). Antigenbased rapid diagnostic testing or alternatives for diagnosis of symptomatic COVID-19: A simulation-based net benefit analysis. *Epidemiology* (Cambridge, Mass.). <u>https://pubmed.ncbi.nlm.nih.gov/34292212/</u>
- 7. Centers for Disease Control and Prevention. (2020, August 21). *Allergens and pollen*. Centers for Disease Control and Prevention. <u>https://www.cdc.gov/climateandhealth/effects/allergen.htm</u>
- 8. Centers for Disease Control and Prevention. (2021, October 6). *Common cold*. Centers for Disease Control and Prevention. <u>https://www.cdc.gov/antibiotic-use/colds.html</u>
- Centers for Disease Control and Prevention. (2022a, September 7). Influenza antiviral Drug Baloxavir Marboxil. Centers for Disease Control and Prevention. <u>https://www.cdc.gov/flu/treatment/baloxavir-marboxil.html</u>
- Centers for Disease Control and Prevention. (2022b, September 28). Similarities and differences between flu and covid-19. Centers for Disease Control and Prevention. <u>https://www.cdc.gov/flu/symptoms/flu-vscovid19.htm</u>
- 11. Centers for Disease Control and Prevention. (2022c, October 4). *Disease burden of flu*. Centers for Disease Control and Prevention. <u>https://www.cdc.gov/flu/about/burden/index.html</u>
- 12. Centers for Disease Control and Prevention. (2022d, October 24). *Key facts about influenza (flu)*. Centers for Disease Control and Prevention. <u>https://www.cdc.gov/flu/about/keyfacts.htm</u>
- 13. Centers for Disease Control and Prevention. (2022e, October 24). Symptoms and care of RSV (respiratory syncytial virus). Centers for Disease Control and Prevention. <u>https://www.cdc.gov/rsv/about/symptoms.html</u>
- 14. Centers for Disease Control and Prevention. (2022f, October 28). *RSV surveillance and Research*. Centers for Disease Control and Prevention. <u>https://www.cdc.gov/rsv/research/index.html</u>
- 15. Centers for Disease Control and Prevention. (2023, January 6). *Strep throat: All you need to know.* Centers for Disease Control and Prevention. <u>https://www.cdc.gov/groupastrep/diseases-public/strep-throat.html</u>
- 16. Centers for Disease Control and Prevention. (n.d.-a). *CDC Covid Data tracker*. Centers for Disease Control and

Prevention. https://covid.cdc.gov/covid-data-tracker/#datatracker-home

- 17. Centers for Disease Control and Prevention. (n.d.-b). *CDC's influenza SARS-COV-2 multiplex assay*. Centers for Disease Control and Prevention. <u>https://www.cdc.gov/coronavirus/2019-ncov/lab/multiplex.html</u>
- Commissioner, O. of the. (n.d.). FDA has approved drug treatments and authorized others. U.S. Food and Drug Administration. <u>https://www.fda.gov/consumers/consumer-updates/know-your-treatment-options-covid-19#:~:text=What%20treatments%20are%20available%20for,hospitalized%20and%20non-hospitalized%20settings.</u>
- Flannery B;Meece JK: Williams JV;Martin ET-Gaglani M.Jackson ML-Talbot HK;; (n.d.). Systematic testing for influenza and coronavirus disease 2019 among patients with respiratory illness. *Clinical infectious diseases:* an official publication of the Infectious Diseases Society of America. <u>https://pubmed.ncbi.nlm.nih.gov/32687197/</u>
- 20. Gilchrist, K. (2022, June 13). Diseases suppressed during Covid are coming back in new and peculiar ways. *CNBC*. <u>https://www.cnbc.com/2022/06/10/flu-hepatitis-monkeypox-diseases-suppressed-during-covid-are-back.html</u>
- Li, J., Li, S., Qiu, X., Zhu, W., Li, L., & amp; Qin, B. (2021, May 12). Performance of Diagnostic Model for Differentiating Between COVID-19 and Influenza: A 2-Center Retrospective Study. *Medical Science Monitor*. <u>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8127639/pdf/medscimonit-27-e932361.pdf</u>
- Wiemken, T. L., Khan, F., Puzniak, L., Yang, W., Simmering, J., Polgreen, P., Nguyen, J. L., Jodar, L., & Amp; McLaughlin, J. M. (2023, March 8). Seasonal trends in COVID-19 cases, hospitalizations, and mortality in the United States and Europe. *Nature News*. <u>https://www.nature.com/articles/s41598-023-31057-1</u>
- Tillekeratne, L. G., Bodinayake, C., Nagahawatte, A., Kurukulasooriya, R., Orlando, L. A., Simmons, R. A., Park, L. P., Woods, C. W., & amp; Reed, S. D. (2019, March 30). Use of clinical algorithms and rapid influenza testing to manage influenza-like illness: A cost-effectiveness analysis in Sri Lanka. *BMJ global health*. <u>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6441298/</u>
- 24. Rapid testing. *IDSA Home*. (2022, September 6). <u>https://www.idsociety.org/covid-19-real-time-learning-network/diagnostics/rapid-testing/</u>
- 25. Nojiri, M. (2023, February 7). "tripledemic" affects 40 percent of U.S. households. *HAP*. <u>https://www.haponline.org/News/HAP-News-Articles/Latest-News/tripledemic-affects-40-percent-of-us-households</u>
- 26. Swets, M. (2022, April 16). SARS-CoV-2 co-infection with influenza viruses, respiratory syncytial virus, or adenoviruses. *The Lancet*. <u>https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(22)00383-x/fulltext</u>
- 27. Walker, A. S. (2022, December 16). Just how bad is the "tripledemic"? *The New York Times*. https://www.nytimes.com/interactive/2022/12/16/us/covid-flu-rsv-tripledemic-data.html



Questions?

