



# Dear Colleague

## COVID-19 Updates

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**New York City Department of Health and Mental Hygiene**

Flu Season During COVID-19

October 13, 2020



Staged teaching aid; childhood vaccination administration at a mobile clinic, 1976.  
Image courtesy of [Public Health Image Library](#), Centers for Disease Control and Prevention.

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## **COVID-19 Information and Guidance**

Updated information is available on the New York City (NYC) Health Department's [COVID-19](#) web pages.

- [Information for Providers](#): Recent health alerts, testing information, provider webinars and clinical guidance
- [Resources for Health Care Facilities](#): Guidance for inpatient, outpatient, long-term care and other settings
- [COVID-19 Data](#): Daily updates of recent and overall data on diagnostic and antibody test results, cases, hospitalizations, and deaths by ZIP code of residence, borough, age, sex, race and ethnicity, and neighborhood poverty
- [Telehealth Tips](#): Specific information for providers and patients

### **NYC Guidance**

- [City Health Information: Influenza Prevention and Control, 2020-2021](#)
- [COVID-19 Provider FAQ](#)
- [Health Advisory #37: All Point-of-Care COVID-19 Test Results Must be Reported Electronically](#)
- [Identifying and Triaging Adult Patients at Increased Risk for Severe COVID-19 in Outpatient Settings](#)

### **CDC Guidance**

- [Vaccination Guidance During the COVID-19 Pandemic](#)
- [Pandemic Guidance for Planning Vaccination Clinics Held at Satellite, Temporary, or Off-Site Locations](#)

### **Stay Up to Date**

- Access NYC Health Department's [influenza webpage](#)
- Sign up to receive [NYC Health Alerts](#)
- Join the [City Health Information network](#) to receive this newsletter by email
- Register for the bi-weekly NYC Health Department [COVID-19 Provider Webinar](#)

## **Flu Season During COVID-19**

During the 2019-2020 influenza (flu) season in the United States, the virus caused an estimated 18 to 26 million medical visits, 410,000 to 740,000 hospitalizations, and 24,000 to 62,000 deaths (including 185 deaths among children). In NYC, influenza caused approximately 2,000 deaths per year over the last 20 years, and together, influenza and pneumonia are the third leading cause of death. Other respiratory viruses circulate during a typical flu season, including rhinovirus, seasonal coronavirus (both causes of the “common cold”) and [respiratory syncytial virus](#) (RSV; a common cause of severe respiratory illness in young children and older adults).

This fall and winter, NYC’s health care sector must be ready to serve a large number of New Yorkers who require medical attention for viral respiratory diseases. The co-circulation of respiratory viruses that cause symptoms and illness similar to influenza and COVID-19 (e.g., fever, cough, sore throat, or shortness of breath) has the potential to increase the need for COVID-19 evaluation and testing and place additional demands on the health care system.

A potential second wave of COVID-19 may coincide with the 2020-2021 flu season and create a *syndemic* of respiratory illness. To date, little is known about the potential impact of viral co-infections with COVID-19 or whether past infection with SARS-CoV-2 may increase an individual’s vulnerability to other viral infections. It is conceivable that biological interactions between COVID-19 and other respiratory viruses could exacerbate the severity of disease ([Ozaras 2020](#)).

### **The Urgency of Vaccination**

There is currently no vaccine approved for use against COVID-19 in the United States, but there is a safe and effective vaccine for influenza that [reduces the risk of illness, hospitalization, and death](#). This year’s flu vaccine has been matched to offer protection against the current circulating influenza strains A/H1N1, A/H3N2 and B/Victoria. Getting a flu vaccine will both protect against influenza and help preserve scarce medical resources for use in treating patients with COVID-19.

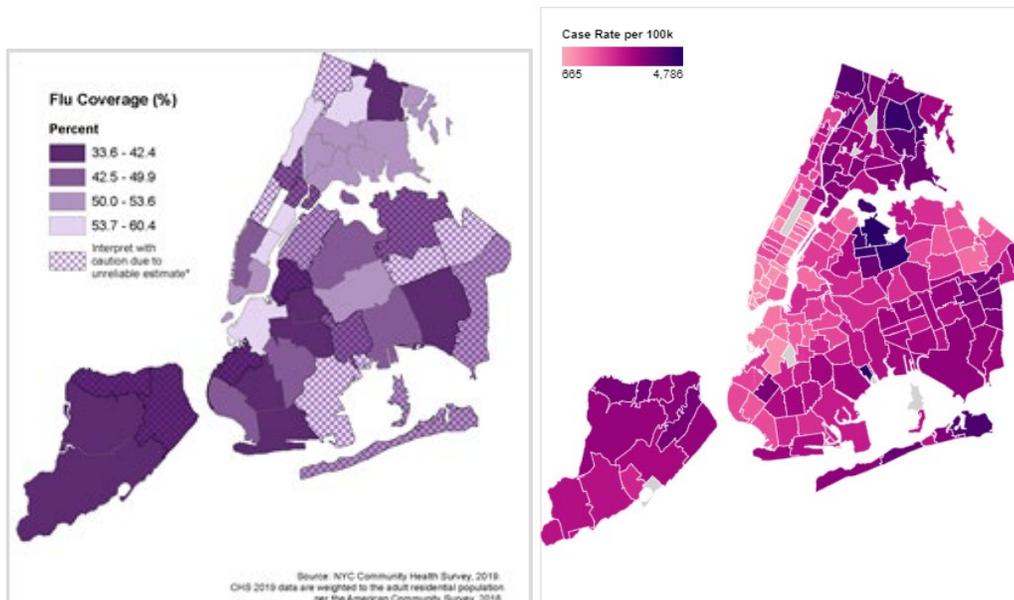
Providers can also encourage pneumococcal vaccination to prevent invasive pneumococcal disease as a complication of severe influenza in at risk-populations: pneumococcal polysaccharide 23-valent vaccine is routinely [recommended](#) for everyone aged 65 years or older, and pneumococcal conjugate vaccine is indicated for people with certain [underlying medical conditions](#).

For COVID-19, a safe and effective vaccine may become available for the general public beginning in early 2021. Providers who are interested in vaccinating their patients against

COVID-19 can prepare by enrolling in the online [Citywide Immunization Registry](#), which is likely to be required for ordering and reporting vaccinations.

## People at Risk for Severe Influenza and COVID-19

The COVID-19 pandemic has highlighted stark racial and ethnic health inequities in NYC. For Black and Latino New Yorkers, systemic racism and other forms of oppression may increase exposure to pathogens and limit access to care, for both COVID-19 and influenza. NYC neighborhoods with historically low flu vaccination coverage are predominantly Black and Latino (NYC Health Department unpublished data; Figure 1). Those same neighborhoods have the highest rates of COVID-19 cases, hospitalizations and deaths ([NYC Health Department data](#); Figure 2).



**Figure 1.** Percent of adult flu vaccine coverage by United Hospital Fund neighborhood, 2019

**Figure 2.** COVID-19 case rates by ZIP code (as of September 14, 2020)

Older adults are at high risk for severe influenza. In NYC, non-Latino, Black older adults had lower flu vaccination coverage in the 2018-2019 season (63%) than non-Latino White (68%), Latino (69%), and non-Latino Asian (76%) older adults (NYC Health Department, 2019 Community Health Survey). Low flu vaccination rates can partially be attributed to deep-seated medical mistrust within Black communities that may experience residual trauma from historical exploitation in medical research dating back to slavery. This was the case for [Henrietta Lacks](#),

whose cells were used in countless experiments without her consent and the men whose syphilis was left untreated in the [Tuskegee experiment](#). The collective memory of this trauma is amplified by present-day systemic racial injustices, including discrimination due to [implicit bias](#) in health care settings. Black Americans still express greater mistrust in flu vaccines (and in health care providers) than other racial and ethnic groups ([Freimuth 2017](#)). The low rates of flu vaccination raise concerns that the co-circulation of influenza and COVID-19 could exacerbate [the extreme burden of COVID-19](#) experienced by Black and Latino communities.

Provider recommendation for flu vaccination can still play an important role in vaccine acceptance, so providers should encourage flu vaccination when meeting with patients ([Nowak 2015](#)). Carefully communicate the benefits and safety of flu vaccination to apprehensive patients and learn about the ways to [address health inequities](#) in health care. Reach out to patients who are at high risk of [severe influenza](#) or [severe COVID-19](#) infection or who live in NYC neighborhoods with historically low flu vaccination coverage to ensure they receive the flu vaccine as soon as possible. Patients at high risk of severe influenza or COVID-19 include those aged 65 years and older or who have obesity, diabetes, a weakened immune system, or chronic renal, respiratory, or heart disease. Given the theoretical risk of complications due to prior COVID-19, providers can also reach out to patients who have had confirmed SARS-CoV-2 infection and encourage them to receive a flu vaccination as soon as possible. Although the risk for severe COVID-19 is low for children and unknown for pregnant people, these groups are at risk for influenza complications and should be encouraged to receive flu vaccination.

## Testing for COVID-19, Influenza and Other Respiratory Viruses

Increased demand for COVID-19 testing and ongoing supply shortages have led to long turnaround times for some commercial laboratory test results. Long turnaround times or shortages in certain test kits may require your facility to adopt a flexible testing algorithm and prioritize testing for certain patients based on current [public health guidance](#).

- **Combined testing:** Consider using combined diagnostic tests that detect influenza and SARS-CoV-2 (and sometimes other viruses as well); six have received [Emergency Use Authorization](#) (EUA) from the U.S. Food and Drug Administration (FDA) and others are under review (Appendix, Table 1).
- **Differential diagnosis:** Testing positive for pathogens other than SARS-CoV-2 does not rule out COVID-19 ([Kim 2020](#)), especially if there is active community transmission of COVID-19 or the patient had a recent exposure to someone with COVID-19. Diagnostic testing for SARS-CoV-2 is not routinely recommended if a patient with new respiratory symptoms has recovered from confirmed COVID-19 in the preceding 3 months and tests positive for another respiratory virus. Patients with new onset symptoms for whom you

cannot identify an alternative etiology [may warrant retesting](#) for SARS-CoV-2. Consider consultation with an infectious disease specialist.

- **COVID-19 rapid tests:** Rapid antigen-based diagnostic tests are generally not as sensitive as nucleic acid amplification (NAA)-based tests. Antigen tests may miss patients with lower viral shedding, especially later in the course of illness. [SARS-CoV-2 rapid antigen tests](#) should not be used to screen asymptomatic individuals. Patients who [test negative](#) on a rapid test should receive a confirmatory NAA test and be instructed to isolate until confirmatory results are available, especially if:
  - the patient had a recent exposure to COVID-19,
  - clinical presentation indicates likely infection with SARS-CoV-2.
- **Specimen collection:** Collect samples for influenza and SARS-CoV-2 as close to symptom onset as possible to improve diagnostic yield. If testing an asymptomatic patient after a known or likely exposure, consider testing around five days after exposure.
  - See [how to collect a nasopharyngeal swab](#) for influenza or SARS-CoV-2 testing.
  - Avoid collecting *lower* respiratory samples, such as induced sputum, in outpatient settings, unless appropriate infection control measures are in place ([IDSA 2018](#)).

## Preparing for a Possible Surge of Patients

Outpatient practices can take these steps to prepare for a potential surge of patients during a syndemic of multiple respiratory viruses, including SARS-CoV-2, influenza and RSV.

### Prepare Your Patients

- [Strongly recommend flu vaccination](#) at every visit to all patients who do not have contraindications.
- [Identify and reach out](#) to patients at risk for severe influenza or COVID-19 to encourage them, their household members and caretakers to receive the flu vaccine as soon as possible.
- Encourage vaccination for health care and other essential workers, or anyone whose job requires regular interaction with the public.
- [Communicate the safety and benefits of flu vaccination](#) to hesitant patients.
- Consider providing or prescribing pulse oximeters and thermometers to symptomatic patients at risk for severe respiratory disease so they can [monitor their oxygen levels and temperature at home](#).
- Counsel patients about [when to seek care](#) and how to [protect themselves and their families](#) against COVID-19 and other respiratory viruses.

- Ensure patients have access to [remote care](#) via telephone or video conference.

### **Prepare Your Office for High-Volume Vaccination and Testing**

- Enroll in the [Citywide Immunization Registry](#) and connect your electronic health record to the Registry to directly report and import vaccination records. Providers in New York State are legally obligated to report all vaccines administered to people aged up to 18 years and can report adult vaccinations with the consent of the patient.
- Review flu vaccination guidance from the [NYC Health Department](#) and CDC's guidance [here](#) and [here](#).
- Implement [non-patient-specific \(standing\) orders](#) to allow registered nurses and pharmacists to offer and administer flu vaccine to all patients.
- Expand testing capacity for SARS-CoV-2 and other respiratory viruses (e.g., influenza, RSV), ideally making point-of-care and combined testing available. Providers must [report results of SARS-CoV-2 point-of-care testing](#).
- Consider [ordering extra doses](#) of the flu vaccine in anticipation of increased demand.
- Plan to avoid shortages of personal protective equipment (PPE), medications (e.g., oseltamivir, antibiotics), testing supplies, medical gases, other medical equipment and vaccination supplies, including syringes, needles and anaphylaxis treatment agents. See the NYC Health Department's list of [PPE suppliers](#).
- If your clinic offers COVID-19 testing, evaluate patients via phone or video conference to shorten in-person encounters for testing and possible treatment.
- Make COVID-19 testing free and flu vaccinations available with [no out-of-pocket costs](#) to patients to ensure equal access for all and to protect public health. If you are unable to offer free testing and vaccinations, refer patients to [COVID Express testing](#) sites, which offer free flu vaccination along with COVID-19 tests, or refer to [NYC Health + Hospitals](#) locations. You can use the [NYC Health Map](#) to find facilities that provide low-to-no cost vaccinations.
- Consider using a combined diagnostic test for SARS-CoV-2 and influenza under an EUA from the FDA (Appendix, Table 1).

### **Ensure Staff Safety and Adequate Staffing**

- Identify essential clinical functions and services that can be suspended if needed during a surge.
- Cross-train staff to ensure continuity of services during possible staffing shortages.
- Train all staff on the safety and [importance of flu vaccination](#) this season and require staff members to get vaccinated for influenza, unless contraindicated.

- Train all staff on the [appropriate use of PPE](#), including safe donning and doffing procedures.
- Have staff wear a face mask and face shield or goggles during [all clinical encounters](#) to protect against SARS-CoV-2 and other viruses.
- Have staff follow [COVID-19 infection control precautions](#) with patients with symptoms of influenza, COVID-19, or other respiratory infections, until COVID-19 is ruled out.
- Share [guidance](#) with health care workers on:
  - flu vaccination this season,
  - self-monitoring for fever and other symptoms of COVID-19 and influenza,
  - restrictions on working when sick or following exposure or travel,
  - returning to work following SARS-CoV-2 exposure or confirmed or suspected [COVID-19](#) or [influenza](#).

### Create Safe Clinical Spaces

- Follow the NYC Health Department’s guidance on [infection control and safe operations in outpatient settings](#) during COVID-19.
- Consider establishing separate waiting and consultation areas, separate hours later in the day, or a dedicated clinical site for the evaluation and care of patients with respiratory symptoms. In addition, consider dedicating clinical staff to reduce potential exposures and [conserve supplies of personal protective equipment](#).
- Partner with community organizations to create [pop-up clinics for flu vaccination](#).
- Screen patients for symptoms of COVID-19 and influenza before they come to the facility.
- Require everyone entering the facility to wear a face covering.
- Screen everyone for fever and other symptoms of COVID-19 and influenza *upon arrival* to the facility, ideally before entry.
- Post [signage](#) to direct patients with symptoms of influenza or COVID-19 to designated triage and waiting areas, and to instruct patients on [respiratory etiquette](#), [hand hygiene](#), and physical distancing. Provide signage and [patient materials in multiple languages](#).
- Use barriers and physical distancing in waiting areas to reduce the risk of COVID-19 transmission.
- Assess air circulation and ventilation in shared clinical spaces.
  - If permanent solutions are not feasible, consider the use of portable HEPA filter units to increase air quality or create [temporary negative pressure rooms](#) for performing nebulizer treatments and other procedures that may generate aerosols.

- Follow [CDC guidelines](#) when administering vaccines.
  - For intranasal or oral vaccine, wear gloves. There is an increased likelihood of coming into contact with a patient’s mucous membranes and body fluids.
  - Between patients, change gloves and wash hands.
  - For injectable vaccines, if gloves are worn, change gloves and wash hands between patients.
  - Use of an N95 or higher-level respirator is not recommended at this time as administration of flu vaccines is not considered an aerosol-generating procedure.

## Flu Vaccine Supply

With a record number of vaccine doses being shipped this flu season, distribution is taking longer than usual. Facilities that have yet to receive their full order still have time, as October is an ideal time to vaccinate patients. If your facility runs low on flu vaccine, order more through distributors listed with the [Influenza Vaccine Availability Tracking System](#). Vaccinate your patients as you see them. If you do not have flu vaccine on hand, keep a list of patients who were seen and not vaccinated so you can call them back to the office for vaccination, or use the [NYC Health Map](#) to refer patients to pharmacies and other facilities that provide vaccination.

## Clinical Management of Patients With Possible COVID-19 or Influenza

### While Awaiting Test Results

Patients who have symptoms of COVID-19 or influenza with either pending or preliminary test results for SARS-CoV-2 and influenza can receive [empiric therapy](#) for influenza as appropriate (e.g., oral oseltamivir, oral baloxavir). Those who test positive for influenza or another respiratory virus and have pending COVID-19 test results can also receive appropriate therapies (e.g., inhalers, oral oseltamivir, oral baloxavir). As you wait for confirmed COVID-19 test results, assess severity of symptoms and [risk of severe COVID-19](#); counsel patients on how to [isolate safely](#); and closely monitor their disease progression since patients with COVID-19 can experience a precipitous decompensation in the second week of illness.

### Home Isolation

All patients who have mild to moderate symptoms of COVID-19 or influenza and a pending or positive COVID-19 test result should isolate at home, advise their medical provider if their symptoms worsen, and call 911 if they have [signs of a medical emergency](#). If patients are unable to safely isolate at home, they can access a free hotel room through the [NYC Take Care program](#).

## Follow-up With Patients at Higher Risk

Provide close follow-up to patients aged 65 years or older or who have an underlying health condition that may put them [at risk for severe COVID-19](#), following [guidance](#) from the NYC Health Department. Consider having them use pulse oximeters to monitor their blood oxygen levels and provide clear instructions on when to seek care if symptoms worsen. For detailed instructions for patients in multiple languages on home oxygen monitoring and managing COVID-19 at home, see the [NYC Test & Trace Corp Take Care Booklet](#).

## Looking Ahead

The ongoing COVID-19 pandemic will present challenges to managing the upcoming annual flu season and require adjustments at health care facilities. Black and Latino communities, older adults, and people with underlying health conditions were disproportionately affected during the first wave of COVID-19 and may face a disproportionate health burden from multiple, co-circulating respiratory diseases in the coming months. Thoughtful planning and preparedness for vaccination, testing and infection control will allow the health care system to carry out a safe, effective and equitable response, and can lay the groundwork for building a better prepared, more resilient and more equitable health care system.

## Selected Publications

Belongia EA, Osterholm MT. [COVID-19 and flu, a perfect storm](#). *Science*. 2020;368(6496):1163.

This editorial argues for comprehensive combined COVID-19 and influenza virus testing to avoid overwhelming health care systems during flu season.

Cowling BJ, Ali ST, Ng TW, et al. [Impact assessment of non-pharmaceutical interventions against coronavirus disease 2019 and influenza in Hong Kong: an observational study](#). *Lancet Public Health*. 2020;5(5):e279-e288.

This study describes the impact of various public health measures (quarantine, travel restriction, social distancing, etc.) on influenza rates during the COVID-19 epidemic.

Konala VM, Adapa S, Gayam V, et al. [Co-infection with influenza A and COVID-19](#). *Eur J Case Rep Intern Med*. 2020;7(5):001656.

This report summarizes some of the key differences between COVID-19 and influenza, which can present with similar symptoms and co-occur.

Kuo S-C, Shih S-M, Chien L-H, Hsiung CA. [Collateral benefit of COVID-19 control measures on influenza activity, Taiwan](#). *Emerg Infect Dis*. 2020;26(8):1928-1930.

Taiwan has noted a significant decline in influenza cases compared to 2019, which the authors attribute to health measures aimed at preventing the spread of COVID-19.

Liu M, Zeng W, Wen Y, Zheng Y, Lv F, Xiao K. [COVID-19 pneumonia: CT findings of 122 patients and differentiation from influenza pneumonia](#). *Eur Radiol*. 2020;30(10):5463-5469.

This study compares the radiographic findings in lung CT scans of patients infected with COVID-19 or influenza, finding significant differences in CT manifestations that may aid diagnosis.

Marín-Hernández D, Schwartz RE, Nixon DF. [Epidemiological evidence for association between higher influenza vaccine uptake in the elderly and lower COVID-19 deaths in Italy](#). *J Med Virol*. Published online June 4, 2020.

Regions in Italy where a higher percentage of patients aged older than 65 years had received the flu vaccine had lower rates of death from COVID-19 in that age group.

Ozaras R, Cirpin R, Duran A, et al. [Influenza and COVID-19 co-infection: report of 6 cases and review of the literature](#). *J Med Virol*. 2020;92:2657-2665.

A review of 34 cases of patients co-infected with COVID-19 and influenza suggests that thoracic imaging may be useful in differentiating the viruses and that providers maintain a high index of suspicion of co-infection in certain patients.

Soo RJJ, Chiew CJ, Ma S, Pung R, Lee V. [Decreased influenza incidence under COVID-19 control measures, Singapore](#). *Emerg Infect Dis*. 2020;26(8):1933-1935.

Singapore noted an early decrease in overall incidence in influenza cases as a result of social distancing measures designed for COVID-19 prevention.

## Appendix

**Table 1.** Combined diagnostic tests that detect influenza and SARS-CoV-2 and that have received FDA Emergency Use Authorization

Company	Device	Organisms	Type of Test	Sample	Laboratory	COVID-19 Performance According to Developer	Factsheets
<b>BioFire</b>	BioFire Respiratory Panel 2 (RP2.1) to be used with FilmArray 2.0 and FilmArray Torch Systems	<ul style="list-style-type: none"> <li>• SARS-CoV-2 (E and S genes)</li> <li>• Adenovirus</li> <li>• CoV 229E</li> <li>• CoV HKU1</li> <li>• CoV NL63</li> <li>• CoV OC43</li> <li>• Human metapneumovirus</li> <li>• Human rhinovirus/enterovirus</li> <li>• Influenza A (H1, H1-2009, H3)</li> <li>• Influenza B</li> <li>• Parainfluenza virus 1, 2, 3, 4</li> <li>• RSV</li> <li>• <i>Bordetella parapertussis</i></li> <li>• <i>Bordetella pertussis</i></li> <li>• <i>Chlamydia pneumoniae</i></li> <li>• <i>Mycoplasma pneumoniae</i></li> </ul>	Multiplex nucleic acid real-time PCR	Nasopharyngeal swabs	CLIA High Complexity	<ul style="list-style-type: none"> <li>• 98 stored specimens:               <ul style="list-style-type: none"> <li>○ 98% positive predictive value</li> <li>○ 100% negative predictive value</li> </ul> </li> <li>• Limit of detection of infectious virus: 160 copies/mL or 0.011 TCID<sub>50</sub>/mL</li> <li>• Cross-reactivity: amplification of small selection of sequences from Bat and pangolin coronavirus</li> </ul>	<ul style="list-style-type: none"> <li>• Providers: <a href="https://www.fda.gov/media/137581/download">fda.gov/media/137581/download</a></li> <li>• Patients: <a href="https://www.fda.gov/media/137582/download">fda.gov/media/137582/download</a></li> </ul>
<b>QIAGEN GmbH</b>	QIAstat-Dx Respiratory SARS-CoV-2 Panel to be used with QIAstat Dx Analyzer System	<ul style="list-style-type: none"> <li>• SARS-CoV-2 (Orf1b poly gene and E gene)</li> <li>• Adenovirus</li> <li>• CoV 229E</li> <li>• CoV HKU1</li> <li>• CoV NL63</li> <li>• CoV OC43</li> <li>• Human metapneumovirus A+B</li> <li>• Influenza A (H1, H1/pdm2009, H3)</li> <li>• Influenza B</li> <li>• Parainfluenza virus 1, 2, 3, 4</li> <li>• Human rhinovirus/enterovirus</li> <li>• RSV A+B</li> <li>• <i>Bordetella pertussis</i></li> <li>• <i>Chlamydia pneumoniae</i></li> <li>• <i>Mycoplasma pneumoniae</i></li> </ul>	Multiplex nucleic acid real-time PCR	Nasopharyngeal swabs	CLIA High Complexity	<ul style="list-style-type: none"> <li>• 60 clinical specimens:               <ul style="list-style-type: none"> <li>○ 100% positive predictive value</li> <li>○ 100% negative predictive value</li> </ul> </li> <li>• Limit of detection: 500 copies/mL</li> <li>• No cross-reactivity observed in spiked samples</li> </ul>	<ul style="list-style-type: none"> <li>• Providers: <a href="https://www.fda.gov/media/136568/download">fda.gov/media/136568/download</a></li> <li>• Patients: <a href="https://www.fda.gov/media/136570/download">fda.gov/media/136570/download</a></li> </ul>

CLIA, Clinical Laboratory Improvement Amendments; C<sub>t</sub>, threshold cycle; ID<sub>50</sub>, 50% infectious dose; PCR, polymerase chain reaction; RSV, respiratory syncytial virus; TCID<sub>50</sub>, 50% tissue culture infectious dose

**Table 1.** Combined diagnostic tests that detect influenza and SARS-CoV-2 and that have received FDA Emergency Use Authorization (*continued*)

Company	Device	Organisms	Type of Test	Sample	Laboratory	COVID-19 Performance According to Developer	Factsheets
CDC	Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay to be used with an authorized real-time PCR instrument	<ul style="list-style-type: none"> <li>• SARS-CoV-2 (N gene)</li> <li>• Influenza A</li> <li>• Influenza B</li> </ul>	Multiplex nucleic acid real-time PCR	Nasopharyngeal, oropharyngeal and nasal swabs, sputum, lower respiratory tract aspirates, bronchoalveolar lavage, and nasopharyngeal wash/aspirate or nasal aspirate	CLIA High Complexity	<ul style="list-style-type: none"> <li>• 227 clinical specimens:                             <ul style="list-style-type: none"> <li>○ 100% positive predictive value</li> <li>○ 100% negative predictive value</li> </ul> </li> <li>• 100% agreement in samples from different specimen types</li> <li>• No cross-reactivity observed</li> <li>• Limit of detection: 0.01 ID<sub>50</sub>/reaction</li> </ul>	<ul style="list-style-type: none"> <li>• Providers: <a href="https://www.fda.gov/media/139742/download">fda.gov/media/139742/download</a></li> <li>• Patients: <a href="https://www.fda.gov/media/139745/download">fda.gov/media/139745/download</a></li> </ul>
Roche	cobas SARS-CoV-2 and Influenza A/B to be used with cobas® 6800/8800 system	<ul style="list-style-type: none"> <li>• SARS-CoV-2 (ORF1a/b and E gene)</li> <li>• Influenza A</li> <li>• Influenza B</li> </ul>	Multiplex nucleic acid real-time PCR	Provider-collected nasal and nasopharyngeal swab, self-collected nasal swab at provider's office	CLIA High and Moderate Complexity	<ul style="list-style-type: none"> <li>• 348 clinical specimens:                             <ul style="list-style-type: none"> <li>○ 96.4% positive predictive agreement</li> <li>○ 98% negative predictive agreement</li> </ul> </li> <li>• 8 discordant samples with late C<sub>t</sub> values (35-43)</li> <li>• Limit of detection of infectious virus: 0.12 ID<sub>50</sub>/mL</li> <li>• No cross-reactivity observed with 41 viruses, bacteria and fungi</li> </ul>	<ul style="list-style-type: none"> <li>• Providers: <a href="https://www.fda.gov/media/141885/download">fda.gov/media/141885/download</a></li> <li>• Patients: <a href="https://www.fda.gov/media/141886/download">fda.gov/media/141886/download</a></li> </ul>

CLIA, Clinical Laboratory Improvement Amendments; C<sub>t</sub>, threshold cycle; ID<sub>50</sub>, 50% infectious dose; PCR, polymerase chain reaction; RSV, respiratory syncytial virus; TCID<sub>50</sub>, 50% tissue culture infectious dose

**Table 1.** Combined diagnostic tests that detect influenza and SARS-CoV-2 and that have received FDA Emergency Use Authorization (*continued*)

Company	Device	Organisms	Type of Test	Sample	Laboratory	COVID-19 Performance According to Developer	Factsheets
<b>Cepheid</b>	Xpert® Xpress SARS-CoV-2/Flu/RSV to be used with Cepheid’s GeneXpert® Systems	<ul style="list-style-type: none"> <li>• SARS-CoV-2 (N2 and E genes)</li> <li>• Influenza A</li> <li>• Influenza B</li> <li>• RSV</li> </ul>	Multiplex nucleic acid real-time PCR	Nasopharyngeal swab, nasal wash/aspirate	CLIA High, Moderate or waived (i.e., point-of-care) complexity tests	<ul style="list-style-type: none"> <li>• 240 clinical specimens: <ul style="list-style-type: none"> <li>○ 97.9% positive predictive agreement</li> <li>○ 100% negative predictive agreement</li> </ul> </li> <li>• Limit of detection: 131 copies/mL</li> <li>• Cross-reactivity: <ul style="list-style-type: none"> <li>○ In silico: No cross-reactivity detected with 39 viruses, bacteria and fungi</li> <li>○ No cross-reactivity observed with 44 cultures: 16 viral, 26 bacteria and 2 yeasts.</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• Providers: <a href="https://www.fda.gov/media/142435/download">fda.gov/media/142435/download</a></li> <li>• Patients: <a href="https://www.fda.gov/media/142436/download">fda.gov/media/142436/download</a></li> </ul>
<b>Quidel Corporation</b>	Sofia 2 Flu + SARS Antigen FIA	<ul style="list-style-type: none"> <li>• SARS-CoV-2 (nucleocapsid protein; does not differentiate SARS-CoV-1 and 2)</li> <li>• Influenza A (nucleocapsid protein)</li> <li>• Influenza B (nucleocapsid protein)</li> </ul>	Immuno-fluorescence antibody sandwich	Nasopharyngeal swab, nasal swab	CLIA High, Moderate, or waived (i.e., point-of-care) complexity tests	<ul style="list-style-type: none"> <li>• 164 specimens, reference extracted SARS-CoV-2 real-time PCR assay: <ul style="list-style-type: none"> <li>○ 95.2% positive predictive agreement</li> <li>○ 100% negative predictive agreement</li> <li>○ 100% positive predictive value</li> <li>○ 98.4% negative predictive value</li> </ul> </li> <li>• Limit of detection of infectious virus: 91.7 TCID<sub>50</sub>/mL</li> <li>• No cross-reactivity observed with 28 viruses, bacteria and fungi</li> </ul>	<ul style="list-style-type: none"> <li>• Providers: <a href="https://www.fda.gov/media/142702/download">fda.gov/media/142702/download</a></li> <li>• Patients: <a href="https://www.fda.gov/media/142703/download">fda.gov/media/142703/download</a></li> </ul>

CLIA, Clinical Laboratory Improvement Amendments; C<sub>t</sub>, threshold cycle; ID<sub>50</sub>, 50% infectious dose; PCR, polymerase chain reaction; RSV, respiratory syncytial virus; TCID<sub>50</sub>, 50% tissue culture infectious dose