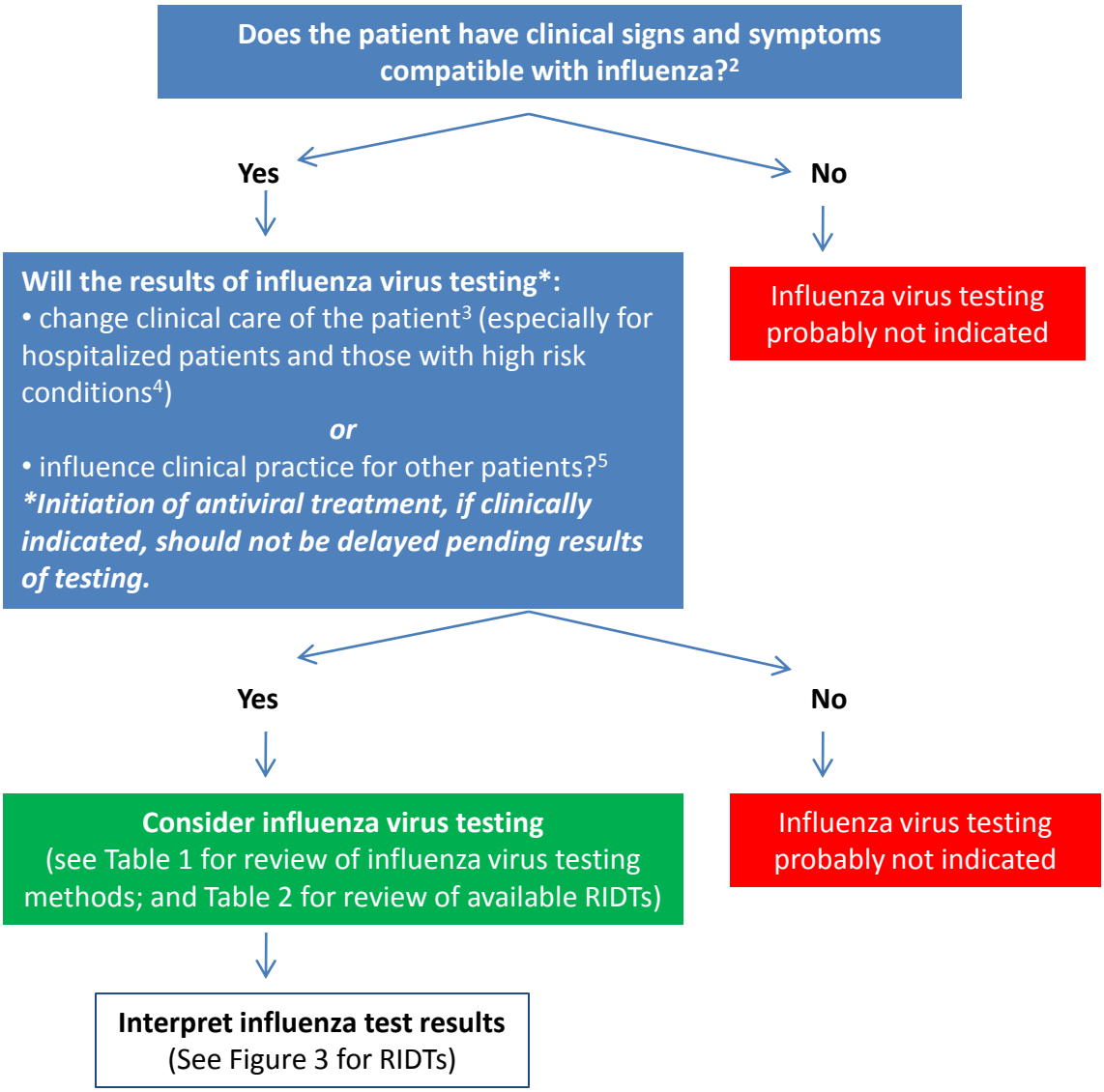
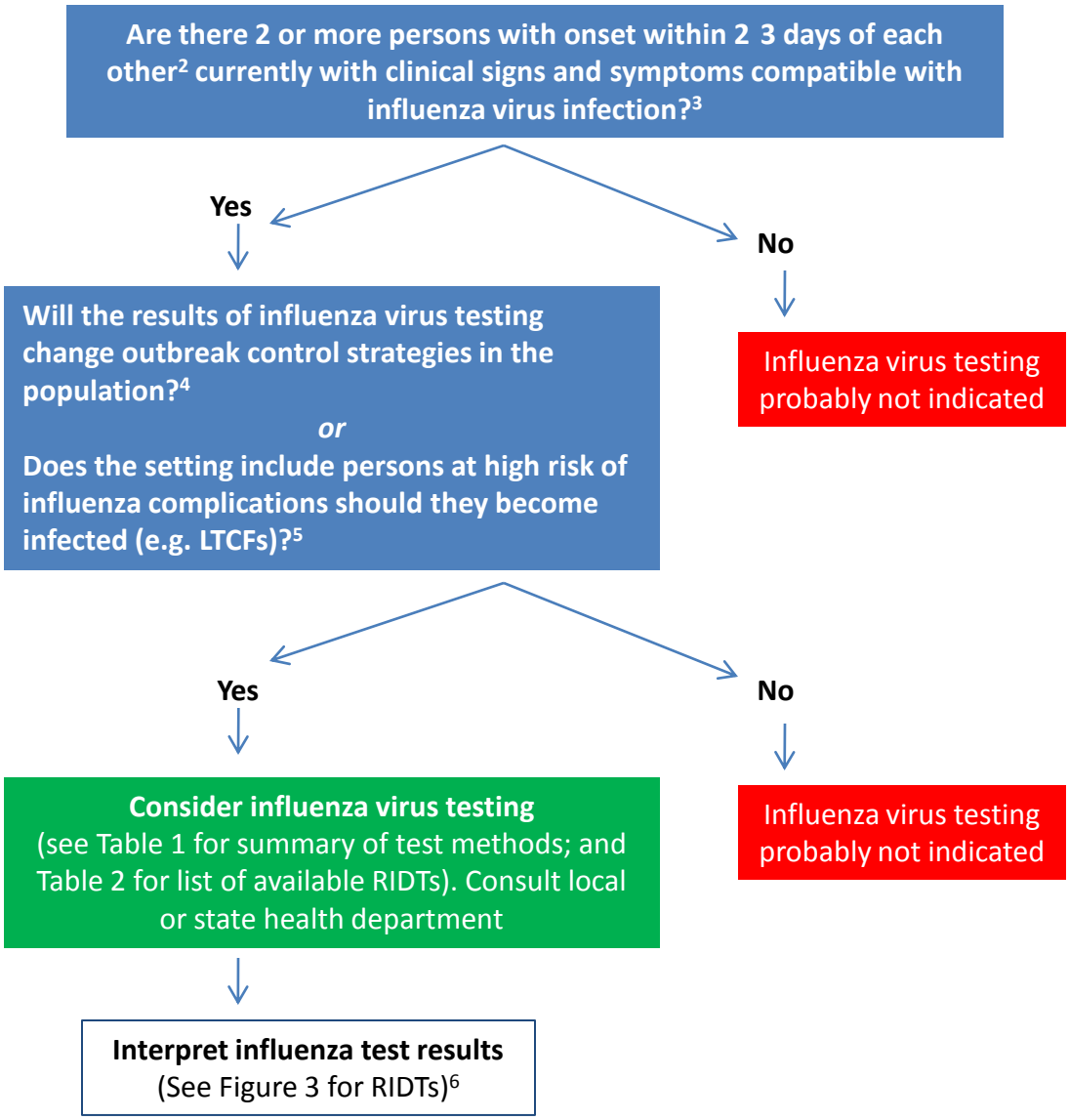
Figure 1. Guide for considering influenza virus diagnostic tests for individual patients when influenza viruses are circulating in the community[1]



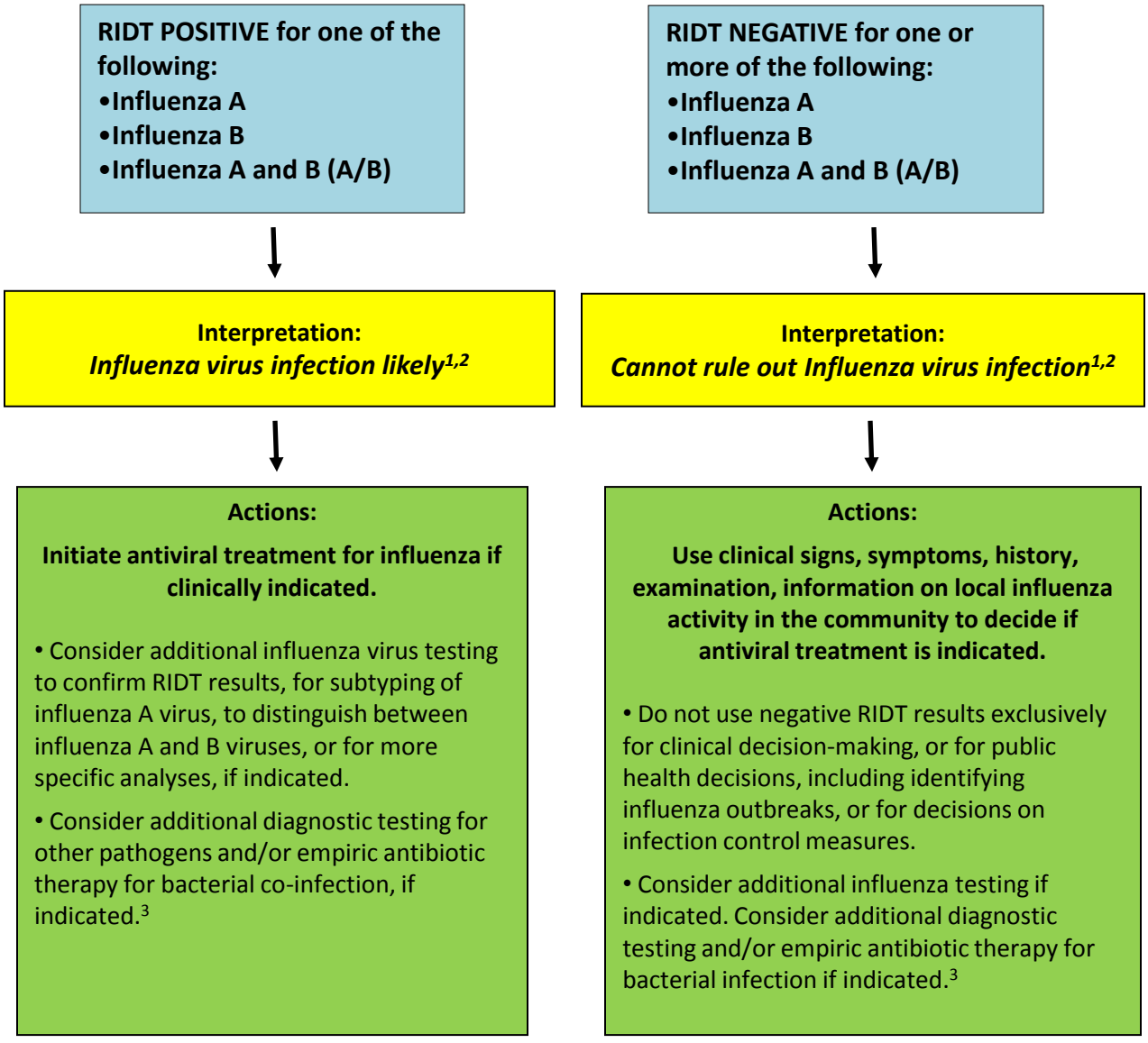
1. Confirmation of influenza virus infection by diagnostic testing is not required for clinical decisions to prescribe antiviral medications. Decisions to administer antiviral medications for influenza treatment or chemoprophylaxis , if indicated, should be based upon clinical illness and epidemiologic factors, and start of therapy should not be delayed pending testing results. (*place link to CDC website guidance)*. **Respiratory specimens should be collected from an ill patient as early as possible after onset of symptoms (ideally <48-72 hours after onset) to help maximize influenza testing sensitivity.**
2. Influenza like-illness (history of feverishness or documented fever with either cough or sore throat), fever with other respiratory symptoms, etc. Note that some persons may have atypical presentations (e.g. elderly , very young infants, immunosuppressed, and patients with certain chronic medical conditions). Fever is not always present (e.g. premature infants, young infants, elderly, immunosuppressed). Other symptoms associated with influenza include myalgias, headache, fatigue. Complications include exacerbation of underlying chronic disease, (e.g. congestive cardiac failure, asthma), pneumonia, bacterial co-infection, bronchiolitis, croup, encephalopathy, seizures, myositis, and others.
3. e.g. Decisions on use of antibiotics or antiviral medications, on conducting further diagnostic tests, on recommendations for home care, or on recommendations for ill persons living with persons with high-risk conditions. Consult IDSA, ATS, AAP, ACIP for antibiotic guidance.
4. Persons ≥65 years or <2 years; pregnant women; persons with chronic lung disease (including asthma), heart disease, renal, metabolic, hematologic and neurologic disease; immunosuppression; and morbid obesity.
5. e.g. Decisions on changing infection control practices (such as in hospitalized patients); if a positive influenza test result is used for confirming influenza virus circulation in the community which might inform clinical practices related to home care guidance, hospital infection control practices, future testing practices, etc

Figure 2. Guide to use of influenza virus diagnostic tests in investigating outbreaks in institutional or other closed settings[1]



1. Examples of institutional or closed settings include long-term care facilities, nursing homes, schools, correctional facilities, hospitals, ships.
2. In settings where persons at high-risk of influenza complications reside, a single case of suspected influenza is sufficient for triggering influenza testing and consideration of implementation of empiric control measures, including active surveillance for new illness cases.
3. e.g., Influenza like-illness (fever with either cough or sore throat), fever with other respiratory symptoms, etc. Note that some persons may have atypical presentations (e.g. elderly , very young infants, immunosuppressed, and patients with certain chronic medical conditions). Fever is not always present. Other symptoms associated with influenza include myalgias, headache, fatigue. Complications include exacerbation of underlying chronic disease, (e.g. congestive cardiac failure, asthma), pneumonia, bacterial co-infection, bronchiolitis, croup, encephalopathy, seizures, myositis, and others.
4. e.g., use of antivirals empirically for treatment or for chemoprophylaxis of influenza, changes in infection control practices (isolation or cohorting of ill, quarantine of exposed), changes in admission or staffing policies, or changes in social distancing recommendations , etc.
5. Persons ≥65 years or <2 years; pregnant women; persons with chronic lung disease (including asthma), heart disease, renal, metabolic, hematologic and neurologic disease; immunosuppression; and morbid obesity.
6. In an outbreak setting, because of the low sensitivity of RIDTs, use of the tests on specimens from more than one ill person is recommended. The presence of any influenza positives among persons with clinically compatible illnesses is supportive of influenza as the probable cause of the outbreak. Confirmation of RIDT results by more specific influenza testing is indicated.

Figure 3. Algorithm to assist in the interpretation of RIDT results and clinical decision-making during periods when influenza viruses are circulating in the community[1]



1. During periods when influenza activity is high and influenza viruses are circulating among persons in the community (see 3. below), the positive predictive value of a test result is high (that is, the chance that a positive result indicates that the patient has influenza is high), and the negative predictive value of a test result is low (the chance that a negative result is a true negative is low) due to low sensitivity of RIDTs to detect influenza virus in respiratory specimens compared to RT-PCR or viral culture**: false negative results are common**.
2. Influenza virus infection may include seasonal influenza A (H3N2), 2009 H1N1, influenza B, or rarely, a novel influenza A virus infection. The interpretation of RIDTs will, in part, depend on the test used - some will detect influenza A, some will detect influenza B and some will detect both A and B viruses. If tests for both influenza A and influenza B are positive, refer specimen to a public health laboratory for resolution, as dual infections are uncommon.
3. Consult local or state health departments or other sources (e.g. virology testing at a local hospital) for local activity on other respiratory pathogens associated with acute respiratory illness. Empiric antibiotic coverage should include coverage for *Streptococcus pneumoniae*, *Staphylococcus aureus* (including MRSA), Group A *Streptococcus*, and others, especially for hospitalized adult patients per IDSA/ATS CAP guidelines.

Figure 4. Algorithm to assist in the interpretation of RIDT results and clinical decision-making during periods when influenza viruses are not circulating or influenza activity is low in the community[1]

1. During periods when influenza activity is low and there is low influenza virus circulation among persons in the community, the positive predictive value of a rapid influenza diagnostic test is low (that is, the chance that a positive result indicates that the patient has influenza is **low**), and the negative predictive value is high (the chance that a negative result is a true negative is high). Even though RIDTs have high specificity, **false positive RIDT results are more common when influenza activity is low.**
2. Influenza virus infection may include seasonal influenza A (H3N2), 2009 H1N1, influenza B, or rarely, a novel influenza A virus infection. The interpretation of RIDTs will, in part, depend on the test used - some will detect influenza A, some will detect influenza B and some will detect both A and B viruses. If tests for both influenza A and influenza B are positive, refer specimen to a public health laboratory for resolution, as dual infections are uncommon.
3. Consult local or state health departments or other sources (e.g. virology testing at a local hospital) for local activity on other respiratory pathogens associated with acute respiratory illness. Empiric antibiotic coverage should include coverage for *Streptococcus pneumoniae*, *Staphylococcus aureus* (including MRSA), Group A *Streptococcus*, and others, especially for hospitalized adult patients per IDSA/ATS CAP guidelines.

Table 1. Influenza Virus Testing Methods

Method[1]	Types Detected	Acceptable Specimens[3]	Test Time[3]	CLIA Waived
Viral cell culture (conventional)	A and B[2]	NP swab, throat swab, NP or bronchial wash, nasal or endotracheal aspirate, sputum	3-10 days	No
Rapid cell culture (shell vials; cell mixtures)	A and B[2]	As above	1-3 days	No
Immunofluorescence, Direct (DFA) or Indirect (IFA) Antibody Staining	A and B[2]	NP swab or wash, bronchial wash, nasal or endotracheal aspirate	1-4 hours	No
RT-PCR[4] (singleplex and multiplex; real-time and other RNA-based)	A and B[2]	NP swab, throat swab, NP or bronchial wash, nasal or endotracheal aspirate, sputum	Varied (Generally 1-6 hours)	No[5]
Rapid Influenza Diagnostic Tests[6]	A and B	NP swab, (throat swab), nasal wash, nasal aspirate	<30 min.	Yes/No

1. Serologic (antibody detection) testing is not recommended for routine patient diagnosis.
2. May be adapted to identification of specific subtypes
3. Ref: Leland, et al. 2007, Clin Micro Rev 20: 49-78. **Approved respiratory specimens vary among FDA cleared influenza assays.**
4. Reverse transcriptase polymerase chain reaction, including FDA-approved test systems, reference laboratory testing using ASR or lab-developed reagents
5. Random-access, single cartridge tests may be moderately complex
6. Immunochromatographic lateral flow and membrane-based immunoassays

Table 2: Characteristics of Rapid Influenza Diagnostic Tests[1]

Procedure (Manufacturer/Distributor)	Influenza Virus Types Detected	Approved Specimens[1]	Test Time
3M™ Rapid Detection Flu A+B Test[4,6] (3M)	A and B	NP[2] swab/aspirate Nasal wash/aspirate	15 minutes
BinaxNOW® Influenza A&B[5,6] (Alere)	A and B	NP[2] swab Nasal wash/aspirate/swab	15 minutes
BioSign® Flu A+B[4,6] (Princeton BioMedtech)	A and B	NP[2] swab/aspirate/wash, nasal swab	15 minutes
Clearview® Exact Influenza A & B[4,6] (Alere)	A and B	Nasal swab	15 minutes
Directigen™ EZ Flu A+B[4,6] (Becton-Dickinson)	A and B	NP[2] wash/aspirate/swab Throat swab	15 minutes
OSOM® Influenza A&B[4,6] (Genzyme)	A and B	Nasal swab	10 minutes
QuickVue® Influenza Test[3,5] (Quidel)	A or B	Nasal wash/aspirate/swab	10 minutes
QuickVue® Influenza A+B Test[5,6] (Quidel)	A and B	NP[2] swab Nasal wash/aspirate/swab	10 minutes
SAS™ FluAlert A&B[4,6] (SA Scientific)	A and B	Nasal wash/aspirate	15 minutes
SAS™ FluAlert A[3,5] (SA Scientific)	A only	Nasal wash/aspirate	15 minutes
SAS™ FluAlert B[3,5] (SA Scientific)	B only	Nasal wash/aspirate	15 minutes
TRU FLU®[4,6] (Meridian Bioscience)	A and B	NP[2] aspirate/swab Nasal wash	15 minutes
XPECT™ Flu A&B[4,6] (Remel/Thermofisher)	A and B	Nasal wash/swab Throat swab	15 minutes

1. List may not include all test kits approved by the U.S. Food and Drug Administration. Discontinued tests not included. Approved respiratory specimens according to manufacturer's package insert. Note that test performance may vary if other respiratory specimens are used.
2. NP = nasopharyngeal.
3. Does not distinguish between influenza A and B virus infections when used alone.
4. Moderately complex test – requires specific laboratory certification.
5. CLIA-waived test. Can be used in any office setting. Requires a certificate of waiver or higher laboratory certification.
6. Distinguishes between influenza A and B virus infections.

Disclaimer: Use of trade names or commercial sources is for identification only and does not imply endorsement by the Centers for Disease Control and Prevention or the Department of Health and Human Services.

References For Additional Information

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