

LCD - MoIDX: Multiplex Nucleic Acid Amplified Tests for Respiratory Viral Panels (L37315)

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Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATES
Noridian Healthcare Solutions, LLC	A and B MAC	02101 - MAC A	J - F	Alaska
Noridian Healthcare Solutions, LLC	A and B MAC	02102 - MAC B	J - F	Alaska
Noridian Healthcare Solutions, LLC	A and B MAC	02201 - MAC A	J - F	Idaho
Noridian Healthcare Solutions, LLC	A and B MAC	02202 - MAC B	J - F	Idaho
Noridian Healthcare Solutions, LLC	A and B MAC	02301 - MAC A	J - F	Oregon
Noridian Healthcare Solutions, LLC	A and B MAC	02302 - MAC B	J - F	Oregon
Noridian Healthcare Solutions, LLC	A and B MAC	02401 - MAC A	J - F	Washington
Noridian Healthcare Solutions, LLC	A and B MAC	02402 - MAC B	J - F	Washington
Noridian Healthcare Solutions, LLC	A and B MAC	03101 - MAC A	J - F	Arizona
Noridian Healthcare Solutions, LLC	A and B MAC	03102 - MAC B	J - F	Arizona
Noridian Healthcare Solutions, LLC	A and B MAC	03201 - MAC A	J - F	Montana
Noridian Healthcare Solutions, LLC	A and B MAC	03202 - MAC B	J - F	Montana
Noridian Healthcare Solutions, LLC	A and B MAC	03301 - MAC A	J - F	North Dakota
Noridian Healthcare Solutions, LLC	A and B MAC	03302 - MAC B	J - F	North Dakota
Noridian Healthcare Solutions, LLC	A and B MAC	03401 - MAC A	J - F	South Dakota
Noridian Healthcare Solutions, LLC	A and B MAC	03402 - MAC B	J - F	South Dakota
Noridian Healthcare Solutions, LLC	A and B MAC	03501 - MAC A	J - F	Utah
Noridian Healthcare Solutions, LLC	A and B MAC	03502 - MAC B	J - F	Utah
Noridian Healthcare Solutions, LLC	A and B MAC	03601 - MAC A	J - F	Wyoming
Noridian Healthcare Solutions, LLC	A and B MAC	03602 - MAC B	J - F	Wyoming

LCD Information

Document Information

LCD ID
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LCD Title

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MolDX: Multiplex Nucleic Acid Amplified Tests for Respiratory Viral Panels

Proposed LCD in Comment Period

N/A

Source Proposed LCD

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CMS National Coverage Policy

Title XVIII of the Social Security Act, §1862(a)(1)(A). Allows coverage and payment for only those services that are considered to be reasonable and necessary.

Title XVIII of the Social Security Act, §1833(e). Prohibits Medicare payment for any claim which lacks the necessary information to process the claim.

42 Code of Federal Regulations (CFR) 410.32(a). Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests: Conditions.

CMS On-Line Manual, Publication 100-02, *Medicare Benefit Policy Manual*, Chapter 15, §§80.0, 80.1.1, 80.2. Clinical Laboratory services.

CMS Internet-Only Manuals, Publication 100-04, *Medicare Claims Processing Manual*, Chapter 16, §50.5 Jurisdiction of Laboratory Claims, 60.12 Independent Laboratory Specimen Drawing, 60.2. Travel Allowance.

CMS Internet Online Manual Pub. 100-04 (*Medicare Claims Processing Manual*), Chapter 23 (Section 10) "Reporting ICD Diagnosis and Procedure Codes"

Coverage Guidance

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Coverage Indications, Limitations, and/or Medical Necessity

This policy limits coverage of multiplex PCR respiratory viral panels. Panels of 3-5 pathogens are covered under limited circumstances. Specifically, the test must be ordered either in a healthcare setting that is equipped to care for and routinely does care for critically ill patients, or it must be ordered by an infectious disease specialist, unless an infectious disease specialist is not available.

Multiplex PCR respiratory viral panels of 6 or more pathogens are non-covered. The pathogen targets that compose the panels are determined by the manufacturers that make them, and do not represent specific pathogens that cause a common syndrome, or the organisms that commonly are found in a specific sample type or patient population or reflect seasonal variations. The fixed nature of these multiplex panels includes pathogens that cause infections different enough that simultaneous testing for these pathogens should be rare. Examples include *Chlamydia pneumoniae* or *Bordetella pertussis* in combination with rhinovirus, influenza viruses, and respiratory syncytial virus (RSV). The multiplex PCR respiratory viral panels are effectively a "one size fits all" diagnostic approach, and do not meet Medicare's "reasonable and necessary" criteria. Non-coverage of these multiplex PCR respiratory viral panels does not deny patient access because appropriate clinician directed testing is available.

Respiratory Pathogen Diagnosis in Elderly Patients

Viral pathogens are the most common cause of upper respiratory tract infections (URIs). Most URIs occur more frequently during the cold winter months, because of overcrowding. Adults develop an average of 2 to 4 colds annually. Rhinovirus, parainfluenza virus, coronavirus, adenovirus, respiratory syncytial virus, Coxsackie virus, human metapneumovirus, and influenza virus account for most cases.¹ Antigenic variation of hundreds of respiratory viruses result in repeated circulation in the community.

Children with viral respiratory diseases typically present with classic symptoms, high viral titers, and positive results of viral cultures or rapid antigen tests. Unlike children, elderly individuals may present with atypical symptoms such as confusion, anorexia, dizziness, or falls.² Elderly patients may lack fever and be unable to articulate classic symptoms of viral infection, such as sore throat or myalgias. Some elderly patients experience exacerbations of underlying chronic cardiopulmonary.

Influenza classically presents with the acute onset of fevers, myalgias, and cough, unlike RSV which presents with nasal congestion, wheezing, and cough. In a prospective study of patients with obstructive lung disease, fever when compared with culture and serological test results had a sensitivity of only 26% when used to diagnose influenza in older adults.³ In a study of hospitalized adults, clinical symptoms had poor sensitivity (43%) for identification of influenza-like illness in adults, one-half of whom were aged ≥ 65 years.⁴

Influenza is the predominant viral cause of community acquired pneumonia (CAP) in adults. Other commonly recognized viruses include RSV, adenovirus, and parainfluenza virus. In a study of immunocompetent adult patient admitted to hospital with CAP, 18% had a viral etiology, and in 9%, a respiratory virus was the only pathology identified. Studies that include outpatients find viral pneumonia rates as high as 36%.

The identification of viral infections in older adults is of practical importance when it guides individualized treatment decisions in a way that would be expected to improve outcomes. The diagnosis of influenza can help guide antiviral treatment for individual patients and is critical in long-term care facilities and other closed populations in the event that institutional chemoprophylaxis is needed to limit outbreaks. Although the evidence on tailored pathogen-specific treatment is limited for other respiratory viral pathogens, broad antiviral treatment may have use in the treatment of particularly vulnerable populations, for example ribavirin possibly in conjunction with intravenous immunoglobulin in the treatment of respiratory syncytial virus, parainfluenza, and metapneumovirus in patients who have received transplants.

The diagnosis of CAP is based on the presence of clinical features including cough, fever, sputum production and pleuritic chest pain, and is supported usually by chest radiograph. However, clinical features, and rales or bronchial breath sounds by physical examination may be lacking or altered in elderly patients. The need for diagnostic testing to determine the etiology of CAP is justified when test results will change antibiotic management for an individual patient,⁶ and as such limited virus testing in susceptible populations may be appropriate.

Clinical Indications for Viral Testing

Because viruses cause most URIs, the diagnostic role of laboratory investigations and radiologic studies is limited. Only after common conditions are ruled out, should uncommon viral conditions be tested.

Influenza Infection:

Influenza testing is not needed for all patients with signs and symptoms of influenza to make antiviral treatment decisions. The CDC indicates that once influenza activity has been identified in the community or geographic area, a clinical diagnosis of influenza can be made for outpatients with signs and symptoms consistent with suspected influenza, especially during periods of peak influenza activity in the community. While molecular testing is not needed on all patients with suspected influenza, influenza testing is most appropriate for hospitalized patients if a positive test would result in a change in clinical management. The CDC advises that if treatment is clinically indicated, antiviral treatment should NOT be withheld from patients with suspected influenza while awaiting test results during peak influenza periods in the community when the likelihood of influenza is high because the greatest clinical benefit is when treatment is initiated as close to illness onset as possible.

Upper respiratory tract specimens should be collected for influenza testing in hospitalized patients without lower respiratory tract disease. In the hospitalized patient with suspected influenza and pneumonia or respiratory failure on mechanical ventilation, and a negative upper respiratory tract test result, induced sputum, protected brush samples, endotracheal aspirate or bronchoalveolar lavage specimens can be considered for testing using tests validated for lower respiratory tract specimens.

Parainfluenza Infection:

Human parainfluenza virus commonly causes upper and lower respiratory illnesses in infants and young children. Symptoms include fever, runny nose and cough. Severe lower respiratory illness symptoms include croup, bronchitis, bronchiolitis and pneumonia. Adults with weakened immune systems are at risk of more severe illness. There is no specific antiviral treatment, and most people recover on their own with rest and fluids.

RSV Infection:

Adults, particularly in healthcare workers or caretakers of small children, are susceptible to symptomatic RSV infection. Symptoms usually consist of rhinorrhea, pharyngitis, cough, headache, fatigue, and fever. Some high-risk adults, such as those with chronic illness or immunosuppression, may have more severe symptoms consistent with a lower respiratory tract infection, such as pneumonia.

RT-PCR assay are commercially available for RSV testing. Use of highly sensitive RT-PCR assay should be considered when testing adults because they may have low viral loads in their respiratory specimens. Palivizumab is a monoclonal antibody recommended by the American Academy of Pediatrics (AAP) to be administered to high risk infants and young children likely to benefit from immunoprophylaxis based on gestational age, certain underlying medical conditions, and RSV seasonality. No recommendation can be made for the use of RSV immune globulin or

monoclonal antibody to control outbreaks of RSV infection in the health-care setting (Unresolved issue).

Human Metapneumovirus Infection:

Human metapneumovirus (HMPV) can cause upper and lower respiratory disease in people of all ages, especially among young children, older adults, and people with weakened immune systems. Symptoms commonly associated with HMPV include cough, fever, nasal congestion, and shortness of breath. Clinical symptoms of HMPV infection may progress to bronchiolitis or pneumonia. There is no specific antiviral therapy for HMPV. Medical care is supportive.

Adenovirus Infection:

Adenoviruses can cause a wide range of illnesses such as the common cold, pharyngitis, bronchitis, pneumonia, diarrhea, conjunctivitis, fever, cystitis, gastroenteritis, and neurologic disease. Adenoviruses rarely cause serious illness or death. However, infants and people with weakened immune systems, or existing respiratory or cardiac disease, are at higher risk of developing severe illness from an adenovirus infection. There is no specific treatment for people with adenovirus infection. Most adenovirus infections are mild and may require only care to help relieve symptoms.

Rhinovirus infection:

Many different viruses can cause the common cold, but rhinoviruses are the most common. Symptoms are non-specific including sore throat, runny nose, coughing, sneezing, headache and body aches. Rhinovirus infection is usually self-limited but in individuals with a weakened immune system, asthma, or other respiratory condition, may develop pneumonia. Treatment is directed towards symptom relief and hydration.

Laboratory Diagnosis of Viral Infections in Elderly Patients

Culture: Traditionally, culture has been the gold standard for the diagnosis of viral respiratory disease. Viral culture is fraught with numerous issues:

- Requires specialized facilities and well-trained staff;
- Definitive identification of a viral pathogen may take days to weeks to identify;
- Older adults generally have lower viral loads in their respiratory secretions which may affect the sensitivity of cultures;
- Viral culture is most useful for relatively hardy viruses, such as influenza virus, where labile viruses such as RSV may not survive transportation to a laboratory;
- No single cell culture line can grow all medically important viruses
- Shell vial cultures can be used to increase the number of identifiable pathogens and decrease the time of diagnosis from 2-5 days to 1-2 days, and yet retain the sensitivity and specificity of conventional culture;
- Viral culture is most useful in highly febrile patient who has been ill only 2-3 days
- Viral culture is relatively insensitive to serologic tests and PCR

Rapid Antigen Testing: Rapid antigen testing is an enzyme immunoassay (EIA) that can easily be performed at point of care with the following characteristics:

- Very successful for the diagnosis of influenza and RSV infection in children;
- Poor results for influenza and RSV in older adults due to lower viral loads in respiratory secretions; sensitivity of EIA for the diagnosis of influenza decreases with increasing patient age and can be as low as 8%–22% in patients aged ≥ 80 years Steininger 2009; however, despite low sensitivities associated with EIA, the test does have good specificity in older adults such that a positive EIA result is likely a true positive test result, but a

negative does not rule out influenza;

- EIA sensitivity for RSV in older adults is very low ($\leq 10\%$ when compared with serologic testing and PCR).

Fluorescent Antibody Assays: Fluorescent antibody staining is another rapid method of diagnosing respiratory viral diseases that:

- Involves placing a pellet of cells from the sample on a microscope slide followed by staining with viral specific fluorescent antibodies;
- Results available in a matter of hours but requires trained staff;
- Can be used to test for adenoviruses, influenza viruses A and B, RSV, and other viruses;

Serologic Testing: Serologic testing to detect viral specific immunoglobulin G is not useful for diagnosis because viral respiratory infections in older adults represent reinfection. Instead, a ≥ 4 -fold increase in antibody (baseline compared with convalescent-phase specimen) is required to identify a recent infection and confirm a diagnosis. However, serological attesting is not useful for clinicians and patient care decisions.

Polymerase Chain Reaction: PCR testing has become a common test in the clinical lab because it can:

- Detect minute amounts of viral nucleic acid and does not require infectious organism for detections;
- Surmount problems of poor culture and antigen detection sensitivity in older adults;
- Requires extreme care to avoid contamination due to the extreme sensitivity of PCR;
- More accurately detects influenza virus, RSV, hMPV, parainfluenza virus, rhinoviruses and coronaviruses in the lower respiratory tract illness in old adults;
- Has been used successfully in nursing homes to identify sources of outbreaks;
- Diagnosis coronaviruses and group C rhinoviruses, unlike other testing methods;
- Test for individual viruses (single-virus assays) or multiple viruses simultaneously (multiplex PCR).

Commercially Available Viral Tests by Amplified Probe Technique and Multiplex Nucleic Acid Amplified Test Panels

Multiple FDA approved/cleared influenza⁸ and respiratory molecular assays⁹ are currently commercially available. Most consist of combinations of influenza A and B with or without RSV.

Large respiratory viral panels with and without bacterial pathogens have also been approved/cleared by the FDA and include the following include:

1. **Luminex xTAG Respiratory Viral Panel (RVP)** – The 510(k) summary specifies that the intended use from nasopharyngeal swabs from individuals suspected of respiratory tract infections. It states that “it is recommended that specimens found to be negative for Influenza B, RSV subtypes A and B, Parainfluenza 1, 2 and 3, and adenovirus, after examination using RVP, be confirmed by cell culture. Negative results do not preclude respiratory virus infection and should not be used as the sole basis for diagnosis, treatment or other management decision. Positive results do not rule out bacterial infection, or co-infection with other viruses. The agent detected may not be the definite cause of disease. The use of additional laboratory testing (e.g. bacterial culture, immunofluorescence, radiography) and clinical presentation must be taken into consideration in order to obtain the final diagnosis of respiratory viral infection”.

Clinical viral targets:

- Influenza A,
- Influenza A subtype H1,
- Influenza A subtype H3,
- Influenza B,
- Respiratory Syncytial Virus subtype A,
- Respiratory Syncytial Virus subtype B,
- Parainfluenza 1 virus
- Parainfluenza 2 virus
- Parainfluenza 3 virus,
- Human Metapneumovirus,
- Rhinovirus,
- Adenovirus

2. **Luminex xTAG Respiratory Viral Panel FAST – K103776** - The 510(k) summary specifies that “the intended use from nasopharyngeal swabs from individuals suspected of respiratory tract infections.” “Negative results do not preclude respiratory viral infection and should not be used as the sole basis for diagnosis, treatment or other management decisions. Positive results do not rule out bacterial infection or co-infection with other organisms. The agent detected may not be the definite cause of disease. The use of additional laboratory testing (e.g. bacterial and viral culture, immunofluorescence, and radiography) and clinical presentation must be taken into consideration in order to obtain the final diagnosis of respiratory infection”.

Clinical viral targets:

- Influenza A,
- Influenza A subtype H1,
- Influenza A subtype H3,
- Influenza B,
- Respiratory Syncytial Virus,
- Human Metapneumovirus,
- Rhinovirus,
- Adenovirus

3. **eSensor[®] Respiratory Viral Panel (RVP) – K113731** The 510(k) summary specifies that the test is for the “identification of multiple respiratory viral nucleic acids in nasopharyngeal swabs (NPS)”. This test is a multiplex microarray-based genotyping test system.

Clinical viral targets:

- Influenza A,
- Influenza A H1 Seasonal Subtype,

- Influenza A H3 Seasonal Subtype,
- Influenza A 2009 H1N1 subtype,
- Influenza B,
- Respiratory Syncytial Virus subtype A,
- Respiratory Syncytial Virus subtype B,
- Parainfluenza Virus 1,
- Parainfluenza Virus 2,
- Parainfluenza Virus 3,
- Human Metapneumovirus,
- Human Rhinovirus,
- Adenovirus species B/E,
- Adenovirus species C

4. **Nanosphere Verigene Respiratory Pathogens Plus Nucleic Acid Test** – K103209 The 510(k) specifies “qualitative nucleic acid multiplex test intended to simultaneously detect and identify multiple respiratory virus nucleic acids in nasopharyngeal (NP) swab specimens from individuals with signs and symptoms of respiratory tract infection”. It also notes that “Negative results for Influenza A, Influenza B, or RSV do not preclude influenza virus or RSV infection and should not be used as the sole basis for diagnosis, treatment, or patient management decisions. Conversely, positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. The use of additional laboratory testing and clinical presentation must be considered in order to obtain the final diagnosis of respiratory viral infection”.

Clinical pathogen targets:

- Influenza A,
- Influenza A subtype H1,
- Influenza A subtype H3,
- Influenza A 2009 H1N1 subtype,
- Influenza B,
- Respiratory Syncytial Virus subtype A,
- Respiratory Syncytial Virus subtype B

5. **BioFire FilmArray Respiratory Panel (RP)** – K123620 – the 510(k) summary specifies that simultaneous qualitative detection and identification of multiple respiratory viral and bacterial nucleic acids in nasopharyngeal swabs (NPS) obtained from individuals suspected of respiratory tract infections. The summary also has disclaimers similar to that of Luminex regarding positive and negative results, including the statement that “Negative results in the setting of a respiratory illness may be due to pathogens that are not detected by this test or lower respiratory tract infection that is not detected by a nasopharyngeal swab specimen.

Clinical pathogen targets:

- Adenovirus,

- Coronavirus 229E,
- Coronavirus HKU 1,
- Coronavirus NL63,
- Coronavirus OC43,
- Human Metapneumovirus,
- Influenza A,
- Influenza A subtype H1,
- Influenza A subtype H3,
- Influenza A subtype H1-2009,
- Influenza B, Parainfluenza Virus 1,
- Parainfluenza Virus 2,
- Parainfluenza Virus 3,
- Parainfluenza Virus 4,
- Human Rhinovirus/Enterovirus,
- Respiratory Syncytial Virus,
- Bordetella pertussis,
- Chlamydomphila pneumoniae,
- Mycoplasma pneumonia

6. BioFire FilmArray Respiratory Virus Panel, CLIA-waved

Clinical pathogen targets:

- Adenovirus,
- coronavirus,
- Human metapneumovirus,
- Human rhinovirus/enterovirus,
- Influenza A, influenza A/H1,
- Influenza A/H1-2009,
- Influenza A/H3,
- Influenza B,
- Parainfluenza,
- Respiratory syncytial virus,
- Bordetella pertussis,

- Chlamydomytila pneumoniae,
- Mycoplasma pneumoniae

Summary of Evidence

Level of Evidence

Quality – Moderate
Strength – Moderate
Weight – Moderate

Analysis of Evidence (Rationale for Determination)

The use of limited multiplex viral panels in susceptible populations may be reasonable and necessary. The use of highly multiplexed NAAT tests as front-line diagnostics cannot be justified at the current time. A panel that includes pathogens that are very rare, or a panel in which all pathogens do not cause overlapping clinical syndromes, or when some pathogens are found only in specific patient populations (immunocompromised patients) is not reasonable and necessary. Despite an individual patient having signs or symptoms of a respiratory illness, the above highly multiplexed NAAT tests are not reasonable and necessary: a one size fits all diagnostic approach. The use of limited simplex or multiplex direct probe technique tests for respiratory viruses, such as Influenza A/B with, or without inclusion of other several other viruses is a Medicare covered benefit.

Understanding the performance characteristics of all members of the panel is essential, as the sensitivity and specificity for the detection of each pathogen may vary. The prevalence of the pathogen will greatly affect the positive and/or negative predictive value of the test. A negative test result does not necessarily rule out a virus and requires additional testing to confirm its negativity, as implied in the 510(k) documents for some of the tests discussed above. No clinical utility studies demonstrate that rapid, accurate highly multiplexed NAAT tests decrease the use of empirical antibiotics and allow for a more targeted approach to using antivirals.

Syndromic surveillance (testing to improve early detection of outbreaks) and/or public monitoring of disease transmission in nursing homes or other facilities to follow disease transmission or mutational change are not Medicare benefits.

General Information

Associated Information

N/A

Sources of Information

See Bibliography

Bibliography

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Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
10/01/2019	R2	<p>10/01/2019: At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all of the fields included on the LCD are applicable as noted in this policy.</p> <p>This LCD was converted to the "no-codes" format.</p>	<ul style="list-style-type: none"> • Revisions Due To Code Removal
10/01/2019	R1	<p>10/01/2019: At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all of the fields included on the LCD are applicable as noted in this policy.</p> <p>Under Covered ICD-10 Codes Group 1: Codes ICD-10 code D81.3 was deleted and ICD-10 codes D81.30, D81.31, D81.32, and D81.39 were added. This revision is due to the 2019 Annual</p>	<ul style="list-style-type: none"> • Revisions Due To ICD-10-CM Code Changes • Revisions Due To Code Removal

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
		<p>ICD-10 Code Update and is effective on October 1, 2019.</p> <p>Under Article Text added all verbiage and corresponding bullet points under the first paragraph. Under CPT/HCPCS Codes Group 1: Codes added codes 0098U, 0099U, and 0100U. Under Covered ICD-10 Codes Group 1: Paragraph added the verbiage "0098U, 0099U, and 0100U" to the first sentence. This revision is due to the Q3 2019 CPT/HCPCS Code Update and is effective for dates of service on or after 7/1/2019.</p>	

Associated Documents

Attachments

N/A

Related Local Coverage Documents

Articles

[A57340 - Billing and Coding: MoIDX: Multiplex Nucleic Acid Amplified Tests for Respiratory Viral Panels](#)

[A56255 - Response to Comments: MoIDX: Multiplex Nucleic Acid Amplified Tests for Respiratory Viral Panels](#)

LCDs

[DL37315 - \(MCD Archive Site\)](#)

Related National Coverage Documents

N/A

Public Versions

UPDATED ON	EFFECTIVE DATES	STATUS
09/24/2019	10/01/2019 - N/A	Currently in Effect (This Version)

Some older versions have been archived. Please visit the MCD Archive Site to retrieve them.

Keywords

- MoIDX
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- Nucleic
- Acid
- Amplified
- Respiratory
- Viral
- PCR