NasoSwab®

One Vial... Multiple Pathogens

Simple & Convenient Nasal Specimen Collection

Medical Diagnostic Laboratories
2439 Kuser Road • Hamilton, NJ 08690-3303
www.mdlab.com • Toll Free 877 269 0090

NasoSwab®

MULTIPLE PATHOGENS

The introduction of molecular techniques, such as the Polymerase Chain Reaction (PCR) method, in combination with flocked swab technology, offers a superior route of pathogen detection with a high diagnostic specificity and sensitivity. MDL offers a number of assays for the detection of multiple pathogens associated with respiratory tract infections. The unrivaled sensitivity and specificity of the Real-Time PCR method in detecting infectious agents provides the clinician with an accurate and rapid means of diagnosis. This valuable diagnostic tool will assist the clinician with diagnosis, early detection, patient stratification, drug prescription, and prognosis. Tests currently available utilizing the ***NasoSwab***® specimen collection platform are listed below.

Acinetobacter baumanii
Adenovirus
Bordetella parapertussis
Bordetella pertussis (Reflex to Bordetella holmesii by Real-Time PCR)
Chlamydophila pneumoniae
Coxsackie virus A & B
Enterovirus D68
Group A Streptococcus
Haemophilus influenzae
Human Bocavirus
Human Coronavirus (229E, OC43, NL-63)
Human Metapneumovirus
Influenza A Virus R (Reflex to amantadine resistance)
Influenza A Virus
Influenza B Virus
MRSA: Methicillin Resistant and Methicillin Susceptible (MSSA) *Staphylococcus aureus*
Panton-Valentine Leukocidin (PVL)
Moraxella catarrhalis
Mycoplasma pneumoniae
Neisseria meningitidis
Parainfluenza Viruses 1-4
Pseudomonas aeruginosa
Respiratory Syncytial Virus A (RSV A)
Respiratory Syncytial Virus B (RSV B)
RSV A & RSV B by Multiplex Real-Time PCR
Rhinovirus and Enterovirus by Real-Time PCR
Severe Acute Respiratory Syndrome (SARS)
Streptococcus pneumoniae

- One vial, multiple pathogens
- DNA amplification via PCR technology
- Microbial drug resistance profiling
- High precision robotic accuracy
- High diagnostic sensitivity & specificity
- Specimen viability up to 5 days after collection
- Test additions available up to 30 days after collection
- No refrigeration or freezing required before or after collection

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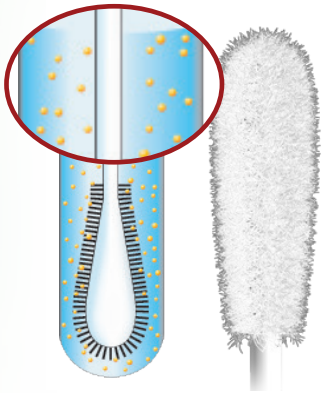
Flocked Swab Technology

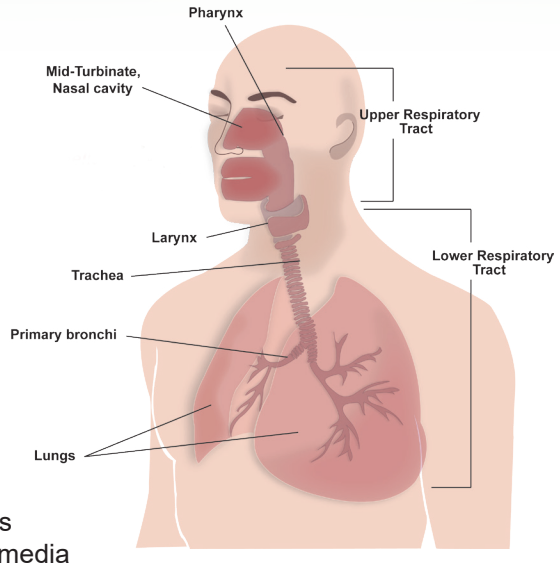
MDL's ***NasoSwab*** ® is an anatomically engineered collection device that specifically targets the mid-turbinate region of the nasal passageway. The length and design of the swab allows for consistent specimen collection. The unique conical shape and use of flocked technology combine to provide an increased surface area with greater particle retention than traditional swabs. Sprayed on nylon fibers provide a velvet-like texture that serves to both disrupt and capture pathogenic particles. When placed in transport media, a high percentage of sampled particles are released as opposed to traditional swabs that trap particles within their fibers. Higher yields are achieved, improving the accuracy of diagnostic testing.

- Flocked swab technology
- Simple, convenient, less invasive
- Anatomic design contours to the mid-turbinate region
- Nylon flocked texture efficiently absorbs and rapidly releases more sample particles

Comparison of Flocked Swabs to Fiber Swabs

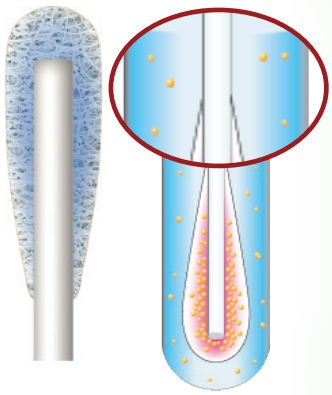
Flocked Swabs





- Velvet brush-like texture
- Improves collection of cell samples
- Allows easy elution into transport media
- 80% of the sample analyte is released
- Synthetic swab components means no risk of infections or interference
- Tailored to fit the nasal anatomy

Fiber Swabs



- Sample entrapment
- Release of only 18% to 30% of sample

Collecting samples with NasoSwab®

Step 1. Aseptically remove the sterile swab from package, without touching the swab head.

Step 2. Tilt the patient's head slightly upwards. Insert the brush end downwards into the nostril all the way to the guard. Be sure to direct the swab down towards the throat and not up towards the forehead. Rotate the swab 360º.

Step 3. Aseptically remove cap from vial.

Step 4. Break swab at molded break point and insert into transport medium.

Step 5. To prevent leakage, be sure the swab fits into the vial prior to capping. Tightly cap the vial and label with a minimum of two patient identifiers such as name and date of birth. For packaging and shipping instructions, please refer to MDL's catalog of services.

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Founded in 1998, Medical Diagnostic Laboratories (MDL) serves mainly as a reference laboratory for molecular diagnostic based testing to laboratories, hospitals and physicians worldwide. The success of MDL is attributed directly to client retention through our ability to customize our unique services to specifically address the individual needs of our clients. Enhanced turn-around time, cost effectiveness, and the capability to tailor services to best suit the needs and budgets of our clients gives MDL a distinct advantage over its competitors.

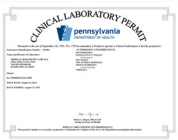
MDL specializes in high complexity, state-of-the-art, automated DNA-based molecular analysis. By utilizing molecular techniques, MDL is able to provide clinicians from many different specialties valuable diagnostic information to assist in the detection, diagnosis, evaluation, and treatment of bacterial, viral and fungal infections as well as genetic based testing and cancer diagnostics. For example, the unique testing MDL offers for the specialties of Urology, Gynecology and Pediatric Medicine enables the detection of multiple pathogens from a single swab by Polymerase Chain Reaction (PCR) testing. MDL's primary focus is in the fields of infectious disease testing for Women's Health and Gynecology, Pediatric Respiratory Infections, Urology, Vector-borne Diseases, Mycology and chronic illnesses.

Laboratory Licenses and Permits

MDL is routinely inspected by both the New Jersey State Department of Health and the College of American Pathologists (CAP). MDL also participates in the proficiency testing programs administered by both CAP as well as the American Proficiency Institute to maintain licensing in multiple states. MDL is accredited by CAP which is an internationally recognized program designed to advance the quality of Laboratory Services. Through the use of rigorous checklists designed to improve the overall quality practice of the management and operation of a clinical laboratory in combination with routine peer-led inspections, a laboratory can gain accreditation by meeting or exceeding CAP standards. CAP standards are recognized to be the highest standards of excellence. MDL has continually maintained exemplary ratings by these agencies.







New Jersey - Clinical Laboratory License - ID #0000875
New York - Clinical Laboratory Permit - PFI #7469
Maryland - Medical Laboratory Permit - ID #1133

Pennsylvania - Clinical Laboratory Permit - ID #26538A
Rhode Island - Clinical Laboratory License - ID #LCO00420
California - Clinical Laboratory License - ID #CDS00800136
CLIA - ID #31D0938156

The testing offered by Medical Diagnostic Laboratories is developed and validated by MDL's Research & Development Department. The R&D Department performs studies on sensitivity, specificity, interference, optimization, accuracy, and precision prior to offering testing for a specific pathogen by PCR. These studies are used to establish the ability of the PCR method to detect specific genetic sequences of a target pathogen within a given clinical specimen.

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A MEMBER OF GENESIS BIOTECHNOLOGY GROUP

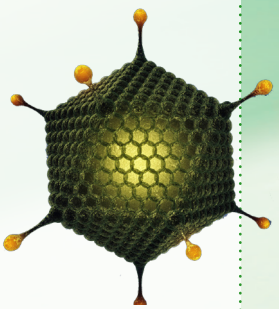
A DIVISION OF GENESIS CLINICAL DIAGNOSTICS

369 *Acinetobacter baumannii* by Real-Time PCR

Clinical significance: *Acinetobacter baumannii* is an aerobic, Gram-negative bacterium that is resistant to most antibiotic treatments and is responsible for many hospital patient deaths, the first case being linked directly to wounded soldiers returning from the Iraq war. An emerging, opportunistic, multi-drug resistant bacterium, *Acinetobacter baumannii* infection cases are expected to rise and have the potential to become the next superbug with a magnitude and scope similar to that of MRSA. *A. baumannii* is associated with long term wound skin and soft tissue infections, catheter-associated UTIs, ventilator associated infections, bloodstream infections, surgical site infections, and co-infections with other bacteria, such as MRSA, are common. Those with compromised immunity are at greatest risk of infection. A few studies have looked for *A. baumannii* as well as MRSA colonization of anterior nares, skin, sputum, perianal, wounds, and other areas. This can be an environmental contaminant of hospitals and long-term care facilities. Colonization of healthy individuals occurs in an asymptomatic fashion but poses an increased risk of dissemination throughout hospital wards.

222 Adenovirus by Real-Time PCR

Clinical significance: Adenoviruses cause a number of self-limiting, but often highly infectious diseases that affect multiple organs, most commonly those associated with the respiratory and genitourinary tracts. Adenovirus is a relatively harmless pathogen in healthy individuals, but can cause a variety of symptoms in young children and the immunocompromised. Transmission can occur from direct, person-to-person contact or through contact with a contaminated surface or object. Adenovirus infections are usually asymptomatic and may cause a variety of symptoms, including: respiratory problems, gastroenteritis, pink eye, pharyngoconjunctival fever, skin rashes, and genitourinary tract infections including cervicitis, urethritis and hemorrhagic cystitis. The most severe cases of adenovirus infection may result in pneumonia, croup, and bronchitis.



1101 *Bordetella holmesii* by Real-Time PCR

Clinical significance: *Bordetella parapertussis* is a Gram-negative aerobic coccobacilli that cause pharyngitis and Whooping Cough. *Bordetella parapertussis*, lacking many of *B. pertussis*' virulence factors, induces milder forms of disease. Despite their association with Whooping Cough, they are not the only pathogenic causes; *Bordetella bronchiseptica*, *Mycoplasma pneumoniae* and *Chlamydophila trachomatis* have also been associated. Once a highly lethal infection in children and infants, vaccination has decreased the major risks associated with infection. However, studies have demonstrated a drop in immunity 3-5 years post-vaccination that reaches undetectable levels within 12 years. Since the 1980's the incidence rate has increased cyclically, peaking every 3-4 years. Seasonality is from June through September. Infection is in three stages: catarrhal, paroxysmal, and convalescent. The initial stage, catarrhal, is largely indistinguishable from other common respiratory tract infections, which might be problematic considering it is the most infectious stage.

1102 *Bordetella pertussis* by Real-Time PCR (*Reflex to Bordetella holmesii* by Real-Time PCR)

Clinical significance: *Bordetella pertussis* is a Gram-negative aerobic coccobacilli that cause pharyngitis and Whooping Cough. Despite their association with Whooping Cough, they are not the only pathogenic causes; *Bordetella bronchiseptica*, *Mycoplasma pneumoniae* and *Chlamydophila trachomatis* have also been associated. Once a highly lethal infection in children and infants, vaccination has decreased the major risks associated with infection. However, studies have demonstrated a drop in immunity 3-5 years post-vaccination that reaches undetectable levels within 12 years. Since the 1980's the incidence rate has increased cyclically, peaking every 3-4 years. Seasonality is from June through September. Infection is in three stages: catarrhal, paroxysmal, and convalescent. The initial stage, catarrhal, is largely indistinguishable from other common respiratory tract infections, which might be problematic considering it is the most infectious stage.

319 *Chlamydophila pneumoniae* by Real-Time PCR

Clinical significance: *Chlamydophila* are obligate intracellular parasites. *Chlamydophila pneumoniae*, also known as Taiwan acute respiratory agent (TWAR), is the most recently identified of the *Chlamydophila* species. It is a common cause of infection throughout the world. Although first isolated in 1965, it was not established as a human pathogen until it was obtained from a respiratory specimen in 1983. Infection is spread via exposure to respiratory secretions. It has been associated with community acquired acute respiratory infection, adult onset asthma, atherosclerotic cardiovascular disease, arthritis, and chronic fatigue syndrome.

288 Coxsackie virus A & B by Sanger Sequencing

Clinical significance: Coxsackieviruses are a part of the Picornaviridae family belonging to the Enterovirus genus. There are two groups of Coxsackieviruses, A and B, differentiated by their effects on mice. Generally, Coxsackie A infects the skin and mucous membranes, causing hand, foot and mouth disease, a common childhood illness. Symptoms associated with hand, foot and mouth disease include: fever, herpangina (blisters in the mouth), and blisters on the palms and fingers of the hand or on the soles of the feet. Acute hemorrhagic conjunctivitis can also be onset from Coxsackie A viral infection. Group B Coxsackie virus causes pleurodynia or Bornholm disease. Symptoms found associated with Coxsackie B virus include fever, headache, sore throat, chest and muscle pain, and gastrointestinal distress. In some instances, Coxsackievirus B may lead to infectious pericarditis or viral myocarditis. Both group A and group B Coxsackieviruses can cause nonspecific febrile illnesses, rashes, upper respiratory tract disease, and aseptic meningitis.

1128 Enterovirus D68 by Real-Time PCR

Clinical Significance: Although Enteroviruses are associated with various clinical symptoms including mild respiratory illness, febrile rash illness, and neurologic illness, such as aseptic meningitis and encephalitis, Enterovirus D68 (EV-D68) primarily causes respiratory illness. EV-D68 causes a spectrum of symptoms ranging from mild which may include fever, runny nose, sneezing, cough, body and muscle aches, up to severe such as wheezing and difficulty breathing. EV-D68 is known to cause infections primarily in children but has been known to infect adults. An outbreak of EV-D68 in 2014 was notable for its high number of hospitalizations involving infected children.

1112 Group A Streptococcus by Real-Time PCR

Clinical significance: *Streptococcus pyogenes* (**Group A Streptococcus**) is a Gram-positive extracellular bacteria that colonizes the throat and skin. It is the cause of many human diseases which range from mild skin infections to invasive life-threatening disease. Group A Streptococcus is the most common cause of bacterial pharyngitis (Strep throat) and is also associated with scarlet fever, impetigo, Streptococcal toxic shock syndrome and necrotizing fasciitis. Autoimmune mediated post infection sequelae such as rheumatic fever, rheumatic heart disease, glomerulonephritis and reactive arthritis can potentially result in disability or death.

1117 *Haemophilus influenzae* by Real-Time PCR

Clinical significance: *Haemophilus influenzae* is a small, nonmotile Gram-negative bacterium. *H. influenzae* most commonly causes ear, eye and sinus infections as well as pneumonia. A more serious strain of the bacteria called *H. influenzae* type b has been nearly abolished in the United States due to effective vaccine development, which has been available since 1988. The more serious strain can be found in cerebrospinal fluid and is responsible for causing meningitis (infection of the membranes that surround the brain) and a life-threatening infection called epiglottitis (infection of the area of the throat that covers and protects the voice box and trachea during swallowing). In rare cases, children may still develop *H. influenzae* type b infections. This can occur if the child has not completed their series of immunizations or in older children who did not receive the vaccine as an infant.

1114 Human Bocavirus by Real-Time PCR

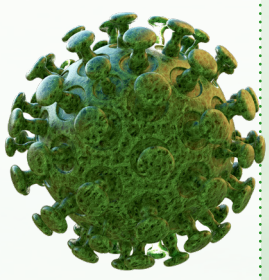
Clinical significance: Human Bocavirus (HBoV) is a relatively new and poorly characterized respiratory pathogen. Identified in 2005 as a novel parvovirus closely related to both bovine and canine strains, it is capable of infecting humans. Due to its recent isolation, the full clinical relevance of HBoV has yet to be fully realized. The initial study in which it was identified has associated HBoV infection with 3.1% of children hospitalized with respiratory distress. A retrospective study that followed reported an infectivity rate of 5.6% during the winter months, half of which were co-infected with another respiratory pathogen.

1115 Human Coronavirus (Human Coronaviruses 229E, OC43, NL-63) by Real-Time PCR

Clinical significance: Human Coronaviruses are single-stranded, enveloped RNA viruses. Although there are many viral strains capable of infecting various mammals, only four human strains exist: 229E, OC43, NL-63 and SARS. Coronaviruses are responsible for 10% to 30% of all common colds and to date, only the 229E and OC43 strains have been associated with high rates of infection within the United States. Infection occurs across large age groups, although the more severe infections occur among the young and the elderly. Reinfection with the same serotype is quite common, suggesting a short-lived humoral response. Confirmatory tests should exclude standard culturing methods due to the fastidious nature of these viruses.

1105 Human Metapneumovirus by Real-Time PCR

Clinical significance: Human Metapneumovirus (hMPV) is a negative sense, non-segmented RNA virus that was identified in 2001 as a new respiratory pathogen. The spectrum of symptoms that result are often indistinguishable from other respiratory infections, especially RSV, including fever, severe cough, breathing difficulties and wheezing. It is one of four pathogens known to induce bronchiolitis and is estimated to account for 5% to 15% of all bronchiolitis cases. Instances of severe respiratory distress requiring mechanical ventilation have been associated with hMPV. Infections are very common in the United States and 78% of infections occur between the months of December and April. Standard culture identification is difficult due to the virus' slow growth making PCR more suitable methods. In this assay, RNA is extracted from the specimen and subjected to PCR amplification.



1106 Influenza A virus by Real-Time PCR (Reflex to amantadine resistance by Pyrosequencing)
1124 Influenza A virus by Real-Time PCR
1107 Influenza B virus by Real-Time PCR

Clinical significance: Influenza virus is a segmented, negative-sense, single-stranded RNA virus capable of infecting epithelial cells of the upper respiratory tract. Infection results in the desquamation of the epithelial cells and viral entry of the lungs, which could result in influenza pneumonia. Three infectious strains exist, A, B and C; only A and B strains pose a threat to humans. Infections follow a winter

seasonal pattern within the United States. The high degree of mutation and reassortment associated with influenza viruses makes them a public health issue. Vaccination is highly effective at mitigating the infectious process and is recommended annually for adults 55 and over and two doses are recommended for children who have never been immunized or infected previously. In this assay, RNA is extracted from the specimen and subjected to PCR amplification; positive specimens are further analyzed by Pyrosequencing to determine whether the virus demonstrates resistance to amantadine.

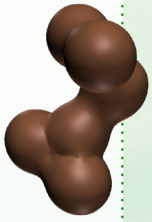
1109 *Moraxella catarrhalis* by Real-Time PCR

Clinical significance: *Moraxella catarrhalis* is a Gram-negative, aerobic, diplococcus clinically associated with bronchitis, sinusitis, laryngitis and otitis media. It is the third leading cause of otitis media within the United States. Infectious outcome is somewhat age dependent, affecting the upper respiratory tract in children and lower tract in adults. Colonization of children does occur, peaking at age 2, but wanes in adulthood. *M. catarrhalis* is also associated with chronic pulmonary disease in the elderly and long-time smokers and is known to exacerbate chronic obstructive pulmonary disease (COPD). Treatment should not include penicillin as the majority of the isolated organisms demonstrate penicillin resistance.

1118 Methicillin Resistant and Methicillin Susceptible (MSSA) *Staphylococcus aureus*
1119 Panton-Valentine Leukocidin (PVL) DNA by Real-Time PCR

Clinical significance: *Staphylococcus aureus*, often referred to simply as “staph” are bacteria commonly carried on the skin or in the nose of healthy people. Methicillin-resistant *Staphylococcus aureus* (MRSA), often pronounced “mersa”, is the resistant variant of this bacteria which is resistant to β-lactam antibiotics such as methicillin, oxacillin, penicillin, and amoxicillin. Risk of infection is greater for patients in hospitals, nursing homes, and other healthcare facilities who have open wounds and/or weakened immune systems. Colonization can occur in the anterior nares, skin, open wounds, and urinary tract. MRSA can be treated with alternate antibiotics which included glycopeptides (vancomycin and teichoplanin), linizolid, and daptomycin. Pre-screening patients upon admission for MRSA will also allow facilities to care for patients accordingly.

Staph and MRSA can also cause illness in persons outside of hospitals and healthcare facilities. MRSA infections that are acquired by persons who have not been hospitalized within the previous year or had a medical procedure, are known as community acquired MRSA (CA-MRSA) infections. Staph or MRSA infections in the community usually manifest as skin infections, such as pimples and boils, and occur in otherwise healthy people. CA-MRSA strains were first reported in the late 1990s and were defined by a lack of exposure to the health care setting. In the next several years, it became clear that CA-MRSA infections were caused by strains of MRSA that have different genetic characteristics than other strains. Panton-Valentine leukocidin (PVL) is a cytotoxin which is associated with increased virulence of certain strains of *Staphylococcus aureus*. It is present in the majority of community-associated Methicillin-resistant *Staphylococcus aureus* (CA-MRSA) isolates studied and is the cause of necrotic (“flesh-eating”) lesions involving the skin or mucosa, including necrotic hemorrhagic pneumonia. The new CA-MRSA strains have rapidly spread in the United States to become the most common cause of cultured skin infections among individuals seeking medical care for these infections at emergency rooms in cities. These strains also commonly cause skin infections in athletes, jail and prison detainees, and soldiers.



336 *Mycoplasma pneumoniae* by Real-Time PCR

Clinical significance: Mycoplasma species are the smallest and genetically simplest self-replicating bacteria. Mycoplasma species are ubiquitous in nature and are widely distributed throughout the animal kingdom. *Mycoplasma pneumoniae* is the most common cause of pneumonia and febrile upper-respiratory tract infections. Transmission occurs person-to-person via respiratory droplets produced by coughing. Other complications may develop with infections ranging from mild to life threatening.

1121 *Neisseria meningitidis* by Real-Time PCR (Reflex to penicillin resistance by Pyrosequencing)

Clinical significance: *Neisseria meningitidis*, also simply known as meningococcus, is a Gram-negative diplococcal bacterium. It is only known to infect humans and can be found as normal flora in the nasopharynx of 40% of adults. Meningococcal disease includes serious infections of the fluid and lining surrounding the brain (meningitis), bloodstream (bacteremia and sepsis), lungs (pneumonia), and joints (arthritis). It causes the only form of bacterial meningitis known to cause epidemics. N. meningitidis is responsible for considerable morbidity and mortality throughout the world. Meningococcus is spread through the exchange of saliva and other respiratory secretions during activities like coughing and kissing. Though it initially produces with general symptoms like fatigue, it can rapidly progress from fever, headache and neck stiffness to coma and death. Death occurs in approximately 10% of cases. Those with impaired immunity may be at particular risk of meningococcus.

1110 Parainfluenza viruses 1-4 by Real-Time PCR

Clinical significance: Human Parainfluenza viruses are RNA viruses that serve as a common cause of upper and lower respiratory tract infections, second only to Respiratory Syncytial virus. There are four viral serotypes, designated 1 thru 4, each having varying infectious frequencies and clinical outcomes; therefore, speciation offers a diagnostic advantage. HPIVs 1 and 2 are both associated with croup in children; however, HPIV-1 is more common. Bronchiolitis and pneumonia are more often associated with HPIV-3, while HPIV-4 has thus far only been associated with mild disease. The incubation period ranges from one to seven days. Symptoms include fever, irritability, barky cough and harsh breathing.

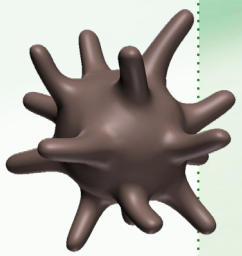
174 *Pseudomonas aeruginosa* by Real-Time PCR

Clinical Significance: *Pseudomonas aeruginosa* is a Gram-negative, opportunistic bacterial pathogen and is mainly associated with nosocomial infections hospital patients. It is free living and found in water, soil, as normal skin flora, and on the surfaces of plants. Commonly associated urinary tract infections (UTI), it is the most common organism isolated from patients hospitalized for longer than one week. In healthy individuals, mild illness typically develops often associated with exposure to water such as in ear infections and skin rashes due to inadequate chlorination of swimming pools and hot tubs. Although infections in healthy individuals can be mild and self limiting, in immunocompromised patients Pseudomonal infections are complicated and can be life-threatening and can include infections of the urinary tract, respiratory and gastrointestinal systems, skin and soft tissues, blood, bone and joint infections. Routine clinical diagnosis usually takes up to 48 hours to report. In this assay, DNA is extracted from the specimen and subjected to PCR amplification.

Respiratory Syncytial virus

1103 Respiratory Syncytial virus A (RSV A) by Real-Time PCR
1116 Respiratory Syncytial virus A and B by Real-Time PCR
1104 Respiratory Syncytial virus B (RSV B) by Real-Time PCR

Clinical significance: Respiratory Syncytial virus (RSV) is a negative-sense, enveloped RNA virus and is a common viral pathogen which causes yearly winter epidemics that are widely associated with lower respiratory tract infections (LRTI), as well as bronchiolitis and viral pneumonia. Although infections can occur throughout one's lifetime, bronchiolitis is typically limited to the first infection whereby approximately 25% to 40% of children demonstrate signs and symptoms of bronchiolitis and 0.5% to 2% require hospitalization. Subsequent infections are limited to moderate-to-severe cold- like symptoms in healthy adults and children but pose a significant health issue to the elderly and those with compromised pulmonary, cardiac, or immune systems. Two viral subtypes are known, A and B, each having multiple genotypes. Studies have demonstrated greater annual circulation rates, as well as greater virulence to be associated with RSV A. However, there have been years when RSV B strains predominated and some studies have indicated a higher preponderance of RSV B infections during the early portion of the infectious season. In this assay, RNA is extracted from the specimen and subjected to reverse transcriptase PCR amplification utilizing an assay capable of speciating the infectious strain.



1127 Rhinovirus and Enterovirus by Real-Time PCR

Rhinoviruses and non-polio Enteroviruses are very common infections and are the predominant cause of the common cold. These viruses are ubiquitous and are transmitted person-to-person via direct contact with viral particles shed in the feces and upper respiratory tract secretions. Viral shedding may persist for days prior to the onset of symptoms. The average incubation period is 3-10 days. Although infections occur year-round, there is a seasonal distribution with the highest incidences in the fall and spring. Only 70%-80% of person exposed to these viruses will experience symptoms which are usually mild and self-limiting. Infections are typically limited to the upper respiratory tract. However, they may cause otitis media and sinusitis, as well as exacerbate asthma, cystic fibrosis, chronic bronchitis, and cause serious lower respiratory tract illness in infants, the elderly and immunocompromised. Real-time PCR has been shown to be a rapid and effective way of detecting these viruses and has been proposed as the clinical detection method of choice. In this assay, DNA is extracted from the specimen and subjected to PCR amplification.

1120 Severe Acute Respiratory Syndrome (SARS) by Real-Time PCR

Clinical significance: Severe acute respiratory syndrome, SARS, is a highly contagious RNA viral disease (BSL-3 containment) of the *Coronaviridae* family, which caused the first pandemic infectious disease of the new millennium. SARS results in infection of both the upper and lower respiratory tracts and sometimes leads to gastroenteritis. A common symptom among patients is high fever above 38°C (100.4°F); other symptoms may include myalgia, lethargy, gastrointestinal symptoms, cough, sore throat, and other non-specific symptoms. Early diagnosis is crucial for appropriate treatment and survival of the patient; therefore, a Real-Time reverse transcriptase PCR assay was developed for the rapid detection of SARS.

1111 *Streptococcus pneumoniae* by Real-Time PCR

Clinical significance: *Streptococcus pneumoniae* is a Gram-positive, alpha hemolytic diplococcus that is a major cause of pneumonia as well as one of the most common causes of death in the United States. Approximately 5% to 10% of healthy adults and 20% to 40% of children are colonized with *S. pneumoniae* and, as a result, can spread it to others through the aerosolization of their respiratory secretions and coughing. Its polysaccharide coat protects it from phagocytosis; therefore, antibiotic treatment is required. Resistance to multiple antibiotic classes (penicillin, cephalopsporins, macrolides, tetracycline) has been reported. An effective vaccine is available and is recommended for children under the age of 2 and adults over the age of 65.

Medical Diagnostic Laboratories
2439 Kuser Road
Hamilton, NJ 08690
Toll Free: 877-269-0090
Fax: 609-570-1050
www.mdlab.com

PATIENT

MDL # 13364148

DOE, JANE
555 MAIN ROAD
ANYTOWN, NJ 12345-6789
DOB: 11/30/1998 (Age 25)
Gender: Female
Ethnicity: Not provided
Patient ID: 82100
Home #: 123-456-7890

FINAL

SPECIMEN

Type	Source	Collected	Received	Reported
NasoSwab		04/15/2024	04/16/2024	04/19/2024

CLIENT

NPI: 0987654321

DOE FAMILY PRACTICE
JOHN DOE, MD
1234 FIRST AVENUE
ANYTOWN, NJ 12345-6789

Tel: (555) 555-1234
Fax: 555-555-1235

Pathogens Detected

1118 Methicillin Resistant (MRSA) and Methicillin Susceptible (MSSA) Staphylococcus aureus * — POSITIVE
MRSA negative; Methicillin Susceptible Staphylococcus aureus (MSSA) Positive.

Pathogens Not Detected

Other Pathogens

222 Adenovirus *
1101 *Bordetella parapertussis* *
1102 *Bordetella pertussis* (Reflex to Bordetella holmesii) *
319 *Chlamydophila pneumoniae* *
1112 Group A Streptococcus *
1115 Human Coronavirus (Human Coronaviruses 229E, OC43, NL-63) *
1105 Human Metapneumovirus *
1136 Influenza A and B detection (Influenza A,Influenza B) *
336 *Mycoplasma pneumoniae* *
1110 Parainfluenza Viruses 1-4 *
1116 Respiratory Syncytial Virus Strain A and B (RSV-A,RSV-B) *
1127 Rhinovirus and Enterovirus *
1131 SARS-CoV-2 [COVID-19]
A Not Detected result does not exclude COVID-19 and should not be used as the sole basis for patient management or treatment decisions.
1111 *Streptococcus pneumoniae* *

*This test was developed and its performance characteristics determined by the laboratory. It has not been cleared or approved by the U.S. Food and Drug Administration. The FDA has determined that such clearance or approval is not necessary.

A positive result is provided for bacteria, virus, parasites, and/or fungal species when PCR amplification (real-time PCR), sequence information (Pyrosequencing), and/or sequencing analysis occurs above cut-off levels established by the laboratory. Pertinent reference intervals for the tests reported above are available from the laboratory upon request.

Medical Director, Jing-Jing Yang, M.D.

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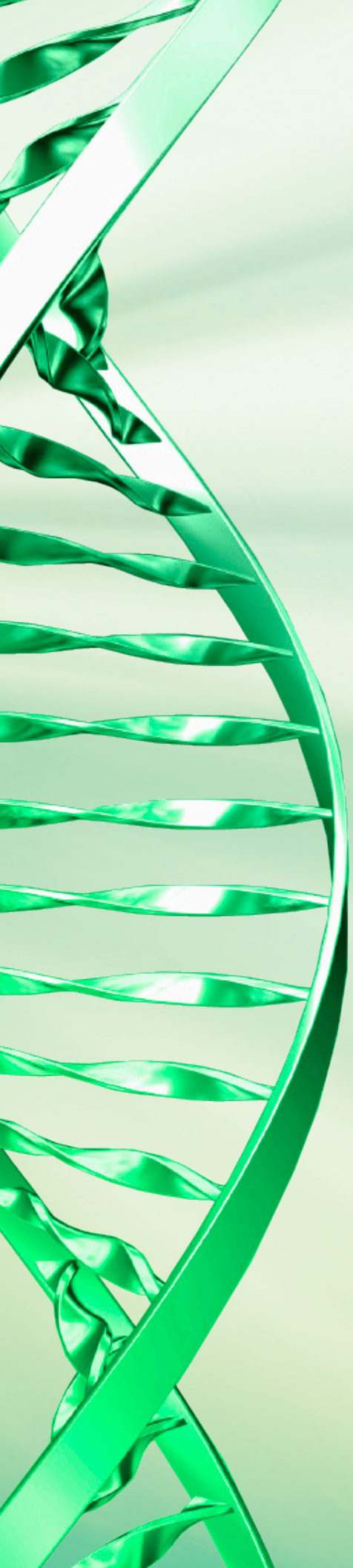

Medical Diagnostic Laboratories
2439 Kuser Road • Hamilton, NJ 08690-3303
www.mdlab.com • Toll Free 877 269 0090

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