Metropolitan Medical Laboratory, P.L.C.
1520 7th Street, Moline, IL 61265 and 1828 E. Locust Street, Davenport, IA 52803
309.762.8555 (IL) and 563.324.0471 (IA) | www.metromedlab.com

June 19, 2018

NEW TEST ANNOUNCEMENT

Mycoplasma pneumoniae DNA

Metropolitan Medical Laboratory PLC is pleased to announce a new rapid test useful for the diagnosis of *Mycoplasma pneumoniae* infections.

Mycoplasma pneumoniae is a respiratory pathogen which causes such diseases as tracheobronchitis, pneumonia, pharyngitis, as well as some extrapulmonary complications (meningoencephalitis, arthritis, etc.). The most common clinical syndrome is tracheobronchitis with or without upper respiratory tract manifestations such as pharyngitis. Pneumonia (walking pneumonia/primary atypical pneumonia) develops in about one-third of persons who are infected. Although *M. pneumoniae* has been associated with pneumonias in school-aged children, adolescents and young adults, infections with this organism can occur in older persons as well as children under five years of age. Testing for *M. pneumoniae* is helpful for diagnosis and guiding appropriate antimicrobial therapy which can be different from other respiratory pathogens.

The **Mycoplasma pneumoniae DNA** test is a qualitative nucleic acid amplification test which is performed on throat swabs from patients suspected of having infections with *Mycoplasma pneumoniae*. The illumigene® Mycoplasma Direct is a FDA-approved isothermal DNA amplification test with a manufacturer stated sensitivity/specificity of 96.0%/97.7%.

The new ***Mycoplasma pneumoniae* DNA** test will replace traditional serological testing (*Mycoplasma pneumoniae* IgM screen – Unit code 106090) at Metro Lab. Testing for *Mycoplasma pneumoniae* will continue to be offered daily as well as on a STAT basis.

The *Mycoplasma pneumoniae* DNA test (Unit Code 106460) will be available on July 1st, 2018.

Mycoplasma pneumoniae DNA
Test Code: 106460

Specimen Required: Collect a throat swab specimen on BBL™ CultureSwab™ (Dual-Swab).

1. Obtain specimen with a BBL™ CultureSwab™ (Dual-Swab).
2. Remove cap and swab from tube.
3. Tilt the patient's head back to assist opening the mouth as wide as possible.
4. Depress the tongue with a tongue depressor so the swab does not touch the tongue.
5. DO NOT swab the throat in cases of acute epiglottitis.
6. In one continuous motion, swab the posterior pharynx, both tonsils, any area of inflammation, ulceration, or exudation.
7. Remove swab being careful not to touch the tongue or lips. Insert swab back into transport and label specimen.

Label specimen with two patient identifiers, the specimen source (i.e. throat), along with the date and time of collection.

Store/transport specimen refrigerated (between 2-8°C) for up to 2 weeks.

Patient Preparation: Patients should refrain from using nasal decongestants containing Phenylephrine HCl and/or using Robitussin Cough and Congestion Cough syrup prior to specimen collection.

Reference Values:
MYCOPLASMA PNEUMONIAE DNA NOT DETECTED

Test:

Days Performed: Daily (Monday through Sunday)

Reported: Daily (Monday through Sunday)

Interference: Nasal decongestants containing Phenylephrine HCl at concentrations greater than 0.595 mg/mL may produce false negative results with low positive specimens. Whole blood at concentrations greater than 2% may interfere with the illumigene® Mycoplasma Direct assay. Robitussin Cough and Congestion Cough syrup may produce invalid initial results which may delay results. Test performance not established for immunocompromised or asymptomatic patients.

Rejection:

- Mini-tip swabs (absorbance capacity less than 60 µL) or swabs other than BBL™ CultureSwab™ (Dual-Swab)
- Unlabeled specimens
- Specimens at room temperature >24 hours
- Grossly bloody swabs
- Specimens submitted other than a throat swab
- Refrigerated specimens >14 days old
- Remel, Starplex, Fisher Finest Brand swabs

CPT Code(s): 87581 – *Mycoplasma pneumoniae* Amplified Probe Technique

BBL™ CultureSwab™ (Dual-Swab)