Test Menu

Infectious Diseases Laboratory

Division of Infectious Diseases
Department of Medicine

July 2017

UNIVERSITY OF
LOUISVILLE®
SCHOOL OF MEDICINE

Atypical Pneumonia PCR Panel (APP)*

The **APP** is an in-house developed, real-time (RT) PCR assay, for the detection of agents of "atypical pneumonia". The assay utilizes Luminex ARIES® technology to generate a result in approximately two hours.

Bacterial Targets:
*Mycoplasma pneumoniae**
*Legionella pneumophila**
*Chlamydia pneumoniae**

Accepted Specimens:
Oropharyngeal swabs (**OP**) or broncho-alveolar lavage (**BAL**). For OP specimens, collect a Dacron-tipped, plastic-shafted swab (Copan Flocked swab, if available) and place in UTM media. Maintain at 4° C. Collect 5.0 ml of BAL and maintain at 4° C.

OP collection kits are supplied by the Infectious Diseases Laboratory upon request.

Specimens Receipt:
Specimens are accepted Monday through Friday.

Assay Schedule:
APP assay is set up Monday through Friday, with final results usually available by 2:00 pm on the day of receipt.

Normal Range:
Not detected

CPT Codes:
87541, 87581, 87486

** This test was developed and its performance characteristics determined by the Infectious Diseases Laboratory using Analyte Specific Reagents. It has not been cleared or approved by the FDA. The FDA has determined that such clearance is not necessary. This test is used for clinical purposes and should not be regarded as investigational or for research. This laboratory is regulated under the CLIA Amendments of 1988 as qualified to perform high-complexity clinical testing of this nature.*

Respiratory Viral Panel (RVP)

The **RVP** is an FDA-approved, multiplexed, reverse-transcriptase-PCR assay, for the detection of 17 viral targets in a single specimen.

Viral Targets:

Influenza A
Influenza A, subtype H1
Influenza A, subtype H3
Influenza A, subtype H1-2009
Influenza B
Respiratory Syncytial Virus (RSV)
Coronavirus HKU1
Coronavirus NL63
Coronavirus 229E
Coronavirus OC43
Parainfluenzavirus 1
Parainfluenzavirus 2
Parainfluenzavirus 3
Parainfluenzavirus 4
Human metapneumovirus
Rhinovirus
Adenovirus

Accepted Specimens:

Nasopharyngeal swabs (**NP**), nasal washing (**NW**) or broncho-alveolar lavage (**BAL**). For NP specimens, collect using a Dacron-tipped, plastic-shafted swab (Copan Flocked swab, if available) and place in viral transport media (i.e., UTM, M4, etc.). Maintain at 4° C. Collect 5.0 ml of BAL and maintain at 4° C.

NP collection kits are supplied by the Infectious Diseases Laboratory upon request.

Specimen Receipt:

Specimens are accepted Monday through Friday.

Assay Schedule:

RVP assay is set up Monday through Friday, with final results usually available by 2:00 pm on the day of receipt.

Normal Range:

Not detected

CPT Codes:

87798 x 12 (i.e., 17 viral targets)

Respiratory Pathogen Panel (RPP)

Accepted Specimens: An oropharyngeal swab (**OP**) and a naso- pharyngeal swab (**NP**) or a broncho-alveolar lavage (**BAL**). For OP and NP specimens, collect using a Dacron-tipped, plastic-shafted swab (Copan Flocked swab, if available) and place in UTM transport media. Collect 5.0 ml of BAL and maintain at 4° C.

Targets:
*Mycoplasma pneumonia**
*Legionella pneumophila**
*Chlamydia pneumoniae**
Influenza A
Influenza A, subtype H1
Influenza A, subtype H3
Influenza A, subtype H1-2009
Influenza B
Respiratory Syncytial Virus (RSV)
Coronavirus HKU1
Coronavirus NL63
Coronavirus 229E
Coronavirus OC43
Parainfluenzavirus 1
Parainfluenzavirus 2
Parainfluenzavirus 3
Parainfluenzavirus 4
Human metapneumovirus
Rhinovirus
Adenovirus

Specimens Receipt: Specimens are accepted Monday through Friday.

Assay Schedule: **RPP** assay is set up Monday through Friday, with final results usually available by 2:00 pm on the day of receipt.

Normal Range: Not detected

CPT Codes: 87541, 87581, 87486
87798 x 17 (i.e., 17 viral targets)

** This test was developed and its performance characteristics determined by the Infectious Diseases Laboratory using Analyte Specific Reagents. It has not been cleared or approved by the FDA. The FDA has determined that such clearance is not necessary. This test is used for clinical purposes and should not be regarded as investigational or for research. This laboratory is regulated under the CLIA Amendments of 1988 as qualified to perform high-complexity clinical testing of this nature.*

APP Individual Molecular Tests

Single, in-house developed, real-time (RT) PCR assays for the detection of agents of "atypical pneumonia". The assays utilize **Luminex ARIES®** technology to generate a result in approximately two hours.

Available Bacterial Targets (Indicate One):

1. ***Mycoplasma pneumoniae*** **(MCR)***
2. ***Legionella pneumophila*** **(LCR)***
3. ***Chlamydia pneumoniae*** **(CCR)***

Accepted Specimens: Oropharyngeal swabs (**OP**) or broncho- alveolar lavage (**BAL**). For OP specimens, collect using a Dacron-tipped, plastic-shafted swab (Copan Flocked swab, if available) and place in UTM transport media. Maintain at 4° C. Collect 5.0 ml of BAL and maintain at 4° C.

OP collection kits are supplied by the Infectious Diseases Laboratory upon request.

Specimens Receipt: Specimens are accepted Monday through Friday.

Assay Schedule: Each assay is set up Monday through Friday, with final results usually available by 2:00 pm on the day of receipt.

Normal Range: Not detected

CPT Codes:

MCR	87541
LCR	87581
CCR	87486

** This test was developed and its performance characteristics determined by the Infectious Diseases Laboratory using Analyte Specific Reagents. It has not been cleared or approved by the FDA. The FDA has determined that such clearance is not necessary. This test is used for clinical purposes and should not be regarded as investigational or for research. This laboratory is regulated under the CLIA Amendments of 1988 as qualified to perform high-complexity clinical testing of this nature.*

CT/GC PCR

The Xpert® CT/NG Assay, performed on the GeneXpert® Instrument Systems, is a qualitative *in vitro* real-time PCR test for the automated detection and differentiation of genomic DNA from *Chlamydia trachomatis* (CT) and/or *Neisseria gonorrhoeae* to aid in the diagnosis of chlamydial and gonorrheal urogenital disease.

PCR:	***Chlamydia trachomatis (CT)***
	Neisseria gonorrhoeae (NG)
Accepted Specimens:	10.0 ml minimum urine
Specimens Receipt:	Specimens are accepted Monday through Friday.
Assay Schedule:	CT/GC assay is set up Monday through Friday, with final results usually available by 2:00 pm on the day of receipt.
Normal Range:	Not detected
CPT Codes:	**CT** 87491 **GC** 87591

Tick-Borne Disease Panel (TDP)

The **TDP** is a combination of serological and molecular assays to aid in the diagnosis of acute or chronic infection by the most common tick-borne agents in this area. This includes testing for Lyme Disease (*B. burgdorferii*), Rickettsial diseases [both Spotted-Fever Group (which includes Rocky Mountain Spotted Fever) and Typhus Group], Pan *Ehrlichia spp.-chaffeensis, muris, ewingii* (Human Monocytic Ehrlichiosis) and *Anaplasma phagocytophilum* (Human Granulocytic Anaplasmosis).

Serology:	***B. burgdorferii***	**(LYM)**
	Rickettsia	**(RIC)**
PCR:	**Pan *Ehrlichia spp.***	**(ECP)** *
	A. phagocytophilum	**(APH)** *

Accepted Specimens: (1) 1.0 ml of serum. (2) 5.0 ml of of whole blood collected in EDTA. For pediatric specimens, collect 1.0 ml whole blood in EDTA. Maintain at 4° C until delivered.

Specimens Receipt: Specimens are accepted Monday through Friday.

Assay Schedule: Each assay is set up Monday through Friday, with final results usually available by 2:00 pm on the day of receipt.

Normal Range:

Lyme	IgG/M	Negative
Rickettsia	IgG	<1:64
Rickettsia	IgM	<1:64
Pan *Ehrlichia spp*	PCR	Not detected
A. phagocytophilum	PCR	Not detected

CPT Codes:

LYM	86618
RIC	86757
ECP	87798
APH	87798

** This test was developed and its performance characteristics determined by the Infectious Diseases Laboratory using Analyte Specific Reagents. It has not been cleared or approved by the FDA. The FDA has determined that such clearance is not necessary. This test is used for clinical purposes and should not be regarded as investigational or for research. This laboratory is regulated under the CLIA Amendments of 1988 as qualified to perform high-complexity clinical testing of this nature.*

Pan *Ehrlichia spp./A. phagocytophilum* PCR*

Infections with Pan *Ehrlichia spp.- chaffeensis, muris, ewingii* (HME) or *A. phagocytophilum* (HGA) usually cause a very high rate of bacteremia. As a result, large amounts of bacterial DNA may be present in the circulation, lending itself to rapid detection using molecular techniques. Since rapid detection is a key to effective clinical management, the Luminex ARIES® has been used to validate the detection of these agents in whole blood specimens.

Available Bacterial Targets (Indicate One):

1.	**Pan *Ehrlichia spp.***	**(ECP)***
2.	***A. phagocytophilum***	**(APH)***

Accepted Specimens: 5.0 ml of of whole blood collected in EDTA. For pediatric specimens, collect 1.0 ml whole blood in EDTA. Maintain at 4° C until delivered.

Specimens Receipt: Specimens are accepted Monday through Friday.

Assay Schedule: Assay is set up Monday through Friday, with final results usually available by 2:00 pm on the day of receipt.

Normal Range: Not detected

CPT Codes:

ECP	87798
APH	87798

** This test was developed and its performance characteristics determined by the Infectious Diseases Laboratory using Analyte Specific Reagents. It has not been cleared or approved by the FDA. The FDA has determined that such clearance is not necessary. This test is used for clinical purposes and should not be regarded as investigational or for research. This laboratory is regulated under the CLIA Amendments of 1988 as qualified to perform high-complexity clinical testing of this nature.*

RPR (Rapid Plasma Reagin)

The Macro-Vue® RPR (Rapid Plasma Reagin) 18mm Circle Card test is a non-treponemal testing procedure for the serologic detection of syphilis.

Accepted Specimens: 1.0 ml Serum.

Specimens Receipt: Specimens are accepted Monday through Friday.

Assay Schedule: Assay is set up 2 to 3 times per week with final results usually available by 2:00 pm on day of receipt.

Normal Range: Nonreactive

CPT Codes: **RPR** 86592

Serum Bactericidal Level (SBL)*

The Serum Bactericidal Level (**SBL**) is an assay used in monitoring total serum antibiotic bactericidal activity in patients receiving long-term antibiotic therapy. The majority of these patients are receiving treatment for chronic infections, such as osteomyelitis and endocarditis.

Accepted Specimens: Two (2) specimens are required for the SBL.

1. Pure culture of the isolated organism along with the proper bacterial Identification.
2. Serum sample (1.0 ml) taken 30 minutes post antibiotic administration. Specimen should be frozen at -20° C and remain so until delivered.

Specimens Receipt: Specimens are accepted Monday through Friday.

Assay Schedule: Assay is set up Monday, with final results usually available by 2:00 pm on Friday.

Normal Range: Varies for individual patient sample

CPT Code: **SBL** 87197

** This test was developed and its performance characteristics determined by the Infectious Diseases Laboratory. It has not been cleared or approved by the FDA. The FDA has determined that such clearance is not necessary. This test is used for clinical purposes and should not be regarded as investigational or for research. This laboratory is regulated under the CLIA Amendments of 1988 as qualified to perform high-complexity clinical testing of this nature.*

Quanti-FERON®-TB Gold (QFT)*

The QuantiFERON®-TB Gold In-Tube (**QFT**) assay is a whole-blood screening test for active tuberculosis (TB) or latent tuberculosis infection (LTBI).

Accepted Specimens: Three separate **1.0 ml** QuantiFERON® collection tubes. **Must be received within 16 hrs of collection**. These kits are supplied by the Infectious Diseases Laboratory.

Specimens Receipt: Specimens are accepted Monday through Thursday by 2:30 pm.

Assay Schedule: Assay is set-up 2 to 3 times per week, with final results available by 2:00pm. Only Client-Incubated (**QFT-CL**) specimens accepted on Friday.

Normal Range: **Negative:** *M. tuberculosis* infection unlikely, but cannot be excluded, especially when:

- **(a)** any illness is consistent with TB disease;
- **(b)** likelihood of progression to disease is increased (i.e., immunosupression).

CPT Code: **QFT** 86480

**The QFT is not FDA approved for patients under the age of 17. The Infectious Diseases Laboratory will add the appropriate disclaimer to test results on those patients that do not meet this criteria.*

Quanti-FERON®TB Gold-Client Incubated (QFT-CI)*

The **QFT-CI** format allows for collection of specimens from patients at virtually any time-point necessary. Since the "post-incubated" tubes are stable for 72 hrs at room temperature, the specimens can then be delivered to our laboratory M-F 7:00 am to 2:30 pm, for testing.

Accepted Specimens: Three separate **1.0 ml** QuantiFERON® collection tubes. These kits are supplied by the Infectious Diseases Laboratory.

Procedures:

1. Follow sample collection instructions on the QFT-TB Blood Collection Kit, supplied by the Infectious Diseases Laboratory.
2. **Invert tubes ten times**, just firmly enough to ensure the entire surface of the tube is coated with blood, to solubilize antigens on tube walls.
3. **Incubate the three (3) tubes upright at 36-38° C for 16 to 24 hours.**
4. Make sure to document the "Incubator Date/Time" information on the Test Request Form. **This must accompany specimens to avoid rejection**.
5. Following incubation, transport the three incubated collection tubes to the Infectious Diseases Laboratory, maintaining at room temperature. Samples are stable for 72 hrs at room temp.

Specimens Receipt: Specimens are accepted Monday through Friday.

Normal Range: **Negative:** *M. tuberculosis* infection unlikely, but cannot be excluded, especially when:
(a) any illness is consistent with TB disease;
(b) likelihood of progression to disease is increased (i.e., immunosupression).

CPT Code: **QFT** 86480

**The QFT is not FDA approved for patients under the age of 17. The Infectious Diseases Laboratory will add the appropriate disclaimer to test results on those patients that do not meet this criteria.*

The Infectious Diseases Laboratory is a CLIA-certified, high-complexity laboratory, offering state-of-the-art testing for the diagnosis of infectious diseases. This booklet contains the pertinent details of our testing menu.

Please contact us with additional questions.

Leslie A Wolf, PhD, HCLD(ABB)
Director

Infectious Diseases Laboratory

Division of Infectious Diseases
Medical Dental Research Building
Rm 104, 511 South Floyd Street
University of Louisville
Louisville, KY 40292

P: 502-852-1152
F: 502-852-1512
E: idlab@louisville.edu

uoflidlab.com

Licensure:
Kentucky: 200100
CLIA: 18D064848