Test Menu

Infectious Diseases Laboratory

Division of Infectious Diseases
Department of Medicine

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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.

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:	87581, 87541, 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.*

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.

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	87581
LCR	87541
CCR	87486

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Pneumocystis jirovecii (PJP)*

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

Target:	***Pneumocystis jirovecii***
Accepted Specimens:	Broncho-alveolar lavage (**BAL**). Maintain at 4° C. Collect 5.0 ml of BAL and maintain at 4° C.
Specimens Receipt:	Specimens are accepted Monday through Friday.
Assay Schedule:	**PJP** 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:	**PJP** 87798

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Atypical Pneumonia PCR Panel Plus (APP-Plus)*

PCR for the detection of agents of "atypical pneumonia" and "pneumocystis pneumonia". The assay utilizes Luminex ARIES® technology to generate a result in approximately two hours.

Targets:
Mycoplasma pneumoniae*
Legionella pneumophila*
Chlamydia pneumoniae*
Pneumocystis jirovecii*

Accepted Specimens:
Oropharyngeal swabs (**OP**) or broncho-alveolar lavage (**BAL**) for **APP**. BAL only for **PJP**. 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 Plus 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:
87581, 87541, 87486, 87798

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Gastrointestinal Pathogen Panel (GIP)

The **GIP** is an FDA-approved, multiplexed, reverse transcriptase-PCR assay, for detection of 22 targets using the Filmarray® platform.

Targets:	*Campylobacter* *Clostridium difficile toxin A/B* *Pleisiomonas shigelloides* *Salmonella* *Vibrio* *Vibrio cholerae* *Yersinia enterocolitica* *Enteroaggregative E.coli (EAEC)* *Enteropathogenic E. coli (EPEC)* *Enterotoxigenic E.coli (ETEC) lt/st* *Shiga-like toxin producing E.coli (STEC) stx1/stx2* *E. coli 0157* *Shigella/Enteroinvasive E.coli (EIEC)* *Cryptosporidium* *Cyclospora cayetanensis* *Entamoeba histolytica* *Giardia lambia* *Adenovirus F 40/41* *Astrovirus* *Norovirus GI/GII* *Rotovirus A* *Sapovirus*
Accepted Specimens:	Stool collected in approved Cary Blair media.
Specimens Receipt:	Specimens are accepted Monday through Friday.
Assay Schedule:	**GIP** 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 22

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* (**NG**) to aid in the diagnosis of chlamydial and gonorrheal urogenital disease.

Targets:	***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: 1.0 ml of serum AND 5.0 ml of of whole blood collected in EDTA. For pediatric specimens, collect 1.0 ml of serum and 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

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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.

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

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Reflex Lyme Western Blot IgG and IgM (LWB)

The MarDx *Borrelia burgdorferi* (IgG and IgM) Marblot Strip Test System is a Western blot assay for the qualitative *in vitro* detection of human IgG and IgM antibodies to individual proteins of B. burgdorferi in human serum. This test system is intended for use in testing serum samples which have been found positive or equivocal by EIA or IFA to provide supportive evidence of infection with *B. burgdoferi*.

Targets:	***B. borgderferii* IgG** ***B.borgderferii* IgM**
Accepted Specimens:	1.0 ml Serum
Specimens Receipt:	Specimens are accepted Monday through Friday. Automatically reflexed upon a positive or equivocal Lyme test.
Assay Schedule:	Varies.
Normal Range:	Negative
CPT Code:	LWB 86617 X 2

Rapid Plasma Reagin (RPR)

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

Target:	**Non-specific antibodies to *T. pallidum***
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

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*Quanti-FERON®-TB Plus (QFT-TB Plus)**

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

Target:	**Cell-mediated immune response to antigens associated with M. tuberculosis complex**
Accepted Specimens:	Four 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-TB CI**) specimens accepted on Friday.
Normal Range:	**Negative:** M. tuberculosis infection unlikely, but cannot be excluded, especially when: • any illness is consistent with TB disease; • likelihood of progression to disease increased (i.e.,immunosuppression).
CPT Code:	**QFT-TB Plus** 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 Plus-Client Incubated (QFT TB Plus-CI)*

The **QFT Plus-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.

Target: **Cell-mediated immune response to antigens associated with M. tuberculosis complex**

Accepted Specimens: Four 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 Plus** 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 four (4) 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 four 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 TB Plus-CI** 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.

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