

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.

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:	<p>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</p>
Accepted Specimens:	<p>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.</p> <p><u>NP collection kits are supplied by the Infectious Diseases Laboratory upon request.</u></p>
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 pneumoniae**
*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)

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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

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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:	<i>Chlamydia trachomatis</i> (CT)
	<i>Neisseria gonorrhoeae</i> (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:	<i>B. burgdorferii</i>	(LYM)
	Rickettsia	(RIC)
PCR:	Pan <i>Ehrlichia spp.</i>	(ECP) *
	<i>A. phagocytophilum</i>	(APH) *
Accepted Specimens:	(1) 1.0 ml of serum. (2) 5.0 ml 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 <i>Ehrlichia spp</i>	PCR Not detected
	<i>A. phagocytophilum</i>	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.

Available Bacterial Targets (Indicate One):

- | | | |
|----|---------------------------|--------|
| 1. | Pan <i>Ehrlichia</i> spp. | (ECP)* |
| 2. | <i>A. phagocytophilum</i> | (APH)* |

Accepted Specimens: 5.0 ml 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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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

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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., immunosuppression).
- 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., immunosuppression).

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.



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