UNIVERSITY OF LOUISVILLE

OCTOBER 2021

LAB TEST MENU

Infectious Diseases Laboratory

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.

P: 502-852-1152

F: 502-852-1512

E: idlab@louisville.edu

Request Testing

UNIVERSITY OF LOUISVILLE®

Atypical Pneumonia PCR Panel (APP)*

The **APP** is a multiplexed, laboratory 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* (MCR)*** ***Legionella pneumophila* (LCR)*** ***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 media. For BAL **only**, collect 5.0 ml. Maintain at 4ºC.
Specimens Reciept	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	**MCR:** 87581 **LCR:** 87541 **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, 42 U.S.C. §263a as qualified to perform high-complexity clinical testing of this nature.w*

APP Individual Molecular Tests*

Single, laboratory 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)***	***Mycoplasma pneumoniae* (MCR)*** ***Legionella pneumophila* (LCR)*** ***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 media. For BAL **only**, collect 5.0 ml. Maintain at 4ºC.
Specimens Reciept	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	**MCR:** 87581 **LCR:** 87541 **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, 42 U.S.C. §263a as qualified to perform high-complexity clinical testing of this nature.w*

Pneumocystis jirovecii Pneumonia (PJP)*

PJP is a laboratory 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.

Targets	***Pneumocystis jirovecii*** **(PJP)***
Accepted Specimens	Broncho-alveolar lavage (**BAL**) **only**. Collect 5.0 ml of BAL and maintain at 4ºC.
Specimens Reciept	Specimens are accepted Monday through Friday.
Assay Schedule	**PJP** assay is set up Monday through Friday, with results usually available by 2:00 pm on the day of receipt.
Normal Range	Not detected
CPT Codes	**PJP:** 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, 42 U.S.C. §263a as qualified to perform high-complexity clinical testing of this nature.*

Atypical Pneumonia PCR Panel Plus (APP-Plus)*

Laboratory developed (RT-PCR) assays for the detection of agents of "atypical pneumonia" and "pneumocystis pneumonia". These assays utilize Luminex ARIES® technology to generate a result in approximately two hours.

Targets	***Mycoplasma pneumoniae* (MCR)*** ***Legionella pneumophila* (LCR)*** ***Chlamydia pneumoniae* (CCR)*** ***Pneumocystis jirovecii* (PJP)***
Accepted Specimens	Oropharyngeal swabs (**OP**) or broncho-alveolar lavage (**BAL**) accepted for **APP**. For **PJP** collect BAL **only**. For OP specimens, collect using a Dacron-tipped, plastic-shafted swab (Copan Flocked swab, if available) and place in UTM media. For BAL specimens, collect 5.0 ml of BAL and maintain at 4ºC.
Specimens Reciept	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	**MCR:** 87581 **LCR:** 87541 **CCR:** 87486 **PJP:** 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, 42 U.S.C. §263a as qualified to perform high-complexity clinical testing of this nature.w*

SARS-CoV-2/COVID-19 PCR*

The **SARS-CoV-2** assay is a real-time (RT-PCR) assay intended for the qualitative detection of nucleic acid from the SARS-CoV-2 virus in nasopharyngeal (NP) swabs from individuals suspected of COVID-19 disease. SARS-CoV-2 RNA is generally detectable in respiratory specimens during the acute phase of infection.

The performance of this test was established based on the evaluation of a limited number of clinical specimens. Clinical performance has not been established with all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.

Positive results are indicative of the presence of SARS-CoV-2 RNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.

Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

Targets	**SARS-CoV-2 RNA***
Accepted Specimens	Nasopharyngeal swab (**NP**), collect using a Dacron-tipped, plastic-shafted swab (Copan Flocked swab, if available) and place in UTM media. Maintain at 4ºC.
Specimens Reciept	Specimens are accepted Monday through Friday.
Assay Schedule	**SARS-CoV-2** 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	**SARS-CoV-2:** 87635

**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, 42 U.S.C. §263a as qualified to perform high-complexity clinical testing of this nature.w*

CT/NG PCR*

The *Chlamydia trachomatis* (**CT**) and *Neisseria gonorrhoeae* (**NG**) real-time PCR assay is a laboratory-developed test performed on the Luminex ARIES® for the diagnosis of chlamydia and/or gonorrhea urogenital disease.

This assay is a qualitative in vitro assay for the automated detection of genomic bacterial CT and GC DNA, the causative agents of the most common bacterial sexually transmitted infections (STI). The assay uses urine specimens collected in a clinical setting from primarily asymptomatic individuals, who require screening for immigration purposes.

Targets	***Chlamydia trachomatis* (CT)*** ***Neisseria gonorrhoeae* (NG)***
Accepted Specimens	20-50 ml of initial urine stream. Preferably, patient should not have urinated 1 hour prior to collection.
Specimens Reciept	Specimens are accepted Monday through Friday.
Assay Schedule	**CT/NG** 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 **NG:** 87591

**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, 42 U.S.C. §263a as qualified to perform high-complexity clinical testing of this nature.w*

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. burgdorferi*); Rickettsial diseases, both Spotted-Fever Group (which includes Rocky Mountain Spotted Fever) and Typhus Group; *Pan-Ehrlichia* (*E. chaffeensis*, *E. muris eauclairensis*, *E. ewingii* (Human Monocytic Ehrlichiosis); and *Anaplasma phagocytophilum* (Human Granulocytic Anaplasmosis).

Serology	***B. burgdorferi* (LYM)** **Rickettsia (RIC)**
PCR	**Pan-*Ehrlichia spp.* (ECP)*** ***A. phagocytophilum* (APH)***
Accepted Specimens	1.0 ml of serum **AND** 5.0 ml 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 4ºC until delivered.
Specimens Reciept	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/IgM-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, 42 U.S.C. §263a as qualified to perform high-complexity clinical testing of this nature.w*

Borrelia MTTT™ (Lyme) Screen Test

The ZEUS® ELISA Borrelia VlsE1/pepC10 IgG/IgM Test System is an enzyme-linked immunosorbent assay (ELISA) for the qualitative detection of IgG and IgM class antibody to VlsE1 and pepC10 antigens from *Borrelia burgdorferi* in human sera. This assay is intended for testing serum samples from symptomatic patients or those suspected of Lyme Disease. Positive test and equivocal results with the ZEUS® ELISA Borrelia VlsE1/pepC10 IgG/IgM Test for the presence of *Borrelia burgdorferi* antibodies must be confirmed by the FDA-approved Modified two-tier test method (MTTT).

Targets	***B. burgdorferi IgG/IgM*** **(LYM)**
Accepted Specimens	1.0 ml of serum
Specimens Reciept	Specimens are accepted Monday through Friday. Automatically reflexes to a Zeus Borrelia MTTT™ Lyme Supplemental Test upon a positive or equivocal Zeus Borrelia MTTT™ (Lyme) Screen IgG/IgM Test.
Assay Schedule	**Borrelia MTTT™ (Lyme) Screen** assay is set up Monday through Friday, with final results usually available by 2:00 pm on the day of receipt.
Normal Range	Negative
CPT Codes	**LYM:** 86618

Rickettsia (IFA) Test

The DiaSorin® Diagnostics Rickettsia Indirect Immunofluorescence Antibody (IFA) assay is intended for the detection and semi-quantitation of human IgG and IgM antibodies to Spotted Fever and Typhus Fever Group Rickettsia, as an *in vitro* aid in diagnosis of diseases caused by these agents.

Targets	**Rickettsia Spotted Fever/Typhus Group IgG (RIC)** **Rickettsia Spotted Fever/Typhus Group IgM (RIC)**
Accepted Specimens	1.0 ml Serum
Specimens Reciept	Specimens are accepted Monday through Friday.
Assay Schedule	**Rickettsia (IFA)** assay is set up Monday through Friday, with results usually available by 2:00 pm on the day of receipt.
Normal Range	Rickettsia: IgG<1:64 Rickettsia: IgM <1:64
CPT Codes	**RIC:** 86757 X 2

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

Infections with Pan-*Ehrlichia spp.* (*E. chaffeensis, E. muris eauclairensis, E. 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)***	**Pan-*Ehrlichia spp.* (ECP)*** ***A. phagocytophilum* (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 4ºC until delivered.
Specimens Reciept	Specimens are accepted Monday through Friday.
Assay Schedule	Pan-*Ehrlichia spp./A. phagocytophilum* PCR is set up Monday through Friday, with 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, 42 U.S.C. §263a as qualified to perform high-complexity clinical testing of this nature.w*

Zeus Borrelia MTTT™ (Lyme) Supplemental Test

The ZEUS® ELISA IgG and IgM Test System is an enzyme-linked immunosorbent assay (ELISA) for the qualitative detection of IgG or IgM class antibody to *Borrelia burgdorferi* in human sera. This assay is intended for testing serum samples from symptomatic patients or those suspected of Lyme Disease. Positive test results by the MTTT methodology is supportive evidence for the presence of antibodies and exposure to *Borrelia burgdorferi*, the cause of Lyme disease.

Targets	***B. burgdorferi IgG*** **(LWB)** ***B. burgdorferi IgM*** **(LWB)**
Accepted Specimens	1.0 ml Serum
Specimens Reciept	Specimens are accepted Monday through Friday. Automatically reflexed upon a positive or equivocal Zeus® Borrelia MTTT (Lyme) Screen IgG/IgM Test
Assay Schedule	Assay is set up 2 to 3 times per week with results usually available by 2:00 pm on day of testing.
Normal Range	Negative
CPT Codes	**LWB:** 86617 X 2

Rapid Plasma Reagin (RPR)

The Macro-Vue® **RPR** (Rapid Plasma Reagin) 18mm Circle Card assay is a non-treponemal testing procedure for the serologic detection of syphilis, a sexually transmitted infection that can cause serious health problems if it is not treated.

Targets	**Non-specific antibodies to *Treponema pallidum (RPR)***
Accepted Specimens	1.0 ml Serum
Specimens Reciept	Specimens are accepted Monday through Friday. Automatically reflexes to a TPPA (*Treponema pallidum* particle agglutination) test upon a positive RPR result.
Assay Schedule	Assay is set up 2 to 3 times per week with results usually available by 2:00 pm on day of testing.
Normal Range	Nonreactive
CPT Codes	**RPR:** 86592

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) caused by the *Mycobacterium tuberculosis* complex, a complex that includes *M. tuberculosis, M. africanum,* and *M. bovis, M. microti, M. canetti,* and *M. caprae.*

Targets	**Cell-mediated immune response to antigens associated with *M. tuberculosis* complex (QFT-TB Plus)**
Accepted Specimens	Four separate **1.0 ml** Quanti-FERON® collection tubes. Must be received within 16 hrs of collection.
Procedures	Follow sample collection instructions on the label of **QFT-TB Plus** Blood Collection kit, supplied by the Infectious Diseases Laboratory. **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.
Specimens Reciept	Specimens are accepted Monday through Thursday by 2:30 pm.
Assay Schedule	Assay is set-up 2 to 3 times per week, with results usually available by 2:00pm.
Normal Range	**Negative**: *M. tuberculosis* infection unlikely, but cannot be excluded, when: a) any illness is consistent with TB disease b) likelihood of progression to disease increased (i.e., immunosuppression).
CPT Codes	**QFT-TB Plus:** 86481

**The QFT-TB Plus 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-TB 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 the IDL laboratory M-F 7:00 am to 2:30 pm for testing

Targets

Cell-mediated immune response to antigens associated with *M. tuberculosis* complex (QFT-TB Plus CI)

Accepted Specimens

Four separate **1.0 ml** Quanti-FERON® collection tubes. These kits are supplied by the Infectious Diseases Laboratory.

Procedures

1. Follow sample collection instructions on the label of 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. Tubes must be incubated within 16 hours of collection.
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. Incubated samples are stable for 72 hrs at room temp.

Specimens Reciept

Client-incubated specimens are accepted Monday through Friday.

Assay Schedule

Assay is set-up 2 to 3 times per week, with results usually available by 2:00pm. Only QFT-TB Plus CI Client Incubated specimens accepted on Friday.

Normal Range

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

a) any illness is consistent with TB disease

b) likelihood of progression to disease increased (i.e., immunosuppression).

CPT Codes

QFT-TB Plus CI: 86481

**The QFT-TB Plus CI 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.*

UNIVERSITY OF LOUISVILLE

Leslie A. Wolf, PhD, HCLD (ABB)

Laboratory Director
Delia B. Baxter Research Bldg.II
580 S. Preston St., Rm 102

Louisville, KY 40202

P: 502-852-1152

F: 502-852-1512

E: idlab@louisville.edu

Licensure: Kentucky: 200100
CLIA: 18D0648480