

Illinois Department of Public Health

Division of Laboratories

Manual of Services

December 2024

Mission Statement

The mission of Illinois Department of Public Health (IDPH) Division of Laboratories is to support public health epidemiology programs by providing surveillance data.

Introduction

The Division of Laboratories serves Illinois' public health system and environmental protection network with high quality diagnostic and analytical laboratory testing. As enormous strides continue to take place in all medical and scientific disciplines, division personnel located in Carbondale, Chicago, and Springfield strive to maintain advanced laboratory capabilities in order to improve public health and environmental quality throughout Illinois. The division participates in numerous certification programs to ensure the accuracy of its testing data. The following is a list of those certification programs:

- Clinical Laboratory Improvement Amendments (CLIA) Each laboratory in the division has a CLIA certificate. The objective of the CLIA program is to ensure quality clinical laboratory testing.
- Federal Select Agent Program Each laboratory in the division has a Select Agent Certificate. This certificate is necessary for biological threat agent testing.
- American Association for Laboratory Accreditation (A2LA, certificate number 4358.01) The Springfield Laboratory is accredited for food microbiology testing.
- American Industrial Hygiene Association Laboratory Accreditation Programs (AIHA LAP, LLC). The Chicago
 Laboratory is accredited to test paint, soil, dust wipes, and air filters to determine the level of lead in these
 samples.
- Certified water microbiology and dairy labs The division's Carbondale and Chicago laboratories are certified by IDPH certification/evaluation officers to perform water and dairy testing.
- U. S. Food and Drug Administration (FDA) The Springfield Laboratory holds a certificate for dairy lab grade testing.
- U. S. Environmental Protection Agency (EPA) –The Springfield Laboratory is accredited by the EPA for drinking water testing.

This manual is a guide to the testing offered by the IDPH Division of Laboratories and describes the requirements for submitting samples. At times, it may be difficult to meet these requirements, however, without them the test may be impossible to perform, or the quality of results may be compromised. The quality of the laboratory's work depends directly on the quality of samples submitted. By observing these sample requirements, clients help the laboratory to provide uncompromised, high quality test results. Shipping of clinical materials and isolates must be in compliance with the rules and regulations for transport of infectious substances as set forth by the U. S. Department of Transportation, U. S. Postal Service, and the International Air Transport Association – Dangerous Goods regulations.

By sending samples to the laboratory, clients enter into a partnership. As in any partnership, good communication is the key to success. The purpose of this manual is to provide information about each of the tests performed and any special requirements for those tests. There will be times when more information is needed than this manual can provide. Appropriate laboratory phone numbers are provided on the first page of this manual. Interpretative consultations for all clinical tests performed by IDPH laboratories are available to authorized submitters from the director of laboratories or the clinical consultant.

Authorization for submitting specimens for testing

This manual of services covers a large number of testing areas. Each test performed by the Division of Laboratories supports public health programs by providing surveillance data. As a result, it is critical that the testing services provided are authorized by the relevant local health departments (LHDs) and IDPH programs. Throughout this manual of services, information about the requirements to authorize the submission of specimens is provided. Authorization to obtain testing services is based on the need for public health surveillance data with consideration of available private testing

availability. Samples or specimens submitted to the laboratory without proper authorization will not be tested. Lab staff will contact the submitter and determine if the sample/specimen will be returned or destroyed.			

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General Specimen/Sample Requirements and Information

It is vital to ensure that the quality of samples is not compromised, the etiological agents remain viable, and the samples do not endanger the safety of those delivering or receiving them. The laboratories are required to reject any sample that is leaking or otherwise unsafe. The laboratory will be able to complete testing of samples without delay if the submitter:

- Provides all the information requested on the appropriate submission form or in the Electronic Test Ordering and Reporting (ETOR) portal.
- Sends pure cultures on fresh media in the appropriate transport container.
- Avoids sending cultures on inhibitory media.
- Packages sample containers in a leak-proof inner container, ensures that caps are tight to prevent leakage, and uses custody seals for environmental samples.
- Follows proper chain of custody procedures when submitting forensic samples or samples submitted for regulatory enforcement.
- Observes any special temperature requirements.
- Ensures that the outside of the mailing container indicates which laboratory section is to receive the samples (e.g., Enteric, Bacteriology, Parasitology, Environmental Chemistry, etc.).
- Avoids shipping over the weekend, except in an emergency.
- Conforms to current U.S. Postal Service regulations when shipping by U.S. mail.
 - o Contact your local post office for more information on these regulations.
- Conforms to current U.S. Department of Transportation regulations when shipping by courier or other means.

Each test that is performed by the Division of Laboratories supports public health programs by providing surveillance data. As a result, it is critical that the reports for tests conducted by the Division of Laboratories are provided to submitters, LHDs, and IDPH programs. Results are provided through a combination of mechanisms, which include electronic laboratory reporting, fax, and mailed paper results. If you have questions about a particular test and the mechanism by which it is reported, contact the Springfield Laboratory at dph.labs.dmg@illinois.gov.

Ordering or Requesting Clinical or Environmental Supplies

All supplies are ordered through Electronic Test Ordering and Reporting (ETOR) portal. To request access to ETOR and ordering supplies, send an email to dph.labs.dmg@illinois.gov.

Division of Laboratories – Hours and Contact Information

Each laboratory location is open and accepts samples/specimens during regular business hours Monday – Friday. Division of Laboratories hours are 8 a.m.- 4:30 p.m. except on state designated holidays. The state of Illinois holiday schedule is available by clicking this link: Holiday schedule.

To contact IDPH

TTY (hearing impaired use only)

800-547-0466

Carbondale Laboratory

Illinois Department of Public Health Division of Laboratories 1155 S. Oakland Ave. Carbondale, IL 62901 Main Number (all sections)

618-457-5131

(Fax) 618-457-6995

Chicago Laboratory

Illinois Department of Public Health Division of Laboratories 2121 W. Taylor St. Chicago, IL 60612 Main Number (all sections)

312-793-4760

(Fax) 312-793-8152

Springfield Laboratory

Illinois Department of Public Health Division of Laboratories 825 N. Rutledge St. Springfield, IL 62702 Main Number (all sections)

217-782-6562

(Fax) 217-524-7924

Emergency Response Procedures

Assistance for after-hour emergencies (e.g., human exposure to a potentially rabid animal) is available through the Illinois Emergency Management Agency (IEMA) statewide emergency response system. In these special cases, arrangements can be made to submit samples/specimens or to report public health emergencies by calling the following:

217-782-7860

Toll free: 800-782-7860 TTY (hearing impaired use only) 800-547-0466

Ask to be directed to IDPH's emergency officer, who can provide you further instructions. If warranted, the emergency officer will arrange to have the closest IDPH laboratory open to receive the samples/specimens and to begin testing that same day.

If a natural or other emergency event causes the closure of one division laboratory, testing services may be transferred to another division lab. In this way, surge capacity for the division is provided by the other labs or through contractual arrangements with private or public facilities.

Services Available at U.S. Centers for Disease Control and Prevention

Collaboration between local, state, and federal laboratories provides the foundation for a successful nationwide program for the prevention and control of infectious diseases. The U.S. Centers for Disease Control and Prevention (CDC) provides state laboratories with reference and diagnostic services (RDS) for certain rare or unusual procedures. **All RDS samples must be submitted to the CDC by or through a state laboratory.**

The IDPH Division of Laboratories is available to facilitate submission of specimens to CDC for testing that is not available through commercial resources. Submission of specimens to CDC laboratories also requires approval from your LHD or the applicable IDPH Division of Infectious Diseases section. If you have questions about submission of specimens to CDC for testing, contact your LHD or IDPH at 217-782-2016.

Once approval to submit the specimen has been obtained through the IDPH Division of Infectious Diseases or LHD, work with your regional public health laboratory in Carbondale, Springfield, or Chicago to complete the appropriate submission form. The CDC may reject the specimen if complete data are not provided. **Do not ship the specimen** directly to CDC unless prior arrangements have been made with IDPH.

CDC provides RDS for:

- Clinical samples to aid in the diagnosis of life-threatening, unusual, or exotic infectious diseases.
- Cultures, paired serum samples, or both from patients suspected of having unusual or infectious diseases.
- Cultures or serum samples obtained from patients who have sporadic infections or who are involved in an outbreak from an organism for which testing reagents are not commercially or widely available.
- Organisms that:
 - a) Cannot be identified otherwise.
 - b) Are isolated from normally sterile anatomic sites.
 - c) Are isolated repeatedly from one or more sites of the same patient or group of patients.
 - d) Have atypical phenotypic characteristics.
 - e) Does not appear to be a "usual" pathogen.
 - f) Are associated with nosocomial infections.
- Clinically important serum samples or cultures sent for confirmation.

See submission criterion for various diseases at CDC.

Environmental Laboratory Certification

IDPH has been designated by the U.S. Department of Health and Human Services and the U.S. Environmental Protection Agency as the certifying agency for approval of microbiological laboratories processing official samples of milk and water. The laboratory certification program ensures that approved laboratories use methods and techniques that are in substantial agreement with the current editions of the *Grade A Pasteurized Milk Ordinance, Standard Methods for the Examination of Water and Wastewater*, and Official Methods of Analysis of the A.O.A.C. (Association of Official Analytical Chemists). Training workshops and seminars are given to provide continuing education and regulatory updates to environmental laboratory personnel.

Guidelines to Follow for Certification of Milk Laboratories and Certified Industry Supervisors of Milk Drug Sites (Capable of Confirming Screening Results)

- 1. The applicant seeking certification shall contact IDPH's laboratory evaluation officer to receive a packet containing the Grade A milk laboratory request and agreement form, a copy of the evaluation forms, and personnel questionnaire forms.
- 2. When the applicant feels the requirements can be met, a written request shall be sent to:

Laboratory Evaluation Officer Illinois Department of Public Health Division of Laboratories 825 N. Rutledge St. Springfield, IL 62702

- 3. Following receipt of the request, the laboratory evaluation officer will, upon a mutually agreeable date, perform an on-site survey, including the evaluation of facilities, equipment, procedures, and preliminary quality control records according to the requirements of the *Grade A Pasteurized Milk Ordinance*.
- 4. Upon successfully meeting the requirements of the evaluation, accreditation is given to the laboratory and conditional certification is given to the certified industry supervisors and analysts.
- 5. Split milk samples are provided by IDPH to milk laboratories and certified industry supervisors annually. Analyses of split samples are required by industry supervisors and analysts and approval shall be revoked for lack of participation or poor performance for two successive submissions.
- 6. Every two years, certified laboratories and certified industry supervisor sites shall be re-evaluated through on-site inspection by laboratory certification officers.

Guidelines to Follow for Approval of Milk Drug (Antibiotics) Screening Sites

- 1. The applicant seeking certification shall contact IDPH's laboratory evaluation officer to receive a packet containing the Grade A milk laboratory request and agreement form, a copy of the evaluation forms, and personnel questionnaire forms.
- 2. When the applicant feels the requirements can be met, a written request shall be sent to:

Laboratory Evaluation Officer Illinois Department of Public Health Division of Laboratories 825 N. Rutledge St. Springfield, IL 62702

- 3. Following receipt of the request, the laboratory evaluation officer will provide training for the prospective industry supervisor. Upon completion of training, the industry supervisor will provide documented training of prospective analysts. A copy of all training records will be submitted to the laboratory evaluation officer.
- 4. Upon receipt of the training records, the laboratory evaluation officer will, upon a mutually agreeable date, perform an on-site survey and evaluation of facilities, equipment, performance, procedures, and preliminary quality control records.
- 5. Upon successfully meeting the requirements of the evaluation, approval is given to the milk drug testing site/industry supervisor and analysts.

- 6. Split milk samples are provided by IDPH to all milk drug testing sites annually. Analyses of split samples are required by industry supervisors and analysts and approval shall be revoked for lack of participation or poor performance for two successive submissions.
- 7. Every two years, approved drug screening sites shall be re-evaluated through on-site inspection by laboratory evaluation officers.
- 8. It is the responsibility of the approved industry supervisor to train new analysts and subsequently send training records to the laboratory evaluation officer. Upon review of the training record, the laboratory evaluation officer will either notify the supervisor that training is inadequate or issue a statement that training is acceptable, and the analyst is approved to screen milk samples for drugs (antibiotics).

Guidelines to Follow for Certification of Water Laboratories

- 1. The applicant seeking certification shall contact the IDPH's laboratory certification officer to receive a packet containing a copy of the regulations and requirements, a request for laboratory certification form, and a copy of the evaluation and personnel questionnaire forms.
- 2. When the applicant believes the requirements can be met, a written request shall be sent to:

Laboratory Certification Officer Illinois Department of Public Health Division of Laboratories 825 N. Rutledge St. Springfield, IL 62702

- 3. Following receipt of the request, the laboratory certification officer will, upon a mutually agreeable date, perform an on-site survey and evaluation of facilities, equipment, performance, procedures, and preliminary quality control records. The quality assurance plan must be prepared and in use at the time of the evaluation. Proficiency test samples must be successfully analyzed prior to the evaluation date.
- 4. Periodic analyses of proficiency test samples are required, and laboratory certification shall be revoked for lack of participation or poor performance for two successive submissions.
- 5. Every two years, certified laboratories shall be re-evaluated through on-site inspection by laboratory certification officers.

Bacillus anthracis (Anthrax)

Test Name: Identification of *Bacillus anthracis* (potential bio-threat agent)

Method Name: Rapid presumptive identification by real-time polymerase chain reaction (PCR) assay.

Confirmation by biochemical identification of culture isolate.

Results: Negative/Positive for the identification of *B. anthracis*.

Note: If the test is negative and the isolate is genus Bacillus, speciation will not be

performed.

Reference Ranges: Negative for *B. anthracis.*

Clinical Significance: Humans can become infected with <u>B. anthracis</u> by handling products or consuming

undercooked meat from infected animals. Infection may also result from inhalation of *B. anthracis* spores from contaminated animal products, such as wool, or the intentional release of spores during a bioterrorist attack. Human-to-human transmission has rarely been reported, and only with the cutaneous form of the disease. Three forms of anthrax

occur in humans: cutaneous, gastrointestinal, and inhalation.

Submission Criteria: Request testing if you suspect an isolate may be *B. anthracis*. See <u>ASM.org</u> for the rule-

out/in protocols. Submit a pure isolate/culture on an agar slant with any media that will support growth. Do not submit the isolate on an agar plate unless the specimen is being transported by courier. Do not perform further tests. Environmental sample testing is also available through special arrangement. Contact the Division of Laboratories if

environmental testing is requested.

Rejection Criteria: Specimens other than those detailed above, improperly filled out test request form, no

patient identifier on specimen, or broken specimen tube.

Authorization: No authorization number is required. Submission is required by Illinois Administrative

Rule Part 690. Notify your LHD if you suspect this infection.

Turn-around Time: Presumptive PCR: 1 day

Culture confirmation: 5 days

Ship to: <u>Carbondale, Chicago, or Springfield IDPH Laboratories</u>

Bacillus anthracis - BioFire Global Fever Special Pathogens Panel

Test Name: Identification of *Bacillus anthracis* (potential bio-threat agent)

Method Name: Rapid presumptive identification by polymerase chain reaction (PCR) assay.

Results: Detected/Not detected for *Bacillus anthracis*.

Reference Ranges: Negative for *Bacillus anthracis*.

Clinical Significance: The BioFire® Global Fever Special Pathogens Panel is a qualitative, multiplexed, nucleic

acid-based test for the simultaneous detection and identification of multiple pathogens directly from EDTA whole blood collected from symptomatic individuals or those suspected of exposure to the targeted pathogens. Results are meant to be used in conjunction with other clinical, epidemiologic, and laboratory data. This test would be used on international travelers, so that treatment and public health measures can be

quickly implemented.

Bacillus anthracis is a gram-positive spore-forming bacterium and is the etiological agent of anthrax. Anthrax is endemic to the United States but is uncommon. Outside the U.S. the disease occurs most commonly as a cutaneous infection among persons working

closely with animals or animal products through the introduction of spores

subcutaneously. Anthrax may also occur through inhalation or ingestion of spores. This

species is classified as a select agent per the Federal Select Agent Program.

Submission Criteria: Specimens must be collected in EDTA blood collection tubes and stored at 2-8°C.

Specimens may be stored at refrigerated temperatures (2-8°C) but must be received at the testing laboratory within seven days of collection. Specimens must be shipped to the testing laboratory using enough cold packs to maintain refrigerated temperature. Do

not freeze specimens.

Rejection Criteria: Specimens other than EDTA whole blood, improperly filled out test request form, no

patient identifier on specimen, broken specimen tube, or specimens improperly

shipped.

Authorization: Authorization number is required. Number should be obtained from local health

department in consultation with IDPH Communicable Disease Section and CDC. For questions, contact your local health department or the IDPH Communicable Disease

Control Section at 217-782-2016.

Turn-around Time: Presumptive PCR: 1 day

Confirmation testing 7 days (IDPH)

Ship to: <u>Chicago or Springfield IDPH Laboratories</u>

Bioterrorism Threat Agents

The IDPH laboratories test for the presence of the following potential bioterrorism threat agents:

Biothreat Agent*	Disease	Preferred Specimen Type(s)
Bacillus anthracis	Anthrax	Referred isolate
Brucella spp.	Brucellosis	Referred isolate
Burkholderia pseudomallei/mallei	Melioidosis/Glanders	Referred isolate
Coxiella burnetii	Q Fever	Whole blood
Francisella tularensis	Tularemia	Referred isolate
<i>Variola</i> virus	Smallpox	Swabs; scabs
Yersinia pestis	Plague	Referred isolate

^{*}See links on individual agent page for more information on specimen collection and submission for each threat agent.

The sentinel laboratory plays a key role in the early detection of these threat agents by recognizing the potential of having isolated one of the bacterial agents or that a patient presents with clinical symptoms consistent with the contraction of the agent. The American Society of Microbiology has developed protocols for use in the presumptive identification of a bacterial threat agent (See link.) and the CDC has developed an algorithm for clinical diagnosis of the various disease syndromes caused by the orthopox viruses (including smallpox).

If you, as a sentinel laboratory, suspect a patient is infected with any of these agents, contact your <u>LHD</u> or IDPH's Communicable Disease Control Section at 217-782-2016.

The IDPH utilizes protocols developed by the CDC's Laboratory Response Network for the definitive identification of the biothreat agents. If an isolate tests negative for a biothreat agent, further identification will NOT be performed.

Environmental sample testing is also available through special arrangement for Biological Threat agents. Contact the Division of Laboratories if environmental testing is requested. Use the Threat Agent Laboratory Test Request form for environmental sample submission.

Brucella spp. (brucellosis)

Test Name: Culture Identification of *Brucella spp.* (potential biothreat agent)

Method Name: Rapid presumptive identification by real-time polymerase chain reaction (PCR) assay.

Confirmation by biochemical identification of culture isolate.

Results: Negative/Positive for *Brucella spp., Brucella abortus, Brucella suis, Brucella melitensis,* or

Brucella canis.

Note: If the tests are negative and the isolate is the genus Brucella, further speciation

tests will not be performed.

Reference Ranges: Negative for *Brucella spp.*

Clinical Significance: Brucella spp. are facultative intracellular gram-negative staining bacilli capable of

producing the disease brucellosis in humans. The disease is likely acquired by contact with animals infected with *Brucella abortus*, *Brucella suis*, *Brucella melitensis*, and occasionally *Brucella canis*, or by ingestion of infected meat or milk. Animals most commonly infected include sheep, cattle, goats, pigs, and dogs. Symptoms of brucellosis may include fever, night sweats, chills, weakness, malaise, headache, and anorexia. A physical examination may reveal lymphadenopathy and hepatosplenomegaly. A definitive diagnosis of brucellosis is made by recovering the organism from blood, fluid

(including urine), or tissue specimens.

Submission Criteria: Request testing if you suspect an isolate may be *Brucella spp*. See <u>ASM.org</u> for the rule-

out/in protocols. Submit a pure isolate/culture submitted on an agar slant with any media that will support growth. Do not submit the isolate on an agar plate unless the specimen is being transported by courier. Primary clinical specimens or blood culture bottles are not acceptable specimens. Do not perform further tests. **Note:** Brucellosis is

the most commonly reported laboratory-associated bacterial infection. Certain characteristics of the bacterium, such as its low infectious dose and ease of

aerosolization, contribute to the risk of infection by the organism in a laboratory setting. Environmental sample testing is also available through special arrangement. Contact the

Division of Laboratories if environmental testing is requested.

Rejection Criteria: Specimens other than those detailed above, improperly filled out test request form, no

patient identifier on specimen, or broken specimen tube.

Authorization: No authorization number is required. Submission is required by Illinois Administrative

Rule Part 690. Notify your LHD if you suspect this infection.

Turn Around Time: Presumptive PCR: 1 day

Culture confirmation: 5-7 days

Ship to: <u>Carbondale, Chicago, or Springfield IDPH Laboratories</u>

Burkholderia pseudomallei (Melioidosis) Burkholderia mallei (Glanders)

Test Name: Identification of *Burkholderia pseudomallei* and *Burkholderia mallei* (potential biothreat

agents)

Method Name: Rapid presumptive identification by real-time polymerase chain reaction (PCR) assay.

Confirmation by biochemical identification of culture isolate.

Results: Negative/Positive for the identification of *Burkholderia pseudomallei*.

Negative/Positive for the identification of *Burkholderia mallei*.

If the tests are negative and the isolate is the genus Burkholderia, further speciation will

not be performed.

Reference Ranges: Negative for the identification of *B. pseudomallei and B. mallei*.

Clinical Significance: B. pseudomallei is the cause of melioidosis, a disease prevalent in Southeast Asia and

northern Australia. Chronic infections can mimic *Mycobacterium tuberculosis* infections by producing granulomatous lesions in tissues. B. malei causes glanders. Acute

infections cause septicemia and death while chronic infections cause nodules that can ulcerate. Survivors can be carriers. Definitive confirmation of infection is critical for

effective antibiotic therapeutic intervention.

Submission Criteria: Request testing if you suspect an isolate may be *Burkholderia spp*. See ASM.org for the

rule-out/in protocols. Submit a pure isolate/culture submitted on an agar slant with any media that will support growth. Do not submit the isolate on an agar plate unless the specimen is being transported by courier. Primary clinical specimens or blood culture bottles are not acceptable specimens. Do not perform further tests. Environmental sample testing is also available through special arrangement. Contact the Division of

Laboratories if environmental testing is requested.

Rejection Criteria: Specimens other than those detailed above, improperly filled out test request form, no

patient identifier on specimen, or broken specimen tube.

Authorization: No authorization number is required. Submission is required by Illinois Administrative

Rule Part 690. Notify your LHD if you suspect this infection.

Turn Around Time: Presumptive PCR: 1 day

Culture confirmation: 5-7 days

Ship to: Carbondale, Chicago, or Springfield IDPH Laboratories

Carbapenem Resistant Enterobacteriaceae (CRE) and Carbapenem Resistant Pseudomonas aeruginosa (CRPA) and Other related 6-lactamase Producing Gram Negative Bacteria

Test Name: Antimicrobial Resistance Testing for Carbapenem Resistant Enterobacteriaceae (CRE),

Carbapenem Resistant Pseudomonas aeruginosa (CRPA), and Related Species

Method Name: Biochemical Species Identification; Carbapenemase activity; MultiPlex PCR: β-lactamase

genes.

Results: Species Identification

mCIM: Carbapenemase Activity Detected/Not Detected. (This is for surveillance only.)

PCR: β-lactamase detected/Not detected.

β-lactamase Genes Detected: CTX-M-14, CTX-M-15, VIM, NDM, IMP, KPC, OXA-23, OXA-

24/40, OXA-48, OXA-51, OXA-58, OXA-143, MOX, ACC, FOX, DHA, EBC, CMY-2.

Reference Ranges: No carbapenem resistance detected in culture; No β -Lactamase gene families (CMY,

DHA, CTX-M-14, CTX-M-15, VIM, NDM, IMP, KPC, and OXA-23, OXA-24/40, OXA-48, OXA-51, OXA-58, and OXA-143), or plasmid-associated ampC β–Lactamase gene families

(MOX, ACC, FOX, DHA, EBC, CMY-2) detected by real-time multi-plex PCR.

Clinical Significance: Beta-lactam-resistant Gram-negative organisms, producing multiple β-lactamases, are

difficult to distinguish phenotypically and necessitate specific detection methods to identify clinically important β -lactamases. Some of the most disconcerting of these organisms, and the ones that pose serious threats to hospitalized patients, are the CRE and CRPA. These organisms often demonstrate resistance to many other classes of antibiotics and may harbor a combination of β -lactamase genes. Genetic identification of these resistance mechanisms, along with species identification and phenotypic tests for

the evaluation of carbapenemase-producing isolates, is therefore critical for infection

control and antimicrobial outbreak surveillance.

Submission Criteria: Local health department authorization

Specimen Acceptance Criteria:

See website for more information.

Pure isolate of suspected CRE or CRPA grown on slant or plate media (such as blood, nutrient, or to-soy agar) or other β -lactamase producing Gram Negative bacteria, such as Acinetobacter species.

CRE

- Isolate belongs to Enterobacteriaceae family
- Resistant to at least one carbapenem
- MIC of >4 μg/mL for imipenem, meropenem, or doripenem
- MIC of >2 μg/mL for ertapenem

CRPA

- Isolate identified as P. aeruginosa
- Resistant to at least one carbapenem
- MIC of >8 μg/mL for imipenem, meropenem, or doripenem

Rejection Criteria: Specimens are rejected if they are not viable isolates, improper specimen identification,

specimens other than those detailed above, no authorization, or broken specimen tube.

Authorization: Contact local health department for authorization.

Turn Around Time: 5-15 business days

Ship to: Chicago IDPH Laboratory

Shipping Kits: N/A

Submission Form: <u>Communicable Disease Test Requisition Form</u>

Copy of submitting clinical laboratory Antimicrobial Susceptibility Testing (AST) results required for IDPH to confirm that the isolate meets the CRE/CRPA definition for testing

to obtain preliminary indication that isolate may be pan-resistant.

Chikungunya Virus - BioFire Global Fever Special Pathogens Panel

Test Name: Identification of Chikungunya virus

Method Name: Rapid positive identification by polymerase chain reaction (PCR) assay.

Results: Detected/Not detected for Chikungunya virus.

Reference Ranges: Negative for Chikungunya virus.

Clinical Significance: The BioFire® Global Fever Special Pathogens Panel is a qualitative, multiplexed, nucleic

acid-based test for the simultaneous detection and identification of multiple pathogens directly from EDTA whole blood collected from symptomatic individuals or those suspected of exposure to the targeted pathogens. Results are meant to be used in conjunction with other clinical, epidemiologic, and laboratory data. This test would be used on international travelers, so that treatment and public health measures can be

quickly implemented.

Chikungunya virus is a positive-sense single-stranded RNA virus (genus Alphavirus). The virus is transmitted to humans by infected mosquitoes. The infection causes severe joint pain. Chikungunya infections are rarely lethal, but symptoms may be severe and disabling. Persons at risk for more severe disease include infants, and older adults, as well as persons with underlying medical conditions such as high blood pressure, diabetes, or heart disease. Differential diagnosis of chikungunya disease can be difficult

due to overlapping symptoms, transmission, and geographic distribution of Dengue

virus and Zika virus.

Submission Criteria: Specimens must be collected in EDTA blood collection tubes and stored at 2-8°C.

Specimens may be stored at refrigerated temperatures (2-8°C) but must be received at the testing laboratory within seven days of collection. Specimens must be shipped to the testing laboratory using enough cold packs to maintain refrigerated temperature. Do

not freeze specimens.

Rejection Criteria: Specimens other than EDTA whole blood, improperly filled out test request form, no

patient identifier on specimen, broken specimen tube, or specimens improperly shipped.

Authorization: Authorization number is required. Number should be obtained from local health

department in consultation with IDPH Communicable Disease Section and CDC. For questions, contact your local health department or the IDPH Communicable Disease

Control Section at 217-782-2016.

Turn-around Time: Positive PCR: 1 day

Ship to: Chicago or Springfield IDPH Laboratories

Chlamydia trachomatis/Neisseria gonorrhoeae (Molecular STD Screening Panel)

Test Name: Detection of Neisseria gonorrhoeae (GC) and/Chlamydia trachomatis (CT)

Method Name: Qualitative target amplification nucleic acid probe test.

Results: Positive/Negative for the detection of Neisseria *gonorrhoeae* (GC) and/or Chlamydia

trachomatis (CT).

Reference Ranges: Negative for the detection of Neisseria *gonorrhoeae and* Chlamydia *trachomatis*.

Clinical Significance: Neisseria gonorrhoeae infection of women can lead to pelvic inflammatory disease,

infertility, ectopic pregnancy, and chronic pelvic pain. In men *Neisseria gonorrhoeae* can lead to acute urethritis and dysuria. *Chlamydia trachomatis* infections in women can cause long-term sequelae, such as pelvic inflammatory disease and infertility, in addition to the birth of underweight babies. *Chlamydia trachomatis* infection of men can result in acute urethritis or epididymitis and chronic proctitis. Transmission of *N. gonorrhoeae* and *C. trachomatis* occurs through sexual contact but can also take place in the birth canal leading to neonatal conjunctivitis and/or *Chlamydia pneumonia*. Infections with *C. trachomatis* and *N. Gonorrhoeae* are common in extragenital sites in certain

populations, such as men who have sex with men (MSM). Since extragenital infections

are common in MSM and most infections are asymptomatic, annual screening is recommended. No recommendations for extragenital screening exist for women, but

rectal and oropharyngeal infections are not uncommon.

Submission Criteria: Endocervical swab, vaginal swab, rectal swab, throat swab, and male and female urine

specimens. Urine (neat) must be transferred into the urine collection tube within 24

hours of collection. See specimen collection instruction at this link.

Rejection Criteria: The specimen is too old for testing (Urine: Must be tested within 30 days of collection

and be stored at 2-30°C; Swab: Must be tested within 60 days of collection and be stored at 2-30°C); expired swab collection kit or urine transport tube; no identifier on specimen; improperly collected specimen; quantity not sufficient or tube over-filled; provider not authorized for testing; tube contains more than one swab; or specimen

collected in wrong collection kit.

Authorization: Providers are authorized by the IDPH Office of Disease Control, STD Section, at 217-782-

2747. A provider number will be given and should be included on the submission form.

Turn Around Time: 4 business days

Ship to: <u>Carbondale IDPH Laboratory</u>

Shipping Kits: See Ordering or Requesting Clinical or Environmental Supplies.

Submission Form: Tests must be ordered online using the Electronic Test Ordering and Reporting (ETOR)

portal. Print the submission form from the portal and submit copy with specimen. Contact dph.labs.dmg@illinois.gov for enrollment or questions regarding online test

ordering.

Cremean-Congo Hemorrhagic Fever Virus - BioFire Global Fever Special Pathogens Panel

Test Name: Identification of Crimean-Congo hemorrhagic fever virus (potential bio-threat agent)

Method Name: Rapid presumptive identification by polymerase chain reaction (PCR) assay.

Results: Detected/Not detected for Crimean-Congo hemorrhagic fever virus.

Reference Ranges: Negative for Crimean-Congo hemorrhagic fever virus.

Clinical Significance: The BioFire® Global Fever Special Pathogens Panel is a qualitative, multiplexed, nucleic

acid-based test for the simultaneous detection and identification of multiple pathogens directly from EDTA whole blood collected from symptomatic individuals or those suspected of exposure to the targeted pathogens. Results are meant to be used in conjunction with other clinical, epidemiologic, and laboratory data. This test would be used on international travelers, so that treatment and public health measures can be

quickly implemented.

Crimean-Congo hemorrhagic fever (CCHF) virus is a negative-stranded, enveloped RNA virus and is a member of the Nairovirus genus. CCHF is a zoonotic disease transmitted primarily by bites from ticks of the genus Hyalomma. Contact with blood and bodily fluids from infected animals or persons is also a mode of transmission. Wild animals and domestic livestock are the primary reservoirs of the virus which is endemic to the

uncommon within the United States. CCHF is classified as a select agent per the Federal

Middle East, southeastern Europe, and parts of Africa, and Asia. Infections are

Select Agent Program.

Submission Criteria: Specimens must be collected in EDTA blood collection tubes and stored at 2-8°C.

Specimens may be stored at refrigerated temperatures (2-8°C) but must be received at the testing laboratory within seven days of collection. Specimens must be shipped to the testing laboratory using enough cold packs to maintain refrigerated temperature. Do

not freeze specimens.

Rejection Criteria: Specimens other than EDTA whole blood, improperly filled out test request form, no

patient identifier on specimen, broken specimen tube, or specimens improperly

shipped.

Authorization: Authorization number is required. Number should be obtained from local health

department in consultation with IDPH Communicable Disease Section and CDC. For questions, contact your local health department or the IDPH Communicable Disease

Control Section at 217-782-2016.

Turn-around Time: Presumptive PCR: 1 day

Confirmation testing 14 days (CDC)

Ship to: Chicago or Springfield IDPH Laboratories

Dengue Virus - BioFire Global Fever Special Pathogens Panel

Test Name: Identification of Dengue Virus

Method Name: Rapid positive identification by polymerase chain reaction (PCR) assay.

Results: Detected/Not detected for Dengue virus.

Reference Ranges: Negative for Dengue virus.

Clinical Significance: The BioFire® Global Fever Special Pathogens Panel is a qualitative, multiplexed, nucleic

acid-based test for the simultaneous detection and identification of multiple pathogens directly from EDTA whole blood collected from symptomatic individuals or those suspected of exposure to the targeted pathogens. Results are meant to be used in conjunction with other clinical, epidemiologic, and laboratory data. This test would be used on international travelers, so that treatment and public health measures can be

quickly implemented.

Dengue virus is a Flavivirus with four serotypes. The serotypes are phylogenetically and antigenically distinct, and acquired long-term immunity from one serotype does not extend to the other three. The viruses are transmitted through mosquitoes. While most dengue infections are asymptomatic, the most severe cases may result in life-threatening dengue hemorrhagic fever (DHF), or dengue shock syndrome (DSS). The DHF and DSS forms of the disease are most often associated with secondary infections of a different serotype, which

is especially of concern in regions where all four serotypes are co-circulating.

Submission Criteria: Specimens must be collected in EDTA blood collection tubes and stored at 2-8°C.

Specimens may be stored at refrigerated temperatures (2-8°C) but must be received at the testing laboratory within seven days of collection. Specimens must be shipped to the testing laboratory using enough cold packs to maintain refrigerated temperature. Do

not freeze specimens.

Rejection Criteria: Specimens other than EDTA whole blood, improperly filled out test request form, no

patient identifier on specimen, broken specimen tube, or specimens improperly

shipped.

Authorization: Authorization number is required. Number should be obtained from local health

department in consultation with IDPH Communicable Disease Section and CDC. For questions, contact your local health department or the IDPH Communicable Disease

Control Section at 217-782-2016.

Turn-around Time: Positive PCR: 1 day

Viral Serotyping testing 14 days (CDC)

Ship to: Chicago or Springfield IDPH Laboratories

Ebola Zaire Virus

Test Name: Identification of Ebola Zaire Virus in Acute Specimens

Method Name: Real-time, reverse transcriptase - polymerase chain reaction (RT-PCR) for the

identification of Ebola Zaire Virus (NP and VP40 gene target assays).

Results: Negative/Positive/Equivocal/Inconclusive for the identification of Ebola Zaire Virus RNA.

Reference Ranges: Negative for the identification of Ebola Zaire Viral RNA.

Clinical Significance:

Submission Criteria:

Rejection Criteria:

Turn Around Time:

Authorization:

vaccines or pharmaceuticals to treat Ebola virus infection. Testing by EUA (emergency use authorization) was approved in January 2016 by the U.S. Department of Health and Human Services.

Whole blood is the preferred specimen type for Ebola virus disease (EVD) testing.

See CDC guidance for collection, transport, and submission at this <u>link</u>.

Serum, plasma, and urine are also acceptable specimens for testing. Urine should not be the sole specimen type tested from a patient and must be sent with a paired specimen.

Ebola virus is detected in blood only after onset of symptoms, most notably fever, which accompany the rise in circulating virus within the patient's body. It may take up to three days after symptoms start for the virus to reach detectable levels. Ebola infection is extremely contagious, making the identification of infected individuals a public health emergency. Ebola spreads through direct contact (through broken skin or mucous membranes in, for example, the eyes, nose, or mouth) with blood or body fluids of a person who is sick with or has died from Ebola; objects (like needles and syringes) that have been contaminated with body fluids from a person who is sick with Ebola or who has died from Ebola; infected fruit bats or primates (apes and monkeys); and possibly from contact with semen from a man who has recovered from Ebola. There are no

- a. Whole blood Collect two lavender top blood tubes containing whole blood preserved with EDTA (minimum volume of 4 mL each). Collect blood in plastic tubes only. Do not collect in glass tubes. Do not centrifuge specimens. Store and transport specimens at 2-8°C.
- b. Serum Collect serum in a gold top serum separator tube and centrifuge to separate. Store and transport specimens at 2-8°C.
- c. Plasma Collect whole blood into commercially available anticoagulant-treated tubes e.g., EDTA-treated (lavender tops) or citrate-treated (light blue tops). Cells are removed from plasma by centrifugation for 10 minutes at 1,000–2,000xg using a refrigerated centrifuge. The resulting supernatant is designated plasma. Following centrifugation, it is important to immediately transfer the liquid component (plasma) into a clean polypropylene tube using a Pasteur pipette. Store and transport specimens at 2-8°C.
- d. Urine Collect urine in a 15 mL conical plastic tube. Store and transport specimens at 2-8°C.

Specimens other than those detailed above, improperly filled out test request form, no patient identifier on specimen, or broken specimen tube.

Prior approval from your LHD is required. For questions, contact your LHD or the IDPH Communicable Disease Control Section at 217-782-2016.

2 days

Ship to: <u>Chicago IDPH Laboratory</u>

Ebola Virus - BioFire Global Fever Special Pathogens Panel

Test Name: Identification of Ebola Virus (potential bio-threat agent)

Method Name: Rapid presumptive identification by polymerase chain reaction (PCR) assay.

Results: Detected/Not detected for Ebola Virus.

Reference Ranges: Negative for Ebola Virus.

Clinical Significance: The BioFire® Global Fever Special Pathogens Panel is a qualitative, multiplexed, nucleic

acid-based test for the simultaneous detection and identification of multiple pathogens directly from EDTA whole blood collected from symptomatic individuals or those suspected of exposure to the targeted pathogens. Results are meant to be used in conjunction with other clinical, epidemiologic, and laboratory data. This test would be used on international travelers, so that treatment and public health measures can be

quickly implemented.

Ebola virus spp. are members of the Filoviridae family, with six known species (Bombali, Bundibugyo, Reston, Sudan, Taï Forest, and Zaire). Only the Bundibugyo, Sudan, Taï Forest, and Zaire cause disease in humans, with Zaire the most commonly responsible for outbreaks. The viruses spread through direct contact with blood, body fluids, or tissues from infected persons or animals. Transmission through sexual contact with an infected individual is also possible. Due to the risk to national security Ebola viruses are

designated as a select agent per the Federal Select Agent Program.

Submission Criteria: Specimens must be collected in EDTA blood collection tubes and stored at 2-8°C.

Specimens may be stored at refrigerated temperatures (2-8°C) but must be received at the testing laboratory within seven days of collection. Specimens must be shipped to the testing laboratory using enough cold packs to maintain refrigerated temperature. Do

not freeze specimens.

Rejection Criteria: Specimens other than EDTA whole blood, improperly filled out test request form, no

patient identifier on specimen, broken specimen tube, or specimens improperly

shipped.

Authorization: Authorization number is required. Number should be obtained from local health

department in consultation with IDPH Communicable Disease Section and CDC. For questions, contact your local health department or the IDPH Communicable Disease

Control Section at 217-782-2016.

Turn-around Time: Presumptive PCR: 1 day

Confirmation testing 14 days (CDC) for species other than Zaire Zaire only can be confirmed at the Chicago Laboratory in 1 day

Ship to: Chicago or Springfield IDPH Laboratories

Enteric Pathogens Overview

Test Name: Enteric Pathogen Culture (includes clinical and referred isolates)

Method Name: Salmonella, Shigella, Shiga Toxin Producing E. coli, Vibrio, Yersinia (only when requested

during outbreaks) (includes identification, serotyping, and molecular Shiga toxin). For routine Salmonella, Shiga toxin producing E. coli and Vibrio isolates, whole genome sequencing (WGS) is performed, and results are sent to the CDC PulseNet national

database.

Results: Negative or confirmation of *Salmonella* (Typhi or Non-Typhi), *Shigella*, Shiga toxin

producing *E. coli, Vibrio, Yersinia*. WGS data submitted to CDC PulseNet national database for cluster analysis and outbreak detection **(WGS for epidemiological use**

only).

Reference Ranges: Negative or confirmation of *Salmonella, Shigala*, Shiga toxin producing *E. coli*, Vibrio,

Yersinia.

Clinical Significance: Enteric pathogens cause a variety of human diseases. The severity of the disease

depends on the virulence of the strain and the condition of the host and can be a mild self-limiting gastroenteritis or become more severe with bacteremia or typhoid fever, which can be life threatening. Early detection allows for effective management and

identification of possible outbreaks.

Submission Criteria: Clinical - Stool submitted at room temperature in Cary-Blair vial or swab; received by

IDPH within 72 hours (swab) or 96 hours (vial).

Referred Isolates – Submit isolate at room temperature on slant [e.g., BHI, Heart infusion (HI) slant], or on sealed plates (if delivered by courier) on solid media that is

non-inhibitory (e.g., BAP). Indicate source on request form and specimen.

Rejection Criteria: Specimen received without unique identifier (name or other ID) on the specimen or the

identifier does not match the identifier on the submission form. Specimen received without date of collection. Specimen received without submission form. Specimens not submitted according to submission criteria or according to rules and regulations for

transporting clinical specimens or infectious substances.

Authorization: For questions, contact your LHD or the IDPH Communicable Disease Control Section at

217-782-2016. No authorization number is required. Submission is required by Illinois

Administrative Rule Part 690.

Turn Around Time: 7 days

Ship to: Chicago or Springfield IDPH Laboratories

Shipping Kits: See <u>Ordering or Requesting Clinical or Environmental Supplies</u>.

Escherichia coli (Shiga toxin producing)

Test Name: Isolation and Identification of Shiga Toxin-Producing *E. coli*

Method Name: Culture and biochemical reactions are used for the isolation, identification, and

serotyping of E. coli.

Real-time polymerase chain reaction (RT-PCR) assay is used for the identification of

Shiga toxin (types 1 and 2) producing E. coli.

Results: Negative for the detection of Shiga toxin-producing *E. coli*.

Reference Ranges: Negative for the detection Shiga toxin producing *E. coli*.

Clinical Significance: Enteric pathogens cause a variety of human diseases. The severity of the disease

depends on the virulence of the strain and the condition of the host and can be a mild, self-limiting gastroenteritis or become more severe with bacteremia or typhoid fever, which can be life threatening. Early detection allows for effective management and

identification of possible outbreaks.

Submission Criteria: Clinical - Stool submitted at room temperature in Cary-Blair vial or swab, received by

IDPH within 72 hours (swab) or 96 hours (vial). Stool submitted in enrichment broth. Referred Isolates – Submit isolate at room temperature on slant [e.g., BHI, Heart infusion (HI) slant] or on sealed plates (if delivered by courier) on solid media that is

non-inhibitory (e.g., BAP). Indicate source on request form and specimen.

Rejection Criteria: Specimen received without unique identifier (name or other ID) on the specimen, or the

identifier does not match the identifier on the submission form. Specimen received without date of collection. Specimen received without submission form. Specimens not submitted according to submission criteria or according to rules and regulations for

transporting clinical specimens or infectious substances.

Turn Around Time: 7 days

Ship to: Chicago or Springfield IDPH Laboratories

Shipping Kits: See <u>Ordering or Requesting Clinical or Environmental Supplies</u>.

Francisella tularensis (tularemia)

Test Name: Culture Identification of *F. tularensis* (potential biothreat agent)

Method Name: Rapid presumptive identification by real-time polymerase chain reaction (RT-PCR) assay.

Confirmation by biochemical identification of culture isolate.

Results: Negative/Positive for the identification of *F. tularensis*.

Note: If the test is negative and the isolate is the genus Francisella, speciation will not be

performed.

Reference Ranges: Negative for the identification of *F. tularensis*.

Clinical Significance: Tularemia is a rare infectious disease that can attack the skin, eyes, lymph nodes, lungs,

and, less often, other internal organs. It is caused by the bacterium *Francisella tularensis*, which is transmitted by several routes, such as insect bites and direct exposure to an infected animal. The infection is highly contagious and potentially fatal. Early confirmation of infection aids in appropriate antibiotic therapeutic intervention.

Submission Criteria: Request testing if you suspect an isolate may be *F. tularensis*. See <u>ASM.org</u> for the rule-

out/in protocols for *F. tularensis*. Submit an isolate on an agar slant with any media that will support growth. Do not submit the isolate on an agar plate unless the specimen is

being transported by courier. Do not perform further tests.

Note: *Francisella tularensis* is highly infectious when grown in culture, and laboratory-acquired infections have been documented. The isolation of *F. tularensis* from clinical specimens, especially if unanticipated, can generate concern among laboratory workers about possible exposure. Environmental sample testing is also available through special arrangement. Contact the Division of Laboratories if environmental testing is requested.

Rejection Criteria: Specimens other than those detailed above, improperly filled out test request form, no

patient identifier on specimen, or broken specimen tube.

Authorization: No authorization number is required. Submission is required by Illinois Administrative

Rule Part 690. Notify your LHD if you suspect this infection.

Turn Around Time: Presumptive PCR: 1 day

Culture confirmation: 5-7 days

Ship to: <u>Carbondale, Chicago, or Springfield IDPH Laboratories</u>

Francisella tularensis – BioFire Global Fever Special Pathogens Panel

Test Name: Identification of *Francisella tularensis* (potential bio-threat agent)

Method Name: Rapid presumptive identification by polymerase chain reaction (PCR) assay.

Results: Detected/Not detected for *Francisella tularensis*.

Reference Ranges: Negative for *Francisella tularensis*.

Clinical Significance: The BioFire® Global Fever Special Pathogens Panel is a qualitative, multiplexed, nucleic

acid-based test for the simultaneous detection and identification of multiple pathogens directly from EDTA whole blood collected from symptomatic individuals or those suspected of exposure to the targeted pathogens. Results are meant to be used in conjunction with other clinical, epidemiologic, and laboratory data. This test would be used on international travelers, so that treatment and public health measures can be

quickly implemented.

Francisella tularensis is an aerobic, gram-negative coccobacillus and is the causative agent of tularemia. Tularemia occurs throughout North America in addition to Europe, Asia, and the Middle East although it is relatively uncommon. The disease affects both animals and humans and is transmitted primarily through contact with infected animals or bites from ticks and flies. Transmission may also occur through the inhalation of dust or aerosols containing the bacterium. F. tularensis is also designated as a select agent.

Submission Criteria: Specimens must be collected in EDTA blood collection tubes and stored at 2-8°C.

Specimens may be stored at refrigerated temperatures (2-8°C) but must be received at the testing laboratory within seven days of collection. Specimens must be shipped to the testing laboratory using enough cold packs to maintain refrigerated temperature. Do

not freeze specimens.

Rejection Criteria: Specimens other than EDTA whole blood, improperly filled out test request form, no

patient identifier on specimen, broken specimen tube, or specimens improperly

shipped.

Authorization: Authorization number is required. Number should be obtained from local health

department in consultation with IDPH Communicable Disease Section and CDC. For questions, contact your local health department or the IDPH Communicable Disease

Control Section at 217-782-2016.

Turn-around Time: Presumptive PCR: 1 day

Confirmation testing 7 days (IDPH)

Ship to: Chicago or Springfield IDPH Laboratories

Haemophilus influenzae

Test Name: Identification of *Haemophilus influenzae*

Method Name: Biochemical confirmation of *Haemophilus influenzae*.

Antiserum slide agglutination to identify serotypes.

Results: Positive/Negative for the detection of *Haemophilus influenzae*

Serotypes detected; a, b, c, d, e, and f.

Reference Ranges: Negative for *Haemophilus influenzae*.

Clinical Significance: H. influenzae can affect many organ systems. Type "b" can cause septicemia, meningitis,

septic arthritis, and purulent pericarditis. Non-"b" bacteria can cause disease similar to

type "b." Nontypeable H. influenzae can cause invasive disease.

Submission Criteria: Isolate grown on a chocolate agar slant. If sent by courier, isolates grown on chocolate

agar plates are also acceptable. Submissions of H. influenzae isolates from sterile body

sites (blood, CSF, or synovial fluids) are required by the state.

Rejection Criteria: Improperly filled out requisition form, no patient identifier on specimen, mismatched

names, or broken or leaking specimen tube.

Authorization: No authorization number is required. Submission is required by Illinois Administrative

Rule Part 690. Notify your LHD if you suspect this infection.

Turn Around Time: 3-5 days

Ship to: Chicago IDPH Laboratory

Human Immunodeficiency Virus (HIV), Types 1 and 2 – Serum

Test Name: Detection of HIV Types 1 and 2 Antibody and p24 Antigen

Method Name: Chemiluminescent microparticle immunoassay (CMIA) for the detection of HIV

antibodies/p24 antigen.

Results: Positive/Negative for HIV-1 antibody/p24 antigen.

Positive/Negative for HIV-2 antibody.

NOTE: If the test is positive, additional confirmatory testing to differentiate HIV-1 from HIV-2 and/or for direct detection of the HIV-1 RNA by the polymerase chain reaction (PCR) assay will be performed according to the HIV testing algorithm. If the patient is an HIV PrEP patient, a negative initial CMIA result will automatically reflex to the HIV-1 RNA PCR assay. Submitters must indicate in the ETOR portal when ordering the test if the

patient is an HIV PrEP patient.

Reference Range: Negative for the detection of HIV-1/HIV-2 antibodies/p24 antigen.

Clinical Significance: Early detection of <u>HIV</u> in the acute phase, using the CMIA, is essential to the rapid

linkage of individuals infected with HIV to care and prevention of transmission.

Submission Criteria: Collect 2 mL of blood in a gold top/serum separator tube (SST). Allow blood to clot at

room temperature. Centrifuge for 10 minutes. Blood collected in a serum separator tube (SST) and centrifuged should be shipped in a cooler on cold packs on the same day

as collected. Every effort should be made to ship specimens on the same day as collected. If it is not possible to ship the same day as collected, store at 2-8°C and ship in

a cooler on cold packs the next business day. Label specimens with a unique identifier.

Rejection Criteria: Specimens will be rejected if they are:

· Grossly hemolyzed

- No submission form is provided
- Insufficient quantity
- No unique identifier on specimen
- Broken or leaking specimen
- Specimen greater than 7 days old from collection if stored and shipped cold
- Specimen greater than 3 days old from collection if stored and shipped at room temperature

Authorization: Prior approval is necessary from the IDPH Office of Disease Control, STD Section, at 217-

782-2747.

Turn Around Time: 2 days for screening; 2-3 days for additional tests

Ship to: Carbondale IDPH Laboratory

Shipping Kits: See Ordering or Requesting Clinical or Environmental Supplies.

Submission Form: Tests must be ordered online using the Electronic Test Ordering and Reporting (ETOR)

portal. Print the submission form from the portal and submit copy with specimen. Contact dph.labs.dmg@illinois.gov for enrollment or questions regarding online test

ordering.

Influenza Virus (For Clinical and Epidemiology use.)

Test Name: Detection of Influenza

Method Name: Real-time reverse transcriptase polymerase chain reaction (RT-PCR) assay.

Results: Positive and Negative for the detection of Influenza A, subtypes H3, H1N1 pdm2009,

H3N2 variant, and Influenza B, subtypes Yamagata (YAM) and Victoria (VIC). Avian influenza H5N1 and H7N9 are tested only if epidemiologically consistent with infection.

Reference Ranges: Negative for Influenza A and Influenza B.

Clinical Significance: Early detection allows for effective clinical management and identification of possible

outbreaks of influenza.

Submission Criteria: Specimens should be collected during the acute phase of illness (within 3 days of onset).

Complete the appropriate submission form, including authorization outbreak code (See Authorization section below) for each specimen. Acceptable swab specimens (submitted

in viral transport medium) include nasopharyngeal, nasal, throat, and dual

nasopharyngeal/throat. Acceptable non-swab specimens include nasal aspirates, nasal washes, bronchoalveolar lavages, tracheal aspirates, bronchial washes, sputum, lung tissue, and viral cultures. Click here for further instructions. Store and ship specimens at 4°C. Specimens must be received at the IDPH laboratory within 72 hours of collection. The 72 hours limitation may be waived if specimens have been immediately frozen following collection and shipped on dry ice. Contact any of the three IDPH laboratories for further information concerning freezing and shipping of frozen influenza specimens.

Rejection Criteria: Specimens other than those outlined in the submission criteria section above,

improperly completed submission form, specimens without submission form, submission form/specimen tube do not match, no patient identifier on specimen, broken specimen tube, specimens sent as dry swabs (no VTM), specimens shipped at improper temperatures, specimen stored and shipped at 4°C when received greater

than 72 hours from collection, or specimens shipped at room temperature.

Authorization: Individual specimen authorization is not needed for sentinel sites. All other submissions

need approval from your LHD. For questions, contact your LHD or the IDPH

Communicable Disease Control Section at 217-782-2016. Additional information can be

found at this <u>link</u>.

Turn Around Time: 3-5 days

Ship to: Carbondale, Chicago, or Springfield IDPH Laboratories

Shipping Kits: See <u>Ordering or Requesting Clinical or Environmental Supplies.</u>

Submission Form: Respiratory/Influenza Submission Form.

Influenza/COVID-19 Virus

Test Name: Detection of Influenza and COVID-19

Method Name: Real-time reverse transcriptase polymerase chain reaction (RT-PCR) assay.

Results: Positive and Negative for the detection of influenza A, influenza B, and COVID-19.

Reference Ranges: Negative for influenza A, influenza B, and COVID-19.

Clinical Significance: Early detection allows for effective clinical management and identification of possible

outbreaks of influenza and COVID-19.

Submission Criteria: Specimen type includes upper and lower respiratory specimens, such as nasopharyngeal

or oropharyngeal swabs, sputum, lower respiratory tract aspirates, bronchoalveolar lavage, and nasopharyngeal wash/aspirate or nasal aspirate. The minimum sample volume required is 2 mL in viral transport media (VTM). Collection should occur as quickly as possible and performed according to standard technique and placed in VTM or UTM. Store specimens at 2-8°C and ship overnight to the laboratory on ice pack. Specimens must be received cold (2-8°C) and within 72 hours of collection. Specimens can be tested if they are received beyond 72 hours of collection provided they have

been frozen and maintained at -70°C or below and received on dry ice.

Rejection Criteria: Rejection criteria include, but are not limited to, those with:

1. Mismatched requisitions

- 2. Specimens without patient identifiers
- 3. Specimens stored or shipped incorrectly
- 4. Specimens collected using expired viral transport media
- 5. Specimens without IDPH Communicable Disease Control Section/local health department (LHD) testing pre-approval and for which approval cannot be obtained after specimen receipt.

Authorization: Individual specimen authorization is not needed for sentinel sites.

Turn Around Time: 3-5 days

Ship to: <u>Carbondale, Chicago, or Springfield IDPH Laboratories</u>

Shipping Kits: See <u>Ordering or Requesting Clinical or Environmental Supplies.</u>

Submission Form: Specimens are submitted via the Electronic Transfer of Records (ETOR) portal.

Lassa Virus - BioFire Global Fever Special Pathogens Panel

Test Name: Identification of Lassa Virus (potential bio-threat agent)

Method Name: Rapid presumptive identification by polymerase chain reaction (PCR) assay.

Results: Detected/Not detected for Lassa Virus.

Reference Ranges: Negative for Lassa Fever Virus.

Clinical Significance: The BioFire® Global Fever Special Pathogens Panel is a qualitative, multiplexed, nucleic

acid-based test for the simultaneous detection and identification of multiple pathogens directly from EDTA whole blood collected from symptomatic individuals or those suspected of exposure to the targeted pathogens. Results are meant to be used in conjunction with other clinical, epidemiologic, and laboratory data. This test would be used on international travelers, so that treatment and public health measures can be

quickly implemented.

Lassa virus causes Lassa fever, a zoonotic viral illness endemic to regions of West Africa and uncommon within the United States. The virus is a bi-segmented single-stranded RNA virus of the Arenaviridae family. Transmission occurs primarily through direct or indirect contact with urine and feces from the rodent reservoir of the virus. Transmission from an infected individual is also possible through direct contact with bodily fluids. Lassa fever manifests as a broad range of symptoms, and approximately 80% of infected individuals have only mild symptoms. Lassa virus is categorized as a select agent under the Federal Select Agent

Program.

Submission Criteria: Specimens must be collected in EDTA blood collection tubes and stored at 2-8°C.

Specimens may be stored at refrigerated temperatures (2-8°C) but must be received at the testing laboratory within seven days of collection. Specimens must be shipped to the testing laboratory using enough cold packs to maintain refrigerated temperature. Do

not freeze specimens.

Rejection Criteria: Specimens other than EDTA whole blood, improperly filled out test request form, no

patient identifier on specimen, broken specimen tube, or specimens improperly

shipped.

Authorization: Authorization number is required. Number should be obtained from local health

department in consultation with IDPH Communicable Disease Section and CDC. For questions, contact your local health department or the IDPH Communicable Disease

Control Section at 217-782-2016.

Turn-around Time: Presumptive PCR: 1 day

Confirmation testing 14 days (CDC)

Ship to: Chicago or Springfield IDPH Laboratories

Lead, Blood

Test Name: Quantification of Lead Levels in Blood

Method Name: Inductively coupled plasma mass spectrometry (ICP-MS).

Results: Lead measurements are reported as microgram/deciliter blood (μg/dL). Detection level

is 1 µg/dL.

Clinical Significance: Early detection of lead poisoning allows for the effective clinical management of

patients. Complications of lead poisoning include learning disabilities, impaired growth,

impaired hearing, IQ decline, mental retardation, and death.

Submission Criteria: Micro Specimens: For capillary specimens, fill EDTA micro-collection tube to at least

above the first line marked on the tube. 100 μL (microliter) of whole blood is required.

Macro Specimens: Submit a minimum of 1 mL (milliliter) of whole blood drawn into a

trace metal free vacutainer containing either EDTA or Heparin anticoagulant.

Mix both capillary and venous specimens by gentle inversion 5 to 10 times. The specimen must be labeled with the patient's full name and date of birth. For capillary specimens, use a black permanent marker. Place **each** specimen into an **individual** small plastic bag. **Blood lead specimens should reach the Chicago laboratory within 15 days**

of collection. For more information, see the following for specimen collection.

Rejection Criteria: Insufficient volume of blood, clotted blood, specimens collected in wrong container

(e.g., serum tubes), no patient identifier on specimen, requisition form not submitted, patient identifier on specimen and requisition form do not match, leaking specimen, or

specimens reach the Chicago lab more than 15 days of collection.

Authorization: Prior approval through the local health department or IDPH Division of Environmental

Health is required.

Turn Around Time: 3 days

Ship to: Chicago IDPH Laboratory

Shipping Kits: See <u>Ordering or Requesting Clinical or Environmental Supplies.</u>

Submission Form: Specimens are submitted via the Electronic Transfer of Records (ETOR) portal.

Legionella Urinary Antigen

Test Name: Detection of *Legionella* Urinary Antigen

Method Name: Immunochromatographic membrane assay.

Results: Presumptive Positive for *L. pneumophila* serogroup 1 antigen in urine, suggesting

current or past infection.

Presumptive Negative for *L. pneumophila* serogroup 1 antigen in urine, suggesting no recent or current infection. Infection due to *Legionella* cannot be ruled out since other serogroups and species may cause disease, antigen may not be present in urine in early infection, and the level of antigen present in the urine may be below the detection limit

of the test.

Reference Range: Negative

Clinical Significance: Legionella pneumophila is responsible for 80-90% of reported cases of Legionella

infection with serogroup 1 accounting for greater than 70% of all legionellosis. This test allows for presumptive early diagnosis of *Legionella pneumophila* serogroup 1 infection through detection of a specific soluble antigen present in the urine of patients with Legionnaires' disease. *Legionella pneumophila* serogroup 1 antigen has

been detected in urine as early as three days after the onset of symptoms.

Submission Criteria: Urine specimens ONLY; random collection; >2 mL of urine. Collect in a sterile specimen

container. Specimens must be shipped 2-8°C or ≤-10°C.

Rejection Criteria: Any specimen other than urine, < 2 mL of urine, non-sterile specimen container,

received room temperature, improperly completed submission form, specimen without

submission form, submission form/specimen container do not match, no patient

identifier on specimen, or broken/leaking specimen container.

Authorization: Submissions need approval from the IDPH Communicable Disease Control Section at

217-782-2016.

Turn Around Time: 1 day

Ship to: Springfield IDPH Laboratory

Shipping Kits: See Ordering or Requesting Clinical or Environmental Supplies.

Leishmaniasis, Visceral - BioFire Global Fever Special Pathogens Panel

Test Name: Identification of *Leishmania spp.*

Method Name: Rapid presumptive identification by polymerase chain reaction (PCR) assay.

Results: Detected/Not detected for *Leishmania spp.*

Reference Ranges: Negative for *Leishmania spp.*

Clinical Significance: The BioFire® Global Fever Special Pathogens Panel is a qualitative, multiplexed, nucleic

acid-based test for the simultaneous detection and identification of multiple pathogens directly from EDTA whole blood collected from symptomatic individuals or those suspected of exposure to the targeted pathogens. Results are meant to be used in conjunction with other clinical, epidemiologic, and laboratory data. This test would be used on international travelers, so that treatment and public health measures can be

quickly implemented.

Leishmania spp., a group of protozoan parasites belonging to the genus Leishmania, cause leishmaniasis. The parasites are transmitted through the bites of phlebotomine sand flies and are widely distributed throughout the world, although uncommon within the United States. Leishmaniasis may manifest as either cutaneous (skin lesions) or visceral (internal organs) forms. Visceral leishmaniasis is primarily caused by *L. donovani* and *L. infantum*. The panel detects all species within the Leishmania genus, including visceral and cutaneous

species; however, reduced sensitivity was observed for L. infantum. Only visceral

leishmaniasis is expected to be detected in whole blood specimens.

Submission Criteria: Specimens must be collected in EDTA blood collection tubes and stored at 2-8°C.

Specimens may be stored at refrigerated temperatures (2-8°C) but must be received at the testing laboratory within seven days of collection. Specimens must be shipped to the testing laboratory using enough cold packs to maintain refrigerated temperature. Do

not freeze specimens.

Rejection Criteria: Specimens other than EDTA whole blood, improperly filled out test request form, no

patient identifier on specimen, broken specimen tube, or specimens improperly

shipped.

Authorization: Authorization number is required. Number should be obtained from local health

department in consultation with IDPH Communicable Disease Section and CDC. For questions, contact your local health department or the IDPH Communicable Disease

Control Section at 217-782-2016.

Turn-around Time: Positive PCR: 1 day

Speciation testing 21 days (CDC)

Ship to: Chicago or Springfield IDPH Laboratories

Leptospira spp. BioFire Global Fever Special Pathogens Panel

Test Name: Identification of *Leptospira spp.*

Method Name: Rapid positive identification by polymerase chain reaction (PCR) assay.

Results: Detected/Not detected for *Leptospira spp*.

Reference Ranges: Negative for *Leptospira spp.*

Clinical Significance: The BioFire® Global Fever Special Pathogens Panel is a qualitative, multiplexed, nucleic

acid-based test for the simultaneous detection and identification of multiple pathogens directly from EDTA whole blood collected from symptomatic individuals or those suspected of exposure to the targeted pathogens. Results are meant to be used in conjunction with other clinical, epidemiologic, and laboratory data. This test would be used on international travelers, so that treatment and public health measures can be

quickly implemented.

Leptospira spp. (Family Leptospiraceae) are spirochete bacteria and the causative agents of leptospirosis. Leptospirosis is a zoonotic disease with worldwide distribution. Leptospira bacteria are transmitted through direct contact with urine or tissues from infected animals, or indirectly through contaminated soil or water. Exposure may occur through abrasions and cuts in the skin, or mucous membranes. The genus is divided into three subgroups, with one pathogenic subgroup. The pathogenicity of the Group I

members ranges from subclinical infections to severe disease and death.

Submission Criteria: Specimens must be collected in EDTA blood collection tubes and stored at 2-8°C.

Specimens may be stored at refrigerated temperatures (2-8°C) but must be received at the testing laboratory within seven days of collection. Specimens must be shipped to the testing laboratory using enough cold packs to maintain refrigerated temperature. Do

not freeze specimens.

Rejection Criteria: Specimens other than EDTA whole blood, improperly filled out test request form, no

patient identifier on specimen, broken specimen tube, or specimens improperly

shipped.

Authorization: Authorization number is required. Number should be obtained from local health

department in consultation with IDPH Communicable Disease Section and CDC. For questions, contact your local health department or the IDPH Communicable Disease

Control Section at 217-782-2016.

Turn-around Time: Positive PCR: 1 day

Confirmation/speciation testing 14 days (CDC)

Ship to: Chicago or Springfield IDPH Laboratories

Marburg Virus - BioFire Global Fever Special Pathogens Panel

Test Name: Identification of Marburg Virus (potential bio-threat agent)

Method Name: Rapid presumptive identification by polymerase chain reaction (PCR) assay.

Results: Detected/Not detected for Marburg Virus.

Reference Ranges: Negative for Marburg Virus.

Clinical Significance: The BioFire® Global Fever Special Pathogens Panel is a qualitative, multiplexed, nucleic

acid-based test for the simultaneous detection and identification of multiple pathogens directly from EDTA whole blood collected from symptomatic individuals or those suspected of exposure to the targeted pathogens. Results are meant to be used in conjunction with other clinical, epidemiologic, and laboratory data. This test would be used on international travelers, so that treatment and public health measures can be

quickly implemented.

Marburg viruses are Filoviridae with two lineages that have been characterized to date: Marburg virus (MARV) and Ravn virus (RAVV). Viruses from both lineages cause Marburg virus disease and infections are rare. The primary reservoir of Marburgvirus is believed to be the African fruit bat, and the viruses are suspected to be endemic throughout most of sub-Saharan Africa. The mechanism of transmission to humans is not currently known. However, person-to-person transmission occurs through direct contact with blood and body fluids. Sexual transmission is also possible. Marburg virus has been

designated as a select agent under the Federal Select Agent Program.

Submission Criteria: Specimens must be collected in EDTA blood collection tubes and stored at 2-8°C.

Specimens may be stored at refrigerated temperatures (2-8°C) but must be received at the testing laboratory within seven days of collection. Specimens must be shipped to the testing laboratory using enough cold packs to maintain refrigerated temperature. Do

not freeze specimens.

Rejection Criteria: Specimens other than EDTA whole blood, improperly filled out test request form, no

patient identifier on specimen, broken specimen tube, or specimens improperly

shipped.

Authorization: Authorization number is required. Number should be obtained from local health

department in consultation with IDPH Communicable Disease Section and CDC. For questions, contact your local health department or the IDPH Communicable Disease

Control Section at 217-782-2016.

Turn-around Time: Presumptive PCR: 1 day

Confirmation testing 14 days (CDC)

Ship to: Chicago or Springfield IDPH Laboratories

Measles Virus (Rubeola)

Test Name: Detection of Measles Virus (Rubeola)

Method Name: Real-time reverse transcriptase polymerase chain reaction (RT-PCR) assay.

Shipment of sera specimens to CDC is also available.

Results: Negative and positive for the detection of Measles virus RNA.

Reference Ranges: Negative for measles.

Clinical Significance: Measles virus is a member of the family Paramyxoviridae, genus Morbillivirus. Clinical

infection with measles virus is characterized by high fever, cough, coryza, conjunctivitis, malaise, Koplik spots inside the mouth, and rash developing behind the ears and over

the forehead, spreading to the trunk.

Detection of measles virus RNA is most successful when samples are collected on the first day of rash through the three days following onset of rash. Detection of measles virus RNA by RT-PCR may be successful as late as 10-14 days after rash onset. Collect throat or nasopharyngeal swab samples as soon as measles disease is suspected, but

within 10 days of rash onset.

Measles is highly contagious with an incubation period of 4-12 days. Infected individuals

are contagious from the first appearance of symptoms until 3-5 days after the rash

appears.

Submission Criteria: Testing is validated for throat and nasopharyngeal swabs in viral transport medium

(VTM), viral carrier medium (VCM), or universal transport media (UTM). If collecting both nasopharyngeal and throat, place both swabs in the same VTM/VCM/UTM tube. Swabs must be submitted cold (ice packs) and shipped for overnight delivery. Swabs must be received **no later than eight** days of collection and arrive at the laboratory cold

or frozen. For additional information on specimen submission, click here.

Rejection Criteria: Unacceptable specimens include those with mismatched requisitions; specimens

without patient identifiers; specimens without prior approval for testing (See authorization.); specimens not shipped in VTM, VCM, or UTM; non-respiratory

specimens; specimens not shipped cold (ice packs); and specimens not received no later

than eight days of collection; duplicate submissions.

Authorization: Prior approval from your LHD with an outbreak investigation number is required. For

questions, contact your LHD or the IDPH Communicable Disease Control Section at 217-

782-2016.

Turn Around Time: 3 days

Ship to: Chicago or Springfield IDPH Laboratories

Shipping Kits: See <u>Ordering or Requesting Clinical or Environmental Supplies</u>.

Mumps Virus

Test Name: Detection of Mumps Virus

Method Name: Real-time reverse transcriptase polymerase chain reaction (RT-PCR) assay.

Results: Negative and positive for the detection of mumps virus RNA.

Reference Ranges: Negative for mumps.

Clinical Significance: Mumps virus is a member of the family *Paramyxoviridae*, genus *Rubularvirus*. Clinical

infection with mumps virus is characterized by parotitis with complications, such as meningitis, pancreatitis, and orchitis. Although the majority of infections are benign, more serious but rare consequences of infection include encephalitis, cerebellar ataxia,

and hearing loss.

Mumps is highly contagious with an incubation period of 16-18 days but can range from 12-25 days. Infected individuals are contagious from a few days before until five days

after the onset of parotitis.

Submission Criteria: Collect buccal swabs as soon as mumps disease is suspected. RT-PCR has the greatest

diagnostic sensitivity when samples are collected within three days of symptom onset (Collect prior to nine days after symptom onset.). The buccal swab specimens are obtained by massaging the parotid gland area for 30 seconds prior to swabbing the area around Stensen's duct. Swab specimens are placed in viral transport medium (VTM), viral carrier medium (VCM), or universal transport medium (UTM). Swabs must be submitted cold (ice packs) and shipped for overnight delivery. Swabs must be received no later than eight days of collection and arrive at the laboratory cold or frozen. For

additional information on mumps submission, click <u>here</u>.

Rejection Criteria: Unacceptable specimens include those with mismatched requisitions; specimens

without patient identifiers; specimens without prior approval for testing (See authorization); specimens not shipped in VTM, VCM, or UTM; non-buccal specimens; specimens not shipped cold (ice packs); and specimens not received **no later than eight**

days of collection.

Authorization: Prior approval from your LHD with an outbreak investigation number is required. For

questions, contact your LHD or the IDPH Communicable Disease Control Section at 217-

782-2016.

Turn Around Time: 3 days

Ship to: Chicago or Springfield IDPH Laboratories

Shipping Kits: See Ordering or Requesting Clinical or Environmental Supplies.

Mycobacterium tuberculosis, Acid Fast Bacilli (AFB) Smear Analysis

Test Name: Detection of Acid-Fast Bacilli (AFB) in Primary Clinical Specimens

Method Name: AFB detected by Auramine-Rhodamine stain and fluorescent microscopy.

Results:

Kinyoun-stained 300 Field-1000X	Auramine-Rhodamine 50 Fields- 200X	Report
No AFB per slide	No AFB per slide	Negative
1-2 AFB per slide	1-2 AFB per slide	Document in notes and report Negative
1-9 AFB, 100 fields	1-9 AFB, 10 fields	Rare
1-9 AFB, 10 fields	1-9 AFB per field	Few
>9 AFB per field	>90 AFB per field	Many

Reference Ranges: Negative for the detection of *AFB*.

Clinical Significance: AFB may signify *M. tuberculosis* infection. Test does not distinguish from *M. tuberculosis*

versus non-tuberculous AFB. Test does not distinguish between live versus dead

infection.

Submission Criteria: Click here for acceptable specimens; collection and shipping instructions.

Rejection Criteria: Specimens other than those detailed above, improperly filled out test request form, no

patient identifier on specimen, broken specimen tube, or specimen received greater

than 10 days after collection.

Authorization: Local health departments (LHD) are authorized to submit specimens. Other private

submitters will require LHD approval to submit specimens.

Turn Around Time: 24 Hours

Ship to: Chicago IDPH Laboratory

Shipping Kits: See <u>Ordering or Requesting Clinical or Environmental Supplies.</u>

Mycobacterium tuberculosis, Primary Clinical Specimens

Test Name: Direct Detection of the *M. tuberculosis* in Primary Clinical Specimens

Method Name: Detection of rifampin-resistant Mycobacterium tuberculosis complex (MTBC) by

Cephied GeneXpert Assay.

Results: 1) MTB NOT DETECTED

2) MTB DETECTED; Rifampin Resistance NOT DETECTED3) MTB DETECTED; Rifampin Resistance DETECTED4) MTB DETECTED; Rifampin Resistance INTERMEDIATE

5) INVALID; (presence or absence of MTB cannot be determined)

Reference Ranges: MTBC not detected; Rifampin resistance not detected.

Clinical Significance: Direct detection of the rifampin-resistant *M. tuberculosis* complex provides early

presumptive evidence of infection; allows for early therapeutic intervention and patient isolation. The test does not distinguish among the members of the *M. tuberculosis* complex (*M. tuberculosis, M. bovis, M. bovis* BCG, *M. canetii, M. africanum, M. caprae, M. microti, M. pinnipedii*). Test does not distinguish between live versus dead infection.

Submission Criteria: Click here for acceptable specimens; collection and shipping instructions.

Rejection Criteria: Specimens other than those detailed above, improperly filled out test request form, no

patient identifier on specimen, or broken specimen tube.

Authorization: Local health departments (LHD) are authorized to submit specimens. Other private

submitters will require LHD approval to submit specimens.

Turn Around Time: 24 Hours

Ship to: Chicago IDPH Laboratory

Shipping Kits: See Ordering or Requesting Clinical or Environmental Supplies.

Mycobacterium tuberculosis, Culture confirmation

Test Name: Culture Confirmation of *M. tuberculosis* Complex Infection

Method Name: Confirmation of AFB in culture by Cephied GeneXpert Assay.

Detection of rifampin-resistant Mycobacterium tuberculosis complex (MTBC) by

Cephied GeneXpert Assay.

Results: 1) MTB NOT DETECTED

2) MTB DETECTED; Rifampin Resistance NOT DETECTED3) MTB DETECTED; Rifampin Resistance DETECTED4) MTB DETECTED; Rifampin Resistance INTERMEDIATE

5) INVALID (presence or absence of MTB cannot be determined)

Reference Ranges: MTBC not detected; Rifampin resistance not detected.

Clinical Significance: Culture identification provides confirmation of infection with the M. tuberculosis

complex and confirms detection in primary sputum by NAAT. The test does not distinguish among the members of the *M. tuberculosis* complex (*M. tuberculosis, M. bovis, M. bovis* BCG, *M. canetii, M. africanum, M. caprae, M. microti, M. pinnipedii*). The

laboratory does not identify non-tuberculous Mycobacterium cultures.

Submission Criteria: Click here for acceptable specimens; collection and shipping instructions.

Mycobacterium isolates. Submit on agar slant tubes (See shipping instructions).

Rejection Criteria: Specimens other than those detailed above, improperly filled out test request form, no

patient identifier on specimen, broken specimen tube, or primary specimen received

greater than 10 days after collection.

Authorization: Local health departments (LHD) are authorized to submit specimens. Other private

submitters will require LHD approval to submit specimens.

Turn Around Time: Variable – dependent upon culture growth rate.

Ship to: Chicago IDPH Laboratory

Shipping Kits: See <u>Ordering or Requesting Clinical or Environmental Supplies.</u>

Mycobacterium tuberculosis, Drug Susceptibility in Culture

Test Name: Identification of First Line Drug Susceptible/Resistant Isolates of the *M. tuberculosis*

Complex in Culture

Method Name: Growth of the *M. tuberculosis* complex in MGIT cultures supplemented with the

following first line drugs:

Rifampin tested at a concentration of 1 µg/mL

Isoniazid (INH) tested at concentrations of 0.1 µg/mL and 0.4 µg/mL

Ethambutol tested at a concentration of 5.0 μg/mL

Pyrazinamide (PZA) tested at a concentration of 100 μg/mL

Note: Second line drugs not tested

Results: Drug susceptible/resistant.

Reference Ranges: Susceptible for all drugs tested.

Clinical Significance: The efficacy of drug therapy in the treatment of M. tuberculosis complex disease can be

compromised by the infection with or development of a drug-resistant TB strain. It is vitally important to understand when a patient is infected with a drug-resistant strain so therapy can be changed to limit the spread of the infection and to improve clinical

outcome.

The IDPH laboratory performs the drug susceptibility assay on all new TB isolates. Thereafter, the test is only performed for patients who are not responding to therapy (although they are adhering to their drug regimen) AND it has been more than 60 days since the original or previous drug susceptibility test was performed for the patient.

Submission Criteria: 1. Click here for acceptable specimens; collection and shipping instructions.

2. Mycobacterium tuberculosis complex isolates. Submit on agar slant tubes.

Rejection Criteria: Specimens other than those detailed above, improperly filled out test request form, no

patient identifier on specimen, or broken specimen tube.

Authorization: Local health departments (LHD) are authorized to submit specimens. Other private

submitters will require LHD approval to submit specimens.

Turn Around Time: 7-10 days after the identification of culture isolate as *M. tuberculosis* complex

Ship to: <u>Chicago IDPH Laboratory</u>

Shipping Kits: See Ordering or Requesting Clinical or Environmental Supplies.

Mycobacterium tuberculosis Strain Genotyping

Test Name: Identification of Mycobacterium Tuberculosis Strain by Genotyping

Method Name: Molecular based assays performed by the Michigan Department of Community Health.

Results: Strain identification reported to the state for epidemiological investigations. Submitters

are not forwarded the results.

Reference Ranges: Not applicable.

Clinical Significance: Strain typing allows for epidemiological studies to be performed to identify infection

clusters, routes or transmission, and outbreaks of M. tuberculosis.

Submission Criteria: All facilities are obligated by law to forward M. tuberculosis isolates to the IDPH

Mycobacteriology Laboratory for genotyping. Submit the isolates on an agar slant tube

(See shipping instructions).

Rejection Criteria: Specimens other than those detailed above, improperly filled out test request form, no

patient identifier on specimen, or broken specimen tube.

Authorization: Local health departments (LHD) are authorized to submit specimens. Other private

submitters will require LHD approval to submit specimens.

Turn Around Time: N/A

Ship to: Chicago IDPH Laboratory

Shipping Kits: See Ordering or Requesting Clinical or Environmental Supplies.

Neisseria gonorrhoeae Culture

Test Name: Identification of *Neisseria gonorrhoeae*

Method Name: Biochemical confirmation of *Neisseria gonorrhoeae*.

Results: Positive/Negative for the detection of *Neisseria gonorrhoeae*.

Reference Ranges: Negative for *Neisseria gonorrhoeae*.

Clinical Significance: N. gonorrhoeae is always considered a pathogen when isolated from human sources. It

is sexually transmitted and can be isolated from genital, rectal, and throat specimens. The organism is capable of dissemination and has been isolated from blood and joint

fluid.

Submission Criteria: Isolate grown on a chocolate agar slant. If sent by courier, isolates grown on chocolate

agar plates are also acceptable.

Rejection Criteria: Improperly filled out requisition form, no patient identifier on specimen, mismatched

names, or broken or leaking specimen tube.

Authorization: Submission of specimens for *N. gonorrhoeae* testing requires authorization from the

IDPH Office of Disease Control, STD Section. The STD Section can be reached at 217-782-

2747.

Turn Around Time: 3-5 days

Ship to: Chicago IDPH Laboratory

Shipping Kits: N/A

Neisseria meningitidis

	5
Test Name:	Identification of Neisseria meningitidis
Method Name:	Biochemical confirmation of <i>Neisseria meningitidis</i> . Antiserum slide agglutination to identify serogroups.
Results:	Positive/Negative for the detection of <i>Neisseria meningitidis</i> . Serogroups detected: A, B, C, D, W135, X, Y, and Z.
Reference Ranges:	Negative for <i>Neisseria meningitidis</i> .
Clinical Significance:	<i>N. meningitidis</i> infection in normally sterile site (such as spinal fluid and blood) is highly pathogenic and life threatening and required to be submitted according to Illinois Administrative Rule Part 690.
Submission Criteria:	Isolate grown on a chocolate agar slant. If sent by courier, isolates grown on chocolate agar plates are also acceptable. Hospitals are required to submit known <i>Neisseria meningitidis</i> isolates to the IDPH labs for confirmatory identification and serogrouping.
Rejection Criteria:	Improperly filled out submission form, no patient identifier on specimen, mismatched names, or broken or leaking specimen tube.
Authorization:	No authorization number is required. Submission is required by Illinois Administrative Rule Part 690. Notify your LHD if you suspect this infection.
Turn Around Time:	3-5 days
Ship to:	Chicago IDPH Laboratory

Communicable Disease Test Requisition Form

Shipping Kits:

Submission Form:

N/A

Newborn Screening Panel

Test Name: Newborn Screening Panel

Information about the IDPH Newborn Screening Program is available here.

Methods: Varies between disorders; more details available upon request.

Results: Normal, Borderline, Positive, Unsatisfactory, Invalid (reported per disorder).

Endocrine Disorders

- Congenital adrenal hyperplasia (CAH)
- Congenital hypothyroidism (TSH)

Hemoglobinopathies

- Sickle cell disease (S, S)
- Sickle cell disease (S, C)
- Alpha thalassemia
- Beta thalassemia major
- Hemoglobin trait conditions
- Sickle-C disease
- Other hemoglobinopathies

Amino acid disorders

- Argininemia
- Argininosuccinic aciduria
- Biopterin defect in cofactor biosynthesis
- Biopterin defect in cofactor regeneration
- Citrullinemia, type I
- Citrullinemia, type II
- Homocystinuria
- Hypermethioninemia
- Hyperphenylalaninemia
- Maple syrup urine disease
- Non-ketotic Hyperglycinemia
- Orthithine transcarbamylase deficiency (OTC)
- Phenylketonuria (PKU)
- Tyrosinemia, type I
- Tyrosinemia, type II tyrosine levels may not be sufficiently elevated for detection
- Tyrosinemia, type III tyrosine levels may not be sufficiently elevated for detection

Organic acid disorders

- 2-methylbutyryl-CoA dehydrogenase deficiency (2MBD)
- 3-methylcrotonyl-CoA carboxylase deficiency (3MCC)
- 3-hydroxy-3-methylglutaric-CoA lyase deficiency (3HMG)
- 3-methylglutaconic aciduria (3MGA)
- Beta-ketothiolase deficiency (BKT)
- Glutaric aciduria, type 1 (GA1)
- Isobutyryl-CoA dehydrogenase deficiency
- Isovaleric acidemia (IVA)
- Malonic aciduria (MA)
- Methylmalonic acidemia (cobalamin disorders)
- Methylmalonic acidemia (methylmalonyl-CoA mutase)
- Methylmalonic acidemia with homocystinuria

- Multiple carboxylase deficiency
- Propionic acidemia (PA)

Fatty acid oxidation disorders

- 2,4 Dienoyl-CoA reductase deficiency (DE RED)
- Carnitine palmitoyl transferase deficiency type 1 (CPT1A)
- Carnitine palmitoyl transferase deficiency type 2 (CPT2)
- Carnitine/acylcarnitine translocase deficiency (CACT) neonatal form, extremely rare
- Glutaric aciduria, type 2/Multiple acyl-CoA dehydrogenase deficiency
- Long chain 3-hydroxyacyl-CoA dehydrogenase deficiency (LCHAD)
- Medium chain acyl-CoA dehydrogenase deficiency (MCAD)
- Medium/Short chain L-3-hydroxyacyl-CoA-dehydrogenase deficiency (M/SCHAD)
- Short chain acyl-CoA dehydrogenase deficiency (SCAD)
- Trifunctional protein deficiency (TFPD)
- Very long chain acyl-CoA dehydrogenase deficiency (VLCAD)

Lysosomal Storage Diseases

- Fabry Disease
- Gaucher Disease
- Pompe Disease
- Krabbe Disease
- Niemann Pick Disease
- Hurler's Disease (MPS-I)
- Hunter Syndrome (MPS-II)

Other Disorders

- Adrenoleukodystrophy (X-ALD)
- Biotinidase deficiency
- Cystic Fibrosis first-tier immunoreactive trypsinogen (IRT) with second-tier genetic mutation analysis on top 4% of IRT specimens
- Galactosemia
- Severe combined immunodeficiency (SCID) and other T-cell lymphopenias
- Spinal Muscular Atrophy (SMA)

Reference Ranges:

Dependent upon test/analyte; provided upon request.

Clinical Significance:

Newborn screening provides an opportunity to rapidly identify otherwise healthy-appearing infants who are at high risk of developing various conditions. Early intervention can have significant reductions in morbidity and mortality, while reducing health care costs associated with treatment of lifelong debilitating conditions. A screening test cannot confirm or rule out a particular condition. Stated differently, newborn screening is not a diagnostic test. It identifies individuals who may have the condition so that definitive follow-up testing can be offered to determine if the condition is truly present. See also: www.babysfirsttest.org/newborn-screening/screening-101.

Submission Criteria:

Acceptable specimens must be collected on special filter paper specimen cards supplied by IDPH. Newborn screening blood spot specimens should be collected as soon as possible after the first 24 hours of life. If the newborn is to be discharged from the birth center prior to 24 hours of age, collect the specimen before discharge. After drying, the specimen cards are to be sent by courier to IDPH's Newborn Screening Laboratory in Chicago for testing.

Rejection Criteria: Unsatisfactory specimen reports indicate the specimen was improperly collected,

handled, or submitted, as determined by the IDPH's Division of Laboratories. Specimens must be of good quality to assure reliable, valid newborn screening; unsatisfactory specimens require collection and submission of a new sample to assure that every baby receives a valid newborn screening. Unsatisfactory results are reported from the program by letter indicating the nature of the specimen and the need for immediate repeat specimen collection. The letter is sent by mail to the submitting physician or facility. Additional information about specimen collection and submission is available

here.

Turn Around Time: 4 days for abnormal test results and 10 days for normal test. Positive or abnormal

results are provided as quickly as possible.

Authorization: No authorization number is required.

Ship to: <u>Chicago IDPH Laboratory</u>

Shipping Kits: See <u>Ordering or Requesting Clinical or Environmental Supplies.</u>

Submission Form: Newborn Screening Submission Form

Orthopoxvirus Screen, Molecular

Test Name: Screening Assay to Detect the Following orthopoxviruses: *Variola, Vaccinia*, cowpox,

monkeypox, camelpox, ectromelia, and gerbilpox

Method Name: Real-time polymerase chain reaction (PCR) assay.

Results: Positive/Negative for the detection of Orthopoxvirus. Assay does not distinguish among

the viruses.

Reference Ranges: Negative for the detection of orthopoxvirus.

Clinical Significance: This test is intended for patients who present with a vesicular/pustular rash illness of

unknown of origin with a low-to-moderate risk of having contracted *Variola* virus (smallpox). If the test result is positive, further appropriate reflex testing would need to

be done to identify the specific orthopoxvirus contracted.

Submission Criteria: Evaluation of patients for potential orthopox infection/testing is based on the Acute,

Generalized Vesicular, or Pustular Rash Illness Protocol.

Specimen Type	Room Temp	2° C to 8° C	-20 to -70° C
Vesicle/pustule skin or crust	NO	YES (up to 24 hours)	YES
Slide of fluid	YES	YES (up to 24 hours)	NO
Swab of lesion fluid	NO	YES (up to 24 hours)	YES
Punch biopsy (no formalin)	NO	YES (up to 24 hours)	YES
Ocular impression (slide)	YES	YES (up to 24 hours)	NO
Swab of ocular site	NO	YES (up to 24 hours)	YES
Serum-gold top/SST	NO	YES (up to 24 hours)	YES (if aliquoted)

All specimen tubes must be labeled with at least the patient's name. Ship the specimens as soon as possible after collection. Follow storage conditions listed in the table above.

Rejection Criteria: Specimens other than those detailed above, improperly filled out test request form, no

patient identifier on specimen, broken specimen tube, or calcium alginate swab

specimens.

Authorization: No authorization number is required. Submission is required by Illinois Administrative

Rule Part 690. Notify your LHD if you suspect this infection.

Turn Around Time: 1-2 days

Ship to: Carbondale, Chicago, or Springfield IDPH Laboratories

Plasmodium spp. (Malaria)

Test Name: Detection of *Plasmodium spp.* (Malaria)

Method Name: Real-time Polymerase chain reaction (RT-PCR) for *Plasmodium spp.*

Results: Negative/Positive for *Plasmodium falciparum*, *Plasmodium vivax*, *Plasmodium malariae*,

or Plasmodium ovale.

Reference Ranges: Negative for *Plasmodium sp.*

Clinical Significance: Malaria is a major tropical disease caused primarily by four species of the protozoa

Plasmodium: Plasmodium falciparum, Plasmodium vivax, Plasmodium malariae, and Plasmodium ovale. Malaria infects approximately 500 million people and causes 1.5 to 2.7 million deaths annually. Ninety percent of the deaths occur in sub-Saharan Africa and most of these occur in children <5 years old; it is the leading cause of mortality in this age group. This disease is also widespread in Central and South America, Hispaniola, the Indian subcontinent, the Middle East, Oceania, and Southeast Asia. In the United States, individuals at risk include travelers to and visitors from endemic areas.

PCR is a sensitive and specific method of detection for *Plasmodium* species DNA in peripheral blood. PCR may be more sensitive than conventional microscopy in very low

parasitemias and is more specific for species identification.

Submission Criteria: Submit a purple capped (EDTA) blood tube. Complete patient demographics (patient's

first and last name, date of birth, ethnicity, and date of onset). Preliminary microscopic observations including semi-quantitation, such as low level of parasitemia, etc., should

be included on page two in the "Other Pertinent Information" section of the Communicable Diseases Laboratory Test Requisition form. Prior to shipping, hold

specimens at 2-8°C and then ship the specimen (overnight).

Rejection Criteria: Specimen received without a test request form. Specimen received without unique

identifier (name or other ID) on the specimen, or the identifier does not match the identifier on the submission form. Specimen received without date of collection.

Specimens not submitted according to submission criteria.

Authorization: Hospitals are required to send positive purple capped (EDTA) blood tube to IDPH's

Springfield Laboratory for confirmation of malaria.

Turn Around Time: 7 days

Ship to: Springfield IDPH Laboratory

Shipping Kits: See <u>Ordering or Requesting Clinical or Environmental Supplies.</u>

Plasmodium spp. BioFire Global Fever Special Pathogens Panel

Test Name: Identification of *Plasmodium spp.*

Method Name: Rapid presumptive identification by polymerase chain reaction (PCR) assay.

Results: Detected/Not detected for *Plasmodium spp., P. falciparum* and *P. vivax/ovale*.

Reference Ranges: Negative for *Plasmodium spp.*

Clinical Significance: The BioFire® Global Fever Special Pathogens Panel is a qualitative, multiplexed, nucleic

acid-based test for the simultaneous detection and identification of multiple pathogens directly from EDTA whole blood collected from symptomatic individuals or those suspected of exposure to the targeted pathogens. Results are meant to be used in conjunction with other clinical, epidemiologic, and laboratory data. This test would be used on international travelers, so that treatment and public health measures can be

quickly implemented.

Malaria is primarily caused by five species of the Plasmodium genus (*P. falciparum*, *P. knowlesi*, *P. malariae*, *P. ovale*, and *P. vivax*). Transmission of these parasitic protozoans occurs through bites from Anopheles mosquitoes. The five species vary by geography, and treatment depending on the species and the incidence of drug resistance. Early identification of the species is important for selecting the appropriate treatment. The most common malaria infections are caused by *P. falciparum* and *P. vivax*, whereas infections of *P. ovale* and *P. malariae* are less common. *P. knowlesi* is emerging as a significant cause of zoonotic malaria in Southeast Asia. Co-infection with multiple Plasmodium species is possible and

humans and provides species identification for *P. falciparum* and *P. vivax/ovale*.

Submission Criteria: Specimens must be collected in EDTA blood collection tubes and stored at 2-8°C.

Specimens may be stored at refrigerated temperatures (2-8°C) but must be received at the testing laboratory within seven days of collection. Specimens must be shipped to the testing laboratory using enough cold packs to maintain refrigerated temperature. Do

should always be considered. The panel detects all Plasmodium species known to infect

not freeze specimens.

Rejection Criteria: Specimens other than EDTA whole blood, improperly filled out test request form, no

patient identifier on specimen, broken specimen tube, or specimens improperly

shipped.

Authorization: Authorization number is required. Number should be obtained from local health

department in consultation with IDPH Communicable Disease Section and CDC. For questions, contact your local health department or the IDPH Communicable Disease

Control Section at 217-782-2016.

Turn-around Time: Positive PCR: 1 day

Ship to: Chicago or Springfield IDPH Laboratories

Respiratory Pathogens Panel 2 – GenMark ePlex®

Test Name: GenMark ePlex® Respiratory Pathogens Panel

Method Name: The test is a multiplexed nucleic acid *in vitro* diagnostic test intended for use on the

ePlex Instrument for the simultaneous qualitative detection and identification of

multiple respiratory viral and bacterial nucleic acids.

Results: Adenovirus (A-F); Coronavirus (229E, HKU1, NL63, OC43); Human metapneumovirus;

Human Rhinovirus/Enterovirus; Influenza A; Influenza A H1; Influenza A H1-2009; Influenza A H3; Influenza B; Parainfluenza Virus 1; Parainfluenza Virus 2; Parainfluenza Virus 3; Parainfluenza Virus 4; Respiratory Syncytial Virus A; Respiratory Syncytial Virus

B; Chlamydia pneumoniae; Mycoplasma pneumoniae; SARS-CoV-2.

Reference Ranges: Not Detected for all targets on panel (Detected for Internal Control).

Clinical Significance: Influenza and influenza-like illness (ILI) are the most common cause of acute illness in

developed countries, causing an estimated 500 million non-influenza cases yearly in the

United States alone.

Submission Criteria: An IDPH Communicable Diseases Laboratory Test Requisition must accompany

specimens and include the test ordered; full patient name and identifiers (including sex and date of birth); source of specimen; date of collection; the submitting organization; referring physician, if appropriate; and contact information. Submitters, who are part of the ILINET surveillance program, should submit specimens via the Electronic Transfer of Records (ETOR) portal. Print the submission form from the portal and submit with

the specimen.

Specimen type is a nasopharyngeal swab (NP Swab) specimen. Collection should be performed according to standard technique and placed in viral transport media (VTM)

or universal transport media (UTM).

Clinical specimens should be stored refrigerated after collection at 2-8°C. Specimens are valid for up to 12 hours at room temperature (15-30°C); up to 10 days after collection while refrigerated. Specimens can also be stored at -20°C or -80°C for 12 months with

up to two freeze/thaw cycles. Minimum testing volume is 200 μL.

Rejection Criteria: Rejection criteria include, but are not limited to, those with:

Mismatched requisitions, specimens without patient identifiers, specimens stored or shipped incorrectly, specimens collected using expired VTM, or specimens without IDPH Communicable Disease Control Section/local health department (LHD) testing pre-

approval and for which approval cannot be obtained after specimen receipt.

Authorization: Testing authorization must be obtained before submitting a specimen. Approval can be

obtained through the patient's LHD or through the IDPH Communicable Disease Control Section staff. Specimens submitted through ILINet for surveillance that are

negative for influenza and SARS-CoV-2 will be reflexed to this test.

Turn Around Time: <3 business days of receiving the specimen

Ship to: Carbondale, Chicago, or Springfield IDPH Laboratories

Shipping Kits: N/A

Submission Form: Communicable Disease Test Requisition Form; ILINet Influenza form

Salmonella spp.

Test Name: Isolation and Identification of *Salmonella spp*.

Methods: Culture and biochemical reactions are used for the isolation and identification of

Salmonella spp. Isolates are further analyzed to identify serotypes/strains for

epidemiological purposes.

Results: Positive/Negative for the detection of *Salmonella spp*. (Typhi or Non-Typhi).

Reference Ranges: Negative for the detection of *Salmonella spp*.

Clinical Significance: Enteric pathogens cause a variety of human diseases. The severity of the disease

depends on the virulence of the strain and the condition of the host and can be a mild self-limiting gastroenteritis or become more severe, with bacteremia or typhoid fever, which can be life threatening. Early detection allows for effective management and

identification of possible outbreaks.

Submission Criteria: Clinical – Stool submitted at room temperature in Cary-Blair vial or swab; received by

IDPH within 72 hours (swab) or 96 hours (vial).

Referred Isolates – Submit isolate at room temperature on slant [e.g., BHI, Heart infusion (HI) slant] or on sealed plates (if delivered by courier) on solid media that is

non-inhibitory (e.g., BAP). Indicate source on request form and specimen

Rejection Criteria: Specimen received without unique identifier (name or other ID), or the identifier does

not match the identifier on the submission form. Specimen received without date of collection. Specimen received without submission form. Specimens not submitted according to submission criteria or according to rules and regulations for transporting

clinical specimens or infectious substances.

Turn Around Time: 7 days

Authorization: No authorization number is required. Submission is required by Illinois Administrative

Rule Part 690. Notify your LHD if you suspect this infection. Clinical specimens should be

discussed with an LHD.

Ship to: Chicago or Springfield IDPH Laboratories

Shipping Kits: See <u>Ordering or Requesting Clinical or Environmental Supplies</u>.

Shigella spp.

Test Name: Isolation and Identification of *Shigella spp.*

Methods: Culture and biochemical reactions are used for the isolation and identification of

Shigella spp. Isolates are further analyzed to identify serotypes/strains for

epidemiological purposes.

Results: Positive/Negative for the detection of *Shigella spp*.

Reference Ranges: Negative for the detection *Shigella spp*.

Clinical Significance: Enteric pathogens cause a variety of human diseases. The severity of the disease

depends on the virulence of the strain and the condition of the host and can be a mild self-limiting gastroenteritis or become more severe with bacteremia or typhoid fever, which can be life threatening. Early detection allows for effective management and

identification of possible outbreaks.

Submission Criteria: Clinical - Stool submitted at room temperature in Cary-Blair vial or swab; received by

IDPH within 72 hours (swab) or 96 hours (vial).

Referred Isolates – Submit isolate at room temperature on slant [e.g., BHI, Heart infusion (HI) slant] or on sealed plates (if delivered by courier) on solid media that is

non-inhibitory (e.g., BAP). Indicate source on request form and specimen.

Rejection Criteria: Specimen received without unique identifier (name or other ID), or the identifier does

not match the identifier on the submission form. Specimen received without date of collection. Specimen received without submission form. Specimen not submitted according to submission criteria or according to rules and regulations for transporting

clinical specimens or infectious substances.

Turn Around Time: 7 days

Authorization: No authorization number is required. Submission is required by Illinois Administrative

Rule Part 690. Notify your LHD if you suspect this infection. Clinical specimens should be

discussed with an LHD.

Ship to: Chicago or Springfield IDPH Laboratories

Shipping Kits: See Ordering or Requesting Clinical or Environmental Supplies.

Syphilis (Treponema pallidum)

Test Name: Detection of Treponema Pallidum (Syphilis) Antibodies

Method Name: Chemiluminescent microparticle immunoassay (CMIA) for the detection of antibodies to

Treponema pallidum.

NOTE: If the test is positive, additional confirmatory testing by RPR and TP-PA will be

performed according to the syphilis testing algorithm.

Results: Reactive or nonreactive for treponemal antibodies.

Reference Range: Nonreactive for treponemal antibodies.

Clinical Significance: Early detection of <u>syphilis</u>, using the CMIA as a screening test, allows for rapid treatment

and limits further spread of the disease. Additional information about the stage of syphilis infection can be obtained from the RPR and TP-PA tests. Left untreated, syphilis can cause devastating systemic problems and increased risk for co-infection with HIV.

Submission Criteria: Collect 5 mL blood in a gold top/serum separator tube (SST). Allow blood to clot at room

temperature. Centrifuge for 10 minutes. Label specimens with a unique identifier. Blood collected in a serum separator tube (SST) and centrifuged should be shipped in a cooler on cold packs on the same day as collected. Every effort should be made to ship specimens on the same day as collected. If it is not possible to ship the same day as

collected, store at 2-8°C and ship on cold packs the next business day.

Rejection Criteria: Specimens will be rejected if they are:

Grossly hemolyzed specimens.

- No submission form. Insufficient quantity.
- No unique identifier on specimen.
- Broken or leaking specimen.
- Specimen greater than seven days old from collection if stored and shipped cold
- Specimen greater than three days old from collection if stored and shipped room temperature.

Authorization: Providers are authorized by the IDPH Office of Disease Control, STD Section, at 217-782-

2747. A provider number will be given, which should be included on the submission

form.

Turn Around Time: 2 days for CMIA screening; 3-5 days for additional tests

Ship to: <u>Carbondale IDPH Laboratory</u>

Shipping Kits: See <u>Ordering or Requesting Clinical or Environmental Supplies.</u>

Submission Form: Tests must be ordered online using the Electronic Test Ordering and Reporting (ETOR)

portal. Print the submission form from the portal and submit copy with specimen. Contact dph.labs.dmg@illinois.gov for enrollment or questions regarding online test

ordering.

Varicella-zoster Virus (chickenpox), Molecular

Test Name: Detection of Varicella-zoster Virus (VZV)

Method Name: Real-time polymerase chain reaction (PCR) assay.

Results: Positive and Negative for the detection of VZV DNA.

Reference Ranges: Negative for the detection of VZV DNA.

Clinical Significance: This test is intended for patients that present with a vesicular/pustular rash illness of

unknown origin with a low-to-moderate risk of having contracted *Variola* virus (smallpox). Depending on the clinical presentation, this test can be useful if the

orthopoxvirus screening assay is negative.

Submission Criteria: Evaluation of patients for potential orthopox infection/testing is based on the <u>Acute</u>,

Generalized Vesicular, or Pustular Rash Illness Protocol.

Acceptable specimens include:

a. Roof or crust of vesicle

b. Swab (Dacron or rayon) of vesicle

c. Dried vesicular fluid on a slide (touch prep)

d. Fresh biopsy (no formalin)

e. Dry or wet swab of lesion. Dry swab preferred for PCR.

f. Viral cell culture lysate (only when non-variola orthopox virus is suspected).

All specimen tubes must be labeled with at least the patient's name. Ship the specimens as soon as possible after collection. Store the specimens in a refrigerator or freezer if shipping is delayed. Punch biopsy and tissue culture specimens must be shipped on ice.

Other specimen types can be shipped at ambient temperature.

Rejection Criteria: Specimens other than those detailed above, improperly filled out test request form, no

patient identifier on specimen, broken specimen tube, or calcium alginate swab

specimens.

Authorization: Prior approval from your LHD with an outbreak investigation number is required. For

questions, contact your LHD or the IDPH Communicable Disease Control Section at 217-

782-2016.

Turn Around Time: 1-2 days

Ship to: Carbondale, Chicago, or Springfield IDPH Laboratories

Vibrio spp.

Test Name: Isolation and Identification of *Vibrio spp*.

Method Name: Culture and biochemical reactions are used for the isolation, identification of Vibrio spp.

and serotyping of Vibrio cholerae.

Results: Positive/negative for the detection of *Vibrio spp*.

Reference Ranges: Negative for the detection *Vibrio spp*.

Clinical Significance: Enteric pathogens cause a variety of human diseases. The severity of the disease

depends on the virulence of the strain and the condition of the host and can be a mild self-limiting gastroenteritis or become more severe with bacteremia or typhoid fever, which can be life threatening. Early detection allows for effective management and

identification of possible outbreaks.

Submission Criteria: Clinical - Stool submitted at room temperature in Cary-Blair vial or swab; received by

IDPH within 72 hours (swab) or 96 hours (vial).

Referred Isolates – Submit isolate at room temperature on slant [e.g., BHI, Heart infusion (HI) slant], or on sealed plates (if delivered by courier) on solid media that is

non-inhibitory (e.g., BAP). Indicate source on request form and specimen.

Rejection Criteria: Specimen received without unique identifier (name or other ID), or the identifier does

not match the identifier on the submission form. Specimen received without date of collection. Specimen received without submission form. Specimens not submitted according to submission criteria or according to rules and regulations for transporting

clinical specimens or infectious substances.

Turn Around Time: 7 days

Authorization: No authorization number is required. Submission is required by Illinois Administrative

Rule Part 690. Notify your LHD if you suspect this infection. Clinical specimens should be

discussed with an LHD.

Ship to: Chicago or Springfield IDPH Laboratories

Shipping Kits: See Ordering or Requesting Clinical or Environmental Supplies.

West Nile Virus - BioFire Global Fever Special Pathogens Panel

Test Name: Identification of West Nile Virus

Method Name: Rapid presumptive identification by polymerase chain reaction (PCR) assay.

Results: Detected/Not detected for West Nile Virus.

Reference Ranges: Negative for West Nile Virus.

Clinical Significance: The BioFire® Global Fever Special Pathogens Panel is a qualitative, multiplexed, nucleic

acid-based test for the simultaneous detection and identification of multiple pathogens directly from EDTA whole blood collected from symptomatic individuals or those suspected of exposure to the targeted pathogens. Results are meant to be used in conjunction with other clinical, epidemiologic, and laboratory data. This test would be used on international travelers, so that treatment and public health measures can be

quickly implemented.

West Nile virus is a Flavivirus widely distributed throughout the world. The virus causes West Nile fever and is primarily transmitted to humans through mosquito bites. Up to 80% of West Nile virus infections are asymptomatic in humans. Mild cases of West Nile fever are clinically indistinguishable from disease caused by other Flaviviruses such as dengue fever. In rare cases a more severe illness affecting the central nervous system may develop. West Nile virus has been identified in multiple mosquito species. However, mosquitoes of the Culex genus are believed to be responsible for most transmission. Culex species primarily feed on birds which are a natural reservoir of the

virus. West Nile Virus is already endemic to Illinois.

Submission Criteria: Specimens must be collected in EDTA blood collection tubes and stored at 2-8°C.

Specimens may be stored at refrigerated temperatures (2-8°C) but must be received at the testing laboratory within seven days of collection. Specimens must be shipped to the testing laboratory using enough cold packs to maintain refrigerated temperature. Do

not freeze specimens.

Rejection Criteria: Specimens other than EDTA whole blood, improperly filled out test request form, no

patient identifier on specimen, broken specimen tube, or specimens improperly

shipped.

Authorization: Authorization number is required. Number should be obtained from local health

department in consultation with IDPH Communicable Disease Section and CDC. For questions, contact your local health department or the IDPH Communicable Disease

Control Section at 217-782-2016.

Turn-around Time: Positive PCR: 1 day

Ship to: Chicago or Springfield IDPH Laboratories

Yellow Fever Virus - BioFire Global Fever Special Pathogens Panel

Test Name: Identification of Yellow Fever Virus (potential bio-threat agent)

Method Name: Rapid presumptive identification by polymerase chain reaction (PCR) assay.

Results: Detected/Not detected for Yellow Fever Virus.

Reference Ranges: Negative for Yellow Fever Virus.

Clinical Significance: The BioFire® Global Fever Special Pathogens Panel is a qualitative, multiplexed, nucleic

acid-based test for the simultaneous detection and identification of multiple pathogens directly from EDTA whole blood collected from symptomatic individuals or those suspected of exposure to the targeted pathogens. Results are meant to be used in conjunction with other clinical, epidemiologic, and laboratory data. This test would be used on international travelers, so that treatment and public health measures can be

quickly implemented.

Yellow fever virus is a positive-sense, single-stranded RNA virus. The virus belongs to the Flavivirus genus (Flaviviridae) and is primarily transmitted through the mosquitoes of the Aedes or *Haemagogus genuses*. The mosquito vectors facilitate both sylvatic transmission as well as urban human-to-human transmission. Yellow fever disease is endemic to tropical regions of South America and sub-Saharan Africa and cases within the United States are typically travelers to these regions. Most patients have no symptoms or only mild febrile symptoms. In a small number of patients more severe disease may develop including renal dysfunction and hemorrhage which is often fatal.

Submission Criteria: Specimens must be collected in EDTA blood collection tubes and stored at 2-8°C.

Specimens may be stored at refrigerated temperatures (2-8°C) but must be received at the testing laboratory within seven days of collection. Specimens must be shipped to the testing laboratory using enough cold packs to maintain refrigerated temperature. Do

not freeze specimens.

Rejection Criteria: Specimens other than EDTA whole blood, improperly filled out test request form, no

patient identifier on specimen, broken specimen tube, or specimens improperly

shipped.

Authorization: Authorization number is required. Number should be obtained from local health

department in consultation with IDPH Communicable Disease Section and CDC. For questions, contact your local health department or the IDPH Communicable Disease

Control Section at 217-782-2016.

Turn-around Time: Presumptive PCR: 1 day

Confirmation testing 14 days (CDC)

Ship to: Chicago or Springfield IDPH Laboratories

Yersinia pestis (Plague)

Test Name: Culture Identification of *Yersinia pestis* (potential biothreat agent)

Method Name: Rapid presumptive identification by real-time polymerase chain reaction (PCR) assay.

Confirmation by biochemical identification of culture isolate.

Results: Negative/Positive for the identification of *Y. pestis*.

Note: If the test is negative and the isolate is the genus Yersinia, speciation will not be

performed.

Reference Ranges: Negative for the identification of Y. pestis.

Clinical Significance: Plague is a disease that affects humans and other mammals. It is caused by the

bacterium *Yersinia pestis*. Humans usually get plague after being bitten by a rodent flea carrying the bacterium or by handling an infected animal. Plague is infamous for killing millions of people in Europe during the Middle Ages. Today, modern antibiotics are effective in treating plague. However, without prompt treatment, the disease can cause serious illness or death. Presently, human plague infections continue to occur in the western United States, but significantly more cases occur in parts of Africa and Asia.

Submission Criteria: Request testing if you suspect an isolate may be *Y. pestis*. See <u>ASM.org</u> for the rule-

out/in protocols.

Submit a pure isolate/culture submitted on an agar slant with any media that will support growth. Do not submit the isolate on an agar plate unless the specimen is being transported by courier. Do not perform further tests. Environmental sample testing is also available through special arrangement. Contact the Division of Laboratories if

environmental testing is requested.

Rejection Criteria: Specimens other than those detailed above, improperly filled out test request form, no

patient identifier on specimen, or broken specimen tube.

Authorization: No authorization number is required. Submission is required by Illinois Administrative

Rule Part 690. Notify your LHD if you suspect this infection. Clinical specimens should be

discussed with an LHD.

Turn Around Time: Presumptive PCR: 1 day

Culture confirmation: 4 days

Ship to: Carbondale, Chicago, or Springfield IDPH Laboratories

Yersinia pestis - BioFire Global Fever Special Pathogens Panel

Test Name: Identification of *Yersinia pestis* (potential bio-threat agent)

Method Name: Rapid presumptive identification by polymerase chain reaction (PCR) assay.

Results: Detected/Not detected for *Yersinia pestis*.

Reference Ranges: Negative for *Yersinia pestis.*

Clinical Significance: The BioFire® Global Fever Special Pathogens Panel is a qualitative, multiplexed, nucleic

acid-based test for the simultaneous detection and identification of multiple pathogens directly from EDTA whole blood collected from symptomatic individuals or those suspected of exposure to the targeted pathogens. Results are meant to be used in conjunction with other clinical, epidemiologic, and laboratory data. This test would be used on international travelers, so that treatment and public health measures can be

quickly implemented.

Yersinia pestis is an aerobic gram-negative bacterium which causes plague. The disease is spread to humans from rodents and other wild animals by flea bites, although contact with contaminated fluids or tissue are also modes of transmission. Within the United States Y. pestis is endemic to rural areas in all Western state. The disease manifests as three major clinical syndromes: bubonic plague, septicemic plague, and pneumonic plague. Y. pestis is designated as a select agent per the Federal Select Agent Program.

Submission Criteria: Specimens must be collected in EDTA blood collection tubes and stored at 2-8°C.

Specimens may be stored at refrigerated temperatures (2-8°C) but must be received at the testing laboratory within seven days of collection. Specimens must be shipped to the testing laboratory using enough cold packs to maintain refrigerated temperature. Do

not freeze specimens.

Rejection Criteria: Specimens other than EDTA whole blood, improperly filled out test request form, no

patient identifier on specimen, broken specimen tube, or specimens improperly

shipped.

Authorization: Authorization number is required. Number should be obtained from local health

department in consultation with IDPH Communicable Disease Section and CDC. For questions, contact your local health department or the IDPH Communicable Disease

Control Section at 217-782-2016.

Turn-around Time: Presumptive PCR: 1 day

Confirmation testing 7 days (IDPH)

Ship to: Chicago or Springfield IDPH Laboratories

Yersinia spp.

Test Name: Isolation and Identification of *Yersinia spp.* (only when requested during an outbreak)

Method Name: Culture and biochemical reactions are used for the isolation and identification of

Yersinia spp.

Results: Positive/Negative for the detection of *Yersinia spp*.

Reference Ranges: Negative for the detection *Yersinia spp*.

Clinical Significance: Enteric pathogens cause a variety of human diseases. The severity of the disease

depends on the virulence of the strain and the condition of the host and can be a mild self-limiting gastroenteritis or become more severe with bacteremia or typhoid fever, which can be life threatening. Early detection allows for effective management and

identification of possible outbreaks.

Submission Criteria: Clinical - Stool submitted at room temperature in Cary-Blair vial or swab; received by

IDPH within 72 hours (swab) or 96 hours (vial).

Referred Isolates – Submit isolate at room temperature on slant [e.g., BHI, Heart infusion (HI) slant], or on sealed plates (if delivered by courier) on solid media that is

non-inhibitory (e.g., BAP). Indicate source on request form and specimen.

Rejection Criteria: Specimen received without unique identifier (name or other ID), or the identifier does

not match the identifier on the submission form. Specimen received without date of collection. Specimen received without submission form. Specimens not submitted according to submission criteria or according to rules and regulations for transporting

clinical specimens or infectious substances.

Turn Around Time: 7 days

Authorization: No authorization number is required. Submission is required by Illinois Administrative

Rule Part 690. Notify your LHD if you suspect this infection. Clinical specimens should be

discussed with an LHD.

Ship to: Chicago or Springfield IDPH Laboratories

Shipping Kits: See Ordering or Requesting Clinical or Environmental Supplies.

Aerobic and Coliform Count in Dairy Products using Petri-film

Test Name: Aerobic and Coliform Count in Dairy Products

Method Name: Petri-film

Results: Reported as Petrifilm Aerobic Count (PAC) per 1 mL or 1 gram and Petri-film Coliform

Count per 1 mL or 1 gram.

Reference Ranges: Acceptable results are as follows:

	Grade A Finished Products	Grade B Finished Products	Grade A Raw Samples	Grade B Raw Samples
PAC	≤20,000	≤50,000	≤300,000	≤1,000,000 for cheese plants and ≤500,000 for ice cream plants
HSCC	≤10	≤20	N/A	N/A

Clinical Significance: High bacterial counts in dairy samples could indicate the presence of pathogenic

bacteria. Pathogenic bacteria in dairy samples could lead to an outbreak of illness

among consumers.

Submission Criteria: Samples collected for analysis must be refrigerated (0° to 4.5°C) at the time of

collection. Samples received <3 hours from time of collection may be ≤7°C if the samples

are cooler than when they were collected. Record the times and dates of sample collection for each set of samples. Upon receipt in the laboratory, the temperature of each set of samples is determined by recording the temperature of a separate container that has been treated exactly like the samples and transported with them. This pilot sample must be at least one half the size of the largest container in the cooler.

Rejection Criteria: Testing will not be performed if samples are not within the required temperature range

(0° to 4.5°C) or are not received within the time required to start testing (60 hours).

Samples received in leaky containers will also be rejected.

Authorization: Dairy samples are accepted from milk sanitarians employed by the IDPH regional offices.

Testing requirements and frequency of testing are determined by the FDA and

monitored by the IDPH Division of Food, Dairies, and Devices as part of the Grade A Milk

Program.

Turn Around Time: 5 days

Ship to: Carbondale, Chicago, or Springfield IDPH Laboratories

Shipping Kits: No shipping kits are provided by IDPH laboratory. Milk sanitarians transport samples in

coolers provided by IDPH regional offices.

Submission Form: Dairy Sample Submission Form

Alkaline Phosphatase in Dairy Samples

Test Name: Alkaline Phosphatase in Dairy Samples

Method Name: Charm Paslite

Results: Reported as positive or not found. If positive, reported as residual phosphatase,

microbial phosphatase, or reactivated phosphatase present.

Reference Ranges: >350 mU/L is considered a positive result.

Clinical Significance: Detection of improper milk pasteurization or the addition of raw milk to pasteurized

milk.

Submission Criteria: Samples collected for analysis must be refrigerated (0 to 4.5°C) at the time of collection.

Samples received <3 hours from time of collection may be ≤7°C if the samples are cooler than when they were collected. Record the times and dates of sample collection for each set of samples. Upon receipt in the laboratory, the temperature of each set of samples is determined by recording the temperature of a separate container that has been treated exactly like the samples and transported with them. This pilot sample must

be at least one half the size of the largest container in the cooler.

Rejection Criteria: Testing will not be performed if samples are not within the required temperature range

(0 to 4.5°C) or are not received within the time required to start testing (60 hours).

Samples received in leaky containers will also be rejected.

Authorization: Dairy samples are accepted from milk sanitarians employed by the IDPH regional offices.

Testing requirements and frequency of testing are determined by the FDA and

monitored by the IDPH Division of Food, Dairies, and Devices as part of the Grade A Milk

Program.

Turn Around Time: 5 days

Ship to: Carbondale, Chicago, or Springfield IDPH Laboratories

Shipping Kits: No shipping kits are provided by IDPH laboratory. Milk sanitarians transport samples in

coolers provided by IDPH regional offices.

Submission Form: Dairy Sample Submission Form

E. coli O157:H7 and Shiga Toxin Producing E. coli (STEC) in Food and Environmental Swabs/Sponges

Test Name: E. coli O157:H7 in Food and Environmental Swabs/Sponges

Method Name: PCR Method for STEC, BioMerieux VIDAS Method for E. coli O157:H7 or Cultural Method

for E. coli O157:H7 (cultural method performed only if PCR and/or VIDAS instrument

and/or reagents are not available).

Results: Reported as detected or not detected.

Reference Ranges: E. coli O157:H7 or Shiga Toxin Producing E. coli not detected.

Clinical Significance: Early detection allows for effective clinical management and identification of a possible

outbreak of E. coli O157:H7 or STEC.

Submission Criteria: Samples should be representative of the food being tested. Sample size should be 200-

400 grams (minimum of 25 g) of food per test requested. Food samples less than 25 grams may be tested, if necessary, but the results may not be representative of the sample. Frozen samples should be kept frozen until received in the laboratory. Refrigerated samples should be kept refrigerated until received in the laboratory. Environmental swab/sponge samples are to be kept cool until testing can be performed

and can be sent in the same cooler as food samples if both are being submitted. Samples should be shipped or transported to the laboratory so that they arrive at the laboratory as soon as possible after collection. Each sample should be logged onto a Food Investigation Submission Form. If more than one sample is submitted, a Sample Cover Sheet must also be filled out. The necessary information includes source, location,

temperature, date, time of collection, collector's name, symptoms, and test(s)

requested.

Rejection Criteria: Testing may not be performed if sample labeling or submission form data is insufficient.

Authorization: Food samples are accepted only from regional, county, or city sanitarian personnel. The

sanitarian contacts the epidemiologist of IDPH Division of Infectious Diseases and/or the Division of Food, Dairies, and Devices to receive assistance in determining the necessity of testing food samples for *E. coli* O157:H7. After it is determined by the IDPH Division of Infectious Diseases and/or the IDPH Division of Food, Dairies, and Devices that testing is necessary, the IDPH laboratory should be contacted with the method of shipment and

the expected time of arrival.

Turn Around Time: 7 days

Ship to: Springfield IDPH Laboratory

Shipping Kits: Foodborne Illness Kit: See Ordering or Requesting Clinical or Environmental Supplies.

Submission Form: Sample Cover Sheet and Food Investigation Submission Form

Environmental Lead

Test Name: Environmental Lead

Method Name: Determination of Lead in by Inductively Coupled Plasma Atomic - Emission

Spectroscopy.

Results: Results reported for Dust Wipe: ug/wipe, Air Filter: ug/air filter, paint: %, and Soil: ug/g.

Reference Ranges: Dust Wipe: < 5 ug, Air Filter <5 ug, Paint <0.005%, and Soil <10 ug/g.

Clinical Significance: Source of lead exposure need to be identified. Prolonged exposure to lead causes health

problems, including delayed mental and physical development and learning deficiencies

in infants and young children.

Submission Criteria: The Chicago IDPH Laboratory is accredited for paint, soil, dust wipe, and air filter

matrices by the American Industrial Hygiene Association Laboratory Accreditation Program (AIHA LAP, LLC) according to requirements of the National Lead Laboratory Accreditation Program (NLLAP). The laboratory will supply sample tubes and dust wipe media upon request. Paint chips should be free of underlying matrix and are analyzed as submitted. Submit paint sample in 50 mL digestion tubes. A minimum of 200 mg of paint

sample is required for analysis. Submit soil samples in 50 mL digestion tubes. A minimum of 1.0 gm. of soil sample is required for analysis. Only dust wipes supplied by

the laboratory or wipe materials meeting ASTM E 1792 requirements will be analyzed. Dust wipe samples must be collected separately in 50 mL digestion tubes to avoid cross contamination. A control should be supplied along with each batch of submitted wipe samples. Various foods, toys, flatware, and other items (matrices not accredited by AIHA

LAP, LLC) can also be tested as "Other" upon request. Contact the laboratory for

instructions.

Rejection Criteria: Wipes not supplied by the laboratory or wipe materials not meeting ASTM E1792

requirements will not be accepted. Paint and soil samples not meeting minimum required quantity may not be analyzed. Samples with missing or incomplete forms or

samples not properly identified will not be analyzed by laboratory.

Authorization: Paint chips, dust wipes, soil samples, air filter, and "other" samples will be accepted only

from the IDPH Division of Environmental Health or a local health department.

Turn Around Time: 1-5 days

Ship to: Chicago IDPH Laboratory

Shipping Kits: See Ordering or Requesting Clinical or Environmental Supplies.

Submission Form: Lead Sample Submission Form

Inhibitory Substances in Dairy Samples – Charm

Test Name: Inhibitory Substances in Dairy Samples

Method Name: Charm SL-3

Results: Reported as positive for Beta-lactam or Beta-lactam not found.

Reference Ranges: Beta-lactam not found.

Clinical Significance: To detect the presence of 6 of 6 Beta-lactam antibiotics in raw milk, which would

indicate that the raw milk was obtained from an unacceptable source. The presence of Beta-lactam antibiotics would also invalidate the coliform and aerobic bacteria counts

by inhibiting growth.

Submission Criteria: Samples collected for analysis must be refrigerated (0 to 4.5°C) at the time of collection.

Samples received <3 hours from time of collection may be ≤7°C if the samples are cooler than when they were collected. Record the times and dates of sample collection for each set of samples. Upon receipt in the laboratory, the temperature of each set of samples is determined by recording the temperature of a separate container that has been treated exactly like the samples and transported with them. This pilot sample must

be at least one half the size of the largest container in the cooler.

Rejection Criteria: Testing will not be performed if samples are not within the required temperature range

(0 to 4.5°C) or are not received within the time required to start testing (60 hours).

Samples received in leaky containers will also be rejected.

Authorization: Dairy samples are accepted from milk sanitarians employed by the IDPH regional offices.

Testing requirements and frequency of testing are determined by the FDA and

monitored by the IDPH Division of Food, Dairies, and Devices as part of the Grade A Milk

Program.

Turn Around Time: 5 days

Ship to: Carbondale, Chicago, or Springfield IDPH Laboratories

Shipping Kits: No shipping kits are provided by IDPH laboratories. Milk sanitarians transport samples in

coolers provided by their IDPH regional offices.

Submission Form: Dairy Sample Submission Form

Inhibitory Substances in Dairy Samples – Delvotest

Test Name: Inhibitory Substances in Dairy Samples

Method Name: Delvotest P 5-Pack.

Results: Reported as positive or not found.

Reference Ranges: Beta-lactam not found.

Clinical Significance: To detect the presence of 4 of 6 Beta-lactam antibiotics in raw milk and finished milk

products which would indicate that the raw milk was obtained from an unacceptable source. The presence of Beta-lactam antibiotics would also invalidate the coliform and

aerobic bacteria counts by inhibiting growth.

Submission Criteria: Samples collected for analysis must be refrigerated (0 to 4.5°C) at the time of collection.

Samples received <3 hours from time of collection may be ≤7°C if the samples are cooler than when they were collected. Record the times and dates of sample collection for each set of samples. Upon receipt in the laboratory, the temperature of each set of samples is determined by recording the temperature of a separate container that has been treated exactly like the samples and transported with them. This pilot sample must

be at least one half the size of the largest container in the cooler.

Rejection Criteria: Testing will not be performed if samples are not within the required temperature range

(0 to 4.5°C) or are not received within the time required to start testing (60 hours).

Samples received in leaky containers will also be rejected.

Authorization: Dairy samples are accepted from milk sanitarians employed by the IDPH regional offices.

Testing requirements and frequency of testing are determined by the FDA and

monitored by the IDPH Division of Food, Dairies, and Devices as part of the Grade A Milk

Program.

Turn Around Time: 5 days

Ship to: Carbondale, Chicago, or Springfield IDPH Laboratories

Shipping Kits: No shipping kits are provided by IDPH laboratory. Milk sanitarians transport samples in

coolers provided by their IDPH regional offices.

Submission Form: Dairy Sample Submission Form

Detection of Legionella from Environmental Waters and Swabs

Test Name: Detection of *Legionella* Species by Culture, PCR, and IDEXX Legiolert

Method Name: Culture, PCR, and IDEXX Legiolert.

Results: Culture, PCR, and IDEXX Legiolert methods are used in combination to detect and to

isolate Legionella species from potable, non-potable water, and environmental swabs using PCR and culture methods. The Legiolert test detects Legionella pneumophila at \geq 10 organisms/100 mL when using potable water and Legionella pneumophila at \geq 10

organisms/mL (≥1000 organism/100 mL) when testing non-potable water.

Reference Range: Legionella species Not Detected, Legionella pneumophila Not Detected.

Clinical Significance: Legionella is commonly found in environmental sources, typically in man-made warm

water systems. The mode of transmission from these reservoirs is aerosolization, aspiration, or direct inoculation into the airway. Direct person-to-person transmission does not occur. The spectrum of illness caused by *Legionella* species ranges from a mild, self-limited flu-like illness (Pontiac fever) to a disseminated and often fatal disease characterized by pneumonia and respiratory failure (Legionnaire's disease). Risk factors

include smoking, chronic lung disease, and immunosuppression.

Submission Criteria: Use only laboratory supplied collection containers. Include sample

identification/location, date and time of collection, sample type, and collector's name. Submit 1 liter of bulk water within 30 hours of collection. Submit flocked swabs in 3–7 mL of source water collected in approved sterile collection tubes within 30 hours of collection. Use IDPH approved water submission form appropriate for sample type.

Rejection Criteria: Samples received that are greater than four days or 96 hours from collection.

Unapproved swab types (i.e., wood shafted, calcium alginate). Swabs not collected in source water (i.e., dry swabs). Samples received without a completed test requisition. No date and time of collection. Samples leaked or broken in transit. Samples containing

an interfering substance.

Authorization: Prior approval from the local health department or IDPH regional office is required.

Turn Around Time: 9 days

Ship to: Springfield IDPH Laboratory

Shipping Kits: See Ordering or Requesting Clinical or Environmental Supplies.

Submission Form: Use IDPH approved water submission form appropriate for sample type.

Listeria species in Food and Environmental Swab/Sponge Samples

Test Name: Listeria Species in Food and Environmental Swab/Sponge Samples

Method Name: PCR Method, BioMerieux VIDAS Method or Cultural Method (cultural method

performed only if PCR and/or VIDAS instrument and/or reagents are not available).

Results: Reported as *Listeria monocytogenes* detected or not detected. Also, if another *Listeria*

species is found, it is reported as Listeria species detected. Species detected will be

specified.

Reference Ranges: Listeria species not detected.

Clinical Significance: Early detection allows for effective clinical management and identification of a possible

outbreak of Listeria monocytogenes or another Listeria spp.

Submission Criteria: Samples should be representative of the food being tested. Sample size should be 200-

400 grams (minimum of 25 g) of food per test requested. Food samples less than 25 grams may be tested, if necessary, but the results may not be representative of the sample. Frozen samples should be kept frozen until received in the laboratory. Refrigerated samples should be kept refrigerated until received in the laboratory. Environmental swab/sponge samples are to be kept cool until testing can be performed

and can be sent in the same cooler as food samples if both are being submitted.

Samples should be shipped or transported to the laboratory so that they arrive at the laboratory as soon as possible after collection. Each sample should be logged onto a Food Investigation Submission Form. If more than one sample is submitted, a Sample Cover Sheet must also be filled out. The necessary information includes source, location,

temperature, date, time of collection, collector's name, symptoms, and test(s)

requested.

Rejection Criteria: Testing may not be performed if sample labeling or submission form data is insufficient.

Authorization: Food samples and environmental swab/sponge samples are accepted only from

regional, county, or city sanitarian personnel. The sanitarian contacts the epidemiologist of the IDPH Division of Infectious Diseases and/or the IDPH Division of Food, Dairies, and Devices to receive assistance in determining the necessity of testing samples for *Listeria*. After it is determined by the IDPH Division of Infectious Diseases and/or the IDPH Division of Food, Dairies, and Devices that testing is necessary, the IDPH laboratory should be contacted with the method of shipment and the expected time of arrival.

Turn Around Time: 7 days

Ship to: Springfield IDPH Laboratory

Shipping Kits: Foodborne Illness Kit: See Ordering or Requesting Clinical or Environmental Supplies.

Submission Form: Sample Cover Sheet and Food Investigation Submission Form

Residual Bacterial Count in Milk Container

Test Name: Residual Bacterial Count in Milk Containers

Method Name: Petri-film

Results: Reported as a Petri-film Aerobic Count (PAC) per container and Petri-film Coliform

Count per container.

Reference Ranges: 0 cfu's in milk container.

Clinical Significance: The detection of bacteria in the pasteurized milk container indicates a failure to sterilize

containers by the dairy facility.

Submission Criteria: Milk containers are received at room temperature with the lids securely in place.

Rejection Criteria: Containers with no lids or cracked containers.

Authorization: Milk containers are accepted from milk sanitarians employed by the IDPH regional

offices. Testing requirements and frequency of testing are determined by the FDA and monitored by the IDPH Division of Food, Dairies, and Devices as part of the Grade A Milk

Program.

Turn Around Time: 5 days

Ship to: <u>Carbondale, Chicago, or Springfield IDPH Laboratories</u>

Shipping Kits: No shipping kits are provided by IDPH laboratories. Milk sanitarians transport containers

at room temperature.

Submission Form: Dairy Sample Submission Form

Ricin communis (ricin) Toxin

Test Name: Identification Ricin Toxin

Method Name: Time-Resolved Fluorescence Immunoassay (TRF) for Ricin Toxin.

Results: Ricin toxin.

Reference Ranges: Negative or reactive for ricin toxin.

Clinical Significance: Ricin toxin is a substance found in castor beans (species *Ricinus communis*). It would

take a deliberate act to make ricin toxin and use it as a poison. Unintentional exposure to ricin is highly unlikely, unless through the ingestion of castor beans. Symptoms depend upon the type and level of exposure. Inhalational exposure results in difficulty breathing, fever, cough, and chest tightness, leading up to excess fluid in the lungs and respiratory failure. Ingestional exposure leads to vomiting, diarrhea, dehydration, seizures, and eventual kidney, liver, and spleen failure. There is no antidote to exposure;

only supportive care can be given. Death usually occurs in 36-72 hours.

Submission Criteria: Acceptable specimens include:

a. Environmental sample

Rejection Criteria: Samples not pre-screened by a certified HAZMAT team for explosive, chemical, and

radiological contamination; or samples not submitted by the FBI, CST, or other

designated law enforcement.

Authorization: No authorization number is required. Notify your LHD if you suspect this infection.

Turn Around Time: 2 days for TRF

Ship to: <u>Carbondale, Chicago, or Springfield IDPH Laboratories</u>

Submission Form: Threat Agent Laboratory Test Requisition (also serves as a chain of custody form).

Salmonella in Food and Environmental Swab/Sponge Samples

Test Name: Salmonella in Food and Environmental Swab/Sponge Samples

Method Name: PCR Method, BioMerieux VIDAS Method, Cultural Method (cultural method performed

only if PCR and/or VIDAS instrument and/or reagents are not available).

Results: Reported as detected or not detected.

Reference Ranges: Salmonella species not detected.

Clinical Significance: Early detection allows for effective clinical management and identification of a possible

outbreak of Salmonella.

Submission Criteria: Samples should be representative of the food being tested. Sample size should be 200-

400 grams (minimum of 25 g) of food per test requested. Food samples less than 25 grams may be tested, if necessary, but the results may not be representative of the sample. Frozen samples should be kept frozen until received in the laboratory. Refrigerated samples should be kept refrigerated until received in the laboratory. Environmental swab/sponge samples are to be kept cool until testing can be performed and can be sent in the same cooler as food samples if both are being submitted. Samples should be shipped or transported to the laboratory so that they arrive at the laboratory as soon as possible after collection. Each sample should be logged onto a Food Investigation Submission Form. If more than one sample is submitted, a Sample Cover Sheet must also be filled out. The necessary information includes source, location,

temperature, date, time of collection, collector's name, symptoms, and test(s)

requested.

Rejection Criteria: Testing may not be performed if sample labeling or submission form data is insufficient.

Authorization: Food samples and environmental swab/sponge samples are accepted only from

regional, county, or city sanitarian personnel. The sanitarian contacts the epidemiologist of IDPH Division of Infectious Diseases and/or the IDPH Division of Food, Dairies, and Devices to receive assistance in determining the necessity of testing samples for *Salmonella* species. After it is determined by the IDPH Division of Infectious Diseases and/or the IDPH Division of Food, Dairies, and Devices that testing is necessary, the IDPH laboratory should be contacted with the method of shipment and the expected

time of arrival.

Turn Around Time: 7 days

Ship to: Springfield IDPH Laboratory

Shipping Kits: Foodborne Illness Kit: See <u>Ordering or Requesting Clinical or Environmental Supplies</u>.

Submission Form: Sample Cover Sheet and Food Investigation Submission Form

Total Coliform and E. coli Coliform in Water - Colilert

Test Name: Determination of Total Coliforms and *E. coli* in Water

Method Name: Colilert Presence/Absence, Quanti-Tray 51 and Quanti-Tray 2000.

Results: For Drinking Waters: Total coliform and E. coli present or not found per 100 mL for P/A

and total coliform and E. coli count/100 mL for QT 51 and QT 2000.

For Bathing Beaches: E. coli count/100 mL for QT 2000.

Reference Range: Total and E. coli coliform Not Found or <1/100 mL.

Clinical Significance: Detection of coliform bacteria in water is an indicator of the overall bacteriological

quality of the water. Coliform presence is an indicator that the water may contain other pathogenic or disease-causing bacteria. The presence of E. coli in bathing beaches can

cause illness if ingested by bathers.

Submission Criteria: Use only laboratory supplied collection containers. Sample bottles must be filled to the

fill line on the bottle. Include sample identification/location, date and time of collection, sample type, and collector's name. Submit 120-150 mL of water within 30 hours of collection. Use IDPH approved water submission form appropriate for sample type.

Rejection Criteria: Samples received that are greater than 30 hours from collection. Samples received

without a complete test requisition. No date and time of collection. Samples leaked or

broken in transit. Samples containing an interfering substance.

Authorization: Prior approval from the local health department or regional office is required.

Turn Around Time: 3 days

Ship to: Carbondale, Chicago, or Springfield IDPH Laboratories

Shipping Kits: See Ordering or Requesting Clinical or Environmental Supplies.

Submission Form: Use IDPH approved water submission form appropriate for sample type.

Total Coliform in Dairy Water - MTF

Test Name: Determination of Total Coliform in Dairy Glycol Water

Method Name: Multiple Tube Fermentation (MTF).

Results: Reported as total coliform <1 not found /100 mL or ≥1 present /100 mL.

Reference Range: Total coliform <1 not found.

Clinical Significance: Detection of coliform bacteria in glycol water is an indicator of the overall

bacteriological quality of the water. Coliform presence is an indicator that the water

may contain other pathogenic or disease-causing bacteria.

Submission Criteria: Use only laboratory supplied collection containers. Sample bottles must be filled to the

fill line on the bottle. Include sample identification/location, date and time of collection, sample type, and collector's name. Samples must be submitted within 30 hours of

collection.

Rejection Criteria: Samples received more than 30 hours after collection. Samples received without a

complete test requisition. No date and time of collection. Samples leaking or broken in

transit. Samples containing an interfering substance.

Authorization: Dairy glycol water samples are accepted from milk sanitarians employed by the IDPH

regional offices. Testing requirements and frequency of testing are determined by the FDA and monitored by the IDPH Division of Food, Dairies, and Devices as part of the

Grade A Milk Program.

Turn Around Time: 5 days

Ship to: Carbondale, Chicago, or Springfield IDPH Laboratories

Shipping Kits: See Ordering or Requesting Clinical or Environmental Supplies.

Submission Form: Dairy Water Sample Submission Form

Enteric Pathogens Whole Genome Sequencing (For Epidemiology use only)

Test Name: Whole Genome Sequencing (WGS) - PulseNet

Method Name: Salmonella, Escherichia, Listeria, Vibrio, and Campylobacter – For routine Enteric

isolates, whole genome sequencing (WGS) is performed, and results are sent to the CDC

PulseNet national database.

Results: WGS data submitted to CDC PulseNet national database for cluster analysis and

outbreak detection (WGS for epidemiological use only).

Reference Ranges: N/A

Clinical Significance: Enteric pathogens cause a variety of human diseases. The severity of the disease

depends on the virulence of the strain and the condition of the host and can be a mild, self-limiting gastroenteritis or become more severe with bacteremia or typhoid fever, which can be life threatening. Early detection allows for effective management and

identification of possible outbreaks.

Submission Criteria: Clinical or Environmental Isolate - Isolate submitted at room temperature on

nonselective slant, such as TSA, HIA, etc. Indicate source on request form and specimen. Specimens for Campylobacter should be sent directly to the Springfield laboratory.

Rejection Criteria: Specimen received without unique identifier (name or other ID) on the specimen or the

identifier does not match the identifier on the submission form. Specimen received without date of collection. Specimen received without submission form. Specimens not submitted according to submission criteria or according to rules and regulations for

transporting clinical specimens or infectious substances.

Authorization: No authorization number is required. Submission is required by Illinois Administrative

Rule Part 690. Notify your LHD if you suspect this infection.

Turn Around Time: 7 days

Ship to: Chicago or Springfield IDPH Laboratories

Shipping Kits: See <u>Ordering or Requesting Clinical or Environmental Supplies.</u>

Submission Form: Communicable Disease Test Requisition Form

Listeria monocytogenes (For Epidemiology use only.)

Test Name: Whole Genome Sequencing (WGS) - PulseNet

Method Name: Listeria – For routine Listeria isolates, whole genome sequencing (WGS) is performed,

and results are sent to the CDC PulseNet national database.

Results: WGS data submitted to CDC PulseNet national database for cluster analysis and

outbreak detection (WGS for epidemiological use only).

Reference Ranges: N/A

Clinical Significance: Cause of Listeriosis, a serious infection usually caused by eating food contaminated with

the bacteria *Listeria monocytogenes*. The disease primarily affects older adults, pregnant women, newborns, and adults with weakened immune systems. Symptoms

include fever, muscle aches, and diarrhea.

Submission Criteria: Clinical or Environmental Isolate - Isolate submitted at room temperature on

nonselective slant, such as TSA, HIA, etc. Indicate source on request form and specimen.

Rejection Criteria: Specimen received without unique identifier (name or other ID) on the specimen, or the

identifier does not match the identifier on the submission form. Specimen received without date of collection. Specimen received without submission form. Specimens not submitted according to submission criteria or according to rules and regulations for

transporting clinical specimens or infectious substances.

Authorization: No authorization number is required. Submission is required by Illinois Administrative

Rule Part 690. Notify your LHD if you suspect this infection.

Turn Around Time: 5 days

Ship to: <u>Chicago or Springfield IDPH Laboratories</u>

Shipping Kits: See Ordering or Requesting Clinical or Environmental Supplies.

Submission Form: Communicable Disease Test Requisition Form

Monkey Pox Clade Typing by PCR

Test Name: Monkey Pox Clade Typing by PCR

Method Name: Detection of Monkey Pox with Real-Time PCR (RT-PCR)

Results: MPX Clade II Virus DNA detected, MPX detected, possible Clade I MPX, Equivocal, not

detected

Reference Ranges: MPX not detected

Clinical Significance: None – epidemiological use only

Submission Criteria: See Orthopox Screen, Molecular page for more details. The clade typing assay is used

only on specimens that test positive for Non-Variola Orthopox DNA.

Acceptable specimens for Monkeypox testing are dry swabs taken from the lesion site or dry swabs taken from the lesion site collected in 1-3 mL of viral transport media (VTM) or universal transport media (UTM). Specimens are to be labeled with the full patient's name, date of birth, and date of collection. Specimens are to be shipped on dry

ice or cold packs and arrive at the IDPH testing laboratory between -20 to + 8°C. Specimens must be received at the laboratory within 96 hours of collection and within

24 hours of shipping from the provider. Specimens not meeting these criteria will be rejected from testing. For short-term storage (i.e., \leq 3 days), specimens may be stored at 2-8°C. For long-term storage, specimens are stored at -70°C for up to 12 months.

Rejection Criteria: Unacceptable specimens include those with mismatched requisitions, specimens

without patient identifiers, specimens stored or shipped incorrectly, specimens without testing authorization, and specimens collected using prohibited materials (Swab specimens should be collected only on swabs with a synthetic tip (such as polyester or Dacron®) with aluminum or plastic shafts. Swabs with calcium alginate or cotton tips with wooden shafts are not acceptable. Use only synthetic fiber swabs with plastic

shafts.).

Authorization: Prior approval from the IDPH Communicable Disease Control Section at 217-782-2016.

Turn Around Time: 3-5 days

Ship to: Chicago IDPH Laboratory

Shipping Kits: See <u>Ordering or Requesting Clinical or Environmental Supplies.</u>

Submission Form: <u>ETOR submission only</u>

Norovirus (Norwalk-like virus, NLV)

Test Name: Detection of Norovirus

Method Name: Molecular detection (RT-PCR) of Norovirus Types G1 and G2.

Results: Norovirus types G1 and G2 Detected or Not Detected (Norovirus for epidemiological

use only).

Reference Range: Norovirus not detected.

Clinical Significance: Early detection allows for effective clinical management and identification of possible

outbreaks of Norovirus.

Submission Criteria: Collected stool specimens should be stored refrigerated after collection, shipped cold on

ice packs, and received within ten days from collection. All specimens must be labeled with a unique identifier. Refer to following link for further collection and submission

information. Patient Instructions for Stool Collection.

Rejection Criteria: Specimens other than stool, improperly completed test request, no patient identifier on

specimen, broken or leaking specimen, specimen shipped and/or received at improper

temperature, specimen received greater that ten days from collection shipping.

Authorization: Prior approval from your LHD with an outbreak investigation number is required. For

questions, contact your LHD or the IDPH Communicable Disease Control Section at 217-

782-2016.

Turn Around Time: 5 days

Ship to: Springfield IDPH Laboratory

Shipping Kits: See <u>Ordering or Requesting Clinical or Environmental Supplies.</u>

Submission Form: Communicable Disease Test Requisition Form

Rabies Virus (animal)

Test Name: Detection of Rabies Virus in Animals

Method Name: Direct fluorescent antibody (DFA) test for the detection of rabies virus proteins in

animal tissues.

Results: Positive, negative, and inconclusive for the detection of rabies virus.

Clinical Significance: Early detection allows for rapid post exposure treatment of exposed individuals. Since

clinical rabies is most often fatal, rapid treatment can be lifesaving. See the IDPH Communicable Disease Control Section website for more information here.

Submission Criteria: Submit whole animals for specimens weighing less than 2 pounds (i.e., bat, mouse).

Submit only the head if the animal weighs 2-20 pounds (i.e., dog, cat, raccoon). Brain tissue must be undamaged, allowing proper identification of specific brain sections. The

specimen should be submitted immediately after collection and shipped on ice.

Rejection Criteria: Non-mammalian species. Specimens with damaged or decomposed tissue that cannot

be identified. Use of preservatives other than refrigeration. Specimens received without

all required brain sections.

Authorization: Rabies specimens must be submitted through the local animal control, local health

department, or a veterinarian.

Turn Around Time: 2 days

Ship to: Carbondale, Chicago, or Springfield IDPH Laboratories

Submission Form: Rabies Submission Form

Whole Genome Sequencing of SARS-CoV-2 (For Epidemiological use only)

Test Name: Whole Genome Sequencing of *SARS-CoV-2*

Methods: Whole Genome Sequencing of *SARS-CoV-2* for the detection of variants.

Results: Pangolin Lineage variant information for surveillance and outbreak detection (WGS for

Epidemiological use only).

Reference Ranges: N/A

Clinical Significance: Human infection with 2019-nCoV can produce symptoms from mild to severe. These

symptoms include severe acute respiratory illness with fever, cough, and shortness of breath. Some patients also have shown gastrointestinal distress and/or renal failure. The virus can be transmitted from person to person. Whole Genome Sequencing of SARS-CoV-2 assay is intended for use as an aid in identifying variant information in

individuals with SARS-CoV-2.

Submission Criteria: Specimen type includes upper and lower respiratory specimens, such as nasopharyngeal

or oropharyngeal swabs, sputum, lower respiratory tract aspirates, bronchoalveolar lavage, and nasopharyngeal wash/aspirate or nasal aspirate collected from individuals who meet CDC criteria for 2019-nCoV testing. The minimum sample volume required is 2 mL in VTM. Collection should occur as quickly as possible and performed according to standard technique and placed in viral transport media (VTM). The optimum specimen type and timing for peak viral levels during infections caused by 2019-nCov have not

been determined.

Rejection Criteria: Specimen received without unique identifier (name or other ID), or the identifier does

not match the identifier on the submission form. Specimen received without date of collection. Specimen received without submission form. Specimens not submitted according to submission criteria or according to rules and regulations for transporting clinical specimens or infectious substances. Specimens with gross hemolysis. Specimens

that have been heat-inactivated.

Turn Around Time: 5 days

Authorization: No authorization number is required.

Ship to: Springfield or Chicago IDPH Laboratories

Shipping Kits: See <u>Ordering or Requesting Clinical or Environmental Supplies.</u>

Submission Form: <u>Communicable Disease Test Requisition Form</u>

Tick Surveillance

Test Name: Detection of *Rickettsia parkeri, Rickettsia rickettsia, Ehrlichia chaffeensis,* and *Ehrlichia*

ewingii pathogens isolated from ticks.

Method Name: Polymerase chain reaction for Detection of *Rickettsia parkeri, Rickettsia rickettsia*,

Ehrlichia chaffeensis and Ehrlichia ewingii pathogens isolated from ticks.

Results: DNA Detected/Not for the following targets: *Rickettsia rickettsii* and *Rickettsia parkeri* or

Ehrlichia chaffeensis and Ehrlichia ewingii.

Reference Ranges: DNA not detected for the following targets: Rickettsia rickettsii and Rickettsia parkeri or

Ehrlichia chaffeensis and Ehrlichia ewingii.

Clinical Significance: Rickettsia rickettsii is associated with the American Dog tick (Dermacentor variabilis) and

is the causative agent of Rocky Mountain Spotted fever (RMSF) when passed to a human host. Common signs and symptoms of RMSF are fever, headache, nausea, vomiting and stomach pain. Nearly all RMSF infections will cause a rash development, however onset of rash development is often delayed, and presentation is variable making successful

medical diagnosis difficult. RMSF can be fatal if left untreated.

Rickettsia parkeri is associated with the Gulf Coast tick (*Amblyomma maculatum*) and causes Rickettsiosis in infected humans. Both Rickettsiosis and RMSF have similar presentations of disease but can be differentiated by the appearance of an eschar,

which is not a common manifestation of RMSF.

Ehrlichia chaffeensis and Ehrlichia ewingii are tickborne pathogens associated with the Lone Star tick (Amblyomma americanum) and causes Ehrlichiosis when introduced into a human host. E. chaffeensis is associated with monocytic Ehrlichiosis while E. ewingii is associated with granulocytic Ehrlichiosis. Signs and symptoms include fever, chills, headache, muscle pain and rash. Ehrlichiosis can be severe or fatal in neonatal and

geriatric populations.

Submission Criteria: Whole ticks in 70% Ethanol (EtOH) are the only acceptable specimen type for this assay.

Ticks are collected by participating local county health departments (LHDs) by

performing tick drags in field and submitted to the Vectorborne Disease (VBD) office for speciation and storage in EtOH. Ticks must be of the following species: *Dermacentor*

variabilis, Amblyomma maculatum or Amblyomma Americanum.

Rejection Criteria: Ticks from species other than those listed. Ticks from non-VBD sources. Ticks not

properly stored in ethanol. Ticks collected from individuals.

Authorization: Ticks must be approved and speciated by VBD office.

Turn-around Time: 30 Days

Ship to: Springfield IDPH Laboratory

Submission Form: Ehrlichia Submission Template or Rickettsia Submission Template.