Testing Services Handbook

Fry Laboratories, L.L.C.
14807 N. 73rd Street
Suite #103
Scottsdale, AZ 85260
Monday-Friday
8AM – 5PM Arizona Time

1.866.927.8075 (toll free)
480.292.8560 (phone)
480.292.8457 (billing)
480.656.4932 (fax)
CLIA#: 03D1026968
NPI#: 1457515744

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Laboratory Summary

Fry Laboratories, L.L.C. is an independent clinical diagnostic and research laboratory located in Scottsdale, Arizona. Through research we are committed to improving the understanding of chronic diseases and contributing to their cure through advancements in diagnostics and basic science. We focus on chronic inflammatory diseases, vector-borne diseases, and their intersection.

Our clinical diagnostic laboratory offers infectious disease immunology services. Additionally, we provide standard and cutting edge infectious and vector-borne disease detection and identification technologies. Our signature services include microscopy for visual identification and quantification of a wide range of blood-borne pathogens, comprehensive co-infection serology, and biofilm detection. Furthermore, we provide advanced molecular detection technologies including DNA sequencing for individualized species and/or strain identification. We participate in both CAP and API quality control programs and provide our testing services worldwide.

This Diagnostic Services Handbook is designed to be a convenient and handy desk reference to provide useful and easy to read information about our testing services. Please periodically verify the accuracy of your ordering forms prior to use by visiting the forms section at: www.frylabs.com

We bill insurance for DNA sequencing and are considered out of network for most providers, except Medicare. We do not accept insurance assignment for all our other testing, other than Medicare. Please note that Fry Laboratories currently does not accept samples drawn or obtained in the state of New York. If you have any questions, please visit the contact us section or feel free to call us at our toll-free number: 1.866.927.8075

Letter from the Director

January 11th, 2018

I established Fry Laboratories, L.L.C. to determine the underlying cause of many of the chronic diseases. Our viewpoint is that many chronic illnesses have their origins in non-viral infectious or vector-borne agents including eukaryotes (fungi, protozoa, algae, and metazoan). Once we can determine the causality, we are able to supply clinicians with the underlying etiologic agent. This knowledge has translated into improved, and in some instances startlingly improved, outcomes. Along this journey the laboratory has embraced old standard microscopy, developed new staining and sample preparation technologies, and made use of off-the-shelf serologic assays. The “Gold Standard” for organism identification is rapidly transitioning from culture methods to molecular fingerprinting which has become our primary focus. This shift in diagnostics technology has resulted in the discovery of new organisms, new molecular screening tests, and metagenomics capabilities that we are now bringing to the medical community. It is my hope that with these new diagnostics revelations chronic disease will be viewed in a new light, thus allowing insight into existing therapeutics and the discovery of new treatment strategies.

Stephen E. Fry, M.D.

Mosaic Stain Test
(Fungi and Fluorescent DNA Stains)

Description: This assay is not available at any other laboratory. Two fluorescent stains are used to simultaneously highlight DNA positive material in addition to putative fungal structures in a wet mount blood preparation. A combined photograph and report are generated based upon the laboratory findings showing DNA material in a red color and fungal material in a blue color.

Specimen: Submit one 3-6mL lavender-top (EDTA) tube. Gently invert tube six times immediately after drawing to prevent clotting. Store in refrigerator and transport in specified Fry Laboratories kit along with pre-frozen gel pack. Avoid exposure to extreme hot or cold temperatures.

Method:	Microscopy
Turn Around:	10 Business Days
CPT:	87206-GY
	87205-GY
Reference Ranges:	No Organisms Observed

This stain uses reagents that are not FDA approved and is designated for research use only. The FDA has determined such clearance or approval is not necessary. The results are not intended to be used as the sole means for clinical diagnosis or patient management decisions.

Certain findings from this test may be reportable to certain states: AL, AK, AZ, AR, CA, CO, CT, DE, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WV, WA, DC, WI, WY.

Stained Blood Film Test
(Modified May-Grünwald and Giemsa Stains)

Description: The modified May-Grünwald is a stain developed by our lab to detect blood-borne infections. The traditional Giemsa stain is used to confirm blood-borne infections using a thin and thick smear preparation. A photograph and report are generated based upon the laboratory findings. Traditional Giemsa and Modified May-Grünwald stains are run in conjunction with one another.

Specimen: Submit one 3-6mL lavender-top (EDTA) tube. Gently invert tube six times immediately after drawing to prevent clotting. Store in refrigerator and transport in specified Fry Laboratories kit along with pre-frozen gel pack. Avoid exposure to extreme hot or cold temperatures.

Method:	Microscopy
Turn Around:	10 Business Days
CPT:	87207-GY
	87205
Reference Ranges:	No Organisms Observed

The MMG stain uses a protocol that is not FDA approved. The FDA has determined such clearance or approval is not necessary. The Giemsa stain is a standard pathology methodology. The results are not intended to be used as the sole means for clinical diagnosis or patient management decisions.

Certain findings from this test may be reportable to some states: AL, AK, AZ, AR, CA, CO, CT, DE, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WV, WA, DC, WI, WY.

Advanced Stain Test
(Fluorescent DNA Stain)

Description: This cutting-edge test is not available anywhere else and uses highly specific DNA dyes to aid in visualizing microbes, blood-borne biofilm communities, or neutrophila extracellular traps. A photograph and report are generated based upon the laboratory findings. As an automatic reflex if the Fluorescent DNA Stain test does not yield results, a protocol to produce a higher yield of detectable parasitic infections and biofilm structures maybe performed.

Specimen: Submit one 3-6mL lavender-top (EDTA) tube. Gently invert tube six times immediately after drawing to prevent clotting. Store in refrigerator and transport in specified Fry Laboratories kit along with pre-frozen gel pack. Avoid exposure to extreme hot or cold temperatures.

Method:	Microscopy
Turn Around:	10 Business Days
CPT:	87206-GY
	87205-GY
Reference Ranges:	No Organisms Observed

This stain uses a reagent that is not FDA approved and is designated for research use only. The FDA has determined such clearance or approval is not necessary. The results are not intended to be used as the sole means for clinical diagnosis or patient management decisions.

Certain findings from this test may be reportable to certain states: AL, AK, AZ, AR, CA, CO, CT, DE, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WV, WA, DC, WI, WY.

***Babesia microti* IgG & IgM**
(IFA Serologic Test)

Description: This test uses immunofluorescent technology to detect both IgG and IgM antibodies to *Babesia microti* (a hemolytic disease known as Babesiosis).

Specimen: Submit one 9mL tiger-top. To avoid hemolysis, centrifuge and separate serum from clot within 4 hours of collection. Store in refrigerator and transport in specified Fry Laboratories kit along with pre-frozen gel pack. Avoid exposure to extreme hot or cold temperatures.

Method:	Indirect Immunofluorescence Assay
Turn Around:	10 Business Days
CPT:	86753 (x2)
Reference Ranges:	Negative

Babesia is a genus of protozoan parasites that causes Babesiosis. Babesia microti is the most common Babesia species in the United States. Starting titer for this assay is 1:32 IgG and 1:16 IgM. Positive samples are reflexed for titers. Individuals being treated with medications may not develop titers or will develop low antibody levels. It is suggested that patients be off antibiotics for two weeks prior to testing; however, this is subject to clinical necessity. This test was developed using analyte specific reagents from Fuller Laboratories and Focus Diagnostics and its performance characteristics determined by Fry Laboratories. It has not been cleared or approved by the FDA. The results are not intended to be used as the sole means for clinical diagnosis or patient management decisions. No international standard is currently available for the calibration of this assay. This test is intended for In Vitro Diagnostic Use outside of the United States.

Reportable states: CA, CT, DE, ID, IN, ME, MD, MA, MI, MN, NE, NH, NJ, NY, RI, VT, WI.

Ehrlichia chaffeensis IgG & IgM (IFA Serologic Test)

Description: This test uses immunofluorescent technology to detect both IgG and IgM antibodies to *Ehrlichia chaffeensis* (Human Monocytic Ehrlichiosis).

Specimen: Submit one 9mL tiger-top. To avoid hemolysis, centrifuge and separate serum from clot within 4 hours of collection. Store in refrigerator and transport in specified Fry Laboratories kit along with pre-frozen gel pack. Avoid exposure to extreme hot or cold temperatures.

Method:	Indirect Immunofluorescence Assay
Turn Around:	10 Business Days
CPT:	86666 (x2)
Reference Ranges:	Negative

Ehrlichia is a bacterium transmitted by ticks and considered zoonotic, as the main reservoir for this pathogen is an animal, usually mammal species. Starting titer for this assay is 1:64 IgG and 1:20 IgM. Positive samples are reflexed for titers. Individuals being treated with antibiotics may not develop titers or will develop low antibody levels. It is suggested that patients be off antibiotics for two weeks prior to testing; however, this is subject to clinical necessity. This test was developed using analyte specific reagents from Focus Diagnostics and its performance characteristics determined by Fry Laboratories. No international standard is currently available for the calibration of this assay. The results are not intended to be used as the sole means for clinical diagnosis or patient management decisions. This test is intended for In Vitro Diagnostic Use outside of the United States.

Reportable states: AL, AR, CA, CT, DE, FL, GA, IL, IN, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, NE, NH, NJ, NY, NC, OH, OK, RI, SC, SD, TN, TX, UT, VT, VA, WV, DC, WI, WY.

Anaplasma phagocytophilum IgG & IgM (IFA Serologic Test)

Description: This test uses immunofluorescent technology to detect both IgG and IgM antibodies to *Anaplasma phagocytophilum* (Human Granulocytic Anaplasmosis).

Specimen: Submit one 9mL tiger-top. To avoid hemolysis, centrifuge and separate serum from clot within 4 hours of collection. Store in refrigerator and transport in specified Fry Laboratories kit along with pre-frozen gel pack. Avoid exposure to extreme hot or cold temperatures.

Method:	Indirect Immunofluorescence Assay
Turn Around:	10 Business Days
CPT:	86666 (x2)
Reference Ranges:	Negative

Human Granulocytic Anaplasmosis is disease transmitted by ticks. Co-infection with Borrelia burgdorferi is common, due to the shared vector. Starting titer for this assay is 1:64 IgG and 1:20 IgM. Positive samples are reflexed for titers. Individuals being treated with antibiotics may not develop titers or will develop low antibody levels. It is suggested that patients be off antibiotics for two weeks prior to testing; however, this is subject to clinical necessity. This test was developed using analyte specific reagents from Focus Diagnostics and its performance characteristics determined by Fry Laboratories. It has not been cleared or approved by the FDA. No international standard is currently available for the calibration of this assay. The results are not intended to be used as the sole means for clinical diagnosis or patient management decisions. This test is intended for In Vitro Diagnostic Use outside of the United States.

Reportable states: AL, AR, CA, CT, DE, FL, GA, IN, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, NE, NH, NJ, NY, NC, OH, OK, RI, SC, SD, TN, TX, UT, VT, VA, WV, DC, WI, WY.

Bartonella henselae / quintana IgG & IgM (IFA Serologic Test)

Description: This test uses immunofluorescent technology to detect both IgG and IgM antibodies to *Bartonella henselae* and *Bartonella quintana* (Trench Fever and Cat-Scratch Disease).

Specimen: Submit one 9mL tiger-top. To avoid hemolysis, centrifuge and separate serum from clot within 4 hours of collection. Store in refrigerator and transport in specified Fry Laboratories kit along with pre-frozen gel pack. Avoid exposure to extreme hot or cold temperatures.

Method: Indirect Immunofluorescence Assay

Turn Around: 10 Business Days

CPT: 86611 (x2)

Reference Ranges: Negative

Cat-Scratch Disease is caused by a small gram negative rod of the genus Bartonella (formerly Rochalimaea). Starting titer for this assay is 1:64 IgG and 1:20 IgM. Positive samples are reflexed for titers. Individuals being treated with antibiotics may not develop titers or will develop low antibody levels. It is suggested that patients be off antibiotics for two weeks prior to testing; however, this is subject to clinical necessity. This test was developed using analyte specific reagents from Focus Diagnostics and its performance characteristics determined by Fry Laboratories. It has not been cleared or approved by the FDA. No international standard is currently available for the calibration of this assay. The results are not intended to be used as the sole means for clinical diagnosis or patient management decisions. This test is intended for In Vitro Diagnostic Use outside of the United States.

Reportable states: MN, WY.

Rickettsia rickettsii / typhi IgG & IgM (IFA Serologic Test)

Description: This test uses immunofluorescent technology to detect both IgG and IgM antibodies to *Rickettsia rickettsii* (Rocky Mountain Spotted Fever) and *Rickettsia typhi* (Typhus Fever Group).

Specimen: Submit one 9mL tiger-top. To avoid hemolysis, centrifuge and separate serum from clot within 4 hours of collection. Store in refrigerator and transport in specified Fry Laboratories kit along with pre-frozen gel pack. Avoid exposure to extreme hot or cold temperatures.

Method: Indirect Immunofluorescence Assay

Turn Around: 10 Business Days

CPT: 86757 (x2)

Reference Ranges: Negative

Spotted Fever Group Rickettsia is found throughout the world and is mediated by insect vectors whose bite transfers infections to a mammalian host. Individuals being treated with antibiotics may not develop titers or will develop low antibody levels. . It is suggested that patients be off antibiotics for two weeks prior to testing; however, this is subject to clinical necessity. Starting titer for this assay is 1:64 IgG and 1:64 IgM. Positive samples are reflexed for titers. This test was developed and its performance characteristics determined by Fuller Laboratories. This test is intended for In Vitro Diagnostic Use.

Reportable states: AL, AR, CA, CO, CT, DE, FL, GA, ID, IL, IN, IA, KS, KY, MS, MO, MT, NE, NV, NH, NJ, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WV, DC, WI, WY.

Q-Fever (*Coxiella burnetii*) IgG & IgM
(IFA Serologic Test)

Description: This test uses immunofluorescent technology to detect both IgG and IgM antibodies to phase I and II of *Coxiella burnetii*.

Specimen: Submit one 9mL tiger-top. To avoid hemolysis, centrifuge and separate serum from clot within 4 hours of collection. Store in refrigerator and transport in specified Fry Laboratories kit along with pre-frozen gel pack. Avoid exposure to extreme hot or cold temperatures.

Method: Indirect Immunofluorescence Assay

Turn Around: 10 Business Days

CPT: 86638 (x2)

Reference Ranges: Negative

Coxiella burnettii is an obligate intracellular parasite of eukaryotic cells. Serologic testing has been the primary test in clinical history for diagnosing this disease. Starting titer for this assay is 1:16 IgG and 1:16 IgM. Positive samples are reflexed for titers. Individuals being treated with antibiotics may not develop titers or will develop low antibody levels. It is suggested that patients be off antibiotics for two weeks prior to testing; however, this is subject to clinical necessity. This test was developed and its performance characteristics determined by Fuller Laboratories. This test is intended for In Vitro Diagnostic Use.

Reportable states: AK, AZ, AR, CA, CO, CT, DE, FL, GA, HI, ID, IL, IN, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NJ, NM, NY, NC, ND, OH, OK, OR, RI, SC, SD, TN, TX, UT, VA, WV, WA, DC, WY.

***Toxoplasma gondii* IgG & IgM**
(IFA Serologic Test)

Description: This test uses immunofluorescent technology to detect both IgG and IgM antibodies to *Toxoplasma gondii*.

Specimen: Submit one 9mL tiger-top. To avoid hemolysis, centrifuge and separate serum from clot within 4 hours of collection. Store in refrigerator and transport in specified Fry Laboratories kit along with pre-frozen gel pack. Avoid exposure to extreme hot or cold temperatures.

Method: Indirect Immunofluorescence Assay

Turn Around: 10 Business Days

CPT: 86777, 86778

Reference Ranges: Negative

Primary infection by Toxoplasma gondii is accompanied by the production of antibodies reactive with the organism. IgM antibodies appear within the first week following initial infection, peak within 3-4 weeks, and generally become undetectable within 3 or 4 months. IgG antibodies usually become detectable within 3 weeks following infection and peaks between 2-6 months. Individuals being treated with antibiotics may not develop titers or will develop low antibody levels. Starting titer for this assay is 1:16 IgG and 1:8 IgM. Positive samples are reflexed for titers. This test was developed and its performance characteristics determined by GenBio. This test is intended for In Vitro Diagnostic Use.

Reportable states: AL, AR, DE, FL, GA, HI, KY, ME, MA, MN, OH, PA, WI.

Lyme Line Blot IgG & IgM
(Line Blot Serologic Test)

Description: This test detects human IgG and IgM antibodies to various proteins to the Lyme spirochete, *Borrelia burgdorferi*. Both IgG and IgM antibodies are tested according to the CDC criteria for Lyme disease.

Specimen: Submit one 9mL tiger-top. To avoid hemolysis, centrifuge and separate serum from clot within 4 hours of collection. Store in refrigerator and transport in specified Fry Laboratories kit along with pre-frozen gel pack. Avoid exposure to extreme hot or cold temperatures.

Method: Gold Standard Diagnostics *B. burgdorferi* B31 Line Blot Test System

Turn Around: 10 Business Days

CPT: 86617(x2)

Reference Ranges: Negative

Generally, patients with Lyme disease produce IgM antibodies during the first weeks after exposure and produce IgG antibodies later. Strips that have 5 (or more) out of 10 significant bands for IgG and 2 out of 3 significant bands for IgM are considered positive for antibodies to B. burgdorferi. Individuals being treated with antibiotics may not develop titers or will develop low antibody levels. It is suggested that patients be off antibiotics for two weeks prior to testing; however, this is subject to clinical necessity. This test was developed and its performance characteristics determined by Gold Standard Diagnostics. This test is intended for In Vitro Diagnostic Use.

Reportable States: AL, AK, AR, CA, CO, CT, DE, FL, GA, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NJ, NM, NY, NC, ND, OH, OK, OR, PA, SC, SD, TN, TX, UT, VT, VA, WV, WA, DC, WI.

Pan-Prokaryotic (Bacteria/Archaea) DNA Analysis by Sequencing (Molecular Diagnostic Test)

Description: Screens for the presence of *any* bacterial species in a provided sample and identifies it or the nearest known relative by sequencing analysis using our proprietary Next Generation Sequencing method and bioinformatics analysis. This test requires that the organisms be present in the sample provided and does not discriminate between viable or dead bacterial cells. Potential novel organisms are flagged and the nearest known relative is identified. Does not require culture steps, as it is a direct detection method.

Specimen: For blood tests submit one 6mL lavender-top (EDTA) tube. Gently invert tubes six times immediately after drawing to prevent clotting. For other clear fluid testing submit one 5mL red-top tube (no preservatives) with a minimum of 5mL. For tissues, biopsies, or nonclear/viscous fluids submit approximately 500mg-3g in the provided 15mL sterile/DNA/RNA free sample container. Store in refrigerator and transport in specified Fry Laboratories kit along with pre-frozen gel pack. Avoid exposure to extreme hot or cold temperatures.

Method: Multiplexed Next Generation DNA Sequencing

Turn Around: 15 Business Days

CPT: Various

Reference Ranges: No Significant Sequences

This test uses a kit/reagent designated by the manufacturer as research use only. The FDA has determined such clearance or approval is not necessary. Fry Laboratories, LLC developed this test or some of its components. The performance characteristics of this test have been determined by Fry Laboratories, LLC. No international standard is currently available for the calibration of this assay. The results are not intended to be used as the sole means for clinical diagnosis or patient management decisions. Patent Pending 2013 Fry Laboratories, LLC. US Patent 9,589,101.

Certain findings from this test may be reportable to some states.

Pan-Eukaryotic (Protozoa/Fungi) DNA Analysis by Sequencing (Molecular Diagnostic Test)

Description: Screens for the presence of *most* medically relelvant protozoa and eukaryotic microbial species in a provided sample and identifies it or the nearest known relative by sequencing analysis using our proprietary Next Generation Sequencing method and bioinformatics analysis. This test requires that the organisms be present in the sample provided and does not discriminate between viable or dead microbial cells. Potential novel organisms are flagged and the nearest known relative is identified. Does not require culture steps, as it is a direct detection method. This assay has not been shown to reliably detect *Plasmodium* (Malaria) or *Trichomonas species*, thus it should not be used if these organisms are suspected. Examples of detectable organisms include, but are not limited to: *Trypanosoma*, *Giardia*, *Acanthamoeba*, *Prototheca*, *Leishmania*, *Babesia*, *Cryptococcus*, *Cryptosporidium*, *Blastocystis*, *Entamoeba*, etc.

Specimen: For blood tests submit one 6mL lavender-top (EDTA) tube. Gently invert tubes six times immediately after drawing to prevent clotting. For other clear fluid testing submit one 5mL red-top tube (no preservatives) with a minimum of 5mL. For tissues, biopsies, or nonclear/viscous fluids submit approximately 500mg-3g in the provided 15mL sterile/DNA/RNA free sample container. Store in refrigerator and transport in specified Fry Laboratories kit along with pre-frozen gel pack. Avoid exposure to extreme hot or cold temperatures.

Method: Multiplexed Next Generation DNA Sequencing

Turn Around: 15 Business Days

CPT: Various

Reference Ranges: No Significant Sequences

This test uses a kit/reagent designated by the manufacturer as research use only. The FDA has determined such clearance or approval is not necessary. Fry Laboratories, LLC developed this test or some of its components. The performance characteristics of this test have been determined by Fry Laboratories, LLC. No international standard is currently available for the calibration of this assay. The results are not intended to be used as the sole means for clinical diagnosis or patient management decisions. Patent Pending 2013 Fry Laboratories, LLC. US Patent 9,589,101 and 8,778,843.

Certain findings from this test may be reportable to some states.