Testing Services Handbook

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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 bloodborne 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/forms/

We do not bill private insurance for our services; however, we do accept Medicare and some of the state Medicaid insurance plans. 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

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-theshelf 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
Avg 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
Avg 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 neutrophil 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
Avg 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.

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
Avg 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
Avg 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 relevant 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. Examples of detectable organisms include, but are not limited to: *Trypanosoma*, *Giardia*, *Acanthamoeba*, *Prototheca*, *Leishmania*, *Babesia*, *Cryptococcus*, *Cryptosporidium*, *Blastocystis*, *Entamoeba*, *Coccidioides*, *Candida*, *Naegleria*, 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
Avg 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.