Diagnosis of Lyme Disease: Mainstream Medicine Approach; International Lyme and Associated Diseases Society (ILADS) Approach; and Chung Institute of Integrative Medicine (CIIM) Approach

Lyme disease can be a very challenging diagnosis for both the patients and health-care practitioner (HCP) caring for them. It is the most reported vector-borne disease accounting for more cases in 2018 than all others diagnoses combined[1]. The Centers for Disease Control (CDC) estimates 300,000 new diagnoses are made each year[2]. with the gold standard for diagnosis being a two-tiered serologic test. In 1994 the Second National Conference on Serologic Diagnosis of Lyme Disease convened, comprised of the Association of State and Territorial Public Health Laboratory Directors, CDC, the Food and Drug Administration (FDA), the National Institutes of Health (NIH), the Council of State and Territorial Epidemiologists, and the National Committee for Clinical Laboratory Standards[3]. This has been followed by several Lyme disease guidelines from different medical societies including the Infectious Disease Society of America's (IDSA) Lyme Disease guidelines in 2006. Both the diagnosis and treatment of Lyme disease has been the subject of significant controversy culminating in an anti-trust investigation begun in 2006 by Connecticut attorney general Richard Blumenthal leading to a one-time special review of the IDSA guidelines, which were upheld by an independent scientific review panel. A preliminary update proposed by IDSA in 2019 is pending publication[4].

Stemming from a growing list of patient concerns, Lyme advocacy groups were formed including the Lyme Disease Association (LDA)[https://lymediseaseassociation.org/] in New Jersey, the California Lyme Disease Association (CALDA) [https://www.lymedisease.org/], and the International Lyme and Associated Diseases Society (ILADS)[https://www.ilads.org/]. ILADS is a medical society founded by Lyme focused physicians with alternative view points often referred to by the general public as "Lyme literate medical doctors" (LLMDs). ILADS has dedicated significant resources for the diagnosis and treatment of Lyme and associated diseases including Ehrlichia, Anaplasma, Babesia, and Bartonella with focus on the treatment of persistent symptoms controversially termed "chronic Lyme disease."

Due to disagreement with mainstream diagnosis and management of Lyme disease, ILADS has performed and published a significant body of research and created alternative guidelines including the Burrascano guidelines[6]. ILADS makes a distinction

between diagnostic testing for Borreliosis and the clinical diagnosis of Lyme disease. ILADS focuses on the clinical scenario based on the viewpoint that current laboratory testing methods are not able to identify all infected patients. Some of the limitations to current testing include lack of sensitivity, timing of testing in respect to both infection and treatment, sensitivity to different Borrelia species and strains, and inter-laboratory variation. Based on these limitations, scoring systems such as the Horowitz Multiple Systemic Infectious Disease Syndrome (MSIDS) Questionnaire were created to assist with the diagnosis of Lyme disease if laboratory testing was inconclusive[7]. Small subsets of integrative medicine practitioners have utilized specialized forms of muscle testing such as Autonomic Response Testing (ART)[8] and the Bidigital-O-Ring Test (BIDORT)[9] to assist with assessment of the presence of infection. For the purposes of this article we will review the mainstream approach to diagnosis of Lyme disease and limitations during the three phases of infection. The first encounter a health care provider may have with a patient for potential Lyme infection is following the initial tick bite. Patients are risk stratified according to duration of tick attachment from tick bite to removal. There is significant risk to contract subsequent Lyme infection in those patients in whom the duration of tick attachment was greater than 36 hours. This is based on animal studies with animals seldom being infected during a tick attachment period of less than 24 hours[10] and rarely in the 24-36 hour window[11]. After 48 hours of tick attachment, transmission rates were observed to increase to approximately 10% and reach 70% by 72 hours. Transmission was not observed at less than 24 hours of attachment with a caveat that previously partially fed ticks could more rapidly transmit infection on reattachment[12]. Although testing is available, routine nucleic acid amplification testing(NAAT) for Borrelia in the tick is not recommended nor is testing for the patient as acute phase serology has sensitivity as low as 14% due to lack of time to develop an antibody response[13].

Symptoms of acute Lyme disease can develop within the first few days to weeks after a tick bite. The first symptoms a patient may notice is a non-specific viral like illness with the characteristic bulls eye rash at the site of the tick bite. This rash known as Erythema Migrans (EM) may be absent in 20-30% of patients[14] and many patients never recall noticing a tick bite. The single bulls eye form of the EM rash without further testing is clinical grounds for diagnosis of **stage 1** of Lyme disease, *early localized disease*.

Stage 2 of Lyme disease is termed *early disseminated infection* which occurs within weeks to months with symptoms involving one or more of the following systems: the skin, heart, musculoskeletal or nervous system. The recommended testing algorithm is an initial **enzyme immunoassay (EIA)** or **immunofluorescence assay (IFA)** followed by a **Western blot**. This standard two tiered testing for Lyme disease has been criticized for

focusing on specificity and lacking sensitivity. Sensitivity of 2-tiered testing is low (30%–40%) during early infection while the antibody response is developing (window period). For early disseminated Lyme disease, sensitivity approaches 70%–100%[15]. To increase sensitivity, maintain specificity, and decrease complexity of standard testing, alternative testing approaches have been utilized including updates by the CDC in 2019 for a modified two-tiered approach[16]. Modified algorithms that include two sequential EIAs were cleared by the FDA and considered " substantially equivalent to or better than" standard testing[17].

Stage 3, late Lyme disease, occurs months to years after initial infection with or without experiencing symptoms of prior infection. In the United States this is typically manifest as arthritis or neurologic disease although chronic skin conditions are described in Asia and Europe. This phase of infection is also diagnosed through the same two-tiered approach as early disease with the difference being exclusion of the IgM component typically associated with acute infection. The rationale for exclusion includes persistent antibody response and decreased specificity of IgM testing in general. This also brings to light an issue with the diagnosis of re-infection. The history of exposure or prior infection does not confer immunity to re-infection. Patients at times may sero-convert from positive to negative. Often times patients develop persistent IgM or IgG antibodies. Monitoring of paired serology has been suggested although clinical symptoms are often relied upon to make the final diagnosis.

LLMDs still consider this testing algorithm inadequate and often utilize other forms of testing. These tests include: capture assays for antigens in urine; culture; immunofluorescence staining; cell sorting of cell wall-deficient or cystic forms of *B. burgdorferi; l*ymphocyte Transformation tests; quantitative CD57 lymphocyte assays; "Reverse Western blots"; in-house criteria for interpretation of immunoblots; measurements of antibodies in joint fluid (synovial fluid); and IgM or IgG tests without a previous enzyme-linked immunosorbent assay (ELISA)/EIA/IFA[18]. The CDC has yet to determine the clinical usefulness and does not recommend performance of the above mentioned testing due to inter-laboratory variation and lack of established efficacy[19]. Rationale for utilization of alternative testing includes confounding factors such alternative species of Borrelia known to cause Lyme or a Lyme like illness including B. *Mayonii[20] and B. Miyamotoi[21] and and inability of non-culture based testing to determine active infection.* Alternative interpretation of immunoblots have also been proposed [22] due to exclusion of certain bands including OspA and OspB[23] that are positive in prior Lyme vaccine recipients[24].

The diagnosis of Lyme disease remains a controversial and evolving topic with many

patients suffering from medically unexplained symptoms and lacking a unifying medical diagnosis. Further research remains to be explored to assist with the diagnosis of active disease or guide patients to pursue treatment of other conditions. Increased insight into the group of disorders causing these constellations of symptoms may provide not only better understanding of the disease, but also better understanding of our patients.

Approach of the Chung Institute of Integrative Medicine (CIIM)

Patients of CIIM have already been assessed and treated by mainstream and ILADS approaches. The direction of our treatment approach is dependent upon the results of our primary assessment tool- Autonomic Response Testing (ART). In our experience ART assesses causative factors and maintaining factors of a patient's presenting symptoms. It has also been our experience that ART can often be predictive of effective interventions such as herbals, homeopathic remedies, supplements etc. We have helped many patients who have failed standard medical treatment in the greater Philadelphia area and beyond.

ART Basic Principles

ART postulates five levels of healing which are from lowest to highest: physical, energetic, mental, intuitive, and spiritual[26]. ART identifies 7 categories of factors which initiate, maintain, or aggravate disease conditions: 1. Toxins 2. Biochemical 3. Structural 4. Energetic 5. Food 6. Geographic and 7. Psychological.[26] See Table 3. Toxins include heavy metals, pesticides, bio-toxins from microorganisms in clinical and subclinical infections, etc. In ART a toxin reduces the optimum performance of a person. Thus it is better to think of the toxic burden a substance presents rather than a standard level of toxin which is considered pathological such as a lead level equal to or greater than 5 micrograms per deciliter. Sensitivity to levels lower than 5 micrograms per deciliter will vary across individuals. According to the US government Agency for Toxic Substances and Disease Registry no blood lead level above zero is free of all risk.[27] Biochemical imbalances include hormonal problems, genetic disturbances of metabolism and nutritional problems. Examples of structural problems are malocclusion and vertebral subluxations. Energetic disturbances include phenomena associated with acupuncture points and meridians; chakras; interference fields such as scars and focal infections; nervous system problems; and emotions. Food factors include both intolerances and allergies. Geographical factors pertain to a person's habitual location and the influence of light, electromagnetic smog, underground water streams, and other geophysical influences on patients. Finally, but not least are the influence of psychological factors such as psychological conflict and trauma.[26]

The ART assessment method aims to identify the presence of the above factors and which areas of the body and mind are being affected. The ART examination assesses all parts of the body. The ART assessment procedure also helps predict ameliorating and aggravating factors such as medications, homeopathic remedies, nutrients, herbs, etc.

ART Assessment Method

ART is a version of applied kinesiology. Applied kinesiology was originally developed by George Goodheart, Jr, DC.[28] Today, many forms of applied kinesiology are used clinically. Different originators of applied kinesiology methods believe that their method is an improvement compared to other versions.[29-33] Many chiropractors and integrative physicians use some form of applied kinesiology. The version practiced in our centers, known as ART, was originated by Dietrich Klinghardt, MD, PhD, and Louisa Williams, DC, ND[34] and further extended by Klinghardt.[26] Different forms of applied kinesiology can give results which conflict with the results obtained with other forms. Klinghardt demonstrated this situation in a video on his Web site.[35]

In manual muscle testing an assessment of muscle function is made and recorded. Applied kinesiology expands manual muscle testing assessment to a second muscle function assessment that occurs in the presence of a stimulus such as a food, toxin, allergen, etc. The 2 assessments are compared, determining whether the response to the added stimulus was weakening, no change, or strengthening of the muscle function. The interpretation of the muscular response informs the assessment of the patient and makes a prediction of positive, negative, or neutral responses to therapies. Different forms of applied kinesiology vary in the muscles tested, the interpretation of a weak muscle response, the type and number of preparatory steps, and the manner of presentation of specific stimuli. Thus, different forms of applied kinesiology can give different results.[35] A systematic review by Hall et al[36] of applied kinesiology across different forms of applied kinesiology was unable to draw clear conclusions and recommended studying applied kinesiology using a pragmatic study design. No ART studies were included in that systematic review. Schwartz et al[37] published a negative experimental study; however, no distinction was made regarding the various forms of applied kinesiology. No designation was given as to which form of applied kinesiology was being tested. It was implied that the form studied generalized to all versions of applied kinesiology. The article did state that the utilized protocol was not the approved Goodheart version[38] of applied kinesiology. The concluding statement appeared to lump all versions of applied kinesiology together. It is clear that neither ART[34, 35] nor the official Goodheart protocol[38] was tested in the Schwartz et al[37] study. Just as antibiotics

and diagnostic tests can differ one from another, so can different forms of applied kinesiology differ one from another.

We published a pilot study (14 patients) on the validity of ART for predicting the results of an Immunoglobulin E blood test for allergy identification.[38] Our results were positive: Sensitivity, specificity, positive predictive value, negative predictive value, overall accuracy, phi coefficient, and Cohen's kappa were all in the desired direction. As the correlation was good it was not perfect. The results of ART assessments are to be interpreted in the context of standard medical assessment methods. No other study evaluating the validity of ART assessment has been published to date per our literature search of PubMed (which includes MEDLINE), EMBASE, AMED, and CINAHL. We hope this review of ART will prompt serious attention from the research community toward ART. Our clinical experience with ART as an assessment tool to help identify contributing disease factors and helping to guide the choice of interventions has resulted in positive clinical outcomes in patients who have failed standard medical therapy. 39[-45]

Table 1

Standard Medical Approach for Diagnosis of Lyme Disease[17]	
Stage 1 *Early Localized Lyme Disease*	*Clinical diagnosis is made with Erythema Migrans rash and symptoms consistent with acute Lyme disease. Serologic testing is not recommended.*
Stage 2 *Early Disseminated Lyme Disease*	**Standard two-tiered (STT):** initial enzyme immunoassay (EIA) or immunofluorescence assay (IFA) followed by a Western blot for both IgM and IgG antibodies. ***Modified two-tiered (MTT):*** novel enzyme-linked immunosorbent assays (ELISAs) or different second step tests to validate a positive ELISA. Variable major protein-like sequence 1 (VlsE1) and pepC10 antigens from *B. burgdorferi* followed by a whole-cell ELISA has been approved for use in the United States.
Stage 3 *Late Lyme Disease*	*STT or MTT approach with exclusion of IgM testing.*

CNS Lyme Disease	Positive two tier Lyme serologies with or without positive cerebrospinal fluid [CSF] Lyme antibodies. Polymerase chain reaction (PCR) for *B. burgdorferi* can be performed on CSF, although it has low diagnostic sensitivity and variable specificity.
Lyme Arthritis	*STT or MTT approach with exclusion of IgM testing.* PCR testing of synovial fluid has not been validated for widespread clinical use.
B. Mayonii (In a region of the upper Midwest)	Nucleic Acid Amplification Testing(NAAT).
B. Miyamotoi ("Hard tick-borne relapsing fever")	NAAT (particularly reverse-transcription PCR [RT-PCR]) Whole cell-based ELISA and the C6 ELISA for *B. burgdorferi* can be positive for patients infected with *B. Miyamotoi.*

Table 2

Alternative and Emerging Diagnostics[25]	Methods
Polymerase chain reaction (PCR)	Amplified nucleic acid assay that detects *B. burgdorferi* specific DNA sequences.
Culture	Isolated in modified Kelly-Pettenkofer and Barbour-Stoenner-Kelly II medium from skin biopsy, blood, and CSF .
Urine Antigen	Direct detection of Borrelia burgdorferi specific antigens in urine.

Immune Complex Detection	Qualitative immunoassay for antigen-antibody complex formation in sera .
T Cell Proliferative Response	Detects human T cells reactive to *B. burgdorferi* specific antigens in vitro such as CD57 marker present on natural killer cells and T lymphocytes.
Xenodiagnosis	Investigational test using an uninfected tick vector fed on a host then tested by PCR, culture, and/or isothermal amplification to detect the presence *B. burgdorferi.*
BioMarkers and Biosignatures	Targeted marker analysis to quantify gene expression (transcriptomics), proteins (proteomics) and metabolites (metabolomics).
C6 Peptide	The Food and Drug Administration (FDA) approved complement peptide C6 (C6-peptide) as an attempt to develop a more accurate ELISA test.

Table 1. Seven factors that can initiate, aggravate or maintain disease.

1.Toxins	Includes heavy metals, pesticides, bio-toxins from microorganisms in clinical and subclinical infections, etc.
2. Biochemical	Imbalances include hormonal problems, genetic disturbances of metabolism and nutritional problems.
3. Structural	Examples are problems of malocclusion and vertebral subluxations.
4. Energetic	Disturbances include phenomena associated with acupuncture points and meridians; chakras; interference fields such as scars and focal infections; nervous system problems; and emotions.
5. Food	Factors include both intolerances and allergies.

6. Psychological	Includes psychological conflict and trauma.
7. Geographical	Factors pertain to a person's habitual location and the influence of light, electromagnetic smog, underground water streams, and other geophysical influences on patients.

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