# BABESIA UPDATE 2009

Routine and Advanced Testing Often Fail Standard Treatments Do Not Cure

A Cause of Excess Weight, Migraines and Fatigue?

## JAMES SCHALLER, M.D.

WITH RANDALL BLACKWELL

## **Babesia Update 2009**

by

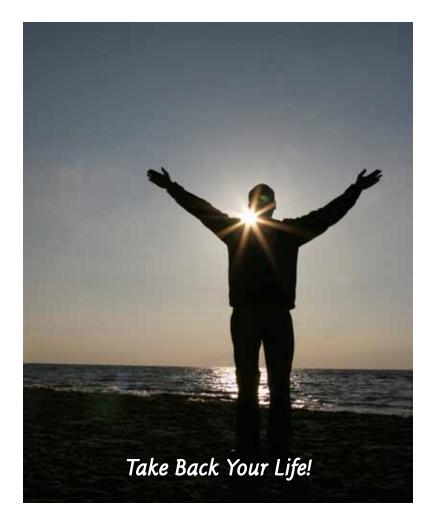
James Schaller, M.D. with Randall Blackwell

A 2009 Supplement to:

The Diagnosis and Treatment of Babesia

and

The Health Care Professional's Guide to the Treatment and Diagnosis of Human Babesiosis



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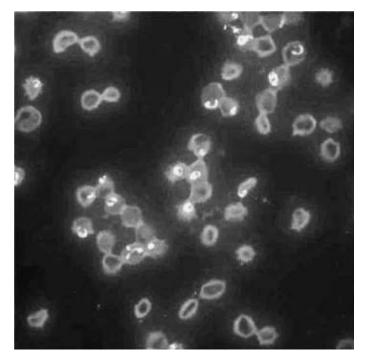
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This patient's blood was sent to a large national lab for Babesia testing. His Babesia PCR, Babesia antibodies and manual blood smear came back negative. Does this look negative? He had severe headaches, chills, night sweats and profound fatigue. Other patients may not show any symptoms. (Image courtesy of J. Shah, Ph.D. Available at 800-832-3200)

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## Disclaimer

Dr. Schaller is not a specialist in infectious disease medicine. He is not a pathologist. Both of these specialties have over 2,000 diseases to treat and study. Dr. Schaller is only interested in four infections and has read and published on only these four. The medical ideas, health thoughts, health comments, products and any claims made about specific illnesses, diseases, and causes of health problems in this book are purely speculative, hypothetical, and are not meant to be authoritative in any setting. No comment or image has been evaluated by the FDA, CDC, NIH, IDSA or the AMA. Never assume any United States medical body, society, or the majority of American physicians endorse any comment in this book. No comment in this book is approved by any government agency, medical body or medical society. Nothing in this book is to be used to diagnose, treat, cure or prevent disease. The information provided in this book is for educational purposes only. It is not intended as a substitute for the advice from your physician or other health care professionals. This book is not intended to replace or adjust any information contained on, or in, any product label or packaging.

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Babesia or Bartonella treatment comments and reports of possible positive or negative treatment outcomes are hypothetical. No treatment should be rejected or embraced by anyone, based on the preliminary research and study in this book. Some reports in this book are the result of various novel dosing, selfinitiated by proactive patients. They were nevertheless monitored often. Some patients were inherited right after various treatment trials. Their outcomes were promptly measured.

In this book, Dr. Schaller makes no authoritative or proven claim about any lab testing or treatment. Dr. Schaller only offers hypothetical ideas. Dr. Schaller makes no authoritative claims about medications, nutrients, herbs or various types of alternative medicine. The ideas in this book will need to be submitted to your local expert in allopathic, osteopathic or progressive medicine, or to other licensed health care practitioners. This book is not meant to be an informal or formal guideline book that presumes to control 800,000 physicians, or the 300 million patients they serve. You are asked to let the wisdom of your health care practitioners, and your own study, be a starting point to guide treatment tailored specifically to your body. Again, Dr. Schaller makes no claim to be an expert in any aspect of medicine. He makes no claim to know more than other physicians.

Additionally, Dr. Schaller makes no claim that any statement in this book is correct.

Names and minor personal details within this book have been changed to preserve privacy.

Since this appears to be the first book exclusively dedicated to advanced modern cutting-edge Babesia diagnosis and treatment, any book with new proposals will contain errors. This is common with books that are the first on such sensitive topics. Every reasonable effort has been made not to try to overstate findings. Further, it is important to realize that any single lab finding or treatment outcome can have multiple causes, and not all of these may be known to this author, or to other health practitioners. Therefore, all health care practitioners should look for other confirmations outside this book before beginning on any treatment plan, if possible. It is also fully appreciated that it is hard to diagnose Babesia infections.



To David Schaller I am sorry you have seen the worst of medicine.



To you the precious reader — if you or a loved one suffer with Babesia, hope is coming!



The Medical Community Has a Profound Need for a Babesia Book Supplement

Current Testing is Amazingly Limited and Simplistic

Current Treatments Fail and Only Reduce Body Load

Babesia Can Cause Obesity, Migraines and Chronic Fatigue

New Diagnostic Testing and Unique Tracking Labs May Add to Detecting Babesia.



The "well" do not need a physician, but those who are sick. (From the writer Luke, the "beloved physician")

Babesia, Lyme and Bartonella create "sickness" and decrease insight, causing those inflicted to feel no need for serious medical care. Many patients with mild symptoms lose insight first and think they are "just fine." Disease is very old and nothing about it has changed. It is we who change as we learn to recognize what was formerly imperceptible.

John Martin Charcot, De l'Expectation en Medecine

Johnny was a fine student and athlete. Then, over a couple of years, his functioning dropped. He went to many specialists in pediatric medicine and many nationally respected medical centers. No one could figure out what was wrong with him. Finally, one individual reported that he was slightly positive for Lyme disease. But despite very aggressive treatments, Johnny showed only modest improvement and never returned to normal.

Over a ten-year period, he was tested for other types of infections. He was negative over eight times using Babesia tests from five different labs. His Epstein Barr virus was high, and he appeared to be positive for Ehrlichia. His physicians felt they had treated both, but he was not improving. His grades fell from A's to D's and was unable to run at all. He was exhausted walking 5 blocks. He could easily sleep 12 hours a day.

Johnny's sister, who had severe Babesia, suffered from debilitating migraines, fatigue and significant weight gain. Noting the similarities between his sister's and his own symptoms, Johnny began self-treating. He "borrowed" some of her medications.



Treatment resistant obesity can be caused by Babesia, and the best efforts at diet and exercise yield modest results.



Babesia often causes migraines.

When Johnny saw another consultant for his fatigue, he was retested for Babesia at an advanced lab specializing in a wide range of infection testing. He had positive antibodies for two Babesia species!

He was placed on a triple treatment of malaria killing medications and is now cured. He is back to normal.

Johnny's experience is not rare. Tick and flea-borne infections are poorly treated all over the world. No developed country has advanced testing or treatment methods. And while over 1,000 medical problems can cause chronic fatigue, Babesia is at the top of the list, and is missed 99% of the time.

Babesia articles often discuss the species that infect humans, the frequency of infection, the optimal diagnostic testing and curative treatment. Such articles are from the 1990's and are useless.

I am calling for a complete "reboot" of the computer and our approach to Babesia. I am calling for humility, a need to face the blunt realities, and to discard simplistic protocols, guidelines and summary articles, which give the false impression that we have this infection all figured out. Such a sophomoric approach would be comical if it did not involve human life. It reminds me of attitudes which convey that we have terrorist Islamic Fascism all figured out and contained.

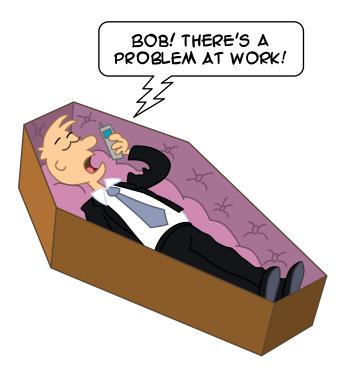


Lisa is the CEO of a large corporation in Europe. She has flown to the United States over 15 times in 10 years to get treatment for various medical problems. She has two types of autoimmunity, restlessness, excess weight, headaches and cognitive troubles such as memory loss, and what I have come to refer to as mental "fogginess." She was diagnosed with Lyme Disease after lab testing supported her likeliness to develop it, due to experiences hiking in mountains and a possible series of insect bites that probably included tick bites. Many gifted infectious disease physicians treated Lisa. While some reported having no idea of the cause of her problems, other physicians offered treatments that allowed her to function just well enough to keep working. She also required a number of "Band-Aid medications," such as anti-depressants and stimulants.

When Lisa read my new two-volume color Bartonella book, she was struck by the ability of Bartonella to cause immune suppression. Lisa was treated for Bartonella, based on the results of many new indirect tests. **As soon as this Bartonella, treatment was over, her lab results changed solidly, and it was clear that she had multiple species of Babesia infections that had been there all along, but were being masked by the Bartonella.** 



Babesia can cause fatigue at home.



Babesia can also cause fatigue at work.

Since being treated for the Babesia, Lisa has markedly improved.

While she initially had to be treated with profoundly low dose treatment, over time, she was eventually able to handle high cure dosing, and not just common body load reduction dosing.

I write this book because of the many "Johnnys" and "Lisas" all over the United States and the world. I will never recover the income used for this update book. But as someone who believes that healing is sacred and life is short, I offer these reflections with the hope that in 20 years, the books of other emerging clinicians and researchers will surpass this writing. We owe it to Johnny and Lisa and the millions like them.

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#### The State of International Babesia Ignorance

When I published the most up-to-date practical and extensive Babesia book in 2006, *The Diagnosis and Treatment of Babesia*, I thought I was done with this infection. So I quickly published a Babesia images lab manual, a large two-part color Bartonella book, and then worked on *The 18 Reasons Lyme Disease Treatment Fails*, because the current Lyme debate had degenerated into a mere **fight over antibiotic duration**. But patients were still suffering with their cluster of tick-borne infections after a month, or even after three years of treatment. Yet the only solutions were more antibiotics, antibiotic cocktails, a referral to a psychiatrist or various alternative medicine options, which were supposedly helpful, but did not meet my direct and indirect testing requirements for a certain and long-term cure of Babesia or other tick-borne infections.

Many physicians and patients seeking cures have amazingly ignored the treatment of other infections commonly passed into the human body with Lyme. The notion of "Lyme disease" is a 1970's notion, since deer ticks, and other vectors like fleas, dust mites, pet saliva and flies carry a wide range of infections.

If a child is playing in his suburban backyard day after day, and rolling in the grass, the concept of acquiring a **single** deer tick bite is wrong. Still more flawed is the notion that any painless deer tick bite will deliver only one infection. Deer ticks and other infectious ticks never carry one infection in their saliva or stomach. Ticks have a "salad stomach." And like the best salads, more infectious "ingredients" or infections in a tick are better — but not for humans.

So the naive and peculiar notion that deer ticks have sterile saliva and sterile stomachs, *except for Lyme bacteria*, deserves to be **quietly put away forever.** This ignorant "Lyme only" approach needs to be discarded in the manner of a small child who accidentally wets himself and looks quickly for a new set of shorts to cover his shame, and who quickly tosses away his urine filled underpants. The view of "Lyme only" infections after a deer tick bite is naive, flawed and simply embarrassing. The fact I once believed it myself is deeply humbling. It is the belief of some Lyme experts that extended patient complaints might simply be repeat infections from new tick bites or residual die-off inflammation that will dissipate in a season. Others believe that ongoing symptoms after Lyme treatment are due to other causes. These include Babesia, Bartonella, Lyme neurotoxins like Bb Tox1, Mycoplasma, dozens of possible viruses, metabolic pathology, various types of "detoxification" troubles, bad diets, yeast infections, poor exercise, hormone deficiency issues, psychiatric illness, heavy metals, genetic liver defects, weak immunity, a "leaky gut," or co-morbid mold biotoxin exposure, which is found in **30% of USA structures due to water intrusion** (per EPA). Some health care workers confuse tick-borne infections with other medical diseases or mental problems. Perhaps some of what they diagnose is valid, but few ask the question, **"What caused this medical or psychiatric problem?"** Fixing some of these medical or psychiatric issues is often not a home run in recovered functioning.

So a solid health practitioner should know the basics of all emerging infections that are common and serious. These would include Bartonella, Ehrlichia, Lyme and Babesia. My impression is that 1/10,000 physicians are on the **cutting edge** of **all** of these emerging infections, including physicians vastly more intelligent and gifted than myself.

Further, having symptoms after a month or years of Lyme treatment shows chaos and uncertainty. The explanation offered by health care workers on their treatment approach is usually what they had been taught by whatever "Popes" they follow. But in 2009, there is no Tick Infection Pope in any government agency, medical society or guideline author.

Unfortunately, some patients still ill with stealth Babesia make treating physicians angry. They feel a patient was given a "reasonable treatment," and their frustration translates into patients being resented and abused for reporting chronic symptoms. Such abuse includes acting like brash Woody Allen movie psychiatrists, with limited 2009 tick infection clinical knowledge, who toss patients to psychiatrists to "fix" them. While all tick and some flea-born infections cause brain and psychiatric defects, this is **just one component** of treatment, an important Band-Aid, but not the cure.

This type of patient abuse is simply an admission of a health care worker's clinical ignorance. It shows a lack of knowledge in new and modern cutting edge tick and flea-borne infections. It is also an admission that they do not know how to use new, highly effective **direct and indirect** labs for detecting Babesia, Bartonella and Lyme.

#### Health Care Workers Treating Babesia and Lyme in 2009

Good health care workers are abused relentlessly, so I do not want to be disrespectful when discussing new Babesia approaches. In this supplement, I need to point out the testing and treatments that fail. It is important to note that the lack of knowledge is not due to defective physicians, because this is very new and progressive information. Some of this medicine has only been discovered in the last three-twelve months.

Most tick infection physicians have dozens of forces sucking away their learning time as they simply try to survive in this profession. Malpractice attorney commercials are as commonplace as car commercials. Government agencies like Medicare, Medicaid and the Social Security Administration demand time-consuming record production with compensation rates equal to those of slave wages. Insurance companies abuse physicians by requiring pounds of free paper and ink for copies of records to process their complex claims. Medical boards attack physicians without due process and often treat them as guilty until proven innocent, according to narrow-minded board members, appointed often due to merely having good political contacts. Medical Board experts are often poor experts in clinical modern medicine. Highly public DEA and Medical Board actions destroy the treatment of severe pain, anxiety and ADHD in tens of millions. Hostile relatives expect health care workers to know everything, work quickly enough to make a living, and to be "caring" and "mother-like" at the same time.

For example, my genius OB/GYN father was never so happy as when he retired from medicine, and he promptly stopped reading piles of medical books and articles.

These are the reasons why **top physicians are already well on their way out.** Passionate self-educating physicians are not going to be researching new Babesia findings. They will be unlikely to buy this book. Why? Because medicine has millions of new articles and thousands of new books published each year. Few can read 1500 articles on one infection.

So I want to offer some new diagnosis and treatment ideas for Babesia infections while offering respect for sincere health care workers. They are the cream of the culture. They try their best everyday and are abused from many sides, making medicine less appealing to bright young adult minds. And many shallow lawyers, politicians who are lawyers, insurance company gamers, and sadistic physicians on Medical Boards are to blame for the decay of the medical profession as a whole. Their goal is often placing perfect chart notes before people. The dirty little secret is that it is impossible to do both *complex and profoundly* detailed "optimal medical notes" and "optimal eye-to-eye attention" within a reasonable time frame. Insurance companies know this, and this is one of their sociopathic scams—"send us the highly detailed notes to justify everything." It's not uncommon for some small practices and all large facilities to appoint one or more Utilization Reviewers, whose job it is to spend countless hours trying to translate the importance of doctors' treatment decisions to various insurance company employees, who come up with even more strict criteria to try to reject paying for quality medical care.

Modern medicine is now run by attorneys, politicians who are attorneys, MBAs, physicians more interested in political medical societies than learning, simplistic physicians who cannot think outside their narrow yearly CME's, and health care insurance reviewers who put *paper before people*.

In this setting of anti-medical forces, it is very hard for any type of physician to be current on all aspects of tick-borne medicine.

A Babesia researcher is also limited in their ability, due to a lack of **clinical experience** with tick-borne infected patients. The research oriented physician is limited for the opposite reason, and only trusts super filtered double-blind studies, or guidelines that are often years or decades behind clinical practice. The full-time clinician is limited, because they work massive hours, which leaves little time to read new books. Indeed, my first large Babesia text from 2006 was purchased almost entirely by smart motivated patients. Perhaps it is because clinicians working slave hours have little time to read a book on one infection.

For these reasons, I offer this new information for smart motivated patients to read and then share with their physicians. It is my sincere hope that physicians will realize Babesia is not rare and feel reading this material is worth their time.

#### Studying Babesia is Very Useful Time

I see many patients being treated unsuccessfully for chronic fatigue, fibromyalgia or Lyme. Had new, advanced knowledge about Babesia been applied to treatment, such failures could have been avoided. **It is utterly amazing to see chronic fatigue and fibromyalgia conferences that do not include Babesia, Bartonella and Lyme disease when each is so common and can cause massive fatigue.** 

This omission is a profound disaster.

And of these three infections, Babesia routinely causes subtle or strikingly crippling fatigue.

Further, if Babesia or Bartonella is present in a patient's body, I do not believe Lyme disease can be cured, especially if it is not treated in the first days after a bite. Certainly, one can *lower the body's Lyme spirochete load* with aggressive treatments. But Lyme spirochetes and cysts will not be fully eradicated in the presence of these infections.

#### **Basic 2009 Babesia Principles**

- 1) No Lyme cure exists if a powerful co-infection like Babesia and/or Bartonella is present and untreated to the point of **full removal.**
- 2) Lyme cure is also likely impossible in the presence of ineffective routine dosing, (i.e. like **750 mg of Mepron twice a day),** which kills some Babesia but leaves some residual Babesia alive.
- 3) The presence of Bartonella causes massive types of immune suppression and will also likely lower antibody testing results for Lyme disease, Babesia, Ehrlichia and Bartonella. So Bartonella actually hides itself **and other infections like Babesia**.
- 4) Current **Bartonella** testing can only detect two of the 32 species published in the world's top genetic gene banks. Current national labs have not invested large sums to improve species or genus level Bartonella testing, or better visualization techniques that would increase the capacity to see Bartonella in a blood drop smear.
- 5) Current **Babesia** testing does not test for all possible human species. Current national labs have not invested large sums to improve species or genus level Babesia testing, or better visualization techniques that would increase the capacity to see Babesia in a blood drop smear.
- 6) Many Babesia species infect humans, and more species or species variants are discovered every year. I believe I am seeing patients with **a mix of Babesia species or species variants.** For example, I have patients with Babesia microti, Babesia duncani (WA-1) and suspected MO-1. This last species is all over North America. Further, I believe microti has more than one strain in the USA, and we already know it has more than one strain in the world. I believe the dose that kills one species or species variant, does not fully remove other species or other species variants. This is a revolutionary component in approaching Babesia treatment.

#### **Critical Babesia Issues**

- 1) Babesia testing is rarely done.
- 2) Lyme cure is likely impossible when Babesia is still present in your body.
- 3) Special tick infection labs also miss Babesia, and new techniques to diagnose Babesia are listed in this book.
- 4) Routine treatments of Babesia lower the number in the body, but do not cure.

Ignoring these four points can be very serious.

#### A Rude Babesia Awakening

After finishing a Babesia book in 2006, I kept track of my many patients treated for Babesia. I also inherited many people with a diagnosis of Babesia who had already been treated by dozens of approaches because of my large Babesia book. Yet as I watched the outcome of my treatment and the outcome of patients treated by top Lyme experts, most had residual Babesia. Dozens of alternative medical options did not cure on **blind** testing, even if patients reported improved function.

After publishing a large Babesia book, I felt I knew Babesia. But after seeing my 18-month treatment outcome results, I was very upset. Why? Because my treatment and dosing suggestions only lowered Babesia body load and led to full relapses after 18 months. And my diagnostic approaches were flawed in so many ways that vast numbers of cases were being missed.

In 2006, I wrote what I hoped was the definitive Babesia book, gleaned from Lyme experts. I did not want to be one of those fools who published "new findings" that are already in print years or decades earlier, so I studied

hard for my first Babesia book. But after extensive follow-up, the testing and dosing in the book clearly had flaws. So I have to eat crow and write this supplement. Babesia can be dangerous. We do not know how often it kills. I do not want to add to the sickness and mortality numbers.

Please understand however, that in some ways I am merely retracting some lines in my original 375 page Babesia textbook and revising some very select things. If you do not read the initial Babesia book, you could be hurt with updated treatments in which risks are not going to be discussed, and you will not be able to apply many of the principles in this supplement. I am not repeating any of the 75 topics discussed in:

The Diagnosis and Treatment of Babesia

or

The Health Care Professional's Guide to the Treatment and Diagnosis of Human Babesiosis

Both books have the same information, and both need this supplement.

#### **Routine Mepron Dosing Fails**

Why are you reading this book? I suspect it is because you or a loved one has already been diagnosed with Babesia. So we will discuss treatment errors first and then diagnosis errors.

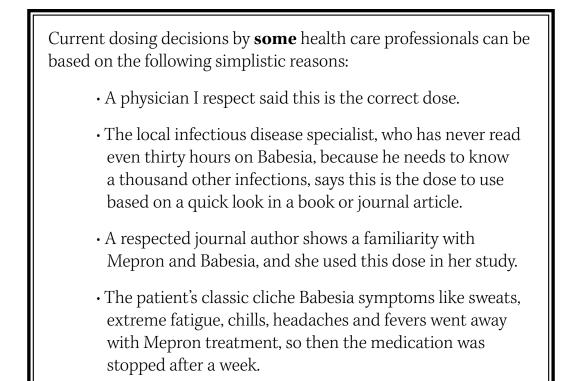
One of the most accepted beliefs among some clinicians treating Babesia is that the first line treatment of Babesia in adolescents and adults is **750 mg per teaspoon of yellow liquid Mepron (atovaquone) given twice a day with fatty food for at least five months.** This thinking is based on some simple reasoning. First, fatty food doubles absorption of this fatty drug. Second, Babesia is a protozoa living inside red blood cells, and since these red blood cells last four months in the body, five months is believed to kill Babesia. The extra month is to allow the Mepron blood level to slowly increase to a Babesia killing dose. It makes sense. It is reasonable. Some patients feel better on this dosing or feel better after it is stopped.

Yet, what is the solid evidence for this dosing in Babesia, using a wide range of new tricks to catch stealth Babesia in the body? We now have many new testing tricks in 2009 that were not around in the 1990's. They show this dose usually fails. Further, one smart retired clinician suggested getting a blood level on all Mepron patients. This is a very good idea. And since all drugs have a bell curve in terms of blood levels, some will have very low blood levels on 1500 mg per day.

But I think *most* patients on 1500 mg/day are taking a dose that will *not* lead to a cure. This is based on aggressive single blind testing of individuals. The "blind" part means the lab had no knowledge of the patient's diagnosis or their treatment. Most were inherited from other physicians prescribing 1500 mg/day.

I believe past determinations of effective dosing have been flawed. For example, the strong reliance on lab testing to determine a cure is a faulty approach. Most labs are terrible at detecting Babesia, and most of the Babesia species in humans cannot even be tested. However, new Babesia **genus** DNA testing being explored in various labs and **huge various Babesia species panels** using FISH technology should help determine if a treatment works. But low Babesia numbers might still allow some residual Babesia to be missed.

Further, vast numbers of traditional and alternative treatments are determined to be cures based on patient report. It is nice when a patient feels better. But many feel better after an excellent meal, a massage or acupuncture. But when trying to determine if residual Babesia is present, I have repeatedly found "feeling better" and "cure" are not the same thing.



#### The Bottom Line on Mepron Dosing

Over the last two years, we have found a wide range of ways to test for Babesia, in new and broad ways, and particularly have found ways to look for possible stealth low levels of Babesia. We have found that 1500 mg per day was a disaster. After 8-12 months of treatment trials by dozens of talented and wise physicians using these doses, we found, in my opinion, clear and certain evidence of residual Babesia.

Sometimes, the Babesia numbers found in a relapse appear to be low in patients who are not cured, but many have Babesia that surges and reproduces, and then their Babesia returns to modest numbers.

So what happens when someone takes 750 mg of Mepron twice a day? You kill those Babesia forms and species in your body that are vulnerable to that particular dose. It could be 20% or 80%. But you rarely get a cure. You may feel wonderful for a week after you are done with your treatment. You might even feel good for five years. But the majority of patients on this dose relapse.

Let me say that again. The recommended standard doses for the treatment of Babesia in the modern world, in my intense patient follow-up testing, merely **lowered Babesia body load, and never once removed Babesia completely.** The 750 mg twice a day dosing has been seen as a virtual 11<sup>th</sup> commandment. It was what I wrote in my Babesia text in 2006 and what most veteran Tick-borne infection experts feel is solid treatment.

So what I am saying is chilling. Every person in the world treated with this routine standard dose for Babesia has probably not been cured.

Of course, a very small number of patients are very poor at metabolizing the drug and may have a blood level equal to doses far in excess of 1500 mg/day. They are poor metabolizers for many possible reasons, including genetic limitations or altered biochemical pathways possible with infections, biotoxins and serious inflammation. So the enzymes that destroy Mepron do not work well, and the blood levels increase **significantly**. These people would get a cure with these high blood levels. But they are definitely not routine patients.

#### Who Are You to Set Babesia Dosing?

Recently I was told of a bizarre defamatory web site, led by a character disordered person and teamed up with a tiny group of markedly ill patients. They write as "all knowing" people, and yet are still obviously ill after many years. On the site, about fifty-five individuals are defamed. It is actually a very sad hate-speech type of place with no real Internet power.

But on the site, some asked a very interesting question: "Who is Schaller to be making authoritative comments?" "Where are his double-blind randomized trials?" "Where is his evidence?!" Usually such people have never done such a study or written a complex textbook themselves. Let me be blunt. I feel absolutely no obligation to convince you or any health care worker of the merits of what I am sharing. If I died next year, I would exit this life with the knowledge that I published this material to help you. It is hardly for me, since I will never recover the income loss of doing books like this one. So since I do not have the time and capacity to spend the next 20 years inefficiently trying to lift my positions to statistical certainty, the arguments in this text will not include two million dollar studies.

Years ago, one of my precious mentors Dr. Harvie Conn would be asked critical questions challenging his teachings, based on his massive study and experience in anthropology and religion. If it was a "question" that was simply far too complex to explain **and** had a critical abrasive edge, he would simply say, "I will let you wrestle with this. I am just offering my reflections." He said it with a kind and patient smile. But he was not going to waste time with immature character disordered students who had no sense that they were sitting at the feet of a serious player. I have spent thousands of hours learning this material. Some might resent my comments, and the way I express certain medical positions with an element of authority. Medicine is not diplomacy. It is sometimes life and death. Period.

To those who question the material in this supplement, I will simply let you determine if you are getting better, and what person(s) or agencies are leading in tick and flea-borne infection treatment and diagnosis. I support anyone who reads thousands of articles, spends their free time reading Babesia data and also carefully examines Babesia treatment outcomes from inherited patients. I also support other careful opinions.

## Simply, I will let you "wrestle" with this material. I am just offering my "reflections."

#### **Traditional Mepron Dosing Errors and Outcomes**

First, traditional dosing is Mepron 750 mg/teaspoon twice a day with fatty food. The same dose is given for all adults. Child dosing follows milligram per kilogram charts that are **not** designed for Babesia use, and are based on very limited research and experience.

### Should Dosing Fit a Standard?

One-size fits all dosing should always raise eyebrows. Ignorant bean counters in insurance companies seem to have their eyebrows shaved off. They ignore that every patient is unique, not clones, as they look at some "guideline" or "protocol" book on "effective approved dosing." All Model T's were made identically, so it follows that any person in a health care agency, medical society or insurance company that treats an individual as anything less than a unique person, with a unique physiology, is treating a patient as an object—a thing. With that in mind, non-surgical guidelines or protocols run the risk of being sociopathic, in addition to being profoundly medically simplistic.

#### Should Dosing and Diagnosis Fit Symptoms?

Second, some patients have very limited Babesia symptoms. In my experience, those with the highest antibodies against Babesia sometimes show no symptoms. Of course this tends to change over years if ignored, and Babesia positive patients who opt for no treatment will typically "crash" over time. This is not a polished word used in journal articles, but every experienced Babesia clinician and patient knows exactly what I mean.

#### Lyme Antibiotics Can Fail After Years of Use

Third, we know many patients do not feel better after a month of Lyme disease antibiotic treatment. Some do not feel completely better after years of antibiotics. This should raise a big flag.

Further, it is essential for tick-born infection medicine of the next twentyfive years, that we accept that patients bitten with deer tick bites rarely have one infection. Patients can have many types of Lyme species and other types of infections such as Babesia or Bartonella. Testing done on ticks to determine what percentage contain Babesia or Bartonella is profoundly flawed, since all labs underreport tick infections, and because no lab in the world has the ability to solidly test for all possible species and species variants for all tick-borne infections. If you or your child is in a suburban backyard, you might be bitten a few times a year by period sized deer ticks. Their bite is utterly painless due to injected painkillers. Their bite also includes the injection of an anticoagulant and an antihistamine. Deer ticks are immensely hard to see and are not black as depicted on routine printed identification materials. All of these facts together make deer tick detection a rare event. Further, the chance that you will only contract Babesia, and not other deer tick infections, is highly suspect based on the diversity of deer tick saliva and gut infections they carry. Having multiple infections should always change treatment, duration and treatment approaches.

# Why Do "Lyme Disease" Patients Stay Sick with Antibiotics?

All seem to agree that Lyme is harder to kill when Babesia is present. And all seem to agree that Babesia can be a very serious red blood cell parasitic infection—it can kill. It can markedly crush one's ability to function. So if this is true and the standard treatment for Babesia cure merely temporarily lowers body load, then this is a **medical disaster**. It is not a minor inconvenience for a patient. It is destroying seasons, years and occasionally decades.

Residual Babesia is a serious disaster that is currently ruining lives.

Further, when concerned clinicians see that a person may have failed their Babesia treatment, they do not unusually consider higher doses of Mepron, higher doses of artesunate (Artemisia) or proguinil — I will discuss all later in this update. Instead of higher dosing, they offer

treatments that I have found to be utterly worthless. One does not need 30 new golf clubs if your golf swing is poor; you need to use a few clubs correctly. After Mepron, artesunate or proguanil failure, some clinicians propose many complex and varied treatments, which offer the **illusion of advanced medical knowledge, but they are not generally effective when using advanced and fully complete Babesia tracking tests.** 

One sometimes hears of a physician or health care worker with five "protocols" for Babesia treatment, and after many of these have been used, we still find the patient has Babesia. It is unknown if it worked partially or had no effect. But in 2010 medicine, full Babesia cure is the only option.

Any person or any medical society can toss out a protocol. When I see some of these, I simply ask, "Where's the beef?" I see people running infectious disease societies, and their Babesia treatments fail. I see physicians or nurse practitioners treating Lyme with IV antibiotics for years and missing the residual Babesia. I see so-called "Lyme malpractice" experts who dress like drunks with impaired cognitions, flying around to do thought control. Some of these Babesia and Lyme denialists act like fascists, and some of their patients have left them, because they were medically useless as healers. In addition, when the patient was not fitting their belief system, some patients were disrespected. "You have been on x for the treatment of Babesia for y weeks. You are done." Period. It is as simple as 2 plus 2. Hardly. Other progressive practitioners tell us that a certain series of experimental herbs, hyperbaric oxygen or various "detox" options cure.

We have tracked patients who have very aggressively tried over twenty Babesia killing herbs. Only the strong derivatives used for malaria have worked. And it was never the weak artemesinin, but other forms. Artemesinin is like water to Babesia, that may cause a die-off reaction of some Babesia, but it is not a cure. I have told hundreds of physicians this fact, and many have not listened. Due to resistance, artemesinin is often found to have a decreased effect on malaria. (I recently wrote a textbook on artemesinin, artesunate and other Artemisia derivatives). In a single blind retrospective study of patients who have had expensive and extensive hyperbaric oxygen treatments (HBOT) at various competent facilities, **the cure rate in our post testing of Babesia was** *zero*. HBOT completely failed to kill Babesia. I recently posted this and a hyperbaric chamber owner, with an obvious conflict of interest, corrected me with no science and merely referred to her experience, saying that HBOT helps people "get better." I have no doubt this amazing medical tool is under-used. And I have also seen some patients report some enhanced functioning after HBOT care. The reason for this is unknown to anyone. But it is not a Babesia cure.

Finally, all modern people have exposure to a wide range of heavy metals and chemicals that do not help the immune system. Anyone wishing to live to be 95 years old should address this in one of many ways. However, I have not seen profound improvement in immune system markers with these interventions, and **I have never seen the human body cure itself from Babesia.** The human body can certainly limit Babesia for a decade in healthy patients, but not forever. Indeed, the human immune system seems to work much better, and the removal of immune undermining substances works better when **all** tick-borne infections are removed.

Some reasonable traditional or exploratory alternative Babesia treatments do cause die-off reactions, and will lower Babesia body numbers in some patients. These **partial treatments** can allow some patients to appear "well," but they are not fully recovered. Over time they will relapse.

#### I Have Babesia, But It Is No Big Deal

Some patients have an antibody response, but do not feel ill. Part of the reason they have an antibody response is often because they have such a small number of Babesia. They start their infection with few organisms. But over time, these definitely multiply. And over time, the power of such large numbers may crush the immune system in various ways.

#### I Have Babesia Alone

While it is possible to have Babesia alone, we generally find that missing other tick-borne infections is due to limited and defective **direct and indirect testing.** Most tick and flea-born infection testing is highly limited. So **one** infection showing up positive is expected, not rare. The use of one or even two laboratories for comprehensive tick-borne infections can lead to various infections being missed.

Further, **Bartonella suppresses the formation of many antibodies** in my opinion. After carefully selecting new and emerging Bartonella treatments that work to decrease Bartonella, we see Lyme, Babesia, Ehrlichia and even Bartonella antibodies increase. Bartonella turns off fevers and is able to float in the blood without causing sepsis death. It is a titanic immune suppressor, and anyone who does not appreciate this impact on testing is doing old medicine.

#### I Feel Better on Treatment X

We will discuss this in further detail, but a substance may cause a feeling of improvement by dozens of ways. It can decrease inflammation, it can increase anti-inflammation chemicals, it can have steroidal properties and it can kill some Babesia. Nonetheless, at least one tick-born species might be killed or reduced by treatment X, and this can create the illusion of cure.

### Mepron Makes Me III at Routine Dosing What Does This Mean?

Some patients kill Babesia by merely taking a crumb of a medication or medicinal herb. Some patient's experience Babesia die-off merely by licking a spoon coated in yellow liquid Mepron. But a common or serious die-off reaction from a Babesia treatment is not the same as cure. Some patients need to start with a very low dose of Mepron, e.g., literally 1/16th of a teaspoon or 1/4th of its less effective tablet form, Malarone. The starting dose is never the ending dose.

If a specific treatment is only effective against Babesia, which causes a feeling of sickness, it is probably a sign that some Babesia is dying. If this is true, nothing is gained by rushing to a high daily cure dose — you are already killing enough large Babesia protozoa parasites to cause illness. As you start to feel nothing on the lower dose, you can increase it. **Also, do not confuse Babesia die-off with the die-off of other infections.** For example, some aggressive physicians place patients on an antibiotic stew with a huge mix of different medications and herbs. So you might then experience a Herx reaction or die-off, and feel worse. But you might also confuse Babesia treatment die-off with that of other infections, such as Lyme disease. Keep in mind that most effective treatments for tick and flea infections can cause body discomfort.

One way to possibly distinguish a Babesia Herx die-off reaction from the death of Lyme or Bartonella bacteria is when your medications are stopped, you feel wiped out or achy. The Lyme and Bartonella misery rarely lasts over 24 hours. If one is using a Lyme cyst buster, it might last longer. Babesia die-off can sometimes make one feel poor for 36-72 hours. Of course, I have seen on rare occasions a perfect antibiotic or antibiotic herb directly hit a vulnerable species of Lyme or Bartonella, and the person was non-functional for days, but this probably happens only in 5% of individuals. Of course, if the starting dose of any antibiotic is very high, a Herx die-off lasting 36 hours is more common.

Obviously, an IV or intramuscular injection with a high starting dose in the first 5 days will result in a massive Lyme die-off in many people. This is one reason I do **not** believe in *starting* IV Rocephin at 2 grams/day or Bicillin injections at 1.2 million units/day. Dose one and two should always be fairly low to allow the body to not be excessively shocked by the treatment. On occasion, so many Lyme bacteria are killed in a couple days, that it is actually too much to handle. This is why your health care provider should consider IM Bicillin shots at 1/4th of the injection on day one, 1/2 the injection on day three and a full needle on day five. After this, jumping 100% from 1.2 million to 2.4 million units of Bicillin LA in a 24hour period can cause a die-off that sometimes lasts 48 hours. (Many liver protection options for these powerful medications are discussed in my 2006 Babesia textbook).

Again, the addition of a Lyme cyst buster, which should always be present at least 3 days a week, can also lead to a 1-3 day Lyme die-off. Why? Because the regular antibiotics have converted many target Lyme bacteria to cysts, and the sudden high dose of an effective cyst buster will cause many Lyme cysts to explode.

Babesia is such a large parasite inside red blood cells and not a little tiny bacteria. When Babesia die, the Herx reaction can last for days if you kill a significant number, and especially if you continue taking the same dose of medication. We generally suggest, if one is very ill on any treatment, to take one day off to allow the debris, inflammatory chemicals and possible biotoxins to be reduced before restarting your treatment. But this is something you and your physician have to discuss. Die-off of any infection in the brain, together with additional inflammation in the brain, can reduce concentration and lead to car accidents, work or childcare errors, inappropriate relational comments and other troubles with functioning.

#### What is the "Correct Dose" of Mepron?

The correct dose of Mepron for you, as a unique person, partly depends on your ability to handle the medication. For example, if you take any dose over 1500 mg/day and have increased liver enzymes, you may need to adjust your treatment. Liver damage can show up such as an ALT of 100, an increased abnormal GGT or a special "chemical biopsy" available from LabCorp called **Hepatitis C Virus (HCV) FibroSURE (test number 550123 with a serum sample protected from light).** If any part of this FibroSURE test result shows damage such as necrosis, fibrosis or inflammation, you may need to look at another treatment option and/ or lower the dose. While increased liver enzymes can be Babesia or other infections, Mepron can bother the liver at any dose. So if this becomes an issue, you may only be able to use Mepron as an augmenting agent instead of a primary killing medication. In my textbook, *The Diagnosis and Treatment of Babesia*, which is required to safely use this medication, I discuss liver protection on pages 224-234. If this is a new idea, and has not been discussed in your treatment, it is a serious concern and is an error. It shows you are getting nutritionally ignorant medical care that does not prevent liver troubles. Such scalpel and synthetic drug company medicine is simplistic. My medical training never discussed organ damage prevention such as supporting the liver. Why? The answer is clear: there was no sponsorship from large pharmaceutical corporations. Yet most drugs, including medications used to treat most tick and flea-born infections go through the liver and can be a challenge to this vital organ. Using items that protect the liver is very basic medical care. It is not routinely done, due to ignorance of liver biochemistry, basic liver detoxification requirements and simple nutrition.

If you are not on agents to support the liver, you may **not** be able to use high killing doses of Mepron. So read the liver sections in my first Babesia text, and use nutritional natural chemicals that the liver already uses in its two phases of detoxification and medication removal.

# The End of The Mepron Cliche Dose

To reiterate, no matter where a patient is in the world, they all seem to be prescribed 750 mg/teaspoon twice a day for a few weeks to eight months. Any dose can lower Babesia body numbers, but patients are found with clear evidence of Babesia eight to twelve months after they stop this dose.

Therefore, our patients wanted higher dosing. Initially, many increased their dosing on their own. They were already getting routine liver checks, so they felt the risk was modest. Some felt profound improvement on the higher doses of Mepron. Others, who had previously felt that 1500 mg/day was "like useless water," now noticed multiple body effects. Once it was obvious that higher dosing was vastly more effective, patients willing to do basic organ health tests were occasionally allowed to be given higher dosing. This was particularly true if indirect testing and other types of testing showed that Babesia was still present after a period of treatment.

The ideal dose to kill your one or more Babesia species is an individual decision made between you and your physician. It means you will go to the lab for liver checks routinely, you should take liver support nutrients, and you know what to do if you have a profound die-off that makes you require a day in bed. The first thing you would do is stop your Mepron until you are back to normal.

# An effective dose might do the following sample things that I will expand on and clarify later:

- \* ECP blood levels usually increase.
- \* Babesia antibodies often can increase at tick and flea specialty labs if a positive antibody is found before treatment. (But if Bartonella is present, this can be suppressed, since Bartonella suppresses some parts of immunity).
- \* The ability to see Babesia by a Geimsa stain and other special blood smears is diminished, because the Babesia numbers will decrease significantly.
- \* If a small amount of Babesia is present, the VEGF might be low.
- \* Bartonella makes VEGF, which is a chemical that causes dozens of unique skin findings. Babesia lowers VEGF. If Bartonella is present with no Babesia, VEGF will be above normal. If Babesia is present, VEGF will usually be in the normal range or quite low.

# Mepron: Dose or Duration?

While the effect of high Mepron doses was devastating to Babesia and resulted in clear die-off effects with a rapid loss of Babesia clinical symptoms, after a year, we found some return of the Babesia. So while higher doses seem to be curative, treatment durations of only four weeks is not 100% effective. So we are currently using these doses for longer periods. The duration depends on many factors such as labs to show the presence of residual Babesia, the cost of the Mepron, treatment fatigue with taking it whereby a patient comes to hate it, and other factors. If someone feels ill on Mepron, they should not take the medication for at least a day. We do not count the day off in their treatment duration. **Further, we will not use this high dosing with patients who will not do liver and basic organ testing every fourteen days.** 

Here is our current reasoning: if 60 days of Mepron removes **roughly** 80% of all Babesia species and variants, and this duration using a *modestly* **"high dosing"** causes Babesia to be invisible on blood smear testing, then I propose that an additional month and even higher dosing is optimal.

Of course, indirect lab testing discussed in detail later can show Babesia, even when a blood smear is negative. Further, most labs can only detect 1-3% of Babesia. This is utterly stunning. One veteran expert Babesia pathologist has said that most labs rarely look closely at red blood cells. Further, most labs do not appear to know that Babesia has forms that are outside the red blood cells. (This is discussed and shown in my recently published Babesia Hematology or laboratory forms textbook).

I cannot post the definition of a "high" dose. It might also depend on the species and variants present. Also, **I do not believe one daily dose or** "**one size fits all.**" The high dose for one person is not the right dose for another. It partly depends on the effectiveness or die-off reaction to the medicine. **One must also be very alert to the sensitivity and inflammation status of the patient.** Further, if more than one species is present, each may require a different dose and duration for eradication. "Guidelines" and "protocols" are often junk medicine and a flawed assembly line approach to Babesia care. It confuses a car needing an oil change with a unique human body.

In summary, both dose and duration are vital to achieve a Babesia cure.

#### Updated Thoughts on Malarone

Another Babesia treatment option is to use the combination medication called "Malarone." It combines weak and poorly absorbed solid Mepron (atovaquone) with proguanil, a medication that has been used since the 1950's. I discuss many issues involved with Malarone in my main Babesia textbook on pages 118-124. Currently, it appears that proguanil, with its ability to damage Babesia DNA formation, is **not** available alone from a compounding pharmacist as of January/2009. It is available to some of my patients in other countries.

It is unlikely Malarone at three tablets a day, which is 300 mg of proguanil, will cure Babesia. Some consider using **much higher doses.** I have seen probable cures, as long as this is not the only treatment used, and that all treatments are at high doses. I am not sure if high dose proguanil can be curative alone, but I think it is possible. We have seen very powerful effects with dosing **over** 300 mg per day. Also, I do not believe the Mepron in the Malarone tablet is doing much to cure Babesia. The **tablet** form of Mepron in the Malarone is poorly absorbed and would only increase the Mepron blood level slightly.

So I would propose that high dose proguanil acting with high dose liquid Mepron might help achieve a cure treatment.

# Artemisia (Artesunate)

Two years ago, I wrote the most up-to-date book in English on the major derivatives of Artemisia. This Chinese herb, grown on every continent, is believed to offer extracts that are the best treatments currently available to treat malaria. This is the opinion of the World Health Organization and the United Nations Children's Fund. The United States Military currently grows it in Wisconsin for our troops in Afghanistan and Iraq. Surprisingly, the FDA has not raided them—I guess they only like raiding smallunarmed expert compounding creative pharmacists, who use top quality replacement bio-identical hormones. (Yet the FDA supports Premarin and Prempro with 200 horse urine components and possible carcinogens).

In my Artemisia and first Babesia book, I went over all the major derivatives of this amazing fern and discussed two that seem to get the most press in the United States. I am not going to rewrite these materials here, but I want to update our experience in Artesunate's ability to kill Babesia. But before I address this, I want to comment on some critical issues.

# "Artemisia is Toxic to the Brain" Is This True?

I am repeatedly asked why many physicians who treat tick and flea infections have not read my Babesia textbook, my Artemisia book or my Bartonella articles and textbook. Perhaps it is because they are profoundly busy trying to pay malpractice premiums and expensive support staff— it never occurred to me that any health care worker had time to read books on one topic.

But recently, I was quite annoyed when a patient received a second opinion by a neurologist interested in tick-borne infections. A common treatment for most of his patients seems to be Intravenous Immunoglobulins. While this can be a useful temporary treatment, it is not a cure and shows a lack of 2010 knowledge about how to treat tick-borne infection clusters. The use of this treatment is well intentioned but is not a cure.

He was told that I felt some Artemisia might be a useful treatment for Babesia based on my textbook on the topic, and with a sweep of his hand, he mocked this notion and pulled down some tiny book on Artemisia. Since I own every book in English published in the last 15 years on this herb, one wonders the source, date and quality of his book. Apparently, this small book was his source for the bizarre statement that "Artemisia damages the brain and should never be used."

First, probably the *majority* of the medical world has decided select Artemisia derivatives should be the first-line treatment for malaria. We are talking about at least 400 million malaria patients infected each year worldwide. The World Health Organization and the United Nation's Children's Fund, as well as many vast numbers of other medical groups support its use. I doubt these physicians and scientists with experience with vast numbers of malaria patients, perhaps as much as a 10,000% more experience than American physicians, are engaged in brain tissue damage. Indeed, based on a chapter recently published in an Oxford Press textbook on cancer by my friend Ching Zhang and my large Artemisia textbook, some Artemisia derivatives appear to have anticancer effects. Second, saying Artemisia damages the brain and should never be used, is like reporting that an overdose with a 30 year-old antidepressant harms the heart, and then deciding all psychiatric medications are dangerous. Artemisia is not a drug, but the name of a fern that is **the source of at least 30 derivatives. For someone to talk as if all these derivatives are the same, shows they are clueless.** In the same manner, I would not say all addiction physicians are bad just because a rare few are sadistic, promote pain or are cognitively impaired.

The evidence shows that **some derivatives** of Artemisia are not useful. Some forms are not safe and are increasingly being rejected, or have already been rejected for use in many places around the world. **Some are useful malaria and Babesia treatments but require high dose specific anti-oxidants,** discussed in my textbook on Artemisia or my first Babesia textbook. We find the same thing in advanced citrus chemistry. Crush a citrus rind and you will find some chemicals that are harmful, and some that are very useful for many medical things, such as the killing of biofilm- making bacteria that also make biotoxins. This is very simple college herbal pharmacology science.

#### Are Artemisia Derivatives Safe?

I am not going to repeat the detailed discussed on this topic addressed already in my Artemisia book or my Babesia textbook. Since no Artemisia derivatives are approved by the FDA and are treated like supplements, I am not going to make any authoritative health claims. But let us focus on two forms of Artemisia that are used commonly and "prescribed" by some trying to apply malaria treatments to Babesia treatment.

Artemisinin was first promoted in North America in the progressive or alternative medicine community as a treatment for Babesia. It was offered with useful sincerity and along with products that are clearly useful to human health. However, those using it had little advanced capacity at new modern testing techniques to determine if it was actually doing much to cure a patient, and often the health care practitioner and patient was left to determine the benefit by **patient report and experience**. But if an agent lowers Babesia body load only, and does not lead to a cure, I consider it a failure. Sure, it is nice to kill off **some** Babesia, but **no one should settle for a treatment that leaves parasites alive in their blood.** According to one of my friends Dr. Ching Zhang, at a recent treatment and dosing outcome meeting with our staff in Naples, he mentioned that the World Health Organization has already rejected Artemisinin as a preferred malaria treatment, due to its "profound weakness" and due to "side effects" far in excess of its effectiveness.

We have found in our artemisinin Babesia outcome testing that artemisinin does cause die-off of Babesia in some patients. But the dieoff only represents a very small percentage of the patient's total parasite body amounts. Further, the death of even small numbers of parasites includes the release of parasitic debris that is far in excess of the debris of dozens of dying bacteria. The point is that even modest numbers of destroyed parasitic Babesia can make a patient feel quite ill and appear to be curative.

I treat many patients who have been to a large number of physicians before me, some of which are talented and very gifted individuals. Some of these brilliant physicians have discovered Babesia or suspected Babesia, based on a complete look at a person's clinical picture, and treated them with high dose artemisinin together with 1500 mg per day of Mepron for over 5 months. Nevertheless, I found that clear and certain Babesia was still present after these trials.

So in conclusion, we regard artemisinin as a herbal drug which *fails* to cure Babesia. Anyone that promotes "Artemisia" with the derivative artemesinin as a *Babesia cure* has not done their research, or they have not done careful and detailed follow-up on its use.

# Is Artesunate Safe and Effective?

This derivative of Artemisia is not FDA approved for any health claim. So if you want an "FDA approved" treatment for Babesia, this is not a treatment option for you. If you are a health care practitioner who feels safe only using FDA approved medications, this is another reason to ignore this section on the derivative artesunate.

Artesunate appears to be "registered" with the FDA, per Dr. Ching Zhang, and based on a FDA form I briefly reviewed. It appears to be registered as a supplement, and so by definition cannot have FDA approval for a formal claim to help a specific disease or illness. **Therefore, no formal claim is made here.** No extensive drug testing required by the FDA has been done on artesunate to pass and receive FDA drug approval.

However, in many parts of the world, artesunate is used routinely in the treatment of malaria and to a far lesser extent in the treatment of Babesia. The most popular or perhaps the best-known company making artesunate as of this month is Hepapro, which can be found at <u>www.hepapro.com</u>. They are directly related to Dr. Zhang. The purity studies by various agencies in China, along with third party testing in the USA, seem to show these products have very high quality. The toll free number for these products such as artesunate is 888-788-4372. It is called "Artemisiae" on their order sheet, and this is what you order should your health care provider decide with you to use this as a treatment. They call it by the general fern name with an added letter "e," perhaps because few have studied the various types of derivatives, and patients do not know what to order.

If you use artesunate and start to feel new ear pain, I would stop the medication immediately. If you are not on anti-oxidants, **If this side effect is a surprise to you, the person suggesting this treatment is** *severely under-educated,* and perhaps you need to purchase one of these three books: my Artemisinin book, the Artemisia Derivatives book or my Babesia 2006 book—all discuss this issue in extensive but clear detail. You only need one of these.

Sometimes patients sense as if they have "a hand over their ear" or a "new fullness" in their ear. **If they start on high doses of select and mixed** 

anti-oxidants, this might fix the ear problem, but we do *not* feel that these sensations are ever acceptable. The dose should be lowered to one that completely eliminates the sudden onset ear pain and/or pressure. If your treating health care provider does not discuss this issue with you, there should be cause for concern. It means they are not offering you an educated and full basic informed consent, and they could harm your hearing by such an omission.

#### The Problems of Artesunate Dosing

When the initial dosing of Dr. Zhang's artesunate was proposed, it was based largely on the dosing often used to kill malaria. The 400 mg capsules, which are not 400 mg of artesunate, were felt to be appropriate for the Babesia parasite that looks markedly close to malaria inside red blood cells. In Zhang's book on Lyme, the proposed dosage for adults is one capsule three times per day as a Babesia dose. In our experience, when following this treatment formula, the following problems arose:

- 1) Some patients are so sick and sensitive that they can only begin with 1/4th of an opened capsule. We generally have them buy empty 0, 00 and 000 sized thin capsules from compounding pharmacists like Myerlee pharmacy 239-482-6232. The use of two or three of these sizes places at least two or three layers around the herb powder from the opened capsules to help reduce rare stomach annoyance. Eating food with each dose is also advised if you have a sensitive stomach, despite any bottle directions that direct you to take on an empty stomach. Generally, over time all of our patients were able to increase their capsule number to high doses. Some needed stomach care, such as slippery elm from vitacost.com to coat the stomach with a slippery protective film.
- 2) Some patients come to us with raw inflamed stomachs, skin or blood vessels and **low** levels of **anti-inflammation** chemicals throughout their entire body. So increasing any dose of any medication needs to be handled in a very tailored way. Imagine the insanity of giving each man or women the same business suit. We consider the fitting of a suit's cloth to the skin. A suit only has about a dozen variables for

an optimal fit. How bizarre if everyone is given the same suit—both men and women, tall or regular height. And yet we routinely accept "guidelines" and "protocols" or "FDA dosing" for a medication or herb when the body has thousands of chemical reactions and is immensely genetically and metabolically unique. Why?

- 3) A number of patients had another reason for being careful with all Babesia medication and herb dosing—because usually no one ever checks to see if you have had a HLA 15/16--6/5--51 genetic pattern (R. Shoemaker) or have indoor mold mycotoxin exposure. Mycotoxins and water intrusion is found in 30% of USA structures (per EPA data). And since 95% of "expert" mold remediations are poor, many still suffer with inflamed tissues and body fluids, after the mold is supposedly removed. We show in *Mold Illness and Mold Remediation Made Simple* and *When Traditional Medicine Fails* the ways to quickly and easily realize if you are exposed to mold, and if your tester or remediator is unskilled. Both books get to the point.
- 4) Another Babesia treatment problem is when a patient also has Bartonella, an infection far more common than Babesia or Lyme, and which **can undermine antibody testing.** Please see my two-part colored books on *The Diagnosis and Treatment of Bartonella*. Anyone who is not familiar with this material is offering suboptimal treatment for tick and flea-borne infections.
- 5) Patients on artesunate 3/day for over nine months still had significant Babesia, so this showed a profoundly flawed dosing problem. One oriental health care worker said the reason this 3 per day dose did not work was due to a "Western" problem of "rushing" treatment. This is complete nonsense and comes from the serious error of plugging in malaria dosing to Babesia dosing. Babesia is usually less deadly, but is much harder to kill than malaria. Further, artesunate at 3/day for **18 months** failed to remove Babesia. Is a non-Western treatment supposed to be used for 50 years? This is unreasonable. Such sloppy dosing comments are also caused because these alternative medicine "experts" are not allowed to do complex multi-faceted direct and indirect post-treatment Babesia testing. You need a physician's license or other professional license to order lab testing. Otherwise, you have to use dubious and non-specific proofs of a cure.

- 6) Increasing the artesunate dose to 2 capsules three times a day for many months studied in inherited patients still did **not** offer a cure, but did reduce Babesia body load. So doubling the suggested dose was not a cure.
- 7) Some patients have many other medical troubles, so some health care providers do not consider artesunate, or even intense searching for any tick or flea-borne infections, including human Babesia. They only look at **a few medical areas**, such as cholesterol, thyroid levels, yeast trouble, heavy metals, immune support, prostate size, liver detox enhancement, hormone replacement, fatigue Band-Aids, colon cleansing, genetic pathway troubles, nutritional optimization, psychiatric symptoms and other narrow medical issues. They are clearly limiting diagnosis and treatment to **their personal areas of expertise and interest**, and are missing other profoundly serious sources of illness such as Babesia. **This applies to progressive, alternative and traditional physicians**.
- 8) Some practitioners have heard that artesunate one capsule three times a day was too low, and did not realize that this herb is so powerful that it should never be used aggressively **without significant antioxidants.** Some have even said artesunate should not be used with anti-oxidants or its effect is lost. Nothing is further from the truth. Indeed, the safe use of artesunate in a high dose setting requires aggressive diverse anti-oxidants, since it is an agent that kills Babesia most likely by its use of free radicals smashing into the parasite. (See either of my Artemisia books or either of my Babesia 2006 books for suggested anti-oxidants).
- 9) Understanding how artesunate works will allow you to dose it correctly and understand the need for nutritional protection.

First, artesunate rapidly rises in the blood and then falls very quickly in approximately three hours, which is safer for the body than a constant high dose of a free radical maker.

But how exactly does artesunate work?

Imagine a drunk man with a gun in a phone booth trying to shoot the Yellow Pages. The Yellow Pages represent the Babesia inside the red blood cell (the phone booth). Free radicals, acting like bullets, are sent out by artesunate in no specific direction. Some hit and destroy the Yellow Pages book representing Babesia, and some hit the glass. If we realize Babesia is inside of red blood cells and the glass represents the red blood cell membrane, then it is clear we need to protect the "glass" or red blood cell membrane. My concern is that red blood cells need to squeeze through very tiny capillaries in the eye, kidneys, brain and other organs, and if the membrane is hit with heavy numbers of free radicals, it might become like fried chicken skin, or damaged in other ways that slow its movement in capillaries. It might cause microscopic blood sludge or clots in very tiny blood vessels, if the red blood cells lose their outer membrane flexibility.

Let me say this in another way and expand the point to capillary walls. If some free radicals destroy parts of the red blood cell membrane or "glass," and free radical "bullets" are able to get out of the red blood cell, they might hit **the capillary walls and cause damage. You do not want capillary wall damage in any organ of your body.** 

This is one reason why my Artemisia and Babesia books go into so much detail on the different free radical catchers or anti-oxidants. We try to only present good research that lists **which anti-oxidants work at catching and controlling stray artesunate derivative free radicals.** If these are used at high doses, it is likely artesunate will usually be safe. Indeed, there is little data on the dangers of artesunate, but a few articles show this issue should not be ignored, and so they are discussed in my Artemisia and Babesia books.

For example, let me mention one study on the use of artesunate for **malaria**. No anti-oxidants were used, and patients were given Zithromax (azithromycin) at **1500 mg** per day—a massive dose compared to routine USA infection specialists dosing—together with artesunate 100 mg twice a day (Plasmotrim-50 Lactabs).

Another group received a profoundly high **2000 mg** of Zithromax per day with a double dose of artesunate of 200 mg twice a day. This was a

superior treatment to Zithromax 1500 per day and traditional quinine for killing the malaria in 28-day trials. The artesunate trials showed excellent effectiveness, and even a mere three days showed clinical benefits. In terms of safety and adverse reactions, the artesunate trials were without incident, though occasional patients had nausea associated with the high Zithromax dosing, which the authors feel is required due to the poor effects of even 1500 mg per day when used alone.

While it appears Zithromax or azithromycin helps kill malaria, our experience doubts its ability to kill Babesia. This shows, yet again, that merely plugging in malaria treatments as if they will be effective Babesia treatments is folly. Finally, in terms of the issue of safety, no hearing or walking disturbances were noted in this study with artesunate. (H. Noedle S. Krudsood, K. Chalermratana, et al. Azithromycin combination therapy. *CID* 2006; 43:1264-1271).

Our extensive research on patients who self treat with artesunate is that ear side effects are **dose related**. A patient with ear pain or ear fullness that is **new** is related to a dose increase or a starting dose that is too high. In addition, a final effective cure dose may be markedly higher than a low starting dose that can only kill a small percentage of Babesia. However, we have seen patients that use 1/4th of an artesunate capsule for two weeks before increasing their dose, because the low dose will kill some very vulnerable Babesia.

Dizziness is usually **not** a sign of artesunate damage. It usually is a sign of Babesia die-off or Lyme die-off. If it is a new symptom, or causes you to be at risk on stairs or while driving, lower the dose and take it every other day. Most patients who report dizziness with Babesia medications have had dizziness **before** Babesia or Lyme treatment. Nevertheless, it can be a die-off reaction in some patients and is not acceptable, because it is dangerous, especially if carrying an infant down stairs or if you are driving. In this regard, any patient with tick-borne disease should allow others to drive as much as possible due to seizure risks. They might be rare, but if the risk is 1/500, it is too high. So consider things that decrease seizure risk such as IV or **sublingual** magnesium. Many other nutrients and herbs are suggested to improve the health of the brain and to decrease seizure risk. But this topic is outside the scope of this book.

## The "Best Dose" of Artesunate

The word "guideline" or "protocol" is more fitting for pet rocks or cars getting an oil change than people. If you are getting "wiped out" with one capsule, that is an effective dose for the next two weeks. If you feel nothing on a higher than expected dose you might increase artesunate with permission from a licensed health care practitioner, who has read extensively on Artemisia derivatives. You might also consider going higher with select anti-oxidants. The ideal top dose for each person is based on ear side effects, patient tolerance and the ability to afford the uncovered expensive Hepapro capsules. Many other sources of artesunate exist, but are outside the scope of this supplement textbook. If artesunate high dosing is financially impossible, consider taking the top tolerated dose **once a day.** 

Another issue in discussing the suggested three times a day dose, is that ill and confused patients sometimes will not divide the dose into **three doses a day,** and will take it all at once. So they hear that their friend or relative is exploring a high number of capsules per day in **three divided doses**, and they take this in **one dose**—this could cause serious damage. Because a dose taken at 8 am is gone by noon. But if you take the morning and afternoon dose together, you could hurt yourself. Artesunate is meant to have a rapidly increased blood level and then leave the body.

Second, I know of patients who know to start very slowly and increase by one capsule every 2-7 days, and for some reason they forget this and share top dose information, and so a friend or relative then starts at the top dose—this is not the way one uses this medication! You do not test baby formula by throwing a large tablespoon in a treasured infant's mouth to see if they are comfortable—you touch the milk to your wrist to see if it is safe.

My concern is that once a "standard" top cure dose from one patient posts their dose on various web sites, patients will **start** with this dose,

and might possibly get a stroke, pulmonary embolism, clot or other body damage from the sudden die-off of large Babesia parasites due to blood sludge.

However, *I will tell you*, if you are using eight capsules three times per day, this is *very* unwise.

# Other Babesia Drug Options-Old and New

In my main Babesia text from 2006, I mention many other Babesia medication options. Most are drugs that are already in use and had some articles reporting they were successful. Some other drugs were recently FDA approved, and others were soon to be released. You are welcome to read about these options.

Simply, in this 2009 supplement, I am only focusing on the best options. But I am always looking for solid new treatment options.

#### Synergistic Babesia Killing

In summary, our current approach to killing Babesia is to use all the treatments that kill it, at the highest tolerable doses, for preferably twelve weeks. We feel that x plus x plus x = 10X.

One way to check if someone is improving, is when they stop these medications, they feel ill again within eight weeks of stopping with a return of classic Babesia signs and symptoms.

Another test for Babesia cure involves a final ECP check. Once the ECP level returns to normal, and at least twelve weeks have passed, take a large volume of medications such as Mepron, Malarone and artesunate for six days, and then test the ECP after a week. **If the ECP goes back up, especially by 30%, it is likely some Babesia is still around.** If serious treatment is started fully, and the ECP goes up even more, longer full treatment will be required. I believe some Babesia is still present. We would suggest getting an ECP with every blood draw, if treatment

is restarted. Other Babesia die-off tracking labs are being explored, and indirect tests are discussed below.

**ECP is not a 100% reliable test,** but it is a very useful one in tracking Babesia treatment. If no Babesia treatment is present, it detects approximately 15% of patients with Babesia. Meaning, if you are **not** on Mepron, Malarone or artesunate, you cannot rely on it to diagnose Babesia in most patients.

# Treating People Who Work or Go to School Full-Time

Robert is a physician working 10-12 hour days seeing seven patients per hour. He is a very smart man and does useful work in the very limited time he has with each patient. When it was clear he had some tick-borne infections, one of the first issues was when we were going to treat him. If he became foggy from a medication, as he was evaluating a possible heart attack or possible cancer patient, then he could not be treated.

Yet Robert is like many of my patients. Others are professional athletes, politicians or media workers that have to give 300% on any day, week, or season they perform. Other patients run companies that must constantly adjust to new economics. Others are caring wise mothers raising many children. None of these individuals can be in bed for two days after a Babesia medication blows up many single celled parasites.

With patients like Robert, we use the weekend or whatever days they are off or have backup, as high dose trial days. We list their infections and then typically use a high dosing twice of two medications on Friday. They take one dose when they get home, and then the other Friday night.

We do this for 3-4 weeks and try every major useful medication for all infections that have been found. We note which medications and which doses have a strong die-off effect that would undermine their functioning. If they decide on their own to use the non-FDA approved artesunate, we note what dose bothers them. They might use a dose of artesunate or other drugs that is 20%-45% **below** the "bothersome" dose during the week, and the full bothersome dose Friday.

In summary, we use the information from 4 weekends to put together a Friday double treatment that includes a treatment as soon as they arrive home and at night. Then they would also have a very large dose Saturday during breakfast. If they have any vacations, we try to use 2-3 days of heavy treatment while they are not traveling.

Sunday is a medication off day in which no medications are taken. Sunday is meant to allow the die-off debris from the potent medications to be removed from the body. We sometimes use cholestyramine on Sundays to mop up medications. This medication has been used in vast numbers of medical papers to mop up biotoxins **as early as the 1970's,** though some curiously write it is a new biotoxin binder discovery. We feel it may clear some medications such as Mepron faster, and theoretically perhaps some Babesia debris with fatty components, but this latter notion is unproven.

If you are going to pursue this high dose "weekend" approach, it is useful to have a number of anti-nausea medications, including medications such as Zofran, belladonna and transdermal promethazine cream. The patient should keep these nausea options in their possession and especially during high dose days. One place to purchase anti-nausea skin creams is from Myerlee Pharmacy who have exceptional service. Their number is 239-482-3022. This way, if the patient is dosed higher than is comfortable, they have three medications to turn off nausea that work by different mechanisms.

Also, we feel that anti-nausea creams or pills should not be used when one is about ready to vomit. They should be used at the first sign of any mild nausea. If it turns out it was only an emerging nausea—great. But emerging mild nausea can be vomiting in fifteen minutes. So do not wait ten minutes to treat the nausea. While this is not usually an issue, it is a side effect with 10% of adults and 20% of children at some point. Further, my impression is flu associated nausea and vomiting is increasing, and so these things are useful to have in the household to prevent an hour of agony.

Finally, weekdays are not necessarily days with no medications. But they are days in which good functioning is preserved, because only modest medication doses are used together with Band-Aid medications.

# The Use of Alternative or Progressive Medicine

As a child, I grew up being exposed every week to advances in modern medicine. My father was an award winning physician and genius biochemist. We share a love of creative clinical medicine.

So decades before writers or experts in natural bio-identical progesterone were discussing its superiority to synthetic options, he was treating PMS/ PDD and peri-menopause symptoms with immense success in **thousands** of women. (The FDA rejects his position, so I cannot legally promote it). And he was using doses far superior to weak non-prescription creams that do not give optimal effects.

When advanced nutritional science emerged as a way to prevent chronic diseases and to replace the useless one vitamin pill per day medical model, he was already working with nutritional leaders and offering top quality nutrients at *full published wholesale prices—not mere discount prices.* As a vitacost.com and NSI medical nutraceutical designer, he mentored me to the point that the elite physician core added me to their nutrition science team, as they have gone on to serve over 3 million customers.

As the years have passed, I have written the only recent book on the clinical use of select malaria **herbal derivatives**—the standard of malaria care worldwide, including use by soldiers in Afghanistan and Iraq. These Artemisia derivatives are recommended by the World Health Organization and the United Nations Children's Fund to treat the malaria that infects 1/12<sup>th</sup> the world each year.

Progressive and alternative medicine has about 200 proposed treatments for Babesia. I believe I have explored the vast majority of these options at a massive self-funded expense. I appreciate that some feel they are improved or even cured with various progressive or alternative medicine treatments. However, such claims require someone to follow behind the "cure"—someone who is independent and knows a wide range of ways to confirm the "cure." If alternative medicine is the diagnostic tool, the method of cure and the means to confirm the success, then I do not feel this is a clear cure. I have treated so called "cures" that ended up *eventually* showing treatment failure. Feeling better is not a "cure." One can feel better for many reasons. I believe we have done very careful post-treatment blind testing for every *major* popular and respected alternative medicine for Babesia treatment in the United States. I have also treated patients "cured" of Babesia from Canada and Europe.

Please do not misunderstand me. I am delighted that many individuals are looking for new ways to kill infections and to enhance the health of their body. I have even been asked why I endorse some health care workers or authors who do not think as I do. Simply, I love physicians or scientists looking at treatments that might be effective, which in their creative passion, they oversell. Simply, any person or any book with **a sample** of solid ideas or thoughtful hypotheses, I feel is making a contribution to medicine. A "cure" might be an augmenting agent for **another infection,** or lead to another type of healing for an entirely different illness.

#### **Optimal Ideal Babesia Testing and Tracking Methods**

I appreciate that it makes more logical sense to place a diagnosis section before a treatment section. But my experience has shown me that the buyers of my first Babesia textbook already had a diagnosis. Of course, as you will see, the vast majority of Babesia is missed, and at times even by exceptional labs. So in light of reader treatment priorities, my first concern in this supplement was to make sure that their treatment was not useless or sub-optimal. While it is certainly very critical to know how to diagnose and track this infection, I hope that our years of close laboratory tracking, with many new twists, will take Babesia testing to a new level.

Since most of our patients have been to 10-50 very talented, smart and experienced health care workers before seeing me, we are never looking for mere Babesia. In North America, the belief in pure Babesia infections in humans is 1980's medicine that ignores ticks. **They carry a flood of diverse infectious organisms in their bodies.** Anyone who thinks a patient bitten by deer ticks in North America only has Lyme disease, is in need of 4,000 research articles and experience with 1,000 patients using

**five** different labs. We are lucky if a sick Lyme patient has a single species with only one variant or one species of Babesia.

In our very comprehensive but targeted intake testing, we always are looking for the following sample problems besides mere Lyme disease:

- \* Of the well-established 100 Babesia species, I want to try to directly or indirectly test for all the various Babesia species that can infect humans. Most are not tested for, and **1/10,000 physicians know all the species that infect humans.** Further, many animal Babesia forms are hypothetically able to jump to humans at times. It is one reason top labs are looking at "cross-over" Babesia animal species possibly infecting humans. We already know that some species infect both humans and other mammals.
- \* The common multi-vector Bartonella has 32 species based on multiple gene databases (S. Fry, MS, MD. Personal communication 2008). This infection, or one with a fairly similar appearance and **very similar immune suppressing properties,** is probably found in tens of millions of people. The basis for this number is outside our topic. But this infection is clearly hard to kill.
- <sup>\*</sup> Genetic variations in humans prevent the removal of Lyme biotoxins (R. Shoemaker of Pocomoke, MD. Personal communications 2002-2004). One of many examples is the patented BbTox1 that is related to botulism and is a neurotoxin. Syphilis also has at least one biotoxin. This can be an overstated issue. **It is worth testing,** but like MSH and VIP levels, it can be an intellectual fetish if this is one's main treatment controlling lab test. It might matter 5-15%. If you know little about Babesia, Bartonella and highly advanced mold remediation, this can be a rigid MSH fixation and waste of time. Many respected court expert remediators know little about serious remediation, since they are not builders skilled in structure defects, and some do not even examine each room, go up into the humid attic or open the backs of cabinets suspected of water intrusion.

- \* **Remove infections, biotoxins and mold exposure, and MSH** *always* **returns.** Of course if you know little about advanced Babesia, Bartonella and advanced mold remediation, then your patients will stay with low MSH or no MSH. (See R. Cone's MSH textbooks starting in 2000 and over 3,000 PubMed publications).
- \* Indoor mold toxin body disruption is documented in hundreds of articles and books over **the last thirty years**. Indoor mold illness is hardly some new prophetic discovery. It killed 10 of 12 archeologists opening King Casimeer's tomb room in Paris in 1973. The fatal species were isolated by one of the scientist survivors. Anyone researching the mold species found in this room, reading grain cleaning research or war mycotoxin science from the last 30 years, would know indoor mold can cause serious illness.
- \* An explosive inflammation system with a weak anti-inflammation system that is largely off causes profound sensitivity. This can manifest in sound sensitivity, light sensitivity, interpersonal relating fatigue, skin reactions and trouble with smells.
- \* At least 14 hormones are easily disrupted by infections or inflammation. For example, it is beyond belief that most infection physicians have no realization that invasive Lyme bacteria often drastically altered free testosterone levels, DHEA, and promote thyroid auto-immunity. This shows simplistic lab testing and poor aggressive education, not to mention limited experience with Lyme impact on endocrine glands. It is unknown exactly what effects Babesia species have on each human endocrine organ, because of so little study.
- \* Many clotting cascade chemicals and other pro-clot chemicals need to be tested to prevent damage or death by a clot of the heart, brain, lungs, eyes, kidneys and other organs.
- \* More labs will be offered below. But unfortunately we have found that some insurance companies will terminate anyone ordering too many labs. Their reviewing clerks or "experts" often know nothing about treatment-resistant patients. Ordering extra thorough labs does not fit the pride of some physicians in their lean lab ordering,

which has led to many patients being missed for a wide range of illnesses. Some physicians who have limited abilities in helping treatment-resistant patients, order mere basic organ failure labs, a cholesterol check, a TSH or PSA, and perhaps add a few other "special" labs like a mono or Epstein-Barr Virus test—all this is like trying to catch a fish in a lake with a spoon.

## Why Bother Testing So Seriously For Babesia? Is It Rare or Common?

Most physicians in 2009 know nothing about Babesia. Even infectious disease physicians know virtually nothing about Babesia. They may know how to handle 2,000 other infections, but ones I meet and discuss my research with, have no idea what I am talking about in terms of modern Babesia in North American human patients. It would suggest it is hard for them to master *thousands* of infections and hundreds of medications. Just treating HIV/AIDS, TB and Hepatitis C requires tremendous years of study and experience.

Most physicians are taught almost nothing about Babesia in medical school, residency and most fellowships. In my case, it was only the near death of two children that got my attention, and made me spend thousands of hours studying this tiny red blood cell parasite and other tick and flea-borne infections.

Besides my personal experience, it is more important to ask why should you or any health care worker be concerned over Babesia in patients with chronic illness? One can only study so much medicine in a year. And many things cause serious illness. So why make a big deal out of Babesia?

Because I believe Babesia is very common all over North America and most parts of the world. And the readers of this book who have been diagnosed with Babesia could also give you many reasons. Most of them would like all their physicians to be very well read on their blood parasite. Further, I would suggest the distinctions between epidemic, endemic, super-endemic, non-endemic counties and states is useless in 2010 medicine. Babesia is all over North America. Period. It is also all over the world. And in my patients coming from outside the United States and Canada, it can clearly exist without Lyme disease. So please note the following, despite **very poor testing**, which misses the vast majority of positively infected humans:

- a. In Mexico, right over the USA border, **38%** of people tested had Babesia canis. Humans are not generally expected to have this dog species.<sup>1</sup>
- b. In Africa, 54% of males tested were found to be positive for Babesia.<sup>2</sup>
- c. Babesia is an "extensive zoonosis" or an extensive disease passed from **any type of animal to humans.**<sup>3</sup>How many of the 100 known Babesia species can cross over to humans?
- d. Studies in areas with high deer tick populations had high rates of Babesia microti (between 3.3—21%).<sup>4</sup> Deer numbers are exploding.
- e. Babesia duncani, which was originally called WA-1, because the first obvious and very ill patient was found in Washington state, was found to be present in 3.5—16%, based on blood antibody testing. Duncani is now found in patients from all over North America. This type of testing can fail if the common antibody suppressing bacteria Bartonella is present.<sup>5</sup>
- f. The discovery of new forms or species infecting humans or dogs, which live in very close contact with people, is a serious concern, and some experts worry about the frequency of Babesia animal species "jumping." Why? Perhaps because the ideal home now seems to be a single home with some rustic fields, wild grasses and woods—so basically the "perfect home" has small mammals that can carry deer ticks easily and routinely into a backyard.

In one study by Miodrag Ristic and others, Babesia was found in a woman. It had a single membrane. Its ultra structural features were similar to those described for Babesia rodhaini, which infects rodents such as mice and gerbils. Indirect fluorescent-antibody tests performed showed that this strain was serologically related to, but not identical with, Babesia canis, which is primarily a dog Babesia. A capillary tube-agglutination test, with an antigen prepared from blood of a dog infected with B. canis, detected antibody in serum of infected monkeys and of the patient.<sup>6</sup>

- g. The discovery of new forms or species is often only due to a confusing death. Examples would be the death of a man from MO-1, and the death of a standard poodle from Babesia gibsoni that was not supposed to be in North America.<sup>7</sup> (MO-1 stands for the first patient found with this new strain in Missouri).
- h. MO-1 Babesia is not limited to one area in the US, but is all over North America. <sup>8</sup>
- i. Babesia EU-1 is just one of many forms that infect humans, and it is likely that many other species in Europe living close to man also infect humans.<sup>9</sup>
- j. Babesia species can have massive variation. For example, the "American" form of Babesia, the microti species, has many clear human variations that may respond to treatment differently and may need different testing. Some variants include Kobe-type, Hobetsu-type and the U.S.-type.<sup>10</sup>
- k. Patients with certain Babesia visualized on a manual blood smear were sent to large national laboratories for yet another manual blood smear exam. Some of these had unique presentations that might mean they are new human Babesia species. The large lab never reported finding any protozoa. Even when asked to "look for malarialike protozoa," they still have never reported a case. Many possible reasons exist for this problem but are discussed in my Babesia Textbook. My only point here is that Babesia is more common than blood parasite smears report.<sup>11</sup>
- In Europe, it seems that if anyone has Babesia, which they miss routinely, they are told they have Babesia divergens. However, a series of patients were found to have a Babesia species that was genetically "clustered" with B. odocoilei, a parasite of white-tailed deer.<sup>12</sup>

- m. It is accepted that Babesia bovis can infect humans. But no major lab tests for it in humans.  $^{\rm 13}$
- n. In Korea, a new human species has been found. The Babesia parasite is being named "KO1," due to its uniqueness. In the patient's blood, it mainly appeared as paired pyriforms and ring forms. Maltese cross forms were not seen, and the parasite showed morphological features consistent with those of the genus Babesia sensu stricto. The sequence of the 18S rRNA gene of KO1 was closely related to that of Babesia species isolated from sheep in China (similarity, 98%).<sup>14</sup>

Some wise and helpful authors publishing many years ago, seem to feel their high infection numbers might be wrong, because in areas with modest deer tick numbers or areas with expected low Babesia duncani numbers, the Babesia microti and the Babesia duncani positive results were still very high. I respectfully appeal to these brilliant researchers that they were right, and should not back away from their initial review of high infection frequencies. If anything, the many species that infect humans and their variants are producing low positive results.

Babesia is all over the world. People also migrate from one country to others. **Many visit other continents.** This allows them to catch Babesia species which are almost always missed. The local lab does not even offer you a poor quality test, because it only checks for **one** species. These "foreign" species can also possibly be passed in the womb after a relocation or vacation, and would often be unable to be diagnosed in future children.

Further. I am confident, based on our research, that the variation in tick-born infections between states in the United States is markedly exaggerated. While variation certainly does exist, I do not trust routine labs who have not invested money into advanced modern testing. For example, the fact that a genus Babesia PCR test does not yet exist at most large national labs is stunning. At least one has been invented as of November 2008. And when about 100 blind samples of patients with Lyme and at least 50% with Babesia were tested, all patients were reported

as negative for Lyme. Yet eight patients were discovered to be Babesia positive (Fry Clinical Labs). Perhaps repeated testing on the same patient might make it more sensitive, along with working with researchers outside the CDC. Currently, most tests only allow clinicians generally to test for one to two species—a genus test is a fine idea. Modifications are clearly planned at this time. Finally, Babesia medications might increase positive genus findings.

So while I find more Babesia in New Jersey and New York than in Florida, I find it in most states. The veterinary research now reports Lyme disease in every state, and human lab results and study are also starting to show Babesia and new Babesia species are dispersed all over the Northern Hemisphere, not merely limited to the locations they are discovered. So for example, while Babesia duncani was initially found in California and Washington, as of 2009, many clinicians have found it throughout the USA and Canada.

In the same way, the potentially fatal Babesia species MO-1 is now known to be all over the Unites States. I have been told learned clinicians have now found it outside its initial "range." My appeal is that this Babesia frequency is like the discovery of pine trees. Some states have more than others, but they are in all states.

# **Babesia Frequency Sample References**

Please do not assume that this list is comprehensive.

- 1. Osorno BM, Vega C, Ristic M, Robles C, Ibarra S. Isolation of babesia. spp. from asymptomatic human beings. *Vet Parasitol.* 1976;2:111-120.
- 2. Leeflang P, Oomen JM, Zwart D, Meuwissen JH. The prevalence of babesia antibodies in nigerians. *Int J Parasitol.* 1976;6(2):159-161.
- 3. Gutierrez Y. Blood apicomplexa: Plasmodium, babesia and entopolypoides. In: *Diagnostic Pathology of Parasitic Infections with Clinical Correlations*. Philadelphia: Lea & Febiger; 1990:146.

4. Popovsky MA, Lindberg LE, Syrek AL, Page PL. Prevalence of babesia antibody in a selected blood donor population. *Transfusion*. 1988;28(1):59-61.

Persing DH, Herwaldt BL, Glaser C, et al. Infection with a babesia-like organism in northern california. *N Engl J Med.* 1995;332(5):298-303.

Dumler JS, Aguero-Rosenfeld M. Microbiology and laboratory diagnosis of tick-borne diseases. In: Cunha BA, ed. *Tick-borne Infectious Diseases. Diagnosis and Management.* New York: M. Dekker; 2000:42.

5. Quick RE, Herwaldt BL, Thomford JW, et al. Babesiosis in washington state: A new species of babesia? *Ann Intern Med.* 1993;119(4):284-290.

Herwaldt BL, Kjemtrup AM, Conrad PA, et al. Transfusion-transmitted babesiosis in washington state: First reported case caused by a WA1-type parasite. *J Infect Dis.* 1997;175(5):1259-1262.

Persing DH, Herwaldt BL, Glaser C, et al. Infection with a babesia-like organism in northern california. *N Engl J Med.* 1995;332(5):298-303.

Dumler JS, Aguero-Rosenfeld M. Microbiology and laboratory diagnosis of tickborne diseases. In: Cunha BA, ed. *Tickborne Infectious Diseases. Diagnosis and Management*. New York: M. Dekker; 2000:42.

Kjemtrup AM, Wainwright K, Miller M, Penzhorn BL, Carreno RA. Babesia conradae, sp. nov., a small canine babesia identified in california. *Vet Parasitol.* 2006;138(1-2):103-111. 10.1016/j. vetpar.2006.01.044.

8. Herwaldt B, Persing DH, Precigout EA, et al. A fatal case of babesiosis in missouri: Identification of another piroplasm that infects humans. *Ann Intern Med.* 1996;124(7):643-650.

Holman PJ, Spencer AM, Droleskey RE, Goethert HK, Telford SR,3rd. In vitro cultivation of a zoonotic babesia sp. isolated from eastern cottontail rabbits (sylvilagus floridanus) on nantucket island, massachusetts. *J Clin Microbiol.* 2005;43(8):3995-4001. 10.1128/ JCM.43.8.3995-4001.2005. Gutierrez Y. Blood apicomplexa: Plasmodium, babesia and entopolypoides. In: *Diagnostic Pathology of Parasitic Infections with Clinical Correlations*. Philadelphia: Lea & Febiger; 1990:146.

9. Wielinga PR, Fonville M, Sprong H, Gaasenbeek C, Borgsteede F, Giessen JW. Persistent detection of babesia EU1 and babesia microti in ixodes ricinus in the netherlands during a 5-year surveillance: 2003-2007. *Vector Borne Zoonotic Dis.* 2008. 10.1089/vbz.2008.0047.

Haselbarth K, Tenter AM, Brade V, Krieger G, Hunfeld KP. First case of human babesiosis in germany - clinical presentation and molecular characterisation of the pathogen. *Int J Med Microbiol.* 2007;297(3):197-204. 10.1016/j.ijmm.2007.01.002.

10. Zamoto A, Tsuji M, Kawabuchi T, Wei Q, Asakawa M, Ishihara C. U.S.type babesia microti isolated from small wild mammals in eastern hokkaido, japan. *J Vet Med Sci.* 2004;66(8):919-926.

Popovsky M, Lindberg L, Syrek A, Page P. Prevalence of Babesia antibody in a selected blood donor population. *Transfusion* 1988;28:59-61.

Saito-Ito A, Takada N, Ishiguro F, et al. Detection of kobe-type babesia microti associated with japanese human babesiosis in field rodents in central taiwan and southeastern mainland china. *Parasitology*. 2008;135(6):691-699. 10.1017/S0031182008004356.

- 11. Anonymous. Personal communications with various physicians with training in microscopy from 1999-2006 who wish to remain anonymous.
- 12. Casati S, Sager H, Gern L, Piffaretti JC. Presence of potentially pathogenic babesia sp. for human in ixodes ricinus in switzerland. *Ann Agric Environ Med.* 2006;13(1):65-70.

Herwaldt BL, Caccio S, Gherlinzoni F, et al. Molecular characterization of a non-babesia divergens organism causing zoonotic babesiosis in europe. *Emerg Infect Dis.* 2003;9(8):942-948.

Haselbarth K, Tenter AM, Brade V, Krieger G, Hunfeld KP. First case of human babesiosis in germany – clinical presentation and molecular characterisation of the pathogen. *Int J Med Microbiol.* 2007;297(3):197-204. 10.1016/j.ijmm.2007.01.002.

- 13. <u>http://prod.hopkins-abxguide.org/pathogens/parasites/babesia</u> <u>species.html?contentInstanceId=255992.</u> Accessed December 15, 2008.
- 14. <u>http://www.pubmedcentral.nih.gov/articlerender.</u> <u>fcgi?artid=1933034.</u> Accessed December 15, 2008.

Kim JY, Cho SH, Joo HN, et al. First case of human babesiosis in korea: Detection and characterization of a novel type of babesia sp. (KO1) similar to ovine babesia. *J Clin Microbiol.* 2007;45(6):2084-2087. 10.1128/JCM.01334-06.

# Does Babesia Simply Die Inside the Body in Weeks to Months?

I recently read that some believe humans destroy Babesia in the blood without any help. Specifically, they seem to say that patients may show symptoms and then become asymptomatic, **and then they have no Babesia.** Perhaps this is a mere hopeful wish.

While it is certainly true that after an initial infection, some patients have serious symptoms such as a high fever that can go away, and high antibody tests at routine labs can fall to normal levels. Yet, we have found that by using some new powerful aggressive "treatment challenges," we can kill off remaining hidden Babesia, and ECP and antibodies will jump up depending on the lab used, and clearly show Babesia is alive and well. Or other indirect labs will show Babesia may be present.

It is true that **Babesia has a highly variable presentation in the human body after an infection.** Sometimes it multiplies fast and makes a person severely ill and unable to return to normal functioning. In some people, it reproduces very slowly and does not have effects for 1-30 years.

I suspect their immune system might keep it in check. In others, it may stay dormant at low levels and then erupt due to a new infection, trauma, e.g., a car accident or major surgery, or some weakening of the immune system, e.g., aging, indoor mold toxins or chronic sinus infections. And in some patients, it simply stays dormant. I have no idea how dangerous it is in patients with a low body load and with minimal reproduction. But who would ever want a malaria-like parasite in their blood? Particularly, when it can probably cause blood sludge that can cause tiny or large clots and harm any organ.

#### Using a Simple New Blood Test

I first became familiar of the use of ECP or Eosinophilic Cationic Protein blood levels in the diagnosis of Babesia when I helped discover a functional "cure" for a rare but deadly eosinophil cancer-like illness called "HES." In that study, we noticed that the patient's eosinophils had emptied its granules that carried the parasite killer chemical ECP. The eosinophils were simply dumping its toxins that were meant to kill parasites like Babesia, into blood. One proof of our "cure" was that eosinophils and ECP went from dangerous and huge numbers to virtually zero.

So how does this relate to Babesia? First, we recently discovered on a requested follow-up to this first world case, that **the patient had stealth-like very low levels of Babesia.** It might have been priming the cancer.

So this Babesia primed cancer made me start to explore very carefully the role of Babesia and eosinophil ECP.

However, it is not as simple as measuring ECP. If you have high levels of Babesia, my opinion is that you crush or decrease the ability of eosinophils to work, and therefore they are not elevated. Or it may be that **eosinophil parasite killing cells are not really intended to kill tiny one-celled protozoa parasites,** and you need to kill some, and disperse their debris, to have any eosinophil reactions. Perhaps this is clearer by a simple analogy. You like lobster. You like it so much you want to reach out and grab it from your friend's plate as soon as it arrives on the table. But if I put you under 2 massive railroad cars with 100,000 lobsters each, and opened them over you, you would hardly survive. My point is that huge numbers of Babesia "falling" into contact with a modest number of eosinophils crush their effectiveness. It does not matter if this is a solid analogy.

The reality is that routine numbers of Babesia do not usually show up with elevated eosinophils. It does happen, but it is not common. Further, our experience is that if a person has even slightly increased eosinophils, I believe it can be a flag for **low** numbers of Babesia. I have not found that there is a large range of disorders that commonly increase eosinophils. While I appreciate that many quality parasite and hematology books offer over twenty causes of increased eosinophils, I simply do not see them increase very often. So when patients have had exposure to wild brush, woods or areas with many small mammals, even for a day, and have any Bartonella, Ehrlichia or Lyme disease, I consider Babesia seriously, regardless of the eosinophil number.

In addition, if a person has an ECP that is high normal or abnormal, it can be a sign that a small number of Babesia are present.

# The ECP Trick to Uncover Very Low Levels of Babesia

Some patients exposed to dense, Babesia-filled woods have no Babesia antibodies, no DNA and no findings on a blood cell smear of two common species of North American Babesia when simultaneously tested at three quality laboratories. Also, their ECP was practically zero or certainly in the lower 20th percentile.

But on some occasions, we have had success with an ECP trick that detects hidden Babesia.

Some feel the trick is a trial of Babesia medications. And if the Babesia medications cause new symptoms **besides** nausea, decreased appetite and diarrhea, some believe this might be a sign of Babesia die-off.

But that is not my trick.

#### My trick is giving Babesia medications to provoke a very wide range of laboratory signs of a Babesia infection.

If this is an approach that you feel could bring out a stealth infection, and is worth exposure to malaria treatments, start with a very low dose on each of these treatments on Day one with 1/2 of a tablet, capsule or teaspoon and then raise it up as quickly as is reasonable. We give adults or mature adolescents one or two of the following for 10-14 days:

- 1) Mepron with fatty food in the am and in the evening.
- 2) Artesunate (<u>www.hepapro.com</u> "Artemisiae") capsules every sixeight hours for three doses per day.
- 3) Malarone tablets in the am and evening with food.

I defer to you and your clinician on what doses to use and which options to combine, since you might have to be highly functional for work or other responsibilities, as these medications can make you fatigued and foggy. Since some patients given Babesia treatments have nausea and diarrhea, we suggest **starting one medicine at a time** and raising it as tolerated. I suggest patients have Imodium in place before this is started, and three nausea medications.

The first nausea option is promethazine given as 25 mg in 1 ml of Lipoderm **transdermal medical cream.** When you feel nauseous the last thing you want to do is take a pill. This goes through the skin into the blood in a few minutes. (This advanced prescription cream can carry many medicines through skin and into the blood stream just below the skin surface. Sample medications that Lipoderm and other transport creams can carry through the skin include Rocephin, Bicillin, Zithromax, amoxicillin and doxycycline).

At the first and smallest sign of nausea, the promethazine cream can be used. Your physician can pick the dose, but we usually use 25 mg of cream applied to the temples and ankles or wrist every 6 hours for nausea. Others dose by weight. One possible dosing plan—that I submit to the expertise of your personal physicians—is 12.5 mg every 8 hours for 75 pounds of weight to the inner shin and ankle. It has a small cardiac risk that I have never seen.

Further, Donnatol or belladona tablets should be considered and have many forms and are known to most physicians with a desire to prevent vomiting. I do not buy the casual comments of some that vomiting is always a healthy cleansing of the stomach. Zofran should also be ordered. Zofran has been used IV and orally in children and fragile adults for many years. It blocks the nausea center in the back of the brain which controls vomiting. I have had many patients go from miserable nausea to complete peace in 30 minutes with these nausea treatment medications, used to decrease possible nausea from Babesia medications. However, most of these medications do not cause nausea if taken with food.

Having addressed two possible intestinal side effects, let me discuss more about our Babesia trick. If Babesia is present when Mepron, artesunate or proguanil in Malarone is used at effective Babesia killing doses, debris from the dead Babesia will float around. Eosinophils see this debris and attack it, and inject it with ECP. Therefore, the ECP levels will go up, typically above the normal range. If you have a resistant tough Babesia strain or strains, the ECP might still be "normal," but **it will clearly increase.** An ECP level that goes from 9 to 20 (LabCorp range) or 3 to 9 (Quest range) is real change. The normal variation in ECP with both LabCorp and Quest is typically trivial in patients with no Babesia, so a change can be very significant.

#### ECP Provocation Using Medications to Uncover Hidden Babesia

Suppose a patient has no positive Babesia lab results, but for various reasons, the health care worker suspects possible Babesia. So they prescribe Mepron at a modest dose on weekdays and a higher dose on the weekend starting at Friday dinner, if the patient has fewer weekend demands. After two weeks, the patient does the same thing with Malarone. At the same time the patient takes artesunate, without any ear pain (which would

show ear injury). [While the doses recommended by some respected Chinese herbalists are too low, you can discuss the provocation dose with your health care provider. Herbal use is not endorsed or approved by the FDA, and you try such a herb at your own risk. Good medicine does not use synthetic medications or herbals in a "cookbook dosing" manner].

So what should you look for if trying these medications for provocation and not treatment?

- \* First, all three medicines mentioned above, Mepron, Malarone and artesunate can cause a headache and marked fatigue from the explosion of large parasitic debris. Please note, Babesia parasites are very large compared to bacteria, so when they die the debris is perhaps 50-300x greater than that of dead bacteria. So new headaches, fatigue, weight gain or loss, worsening concentration, irritability, etc. could be Babesia dying and should make the health care worker a little suspicious.
- \* If the ECP goes to **above** normal **only** when taking these malaria and Babesia killing medications, suspect Babesia death. Specifically, a "12" on a Quest lab ECP test (normal is 2-10), or a "27" on a LabCorp ECP test (normal is <24) should lead you to suspect hidden Babesia. Some articles report that ECP is associated with many different medical troubles. However, it is strong evidence to me of Babesia if a baseline level is 4, and it goes to 14 in 10 days after taking Malarone and artesunate. I do not believe one would expect ECP to go up suddenly with hay fever or leukemia only when Babesia killing medications are used.<sup>1-2</sup>

# A Final Word on Other Means to Uncover Babesia

\* We have introduced the issue of eosinophil numbers in a CBC blood test before, yet I want to add some additional information. While the use of eosinophil numbers is typically of questionable use in the diagnosis of Babesia, some rare patients clearly have abnormally elevated levels due to Babesia. Those researchers or clinicians that say Babesia or other protozoa never increase eosinophils are simply wrong. They feel increased eosinophil numbers due to infections are primarily found with large parasites. I agree, this is correct, but some occasional exceptions exist.

For example, if someone has a type of illness that increases eosinophils, the Babesia may push it higher.

Second, many research articles show protozoa like Babesia, can cause increased eosoinophils.  $^{\rm 3}$ 

Third, I would suggest that Babesia might actually overwhelm eosinophils and reduce their numbers to the lower 20%. We have often had strongly Babesia positive patients with repeated zero eosinophil numbers. So a low eosinophil does not rule-out Babesia either.

In one study on malaria, which is another intra-cellular red blood cell protozoa parasite, patients infected had low eosinophils. At diagnosis, the malaria patients had **low white blood cells** and **very low eosinophil numbers.** But after malaria treatment, eosonophils became normal. So perhaps a level of 0-1 going to a normal range is a sign of progress.

Finally, some studies do show that eosinophils may react to Babesia, and I believe also to low levels of dead Babesia.

- \* The use of steroids in patients with tick-borne infections is complicated. But perhaps patients exposed to corticosteroids can uncover Babesia. Prednisone and dexamethasone allow Babesia and other infections to mobilize. In hamsters, dexamethasone caused a profound increase in Babesia microti. Given this knowledge, can we assume using these steroids for two weeks, followed by testing might reveal an infection? We have yet to try such an experiment, and **do not plan to do so** unless these medications are required by other physicians—such as in patients with a serious asthma attack.<sup>4</sup>
- \* Some report that C3 and C4, which are blood lab tests, are useful in the evaluation or detection of Babesia. We have found these to be grossly unreliable, because they are so non-specific. While Babesia tends

to increase them, we strongly suggest not using them to determine anything other than that a patient has an important medical problem that may be associated with an infection or inflammatory process.  $^5$ 

#### References

- 1. Schaller JL, Burkland GA, Langhoff PJ. Are various babesia species a missed cause for hypereosinophilia? A follow-up on the first reported case of imatinib mesylate for idiopathic hypereosinophilia. MedGenMed. 2007;9(1):38.
- 2. Camacho LH, Wilairatana P, Weiss G, et al. The eosinophilic response and haematological recovery after treatment for plasmodium falciparum malaria. Trop Med Int Health. 1999;4(7):471-475.
- 3. Walker A, Ellis J, Irama M, et al. Eosinophilic glomerulonephritis in children in southwestern uganda. Kidney Int. 2007;71(6):569-573. 10.1038/sj.ki.5002085.
- 4. Eckblad WP, Stiller D, Woodard LF, Kuttler KL. Effect of dexame thas one on babesiasis in hamsters. Am J Vet Res. 1984;45(9):1880-1882.
- 5. Lee HK, Lim J, Kim M, et al. Immunological alterations associated with plasmodium vivax malaria in south korea. Ann Trop Med Parasitol. 2001;95(1):31-39.

# What Type of Babesia Testing is Best for 2009?

When I was young, my father would routinely say, "If you are going to do something, do it **right and completely,** or do not bother at all." Usually he was talking about my use of his tools to invent things, and never completely returning them to the tool box. He was right of course, and his job was not to pick up after me.

The same applies to Babesia testing.

I am going to suggest a wide range of *complete* and *thorough* testing, and I am not going to consider the issue of money. Since Babesia can be deadly and undermine health, my bias is toward fast Babesia diagnosis, especially of stealth forms missed in some tests. I appreciate that the practice of ignoring cost considerations is not the real world we live in. Patients and health care workers cannot always do all they would like due to financial limits. I have similar limits. I want to order another special large microscope, and I simply do not have the money. The same applies to your labs. You might not be able to get all you want to get. If this is your situation, the ECP test, offered by both LabCorp and Quest, might be a good option for you. If it is normal, you might consider the provocation trick we discussed above with Mepron, Malarone and/or artesunate.

ECP LabCorp code—903591 (Frozen specimen)

ECP Quest Labs code—37914 (Frozen specimen)

Some rare Quest processing centers might not be able to do this test.

If you are going to use the ECP level as a guide for treatment, you should know that **ECP stays abnormally high roughly 10-12 weeks after cure.** If it becomes normal, do the trick testing we discussed—it should not become abnormal again, or your treatment was too low, too short or both. You probably still have residual Babesia.

#### Indirect Lab Babesia Patterns

I have recently published a 500-page color Bartonella book, and in this research, have found some useful laboratory patterns that may show when both Bartonella and Babesia are present. Indeed, I have been stunned to find that due to global ignorance about the **vast numbers** of new emerging Bartonella and Babesia species and species variants, which represent just a fraction of what is really out there in our American grassy backyards, that many in North America have not one but both of these infections.

Research articles that propose Babesia or Bartonella species frequencies are useless if they are taken as authoritative, because their detecting probe is not as effective as they report. We have looked at highly respected deer tick infection probes, and some are only sensitive enough to detect 1% of the cases of Babesia or Bartonella! Some of these probes only look for **a fraction** of possible Babesia and Bartonella species or species variants. Other material includes highly rigid 1990's views of Babesia species locations. Their reports indicate that Babesia x is located on the West Coast while Babesia y is only in Middle America. As I have discussed throughout this text, such reports are no longer factual and are indeed misleading in 2010 Babesia medicine.

Bartonella and Babesia species are virtually everywhere, and the notion that a certain species or infection can be pigeonholed into one location is highly questionable.

### Large National Specialty Labs For Indirect Babesia Testing

The use of the following labs assumes that their application to **other** disease states has been considered. They are **not specific to one disorder.** They are not specific to Babesia or Bartonella. But in the full and complete treatment of either, they can reveal the presence of either infection at times, while we wait 20 years for advanced high quality testing for both infections that detects all human and mammal species at a 90% reliability.

The following are the labs we suggest getting if any one has "Lyme disease," Babesia and/or Bartonella. I put the Lyme disease in quotes because it is a serious error to believe that deer ticks carry mere Lyme disease in their stomachs. They carry a flood of infectious entities, and tick infection science and medicine is so preliminary, it might be clinically "fetal."

TNF-a represents Tumor Necrosis Factor-alpha

IL-6 represents Interleukin 6

IL-1b represents Interleukin 1b

VEGF represents Vasoendothelial Growth Factor

I will not go into the function of these common labs, except to say that VEGF makes and opens blood vessels. **Bartonella makes VEGF. If your skin or labs show Bartonella findings and the VEGF is not well above normal, something is likely going on. What could it be? It could be that Babesia is present and suppressing full body blood VEGF levels, but it does not stop the production in some patients of Bartonella skin markings consistent with the 40 different skin markings in my two-volume color Bartonella book. These markings are fewer in children under nine years old, because they have had less time to develop.** 

Bartonella suppresses other labs such as the TNF-a, IL-6 and IL-1b. So in the presence of only Bartonella and Lyme, these labs are **typically low and often** *below* **normal.** 

TNF-a	low
IL-6	low
IL-1b	low
VEGF	high

#### **Bartonella and Lyme Infection**

#### Babesia and Lyme without Bartonella

First, since I believe Bartonella is one of the most common bacterial infections on earth, the notion that Babesia and Lyme would exist without at least one species variant of Bartonella would be unusual. But since Bartonella medicine and lab testing surrounding this powerful stealth infection is 20 years behind the times, the belief some people have just these two infections is common. So lets discuss what it would look like in this theoretical situation. (This assumes no 15/16-6/5-51 HLA).

TNF-a	high
IL-6	normal-high
IL-1b	normal-high
VEGF	low-normal

#### Babesia and Bartonella Together

TNF-a	high
	8

Bartonella lowers the value of this lab, so if it is high, something is driving it high, such as Babesia? It should be low with Bartonella alone.

IL-6	low-normal-high

While Bartonella lowers this, in the presence of Babesia, it may or may not become increased. If it is in the 30th percentile or higher, this is suspicious for Babesia.



While Bartonella lowers this, in the presence of Babesia, it may or may not become increased. If it is in the 30th percentile or higher, this is suspicious for Babesia.

Please do not assume **both** IL-6 and IL-1b will both go up in the presence of Babesia. **In fact, sometimes only TNF-a or IL-6 or IL-1b increases, while the other two remain low.** 

VEGF low-normal

Generally even **very low numbers of Babesia will bring high levels of VEGF down.** At times Babesia will reduce VEGF significantly to moderate or low "normal" blood levels in the accepted range of the test. On occasion Babesia makes VEGF so low it is actually unable to be measured. One new problem with some laboratories is that they have had a new flood of thousands of VEGF tests being done on very ill patients. Some of these have very low VEGF blood levels. So at least one large lab, LabCorp, has revised its normal range markedly downward based on very ill patients. So their new normal range is based on an ill patient population and not healthy and normal patients. So if a lab makes the lowest normal level 0, this is a statistical flaw, and is much like saying the "normal" number of human eyes is 0-2. Some labs use as a low cut off 31. This is reasonable lower normal level for our purposes here.

The critical point is that Bartonella manufactures VEGF directly or indirectly creating a *high level of VEGF* in the blood and also in tissues. (Sometimes the skin shows evidence of VEGF). It is the chemical that sometimes causes various red, burgundy and blue blood vessel findings all over the body. If a person has Bartonella alone with Lyme, VEGF is almost always going to be above the normal range. If VEGF is low or normal, one common cause in a person with Lyme disease or deer tick exposure risk is a Babesia infection.

#### Sample Bartonella Laboratory References

- 1. Cerimele F, Brown LF, Bravo F, Ihler GM, Kouadio P, Arbiser JL. Infectious angiogenesis: Bartonella bacilliformis infection results in endothelial production of angiopoetin-2 and epidermal production of vascular endothelial growth factor. *Am J Pathol.* 2003;163(4):1321-1327.
- 2. Dehio C. Recent progress in understanding bartonella-induced vascular proliferation. *Curr Opin Microbiol.* 2003;6(1):61-65.
- 3. Herremans M, Bakker J, Vermeulen MJ, Schellekens JF, Koopmans MP. Evaluation of an in-house cat scratch disease IgM ELISA to detect bartonella henselae in a routine laboratory setting. *Eur J Clin Microbiol Infect Dis.* 2008. 10.1007/s10096-008-0601-8.

- 4. Kempf VA, Schairer A, Neumann D, et al. Bartonella henselae inhibits apoptosis in mono mac 6 cells. *Cell Microbiol.* 2005;7(1):91-104. 10.1111/j.1462-5822.2004.00440.x.
- 5. Lappin MR, Breitschwerdt E, Brewer M, Hawley J, Hegarty B, Radecki S. Prevalence of bartonella species antibodies and bartonella species DNA in the blood of cats with and without fever. *J Feline Med Surg.* 2008. 10.1016/j.jfms.2008.06.005.
- 6. Mathieu S, Vellin JF, Poujol D, Ristori JM, Soubrier M. Cat scratch disease during etanercept therapy. *Joint Bone Spine*. 2007;74(2):184-186. 10.1016/j.jbspin.2006.05.017.
- 7. Popa C, Abdollahi-Roodsaz S, Joosten LA, et al. Bartonella quintana lipopolysaccharide is a natural antagonist of toll-like receptor 4. *Infect Immun*. 2007;75(10):4831-4837. 10.1128/IAI.00237-07.
- 8. Raoult D, Dutour O, Houhamdi L, et al. Evidence for louse-transmitted diseases in soldiers of napoleon's grand army in vilnius. *J Infect Dis.* 2006;193(1):112-120. 10.1086/498534.
- 9. Resto-Ruiz SI, Schmiederer M, Sweger D, et al. Induction of a potential paracrine angiogenic loop between human THP-1 macrophages and human microvascular endothelial cells during bartonella henselae infection. *Infect Immun.* 2002;70(8):4564-4570.
- Vermeulen MJ, Diederen BM, Verbakel H, Peeters MF. Low sensitivity of bartonella henselae PCR in serum samples of patients with cat-scratch disease lymphadenitis. *J Med Microbiol.* 2008;57(Pt 8):1049-1050. 10.1099/jmm.0.2008/001024-0.

#### Antibody Testing for Babesia

One of the first issues with antibody testing is that some feel antibodies may not remain abnormal if the Babesia is still present in the body. One author reports it might fall to normal in a year, but cautions it could persist longer. However, the key point is that regardless of the time, some feel that Babesia infections can drift to normal levels, yielding a negative result in antibody testing when the infection is still present.<sup>1</sup>

So any use of antibody Babesia testing is a tricky issue for many reasons.

- 1) Many species or species variants in humans are not currently being tested in humans. For example, no antibody test exists for Babesia MO-1.
- 2) I have inherited patients with Babesia who have had blood antibody tests return up to eight times with no positive antibodies.
- 3) Bartonella appears to turn down Babesia antibodies. Bartonella can float in blood, on red blood cells, attach to blood vessels, and it never creates a massive and fatal bacteria reaction, called "sepsis," which other bacteria would do if present in the sacred blood stream. Large numbers of blood bacteria, except for Bartonella, kill. But Bartonella is **immune suppressive.**
- 4) I have seen Bartonella turn off Lyme, Ehrlichia, Babesia and Bartonella antibodies. And when I killed the Bartonella, they returned. But almost all published Bartonella treatments fail. So to test for Babesia, sometimes one needs to remove Bartonella first, if all the other options in this book have failed.
- 5) One final problem is that the titer number cut-off to determine if a patient is positive is at times absurd. Patients with severe symptoms and clear infections viewed in their blood smear are routinely determined to be negative, when the infection is clearly present.

So I suggest a broad approach to testing. And if you have marked symptoms or family members with the infection, you might want to try a very brief trial for 10 days of priming medications six weeks before your antibody testing.

#### Antibody Priming Trial: Is it Really Worth It?

Some have come to me after trials on two Babesia medications, and then a repeat of their IGeneX antibodies showed a conversion to positive Babesia microti or duncani antibodies, with no new tick exposures. We expect other labs to invest in the quality required to test these two species and

also MO-1, without dummied down test kits and absurdly high cut-off titers. These high number lead to many false negatives.

# One antibody priming option is to take *two* of the following for 10 days and then test for newly created antibodies after six weeks:

- 1) Mepron taken with fatty food.
- 2) Artesunate (<u>www.hepapro.com</u> "Artemisae") two times per day.
- 3) Malarone with a non-sedating anti-histamine to prevent proguanil itching.

The dose to use for any of these options is dependent on many factors, so any "protocol" or "guideline" is nonsense. For example, a sensitive patient might require low dosing, while a patient that feels nothing from these treatments should probably try a higher dose. Some have significant work obligations that might be hard to handle if they have a die-off reaction, and so using high dosing of these three medications at once is not an option. Others have limited responsibilities and do not have to care for five young children or speak to a large team of workers, and their main goal is a fast cure. They want such a provocative trial to use all three treatments and to use doses as high as possible. Of course this is not routine medicine and it cannot be proposed as the best way to determine the presence of Babesia.

Due to diagnosis demands and no clear lab outcome, some might want to try this Babesia provocation a second time. Some might reason, if the ECP and a first antibody provocation testing failed to show results when very low dosing was used—try again with higher dosing if you and your health care provider have a high suspicion of Babesia. But that is outside my current supplement book scope and between you and your physician.

I offer no opinion on this approach. Some with serious responsibilities might do an initial or a second trial with high dosing of multiple medicines on Friday night and Saturday am, and lower tolerable dosing during the week for two full weeks. The Friday and Saturday dosing usually results in significant fatigue. This sick feeling with these medications might be due to the death of some Babesia according to some clinicians. A student who is too tired to go back to college might want to really attack this test in June to see if Babesia is contributing to their severe headaches and profound fatigue.

While all these medications certainly have side effects, some patients and practitioners believe **an overall body feeling of new illness or new improvement** is a sign of Babesia being present. The thinking goes that these medications have limited side effects, and unless you have a malaria or Babesia infection, some feel they have limited body effects. I defer this information to be discussed between you and your physician.

Since Babesia antibiotic testing is so profoundly poor, we have found the best results using multiple labs and multiple tests.

Many patients have an insurance company that has a special contract with a laboratory that typically was contracted based on a low cost for the company. The two most common large national labs are LabCorp and Quest Diagnostics. They have both treated my patients well, but they both offer testing only for **one** human species — Babesia microti. Emails and calls to various staff to improve their ability to detect a wide range of tick-borne infections have gone ignored. Their antibody testing is usually negative even in the presence of clear Babesia.

Many other national labs offer testing for Babesia antibodies. For example, one clinical lab, IGeneX, offers antibody testing not merely for Babesia microti but also for Babesia duncani. The latter can be a serious and occasionally deadly form, which is not offered by many labs nationally or internationally. Kits can be ordered at 800-832-3200. Their antibody results tend to match both our clinical picture and fully visualized positive samples.

Other companies offer antibody testing and these include Fry Clinical laboratories, Medical Diagnostic Labs (MDL), ARUP labs, Clongen labs and dozens of others—I will not comment on every laboratory doing Babesia testing. Fry has a modest Babesia antibody test but it still misses many samples. MDL requires 10 samples to be certain a patient's

Babesia is not missed. ARUP has generally had poor results. Stoney Brook labs appreciates Babesia can be persistant, but only shows awareness of Babesia microti and their treatment and understanding of new forms and their geographic expansion seems dated. However, they are exploring the use of a Western Blot for Babesia,<sup>2</sup> which might hold promise,<sup>3</sup> though it would be limited to only the species being tested. Clongen shows promise with Morgellons Syndrome, but only offers a DNA or PCR test for Babesia microti.

#### References

- 1. Dumler JS, Aguero-Rosenfeld M. Microbiology and laboratory diagnosis of tickborne diseases. In: Cunha BA, ed. *Tickborne Infectious Diseases*. Diagnosis and Management. New York: M. Dekker; 2000:42.
- Golightly MG. Tick-Borne Diseases. Tick-Borne Diseases Web site. <u>http://www.path.sunysb.edu/labs/ticktutor/HTML/index.html.</u> Accessed December 15, 2008.
- Ryan RW, Kowalski I, Oliwa N, Aslanzadeh J, Krause P. Use of Western Blot Assay for the Laboratory Diagnosis of Babesia microti Infection. <u>http://gateway.nlm.nih.gov/MeetingAbstracts/ma?f=102245267.</u> <u>html.</u> Updated 1999. Accessed December 15, 2008.

### Babesia DNA or PCR Testing

All labs struggle with detecting the DNA or PCR in Babesia positive blood samples. IGeneX might offer the highest species blood detection at perhaps 10% of microti and duncani samples. I expect other species to be added in coming years.

IGeneX and MDL are probably worth trials for **tissue** PCR. MDL has found **Lyme** in infant circumcision skin, umbilical cord tissue and cord blood, but that is Lyme bacteria and not Babesia red blood cell parasites. It recently missed a patient for all tick-borne infections in a deep tissue sample, and yet the patient had clear Babesia, Lyme and Bartonella. Fry has developed a new **genus** PCR that is meant to detect all Babesia, Lyme and Mycoplasma species. The **genus** Babesia test missed at least forty clear Babesia patients, **but found eight positive.** No Lyme patient was detected.

Further, Fry Clinical labs reported five patients as positive for Babesia, that clearly had symptoms and were **missed by all the other labs** and many other types of testing. Perhaps in late 2009, this test will undergo modifications to increase its sensitivity. Dr. Fry explained it is a test in process and he is seeking improvement. You and your physician will have to decide if **10-20% sensitivity for all Babesia species and variants is functional.** Regardless of sensitivity, it is a great thing that Fry labs has started **genus** testing with a top Human Genome researcher. This type of testing will be a required tool in future decades, and I am excited they have "broken the ice." Also, Babesia medications may increase positive results.

#### Visual Imaging of Babesia

If you have Babesia in your blood, many different chemical stains can visualize it. This type of work has many textbooks that allow a blood microscope expert an almost limitless series of options. Vast numbers of chemicals used alone or in series allow different parts of your blood to become enhanced.

Staining is much like cars. If you see a huge flaming large red truck with huge car crushing tires coming down the street, it is quite different then seeing a Honda Accord. Stains are the same way. Some really do little to enhance one's ability to see Babesia. Other labs or researchers in Babesia science are very creative and cause Babesia to explode into view.

Certainly some counties and states have more Babesia than others, sometimes in part to spotty reporting criteria, but also because physicians and labs vary profoundly in terms of their diagnostic abilities. For example, I have sent certain positive Babesia samples with reasonable numbers found in human red blood cells to a wide range of large respected laboratories, and I have yet to see them report a single positive on a manual differential, even when I specifically **asked for them to "please look for Babesia." This is nothing short of a disaster. It defies any simple explanation.** Some feel this is evidence Babesia is rare. This is nonsense.

It shows what we already know based on malaria research. First, blood examination by machines always misses protozoa infections like malaria or Babesia. Second, protozoa, like malaria, are routinely missed in blood smear analysis. Third, the willingness of laboratory techs or pathologists to spend more than a couple of minutes is rare. Fourth, some practitioners refuse to use messy oil that is **required** for 1,000x visualization. Fifth, most lab techs do not use digital computer enlargement software which makes a pea as large as a quarter and allows the examiner to see inside red blood cells with an amazing new capacity.

Since many physicians have never had a patient found positive for Babesia from a manual blood smear, I strongly believe it is time for all laboratories offering Babesia and malaria diagnostic blood smear readings to reconsider their staining procedures and technology.

I have found that if a practitioner is familiar with a vast array of Babesia testing, performed at a wide number of labs, that Babesia can be detected. In terms of manual or visual blood smear testing, the first lab I want to discuss, IGeneX, does not do a routine stain. It processes the blood drop to make Babesia microti and duncani become **100x** more visible. If you have ever tried to look for Babesia under a microscope, as I have repeatedly done, you will appreciate this technology. They have designed one end of a chemical to attach to **both** Babesia microti and duncani, and the other end to glow a green or red glow to allow significant visual assistance.

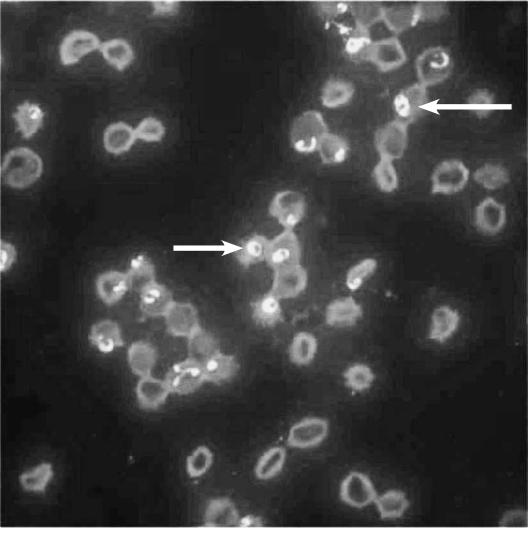
#### IGeneX Visual Testing Using FISH Technology

This special laboratory many years ago decided to seek expertise in all of the most common tick-borne infections. Their blind positive and negative state outcome testing results appear to show they have the best Lyme Western Blot in the world. In terms of Babesia and other protozoa infections, recent conversations with Dr. Shah and Harris report their FISH has now been expanded to detect both Babesia microti and Babesia duncani. Perhaps more important, is that they plan to try to expand the species that their current FISH testing detects to include other human species. In the near future they also hope to possibly **include some Babesia animal species that might cross over into some humans**.

In 2008, they were awarded a Federal grant to use their refined Babesia FISH testing to detect malaria in various parts of the world. (Note: They are also exploring the creation of a Bartonella FISH test. My personal hope is that perhaps this *might* be available in late 2009 due to the great need in Bartonella research. **But no date has been given to me,** probably in part because such creative research and complex development is not simple. As the author of the only current up-to-date textbook on Bartonella, I hope to assist them in their creation of a credible and advanced Bartonella FISH test).

The limitation of the IGeneX FISH test is simply that it will probably not detect Babesia if it is only present in 1/10,000 red blood cells. More than one cell needs to be detected for a specimen to be deemed a positive. It also needs to add more species, such as the MO-1 that is all over the USA. My understanding of their plan is to try to **keep adding species** to their current Babesia FISH test. This is very welcome news. I hope many labs follow their lead. (N. Harris, Personal communications 2008)

## **Babesia FISH Samples**

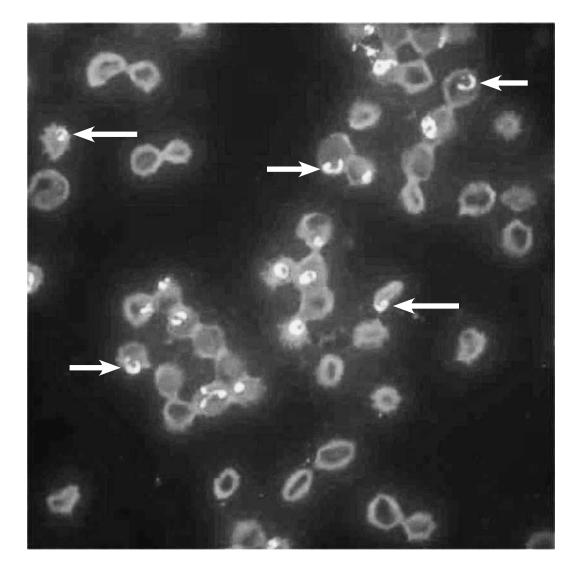




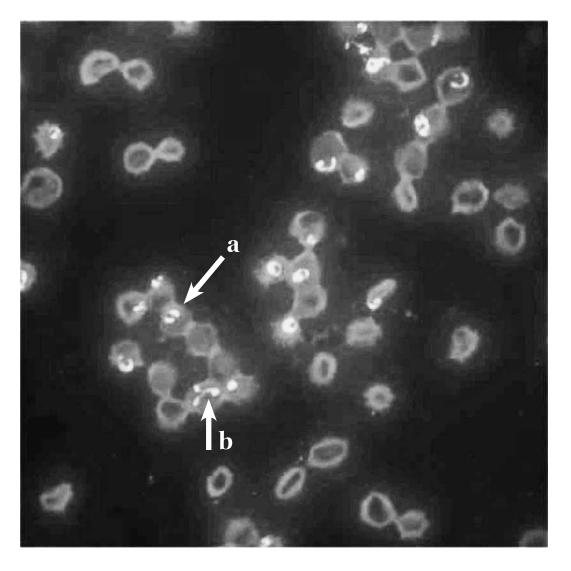
Above: Traditional Babesia ring forms.

Left: Highly complex Babesia positive finding with various forms inside a RBC.

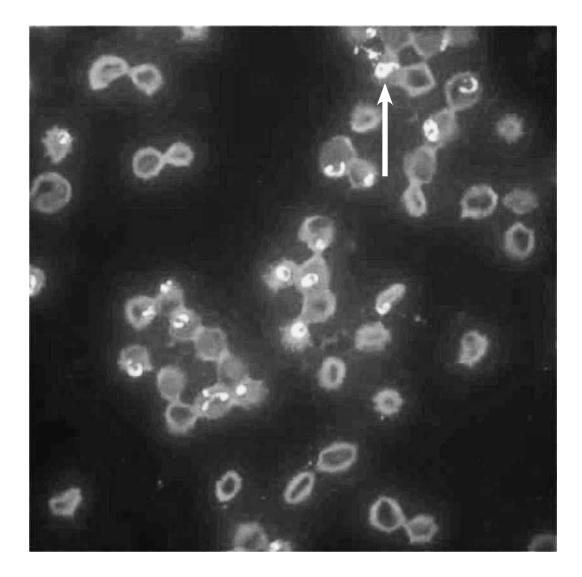
(Images provided by Dr. J. Shah. She can be reached at 800-832-3200).



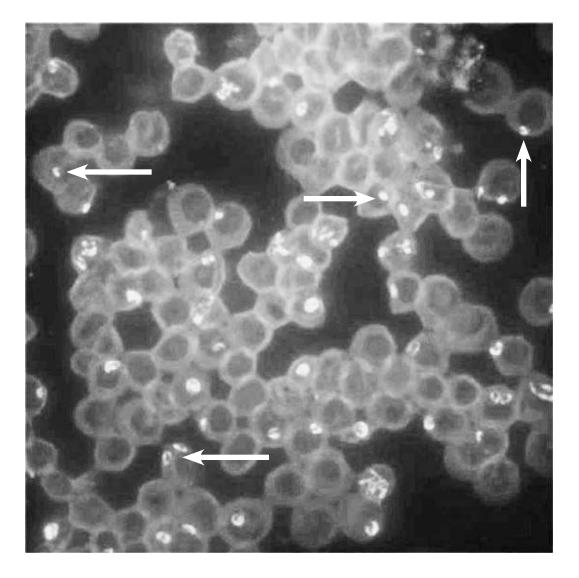
Babesia crescent forms.



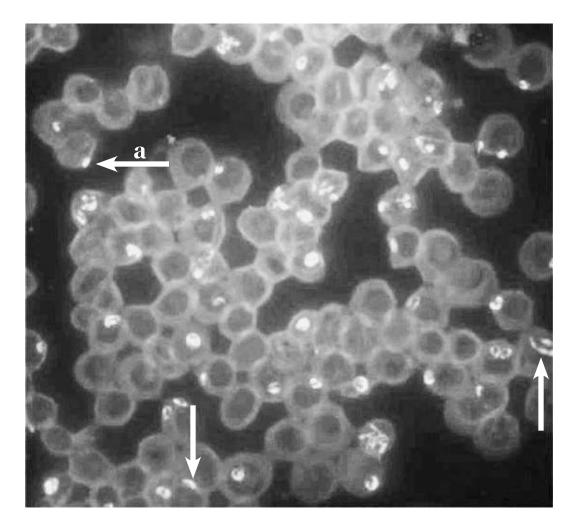
- a. Possibly two Babesia particles or one ring with a profound amount of DNA.
- b. Possibly a triple headed form with three Babesia parts three merozoites.



A pattern with a tail.



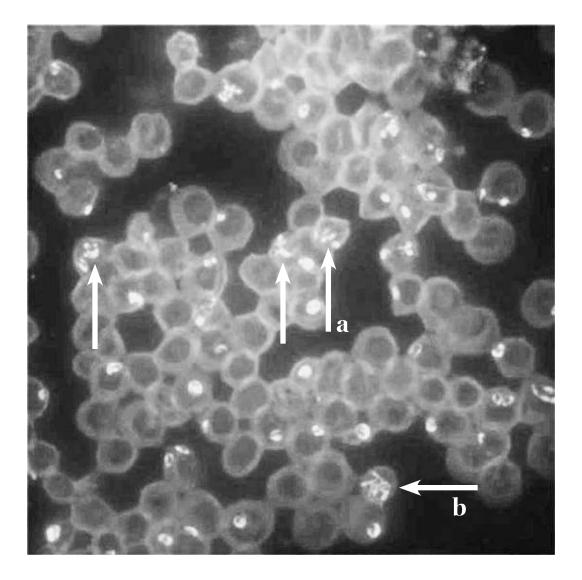
A collection of **micro** rings. These are easily missed in manual blood evaluations, particularly if you are not using digital enlarging software.



Short and long "hotdog" or "sausage" forms.

The form marked "a" is very tiny and on the outer edge of the RBC. It could be mistaken for a platelet.

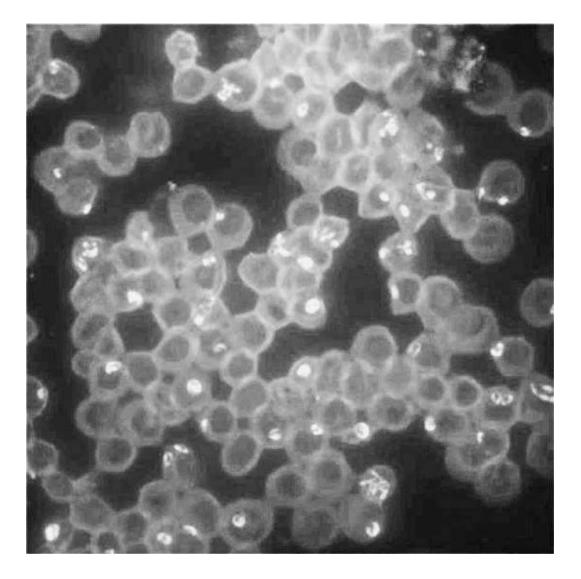
The FISH in this sample only makes Babesia microti and duncani glow, a factor which eliminates the notion of it being a platelet or Bartonella, nor a string of oval Bartonella.



Pictured here are highly complex Babesia forms with multiple shapes in various RBCs. You will find no textbook on parasites or blood examination that shows most of these forms. I recently published a large book on all major Babesia blood smear patterns, because so many parasite books and journal articles were only showing a small number of Babesia blood forms and shapes.

One challenge in the examination of some cells, is that even normal blood may contain some young RBCs or reticulocytes. These cells can have beaded lines of dark material that can look like some of the material in figures marked (a) and (b). However, reticulocyte dark string material does **not** seem to have the width variation in the strings seen in the samples above.

Further, in one article this form is seen as a "Babesia crisis" form which seems to indicate its association with possible serious illness.



In summary, this slide and the other similar ones show about 15 patterns.

This collection of FISH smears is provided courtesy of J. Shah Ph.D. She can be reached (and the test ordered) by calling 800-832-3200.

I have heard that some researchers question the merits of this Babesia FISH test. I have evaluated it and sent them blind positives and negatives, and they did well. The results pictured above seem to be **powerfully obvious** and make any such negative comments downright contradictory. It also shows a peculiar ignorance of their repeated exceptional blind positive and negative testing, together with many state and national certifications.

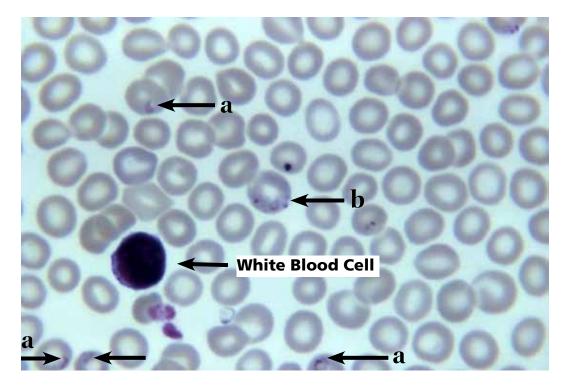
To ignore these obvious protozoa is to show a bias that places sick and fatigued patients into the "unknown mysterious causes" category, which is essentially a black hole diagnosis. Inevitably, patients labeled with "chronic fatigue syndrome" are destined to receive fair or poor care year after year. And more importantly, they are denied the opportunity for actual cure.

Further, since the Federal government has given them a grant to use this exact FISH technology for malaria, they are using a highly respected protozoa clinical technique. (See Appendix FISH grant information).

# Sample Babesia Forms and Stains

#### Some Health Care Workers Do Their Own Blood Evaluations

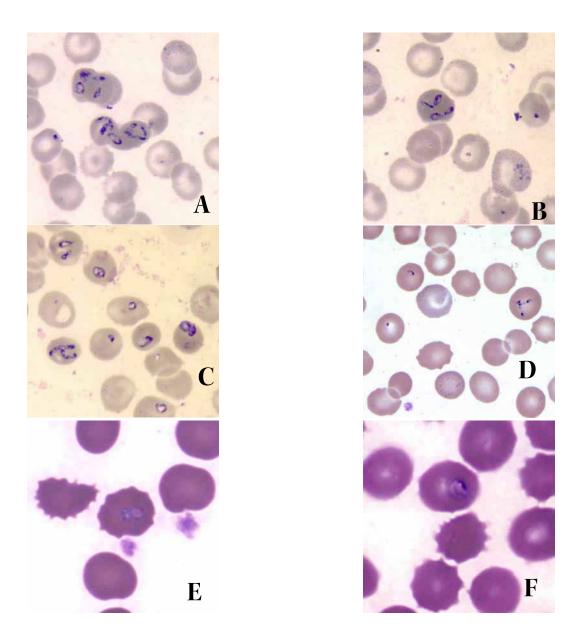
They would prefer to spend 60 minutes looking at their own blood, instead of depending on someone to look for a mere 120 seconds. And during most of that frenetic time, the paid examiner is looking at the big fat white blood cells.



This blood smear reveals Babesia patterns inside erythrocytes. Note that no ring looks like another ring. This means the viewer has to be very careful. Three forms look like crescent forms (a). The huge cell in the left bottom edge is one type of white blood cell.

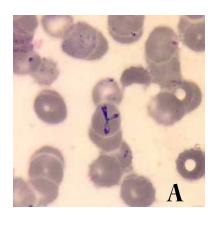
The form marked as (b) has various names depending on the source. Are these single merozoites? Are they trophozoites? Are they sporozoites?

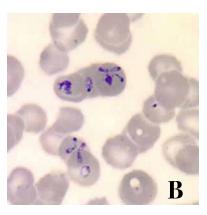
In the end, form names do not matter to our purpose in this book. This is not a book about nomenclature. (Image courtesy of S. Fry, M.D., M.S. using a dated Spring/2007 methodology).

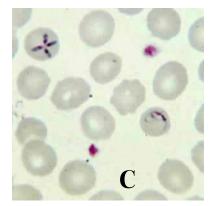


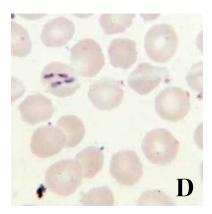
A - F: Babesia species in thin blood smear stained with Giemsa.

Images contributed by the Arizona Department of Health Services, Infectious Disease Laboratory, and provided courtesy of the CDC's Division of Parasitic Diseases.







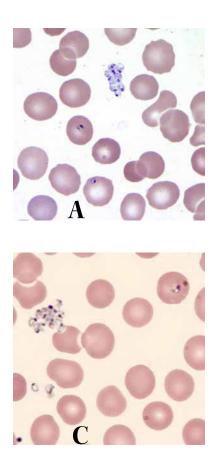


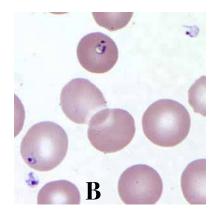
[Babesia divergens] [Babesia microti]

A, B: Babesia sp. in a thin blood smear stained with Giemsa. Note the **rare** tetrads, a dividing form pathognomonic for Babesia, in both images.

C: Babesia sp. in a thin blood smear. Note as in the above A, B: explanations, the tetrad form and ameboid trophozoite.

D: Babesia sp. in a thin blood smear; tetrad form, pairs aligned.



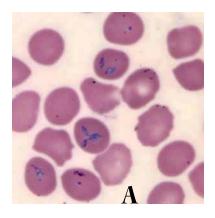


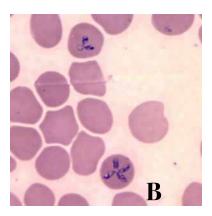
[Babesia divergens] [Babesia microti]

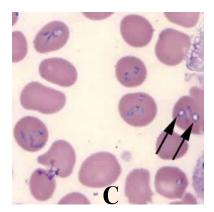
A, B: Babesia sp. in a thin blood smear stained with Giemsa. Note the clumped **extracellular** forms indicative of Babesia in A. B also has **extracellular** forms as well as intra-erythrocytic forms, one of which is vacuolated.

C: Babesia sp. in a thin blood smear stained with Giemsa — extracellular forms.

These images contributed by the Connecticut Department of Public Health Laboratory and provided courtesy of the CDC's Division of Parasitic Diseases.



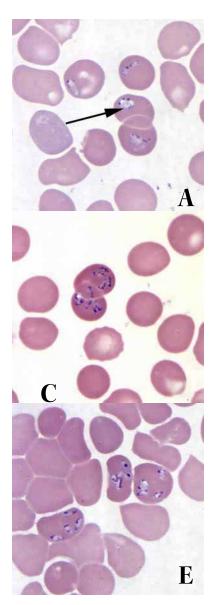


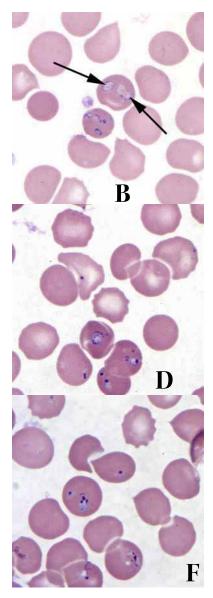


[Babesia divergens] [Babesia microti]

A, B: Babesia microti in a thin blood smear stained with Giemsa.

C: Babesia microti in a thin blood smear stained with Giemsa. Note the intra-erythrocytic vacuolated forms in C (black arrows).



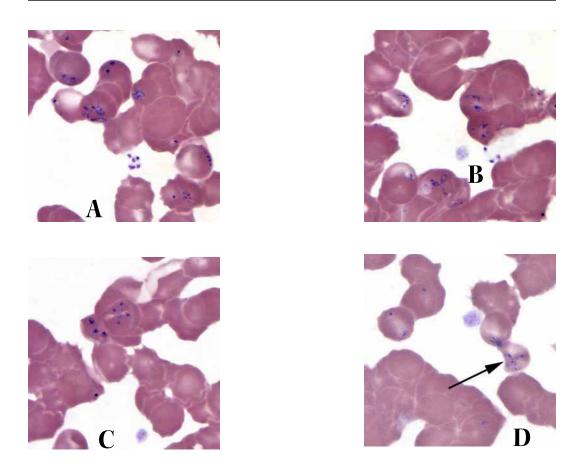


**MO-1 Babesia Forms** 

When this new species of Babesia was first found in Missouri, the first patient was numbered "1," and the case was abbreviated as MO, after the state it was discovered in. However, some researchers and clinicians are finding MO-1 in a wide range of states.

A - F: Babesia MO-1 in a thin blood smear stained with Giemsa. Note the vacuolated parasites (black arrows) in images A and B.

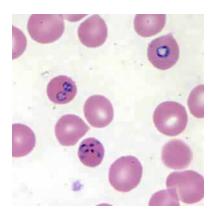
Images provided courtesy of the CDC's Division of Parasitic Diseases.



A - D: Babesia MO-1 in a thick blood smear stained with Giemsa. Parasite morphology can be difficult to visualize clearly when blood films are made too thick, or when images are taken from thick areas of a slide.

Do you see any **extracellular** Babesia forms in any of these slides?

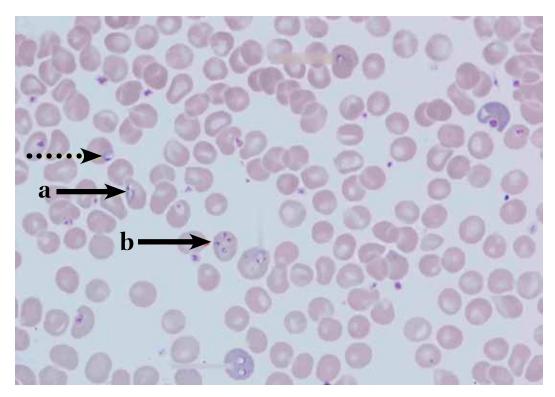
Barbara L. Herwaldt, MD, MPH; David H. Persing, MD, PhD; Eric A. Precigout, PhD; W. L. Goff, PhD; Dane A. Mathiesen, BS; Philip W. Taylor, MD; M. L. Eberhard, PhD; and Andre F. Gorenflot, PhD, A Fatal Case of Babesiosis in Missouri: Identification of Another Piroplasm That Infects Humans. Annals of Internal Medicine. 1996; 124:643-650. Specifically, see figure 1. Giemsa-stained blood smear obtained on 2 July from a patient who acquired babesiosis in Missouri.



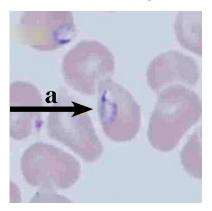
#### WA-1 or Duncani Babesia Forms

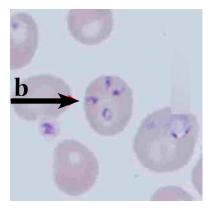
Babesia WA-1 in a thin blood smear stained with Giemsa. Babesia sp. cannot be reliably differentiated by blood slide morphology; additional testing is always recommended for Babesia duncani or WA-1 speciation.

WA-1 represents a first patient found in Washington state.

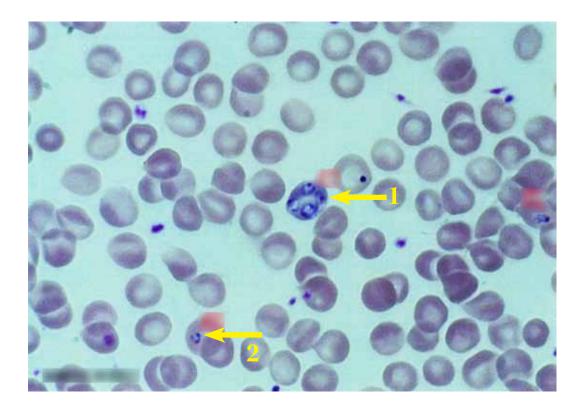


A slide with many Babesia findings, all of which were missed by a major large national laboratory, who were asked to look for "malaria or Babesia." They missed all of these findings. The arrow with a spotted tail is pointing to a classic Babesia ring form.

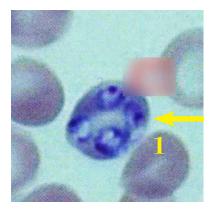


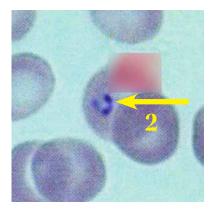


- a. It is unclear how many Babesia particles are in this complex form. I would propose it is two Babesia particles which are fused, but it is not clear.
- b. This example, shown in many parasite textbooks and respected web sites, is actually **four** Babesia forms.

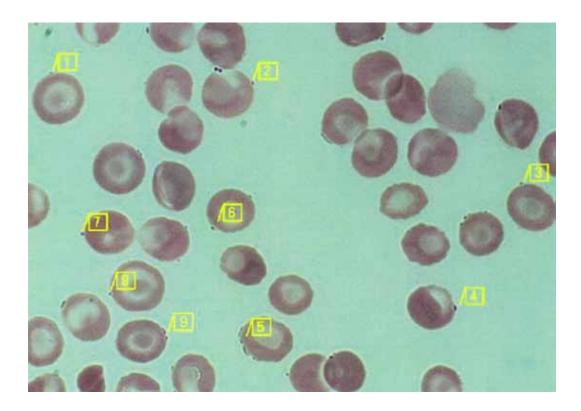


Two very different patterns are seen in this slide.





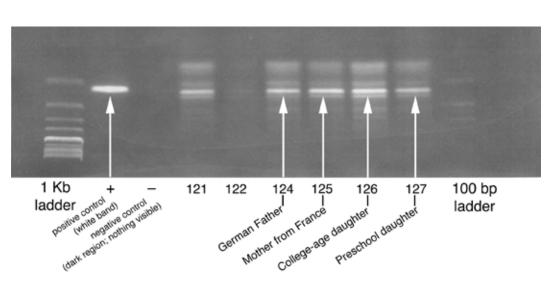
- 1. Four ring forms fill most of the RBC, showing that rings can be large.
- 2. Here is a Babesia earmuff or headphone form. These are not formal pattern names.



This lab suggests that numbers 1-9 are all Bartonella. I agree. I also do not see any certain Babesia activity. However, if these bacteria are not Bartonella, *they have immune altering actions profoundly similar to Bartonella* and are **very hard** to kill. They are also very common.

My dear friend Stephen Fry is working on very careful advanced genetic tests to determine the **exact** type of bacteria shown above. He is presently working aggressively on ways to characterize and detect it in as many ways as possible.

(This page and the previous two pages are based on an **early 2007 Babesia identification methodology**, which has since been changed to fit conservative criteria. The new method rarely yields Babesia images, but detects these bacteria superbly. Blood slides courtesy of S. Fry, M.D., M.S.)



Fry Labs Sample Image of Genus Babesia Positive Patients

Above I am showing you an image of the actual select Babesia fragments that create a positive in this genus lab test. Specifically, this is what a doctor at Fry Labs sees to determine if a Babesia genus test is positive.

This family had confirmed Babesia by at least 2 other methods in addition to clinical history. They were all on two Babesia medications which I hypothesize **might** increase the genus test yield.

They are all from Germany and have traveled to the United States and Asia for vacations, that included hiking into areas that were very rural with possible insect vector exposures. Some places they have lived or vacationed were suburban with deer and small mammal contact in the immediate acres.

### Sample References For Babesia Images

- 1. Auburn University, College of Veterinary Medicine. Erythrocyte Morphologic features and Important Terms. <u>www.vetmed.auburn.</u> <u>edu/distance/clinpath/morphol1/</u>. Accessed June 4th, 2008.
- 2. Carr JH, Rodak BF. *Clinical Hematology Atlas*. 3rd ed. St. Louis, Mo: Saunders Elsevier; 2009:266.
- CDC's Division of Parasitic Diseases (DPD). Centers for Disease Control. Babesia Image Library. <u>http://www.dpd.cdc.gov/dpdx/</u> <u>HTML/ImageLibrary/Babesiosis</u> il.htm. Published 12/05/2008 08:39:27. Updated 2008. Accessed June 5th, 2008.
- 4. Dumler JS, Aguero-Rosenfeld M. Microbiology and laboratory diagnosis of tickborne diseases. In: Cunha BA, ed. *Tickborne Infectious Diseases. Diagnosis and Management*. New York: M. Dekker; 2000:42.
- 5. Gutierrez Y. Blood apicomplexa: Plasmodium, babesia and entopolypoides. In: *Diagnostic Pathology of Parasitic Infections with Clinical Correlations*. Philadelphia: Lea & Febiger; 1990:146.
- 6. O'Connor BH. A Color Atlas and Instruction Manual of Peripheral Blood Cell Morphology. Baltimore: Williams & Wilkins; 1984:316.
- 7. Schaller JL. *A Laboratory Guide to Human Babesia Hematology Forms*. Tampa: Hope Academic Press; 2008:250.
- 8. Schaller JL. The Health Care Professional's Guide to the Treatment and Diagnosis of Human Babesiosis. Tampa: Hope Academic Press; 2006:392.

### Other Laboratories Doing Visual Inspection of Manual Blood Smears

#### **Medical Diagnostics Laboratory**

This laboratory is probably most useful for testing tissue samples or individuals whose testing options are limited by insurance companies. In terms of Babesia testing, I would not rule out Babesia unless the testing is negative 10x. Many clinicians have reported a very high number of unacceptable false negatives.

### **Fry Clinical Laboratories**

Fry Clinical Labs is clearly the best lab at detecting Bartonella in a visual blood smear. They appear very strong in this critical area of Bartonella testing. In 2007, they made the decision to read slides **conservatively in terms of Babesia.** Meaning, they prefer to error on the side of missing Babesia then reporting a false positive. In this regard, it cannot be used to detect Babesia. I have ordered two sets of stained images and on occasion I believe I have seen some Babesia on a slide, based on my Babesia Laboratory forms detection textbook, but this is not something most physicians want to do since they feel only pathologists should read slides.

However, while researching my Babesia lab presentations book, I found that acquiring Babesia identification techniques requires about 80 hours of study to look over and learn all the presentations and forms of Babesia. The other issue is that the Fry staff determine which of the many areas of the blood smear slide to send to you. And if Babesia identification is not an **aggressive** goal, and they are not using my Babesia Forms Hematology book, then they will tend to see few Babesia in your slide. In such a case, a borderline or vague Babesia form will be ignored and you will be sent another part of the blood field in your image— perhaps one that shows off Bartonella better.

### Central Florida Research Incorporated

I have not had enough experience with this laboratory to take any position on their techniques for detecting Babesia.

### LabCorp and Quest

We regret to report that while LabCorp and Quest have **many useful tests** to help you, they missed all the patients with Babesia on manual smears. On some, I asked specifically for a search of the red blood cells for Babesia and malaria. And while I did not call the lab directors and ask them to look even closer, I should not have to do so when I am asking for a manual smear to look for "protozoa inclusions inside red blood cells."

### **Other Laboratories**

Various published articles report that in patients with **extreme illness**, some pathology departments sometimes are able to detect the Babesia, typically with a classic Geimsa stain of the patient's blood. The reality is that these local community hospital laboratories usually miss Babesia.

Some other companies are emerging which are associated with hospital networks or are independent. Many of these exist. I will not comment on them at this time.

### **Alternative or Progressive Medicine Diagnostics**

Some health care workers diagnose Babesia using a wide range of alternative medicine techniques. I will neither endorse nor oppose such approaches in this book. However, if someone is considered positive for Babesia, I prefer to confirm this by as many means possible. Again, this is the same approach we successfully use if someone is told they are "cured" by any traditional or alternative means—I like to confirm that this is true. Why? Simply, because it often is not true—the "cure" did not cure the patient of Babesia. **It may have made them feel better.** But that is not the same as removing from a person's body **all** of their Babesia species and variants. A patient may feel better for any one of a hundred real reasons.

### The End of the Babesia Trilogy

With the completion of this book, the massive sacrifice and service of my entire family comes to an end, as we as one team, have now completed a Babesia trilogy, with three leading Babesia books completed over two years. It remains for others to take over, as I resume my research in many other areas. My next book will attempt to offer full recovery options for **chronic fatigue syndrome** and **fibromyalgia**.

As one family, we have made massive financial and emotional sacrifices to save lives, while I worked full-time as a self-funded researcher. It is sad that the inexperienced believe one makes money from highly specific medical books. My fellow authors understand exactly what I mean. Specifically, that unless you are a celebrity or a top novelist, writing offers no financial reward.

Now it is time to "try to have a life." Only those who have close families and who have written large or complex books could know that medical books only steal money and precious seasons.

To authors of other research books, please receive our respect for your sacrifice and service. We are honored to be in your company.



Dear Reader,

I deeply hope these pages have been worthy of your time and lead to greater health and recovery.

Dr. J.

### Appendix I

Dr. Schaller's Primary Babesia Textbook is meant to strongly increase the ability of physicians to detect and treat all species of Babesia. Nevertheless, it required a supplement. My first Babesia book, *The Diagnosis and Treatment of Babesia*, is actually at least two books in one, and was not replicated in any manner in this supplement. Here is the table of contents to allow you to see if this is worthy of your time. It has received exceptional reviews, and was written to fill the serious lack of a dedicated modern clinical Babesia medical textbook. It was based on the study of over 1500 articles and book entries, and included a strong emphasis on recently published information and interviews with respected clinicians regularly treating complex medical patients with illnesses that include Babesia.



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### **Appendix II**

# The IGeneX Federal Grant for the use of FISH technology for malaria.

*Plasmodium* Genus Fluorescent In Situ Hybridization (P-Genus FISH) assay targeted to ribosomal RNA (rRNA) is a method that detects all the species of malaria on an air-dried blood smear. PFV-FISH assay is a dual probe assay for detecting and differentiating *P. falciparum* (PF) and P. vivax (PV) on a SINGLE air-dried thin blood smear. The P-Genus assay uses P-Genus specific probe labeled with Tamra. Thus all the Plasmodium species will fluoresce red under Texas Red filter. The PFV-FISH assay uses PF and PV specific probes labeled with red and green fluorescent dyes, respectively. Thus, PF fluoresces red and PV fluoresces green under specific dual pass filters. The treatment for *P. falciparum* and *P. vivax* is different. Therefore, PFV-FISH assay would be very useful in areas where both P. falciparum and P. vivax are endemic. The assays are simple and inexpensive (< \$3.00/test and a one-time expense of ~\$1000 for filters). The assays consist of five steps — fixation, hybridization, washing, counterstaining and viewing the processed smear under a fluorescent microscope. The total assay time is less than 1 hour. In Phase I, we optimized the fixation and hybridization conditions and set up Quality Control Procedures for the FISH assays. We demonstrated that the limit of detection was 1 to 9 parasites/300 fields at 1000X, and that the FISH assays are very reproducible. Based on a clinical study performed on over 300 patient smears, the assay sensitivity was better than Giemsa. As compared to PCR, the FISH assay sensitivty was 83-89%, whereas Giemsa sensitivity was between 54-60%. FISH assay specificity as compared to PCR was 100% for both assays. Specific Aims for Phase II (1) Purchase of equipment for Clinical Study and hoods for preparing reagents for kits. (2) Kit manufacturing and determination of shelf-life of reagents. (3) Analytical Sensitivity to be performed on smears prepared by CDC from monkey blood for *P. falciparum*, *P. vivax* and *P. malariae*; from chimpanzee blood with *P. ovale.* (4) Clinical Trials - 4a: Training and competency of Clinical Sites to perform assay. 4b: Reproducibility determination at Clinical Sites to perform assay, and 4c: Smear preparation and assay performance on whole blood samples at Clinical Sites. (5) Evaluations of inexpensive Microscopes and Filters. Proceeding to Phase III will be based on completing the clinical trials and demonstrating specificity of at least 95% specificity and sensitivity equivalent to or better than Giemsa stained smear as compared to PCR. **Specific Aims for Phase III** (1) Filing 510K or PMA. (2)Set up manufacturing in Kenya. (3) Marketing. (4) Work with WHO to obtain their stamp of approval. This will avoid long delays in approval of the tests in many countries. (5) Develop PMO-FISH assay for detecting and differentiating *P. malariae* and *P. ovale* on a SINGLE airdried thin blood smear.

### Selected Bibliography

Abrams Y. Complications of coinfection with babesia and lyme disease after splenectomy. *J Am Board Fam Med.* 2008;21(1):75-77.

Alter HJ, Stramer SL, Dodd RY. Emerging infectious diseases that threaten the blood supply. *Semin Hematol.* 2007;44(1):32-41.

Anderson JF, Magnarelli LA, Donner CS, Spielman A, Piesman J. Canine babesia new to north america. *Science*. 1979;204(4400):1431-1432.

Anderson JF, Magnarelli LA, Sulzer AJ. Raccoon babesiosis in connecticut, USA: Babesia lotori sp. n. *J Parasitol.* 1981;67(3):417-425.

Birkenheuer AJ, Levy MG, Breitschwerdt EB. Development and evaluation of a seminested PCR for detection and differentiation of babesia gibsoni (asian genotype) and B. canis DNA in canine blood samples. *J Clin Microbiol.* 2003;41(9):4172-4177.

Birkenheuer AJ, Neel J, Ruslander D, Levy MG, Breitschwerdt EB. Detection and molecular characterization of a novel large babesia species in a dog. *Vet Parasitol.* 2004;124(3-4):151-160.

Blaschitz M, Narodoslavsky-Gfoller M, Kanzler M, Stanek G, Walochnik J. Babesia species occurring in austrian ixodes ricinus ticks. *Appl Environ Microbiol.* 2008;74(15):4841-4846.

Braga W, Venasco J, Willard L, Moro MH. Ultrastructure of babesia WA1 (apicomplexa: Piroplasma) during infection of erythrocytes in a hamster model. *J Parasitol.* 2006;92(5):1104-1107.

Byrnes V, Chopra S, Koziel MJ. Resolution of chronic hepatitis C following parasitosis. *World J Gastroenterol.* 2007;13(31):4268-4269.

Criado-Fornelio A, Gonzalez-del-Rio MA, Buling-Sarana A, Barba-Carretero JC. The "expanding universe" of piroplasms. *Vet Parasitol.* 2004;119(4):337-345.

Criado-Fornelio A, Martinez-Marcos A, Buling-Sarana A, Barba-Carretero JC. Molecular studies on babesia, theileria and hepatozoon in southern europe. part II. phylogenetic analysis and evolutionary history. *Vet Parasitol.* 2003;114(3):173-194.

Cunha BA, Nausheen S, Szalda D. Pulmonary complications of babesiosis: Case report and literature review. *Eur J Clin Microbiol Infect Dis.* 2007;26(7):505-508.

Dantas-Torres F. The brown dog tick, rhipicephalus sanguineus (latreille, 1806) (acari: Ixodidae): From taxonomy to control. *Vet Parasitol.* 2008;152(3-4):173-185.

De Martino SJ, Carlyon JA, Fikrig E. Coinfection with borrelia burgdorferi and the agent of human granulocytic ehrlichiosis. *N Engl J Med.* 2001;345(2):150-151.

Dodd JD, Aquino SL, Sharma A. Babesiosis: CT and hematologic findings. *J Thorac Imaging*. 2007;22(3):271-273.

Eskow E, Rao RV, Mordechai E. Concurrent infection of the central nervous system by borrelia burgdorferi and bartonella henselae: Evidence for a novel tick-borne disease complex. *Arch Neurol.* 2001;58(9):1357-1363.

Ezzelarab M, Yeh P, Wagner R, Cooper DK. Babesia as a complication of immunosuppression following pig-to-baboon heart transplantation. *Xenotransplantation*. 2007;14(2):162-165.

Florescu D, Sordillo PP, Glyptis A, et al. Splenic infarction in human babesiosis: Two cases and discussion. *Clin Infect Dis.* 2008;46(1):e8-11.

Frerichs WM, Holbrook AA. Babesia spp. and haemobartonella sp. in wild mammals trapped at the agricultural research center, beltsville, maryland. *J Parasitol.* 1970;56(1):130.

Genchi C. Human babesiosis, an emerging zoonosis. *Parassitologia*. 2007;49 Suppl 1:29-31.

Giannini AJ, Black HC, Goettsche RL. Psychiatric, Psychogenic, and Somatopsychic Disorders Handbook: A Laboratory and Clinical Guide to *the Medical Management of Emotional and Intellectual Pathology.* Garden City, N.Y. : Medical Examination Pub. Co.; 1978:86.

Goes TS, Goes VS, Ribeiro MF, Gontijo CM. Bovine babesiosis: Antierythrocyte antibodies purification from the sera of naturally infected cattle. *Vet Immunol Immunopathol.* 2007;116(3-4):215-218..

Guay D. Update on clindamycin in the management of bacterial, fungal and protozoal infections. *Expert Opin Pharmacother.* 2007;8(14):2401-2444.

Halperin JJ, Wormser GP. Of fleas and ticks on cats and mice. *Arch Neurol.* 2001;58(9):1345-1347.

Hamer SA, Roy PL, Hickling GJ, et al. Zoonotic pathogens in ixodes scapularis, michigan. *Emerg Infect Dis.* 2007;13(7):1131-1133.

Harvey WT, Martz D. Motor neuron disease recovery associated with IV ceftriaxone and anti-babesia therapy. *Acta Neurol Scand.* 2007;115(2):129-131.

Haselbarth K, Tenter AM, Brade V, Krieger G, Hunfeld KP. First case of human babesiosis in germany - clinical presentation and molecular characterisation of the pathogen. *Int J Med Microbiol.* 2007;297(3):197-204.

Herwaldt B, Persing DH, Precigout EA, et al. A fatal case of babesiosis in missouri: Identification of another piroplasm that infects humans. *Ann Intern Med.* 1996;124(7):643-650.

Herwaldt BL, Caccio S, Gherlinzoni F, et al. Molecular characterization of a non-babesia divergens organism causing zoonotic babesiosis in europe. *Emerg Infect Dis.* 2003;9(8):942-948.

Holman PJ. Phylogenetic and biologic evidence that babesia divergens is not endemic in the united states. *Ann N Y Acad Sci.* 2006;1081:518-525.

Homer MJ, Aguilar-Delfin I, Telford SR,3rd, Krause PJ, Persing DH. Babesiosis. *Clin Microbiol Rev.* 2000;13(3):451-469.

Hunfeld KP, Hildebrandt A, Gray JS. Babesiosis: Recent insights into an ancient disease. *Int J Parasitol.* 2008;38(11):1219-1237.

Hutchings CL, Li A, Fernandez KM, et al. New insights into the altered adhesive and mechanical properties of red blood cells parasitized by babesia bovis. *Mol Microbiol.* 2007;65(4):1092-1105.

Inokuma H, Yoshizaki Y, Shimada Y, Sakata Y, Okuda M, Onishi T. Epidemiological survey of babesia species in japan performed with specimens from ticks collected from dogs and detection of new babesia DNA closely related to babesia odocoilei and babesia divergens DNA. *J Clin Microbiol.* 2003;41(8):3494-3498.

Kawabuchi T, Tsuji M, Kuwahara S, et al. Isolation of a human erythrocyteadapted substrain of babesia rodhaini and analysis of the merozoite surface protein gene sequences. *J Vet Med Sci.* 2005;67(9):901-907.

Khayat A, Rathore MH. *Babesia* Species. In: Barton, Leslie L; Friedman, Neil R. The neurological manifestations of pediatric infectious diseases and immunodeficiency syndromes. Totowa, N.J. : Humana Press, c2008:343-346.

Kim JY, Cho SH, Joo HN, et al. First case of human babesiosis in korea: Detection and characterization of a novel type of babesia sp. (KO1) similar to ovine babesia. *J Clin Microbiol.* 2007;45(6):2084-2087.

Kosoy M, Morway C, Sheff KW, et al. Bartonella tamiae sp. nov., a newly recognized pathogen isolated from three human patients from thailand. *J Clin Microbiol.* 2008;46(2):772-775.

Kosoy M, Murray M, Gilmore RD,Jr, Bai Y, Gage KL. Bartonella strains from ground squirrels are identical to bartonella washoensis isolated from a human patient. *J Clin Microbiol.* 2003;41(2):645-650.

Krause PJ, Gewurz BE, Hill D, et al. Persistent and relapsing babesiosis in immunocompromised patients. *Clin Infect Dis.* 2008;46(3):370-376.

Krause PJ, Telford S,3rd, Spielman A, et al. Comparison of PCR with blood smear and inoculation of small animals for diagnosis of babesia microti parasitemia. *J Clin Microbiol.* 1996;34(11):2791-2794.

Krause PJ, Telford SR,3rd, Ryan R, et al. Diagnosis of babesiosis: Evaluation of a serologic test for the detection of babesia microti antibody. *J Infect Dis.* 1994;169(4):923-926.

Maggi RG, Chomel B, Hegarty BC, Henn J, Breitschwerdt EB. A bartonella vinsonii berkhoffii typing scheme based upon 16S-23S ITS and Pap31 sequences from dog, coyote, gray fox, and human isolates. *Mol Cell Probes.* 2006;20(2):128-134.

Montero E, Rafiq S, Heck S, Lobo CA. Inhibition of human erythrocyte invasion by babesia divergens using serine protease inhibitors. *Mol Biochem Parasitol.* 2007;153(1):80-84.

Noskoviak K, Broome E. Images in clinical medicine. babesiosis. *N Engl J Med.* 2008;358(17):e19.

Persing DH, Mathiesen D, Marshall WF, et al. Detection of babesia microti by polymerase chain reaction. *J Clin Microbiol.* 1992;30(8):2097-2103.

Pietrobelli M, Cancrini G, Moretti A, Tampieri MP. Animal babesiosis: An emerging zoonosis also in italy? *Parassitologia*. 2007;49 Suppl 1:33-38.

Raju M, Salazar JC, Leopold H, Krause PJ. Atovaquone and azithromycin treatment for babesiosis in an infant. *Pediatr Infect Dis J.* 2007;26(2):181-183.

Rees P, Schoeman JP. Plasma insulin concentrations in hypoglycaemic dogs with babesia canis rossi infection. *Vet Parasitol.* 2008;152(1-2):60-66.

Rodgers SE, Mather TN. Human babesia microti incidence and ixodes scapularis distribution, rhode island, 1998-2004. *Emerg Infect Dis.* 2007;13(4):633-635.

Saito-Ito A, Kasahara M, Kasai M, et al. Survey of babesia microti infection in field rodents in japan: Records of the kobe-type in new foci and findings of a new type related to the otsu-type. *Microbiol Immunol.* 2007;51(1):15-24.

Saito-Ito A, Takada N, Ishiguro F, et al. Detection of kobe-type babesia microti associated with japanese human babesiosis in field rodents in central taiwan and southeastern mainland china. *Parasitology.* 2008;135(6):691-699.

Saito-Ito A, Tsuji M, Wei Q, et al. Transfusion-acquired, autochthonous human babesiosis in japan: Isolation of babesia microti-like parasites with hu-RBC-SCID mice. *J Clin Microbiol.* 2000;38(12):4511-4516.

Setty S, Khalil Z, Schori P, Azar M, Ferrieri P. Babesiosis. Two atypical cases from minnesota and a review. *Am J Clin Pathol.* 2003;120(4):554-559.

Steiner FE, Pinger RR, Vann CN, et al. Infection and co-infection rates of anaplasma phagocytophilum variants, babesia spp., borrelia burgdorferi, and the rickettsial endosymbiont in ixodes scapularis (acari: Ixodidae) from sites in indiana, maine, pennsylvania, and wisconsin. *J Med Entomol.* 2008;45(2):289-297.

Tampieri MP, Galuppi R, Bonoli C, Cancrini G, Moretti A, Pietrobelli M. Wild ungulates as babesia hosts in northern and central italy. *Vector Borne Zoonotic Dis.* 2008;8(5):667-674.

Terkawi MA, Jia H, Zhou J, et al. Babesia gibsoni ribosomal phosphoprotein P0 induces cross-protective immunity against B. microti infection in mice. *Vaccine*. 2007;25(11):2027-2035.

Tsuji M, Wei Q, Zamoto A, et al. Human babesiosis in japan: Epizootiologic survey of rodent reservoir and isolation of new type of babesia microti-like parasite. *J Clin Microbiol.* 2001;39(12):4316-4322.

Tsuji N, Miyoshi T, Battsetseg B, Matsuo T, Xuan X, Fujisaki K. A cysteine protease is critical for babesia spp. transmission in haemaphysalis ticks. *PLoS Pathog.* 2008;4(5):e1000062. 10.1371/journal.ppat.1000062.

Van Gompel A, Van den Ende J, Van den Enden E. The predictive value of a serologic test for the detection of babesia microti antibody. *J Infect Dis.* 1995;171(2):504-506.

Vannier E, Gewurz BE, Krause PJ. Human babesiosis. *Infect Dis Clin North Am.* 2008;22(3):469-88, viii-ix.

Vyas JM, Telford SR, Robbins GK. Treatment of refractory babesia microti infection with atovaquone-proguanil in an HIV-infected patient: Case report. *Clin Infect Dis.* 2007;45(12):1588-1590.

Warlow C. Motor neuron disease. Acta Neurol Scand. 2008;117(3):217.

Wei Q, Tsuji M, Zamoto A, et al. Human babesiosis in japan: Isolation of babesia microti-like parasites from an asymptomatic transfusion donor and from a rodent from an area where babesiosis is endemic. *J Clin Microbiol.* 2001;39(6):2178-2183.

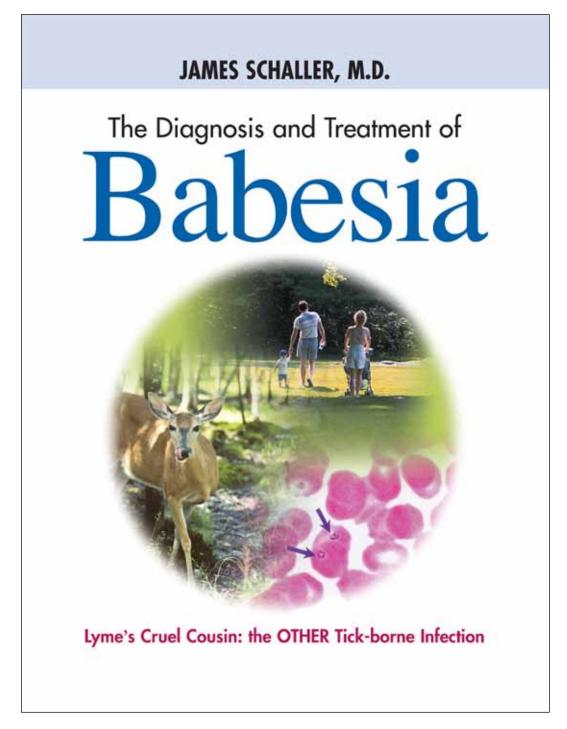
Wielinga PR, Fonville M, Sprong H, Gaasenbeek C, Borgsteede F, Giessen JW. Persistent detection of babesia EU1 and babesia microti in ixodes ricinus in the netherlands during a 5-year surveillance: 2003-2007. *Vector Borne Zoonotic Dis.* 2008.

Wiesner J, Reichenberg A, Heinrich S, Schlitzer M, Jomaa H. The plastidlike organelle of apicomplexan parasites as drug target. *Curr Pharm Des.* 2008;14(9):855-871.

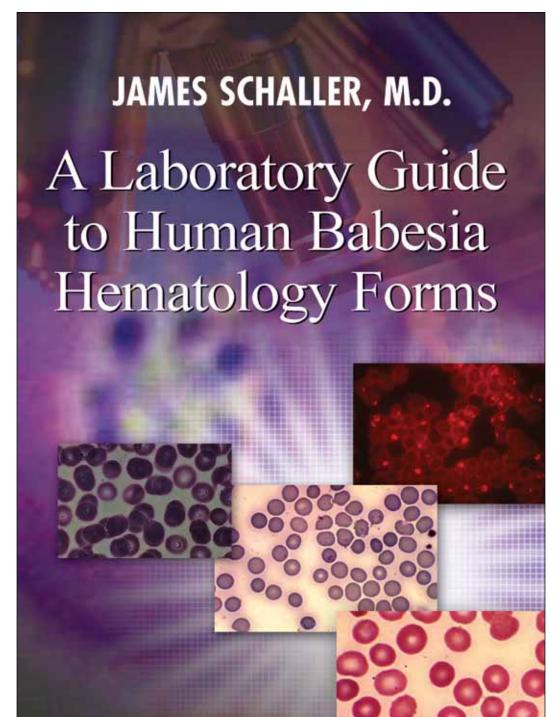
Wong WS, Chung JY, Wong KF. Images in haematology. human babesiosis. *Br J Haematol.* 2008;140(4):364.

# Dr. Schaller has been published in: Journal of the American Medical Association Journal of Clinical Neuroscience Medscape (Academic Journal of WebMD) Journal of the American Society of Child and Adolescent Psychiatry American Journal of Psychiatry European Journal of Child and Adolescent Psychiatry Compounding Pharmaceuticals: Triad Fleming Revell Press (Four Languages) Internal Medicine News Family Practice News Spire Mass Market Books Internet Journal of Family Medicine **Greenwood Press** Child and Adolescent Psychiatry Drug Alerts Hope Academic Press **Clinical Psychiatry News** Psychiatric Drug Alerts Townsend Journal **OB/GYN** News AMA News Currents

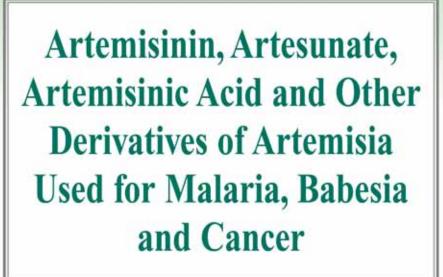
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# Bartonella: Diagnosis and Treatment

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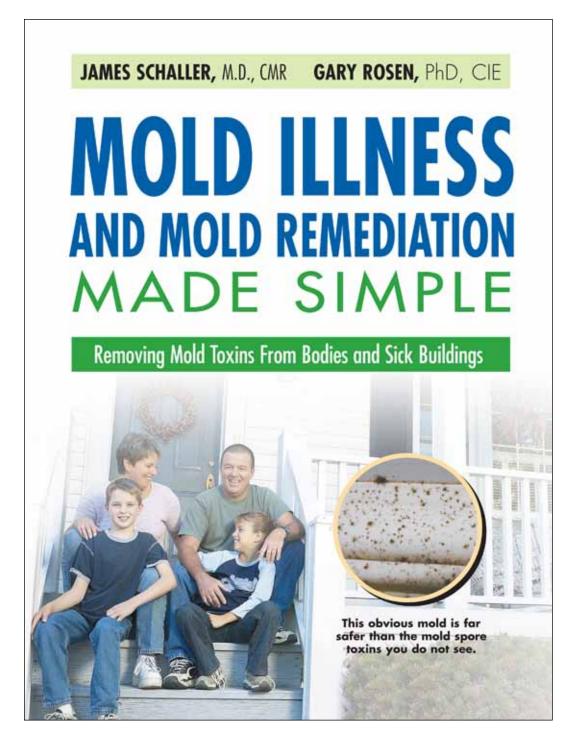


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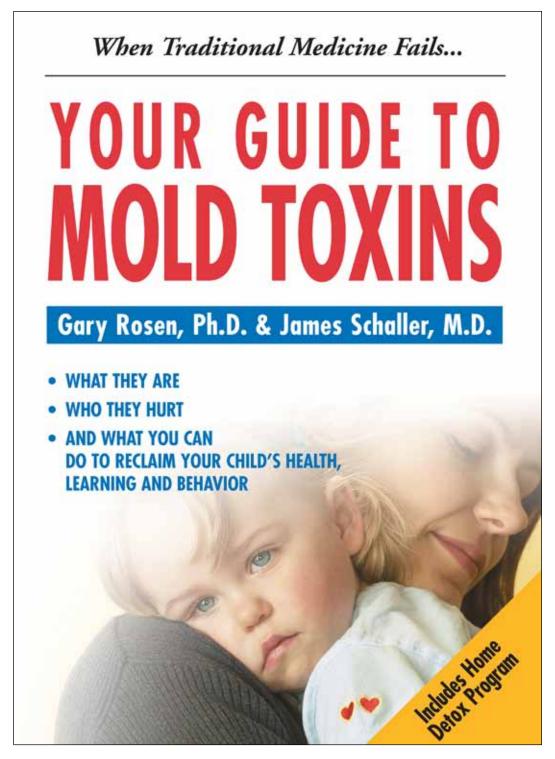
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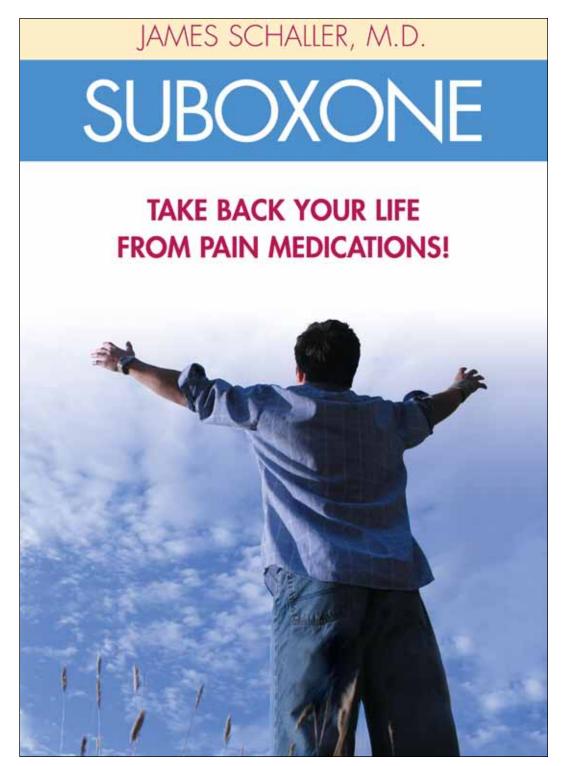
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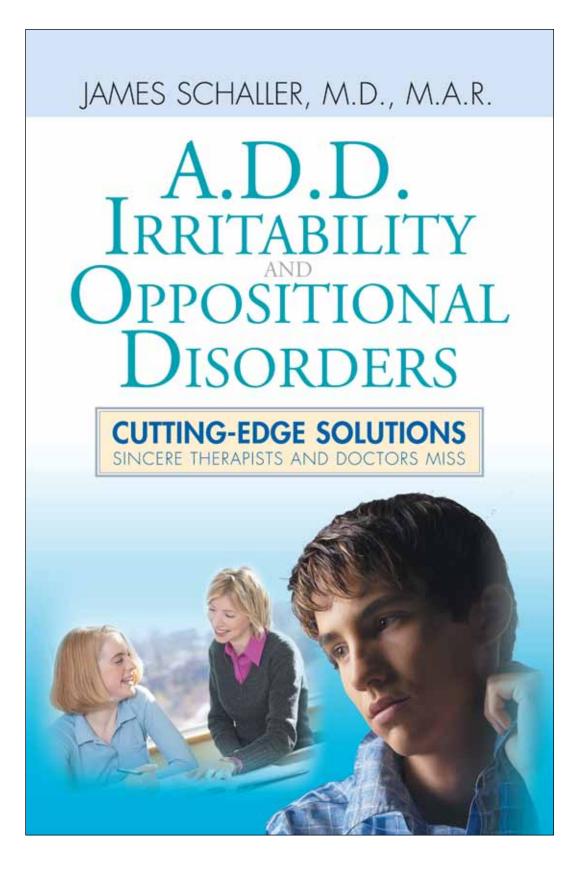
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### **Reminder of Disclaimer**

Dr. Schaller is not a specialist in infectious disease medicine. He is not a pathologist. Both of these specialties have over 2,000 diseases to treat and study. Dr. Schaller is only interested in four infections and has read and published on only these four. The medical ideas, health thoughts, health comments, products and any claims made about specific illnesses, diseases, and causes of health problems in this book are purely speculative, hypothetical, and are not meant to be authoritative in any setting. No comment or image has been evaluated by the FDA, CDC, NIH, IDSA or the AMA. Never assume any United States medical body, society, or the majority of American physicians endorse any comment in this book. No comment in this book is approved by any government agency, medical body or medical society. Nothing in this book is to be used to diagnose, treat, cure or prevent disease. The information provided in this book is for educational purposes only. It is not intended as a substitute for the advice from your physician or other health care professionals. This book is not intended to replace or adjust any information contained on, or in, any product label or packaging.

No patient should use the information in this book for the diagnosis or treatment of any health problem, or for prescription of any medication or other treatment. You should consult with a health care professional before deciding on any diagnosis, or initiating any treatment plan of any kind. Dr. Schaller does not claim to be an expert in any illness, disease or treatment. In this book, he is merely sharing one of his interests. Please do not start any diet, exercise or supplementation program, or take any type of nutrient, herb, or medication, without clear consultation with your licensed health care provider.

Babesia or Bartonella treatment comments and reports of possible positive or negative treatment outcomes are hypothetical. No treatment should be rejected or embraced by anyone, based on the preliminary research and study in this book. Some reports in this book are the result of various novel dosing, selfinitiated by proactive patients. They were nevertheless monitored often. Some patients were inherited right after various treatment trials. Their outcomes were promptly measured.

In this book, Dr. Schaller makes no authoritative or proven claim about any lab testing or treatment. Dr. Schaller only offers hypothetical ideas. Dr. Schaller makes no authoritative claims about medications, nutrients, herbs or various types of alternative medicine. The ideas in this book will need to be submitted to your local expert in allopathic, osteopathic or progressive medicine, or to other licensed health care practitioners. This book is not meant to be an informal or formal guideline book that presumes to control 800,000 physicians, or the 300 million patients they serve. You are asked to let the wisdom of your health care practitioners, and your own study, be a starting point to guide treatment tailored specifically to your body. Again, Dr. Schaller makes no claim to be an expert in any aspect of medicine. He makes no claim to know more than other physicians.

Additionally, Dr. Schaller makes no claim that any statement in this book is correct.

Names and minor personal details within this book have been changed to preserve privacy.

Since this appears to be the first book exclusively dedicated to advanced modern cutting-edge Babesia diagnosis and treatment, any book with new proposals will contain errors. This is common with books that are the first on such sensitive topics. Every reasonable effort has been made not to try to overstate findings. Further, it is important to realize that any single lab finding or treatment outcome can have multiple causes, and not all of these may be known to this author, or to other health practitioners. Therefore, all health care practitioners should look for other confirmations outside this book before beginning on any treatment plan, if possible. It is also fully appreciated that it is hard to diagnose Babesia infections.

### **Contacting Dr. Schaller**

Should you wish to talk to Dr. Schaller he offers individualized education consults, which can be arranged by calling 239-263-0133. Please leave all your phone numbers, a working email and a fax number. These consults are typically in 15 minute units and can last as long as you wish. All that is required is the completion of a short informed consent form.

If you would like a full diagnostic consult or to see Dr. Schaller as a patient, know he treats patients from all over the USA and from outside the country. He meets with you first and then does follow-up care with you by phone. He does require you to have a family doctor, internist or pediatrician, since he is only a consultant.

If you would like to fly in to see Dr. Schaller, his staff are very familiar with all the closest airports, and we have special hotel discounts.

I wish you the very best health!

Warm Regards,

Rona C. MBA Office Manager

## Are you tired of being sick? Are you frustrated with ineffective treatment? Do you feel like something is being missed?

- Why testing for Lyme disease alone is usually an error.
- A presentation of new labs which end stealth Babesia infections.
- Stealth Babesia infections prolong suffering, or eventually lead to a decrease in functioning.
- Traditional treatments fail to cure Babesia and only lower body load.
- This book discusses new treatments directed at cure.
- Lyme disease is never cured if Babesia remains.



**Dr. Schaller** is the author of 23 books, four of which outline tick, flea, and other infections that cause chronic illness and fatigue. Recent popular titles displaying Dr. Schaller's dedication on a variety of important topics include *The Diagnosis and Treatment of Babesia*, A *Laboratory Guide to Human Babesia Hematology Forms, Bartonella: Diagnosis and Treatment, Mold Illness and Mold Remediation Made Simple, The Complete Guide to Artemisinin, When Traditional Medicine Fails, 100 Solutions to Out of Control Youth*, and *Suboxone: Pain Treatment with Addiction Relief.* He is currently preparing the most up-to-date textbook on Bartonella, which, according to Schaller, may be among the top vector infections in the world, possibly more common than Lyme

Disease. He has started textbooks on the cause of treatment failure in people suffering with Chronic Fatigue, Fibromyalgia and Lyme disease.

Dr. Schaller has approximately 27 national and international medical publications in journals such as *JAMA*, *Medscape*, and some of the largest pediatric journals in the world. He was the first to publish a practical cancer cure, now a standard treatment internationally, which hypothesizes the blocking of a single enzyme for a deadly blood disease, Idiopathic Hypercosinophilia Syndrome (HES). Further, he has designed nutritional products, and published nutrient and herb purity and potency research. Dr. Schaller strongly advocates getting to the root cause of illnesses and tailoring treatments to the individual. His primary web site is **www.PersonalConsult.com**.

As a **full-time** researcher, Dr. Schaller is uniquely able to study and invent individualized cures to heal his patients. Dr. Schaller has invested countless hours creating treatments to give hope to the hopeless.

Dr. Schaller lives with his family in the United States.

Randall S. Blackwell is a medical research librarian in southeastern Pennsylvania.

