The Annual Heartworm Testing Mandate:

Clinical Evidence, Guideline Integrity, and Owner Autonomy

March 2026 · Prepared for veterinary, consumer advocacy, and policy outreach
Prepared by: Matt Horvath
Contact: contact@heartwormchoice.org, HeartwormChoice.org

SUMMARY CLAIM

The current standard of requiring annual heartworm antigen testing before dispensing macrocyclic lactone (ML) preventives — and refusing signed owner waivers as an alternative — is not adequately supported by clinical evidence, exceeds the scope of the purpose for which veterinary prescribing authority is delegated, and has been promulgated through a guideline-setting process with undisclosed financial conflicts of interest. This paper documents three integrated lines of argument: the clinical safety rationale fails at renewal, owner autonomy has been eliminated without clinical or legal justification, and the guideline origin is FDA surveillance — not patient safety.

Executive Summary

This paper argues not against heartworm testing, but against mandating it as a non-negotiable precondition for renewing prevention prescriptions for established, compliant patients — a policy shift observable at many U.S. veterinary practices in recent years, in which signed owner waivers are refused and annual antigen testing is required before macrocyclic lactone (ML) preventives will be refilled. Three independent lines of analysis — clinical, autonomy-based, and structural — converge on the same conclusion: this shift is not adequately supported by clinical evidence, exceeds the purpose for which veterinary prescribing authority is delegated, and occurred within a guideline-setting process whose integrity is compromised by undisclosed financial conflicts of interest

I. The Clinical Case Against Mandatory Renewal Testing

The stated clinical rationale for mandatory annual testing rests on two concerns: that a dog may harbor an undetected infection, and that administering ML preventives to an infected dog without full adulticide treatment constitutes inadvertent slow-kill that may foster ML-resistant subpopulations. Both concerns are legitimate in appropriate contexts. Neither justifies mandatory testing at renewal for dogs with documented consistent prevention history.

The renewal paradox: standard practice issues a one-year ML prescription dispensed monthly. If a dose timing gap in month four permitted infection, and the dog resumed monthly dosing from month five, the slow-kill scenario the renewal test is designed to catch was already underway — authorized by the prescribing veterinarian's own existing prescription. A test at month twelve does not prevent this outcome. It detects, retroactively, a condition the prior prescription permitted to develop.

Test reliability compounds the problem. Ongoing ML administration suppresses antigen production, delaying detectable antigenemia from the standard five-to-six month window to approximately nine months post-infection (AHS-documented). At month twelve, the renewal test is applied precisely when ML-induced suppression is at its most confounding — least reliable in exactly the scenario it is most invoked to address. Additionally, ML reach-back efficacy achieves approximately 95% worm burden reduction after twelve months of resumed dosing for susceptible strains, substantially reducing the probability of a persistent adult infection before any test is performed. Large-scale analyses, including CAPC data from millions of annual tests, consistently show that positivity rates are lowest in dogs with documented continuous prevention and rise sharply with compliance gaps (CAPC 2024/2025 Pet Parasite Forecasts; capcvet.org/articles/2025-annual-pet-parasite-forecasts/). For consistently dosed dogs, the rate is lower still.

The baseline renewal patient — asymptomatic, consistent prevention history, no clinical signs — presents no indication for diagnostic testing by any standard clinical criterion. In virtually every other context, this presentation would not generate a testing requirement. Mandatory renewal testing inverts the standard clinical presumption by treating the asymptomatic compliant patient as presumptively at risk unless proven otherwise.

II. The Legal Case: Delegated Authority and Unauthorized Purpose

Veterinary prescribing authority is delegated by the state — and structured by the federal VCPR framework — to protect the individual patient through the exercise of professional clinical judgment. It was not delegated to conscript licensed practitioners as agents in a mandatory population-level disease surveillance program. When the justification offered for withholding a prescription is that the practice needs to collect data on drug-resistant heartworm — as documented in at least one primary source interaction underlying this paper — the stated purpose is epidemiological surveillance, not individual patient care. Using the power to withhold a prescription as the enforcement mechanism for that surveillance is an exercise of delegated authority beyond its grant.

The resistance-detection rationale fails on clinical grounds as well. The standard SNAP antigen test cannot distinguish between ML-susceptible and ML-resistant Dirofilaria immitis isolates — it detects infection, not strain resistance profile. Resistance identification requires genomic characterization. Furthermore, adulticide therapy (melarsomine) remains effective against both susceptible and resistant adult worms, since ML resistance is a property of the larval life stage. A positive test result therefore does not alter the treatment protocol. A diagnostic test whose result cannot change clinical management has no clinical justification, regardless of what professional guidelines recommend.

The signed informed-consent waiver that was previously standard practice represented the profession's correct understanding of this as a shared decision. Its elimination is sometimes defended on Standard of Care grounds — the argument that AHS guidelines define the legal standard of care and cannot be waived. This defense has significant weaknesses: AHS guidelines are advisory, not statutory; the waiver framework coexisted with AHS recommendations for nearly two decades without being deemed impermissible; and the liability concern driving waiver refusal appears in many cases to be insurer-driven rather than legally mandated. Most fundamentally, a direct review of current FDA-approved labels for every major ML preventive confirms that no label requires pre-administration testing at renewal — all testing language is limited to initiation, and Advantage Multi (moxidectin) contains no testing language at all. The mandatory annual renewal testing requirement has no basis in the federal regulatory labels governing these drugs. It is a professional guild standard enforced through AHS guidelines, liability culture, and insurer risk calculus — not a federal regulatory requirement. The full label analysis appears in Section 4.2.1; the Standard of Care analysis appears in Section 3.3.

III. The Structural Case: Guideline Origin, Undisclosed Conflicts, and the AHS's Own Waiver

The American Heartworm Society (AHS) is the primary source of the testing standard. Its sponsor roster includes the four largest manufacturers of ML preventive drugs (Boehringer Ingelheim, Elanco, Merck Animal Health, Zoetis) and IDEXX Laboratories, manufacturer of the SNAP antigen test kits the standard requires. These relationships are not disclosed in the guidelines themselves.

A critical and underappreciated fact cuts directly against the Standard of Care defense: the AHS publishes an official Heartworm Preventive Waiver template (© 2020 American Heartworm Society, incidence map updated 2022; available at heartwormsociety.org/images/pdf/AHS-HW-Preventive-

Waiver.pdf) that covers declination of both the heartworm test and the heartworm preventive. The form includes owner acknowledgment language, a veterinarian's recommendation field, a hold-harmless clause, and filing instructions. A practice that refuses to accept a signed waiver is not following AHS guidance — it is going materially beyond it. The Standard of Care argument cannot be grounded in AHS authority when the AHS itself distributes the waiver instrument.

The origin of the annual testing recommendation has been confirmed by primary source. Tom Nelson DVM, AHS Research Chair and past AHS president, confirmed in March 2026 that the AHS first recommended annual testing in its 2005 guidelines at the request of the FDA, based on a paper presented at the 2004 AHS Triennial Symposium. The referenced FDA paper (Hampshire, V.A., 2005) reveals that the FDA's interest was post-market surveillance of product efficacy and resistance tracking — not individual patient safety. The FDA's recommendation was also explicitly geographically limited to endemic regions. The current uniform national standard is an AHS amplification of that recommendation with the geographic limitation removed.

The AHS's own prevalence map — included in its waiver document — illustrates the geographic problem in concrete terms. The map measures average cases per reporting clinic, not a normalized per-dog or per-test infection rate. This methodology systematically amplifies high-volume urban clinics and may understate genuine rural hotspots. It does not support the geographic claims it is implicitly used to make, and using it to justify a national uniform testing mandate imposes the highest-risk-zone standard on low-risk patients based on a measurement artifact. The CAPC positivity-rate maps provide a materially more accurate geographic picture.

The 2024 AHS guidelines contain a statement that carries analogical force for the preventive context: on page 20, under the Principles of Heartworm Treatment, they state that "treating in the absence of diagnostics, while not ideal, is better than refusing to perform a needed treatment." This language appears specifically in the context of adulticide treatment for dogs already known or suspected to be heartworm-positive, not in the context of preventive prescribing. The analogical principle remains meaningful: the AHS acknowledges in the treatment context that withholding care pending ideal diagnostics causes harm that outweighs the diagnostic benefit. A parallel harm analysis applies to the preventive renewal gap — dogs left unprotected during a mandatory testing delay face a real infection window that the testing requirement itself creates.

IV. What the Evidence Supports

The three lines of analysis above do not argue against heartworm testing. They argue against mandatory testing as a non-negotiable precondition for prescription renewal in any setting, for any patient, enforced by withholding a prescription. The veterinarian's authority to withhold a prescription flows from the obligation to the individual patient, not from a public health surveillance function and not from a professional standard set by a sponsored organization. Informed owner consent — including documented refusal — is the correct mechanism for resolving disagreements about recommended care in all settings.

In high-resistance areas of the Lower Mississippi River Valley, this position does not produce under-testing. Owners who are accurately informed of local resistant-strain prevalence and its

clinical consequences will elect to test in large numbers without being compelled. A veterinarian with direct knowledge of resistant-strain cases in their practice or community is positioned to make a specific, credible clinical recommendation that most informed owners will follow. The mandate adds a mandatory enforcement layer on top of what informed consent would produce on its own — and it does so under the authority of a professional standard whose origin is surveillance, whose sponsor structure benefits directly from the test being mandated, and which no equivalent professional body in any other heartworm-endemic country has adopted.

The international comparison reinforces this. The European Scientific Counsel Companion Animal Parasites (ESCCAP) — the professional guideline body for 19 European countries including genuinely heartworm-endemic Mediterranean nations — operates on a risk-stratified, individual-assessment model without a universal pre-prescription testing mandate. Spain and Portugal, with warm climates, year-round transmission seasons, and historically documented heartworm endemicity, do not require mandatory pre-prescription antigen testing as a condition of dispensing ML preventives. The U.S. mandatory annual testing requirement is a regulatory outlier, not a convergent global clinical standard.

A proportionate standard would restore the signed informed-consent waiver as a universally recognized option for all patients; adopt a recommendation-based approach calibrated to individual risk rather than a blanket mandate; distinguish new patients from established compliant patients; and require disclosure of AHS sponsor relationships in guideline documents. The full evidentiary basis for each of these positions is developed in the sections that follow.

Primary sources: 2005, 2014, and 2024 AHS Canine Heartworm Guidelines; Hampshire (2005) FDA/CVM efficacy evaluation paper (J. Vet. Parasitology 133:191–195); direct correspondence with Tom Nelson DVM, AHS Research Chair, March 2026; CAPC 2024/2025 Pet Parasite Forecasts (capcvet.org).

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1. Background and Scope

This document addresses a specific, time-bounded policy shift: the transition, observable at many U.S. veterinary practices in recent years, from a framework where signed owner waivers were accepted in lieu of annual heartworm antigen testing, to a framework where waivers are refused and testing is a non-negotiable precondition for prescription renewal.

The target audience includes veterinarians, consumer advocacy organizations, and policy professionals with an interest in evidence-based prescribing standards, owner rights, and the structural integrity of professional guideline-setting in veterinary medicine.

This paper integrates three lines of analysis — clinical, autonomy-based, and conflict-of-interest — because they are mutually reinforcing. The clinical argument alone is strong but could be dismissed as a technical dispute. The conflict-of-interest argument alone is suggestive but not conclusive. Together, they describe a situation where professional standards have hardened beyond what the evidence supports, in a direction that consistently benefits commercial sponsors of the standard-setting body, at the expense of pet owners who are the legally responsible parties for their animals.

1.1 The Stated Clinical Rationale

The American Heartworm Society (AHS) guidelines provide two primary clinical justifications for requiring annual testing:

- Undetected infection risk: A dog may be infected without the owner's knowledge. Administering ML preventives to an already-infected dog without full adulticide treatment (doxycycline + melarsomine + activity restriction) constitutes "inadvertent slow-kill" — a practice the AHS discourages because it reduces microfilariae without clearing adult worms, potentially fostering ML-resistant subpopulations.
- Resistance concern: ML-resistant heartworm subpopulations exist primarily in the Mississippi Delta / Gulf Coast region. Inadvertent slow-kill in these areas may select for resistance.

These concerns are legitimate in the appropriate context. The question this paper addresses is whether mandatory annual testing at prescription renewal is an appropriate, necessary, and proportionate response to them — particularly for dogs with documented consistent prior prevention history.

Scope note: This paper addresses canine patients only. Feline heartworm prevention follows materially different diagnostic, clinical, and preventive considerations and is not addressed here.

2. The Clinical Argument: The Safety Rationale Fails at Renewal

2.1 The Heartworm Detection Window

Understanding the limits of the antigen test is essential to evaluating the testing mandate. Key developmental milestones (per AHS 2024 guidelines):

Timeframe Post-Infection	Development Stage
Days 0–12	L3 larvae enter via mosquito bite; molt to L4
Days 50–70	Final molt to immature adult worms
Days 67–120	Immature adults reach the pulmonary arteries
~Day 120	Worms reach sexual maturity
~5–6 months	Earliest antigen detectability (standard SNAP test)
~6–7 months	Earliest microfilariae detectability
7–9 months	Full patent infection typically established

Critical consequence: A dog infected within the prior 5–6 months will test negative on an antigen test regardless of actual infection status. The standard renewal test is a lagging indicator with a structural blind spot for infections acquired in the months immediately preceding the test.

2.2 The Renewal Paradox: Slow-Kill Was Already Underway

This is the analytical core of the case against mandatory renewal testing. The standard prescription cycle issues ML preventives for a one-year supply, dosed monthly. At 12 months, a new test is required before renewal.

Consider the scenario the test is designed to catch: a dog that experienced a brief dose timing gap during the prior year, allowing a theoretical infection window, and then resumed dosing.

THE LOGICAL PROBLEM — AND THE "SECOND YEAR" FALLACY

If a dog was infected during a lapse in month 4, and then resumed monthly ML dosing from month 5 onward — the "inadvertent slow-kill" the test is designed to catch was already underway, authorized by the prescribing veterinarian's own existing prescription. A test at month 12 does not prevent this scenario. It detects, retroactively, a condition that the prescription itself permitted to develop. Critics may argue that the 12-month test prevents an infection from persisting into a second year — but this marginal benefit does not justify removing owner autonomy. The "prescription gap" created by the mandate — where dogs go unprotected during a testing delay — poses a more immediate and probable risk than the rare persistent infection in a compliant dog. Requiring a test at renewal to prevent inadvertent slow-kill is logically moot.

2.3 Test Reliability Degrades in the Exact Scenario It Targets

Three compounding factors undermine the test's reliability in the specific population it is mandated to screen:

LAYER 1 — Baseline Sensitivity Limits
The SNAP antigen test detects circulating proteins from mature female worms only. It produces false negatives in all-male infections, very low female worm burden infections, and cases where immune complex formation masks circulating antigen. These limitations apply regardless of ML status.

LAYER 2 — ML-Induced Antigen Suppression
Ongoing ML administration suppresses antigen production, delaying detectable antigenemia to approximately 9 months post-infection — versus ~5–6 months in dogs not receiving MLs (AHS-documented figure). A renewal test at month 12 is applied precisely when ML-suppressed antigenemia is at its least reliable. The test is therefore least reliable in exactly the scenario it is most invoked to address.

LAYER 3 — The 24-Month Antigen-Negative Paradox
Study data show that after 24 months of monthly ivermectin, approximately 70% of infected dogs have gone antigen-negative. Some represent true clearance; others represent antigen suppression in dogs that still harbor living worms. The SNAP test cannot distinguish between these outcomes.

In the specific target population of the mandatory renewal test — consistently dosed dogs with a possible inadvertent slow-kill infection — all three degradation mechanisms operate simultaneously. The false negative rate in this population is materially higher than the test's nominal sensitivity in a non-dosed dog of unknown status. The test is being mandated for a scenario where it performs worst.

One additional reliability point bears emphasis: none of the SNAP test, nor any step in IDEXX's own recommended confirmatory cascade (reference lab ELISA, microfilariae test, heat-treatment retest), can identify whether the infecting strain is ML-susceptible or ML-resistant. No validated commercial test for routine clinical resistance determination currently exists. The resistance-detection justification for mandatory testing cannot be fulfilled by the tests being mandated. The full analysis of the cascade — including its revenue implications — appears in Section 4.1.1.

2.4 Reach-Back Efficacy Further Reduces the Risk

Most MLs have documented "reach-back" (or safety-net) efficacy: retroactive protection against larvae that have already entered the dog but have not yet matured past the vulnerable window. Understanding the mechanism is important for evaluating the renewal scenario.

After a mosquito bite, infective L3 larvae enter the dog and molt to L4 within approximately 3–5 days. They continue developing for roughly 50–58 days before becoming juvenile adults. MLs kill these early larval stages by disrupting larval physiology — but larvae remain vulnerable only during this developmental window. Beyond approximately 52 days post-infection, larvae reach the juvenile

adult stage and become substantially less susceptible to MLs. This means the safety net has a defined biological limit: it operates in the first 30–60 days post-infection, not indefinitely.

The foundational reference for this is McCall JW et al. (2005), "The safety-net story about macrocyclic lactone heartworm preventives: A review, an update, and recommendations," Veterinary Parasitology (cited 166+ times). McCall et al. document how prolonged ML administration kills young larvae, older larvae, immatures, and even some young adults — the mechanistic basis for the reach-back effect. For non-resistant strains, lab studies consistent with this framework show approximately 95% worm burden reduction after 12 consecutive months of resumed dosing post-lapse.

Critically, the AHS's own guidelines acknowledge this safety net in explicit terms. The 2014 AHS Canine Guidelines state: "The extended post-infection efficacy of macrocyclic lactones is a partial safeguard in the event of inadvertent delay or omission of regularly scheduled doses." This is the organization that mandates annual testing to catch lapsed-dose infections acknowledging, in its own published guidelines, that the drugs provide a built-in biological safeguard against exactly that scenario.

Product labels corroborate this independently. Heartgard Plus, Sentinel Spectrum, and Trifexis labels all include specific missed-dose redosing instructions for lapses of 15–30+ days, in some cases directing continuation for an additional 1–2 months. These instructions are not advisory suggestions — they are FDA-reviewed label provisions that leverage the reach-back window as part of the drug's design.

THE REACH-BACK IMPLICATION FOR THE RENEWAL SCENARIO

For a dog with a brief gap in month 4 that resumed dosing in month 5: larvae from that infection window were either killed by reach-back efficacy within the following 30–60 days, or matured past the ~52-day juvenile adult threshold and are now beyond the ML-susceptible stage. Either way, the critical biological event resolved months before the month-12 renewal test. The AHS's own guidelines confirm the safety net exists. The renewal test at month 12 is detecting — or failing to detect — an outcome that the dog's own immune response and the resumed ML administration have already substantially determined.

This means that for most brief-lapse scenarios with susceptible strains, resumed prevention substantially reduces the probability of a persistent adult infection before any renewal test is performed. Large-scale analyses, including CAPC data from millions of annual tests, consistently show that positivity rates are lowest in dogs with documented continuous prevention and rise sharply with compliance gaps (CAPC 2024/2025 Pet Parasite Forecasts). For consistently-dosed dogs without documented lapses, the rate is lower still.

2.5 The Only Scenario Where Renewal Testing Has Value

The one scenario where a renewal test could change clinical management is a dog that experienced a complete prevention lapse — zero doses for an extended period — during which infection occurred and no MLs were administered to suppress antigen or exert reach-back efficacy.

This counterargument is limited for four reasons: (1) A complete lapse is not a "renewal" scenario — the risk profile differs materially from a consistently-covered dog. (2) The test still misses infections acquired within the prior 5–6 months even in a complete lapse. (3) For dogs that eventually resumed MLs, antigen suppression applies. (4) By analogy, the AHS acknowledges in its adulticide treatment section that withholding a needed treatment pending complete diagnostics causes harm that outweighs the diagnostic benefit — a principle the guidelines state explicitly in the context of suspected-positive dogs. The same harm logic applies here: a dog left unprotected during a mandatory testing delay faces a real, if lower-probability, infection window that the testing requirement itself creates. This is an analogical argument, not a direct application of the guidelines to preventive prescribing.

A historical note is warranted on the fear of adverse reactions from administering preventives to infected dogs. This concern is occasionally raised as a clinical justification for mandatory testing — the suggestion that giving a preventive to a heartworm-positive dog risks severe or fatal reaction. This fear is largely a holdover from the era of diethylcarbamazine (DEC), a daily preventive used through the 1980s that did cause fatal anaphylactic shock in microfilaremic dogs. Modern macrocyclic lactones do not carry this risk profile. The FDA label language "at the discretion of the veterinarian" — retained across current ML labels — reflects the historical regulatory drafting era and the residual caution about high microfilariae burdens, not a documented safety hazard equivalent to DEC in contemporary clinical practice. The transition from DEC to MLs was precisely a safety improvement on this dimension; conflating the two misrepresents the current risk.

THE HARM THE MANDATE CREATES

The mandatory testing requirement introduces its own clinical risk: dogs whose owners cannot afford or decline the mandatory visit go without prevention entirely during the gap between prescription expiration and test completion. An unprotected dog in a heartworm-endemic region is a demonstrably more probable harm than a persistent infection in a consistently-dosed compliant dog. The mandate, by creating a cost-based access barrier to prevention, may increase the total population of unprotected dogs — the opposite of the public health outcome it ostensibly seeks.

2.6 Not All Dogs Are the Same: Abandonment of Clinical Indication Standards

Not all dogs are the same. A hunting dog living full-time in an outdoor kennel near wetlands in rural Mississippi faces materially different heartworm exposure than a small-breed dog that spends nearly all its time indoors. One has near-constant mosquito exposure; the other has brief, controlled outdoor access. Treating these two animals identically — applying the same rigid annual testing precondition before renewing prevention — ignores biological reality, lifestyle differences, and the basic principles of clinical medicine that apply everywhere else in veterinary practice.

Standard clinical practice in both veterinary and human medicine applies diagnostic testing on the basis of clinical indication: symptoms, known exposure, documented risk factors, or change in clinical status that raises the prior probability of disease.

The baseline renewal patient addressed by this paper is an asymptomatic dog with documented consistent prevention history, primarily indoor lifestyle, no clinical signs, and an infection probability that CAPC data consistently places among the lowest in any tested population. In virtually every other clinical context, this presentation would generate no indication for diagnostic testing. A physician does not require an annual diagnostic test to refill a prescription for an asymptomatic, compliant patient. Heartworm is the exception — and the exception is not justified by a corresponding difference in clinical presentation.

A clarifying note on reservoir status is warranted here, as it is sometimes invoked to elevate the public health urgency of annual testing: while infected domestic dogs can contribute microfilariae to the transmission cycle if circulating microfilariae are present, mostly indoor pet dogs with limited mosquito exposure represent far lower reservoir potential than untreated wildlife such as coyotes, foxes, or feral dogs. Coyote populations in some endemic areas show prevalence of 35–75%, they roam widely, live in habitats with high mosquito density, and sustain the parasite cycle independently of domestic pets. Equating a compliant indoor pet at renewal time with a free-roaming wildlife reservoir inaccurately inflates the incremental public health risk that individual dog poses. The focus on low-exposure, consistently-dosed renewal patients reflects this distinction.

INVERSION OF CLINICAL PRESUMPTION

Mandatory renewal testing treats an asymptomatic dog with documented prevention history as presumptively at risk of infection unless proven otherwise. This inverts the standard clinical presumption. Normal practice presumes low probability of disease in healthy, compliant patients. Testing is warranted when something changes that shifts that probability: new symptoms, confirmed lapse, change in geography, or owner concern about a specific event.

2.7 The Shift from Support to Enforcement

A veterinarian's prescribing authority is a service intended to support the health of the animal through the agency of the owner. In many modern practices, the standard has shifted toward a model of enforcement — where the diagnostic test is a mandatory gatekeeper — rather than a model of enablement.

When owner compliance is identified as the primary clinical concern driving mandatory testing, the most direct and least invasive professional response is to enable that owner: automated monthly dosing reminders, client education on the biology of the 30-day safety net, and synchronization of dosing schedules with household routines. These tools address the compliance gap directly, without restricting access to the prescription. The mandate, by contrast, verifies whether compliance failures occurred after the fact — while doing nothing to prevent them. It is a retrospective enforcement mechanism applied to a problem that prospective enablement could substantially reduce.

The preference for enforcement over enablement has a straightforward economic explanation, which is developed in Section 4.5. The clinical point here is simpler: a profession that correctly identifies compliance as the dominant driver of heartworm infections — and then responds with a diagnostic mandate rather than compliance infrastructure — has not optimized for the dog's health. It has optimized for a different variable.

3. The Autonomy Argument: Elimination of Informed Consent

3.1 Legal Framework

Under Florida law and the laws of most U.S. states, companion animals are legally personal property. The owner is the legally recognized decision-maker for the animal's care. The veterinarian holds prescribing authority over prescription drugs — a regulatory function that exists to ensure clinical competence, not to transfer medical decision-making from owner to clinician.

The Veterinarian-Client-Patient Relationship (VCPR) establishes that the vet has sufficient knowledge of the patient to prescribe responsibly. It does not grant the vet authority to override the owner's informed judgment on risk assessment.

3.2 The Waiver as a Proper Consent Framework — Confirmed by AHS's Own Documents

The most direct evidence that the waiver framework is professionally legitimate comes from the American Heartworm Society itself. The AHS publishes an official Heartworm Preventive Waiver template on its website (© 2020 American Heartworm Society, incidence map updated 2022; direct PDF: heartwormsociety.org/images/pdf/AHS-HW-Preventive-Waiver.pdf; landing page: heartwormsociety.org/veterinary-resources/practice-tools/heartworm-preventive-waiver), available to any veterinary practice. The document covers declination of both the heartworm test and the heartworm preventive — a scope that goes well beyond a simple testing waiver. It includes a veterinarian's recommendation field, owner acknowledgment language, a hold-harmless clause, and signature and date lines with the instruction to file with patient records.

> **THE AHS WAIVER: WHAT IT ESTABLISHES**
> The AHS — the same organization whose guidelines are invoked as the Standard of Care justification for refusing waivers — publishes and distributes an official waiver form for exactly this purpose. A veterinary practice that refuses to accept a signed waiver is not following AHS guidance. It is going beyond it, in a direction that restricts owner rights the AHS itself has explicitly preserved. This is not a peripheral point: it means the Standard of Care argument, as applied to waiver refusal, cannot be grounded in AHS authority. The AHS's own published practice contradicts it.

Two additional observations from the waiver document are relevant. First, the AHS waiver's informed consent language covers general disease risk, potential fatality, and treatment cost. It does not require the owner to specifically acknowledge the slow-kill risk, the resistance concern, or the antigen suppression problem — the precise clinical justifications most commonly cited for mandatory testing. This suggests that even the AHS does not consider those specific risks to require explicit owner acknowledgment as a condition of valid waiver execution. Second, the document's prevalence map — discussed further in Section 5 — uses a methodology that the AHS itself acknowledges is based on average cases per reporting clinic, not a normalized per-dog or

per-test rate. The limitations of that metric are directly relevant to any geographic risk argument used to justify the testing mandate.

The signed informed-consent waiver represents the profession's correct understanding of this as a shared decision. Under the waiver model:

- The vet informs the owner of the specific risk (undetected infection, slow-kill, resistance concerns).
- The owner, as the legally responsible party, acknowledges the risk and accepts it in writing.
- The vet prescribes, protected from liability by documented consent.
- The owner retains the right to make a risk judgment they are legally and morally entitled to make.

The elimination of the waiver option does not make the dog safer. It removes the owner's ability to exercise informed judgment on a risk that the owner is best positioned to evaluate (they know the actual dosing history), the owner bears (they are legally responsible for the animal), and the clinical evidence does not clearly establish as significant in the renewal/consistent-coverage scenario.

One would expect that if annual antigen testing were genuinely indicated by patient risk, veterinarians — particularly those who recommend a specific preventive brand, write the prescription, and dispense the product — would routinely highlight the manufacturer warranty as a central point of client education. It is, after all, a compelling reason to test: a negative result on file means that if a dog on continuous prevention develops heartworm disease, the manufacturer covers up to $1,500 in diagnosis and treatment costs. That is meaningful consumer protection worth knowing about. Yet in eight years of keeping two dogs on continuous monthly prevention, signing annual testing waivers across multiple veterinary clinics in the Greater Tampa Bay area, this author was never once informed that by signing, he was waiving eligibility for that manufacturer coverage. The AHS waiver template itself is silent on manufacturer guarantees — the form that practices use to document informed consent contains no mention of the financial protection the owner is forfeiting by declining the test.

To the practicing veterinarian reading this: when discussing monthly heartworm preventives with your clients, do you routinely disclose that the manufacturer warranty — worth up to $1,500 in treatment coverage depending on the product — is contingent on an annual negative antigen test on file? If that disclosure is not part of your standard conversation, it is worth asking what that silence reveals about the operative function of the testing requirement. A mandate driven primarily by patient benefit would produce informed clients. A mandate driven primarily by liability management would produce clients who comply without understanding why — which is precisely what the current framework delivers.

3.3 The Standard of Care Defense — and Its Limits

The most common institutional response to the waiver argument is the Standard of Care defense: veterinarians cannot contractually waive their professional obligations, and if AHS guidelines define

the standard of care, a vet who prescribes without testing is practicing below that standard regardless of what the owner signed.

This defense has three significant weaknesses when examined carefully.

First, AHS guidelines are advisory, not binding law. No U.S. state veterinary practice act directly incorporates AHS guidelines as the statutory standard of care. The legal standard of care is defined by what a reasonably competent practitioner in similar circumstances would do — a standard that is established through expert testimony and professional consensus, not by the self-published guidelines of an industry-sponsored membership organization. Whether AHS guidelines constitute the binding standard of care in a given state is an open legal question, not a settled one. This is precisely why it appears as an open question in Section 6.

Second, the Standard of Care argument has historically coexisted with the waiver framework — not superseded it. For most of the period from 2005 through approximately 2022, many practices both followed AHS recommendations and accepted signed informed-consent waivers. If the Standard of Care truly prohibited waiver-based prescribing, that framework could not have operated as standard practice for nearly two decades. The recent shift to waiver refusal is not a discovery that waivers were always impermissible — it is a new institutional policy that requires its own justification.

THE CRITICAL DISTINCTION

A veterinarian's professional obligation is to inform the owner of clinical risks, document that communication, and exercise competent clinical judgment. It is not to compel owner compliance with the recommended course of action when the owner, fully informed, declines. Informed consent — including documented refusal — is a standard mechanism for resolving exactly this tension in both human and veterinary medicine. The Standard of Care defense conflates the vet's obligation to recommend with an authority to mandate that the profession has never clearly established.

Third, the liability concern driving waiver refusal is often insurer-driven rather than legally required. The shift from waiver-acceptable to waiver-refused at many practices appears to correlate with changes in professional liability insurance terms — meaning the legal barrier may be a product of insurer policy, not state law or settled professional standards. Whether insurers have the authority to define the scope of permissible informed consent is itself an open question that deserves scrutiny. This is noted as a key open question in Section 6.

Fourth, and most fundamentally: the Standard of Care defense assumes that AHS guidelines represent an independent, disinterested professional determination of what good clinical practice requires. That assumption cannot survive examination of how the AHS is funded. The organization that purports to define the standard of care for mandatory heartworm testing receives material financial support from the manufacturer of the test being mandated, and from the manufacturers of the drugs whose sales are driven by the mandatory vet visit the test requires. This is not a peripheral observation — it goes to the legitimacy of the standard itself.

THE SPONSORED STANDARD PROBLEM

A 'standard of care' derived from guidelines produced by an organization financially dependent on the commercial success of the test being mandated is not an independent professional standard. It is a sponsored one. Invoking that standard as a shield against informed owner consent — and as a justification for withholding a prescription — compounds the original conflict: the same financial interest that shaped the guideline is now being used to foreclose the owner's ability to opt out of it. No professionally accepted conflict-of-interest framework in medicine, law, or any regulated industry would treat this arrangement as a legitimate basis for a mandatory clinical standard.

3.4 The Prescription Record Problem

For long-term established patients, the prescribing practice already holds complete compliance data in its own files: the full prescription history, dates of all prior visits, any documented lapses or compliance concerns, and all prior test results.

THE INTERNAL INCONSISTENCY

The same practice that refuses to prescribe without a test because 'we can't know if the dog is infected' has, in its own records, years of prescription dispensing data from which infection probability can be reasonably estimated. The refusal to use that data — treating a 6-year established compliant patient identically to a new patient walk-in — is not clinical reasoning. It is policy applied uniformly to maximize testing volume regardless of individual patient history.

3.5 The Policy Shift and Its Timing

The shift from "testing recommended, waiver acceptable" to "testing mandatory, waivers refused" is a recent phenomenon observable from approximately 2022–2024, based on owner reports and contemporaneous AHS guideline hardening. The 2024 AHS guidelines represent a notable language tightening compared to 2014 and 2005, despite no documented change in heartworm biology, ML efficacy, or resistance prevalence that would independently justify the shift.

The timing of this shift coincides with increasing market penetration of point-of-care antigen test kits — a diagnostic product sold primarily by IDEXX Laboratories, which holds sponsorship status with the AHS. This correlation is developed further in Section 4.

3.6 The Unauthorized Purpose: Prescribing Authority Was Not Delegated for Population Surveillance

A distinct and serious legal argument applies when the justification offered for mandatory testing is not individual patient safety but the detection of ML-resistant heartworm infections at the population level. This framing — increasingly common in practice-level explanations — fundamentally changes the legal character of what is being required.

THE CORE LEGAL CLAIM

Veterinary prescribing authority is delegated by the state — and structured by the federal VCPR framework — for a specific and limited purpose: to protect the individual patient through the

exercise of professional clinical judgment. It was not delegated to conscript licensed practitioners as de facto agents in a mandatory population-level disease surveillance program. Using the power to withhold a prescription as the enforcement mechanism for that surveillance is an exercise of delegated authority for a purpose beyond its grant.

It is critical to distinguish guild-level surveillance from statutory public health mandates. Unlike rabies vaccinations — which are codified in state law for immediate human safety — heartworm resistance tracking is an industry initiative. While epidemiological tracking is a valid professional interest, it lacks the legislative standing to override an owner's right to informed consent regarding their personal property. Using the power to withhold a prescription as the enforcement mechanism for that surveillance is an exercise of delegated authority for a purpose beyond its legal grant.

This is not a semantic distinction. The source and scope of a delegated power defines its lawful uses. A veterinarian's authority to require a diagnostic test before prescribing flows from the professional obligation to the patient — to ensure the drug is clinically appropriate and will not cause harm. That is the basis on which courts and licensing boards have recognized prescription gatekeeping as a legitimate exercise of professional judgment.

Population surveillance — tracking the geographic spread of ML-resistant Dirofilaria immitis isolates, improving the FDA's ability to score product efficacy complaints, building epidemiological datasets — is a public health function. It may be a worthy one. But it is not the function for which prescribing authority was granted. When a veterinarian tells an owner that the test is required because "they need to collect data on drug-resistant heartworm" — as documented in at least one primary source interaction underlying this paper — that veterinarian has stated plainly that the test serves a surveillance purpose, not a clinical one. That admission is legally significant.

PRIMARY SOURCE CONFIRMATION

In a direct conversation documented as part of this investigation, the treating veterinarian, when asked why annual testing is required for a dog on consistent prevention, stated that the mandate exists because "they need to collect data on drug-resistant heartworm." This is not a clinical justification. It is a public health surveillance justification — and it was the explanation offered for withholding a prescription.

The Resistance-Detection Rationale Also Fails Clinically

Even setting aside the legal authority question, the resistance-detection rationale does not survive clinical scrutiny. Three problems compound:

- Geographic mismatch: ML-resistant isolates are confirmed primarily in the Lower Mississippi River Valley. Applying a resistance-detection testing mandate uniformly in Florida — where resistance is not a documented endemic problem — lacks any proportionate clinical basis. The test is not detecting a threat that has been established to exist in the patient population being screened.
- The test cannot identify resistant strains: The standard SNAP antigen test — and the entire IDEXX recommended confirmatory cascade (reference lab ELISA, microfilariae testing,

heat-treatment retest) — detect and characterize infection. None of these tests identify whether the infecting strain is ML-susceptible or ML-resistant. No validated commercial test for routine clinical resistance determination currently exists. Resistance identification requires genomic characterization or controlled experimental challenge conditions, neither of which is part of routine diagnostic practice. If the clinical purpose of mandatory testing is to detect resistant-strain infection specifically, the test being mandated cannot accomplish that purpose — by IDEXX's own protocol design.

- A positive result does not change treatment: Adulticide therapy (melarsomine) remains effective against both ML-susceptible and ML-resistant adult worms — resistance is a property of the larval life stage, not the adults. A positive test result therefore does not alter the adulticide treatment protocol. It may, however, inform the choice of preventive going forward: moxidectin-based products (Advantage Multi, ProHeart, Simparica Trio) consistently show 95–100% efficacy against confirmed resistant isolates in lab studies, compared to 10–64% for ivermectin and milbemycin oxime. But this preventive-selection decision does not require a positive antigen test to trigger — it requires knowledge of local resistance prevalence, which is a geographic and epidemiological question, not a per-dog diagnostic one.

The resistance-detection framing therefore fails on both grounds simultaneously: the authority to withhold a prescription does not extend to compelling participation in population surveillance, and the test being required cannot actually accomplish the surveillance purpose it is invoked to justify. The owner is being told their dog's prescription is contingent on contributing to a dataset the test cannot meaningfully populate.

The Voluntary Path Was Always Available

Nothing in this argument forecloses the legitimate role of testing in resistance surveillance. Veterinarians are free to recommend testing, explain its population-level value, and encourage willing owners to participate. Many will. Owners who understand the genuine public health concern around ML resistance may voluntarily elect testing as a contribution to that effort — and that election, freely made with accurate information, is entirely appropriate.

What the delegated prescribing authority does not permit is making that election compulsory by withholding a prescription from an owner who declines. The distinction between recommendation and coercion is the distinction between a professional exercising clinical judgment and a professional wielding a regulatory power for an unauthorized purpose. The waiver framework that was previously standard practice preserved exactly this distinction: the vet recommends, the owner decides, the prescription follows the decision either way. Its elimination replaced professional recommendation with institutional coercion — and the stated justification, in at least some practices, is a surveillance purpose that the prescribing authority was never designed to serve.

The confirmed origin of the annual testing recommendation — FDA surveillance interest, translated into AHS guidelines, adopted by practices as a mandatory gatekeeping requirement — makes this argument more than theoretical. It is traceable. Section 4 documents that chain of causation in full.

3.7 The Manufacturer Guarantee: An Insurance Underwriting Requirement Functioning as Clinical Necessity

A fourth mechanism driving waiver refusal deserves explicit analysis: the manufacturer satisfaction guarantee. Major ML preventive manufacturers offer financial guarantees that cover the cost of adulticide treatment if a dog on their product develops heartworm disease. These are commercially significant programs — Boehringer Ingelheim's Heartgard Plus Satisfaction Guarantee covers up to $1,000 toward veterinary services plus complimentary adulticide; Elanco's 2025 Canine Parasiticides Satisfaction Guarantee covers up to $1,500 in diagnosis and treatment costs; Zoetis' ProHeart Satisfaction Guarantee covers up to $1,000 plus adulticide acquisition cost.

Every one of these guarantees explicitly conditions eligibility on annual negative antigen testing consistent with AHS guidelines. The Boehringer Ingelheim program requires continuous purchase history and negative heartworm antigen testing per AHS guidelines with annual retesting. The Elanco program requires a negative heartworm antigen test at least six months after initiation, and a negative retest at least six months after restarting if doses were missed. The Zoetis ProHeart program requires two separate negative tests at least six months apart for new or switching dogs. In each case, an owner who signs a waiver and skips the annual test is forfeiting the manufacturer's financial guarantee — not violating a clinical requirement.

THE GUARANTEE REFRAME: FINANCIAL DECISION, NOT CLINICAL DECISION

When a veterinarian refuses a waiver and cites potential liability if the dog develops heartworm on their watch, the operative mechanism is often the manufacturer guarantee: without a negative test on file, the manufacturer will not cover treatment costs, increasing the owner's financial exposure and the practice's perceived liability. This is an insurance underwriting requirement — the manufacturer's warranty terms — dressed up as a clinical necessity. Properly understood, signing a waiver means the owner is waiving the manufacturer's financial guarantee, not bypassing a clinical safeguard. That is a financial decision that belongs to the owner, not a clinical decision that belongs to the veterinarian. The owner's right to make an informed financial decision about their own warranty coverage is not a matter of professional prescribing authority.

This reframe strengthens the autonomy argument materially. The mandate is not just enforcing a clinical standard of uncertain evidentiary basis — it is also enforcing the warranty eligibility terms of manufacturers who are, simultaneously, the financial sponsors of the organization setting the testing standard. The financial interest is triply aligned: the manufacturer sells the drug, sponsors the guideline that mandates the test, and conditions their warranty on the test being performed. The owner who declines the test is not putting their dog at greater clinical risk in any well-documented sense — they are opting out of the manufacturer's commercial warranty program. That distinction is never explained to them at the point of care. It should be.

Sources:

Boehringer Ingelheim. “THE HEARTGARD® Plus Satisfaction Guarantee” (4-page detailer, December 2022, still active in 2025–2026 clinic materials).

URL: https://docs.boehringer-ingelheim.com/HEARTGARD_Satisfaction_Guarantee.pdf

Elanco Animal Health. “2025 Canine Prescription Parasiticides Satisfaction Guarantee” (21-page edition).

URL: https://assets.elanco.com/0cec44ed-3eaa-0009-2029-666567e7e4de/7caeed84-c95d-441f-82a3-7893c453b952/2025%20Canine%20Prescription%20Parasiticides%20Satisfaction%20Guarantee.pdf

Zoetis. “ProHeart Satisfaction Guarantee” (2025 program guidelines).

URL: https://www.zoetisus.com/content/pages/Services-and-Programs/guarantee-programs/resources/documents/proheart-satisfaction-guarantee.pdf

Zoetis. “Simparica Trio and Simparica Satisfaction Guarantee.”

URL: https://www.zoetisus.com/content/_assets/docs/Petcare/Simparicatrio/Simparica-Trio-and-Simparica-Satisfaction-Guarantee.pdf

4. The Conflict of Interest: AHS Sponsorship Structure

The American Heartworm Society guidelines are the primary authoritative source for veterinary heartworm management protocols. The AHS is supported by industry sponsors whose commercial interests are directly affected by the testing and prescribing standards the AHS sets.

4.1 Sponsor Roster, IDEXX Revenue Structure, and Vertical Integration

Tier	Company	Commercial Interest in Guidelines
Platinum	Boehringer Ingelheim	Heartgard Plus (ivermectin/pyrantel ML preventive)
Platinum	Elanco	Trifexis, Interceptor Plus, Advantage Multi (ML preventives)
Platinum	Zoetis	Revolution, Simparica Trio, ProHeart (ML preventives)
Silver	IDEXX Laboratories	SNAP 4Dx Plus antigen test kits; reference lab confirmatory testing cascade
Silver	Merck Animal Health	Sentinel, Sentinel Spectrum, Bravecto (ML preventives)

The entities setting the testing standards include both the manufacturers of the preventive drugs being prescribed AND the manufacturer of the diagnostic tests required before those drugs can be dispensed. Mandatory testing increases IDEXX kit revenue directly. It also drives mandatory vet visits that reliably increase ML preventive sales — benefiting all four Platinum sponsors simultaneously.

Procurement data adds a further dimension to this picture. The IDEXX SNAP Heartworm RT test costs veterinary clinics approximately $9.92 per test at distributor pricing (Fisher Scientific, 30-pack at $297.71, March 2026). This is the kit cost only; the all-in variable cost per test at the clinic level — including vet tech time (typically 5–10 minutes), blood draw supplies, and consumables — is estimated at $20–$30. Owners are typically billed $35–$75 for a standalone in-clinic heartworm antigen test (Sulik K., DVM, PetMD, April 2025), with confirmed real-world pricing of $56 for a standalone test including draw and materials. At that billing level, the net margin after estimated variable costs is substantial — roughly $25–$35 per test — before clinic overhead recovery. The SNAP 4Dx Plus panel (which adds tick-borne disease testing) is billed at $43–$80+, generating higher per-transaction revenue. A competing product — the Bionote CHW Rapid Canine Heartworm Antigen Test — carries a published MSRP of $3.00–$3.30 per test wholesale, with published sensitivity of 99.5% and specificity of 94.0%. The IDEXX premium is not evidently explained by superior sensitivity performance on published metrics. When a positive SNAP result is submitted to IDEXX's reference laboratory, IDEXX's own protocol generates a confirmatory cascade — reference lab ELISA, microfilariae testing, possibly heat-treatment retest — each generating additional revenue. IDEXX is the Silver sponsor of the standard that mandates the initial annual test and the vendor of the follow-up tests a positive result produces.

IMPORTANT CAVEAT
This sponsorship structure does not prove that guidelines are corrupted. It establishes that an independent financial interest exists, that this interest is not disclosed in the guidelines themselves, and that the direction of guideline hardening over 2005–2014–2024 aligns with the commercial interests of sponsors. The standard for concern in professional guideline-setting is not proof of corruption — it is undisclosed financial interest in the direction of the standard.

4.1.1 The IDEXX Confirmatory Cascade: Vertical Integration and Revenue Structure

When an IDEXX in-clinic SNAP test returns a positive result, IDEXX's own recommended protocol includes a confirmatory cascade: retesting the antigen using a different platform or their reference laboratory ELISA, a microfilariae test (modified Knott or filtration) to confirm the result and rule out other filarial species, and in some cases heat treatment of the sample to dissociate antigen-antibody complexes before re-testing. IDEXX also offers complimentary confirmatory antigen testing at their reference laboratories when positive SNAP results are submitted through their programs — no additional charge to the practice for follow-up diagnostics when submitted through IDEXX channels.

These steps serve specific and legitimate purposes: verifying a true positive versus false positive, assessing worm burden indirectly through microfilariae counts, and guiding adulticide treatment decisions. However, none of these tests — not the SNAP, not the reference lab ELISA, not the microfilariae test, not the heat-treatment retest — determine ML resistance. Not one step in IDEXX's own recommended confirmatory protocol identifies whether the infecting strain is ML-susceptible or ML-resistant. That determination is not available through any commercially validated test for routine clinical use.

NO VALIDATED CLINICAL RESISTANCE TEST EXISTS
Research has explored genetic markers (SNPs in P-glycoprotein genes), microfilarial suppression tests (MFST — give an ML dose and check if microfilariae counts drop >90% after ~4 weeks), and other laboratory methods. None are standardized, commercially available, or recommended for routine clinical use. Resistance confirmation typically requires controlled experimental conditions, not routine diagnostics. Even in suspected breakthrough cases, most experts attribute apparent failures to compliance lapses rather than confirmed biological resistance. The resistance-detection justification for mandatory annual testing cannot be fulfilled by the test being mandated — or by any currently available commercial follow-up.

The structural implication is significant. IDEXX provides complimentary follow-up testing through its reference labs when positive SNAP results are submitted — effectively increasing the perceived value of every positive result to the practice at no additional lab cost. This creates a structural loop: IDEXX is the Silver sponsor of the AHS guidelines that mandate the initial annual test, the manufacturer of the test kit itself, and the vendor of the confirmatory cascade that a positive result triggers. The vendor of the diagnostic solution is also a primary sponsor of the body setting the standard that generates demand for that solution. This vertical integration — guideline sponsorship, kit manufacture, and downstream diagnostics under one commercial entity — is the precise arrangement that conflict-of-interest disclosure requirements in clinical guideline-setting are designed to make visible.

4.2 The FDA Origin: Surveillance, Not Patient Safety

The most significant documented finding in this investigation is the confirmed origin of the annual testing recommendation. Tom Nelson DVM — AHS Research Chair and past AHS president — confirmed in a March 2026 response to a research inquiry:

> **PRIMARY SOURCE: TOM NELSON DVM, AHS RESEARCH CHAIR (March 2026)**
> "The AHS first began to recommend annual testing in the '2005 Guidelines for the diagnosis, prevention and management of heartworm (Dirofilaria immitis) infections in dogs.' This was at the request of the FDA based on a paper presented at the 2004 AHS Triennial Symposium that was published in the Journal of Veterinary Parasitology Volume 133, Issues 2-3, October 2005."

The referenced paper (Hampshire, V.A., FDA/Center for Veterinary Medicine, 2005) reveals that the FDA's interest was post-market surveillance of product efficacy — specifically, improving the agency's ability to evaluate and score product ineffectiveness complaints and track resistance patterns. The paper contains no discussion of slow-kill, inadvertent treatment of infected dogs, or individual patient safety as a basis for the testing recommendation.

Additionally, the FDA's recommendation was explicitly geographically qualified: the paper states "at least in endemic regions." The FDA did not recommend a national blanket mandate. The current uniform national standard is an AHS amplification of what the FDA actually said, with the geographic limitation stripped.

4.2.1 FDA Label Analysis: What the Approved Labels Actually Require

A direct review of the current FDA-approved DailyMed labels for every major ML-based heartworm preventive sold in the United States resolves Open Question 4 definitively. The result is unambiguous: not one FDA-approved ML product label requires pre-administration testing at renewal. Every label that addresses testing at all restricts that language to initiation only.

Product	Active ML	Verbatim FDA Label Language on Testing	Applies to Renewals?
Heartgard Plus	Ivermectin	"All dogs should be tested for existing heartworm infection before starting treatment with HEARTGARD Plus..."	No — initiation only
Trifexis	Milbemycin oxime	"Prior to administration of TRIFEXIS, dogs should be tested for existing heartworm infection."	No — initiation only
Sentinel Spectrum	Milbemycin oxime	"Prior to administration of SENTINEL SPECTRUM Chews, dogs should be tested for existing heartworm infections. At the discretion of the veterinarian, infected dogs should be treated..."	No — initiation only

Product	Active ML	Verbatim FDA Label Language on Testing	Applies to Renewals?
Interceptor Plus	Milbemycin oxime	"Prior to administration of INTERCEPTOR PLUS, dogs should be tested for existing heartworm infections. At the discretion of the veterinarian, infected dogs should be treated..."	No — initiation only
Revolution	Selamectin	"Prior to administration of Revolution, dogs should be tested for existing heartworm infections. At the discretion of the veterinarian, infected dogs should be treated..."	No — initiation only
Simparica Trio	Moxidectin	"Prior to administration of SIMPARICA TRIO, dogs should be tested for existing heartworm infections. Infected dogs should be treated with an adulticide..." (Rev. Oct 2024)	No — initiation only
ProHeart 12	Moxidectin	"Prior to administration of ProHeart 12, dogs should be tested for existing heartworm infections. Infected dogs should be treated with an adulticide..."	No — initiation only
Advantage Multi	Moxidectin	No explicit testing language appears in the current FDA label (Precautions, Warnings, or Dosage sections).	No language at all

Several observations follow from this confirmed label record:

- Every label that mentions testing uses the phrases "prior to administration" or "before starting treatment" — language that unambiguously applies to initiation of a new course of prevention, not to renewal of an established prescription for a patient with a documented history of continuous use. Labels are carefully drafted regulatory documents; if annual renewal testing were required, that language would appear.
- Three labels (Sentinel Spectrum, Interceptor Plus, Revolution) include the qualifier "at the discretion of the veterinarian" when describing what to do with an infected dog at initiation. The FDA's own regulatory text treats the management decision as a clinical judgment call, not a mandate — even for the initiation scenario.
- Advantage Multi — containing moxidectin, the ML with the highest documented efficacy against resistant strains — carries no testing language of any kind in its current FDA label. If the FDA's regulatory determination were that pre-administration testing is a patient safety requirement for ML preventives, it would appear on this label. Its complete absence is notable.
- The mandatory annual renewal testing requirement enforced by many U.S. veterinary practices has no regulatory basis in the FDA-approved labels of the drugs being gated. It is a professional guild standard — enforced through AHS guidelines, liability culture, and insurer risk calculus — that exceeds what the federal regulatory floor requires.

NO FDA LABEL REQUIRES ANNUAL RENEWAL TESTING

A review of current DailyMed FDA labels for Heartgard Plus, Trifexis, Sentinel Spectrum, Interceptor Plus, Revolution, Simparica Trio, ProHeart 12, and Advantage Multi confirms: not one requires pre-administration testing at prescription renewal. All testing language is limited to initiation. Advantage Multi contains no testing language at all. The mandatory annual testing requirement enforced as a condition of prescription renewal has no basis in the federal regulatory labels governing these drugs.

4.3 AHS on Withholding Treatment: An Important Contextual Note

The 2024 AHS Canine Heartworm Guidelines contain the following statement on page 20, under the Principles of Heartworm Treatment (full PDF: d3ft8sckhnqim2.cloudfront.net/images/AHS_Canine_Guidelinesweb04APR2024.pdf):

2024 AHS GUIDELINES — TREATMENT SECTION (p. 20)

"treating in the absence of diagnostics, while not ideal, is better than refusing to perform a needed treatment"

This statement appears specifically in the context of adulticide treatment for dogs already known or suspected to be heartworm-positive when full pre-treatment diagnostics cannot be completed. It is not a statement about prescribing ML preventives without prior testing, and should not be cited as a direct contradiction of the preventive testing requirement.

The underlying principle, however, carries genuine analogical force. The AHS explicitly acknowledges in the adulticide context that withholding a needed treatment pending ideal diagnostic completion causes harm that outweighs the diagnostic benefit. A parallel harm analysis applies to preventive renewal: a dog left unprotected during the period between prescription expiration and mandatory test completion faces a real infection window that the testing requirement itself creates. The AHS's own hierarchy of harm — treatment withheld is worse than treatment given without a perfect diagnostic picture — points in the same direction when applied by analogy to preventive gatekeeping. The argument is analogical and should be understood as such, but it draws on a principle the AHS itself has articulated.

4.4 The 2014 Microfilariae Addition: An Implicit Admission

The 2014 AHS guidelines added microfilariae testing to the annual recommendation specifically because of antigen-antibody complex false negative issues — an implicit acknowledgment that single-antigen-test reliability was insufficient. Two consequences:

- Many veterinary practices mandate only the SNAP antigen panel without routinely performing a separate microfilariae test. If the AHS determined in 2014 that antigen testing alone was inadequate, practices relying solely on antigen results are applying a standard the AHS itself found insufficient.
- The ML-induced suppression issue affects both test components simultaneously. A dog actively receiving MLs may have suppressed antigenemia AND suppressed microfilaremia.

Both components of the recommended dual test are degraded by the same ongoing prevention that defines the target scenario.

4.5 The Economic Alignment of Clinical Guidelines

The widespread adoption of mandatory testing — even in the absence of a specific clinical indication for a compliant patient — reflects a systemic alignment between clinical recommendations and practice economics. Because AHS guidelines standardize the annual test, and because those guidelines are produced by an organization heavily sponsored by diagnostic manufacturers, it is natural for practitioners to adopt these turnkey recommendations without independent scrutiny of the underlying evidence base.

The economic alignment extends to the clinic level in a specific and observable way. Modern veterinary practice management systems routinely send automated appointment reminders, promotional communications, and health alerts. The infrastructure to send monthly dosing reminders via SMS or email exists in virtually every practice in the United States and costs nothing beyond what is already deployed for marketing purposes. Yet systematic dosing reminders are rarely offered. When a clinic mandates a diagnostic test to verify whether compliance failures occurred, while bypassing simple, free digital tools that would facilitate compliance in the first place, the pattern suggests optimization for the most profitable intervention rather than the most collaborative one.

THE INFRASTRUCTURE DISCONNECT

The same clinic that declines to send monthly $0-cost dosing reminders will charge $56 for an annual antigen test to verify whether compliance lapses occurred. Both actions address the same underlying concern — owner compliance — but one generates revenue and the other does not. The industry has correctly identified compliance as the dominant driver of positive tests. It has not invested proportionately in enabling compliance. The diagnostic mandate fills the gap through a revenue-generating mechanism; the reminder system would fill it collaboratively.

5. The Geography of Resistance: What the Evidence Supports

The ML resistance concern is real and confirmed in published literature. This section does not dispute the underlying science. It examines whether the geographic distribution of confirmed resistance supports the current national uniform testing mandate.

5.1 Where Resistance Is Confirmed

ML resistance in Dirofilaria immitis is a documented phenomenon and a genuine veterinary concern. This section does not dispute the underlying science — it provides the most current available picture of resistance distribution and qualifies how that picture should inform policy.

ML-resistant Dirofilaria immitis isolates are confirmed primarily in the Lower Mississippi River Valley (LMRV): Louisiana, Mississippi, Arkansas, Tennessee, Missouri (particularly southeast Missouri), and parts of Alabama, Texas, and Illinois. Recent genomic surveillance provides the most precise current picture:

- In southeast Missouri — the northern region of the Mississippi Delta — a 2024 study analyzing 96 microfilariae samples from antigen- and microfilariae-positive dogs found that 91 samples (94.8%) carried genotypes consistent with ML resistance, 4 (4.2%) were mixed, and only 1 (1%) was fully susceptible. The authors described this area as an 'ideal propagation region' for both heartworm infection and potential spread of resistance.
- A broader 2021–2023 surveillance study of 310 microfilariae samples from client-owned dogs across the United States found approximately 31% genotypically resistant, 33% mixed resistant/susceptible, and 36% susceptible. Resistant and mixed genotypes occurred both within and outside the classic LMRV, with detections as far north as Michigan — likely facilitated by dog translocation.

These data confirm that ML resistance is established and at high prevalence in focal LMRV hotspots, and that resistant genotypes have spread to some degree beyond the traditional epicenter. Several important qualifiers apply when evaluating policy responses:

- Resistance is larval-stage specific: Adulticide therapy with melarsomine remains fully effective against both susceptible and resistant adult worms. A positive antigen test, even in a resistant-strain area, does not change the core treatment protocol.
- ML products are not equally affected: Moxidectin (Advantage Multi, ProHeart, Simparica Trio, Credelio Quattro) consistently demonstrates 95–100% efficacy against confirmed resistant isolates in laboratory studies, compared to 10–64% for ivermectin and milbemycin oxime. The choice of preventive product in high-resistance areas is therefore more clinically meaningful than the mandatory test for infection.
- Non-compliance remains the dominant driver nationally: Large-scale analyses, including CAPC data from millions of annual tests, consistently show that positivity rates are lowest in

dogs with documented continuous prevention and rise sharply with compliance gaps. This compliance gradient — confirmed across multiple data sets — points toward adherence as the dominant lever for reducing heartworm incidence, not mandatory testing (CAPC 2024/2025 Pet Parasite Forecasts).

- Indoor/low-exposure pets: Mostly indoor domestic dogs with consistent prevention history contribute far less to the transmission cycle than untreated wildlife reservoirs (coyotes, foxes) or stray/feral dogs. Even in high-resistance zones, the incremental reservoir risk from a single compliant indoor pet at renewal is modest.

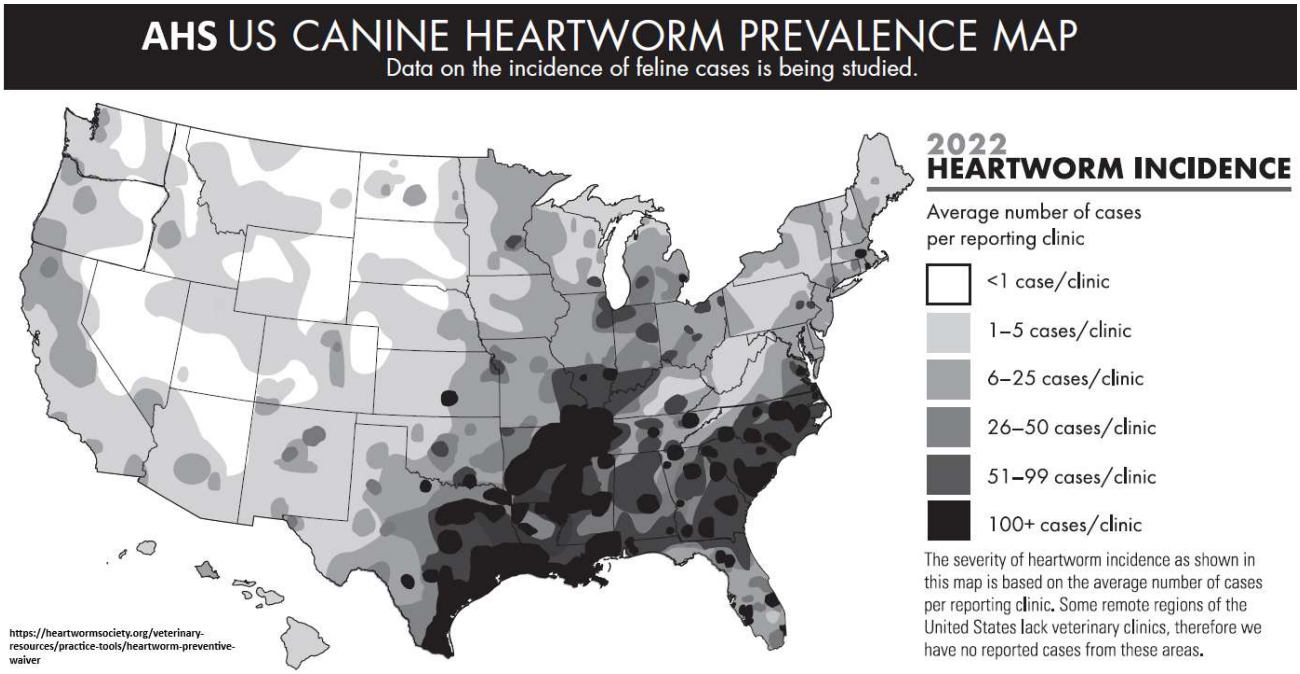
The AHS itself acknowledges that 'the full geographic spread of resistant heartworms is not known.' This uncertainty has sometimes been used to justify uniform national testing mandates. The evidence supports a more proportionate approach: stronger, individualized testing recommendations in confirmed high-resistance LMRV hotspots — where local veterinarians can cite specific case experience — paired with risk-stratified counseling elsewhere.

5.2 The AHS Prevalence Map: A Methodological Problem with Policy Consequences

The AHS Heartworm Preventive Waiver document — the same waiver the AHS publishes for practice use — includes a US Canine Heartworm Prevalence Map that is frequently cited in clinical settings as justification for uniform national testing requirements. The map's own legend discloses its methodology: it measures the average number of cases per reporting clinic, not a normalized infection rate. This distinction has significant consequences for how the map should and should not be used.

THE METRIC THAT DRIVES THE MAP

"The severity of heartworm incidence as shown in this map is based on the average number of cases per reporting clinic." — AHS Heartworm Preventive Waiver, 2022 Incidence Map legend. The map does not measure positivity rate (positives ÷ total tests), prevalence per dog population, or transmission risk. It measures how many positive cases a clinic reports — a figure that is driven as much by clinic volume as by local infection rates.



AHS 2022 Heartworm Incidence Map — measures average cases per reporting clinic. Darker shading reflects higher clinic case volume, not higher per-dog infection probability.

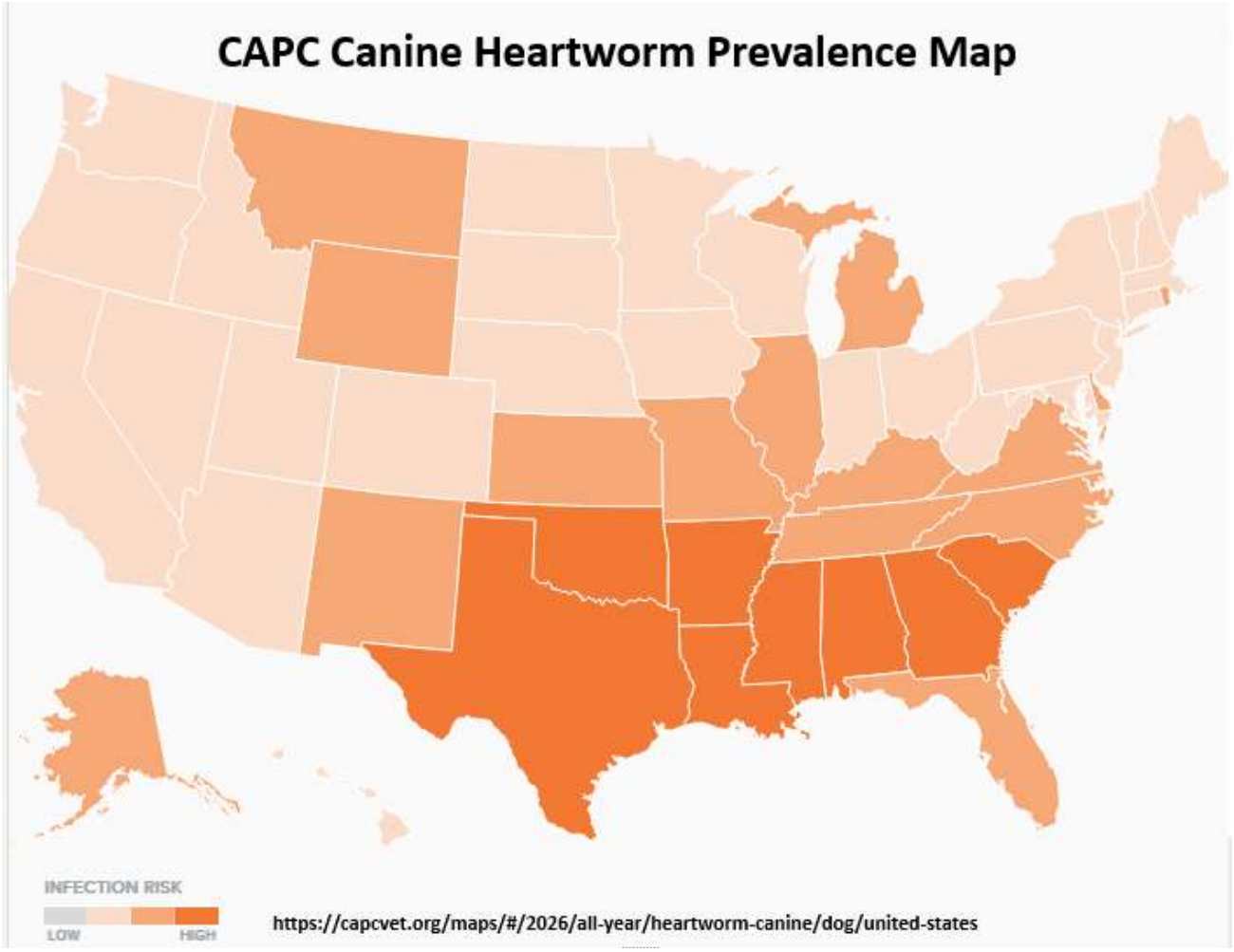
The methodological problem is structural. High-volume urban and suburban practices — corporate multi-doctor hospitals, high-throughput clinics — test far more dogs per year than small rural solo practices. They naturally accumulate higher absolute case counts regardless of local infection rates. This inflates the cases-per-clinic metric in urban areas and suppresses it in rural areas, even where rural per-dog infection rates may be meaningfully higher. The result is a map that amplifies the visual signal from high-volume urban clinics and may systematically under-represent genuine rural and semi-rural hotspots.

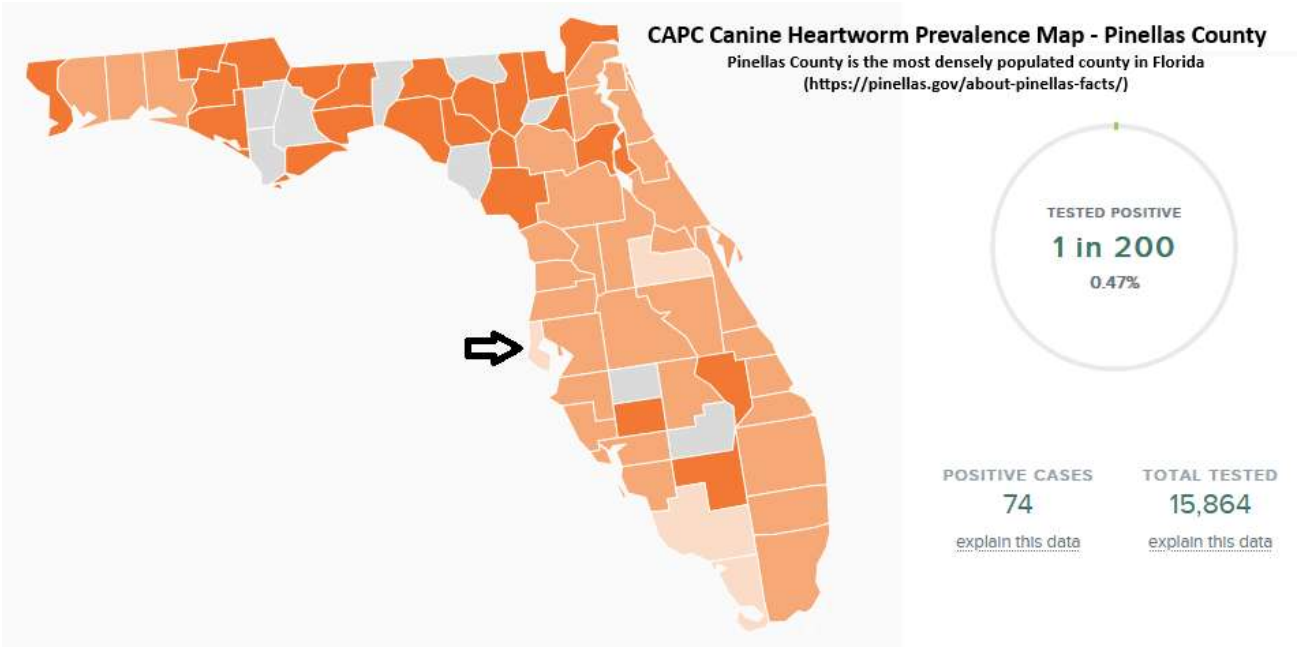
The AHS acknowledges that the map is based on voluntary reporting from thousands of practices and shelters, and that some remote regions lack veterinary clinics and therefore show no reported cases. The AHS does not adjust the map for clinic volume, testing effort, or dog population density. CAPC prevalence maps, which use positivity rates derived from laboratory data (positives ÷ total tests submitted), provide a better-normalized view of actual infection burden and often reveal materially different geographic patterns than the AHS clinic-average approach.

A specific and illustrative example: the Greater Tampa Bay area operates well-funded, organized municipal mosquito control programs that meaningfully reduce local mosquito populations and transmission pressure. Well-managed urban mosquito abatement can lower actual heartworm risk in dense suburban areas below what the AHS map's clinic-volume signal would suggest. Meanwhile, rural and semi-rural areas with natural wetlands, fewer organized control programs, and higher densities of reservoir hosts (feral dogs, coyotes, foxes) may carry genuinely elevated transmission risk that the cases-per-clinic metric understates because those areas have fewer or smaller reporting clinics.

CAPC Canine Heartworm Prevalence Map — measures positive tests as a percentage of total tests submitted. Normalized by testing volume. Positivity rates (positives ÷ total tests submitted), provide

a more normalized view of actual infection burden and reveal materially different geographic patterns than the AHS clinic-volume approach.





CAPC Pinellas County detail — 74 positive cases out of 15,864 tested (0.47%). Florida's most densely populated county, with active municipal mosquito control.

POLICY CONSEQUENCE
The AHS map is used — including in the AHS's own waiver document distributed to practices — to visually communicate national heartworm risk in a way that implicitly supports uniform national testing requirements. But the map's methodology does not support the geographic claims it is invoked to make. A metric that measures clinic reporting volume, not per-dog infection probability, cannot be used to establish that any given patient faces elevated risk. Using a volume-biased map to justify a uniform national testing mandate imposes the highest-risk-zone standard on low-risk patients based on a measurement artifact, not a clinical reality.

5.3 What the Evidence Does Not Support

- National uniformity: Confirmed resistance remains concentrated in the LMRV. The AHS's own statement is that the full geographic spread of resistant heartworms "is not known." Geographic uncertainty is being used to justify a national blanket mandate rather than a regionally differentiated standard.
- Non-compliance as the dominant cause is well-established: synthesized literature explicitly states that non-compliance with preventives remains the far more common cause of apparent lack-of-efficacy (LOE) cases overall. A testing mandate that applies nationally regardless of compliance history conflates the dominant cause (non-compliance, detectable through history) with the minority cause (resistance, detectable through testing).
- The slow-kill rationale does not apply to resistant strains: Against a resistant strain, the ML has no meaningful effect on the worm. There is no slow-kill because nothing is being killed. The primary justification for testing in the resistant strain context must therefore shift to early detection — a different, geographically limited benefit with its own structural detection gap.

5.4 The UK/Europe Real-World Control Group

In the United Kingdom and most of continental Europe, heartworm prevalence is low outside travel-endemic areas. Routine antigen testing is not mandatory before dispensing ML preventives. Clinical outcomes in these low-prevalence populations validate the proportionality argument: in low-risk geographies, the absence of mandatory pre-prescription testing does not produce systematic harm, because the baseline probability of undetected infection is small enough that the benefit of mandatory gatekeeping does not justify the cost.

CAPC and AHS acknowledge this risk gradient implicitly when they recommend twice-yearly testing in high-risk areas. If the risk level justifies different testing frequency in high-risk vs. lower-risk areas, the underlying principle of geographic proportionality is already accepted within the professional standard — it simply has not been applied to the waiver question.

5.5 The Mediterranean Comparison: Endemic Countries Without Mandatory Pre-Prescription Testing

The standard counterargument to the UK/Europe comparison is climate: the UK and northern Europe are cooler, have lower mosquito pressure, and are not meaningfully comparable to the warm, humid climate of the U.S. Gulf Coast and Southeast. This is a fair objection to the UK comparison. It does not survive extension to the Mediterranean.

Spain and Portugal are historically endemic for heartworm. Published peer-reviewed literature confirms Dirofilaria immitis as endemic across the Iberian Peninsula, with year-round transmission risk on southern coasts and islands, peak transmission in spring and summer, and documented prevalence rates in dogs reaching 8–9% in some central Portuguese districts among unprotected animals. The Canary Islands — Spanish territory off the northwest African coast — recorded canine prevalence as high as 67% in the 1990s before preventive programs reduced it substantially. These are not low-prevalence cool-climate populations. The climate of southern Spain and Portugal — warm Mediterranean summers, mild winters, active mosquito season extending well beyond the U.S. heartworm belt's shoulder months — is a reasonable climatic comparator to Florida and the U.S. Southeast.

THE ESCCAP STANDARD: RISK-STRATIFIED, NOT MANDATED

The European Scientific Counsel Companion Animal Parasites (ESCCAP) is the professional guideline body for companion animal parasite management across 19 European countries — the functional equivalent of the AHS/CAPC for Europe. ESCCAP guidelines for heartworm-endemic regions do not mandate pre-prescription antigen testing as a universal gatekeeping requirement. Instead, ESCCAP guidelines direct veterinarians to assess individual animal risk and prescribe accordingly — a risk-stratified, clinician-judgment model rather than a blanket mandate. The professional body governing parasite prevention in countries with genuine, year-round, historically documented heartworm endemicity operates without the mandatory testing requirement that U.S. practices enforce.

ESCCAP's approach to heartworm in endemic regions reflects the proportionality principle this paper argues is missing from the U.S. standard: prevention decisions should be based on individual risk assessment — the dog's geography, lifestyle, compliance history, and clinical presentation — not on a universal gatekeeping rule applied regardless of individual circumstances. Where testing is recommended in the ESCCAP framework, it is framed as clinically indicated for specific presentations, particularly for dogs traveling from or to endemic areas or for newly presenting patients with unknown prevention history. It is not framed as a precondition for prescribing to an established, compliant patient.

One additional data point from the European regulatory environment is instructive. Spain's Royal Decree 666/2023, enacted January 2025 under EU Regulation 2019/6, imposed significant new prescribing restrictions on Spanish veterinarians — generating national protests, Senate resolutions, and ongoing political controversy. The contested restrictions center on antimicrobial drug dispensing and pharmacy access requirements. Notably absent from this controversy, and from the EU regulatory framework itself, is any requirement for pre-prescription diagnostic testing as a condition of dispensing ML heartworm preventives. Even the most restrictive current interpretation of EU veterinary medicines law, actively contested by Spanish veterinarians as overreaching, does not include the mandatory testing gatekeeping that has become standard practice across U.S. veterinary clinics.

The U.S. mandatory annual testing requirement is therefore not a convergent global standard driven by clinical evidence — it is an outlier. The professional body governing veterinary parasite prevention across genuinely heartworm-endemic Mediterranean countries does not require it. The most restrictive current EU regulatory framework does not require it. It exists in the United States, in its current mandatory form, because the AHS — an organization financially sponsored by the manufacturers of the test and the drugs the test gates — hardened its guidelines at the request of the FDA for surveillance purposes, then extended those guidelines into a universal clinical mandate from which the original geographic and purpose limitations were stripped.

5.6 What a Proportionate Policy Looks Like

Not all dogs are the same. A hunting dog living full-time in an outdoor kennel in a rural wetland area near the Mississippi Delta faces materially different exposure than a small-breed dog that spends nearly all its time on a dog bed indoors. One has near-constant mosquito exposure and lives in a confirmed high-resistance zone; the other has brief, controlled outdoor access in a lower-risk geography. Treating these two animals identically — applying the same mandatory annual testing precondition to both — ignores the biological reality of differential exposure and violates the individualized clinical assessment that responsible medicine requires in every other context.

The position that follows from the clinical, legal, and structural arguments in this paper is not that testing should be discouraged — it is that no mandatory pre-prescription testing requirement is justifiable anywhere, for any patient, because the delegated prescribing authority does not extend to that mandatory enforcement function regardless of geography. The appropriate mechanism in all settings is informed owner consent, with the strength of the veterinarian's clinical recommendation calibrated to the individual patient's risk profile.

This distinction matters. In confirmed high-resistance areas of the Lower Mississippi River Valley, rational owners who are accurately informed of local resistant-strain prevalence and the specific clinical consequences will elect to test in large numbers — not because a mandate compels them, but because the information warrants it. A veterinarian practicing in southeast Missouri or Louisiana who has seen resistant heartworm cases in their own practice, or is aware of confirmed cases among nearby colleagues, is in a position to convey that clinical reality with specificity and credibility. That conversation, with a fully informed owner who then makes their own decision, is what the waiver framework was designed to enable. It is not a gap in protection — it is the correct allocation of decision-making authority.

THE CORE POSITION

No mandatory pre-prescription heartworm testing is justified for any patient, in any geography, under the current delegated prescribing authority framework. The veterinarian's role is to inform fully, recommend based on individual risk, document that recommendation, and respect the owner's decision. In high-resistance areas, the clinical information itself — conveyed by a vet with direct local knowledge — will produce rational testing behavior in informed owners without mandatory gatekeeping. Where owners decline despite strong clinical recommendation, the signed informed-consent waiver documents that decision and protects the veterinarian.

- Restore the signed informed-consent waiver as a universally recognized option, for all patients in all geographies, with the veterinarian's specific recommendation documented and the owner's informed decision recorded.
- Calibrate the strength of the testing recommendation to individual risk: new patients with unknown history, dogs with documented lapses, dogs in or returning from confirmed high-resistance zones, and dogs showing clinical signs all warrant stronger and more specific recommendations than an established compliant patient in a low-resistance area.
- Distinguish new patients from renewal patients: a dog presenting for the first time with no documented prevention history has a genuinely unknown baseline status and a clinical indication for testing that an established five-year compliant patient does not share. Policy should reflect this distinction rather than treating both identically.
- Require AHS to disclose sponsor relationships in guideline documents, consistent with conflict-of-interest standards applied to clinical guidelines in human medicine, so that practitioners and owners evaluating the guidelines can assess the independence of the recommendations.
- Replace the AHS cases-per-clinic prevalence map with or alongside CAPC positivity-rate data in any practice-facing materials used to characterize local risk, so that risk communication to owners is based on normalized infection probability rather than clinic reporting volume.

5.6.1 Practical Risk Assessment: Moving from Uniform Policy to Individualized Recommendations

Recognizing that not all dogs are the same allows veterinarians to move beyond one-size-fits-all mandates toward more meaningful, credible conversations with owners. Rather than requiring the same testing protocol for every patient regardless of circumstances, veterinarians could gather a few key pieces of information — without conditioning any prescription on test results — to inform the strength and specificity of their prevention and testing recommendations. This is what individualized clinical assessment looks like in practice, and it takes only a few minutes per visit.

Patient history and compliance profile: Long-term established patients with consistent preventive dispensing carry a materially different risk profile than new patients with unknown prior history. A practice's own dispensing records document refill patterns, any gaps in coverage, prior test results, and clinical signs — data that is already on hand and more directly relevant to infection probability than any single antigen test.

Lifestyle and actual mosquito exposure: A few practical questions — Is this dog primarily indoor or does it have regular outdoor access? Through a doggy door, fenced yard, daily walks, outdoor runs? How many hours per day outside? Any proximity to standing water, wetlands, or wooded areas? Recent travel to or from high-risk regions? — transform the clinical conversation from uniform protocol to individualized assessment. These questions are rarely asked in many practices today. A dog with a doggy door and daily wetland walks is not the same patient as a dog walked briefly on a leash twice a day in a suburban neighborhood with active municipal mosquito control.

Geographic and local context: CAPC positivity-rate maps (positives ÷ total tests, derived from laboratory data) provide a more normalized view of local infection burden than the AHS volume-biased cases-per-clinic map. In confirmed high-resistance LMRV areas, a veterinarian with direct experience of resistant-strain cases in their practice can provide a specific, credible recommendation that most informed owners will follow voluntarily.

WHAT THIS LOOKS LIKE IN PRACTICE

For a low-risk established patient — consistent documented compliance, primarily indoor lifestyle, lower-resistance geography: the veterinarian recommends continued prevention, notes that annual testing is an option for added reassurance, documents the recommendation, and issues the prescription with or without a signed waiver based on the owner's informed choice. For a higher-risk patient — new or unknown history, documented lapses, frequent outdoor access, high-resistance locale, or clinical signs: the veterinarian explains in specific terms why testing may provide greater value in that individual case, while still respecting a fully informed owner's decision after discussion and documentation. The European ESCCAP model demonstrates that this risk-informed, recommendation-based approach works effectively in genuinely heartworm-endemic regions without imposing universal pre-prescription testing requirements.

6. Key Open Questions for Further Investigation

This paper documents what is established. The following questions represent the open investigative threads that would substantially strengthen any advocacy, regulatory, or legal effort:

1. GUIDELINE AUTHORITY: Are AHS guidelines formally incorporated into state veterinary practice acts, or are they advisory? To what extent is the mandatory-testing position a legal requirement vs. a professional norm enforced through liability culture?

2. LIABILITY DRIVER: Is the shift from waiver-acceptable to waiver-refused driven by AHS guidelines, or by changes in professional liability insurance terms? Insurers may have changed coverage conditions independently of clinical guidance.

3. FDA CURRENT POSITION: The Hampshire (2005) paper represents the FDA's documented position at that date. Has the FDA/CVM issued any subsequent guidance or regulatory statements that mandate pre-prescription testing or prohibit waivers? If not, the regulatory floor has not changed.

4. LABEL LANGUAGE — CONFIRMED: A direct review of current FDA DailyMed labels for all major ML preventives (Heartgard Plus, Trifexis, Sentinel Spectrum, Interceptor Plus, Revolution, Simparica Trio, ProHeart 12, Advantage Multi) confirms that no label requires pre-administration testing at prescription renewal. Every label that addresses testing restricts that language to initiation — "prior to administration" or "before starting treatment." Advantage Multi contains no testing language at all. The mandatory annual renewal testing requirement enforced at many practices has no basis in the federal regulatory labels of the drugs being gated. The complete label analysis appears in Section 4.2.1.

5. WAIVER LEGALITY BY STATE: Is there any state in which a signed informed-consent waiver remains legally and professionally acceptable? If so, what is the basis for practices in other states refusing waivers that remain valid elsewhere?

6. AHS BOARD COMPOSITION: What is the full composition of the AHS Board of Directors, and what relationships exist between board members and AHS sponsor organizations? The Guidelines Committee composition has been confirmed (three parasitologists, a cardiologist, an entomologist, one clinician); the Board approval process and its relationship to industry sponsorship is an open question.

7. GUIDELINE EVOLUTION AND TESTING YIELD: An independent review should systematically examine the evidence base cited in the 2005, 2014, and 2024 AHS guideline editions against contemporaneous real-world data on testing outcomes. The 2005 recommendation originated as a surveillance request; subsequent editions retained and reinforced it without documented changes in heartworm biology, ML pharmacology, or resistance epidemiology that would independently justify the hardening. CAPC data from millions of annual tests consistently show that positivity rates are lowest in dogs with

documented continuous prevention and rise sharply with compliance gaps — a pattern pointing toward compliance as the dominant lever, not mandatory testing (CAPC 2024/2025 Pet Parasite Forecasts). No stratified analysis of testing yield specifically in fully compliant, asymptomatic, established renewal patients appears to have been published or commissioned by the AHS. Such an analysis, conducted by a neutral body such as a state veterinary board or academic consortium, would provide a stronger evidentiary foundation for the proportionate policy this paper recommends.

8. INSURER UNDERWRITING CRITERIA: Do professional liability insurers (AVMA PLIT and others) explicitly require AHS guideline compliance as a condition of coverage, or does the risk calculus shift informally based on expert testimony patterns in malpractice claims? If insurers are driving waiver refusal through underwriting rather than through explicit policy requirements, this represents an indirect standard-setting function without formal regulatory authority or independent evidence review.

7. Conclusion and Recommended Actions

The mandatory annual heartworm antigen testing requirement, as currently enforced at many U.S. veterinary practices, rests on three compounding failures:

- A clinical rationale that does not hold at renewal. The slow-kill scenario the test is designed to prevent was already underway or not occurring under the prior prescription. The test is least reliable in exactly the population and scenario it targets. CAPC data consistently show positivity rates are lowest in dogs with documented continuous prevention. No mandatory pre-prescription testing is clinically justified for any established compliant patient regardless of geography.
- An autonomy framework that has been eliminated without legal or clinical justification. The signed informed-consent waiver was the correct professional mechanism for shared decision-making and was published by the AHS itself. Its elimination transfers decision-making authority from the legally responsible party to the prescribing practice. Veterinary prescribing authority does not extend to overriding an owner's informed refusal, and it was never delegated for the purpose of compelling participation in population surveillance.
- A guideline-setting process with undisclosed financial conflicts, a misrepresented origin, and no federal regulatory basis. The primary professional standard-setter is materially sponsored by the manufacturers of both the drugs being prescribed and the test required to prescribe them. The origin of the annual testing recommendation is confirmed FDA surveillance — not patient safety. The geographic limitation of that original recommendation was silently removed when AHS translated it into a national standard. A direct review of current FDA-approved labels for every major ML preventive confirms that no label requires pre-administration testing at renewal — the mandate is a professional guild standard with no basis in the regulatory labels governing these drugs. No equivalent mandatory standard exists in the professional guidelines of any other country, including genuinely heartworm-endemic Mediterranean nations.
- Withholding proven prevention while demanding an unindicated risk-adjusted test, for the compliant low-risk patients, directly violates the veterinary oath's core principle of "first, do no harm." This is especially perverse and counterintuitive in high-risk regions like the Southeastern United States. There, ideal conditions for near year-round mosquito transmission mean that even a brief gap in protection risks infection—precisely the outcome that reliable monthly preventatives would prevent. Yet the added costs of testing and office visits for otherwise healthy animals creates a de facto paywall that makes consistent prevention less likely to be sustained—disproportionately burdening low-income pet owners and increasing overall risk precisely where it is already highest.

7.1 Recommended Actions for Veterinary Organizations

- Restore the signed informed-consent waiver as a universally recognized option for all patients. The AHS's own published waiver template confirms this is professionally permissible. Waiver refusal is a practice-level policy choice, not a legal requirement.

- Seek formal guidance from state veterinary boards clarifying that use of the AHS Preventive Waiver — when properly completed and filed with patient records — satisfies the standard of care for informed consent documentation. This would provide practitioners with the liability protection they currently seek through waiver refusal, without eliminating owner choice.
- Adopt a recommendation-based rather than mandate-based approach to heartworm testing in all settings. Calibrate the strength of the clinical recommendation to individual patient risk — geography, compliance history, clinical presentation, local resistance data — and document the recommendation and the owner's decision. This is what the VCPR and the waiver framework were designed to enable.
- Require disclosure of AHS sponsor relationships in guideline documents, consistent with conflict-of-interest standards applied to clinical guidelines in human medicine, so that practitioners evaluating the guidelines can assess the independence of the recommendations.
- Commission an independent review of the 2005–2014–2024 guideline evolution to assess whether the progressive hardening of testing language tracks clinical evidence or commercial sponsorship patterns.

7.2 Recommended Actions for Consumer Advocacy Organizations

- Document and publicize the elimination of the waiver option as a specific, dateable policy shift and advocate for its universal restoration. The AHS itself publishes the waiver form — the argument that professional standards prohibit its use is not supported by the AHS's own published practice.
- Educate owners on the manufacturer guarantee structure: the annual testing requirement at many practices is driven in part by manufacturer warranty eligibility terms (Boehringer Ingelheim, Elanco, Zoetis all condition their satisfaction guarantees on AHS-aligned annual testing). Owners who sign a waiver are waiving the manufacturer's financial guarantee, not bypassing a clinical safeguard. This distinction is not disclosed at the point of care and should be.
- Advocate for state veterinary board guidance clarifying that signed informed-consent waivers are legally permissible in all settings and provide adequate liability protection, and that mandatory testing as a precondition for any prescription is not required by state law or the VCPR framework.
- Support OTC reclassification efforts for ML heartworm preventives, removing the prescription gateway entirely and returning the prevention decision to owners without any gatekeeping requirement.

7.3 Recommended Actions for Policy Organizations

- Confirm and publicize the FDA label finding: current DailyMed labels for all major ML preventives limit any testing language to initiation only — no label requires annual renewal testing. FDA/CVM should be asked to clarify on the record whether any regulatory requirement for annual renewal testing exists, and whether any subsequent guidance has

been issued since the 2005 Hampshire paper. The answer appears to be no on both counts, but a formal FDA clarification would close the question permanently.

- Examine whether state veterinary practice acts have been interpreted to incorporate AHS guidelines as mandatory clinical standards, and whether that interpretation is consistent with the advisory intent of professional guidelines and the AHS's own parallel publication of a waiver form.
- Examine whether professional liability insurer policies are the operative driver of waiver refusal rather than state law or professional standards, and whether that represents an appropriate exercise of private authority to define the scope of informed consent in a licensed profession.

This paper document was prepared for outreach to veterinary, consumer advocacy, and policy organizations. It is intended as a research foundation for advocacy and further investigation, not as legal or medical advice.

Primary sources on file include: 2005, 2014, and 2024 AHS Canine Heartworm Guidelines (2024 PDF: d3ft8sckhnqim2.cloudfront.net/images/AHS_Canine_Guidelinesweb04APR2024.pdf); Hampshire (2005) FDA/CVM efficacy evaluation paper (J. Vet. Parasitology 133:191–195); direct correspondence with Tom Nelson DVM, AHS Research Chair, March 2026; CAPC 2024/2025 Pet Parasite Forecasts (capcvet.org/articles/2025-annual-pet-parasite-forecasts/); AHS Heartworm Preventive Waiver (© 2020 American Heartworm Society; heartwormsociety.org/images/pdf/AHS-HW-Preventive-Waiver.pdf).

For further information or to discuss the findings of this paper, please contact:
Matt Horvath
contact@heartwormchoice.org