SKIN

IN-DEPTH REVIEW

Bringing Dermatology to the Frontline: Opportunities for DermTech in Primary Care Settings

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ABSTRACT

Background: Melanoma accounts for a small fraction of skin cancer diagnoses in the United States yet is responsible for the most skin cancer-related mortality, highlighting the importance of early, accurate detection. Primary care physicians (PCPs) are first to evaluate suspicious pigmented lesions, but diagnostic accuracy is limited by time constraints, variable dermatologic training, and inconsistent access to dermoscopy, particularly in rural and underserved settings.
Objective: This narrative review examines the evidence supporting DermTech's Pigmented Lesion Assay (PLA), a non-invasive adhesive patch that analyzes genomic markers associated with melanoma and evaluates its potential role in augmenting early skin cancer detection within primary care.
Findings: The PLA demonstrates high sensitivity, moderate specificity, and a negative predictive value exceeding 99%, enabling reliable exclusion of melanoma in clinically equivocal lesions. Clinical studies and registry data show that negative PLA results correlate with a very low likelihood of melanoma and reduced unnecessary biopsies and referrals. Integrating PLA into primary care may enhance triage accuracy, decrease specialty wait times, and expand access to molecular diagnostics in resource-limited settings.
Challenges: Implementation requires standardized training, workflow integration, and more consistent reimbursement. Additional validation in primary care populations is needed to assess real-world accuracy, cost-effectiveness
Conclusions: DermTech's PLA offers a promising adjunct to traditional lesion assessment in primary care by providing a painless, accessible method to rule out melanoma. With further research and implementation support, this technology may improve early detection, streamline referrals, and advance equitable skin cancer care.

INTRODUCTION

Skin cancer remains one of the most common malignancies in the United States, and early detection continues to be essential for reducing disease burden despite longstanding public education efforts and advances in diagnostic technology. Although melanoma accounts for only about one

percent of skin cancer diagnoses, it is responsible for more than 80% of skin cancer–related deaths, underscoring the importance of accurate recognition and timely intervention.[1,2]

Primary care physicians (PCPs) play a central role in this effort, as they are often the first clinicians to evaluate skin lesions during routine or problem-focused visits.[3] Their assessment typically relies on visual examination, patient and family history, and, when available, dermoscopy. Heuristics such as the ABCDE mnemonic, which stands for Asymmetry, Border irregularity, Color variation, Diameter, and Evolving, and the "ugly duckling" sign, a pattern-recognition approach in which a lesion stands out as looking noticeably different from a patient's other nevi, can aid early melanoma recognition, but their accuracy varies with clinician experience, subjective interpretation, and competing clinical priorities.[4,5] Challenges are magnified in underserved and rural communities, where dermatologist shortages and restricted access to specialty care delay diagnosis and worsen melanoma outcomes.[6,7] For example, rural Michigan patients faced significantly higher melanoma-specific mortality compared to those in urban counties, with a nearly 50% increased risk of death (odds ratio = 1.491, 95% CI 1.27-1.74).[8]

Given these constraints, there is a growing need for diagnostic tools that can support PCPs in the early detection and risk stratification of suspicious skin lesions. DermTech's Pigmented Lesion Assay (PLA), a non-invasive adhesive patch that enables molecular analysis of genomic markers associated with melanoma, represents one such innovation.[9] By providing an accessible, painless method to help rule out malignancy in equivocal lesions, the PLA may offer a valuable complement to traditional visual examination in primary care settings. This review summarizes the current evidence on DermTech's technology and examines its potential role in improving early skin cancer detection within primary care.

DERMTECH TECHNOLOGY OVERVIEW

DermTech's approach to non-invasive skin sampling relies on an adhesive "patch biopsy" applied to suspicious pigmented lesions. The patch collects superficial epidermis cells, including melanocytes and keratinocytes, for molecular analysis. The assay, commonly referred to as the PLA, measures expression of two biomarkers, LINC00518 and PRAME, using quantitative reverse transcription polymerase chain reaction (qRT-PCR) techniques.[10]

In the pivotal validation cohort of 398 lesions (87 melanomas, 311 non-melanomas), detectable LINC00518 and/or PRAME expression was present in 91% of melanomas but only 31% of non-melanoma samples, corresponding to a sensitivity of 91% and a specificity of 69% for histopathologic melanoma classification.[11] These findings demonstrate that LINC00518 and PRAME are strongly and selectively associated with melanoma and melanoma in situ, including very early lesions. In an independent multicenter validation study, approximately 30% of melanomas were in situ and the median Breslow thickness of invasive tumors was 0.45 mm.[11] Subsequent prospective and registry studies confirmed that patients with negative results rarely developed melanoma over at least 12 months of follow-up.[9] Collectively, these data support the PLA as a highly validated, clinically meaningful rule-out tool that may reduce unnecessary biopsies with low risk of

missed melanoma in equivocal pigmented lesions.

With respect to melanoma subtypes, the validation and registry studies primarily evaluated pigmented cutaneous melanomas on non-glabrous skin; the assay is not intended for lesions on mucous membranes, palms, soles, or nail units.[11] Within these constraints, the cohorts included both melanoma in situ and thin invasive tumors, suggesting robust performance in early-stage disease. Limited supportive evidence exists for atypical presentations; a case report documented successful detection of an amelanotic melanoma via positive LINC00518 expression on PLA testing, with subsequent histopathology confirming a 0.6-mm invasive tumor.[12] However, systematic subtype-specific performance metrics (e.g., for amelanotic, acral, or other uncommon variants) remain sparse, and these entities may be underrepresented in existing datasets.

Technical limitations remain. Superficial sampling may miss deeper invasive components and sampling adequacy varies by site and lesion type, with a small proportion of samples yielding insufficient RNA.[11,13] Sample selection also represents a limiting factor, particularly when clinicians are uncertain which lesion warrants testing. Lentigo maligna and small melanomas (<6 mm) may be easily overlooked, increasing the risk of inadequate sampling. Additionally, advanced practice providers such as physician assistants have also been reported to perform more skin biopsies per diagnosed skin cancer while identifying fewer melanomas in situ relative to dermatologists, suggesting a pattern of higher benign biopsy rates and less precise lesion selection.[14] Primary care clinicians historically demonstrate lower sensitivity for recognizing skin cancers on clinical examination, with reported sensitivities as low as ~57 % for general identification of skin malignancy in community studies.[15] These findings highlight that, in non-specialty settings without targeted dermatologic training, clinicians may over-sample low-risk lesions and under-sample high-risk lesions, thereby limiting diagnostic yield and increasing unnecessary procedures.

EVIDENCE BASE AND CLINICAL UTILITY

Clinical studies consistently show that the PLA improves diagnostic efficiency by identifying low-risk lesions that can be safely monitored, thereby reducing the number of unnecessary biopsies. Traditional practice often requires 20 to 25 biopsies to detect one melanoma, whereas incorporation of the PLA has reduced this ratio to roughly 2.7 biopsies per melanoma diagnosed in some analyses.[16] In real-world settings, clinicians report fewer benign biopsies and greater confidence in excluding malignancy when the PLA result is negative.[17]

Safety data from prospective follow-up and registry cohorts further reinforce this utility. In one follow-up study, lesions testing negative with the PLA remained benign over a year of observation, with no melanoma conversions detected.[9] Results from the TRUST registry mirrored these outcomes, showing continued negative predictive reliability across large populations.[18] Notably, the assay's performance appears consistent across Fitzpatrick skin types I–VI, an important advantage given the diagnostic disparities in skin of color.[19]

Even so, a few discordant cases underscore that the PLA should complement, not replace, clinical judgment. In cases of early in situ melanoma or in anatomically challenging sites such as the face and acral surfaces,

there was reportedly an increased potential for false negatives, highlighting limitations related to lesion depth and anatomical variability.[20] Additionally, evidence from primary care and mid-level practice patterns suggests that clinicians without specialized dermatologic training frequently biopsy many benign lesions while overlooking higher-risk ones, indicating that imperfect lesion selection, not just test performance, can contribute to missed melanoma.[21,22] Reviews of molecular diagnostics emphasize that while adhesive patch assays offer strong rule-out capability, broader validation in primary-care populations is needed, where lesion prevalence and follow-up rigor differ from dermatology practice (**Table 1**).[23]

Table 1. Summary of Clinical Evidence Evaluating the Pigmented Lesion Assay (PLA) Across Validation, Real-World, and Technical Evidence

Author	Study Design	Key Findings	Primary Conclusions
Gerami et al.	Multicenter clinical validation study	- Sensitivity: 91% - Specificity: 69% - Negative predictive value (NPV): >99% - Gene targets: LINC00518 and PRAME	Established the PLA as a highly sensitive, high-NPV genomic rule-out test for melanoma.
Ferris et al.	Prospective follow-up study	- No PLA-negative lesions converted to melanoma on follow-up - Demonstrated low false-negative rate in real-world use	Confirmed the longitudinal safety and reliability of negative PLA results.
Rivers et al.	Clinical review and synthesis of real-world experience	- Biopsy ratio reduced to ~2.7:1 melanoma diagnosed - Reinforced high NPV consistent with validation studies	Demonstrated substantial reduction in unnecessary biopsies and improved diagnostic efficiency with PLA use.
Marchetti et al.	Real-world clinical utility assessment	- Reported reduced benign biopsy rates - Increased diagnostic confidence with negative PLA results	Highlighted practical clinical utility and workflow benefits of integrating PLA into patient evaluation.
Kaufmann et al.	Real-world evidence analysis	- High NPV maintained across large registry datasets - PLA-negative lesions rarely biopsied and remained benign	Reinforced reproducibility of PLA performance in real-world practice.
Skelsey et al.	Registry-based analysis	- Reported NPV approximately 99% - Consistent performance across patient subgroups	Supported consistent and reliable rule-out capability across diverse clinical populations.
Bass et al.	Expert Review/Technical Assessment	- PLA samples only the superficial epidermis - May miss deeper dermal melanoma components or pose limitations at acral/facial sites	Emphasized PLA as an adjunct to clinical judgment; positive or concerning results require confirmatory biopsy.

In sum, DermTech's adhesive genomic assay has demonstrated robust diagnostic accuracy and real-world safety in dermatology settings, significantly reducing biopsy burden and patient discomfort. Its transition into primary care could extend these benefits to the front lines of skin cancer detection, provided that further implementation studies confirm its effectiveness in community practice.

POTENTIAL APPLICATIONS IN PRIMARY CARE

PCPs are often the first to evaluate skin lesions but face diagnostic challenges due to limited dermatology training, brief appointment times, and reliance on visual inspection. They receive minimal formal education in skin cancer detection and infrequently perform full-body skin exams, leading to both unnecessary referrals and missed diagnoses.[24,25] Incorporating DermTech's non-invasive adhesive patch test into primary care could address this gap by enabling molecular screening and more accurate triage before referral. Because the PLA is reimbursable and can be performed during routine office visits, its use in primary care may increase diagnostic testing frequency, consistent with evidence that physician payment models influence service volume. Fee-for-service reimbursement has been shown to incentivize higher levels of service provision, which may expand testing into lower-prevalence populations and, in turn, affect observed specificity and positive predictive value, underscoring the importance of appropriate lesion selection.[26,27]

One of the most compelling applications of the DermTech PLA in primary care is its potential role as a first-line rule-out test. In a typical primary care setting, many patients present with benign pigmented lesions, yet clinical uncertainty prompts a significant number of dermatology referrals. Given the PLA's negative predictive value exceeding 99%, could use the test to confidently exclude melanoma in lesions that appear atypical but not overtly malignant.[11] A negative result would support monitoring within primary care, whereas a positive or indeterminate result would trigger dermatology referral or biopsy. Such stratification could substantially reduce specialist backlog and improve time to diagnosis for higher-risk patients.

Access and equity represent another key opportunity for DermTech's integration into primary care. Patients in rural and underserved regions face higher melanoma mortality and are more likely to be diagnosed at advanced stages due to limited access to dermatologists and prolonged referral delays.[28,29] Because DermTech's adhesive patch can be administered within a primary care office, without specialized equipment, anesthesia, or suturing, it offers a practical solution to decentralize skin cancer screening. By enabling molecular testing at the point of care, this approach could shorten diagnostic timelines, expand access in health-professional shortage areas, and reduce the geographic inequities that currently contribute to worse melanoma outcomes for rural populations. Additionally, integration of DermTech into digital health ecosystems could further expand its utility. The PLA results can be uploaded directly to electronic health records, allowing for structured documentation, remote consultation, and longitudinal tracking of lesions.

CHALLENGES AND BARRIERS/FUTURE DIRECTIONS

While DermTech's adhesive genomic assay shows strong potential for use in primary care, several practical and systemic barriers must be addressed to achieve widespread adoption. The foremost challenge is clinician training and confidence. Primary care physicians receive limited formal education in dermatologic procedures, which may hinder consistent lesion selection and sampling.[25,30] Although the patch is simple to apply, its reliability depends on proper technique and understanding of test limitations. Structured training programs and integration of standardized protocols into primary care workflows will be essential to ensure accurate use and interpretation.

Economic and policy considerations also influence feasibility. The PLA's reimbursement remains inconsistent, and upfront costs may deter adoption in capitated systems. However, reducing unnecessary biopsies and referrals could offset costs if validated through health-economic studies tailored to primary care populations.[17] Demonstrating cost-effectiveness and safety outside dermatology will be critical for payer coverage and policy inclusion.

Future research would benefit from focusing on validating DermTech's performance specifically within primary care populations, where lesion prevalence, clinician experience, and follow-up practices differ from specialty settings. Large, pragmatic studies are needed to assess diagnostic accuracy, referral efficiency, patient satisfaction, and long-term outcomes. At the policy level, establishing reimbursement consistency and integrating molecular testing into preventive care guidelines could help expand equitable access, particularly in rural and underserved regions.

CONCLUSION

Derm Tech's genomic patch test technology represents a significant advancement with the potential to transform the early detection, analysis, and treatment of suspicious pigmented lesions. The meaningful negative predictive value of this assay offers providers a cost-efficient, accessible, and non-invasive method to rule out melanoma, complimenting the established workflow of managing suspicious lesions while enhancing patient comfort by avoiding unnecessary biopsies. Integration of DermTech's technology in primary care settings can enhance diagnostic accuracy, improve timeliness of intervention, and reduce the growing burden on dermatology services. Primary care physicians play an increasing role in the dermatologic care of patients, especially in rural or underserved communities where access to specialists is limited. DermTech provides a practical tool to bridge this gap, and support earlier and equitable detection of skin cancer. Although further studies are necessary to explore the practical applications and feasibility of integration of DermTech into primary care settings, initial evidence supports the use of this tool as a meaningful addition to dermatologic patient care.

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