DermTech Inc.

www.dermtech.com

A sticky problem solved

DermTech's adhesive patch platform enables non-invasive gene expression analysis.

RNA is synthesized within cells and both indicates and regulates gene activity. RNA is ubiquitous on skin—but so are RNAses, enzymes that digest RNA and protect against infection with viral RNA. DermTech has developed a powerful platform technology to harvest RNA from skin for molecular analysis. This novel, non-invasive method uses adhesive patches to collect tissue of the most superficial skin layers, which can then be analyzed by quantitative PCR or microarray technology to determine gene expression.

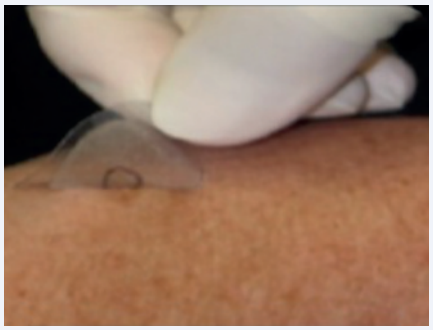
RNA-based gene expression profiles reflect differences in the biological states of various tissues and therefore carry great potential for the development of tailored therapeutic and diagnostic strategies. Until most recently, obtaining the tissue for analysis required invasive biopsies, and skin was no exception. However, research at DermTech[1–5] has shown that epidermal RNA can be readily harvested and used to track biological response with broad applications in drug discovery, inflammation, cancer and aging. It has the potential not only to augment or replace invasive biopsies in circumstances where invasive sampling is the current norm, but also to expand the use of gene expression skin profiling into new areas.

A tool for drug development

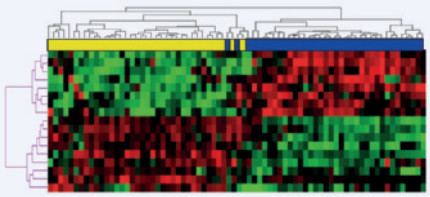
In addition to developing products with direct clinical applications, DermTech also seeks collaborations with biotechnology companies on its platform technology. Current partnerships include agreements with MedImmune and Biogen in which the validated platform technology is being used to support drug discovery and development programs focused on inflammatory diseases. Using DermTech's proprietary technology, drug researchers can stratify and select patients based on initial skin gene expression profiles, identify biomarkers of specific diseases and disease subsets, track drug responses and monitor disease progress. These capabilities are likely to prove useful in research and clinical trials relating to diseases of the skin and possibly other organs, as many internal biological processes affect gene expression in skin.

> **"DermTech has developed a powerful platform technology to harvest RNA from skin for molecular analysis."**

Adhesive Patch Biopsy



Objective Gene Expression Assesssment



Not skin cancer Skin cancer

Figure 1: DermTech's pigmented lesion assay.

A simple patch test for melanoma

Skin cancer is the most common form of cancer in the US, and its deadliest form, melanoma, is responsible for nearly 10,000 deaths annually. The number of melanomas diagnosed each year has been growing up to 7% each year among fair-skinned populations. If melanoma is caught in its early stages, when a lesion is less than 1 mm deep, the prognosis is good, but once lesions develop to a depth over 4 mm, the five-year survival rate drops to <50%. For this reason, classifying pigmented skin lesions early and efficiently can have a significant impact on dermatology practice and patient outcomes. DermTech has identified a specific gene expression 'signature' test that is highly correlated with melanoma[2,5]. Used in combination with stratum corneum tissue collection with adhesive patches, this new, clinically validated test, DermTech's Pigmented Lesion Assay (PLA), is now commercially available in the US.

The PLA can distinguish melanoma from benign pigmented skin lesions such as nevi or moles with a negative predictive value (NPV) of over 99%, sensitivity of 92% and specificity of 77% and without the need for an invasive biopsy. The assay was developed using samples from over 950 pigmented skin lesions, including 250 melanomas, and expression analysis of over 30,000 genes. The PLA performance has been validated in two independent studies. With the current standard of care, a patient who has one or two melanomas in his or her lifetime might undergo ten biopsies or more. With the PLA kit, instead of undergoing an invasive biopsy, the patient has a skin sample harvested using adhesive patches, and this is then sent to DermTech for analysis in its Clinical Laboratory Improvement Amendments (CLIA)-licensed California laboratory. The combination of genes selected for the PLA reliably differentiates between gene expression patterns consistent with melanoma and non-melanoma lesions. Besides being preferred by most, due to improved patient comfort and recovery outcomes, the test also has additional utility in patients who have multiple lesions, lesions in cosmetically sensitive areas, who are taking anti-coagulant medication, or who are at elevated risk for infection, scarring or wound complications.

A mirror to skin aging

Although not usually life threatening, UV exposure causes photo-aging and dramatic changes in skin appearance and underlying biology. These changes are distinct from the effects of chronological aging. While chronological aging causes skin to thin, photo-aged skin can thicken. Photo-aged skin also undergoes collagen formation and acquires structures indicative of wound healing that are absent from chronologically aged skin. Using adhesive nucleic acid capture and gene expression analysis via DermTech's platform technology, the gene expression profiles that underlie these characteristics can be studied and this knowledge applied to improving the diagnosis and treatment of photo-aging, including cosmetic treatments to improve skin quality and appearance.

References

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