

A DERMAL BIOMARKER PATCH DISPLAYS EXCELLENT ANALYTICAL PERFORMANCE AND OUTPERFORMS TAPE STRIPPING IN PSORIATIC SKIN

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SYNOPSIS

The Dermal Biomarker Patch (DBP) platform efficiently captures transcriptomes of >7,000 biomarkers from the lesional skin of psoriasis patients in sufficient quantities for next-generation sequencing protocols. There was no significant body-site variation observed, in contrast to stratum corneum tape stripping*. This platform makes precision medicine in dermatology a reality. It provides a powerful tool for doctors, researchers, and patients to better understand the skin.

OBJECTIVE

To demonstrate the ability of the Mindera Health DBP to extract actionable quantities of mRNA from lesional skin of psoriasis patients, and explore the body-site dependence of this method.

METHODS

Using the DBP, a total of 416 transcriptomes were collected from 24 different body areas; each transcriptome was comprised of ~7,000 biomarkers. Samples were collected from research sites (N=15) under an IRB-approved protocol. After collection, samples were placed in a storage buffer between 2–8°C for transport and processing.

Once received, next generation sequencing (NGS) was performed according to standard procedures. Measurements were made of the gene detection rate and mRNA yield. Additionally, a subset of samples was analyzed at various time points after sample collection (1-10 days) to determine mRNA stability during storage and transport.



FIGURE 1. Dermal Biomarker Patch workflow.

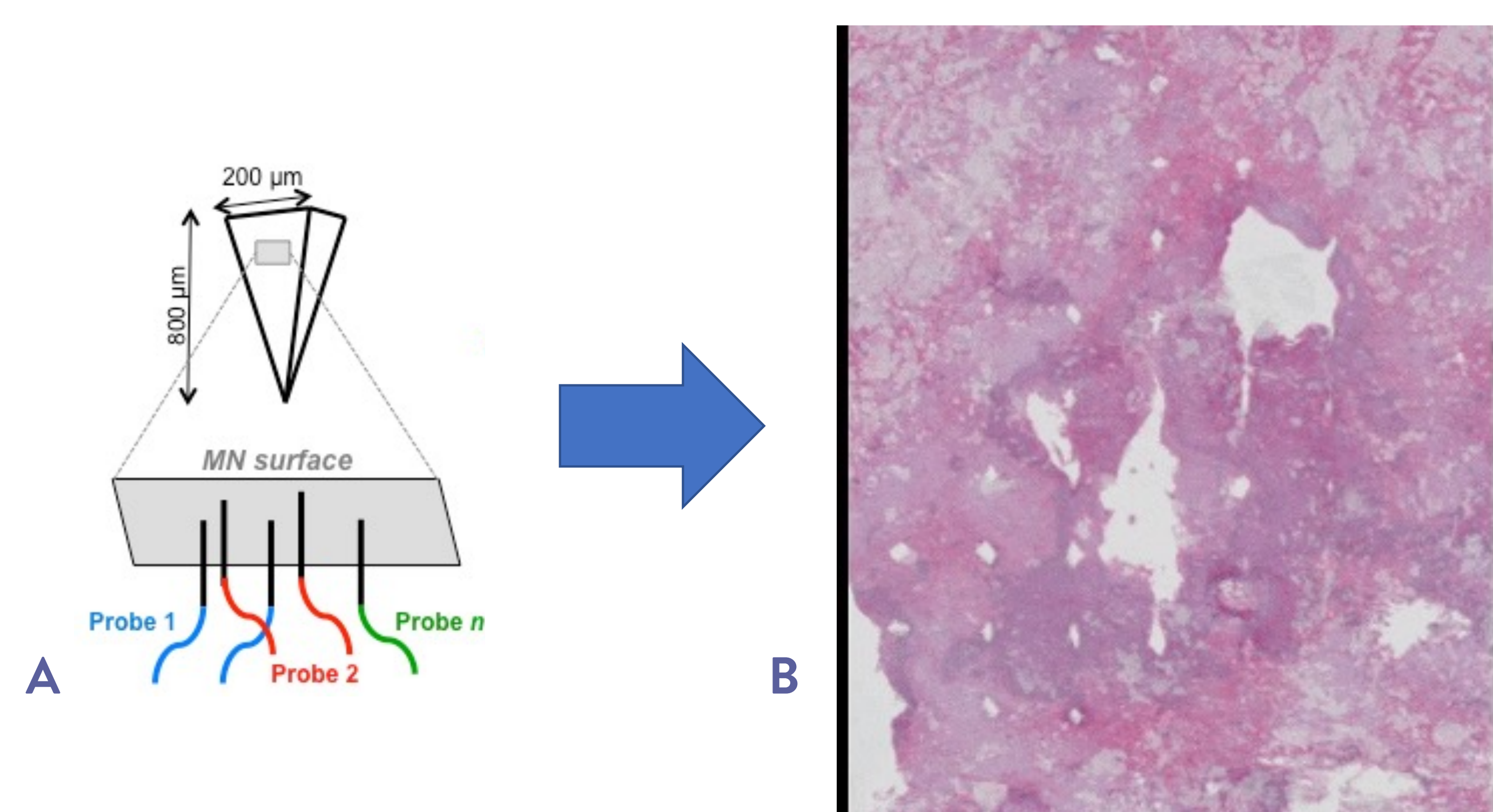


FIGURE 2. (A) Graphical depiction of DBP micro-projections. These projections are chemically modified to specifically bind to mRNA in the skin. (B) *En face* histology of DBP application. To assess the depth of penetration by the DBP, *ex vivo* skin samples were sliced *en face* and resulting puncture sites were quantified. On average, >90% of the DBP projections penetrated 350–400 µm into the skin.

RESULTS

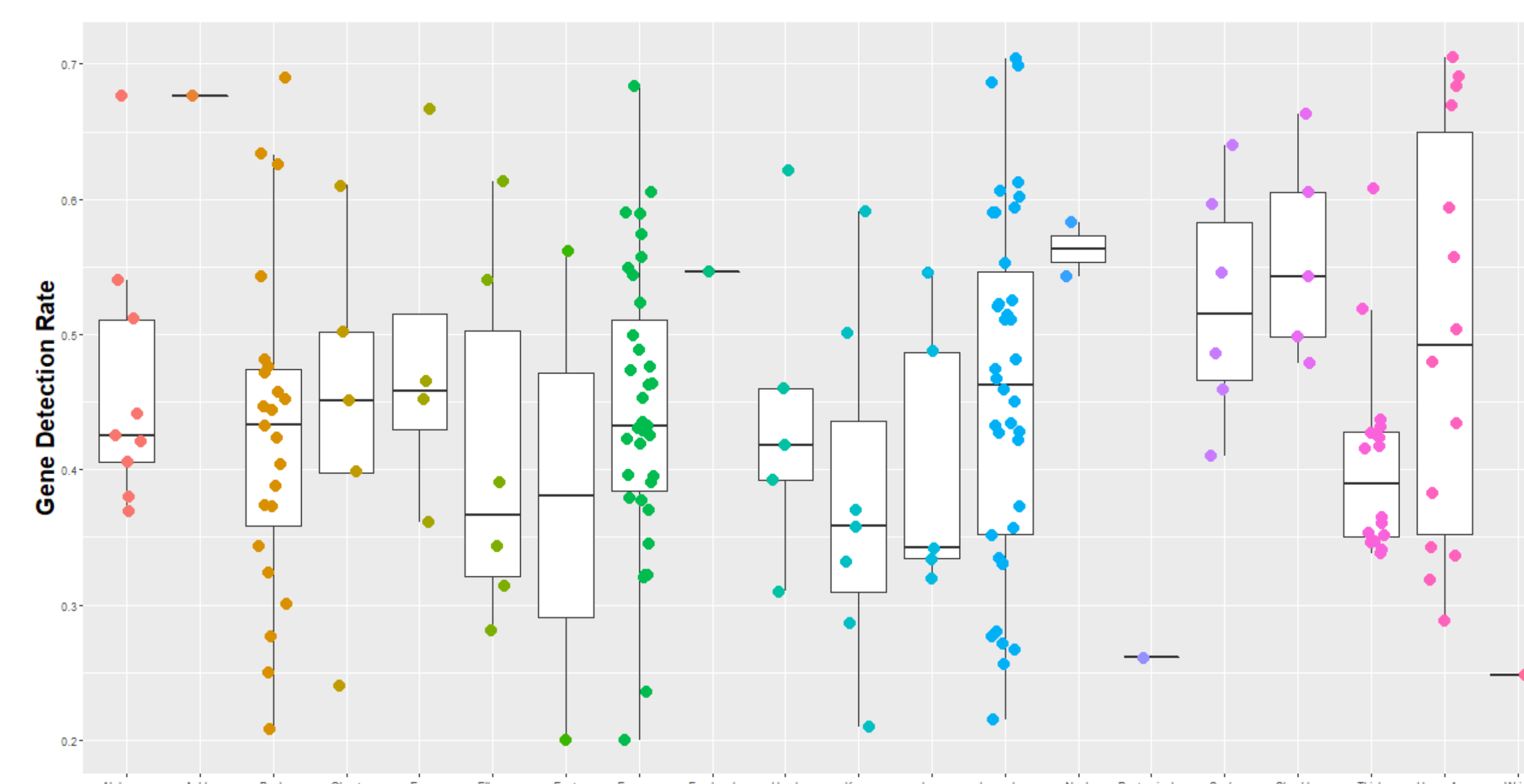


FIGURE 3. Gene detection rates from various body sites (N = 416). The gene detection rate ranged from 1.1% to 76.2%. The average gene detection rate was 43.3%. Based on a $\geq 20\%$ gene detection rate acceptance criterion, >96% of the samples passed quality control metrics. Statistical analysis of the data set demonstrated no statistically significant difference observed between body sites (ANOVA, $p=0.342$), in contrast to previously published data using stratum corneum tape stripping.

FIGURE 4. Yield of mRNA extracted from DBPs (N=412). The acceptance level for minimum concentration was determined to be 2–5 ng of amplified RNA at a concentration of 0.2 ng/µL. The yields of amplified mRNA ranged from 12–2,240 ng with an average yield of 360 ng, >100-times larger than the published average yields from stratum corneum tape stripping. All samples passed the acceptance criterion of >4 ng and yielded acceptable results in downstream sequencing.

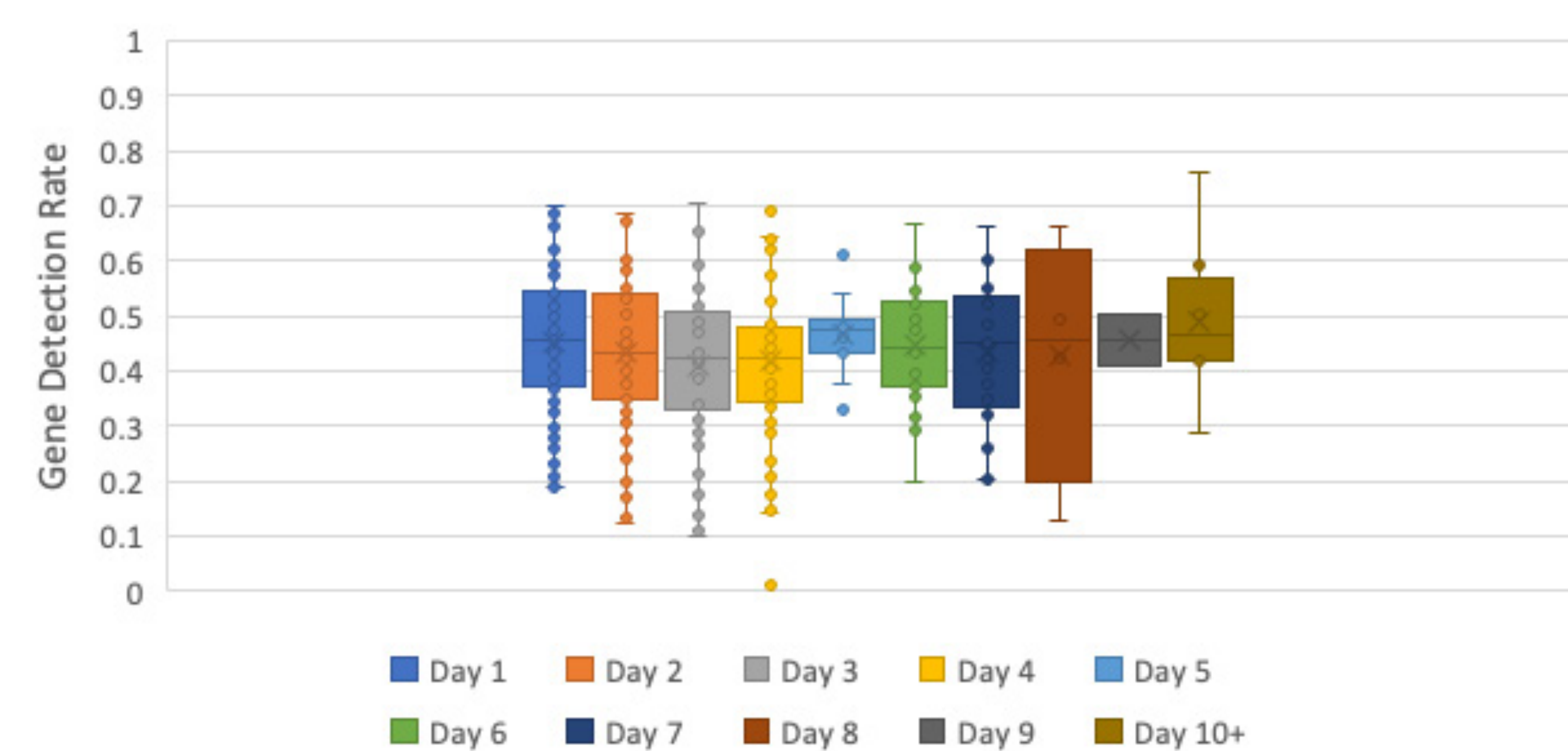
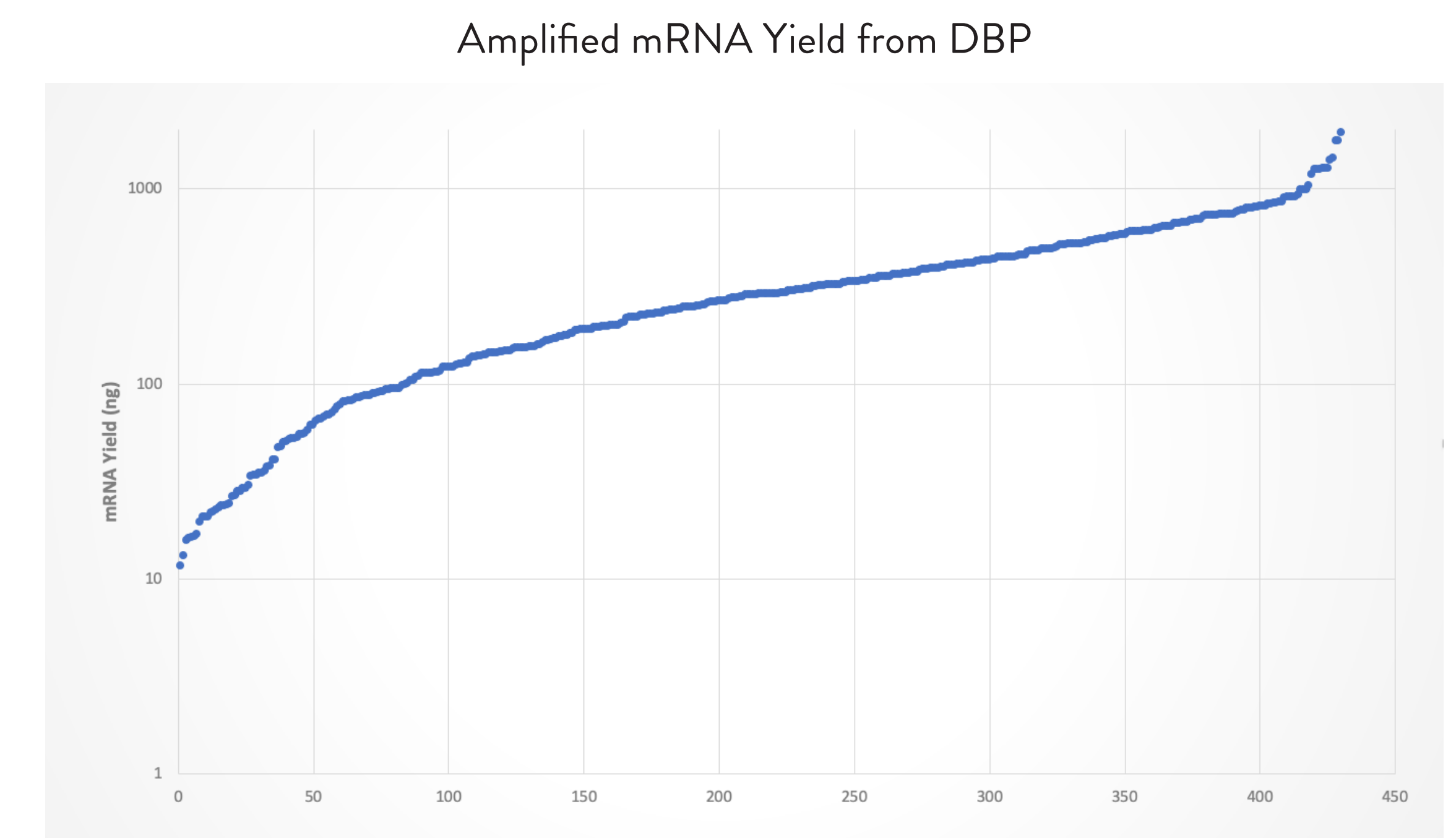


FIGURE 5. Influence of time between collection and processing on quality of DBP RNA-Seq data. A subset of 373 psoriasis skin samples was collected from research sites, stored in storage buffer at 2–8°C, and transported in an insulated shipper system at 2–8°C overnight for downstream analysis. To substantiate mRNA stability, the gene detection rates were determined for samples stored from 1 day to 10+ days. A total of 94.7% of the samples exceeded the QC threshold of 20% gene detection.

CONCLUSION

The Mindera Health Dermal Biomarker Patch platform has been proven to reliably extract the skin transcriptome in a minimally invasive manner.

Success in psoriasis patients includes:

- highly reproducible efficiency of extraction
- excellent mRNA yields suitable for RNA-Seq protocols
- >96% of samples passing quality control metrics
- no body-site bias in transcriptome extraction