Non-invasive Gene Expression Analysis Rules Out Melanoma with High Negative Predictive Value Regardless of Skin Phototype

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This study utilized patient data compiled through an ongoing DermTech Melanoma Test Registry Protocol. Patients of all Fitzpatrick skin types (I-VI) enrolled at 73 clinical practice sites within the U.S. were eligible for the registry, and those for whom Fitzpatrick skin type was unknown were excluded. For the current analysis (April 1, 2021 to an analysis date of November 15, 2023). Most 2-GEP-negative lesions are followed with clinical surveillance and not biopsied. To determine whether a negative 2-GEP result was correct or incorrect, the status of 2-GEP-negative lesions upon follow-up examinations (unchanged or stable versus changing in a manner concerning for melanoma) was recorded. Test performance metrics were calculated for each group (Fitzpatrick I-III and IV-VI) and groups were compared. The 95% confidence intervals for NPV and PPV were calculated using the Clapper-Pearson Exact Binomial Test. Using the function "binom.test". The 95% confidence intervals for the difference in NPV and PPV between the groups were calculated using the Farrington-Manning method, using the function "farrington.manning" in R (DescrTab2).

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### Methods

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### Results (cont.)

Non-melanomas were diagnosed in patients with Fitzpatrick skin type IV-VI whose lesions tested negative. Additionally, analytical PCR performance in Fitzpatrick I-III and Fitzpatrick IV-VI samples was indistinguishable.

### Conclusion

Among Fitzpatrick IV-VI subjects, all melanomas diagnosed by histopathology were correctly identified by the assay as positive for the melanoma associated markers. The performance of the 2-GEP assay in patients with Fitzpatrick skin types IV-VI did not differ from its performance in patients with Fitzpatrick skin types I-III. Sensitivity and specificity were 90% or higher in both groups, and most importantly, the NPV for each group was greater than 99%.

NPV is considered the most relevant metric for a rule-out test3 since a negative test result is often used to defer intervention (such as biopsy or excision) in favor of surveillance.4 During a median follow-up period of over one year, only one melanoma (in situ) was diagnosed among patients whose lesions initially tested negative, further supporting the test’s ability to appropriately guide biopsy decision-making for ambiguous pigmented skin lesions of all skin phototypes.

### References


### Funding

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