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!!!*ELEVATEGENETICS VERIFY*

Independent assessment of clinical genetic or genomic test claims through expert review of the test provider's validation documentation. – For Research Use Only. Not for clinical use.

The test and lab details in this mock report are fictional yet are modeled after real clinical lab scenarios.

NPI #####

Test Name: Cancer Gene Signature

Laboratory: ONCOLOGY TESTING EXPERTS, INC

Date: 04 January 2023

Test Description

A 96 gene signature intended to detect the likelihood of cancer recurrence following cancer treatment.
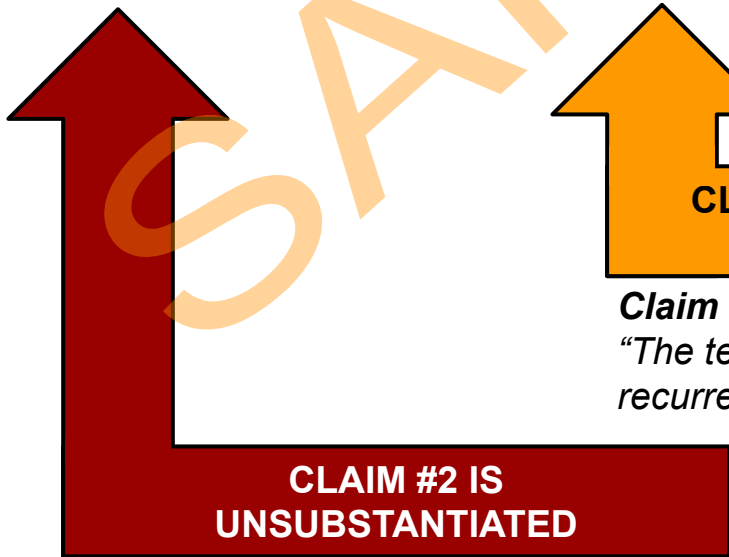

CGI's independent review of validation documentation for *Cancer Gene Signature* concludes that **the two major claims made by Oncology Testing Experts, Inc are NOT fully substantiated by the laboratory's own validation documentation.** (See page 2 for details).

EVIDENCE

Unsubstantiated — **Partially Substantiated** — Substantiated

CLAIM #1 IS PARTIALLY SUBSTANTIATED

Claim #1 Made by Test Provider:
"The test can predict the risk of cancer recurrence better than the standard of care."

CLAIM #2 IS UNSUBSTANTIATED

Claim #2 Made by Test Provider: "The test can predict the benefit of treatment for patients."

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METHODOLOGY & RESULT DETAILS

General Methods

The validation data for the test and claims under investigation were obtained by CGI through contacting the laboratory. CGI scientists were provided with documentation and publications corresponding to the claims assessed on Page 1 of this report. This data was scrutinized for rigorous validation practices, including appropriateness of chosen samples and sample sizes, statistical analyses, and clinical/analytical study design. A summary of ratings provided to each claim are provided below - details can be found in the attached Appendix A.

Claim 1 Methods and Findings

Five internal validation documents were reviewed in reference to this claim. Four peer-reviewed publications related to the claim were also reviewed (see Appendix). Although several of the published clinical studies support the claim that the test is a better predictor of recurrence than standard of care, internal validation data suggests that a subset of the patients tested in one of the clinical studies were also used for development of the test's gene signature algorithm. Therefore, it is difficult to interpret how much of the improved performance in this study, compared to standard of care, results from overfitting of the algorithm to the patient samples used to develop it. CGI rates this claim as "Partially Substantiated" by the other clinical studies in support of the claim.

Claim 2 Methods and Findings

One internal validation document was reviewed in reference to this claim. No peer-reviewed publications were available to support the claim. Upon reviewing the relevant document, CGI scientists disagree with the claim that the test can predict the benefit of treatment to the patient. This claim results from a misapplied statistical test to the dataset supporting the claim. If the correct statistical test is applied, the result is statistically insignificant (p-value = 0.18). Therefore, there was no evidence provided to CGI to support the claim and a rating of "Unsubstantiated" was assigned.

Disclaimer

Results are for research purposes only. Ratings are based on information provided to CGI by the laboratory test provider. CGI is not responsible for assessments that may be inaccurate due to laboratories withholding documentation, or providing inaccurate or other information that may validate or invalidate the claims addressed in this report. The identification of fraudulent data or studies is not within the scope of ELEVATEGENETICS VERIFY. The assessments presented in this report consist of expert opinions from CGI scientists and/or statisticians, who are not affiliated with the laboratory or any of the laboratory's competitors for a third-party, independent review.

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Appendix A

Details of the Ratings

[This is a demonstration sample document. However, in a real analysis, details of how CGI arrived at their ratings would be provided here].

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