Cleveland Clinic Innovations

PRODUCT
Diagnostic test to predict immunotherapy efficacy

INDICATION
Melanoma

VALUE PROPOSITION
Gene expression profile to determine immunotherapy efficacy/response in melanoma patients

DEVELOPMENT STAGE
Diagnostic method validated

INTELLECTUAL PROPERTY
Patent application submitted

RELATED PUBLICATIONS
Li, C., et al. (2022). A high OXPHOS CD8 T cell subset is predictive of immunotherapy resistance in melanoma patients. *The Journal of experimental medicine*, 219(1), e20202084.

CONTACT INFORMATION
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Gene Expression Profile for Immunotherapy Efficacy in Melanoma Patients

Inventor: Brian Gastman, MD

UNMET NEED

Currently, there are limited available techniques for assessing efficacy of immunotherapy treatment for patients with melanoma. In addition, nearly 40% of patients with melanoma develop long term immune-related side effects. In most cases, physicians utilize diagnostic imaging following onset of physical symptoms to assess immunotherapy efficacy. Other assessments involve invasive tissue sampling procedures that pose risk in certain patient populations. There is an urgent need to develop novel diagnostics that effectively predict the outcome of immunotherapies during treatment using rapid and minimally invasive methods.

SOLUTION

Cleveland Clinic researchers have identified a novel subset of CD8+ T-cells in peripheral blood and in the tumor microenvironment (CD8+-TOXPHOS) which have distinct metabolic and gene expression profiles compared to other CD8+ subtypes. Using RNA sequencing, the researchers identified a panel of genes whose differential expression within these cells serves as an indicator of non-responsiveness to therapy. Isolating patient CD8+-TOXPHOS cells and profiling the identified genes can help to stratify non-responders from responders.

The current diagnostic assay is a rapid and non-invasive test to guide treatment of melanoma patients undergoing immunotherapy treatment. This assay enables real-time decision-making and allows clinicians to distinguish non-responders from responders before or early in a treatment regimen. This unique predictive platform has been developed specifically for melanoma but may have utility for other cancers as well.