Immunotherapy biomarker assessment in FFPE samples from solid tumors using IHC, gene expression profiling and mutation burden assessment

Introduction

Recent advances have been made in the treatment of solid tumors and neoplastic malignancies. FF-PL immunohistochemistry (IHC) assays are currently being used as a companion diagnostic to select patients for anti-PD-1 therapies. The assessment of tumor infiltrating lymphocytes (TILs) in addition to PD-L1 staining using IHC has been proposed for patient selection for anti-PD-L1 therapies.

Materials and Methods

1. FFPE samples were analyzed, including breast cutaneous melanoma (BM), colon, breast, lung, prostate, kidney, liver, and glioblastoma.

2. The quality of the FFPE samples was assessed using a multiplex antibody panel. The expression level of CD163, CD31, CD34, CD56, CD105, and CD106 was stained in a FFPE breast biopsy.

3. The Gynecologic Oncology Research Network (GONRN) from The Ohio State University was used to test the FFPE genomics in the patient's condition.

4. 18 FFPE samples were selected and used for the method's performance analysis. The results from those studies highlight the use of FFPE in combination with the skin and in environments.

Results

1. Three different FFPE tumor mutation burden signature sets were used in different assays. The signature included more than 40 known genes.

2. The expression of the genes was assessed using a multiplex antibody panel. The expression level of CD163, CD31, CD34, CD56, CD105, and CD106 was stained in a FFPE breast biopsy.

3. The genotype/phenotype data were used to determine the relevant immune pathways (IHC). The expression level of CD163, CD31, CD34, CD56, CD105, and CD106 was stained in a FFPE breast biopsy.

4. The sensitivity and specificity of the IHC assay were evaluated in FFPE samples. The assay was validated in FFPE breast biopsy samples.

Conclusions

The results indicate that the immunotherapy biomarker assessment in FFPE samples can be used to predict the response to PD-L1 therapy. The results also suggest that this approach can be used to identify patients who may benefit from immunotherapy treatment.

Future Directions

1. Validation of the methodological strategy to assess the tumor mutation burden in FFPE samples.


3. Improvement of the assay performance by optimizing the FFPE sample handling and processing.

References


For Further Information

Please contact the author for further information.