

## MedGenome introduces tumor mutation burden test

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MedGenome Labs has recently launched Tumor Mutation Burden (TMB) test to help clinicians make an informed decision on immuno-therapy for their cancer patients.

Immuno-therapy is a concept in cancer treatment, where the approach is to use body's immune system to kill the cancer cells. A crucial aspect of success of tumor mutation burden test is that the body's immune system should differentiate cancer cells and normal cells. The mechanism by which the body's immune system can differentiate between cancer cells and normal cells is based on the expression of 'neo-antigens'. Neo-antigens are altered self-proteins which result from a change in the self-protein due to a mutation.

TMB is defined as the total number of nonsynonymous mutations in the tumor exome. Tumor cells are genetically unstable and harbor high levels of somatic mutations which may result in the expression of neoantigens. The presentation of tumor-specific neoantigens on major histocompatibility complex molecules is essential for the recognition of tumors by the T-cells of the immune system. This induces a T-cell response towards patient-specific neoantigens. These tumors may be eligible to successful immune-mediated destruction if their T-cell-dependent immune responses against tumor cells could be overreached.

Food and Drug Administration granted accelerated approval to pembrolizumab for the treatment of adult and pediatric patients with unresectable or metastatic tumor mutational burden-high (TMB-H) [ $\geq 10$  mutations/megabase (mut/Mb)] solid tumors, as determined by an FDA-approved test, that have progressed following prior treatment and who have no satisfactory alternative treatment options.

Dr. V L Ramprasad, CEO, MedGenome Labs, Bengaluru said "This is a revolutionary step in the field of cancer and will change the way immunotherapy is prescribed in cancer. The test will help clinicians identify how many mutations occur in a given length of DNA to understand whether immunotherapy would work. Tumor Mutation Burden test by MedGenome provides quantification in terms of TMB score as well as accurate information on actionable gene mutations. Extensive

validation for TMB panel was performed in-house on different cancer types from Indian population and international reference standards.”