VeriStrat® Test Description (CPT 81538)

The VeriStrat® test is a blood-based proteomic test that identifies a chronic inflammatory immune response indicative of aggressive disease in patients with advanced NSCLC. VeriStrat has historically been known as a predictive test for use of EGFR-TKI inhibitor therapies. Though this predictive utility remains proven, more than 10 years of peer-reviewed, published data has proven to provide critical prognostic information for physicians treating patients with NSCLC. With a binary result of VeriStrat Good (VSGood) or VeriStrat Poor (VSPoor), the test identifies patients with an aggressive immune component to their disease state (VSPoor patients) who are unlikely to respond to standard of care therapies. Patients with a VSGood disease state have an overall survival that is twice as long as those patients who test VSPoor. VeriStrat results are independent of treatment choice, Eastern Cooperative Oncology Group (ECOG) Performance Status (a subjective measure of the patient's mobility), the presence of actionable driver mutations, PD-L1 expression, and other clinical factors (such as age, gender, etc.).[i,ii,iii,iv,v,vi,vii] Use of this test in real-world clinical practice has been shown to shift physician treatment strategies away from ineffective therapies, resulting in an improvement in OS, quality of life (QOL), and save costs for health plans.[viii,ix]

VeriStrat testing uses a state-of-the-art (protein analysis) technology called matrix assisted laser desorption/ionization time of flight mass spectrometry (MALDI-TOF MS) plus complex proprietary data algorithms to render a test result. Biodesix, Inc. is the sole-source provider of VeriStrat, performing all tests in its laboratory in Boulder, Colorado. The laboratory is accredited by CLIA (#06D2085730), CAP (#7229634), ISO 13485, New York State, and other states where required by law. Copies of certificates and licenses are available upon request. VeriStrat was granted a specific Category I CPT code effective January 1, 2016. Biodesix, Inc. is the sole source provider of the VeriStrat test, meaning no other laboratory can provide VeriStrat test results or can bill for CPT code 81538.

A diagnosis of advanced NSCLC carries a dire prognosis for the patients and family members facing this disease. For these patients, the goals of treatment are not curative, but are rather to increase the patient's overall survival (OS), improve or maintain quality of life (QOL), and limit the financial burden of care. VeriStrat is a blood-based proteomic test that enables physicians to avoid ineffective, costly treatment, and better understand patient prognosis. VeriStrat is covered by many national, regional, and state health plans including Medicare, Cigna, Humana, and Aetna for commercial beneficiaries. VeriStrat has been validated in many peer-reviewed retrospective studies and a prospective, randomized Phase III trial (PROSE). VeriStrat provides information to clinicians and their patients with advanced NSCLC to help direct treatment options and has been proven to be cost savings in a peer-reviewed cost effectiveness study published in Lung Cancer.[x]

In 70-80% of cases, NSCLC is diagnosed at an advanced stage when it has largely become incurable. VeriStrat is a widely available, non-invasive proteomic test that helps oncologists guide treatment decisions for patients with advanced NSCLC. In those tested, VeriStrat classifies more than 98% of advanced NSCLC patients as VSGood or VSPoor with a simple blood draw, and provides predictive and prognostic guidanc. When test-guided treatment decisions were

made, VeriStrat has been proven to be cost saving and improve OS and QOL while reducing pharmacy costs for health plans by about $4,098.

---

[i] Taguchi F, Solomon B, Gregorc V, et al. Mass spectrometry to classify non-small-cell lung cancer patients for clinical outcome after treatment with epidermal growth factor receptor tyrosine kinase inhibitors: a multicohort cross-institutional study. Journal of the National Cancer Institute. Jun 6 2007; 99(11):838-846. PMID 17551144

[ii] Carbone DP, Ding K, Roder H, et al. Prognostic and predictive role of the VeriStrat plasma test in patients with advanced non-small-cell lung cancer treated with erlotinib or placebo in the NCIC Clinical Trials Group BR.21 trial. J Thorac Oncol. 2012;7(11):1653-1660. PMID 23059783

[iii] Stinchcombe TE, Roder J, Peterman AH, et al. A retrospective analysis of VeriStrat status on outcome of a randomized phase II trial of first-line therapy with gemcitabine, erlotinib, or the combination in elderly patients (age 70 years or older) with stage IIIB/IV non-small- cell lung cancer. J Thorac Oncol. 2013;8(4):443-451. PMID 23370367

[iv] Gregorc V, Novello S, Lazzari C, et al. Predictive value of a proteomic signature in patients with non-small cell lung cancer treated with second-line erlotinib or chemotherapy (PROSE): a biomarker-stratified randomized phase 3 trial. Lancet Oncol. 2014;15(7):713- 721. PMID 24831979

[v] Grossi F, Genova C, Rijavec E et al. Prognostic role of the VeriStrat test in first line patients with non-small cell lung cancer treated with platinum-based chemotherapy. Lung Cancer. 2018;117:64-69. PMID 29395121

[vi] Fidler, MJ. Fhied, CL., Roder, J., et al. The serum-based VeriStrat® test is associated with proinflammatory reactants and clinical outcome in non-small cell lung cancer patients. BMC Cancer 2017 PMID: 29558888

[vii] Amann et al. Genetic and Proteomic Features Associated with Survival after Treatment with Erlotinib in First-Line Therapy of Non-small Cell Lung Cancer in Eastern Cooperative Oncology Group 3503. Journal of Thoracic Oncology; 5:2. February 2010. PMID 20035238

[viii] Hornberger, J., et al., Outcome and economic implications of proteomic test-guided second- or third-line treatment for advanced non-small cell lung cancer: extended analysis of the PROSE trial. Lung Cancer, 2015. 88(2): p. 223-30.

[ix] Page, Ray D., MD, and Alix M. Arnaud. Precision Medicine: Estimated Clinical and Economic Outcomes of Using a Predictive and Prognostic Biomarker to Avoid Ineffective Therapies in Advanced Non-Small Cell Lung Cancer. American College of Medical Quality Poster Presentation March 2017.

[x] Hornberger, J., et al., Outcome and economic implications of proteomic test-guided second- or third-line treatment for advanced non-small cell lung cancer: extended analysis of the PROSE trial. Lung Cancer, 2015. 88(2): p. 223-30